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2nd BBA Notifier Conference (15/16 January 1998)

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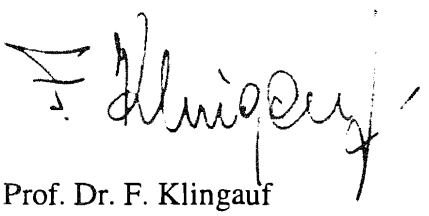
Vorwort

In ihrer Funktion als Benannte Behörde für die nationale Koordinierung der Europäischen Wirkstoffprüfung informierte die Biologische Bundesanstalt für Land- und Forstwirtschaft am 15. und 16. Januar 1998 im Rahmen der 2. BBA-Notifizierer-Konferenz über den aktuellen Stand der EU-Wirkstoffprüfung gemäß Richtlinie des Rates 91/414/EWG.

Vorträge von Vertretern der Europäischen Kommission, des deutschen und des europäischen Industrieverbandes (IVA und ECPA), der Zulassungsbehörden aus Irland und dem Vereinigten Königreich sowie der BBA und des Bundesministeriums für Ernährung, Landwirtschaft und Forsten bildeten den Rahmen für intensive Diskussionen über aktuelle Fragen und vor allem zukünftige Perspektiven der EU-Wirkstoffprüfung. Einigkeit bestand über die bisherigen Erfolge, aber auch über die Notwendigkeit der Weiterentwicklung des bestehenden Verfahrens. Sowohl in den Vorträgen als auch in der Diskussion wurden hierzu von allen Seiten konstruktive Ansätze zur Optimierung aufgezeigt.

Es war mir eine besondere Freude und Ehre, anläßlich des 100-jährigen Bestehens der BBA so viele und bedeutende Vertreter des Pflanzenschutzes aus Europa und darüber hinaus in Braunschweig begrüßen zu dürfen. Der Empfang auf Einladung des Industrieverbandes Agrar e.V. bot eine zusätzliche gute Gelegenheit, bestehende Kontakte zu vertiefen und neue zu knüpfen.

Mit dem vorliegenden Tagungsband werden die Vorträge der Konferenz in gedruckter Form vorgelegt.



Prof. Dr. F. Klingauf
Präsident der Biologischen Bundesanstalt für Land- und Forstwirtschaft

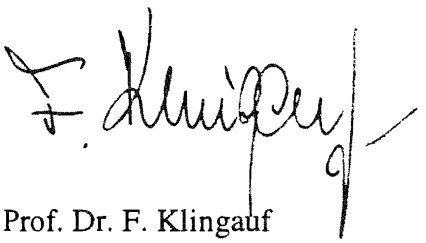
Preface

On the 15 and 16 January, 1998 the Federal Biological Research Centre for Agriculture and Forestry, as the designated authority for national co-ordination of the European Peer Review Programme for evaluation of active substances, informed the participants of the 2nd BBA Notifier Conference on the present situation regarding the EU-Peer Review Programme in accordance with Council Directive 91/414/EEC.

Lectures from representatives from the European Commission, the German and the European agrochemical associations (IVA and ECPA), the competent authorities from Ireland and the United Kingdom, as well as the BBA and the Federal Ministry of Food, Agriculture and Forestry provided the framework for intensive discussions on current matters, and above all on the future perspectives of the EU-Peer Review Programme for evaluation of active substances. Everyone agreed on the success achieved so far, but also on the need for further development of the existing procedure. Both the lectures and the discussions provided constructive ideas for optimising the system.

It was a particular pleasure and an honour for me, on the occasion of the BBA's centenary, to be able to meet so many and such important representatives of plant protection from Europe and elsewhere in Braunschweig. The evening reception, which was organised by the German Agrochemical Association, presented an additional opportunity for deepening existing contacts and establishing new ones.

Please find enclosed the conference proceedings which contain the conference lectures in written form.



Prof. Dr. F. Klingauf
President of the Federal Biological Research Centre for Agriculture and Forestry

TAGUNGSPROGRAMM

	15. Januar 1998
9:00 - 13:30	*Anmeldung im Tagungsbüro*
10:30 - 12:00	**CADDY-Informationsveranstaltung** Dossier auf CD-ROM
12:00 - 13:30	*Mittagspause / Anmeldung im Tagungsbüro*
13:30 - 13:50	**Klingauf** (BBA) Allgemeine Begrüßung und Eröffnung
13:50 - 14:00	**Böttcher** (IVA) Grußwort
14:00 - 14:20	**Scharpé** (COM/GD VI) Status of Legislation and Implementation of Directive 91/414/EEC
14:20 - 14:40	**Lynch** (PCS/IE) EU-Guidelines for the Preparation of Dossiers and Monographs
14:40 - 15:00	**Diskussion**
15:00 - 15:40	*Kaffeepause*
15:40 - 16:00	**Flynn** (PSD/UK) Role of ECCO-Peer Review Meetings and Responsibilities of ECCO-Teams (BBA/PSD)
16:00 - 16:20	**Walsh** (COM/GD XXIV) Practical Implications for the Regulation of PPPs Following the Transfer of Certain Responsibilities to DG XXIV (Consumer Policy and Consumer Health Protection)
16:20 - 17:30	**Diskussion**
19:30	*Empfang mit Buffet im Hotel Mövenpick (auf Einladung des IVA)*

	16. Januar 1998
9:00 - 9:20	**Weißleder** (BML) Verfahrensablauf der EU-Wirkstoffprüfung in Deutschland aus der Sicht des Ministeriums
9:20 - 9:40	**Wilkening** (BBA) Verfahrensablauf und Stand der EU-Wirkstoffprüfung in Deutschland aus der Sicht der Benannten Behörde
9:40 - 10:00	**Julin** (ECPA) Industry-Views on Implementation of Directive 91/414/EEC and Suggestions for Process Improvements
10:00 - 10:40	*Kaffeepause*
10:40 - 13:00	**Abschlußdiskussion** Beantwortung von Fragen der Notifizierer/Antragsteller/Hersteller

CONFERENCE PROGRAMME

	15 Januay 1998
9:00 - 13:30	*Registration*
10:30 - 12:00	**Information morning on CADDY** Dossier on CD-ROM
12:00 - 13:30	*Lunchbreak / Registration*
13:30 - 13:50	**Klingauf** (BBA) Welcome and Opening Address
13:50 - 14:00	**Böttcher** (IVA) Welcome Address
14:00 - 14:20	**Scharpé** (COM/GD VI) Status of Legislation and Implementation of Directive 91/414/EEC
14:20 - 14:40	**Lynch** (PCS/IRL) EU-Guidelines for the Preparation of Dossiers and Monographs
14:40 - 15:00	**Discussion**
15:00 - 15:40	*Coffeebreak*
15:40 - 16:00	**Flynn** (PSD/UK) Role of ECCO-Peer Review Meetings and Responsibilities of ECCO-Teams (BBA/PSD)
16:00 - 16:20	**Walsh** (COM/GD XXIV) Practical Implications for the Regulation of PPPs Following the Transfer of Certain Responsibilities to DG XXIV (Consumer Policy and Consumer Health Protection)
16:20 - 17:30	**Discussion**
19:30	*Reception with buffet dinner at the Mövenpick Hotel (at the invitation of IVA)*

	16 January 1998
9:00 - 9:20	**Weißleder** (BML) Procedure of EU-Peer Review of Active Substances from the Point of View of the Ministry
9:20 - 9:40	**Wilkening** (BBA) Procedure and Actual State of EU-Peer Review of Active Substances from the Point of View of the Designated and Competent Authority
9:40 - 10:00	**Julin** (ECPA) Industry Views on Implementation of Directive 91/414/EEC and Suggestions for Process Improvements
10:00 - 10:40	*Coffeebreak*
10:40 - 13:00	**Final Discussion** Replies to specific questions of the notifiers/applicants/manufacturers

Eröffnungsrede

F. KLINGAUF

Biologische Bundesanstalt für Land- und Forstwirtschaft
Bundesrepublik Deutschland

Die Biologische Bundesanstalt für Land- und Forstwirtschaft führt ihre Gründung auf das Jahr 1898 zurück, als der Reichstag beschloß, eine Einrichtung für den staatlichen Pflanzenschutz zu schaffen. Zunächst wurde eine Biologische Abteilung für Land- und Forstwirtschaft am Kaiserlichen Gesundheitsamt eingerichtet mit der Maßgabe, sie später zu einer eigenen Behörde auszubauen. Bereits 1905 wurde die Biologische Abteilung für Land- und Forstwirtschaft am Kaiserlichen Gesundheitsamt zu einer selbständigen Behörde erhoben und bezog als Kaiserliche Biologische Anstalt für Land- und Forstwirtschaft (KBA) die neu errichteten Anstaltsgebäude an der Königin-Luise-Straße in Berlin-Dahlem. Nach dem Ende des Kaiserreichs wurde die KBA 1919 in Biologische Reichsanstalt für Land- und Forstwirtschaft (BRA) umbenannt. Im Jahre 1946 entstanden in Berlin-Dahlem und in den westlichen Zonen durch Zusammenfassung der hier befindlichen Außeninstitute der früheren BRA jeweils eine Biologische Zentralanstalt für Land- und Forstwirtschaft (BZA). Die Teilung Berlins führte 1949 zur Spaltung der BZA in Berlin-Dahlem. Während ein Teil der Mitarbeiter in Dahlem verblieb, verließ ein anderer Teil das Stammhaus, um als Biologische Zentralanstalt für Land- und Forstwirtschaft in Kleinmachnow zum Pflanzenschutzzentrum für die Sowjetische Besatzungszone zu werden. 1950 wird die BZA Braunschweig in die Verwaltung des Bundes überführt, und 1954 kommt die BZA Berlin-Dahlem hinzu. Die Anstalt heißt nun Biologische Bundesanstalt für Land- und Forstwirtschaft, Berlin und Braunschweig. Mit der Herstellung der Einheit Deutschlands erfolgt auch die Wiedervereinigung der Biologischen Bundesanstalt für Land- und Forstwirtschaft mit der Biologischen Zentralanstalt in Kleinmachnow. Es wurden rund 200 Stellen zusätzlich eingerichtet.

Die Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) ist eine Bundesforschungsanstalt und selbständige Bundesoberbehörde. Sie gehört zum Geschäftsbereich des Bundesministeriums für Ernährung, Landwirtschaft und Forsten (BML). Die hoheitlichen und administrativen Aufgaben umfassen die Unterrichtung und Beratung der Bundesregierung auf dem Gebiet des Pflanzenschutzes, die Prüfung und Zulassung von Pflanzenschutzmitteln, die Prüfung von Pflanzenschutzgeräten sowie die Führung der Pflanzenschutzgeräteliste. Weiterhin wirkt die BBA mit bei der Bewertung von Stoffen nach dem Chemikaliengesetz, bei der Erteilung von Genehmigungen zur Freisetzung von gentechnisch veränderten Organismen sowie bei Regelungen zur Pflanzenbeschau und der Prüfung der Resistenz neuer Pflanzensorten.

Die Forschungen der BBA sind auf die Erarbeitung von Methoden und Systemen gerichtet, die dem Schutz von Pflanzen und Pflanzenerzeugnissen dienen und Gefahren abwenden, die durch Pflanzenschutzmaßnahmen für die Gesundheit von Mensch und Tier und für den Naturhaushalt entstehen können. Die Forschungen umfassen alle Bereiche des Pflanzenschutzes.

Die Biologische Bundesanstalt gliedert sich in 15 Institute, die Abteilung für Pflanzenschutzmittel und Anwendungstechnik und gemeinschaftliche Einrichtungen. Sie verfügt über rund 700 Stellen, darunter 200 Wissenschaftlerinnen bzw. Wissenschaftler. Hinzu kommen etwa 200 weitere Gastwissenschaftlerinnen und Gastwissenschaftler bzw. Doktorandinnen und Doktoranden, die zum großen Teil aus Forschungsaufträgen finanziert werden. Neben den Standorten Braunschweig und Berlin unterhält die BBA Institute in Kleinmachnow, Bernkastel-Kues, Darmstadt, Dossenheim und Münster. Hinzu kommen derzeit drei weitere, kleinere Versuchsstationen.

Die BBA arbeitet eng zusammen mit den Dienststellen und Forschungseinrichtungen des Bundes und der Länder im Bereich des Pflanzenschutzes, insbesondere mit dem Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), dem Umweltbundesamt (UBA), dem Bundessortenamt (BSA) und den Pflanzenschutzdiensten der Länder. Im internationalen Bereich des Pflanzenschutzes bestehen Verbindungen zur Gesellschaft für technische Zusammenarbeit (GTZ), zur Deutschen Stiftung für internationale Entwicklung (DSE), zu den Gremien der Europäischen Gemeinschaft (EG), zur European and Mediterranean Plant Protection Organization (EPPO), zur Food and Agricultural Organization (FAO) der Vereinten Nationen und der International Association of Agricultural Librarians and Documentalists (IAALD).

Der Pflanzenschutz wird in den letzten Jahren zunehmend durch einen Begriff geprägt, der inzwischen als Leitbild für die gesamte gesellschaftliche Entwicklung angesehen werden kann: sustainable development. Dieser Begriff kennzeichnet eine Lebens- und Wirtschaftsweise, die die Bedürfnisse der heutigen Menschen befriedigt, ohne die Entwicklungschancen nachfolgender Generationen einzuschränken. Mit der Konferenz der Vereinten Nationen in Rio de Janeiro im Jahre 1992 hat sich die Staatengemeinschaft auf dieses Leitbild verständigt.

Das Spektrum des Leitbildes beinhaltet Problem- und Themenbereiche, die weit über Umweltfragen hinausreichen. Dies zeigen auch die Weltkonferenzen der in Rio de Janeiro 1992 eingerichteten "Commission of Sustainable Development (CSD)":

- "Bevölkerung und Entwicklung" (1994 in Kairo)
- "Soziale Sicherung" (1995 in Kopenhagen)
- "Frauen" (1995 in Peking)
- "Stadtentwicklung" (1996 in Istanbul)
- "Ernährung" (1996 in Rom).

Bemerkenswert ist, daß sich die deutsche chemische Industrie – und damit auch die Sparte Agrochemie – als erster Industriezweig zusammen mit der Industriegewerkschaft Chemie-Papier-Keramik bereits sehr früh zu diesem Leitbild bekannte. Dabei wurde herausgestellt, daß die Bausteine einer nachhaltigen Entwicklung drei Komponenten umfassen: Ökologie, Soziales und Ökonomie. Umstritten war der Stellenwert der drei Säulen. Regelmäßig entstanden Grundsatzdebatten, ob es ein Primat einer der Dimensionen gäbe oder ob alle drei Aspekte als gleichrangig bewertet werden müssen. Insbesondere der Vorrang der Ökologie war umstritten.

Da sich die Diskussion über Nachhaltigkeit in Deutschland überwiegend mit ökologischen Zielsetzungen beschäftigt hat, liegen vorwiegend Stellungnahmen zu umweltorientierten Zielen vor. Dagegen sind ökonomische und soziale Zielvorstellungen in der bisherigen Diskussion wesentlich weniger thematisiert worden. Mir scheint, daß auch in der jetzigen Diskussion um die Harmonisierung der Zulassung von Pflanzenschutzmitteln ökologische Fragen den Vorrang genießen. Eine nachhaltige Entwicklung ist aber nur in der Integration von Ökologie, Ökonomie und Sozialem zu finden. Diese Forderung wird besonders dringlich durch den weiteren Anstieg der Weltbevölkerung und die steigenden Anforderungen an die Quantität und die Qualität der Nahrung. Die Zulassung von Pflanzenschutzmitteln in der Europäischen Union muß sich künftig dieser Herausforderung anpassen, um dem Anspruch an das Konzept der Sustainable Development gerecht zu werden.

Opening Address

F. KLINGAUF

Federal Biological Research Centre for Agriculture and Forestry
Germany

The foundation of the Federal Biological Research Centre for Agriculture and Forestry goes back to 1898 when the *Reichstag*, the imperial diet at this time, decided to create an institution for national plant protection. First of all a Biological Department for Agriculture and Forestry was established at the Imperial Health Office on the understanding that it would later be extended to an authority in its own right. In 1905 the Biological Department for Agriculture and Forestry at the Imperial Health Office was declared an independent authority and moved into the new buildings in Königin-Luise Street in Berlin-Dahlem as the Imperial Biological Research Centre for Agriculture and Forestry (KBA). In 1919, after the end of the empire, the KBA changed its name to the Biological National Research Centre for Agriculture and Forestry (BRA). By putting together the external institutes belonging to the former BRA, a Biological Central Institute for Agriculture and Forestry (BZA) was founded in Berlin-Dahlem in 1946 and in each of the western zones. The division of Berlin in 1949 lead to the splitting up of the BZA in Berlin-Dahlem. Whilst some of the employees stayed in Dahlem, others left the main institute to form the Biological Central Institute for Agriculture and Forestry in Kleinmachnow, which changed to the Plant Protection Centre for the soviet occupied zone. In 1950, the BZA in Braunschweig was given over to the administration of the Federal Government and was joined in 1954 by the BZA in Berlin-Dahlem. The institution is now called the Federal Biological Research Centre for Agriculture and Forestry, Berlin and Braunschweig. With the unification of Germany, the Federal Biological Research Centre for Agriculture and Forestry was brought back together again with the Biological Central Institute for Agriculture and Forestry in Kleinmachnow. Around 200 additional posts were created.

The Federal Biological Research Centre for Agriculture and Forestry (BBA) is a national research centre and an independent superior federal authority. It belongs under the supervision of the Federal Ministry of Food, Agriculture and Forestry (BML). Its sovereign and administrative duties include informing and advising the Federal Government on the entire field of plant protection, the evaluation and authorisation of plant protection products, the testing of plant protection equipment and monitoring of the Plant Protection Equipment List. Furthermore, the BBA is active in assessing substances in accordance with the Chemical Act, granting approvals for the release of genetically modified organisms, harmonising plant inspections and assessing the resistance of new plant species.

The BBA concentrates its research on methods and systems for protecting plants and plant products and preventing hazards to human and animal health and to the natural balance which

could arise from plant protection measures. This research includes all areas of plant protection.

The Federal Biological Research Centre is composed of 15 institutes, the Department for Plant Protection Products and Application Techniques and common establishments. It comprises around 700 employees, including 200 scientists. In addition, some 200 visiting scientists and doctoral candidates work here, financed largely by research projects. As well as centres in Braunschweig and Berlin, the BBA also has institutes in Kleinmachnow, Bernkastel-Kues, Darmstadt, Dossenheim and Münster. At the moment, it also has three further, smaller experimental stations.

The BBA works closely with regional and national departments and research institutes in the area of plant protection, and in particular with the Federal Institute for Health Protection of Consumer and Veterinary Medicine (BgVV), the Federal Environmental Protection Agency (UBA), the Federal Office for Plant Varieties (BSA) and the regional plant protection services. On an international level, co-operation in the area of plant protection exists between the German Agency for Technical Co-operation (GTZ), the German Foundation for International Development (DSE), the forums of the European Community (EC), the European and Mediterranean Plant Protection Organization (EPPO), the Food and Agricultural Organization (FAO), the United Nations and the International Association of Agricultural Librarians and Documentalists (IAALD).

Plant protection has been moulded increasingly in the past few years by a term which has now come to be seen as a model for our entire social development: sustainable development. This term describes a way of life and economy which satisfies the needs of today's society, without restricting the chances of development for future generations. The community of states agreed to this model during the United Nation's conference in Rio de Janeiro in 1992.

The spectrum of this model includes problem and subject areas which go beyond environmental problems, as can be seen by the world conferences held by the "Commission of Sustainable Development" (CSD), established in Rio de Janeiro:

- "Population and Development" (1994 in Cairo)
- "Social Security" (1995 in Copenhagen)
- "Women" (1995 in Peking)
- "Town Development" (1996 in Istanbul)
- "Nutrition" (1996 in Rome)

It is interesting to note that the German chemical industry - and therefore also the section agrochemistry - was the first industry, together with the industrial trade union for chemistry-paper-ceramics, to identify at a very early stage with this model. It was realised that the

necessary components for a sustainable development include three elements: ecology, the social element and economy. The value of these three pillars was however controversial. There were regular discussions of principle as to whether one of these dimensions took precedence over the others or whether all three aspects should be valued equally. The precedence of ecology was particularly controversial.

Since talk of sustainability in Germany has mainly involved ecological objectives, existing comments are mainly to do with environmentally orientated aims. As a contrast, economic and social aims have been discussed considerably less often. It seems to me that ecological questions also enjoy predominance in the present discussion on harmonising authorisation of plant protection products. A sustainable development is however only possible if ecology, economy and the social element are integrated. This need is particularly urgent due to the further increase in the world's population and the increasing demands on the quantity and quality of food. The authorisation of plant protection products in the European Union must work towards this challenge in the future in order to be able to comply with the demands of the concept of sustainable development.

Grußwort

O. BÖTTCHER

Industrieverband Agrar e.V. (IVA)
Bundesrepublik Deutschland

Die BBA hat durch das ECCO-Verfahren zusammen mit der britischen Zulassungsbehörde PSD eine herausgehobene Verantwortung in Bezug auf die Aufnahme von Wirkstoffen in Annex I der Richtlinie 91/414/EWG. Ich beglückwünsche deshalb die BBA zur Initiative, zu dieser Konferenz einzuladen. Ich verspreche mir davon, daß die auf beiden Seiten, also bei den zuständigen Stellen in den Mitgliedstaaten, und den betroffenen Antragstellern bestehenden Probleme im Zusammenhang mit der Aufnahme von Wirkstoffen in Annex I so sichtbar werden, daß daraus ein Zwang für Abhilfe entsteht. Ich möchte Sie deshalb alle, die Referenten sowie die übrigen Teilnehmer der Konferenz auffordern, Ihre Probleme offen auf den Tisch zu legen, die Nachteile des jetzigen Verfahrens deutlich anzusprechen und Vorschläge für mögliche Verbesserungen zu machen. Es ist wichtig, daß diese Vorschläge in einer Folgekonferenz, zu der die BBA ebenfalls einladen wird, mit den Vertretern der Zulassungsbehörden der übrigen EU-Mitgliedstaaten und der Kommission beraten und zu einem guten Ergebnis geführt werden, damit dann auf EU-Ebene in dem Regelwerk die notwendigen Veränderungen vorgenommen werden können.

Ich bin mir durchaus bewußt, daß jede neue Gesetzgebung und ihre Umsetzung in die Praxis Anfangsschwierigkeiten für alle Betroffenen mit sich bringt. Dies muß und kann man wohl hinnehmen im Vertrauen darauf, daß sich Verbesserungen von selbst einstellen. Was die hier anzusprechenden Probleme angeht, wird man allerdings nicht davon ausgehen können, daß diese sich von allein lösen.

Dies wird deutlich, wenn man sich die Gesetzeslage vergegenwärtigt.

Mitte 1991 wurde die Richtlinie 91/414/EWG verabschiedet. Ende 1992 wurde mit der Verordnung Nr. 3600/92 die erste Liste mit 90 Wirkstoffen, deren Aufnahme in Annex I zu prüfen ist, vorgelegt. Fünf Jahre später, im Dezember 1997 wurde die erste und bislang einzige Substanz in Anhang I aufgenommen. In weiteren gut fünf Jahren, also im Jahr 2003, sollen alle ca. 700 Altwirkstoffe und zusätzlich die neu hinzukommenden (ca. 10 pro Jahr) Wirkstoffe überprüft worden sein. Auch wenn die Zahl der tatsächlich in die Liste aufzunehmenden Wirkstoffe erheblich geringer sein wird, bedarf es keiner Rechenkunststücke, um zu erkennen, daß dieses Ziel mit Sicherheit bei weitem nicht wird erreicht werden können, also verfehlt wird.

Diese Feststellung zeigt die Dimension und Bedeutung der hier anzusprechenden Probleme und beweist zugleich, daß das Verfahren der Aufnahme von Wirkstoffen in Anhang I nach der Richtlinie 91/414/EWG schlicht nicht ausgereift, außerdem zu kompliziert und zu langwierig ist. Wenn man nun hört, daß bei den Wissenschaftlichen Ausschüssen, die in der GD XXIV zusammengefaßt sind, Ambitionen bestehen, eigenständige Beurteilungen der Dossiers vorzunehmen, dann gewinnen die bestehenden Probleme eine zusätzliche Dimension.

Dies wiederum bewirkt, daß die beabsichtigte Harmonisierung bislang nicht den gewünschten Erfolg gebracht hat und daß offensichtlich grundsätzliche Unterschiede in der Bewertung der Daten zwischen den Vertretern der einzelnen Mitgliedstaaten bestehen, die einen Konsens über die Aufnahme einer Substanz in den Anhang I so schwierig machen.

Mit Nachdruck möchte ich in diesem Zusammenhang darauf hingewiesen, daß es eine Illusion ist zu glauben, daß chemische Pflanzenschutzmittel keinerlei Auswirkungen auf Nicht-Zielorganismen haben dürfen. Lassen Sie mich deutlich sagen: Wer dies fordert, verhindert jegliche Zulassung chemischer Pflanzenschutzmittel.
Es muß neben anderen notwendigen Verbesserungen in dem Verfahren ein pragmatischer Konsens bei der Bewertung von Nebenwirkungen von Pflanzenschutzmitteln gefunden werden. Das Verfahren zur Aufnahme von Pflanzenschutzmitteln in den Anhang I ist dringend zu vereinfachen. Nur wenn beide Maßnahmen getroffen werden, kann es zu einer notwendigen Straffung und damit Beschleunigung des Zulassungsverfahrens in der EU kommen. Wir sollten uns bewußt sein, daß eine solche nicht nur im Interesse der Verfahrensbeteiligten liegt, sondern auch eine gesamtwirtschaftliche Dimension hat.

Diese betrifft

- das Interesse der Landwirtschaft an einem schnellen Zugang zu neuen, wirksameren und zugleich umweltschonenden Mitteln und Verfahren,
- Kosteneinsparungen bei Behörden und Industrie und
- die Erhaltung und Stärkung der Wettbewerbsfähigkeit der Wirtschaft in der EU.

Ich bin mir sicher, daß bei etwas gutem Willen, aber auch in der Erkenntnis notwendiger Verbesserungen, diese Konferenz einen entscheidenen Beitrag zur Lösung der anstehenden Probleme liefern wird. Unsere Industrie ist sich bewußt, daß auch sie ihren Anteil hierzu beizutragen hat.

Welcome address

O. BÖTTCHER

Industrieverband Agrar e.V. (IVA)
Germany

The BBA together with the UK authorization body PSD bears an extraordinary responsibility due to the ECCO-procedure with regard to the inclusion of active substances in Annex I of Directive 91/414/EEC. Therefore, I would like to congratulate the BBA for taking the initiative to invite to this conference. I expect of this meeting that the problems existing on both sides, the competent authorities of the Member States and the concerned notifiers, in connection with the inclusion of active substances in Annex I will become visible in order to make the introduction of remedial measures compulsory. Hence, I would like to encourage everybody here, the speakers as well as all other participants of the conference to frankly disclose their problems, to address the drawbacks of the present procedure openly, and to make proposals as to possible improvements. It is important that these proposals will be discussed with representatives of authorization bodies of the remaining EU-Member States and the Commission in a follow-up conference, again with the BBA as host, and will yield results to effect necessary modifications of regulations on EU-level.

I am quite aware that every new legislation and its implementation into practice entails initial teething problems for all parties involved. However, these problems must and can be tolerated by each of us, trusting that improvements will set in by itself. As to the problems which will have to be brought up during this conference, you cannot assume though that they will solve themselves which becomes clear when visualising the legal situation.

Directive 91/414/EEC came into force in the middle of 1991. With the submission of Ordinance No 3600/92 at the end of 1992, the first list of 90 active substances to be evaluated as to their possible inclusion in Annex I came into existence. Five years later, in December 1997, the first and only active substance so far was included in Annex I. In about five years from now, that means the year 2003, all of the approx. 700 existing active substances, in addition to the new ones (approx. 10 each year) are expected to have been evaluated by then. Even if the number of active substances actually intended for an inclusion in the list will be considerably lower, one does not have to be a mathematician to realise that it is impossible to get anywhere near the set goal, in other words it will be missed.

This statement illustrates the dimensions and the significance of the problems to be discussed here and proves at the same time that the procedure of including active substances in Annex I of Directive 91/414/EEC is simply still not sophisticated enough, it is moreover to complicated and takes too long. If one hears on top of that about existing ambitions to

evaluate dossiers autonomously, of the scientific committees combined in the GD XXIV, the current problems gain an additional dimension.

The effect is in return, that the intended harmonisation has up to now not scored the desired results and that apparently general differences in the evaluation of data exist between the representatives of individual Member States, making a consensus on the inclusion in Annex I so difficult.

I would like to stress in this connection that it is illusory to believe that chemical plant protection products should not have any adverse effects on non-target organisms. Let me express it clearly: such claims are preventing an authorization of any chemical plant protection product.

Beside other necessary improvements of the procedure, a pragmatical consensus regarding the evaluation of side effects of plant protection products has to be reached. The procedure for the inclusion of plant protection products in Annex I should be simplified urgently. Only if both indicated measures are taken, the necessary streamlining and thus the acceleration of the authorization procedure in the EU can take place. We should realise that this would not only be in the interest of the parties involved in the procedure but it possesses also an overall economic dimension.

This applies to

- the interest of agriculture in a fast access to new, more effective and, at the same time, environmentally friendly plant protection products and procedures,
- cost saving concerning authorities and the industry, and
- maintaining and reinforcing the economic competitiveness within the EU.

I am sure that with a certain amount of good will, also bearing in mind the necessity of improvements, this conference will be instrumental for solving the upcoming problems. Our industry is aware that it will have to contribute to finding a solution as well.

Progress with Regard to the Implementation of Directive 91/414/EEC Concerning the Placing of Plant Protection Products on the Market[1]

A. SCHARPÉ

European Commission (DG VI)
Belgium

This presentation covers the following issues:

- an overview of the general principles of Directive 91/414/EEC;
- progress with the harmonization process with regard to the implementation of the basic Directive since it was adopted by Council in July 1991, in terms of adopted implementation Directives and developed documents for guidance;
- procedures for evaluation and decision making on new and existing active substances;
- state of progress with the active substances currently under examination;
- some envisaged future developments with regard to the basic Directive 91/414/EEC and its implementation.

[1] This presentation represents the personal views of the autor and does not engage the Commission.

PLANT PROTECTION PRODUCTS REGISTRATION IN THE E.U. BEFORE AND AFTER THE ADOPTION OF DIRECTIVE 91/414/EEC

UNTIL JULY 1991 : 12 (later 15) Member States :

- with each its own registration regime
- operated completely independently, with only scarce collaboration between the Countries
- reluctance to accept harmonisation within the E.U. context :
  - = political sensitivity of the plant protection products area ;
  - = fear for "harmonisation à la baisse"
- limited coordination at E.U. level in international fora

JULY 1991 : ADOPTION OF DIRECTIVE 91/414/EEC (see further slides 4, 5, 6)

- harmonisation of certain aspects with regard to plant protection products registration
- central decision making regime for active substances ; but only very gradual harmonisation : existing active substances almost completely national until they have been included in Annex I
- limited implementation mandate for the Commission

SINCE JULY 1991

- Translation of Directive 91/414/EEC into the national legislation in each of the 15 Member States

- Important further technical harmonisation in the format of detailed implementation directives and guidelines (see further slides 7, 8)

- Starting up of common evaluation and decision making on existing and new active substances

- Development of intensive collaboration/consultation in the E.U. at the level of both the public authorities and the private interests :

  = between Commission and Member States competent authorities (meetings of Standing Committee on Plant Health and working groups thereof) and technical experts (meetings of the working group "evaluation", peer review, organisation of training visits);

  = ECPA and ECCA were created by the industry in order to represent their interests specifically in the E.U. context

- E.U. coordinated positions and important technical input from E.U. in the international fora :

  = OECD Pesticide Forum ;

  = Codex Alimentarius (Codex Committee on Pesticide Residues)

DIRECTIVE 91/414/EEC - MAIN BASIC PRINCIPLES

1. **Inclusion of active substances in annex I (*EC positive list* of authorized active substances)**

→ Slide 5

2. **Authorization of plant protection products by the *Member States***

→ Slide 6

3. ***Mutual recognition* of data submitted by industry, in support of applications**

- demonstration of the comparability of agricultural, plant health and environmental conditions in the regions concerned
- arbitration procedures in case of conflicts

4. ***Mutual recognition* of authorizations granted by a Member State**

- for plant protection products containing active substances included in Annex I of Directive 91/414/EEC;
- demonstration of the comparability of agricultural, plant health and environmental conditions in the regions concerned;
- arbitration procedures in case of conflicts

→ Slide 9

5. **Optional regime for provisional authorization of plant protection products containing a new active substance**

→ Slide 9

6. **Transition regime for 'existing' active substances/ *Reevaluation program***

- until inclusion : national regime continues to apply
- re-evaluation program → Slide 12

7. **Exchange of information between competent authorities**

8. **Regime of extension of authorizations for minor uses**

9. ***Control regime* for correct placing on the market and use**

- general obligation for Member States
- annual report on measures to the Commission and other Member States

INCLUSION OF 'NEW' AND 'EXISTING' ACTIVE SUBSTANCES IN ANNEX I

Basic characteristics of the regime

a *common* evaluation and decision making procedure

- *common* data requirements (**Annex II** of Directive 91/414/EEC) → **see slide 8**

- a *common* dossier structure and presentation
- a *single* decision making procedure for the whole EC

Basic criteria for inclusion

- under envisaged conditions of use of plant protection products containing the active substance : no expected harmful effects on *human and animal health* and no unacceptable influence for the *environment*

- *residues*, consequent to an application in accordance with good plant protection practice, do not have any harmful effects on *human or animal health*

AUTHORIZATION OF PLANT PROTECTION PRODUCTS

Basic characteristics of the regime

1. Each Member States has its **own** authorization regime

2. A number of elements are **harmonised** by Directive 91/414/EEC :

   - maximum period of authorization (10 years)

   - basic conditions for renewal, review, amendment, withdrawal of authorizations
   - content of authorizations in terms of restrictions and detailed use conditions

   - ***harmonized*** **data requirements (Annex III)** → **Slide 8**
   - ***harmonized*** **evaluation and decision making principles (Annex VI)**

   - regime concerning **confidentiality** of submitted data to third parties
   - regime concerning **protection** of submitted data from use by other applicants

   - provisions on **labeling** (i.a. Annexes IV and V)
   - provisions on **packaging**

TECHNICAL HARMONISATION SINCE ADOPTION OF DIRECTIVE 91/414/EEC

(COMMISSION ACTIVITIES)

A. DOSSIERS FROM INDUSTRY

1. Harmonised data requirements for chemical plant protection products (Annexes II and III of Directive 91/414/EEC)

→ Slide 8

2. Guidelines on applicability of Good Laboratory Practice

3. Guidelines for the preparation and presentation of complete dossiers and summary dossiers for inclusion of active substances in Annex I (including the initial checking for completeness) *(under progressive development)*

4. Guidelines for preparation and presentation of data concerning efficacy as provided in Annex III of directive 91/414/EEC *(under progressive development)*

5. Guidance documents for carrying out residue trials *(under progressive development)*

6. Guidance document with regard to modeling of fate and behavior of plant protection products in the environment (groundwater, surface water, soil)

7. Active support to and participation, together with the competent authorities in U.S. and Canada, in a project from industry (ECPA) concerning the presentation of dossiers on CD-ROM (CADDY project)

B. EVALUATION AND DECISION MAKING BY MEMBER STATES

1. Common principles concerning evaluation and decision making with regard to authorisations for plant protection products (Council Directive 97/57/EC)

2. Guidelines for the preparation of "monographs" by the rapporteur Member States *(under progressive development)*

3. Working documents for guidance to the Member States with regard to the implementation of the procedures for evaluation and inclusion of existing and new active substances in Annex I *(under progressive development)*

C. DOCUMENTS CURRENTLY IN PREPARATION

- detailed data requirements for microorganisms ;
- mutual recognition ;
- data protection ;
- establishment of AOELs ;
- evaluation of persistence in soil ;
- toxicology / aquatic organisms ;
- toxicology / terrestrial organisms ;
- analytical methods for residues

D. SUPPORT OF PARTICIPATION IN SPECIFIC WORKING GROUPS

- EUROPOEM
- FOCUS

DETAILED DATA REQUIREMENTS FOR ACTIVE SUBSTANCES AND PLANT PROTECTION PRODUCTS

Annex II Data requirements with regard to inclusion of an active substance in annex I of Directive 91/414/EEC

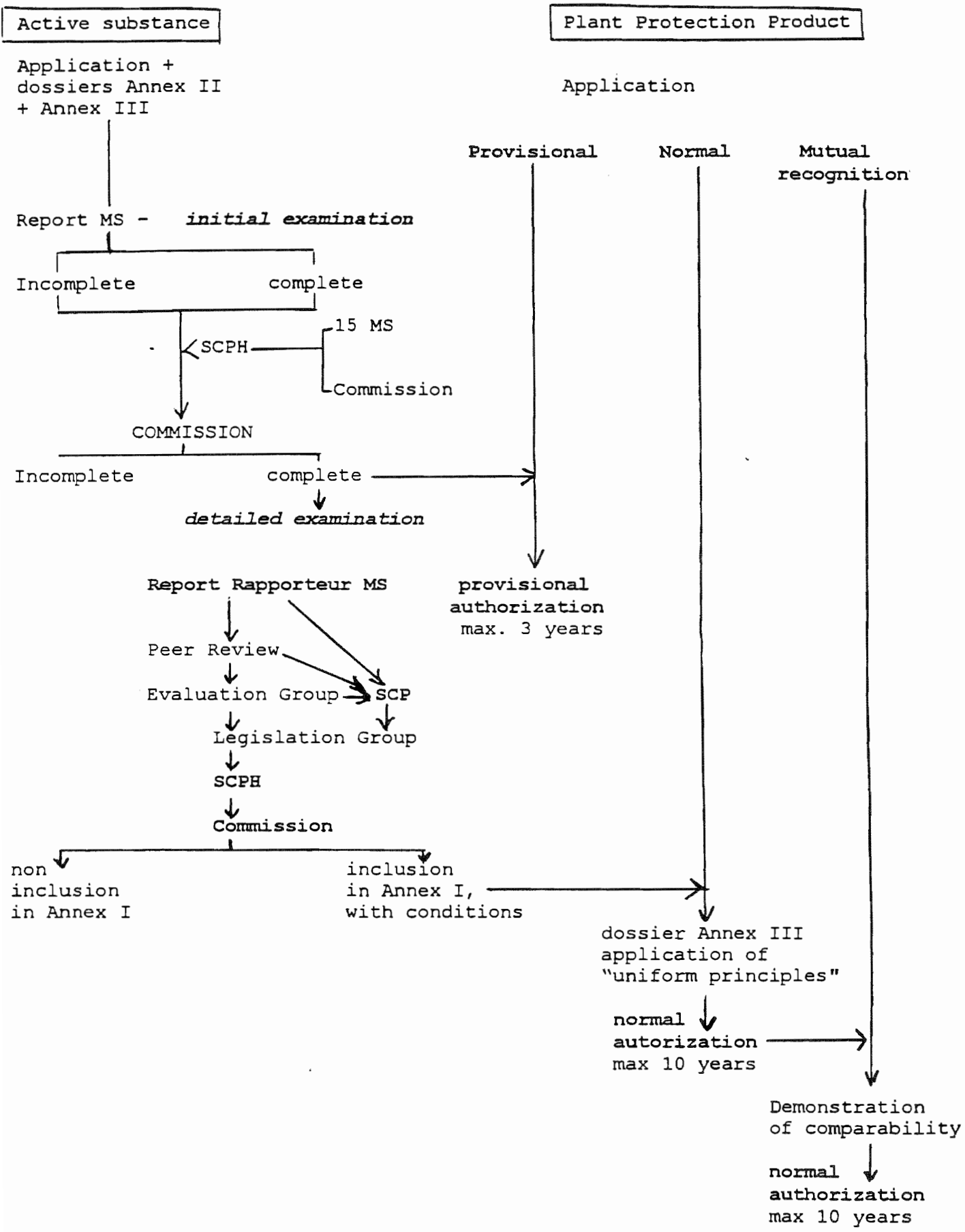
Annex III Data requirements with regard to authorization of a plant protection product.

Both annexes developed in parallel as follows :

Introduction		Directives 93/71/EEC and 95/36/EC
Part A - Chemical active substances		
1.	Identity of the active substance	Directive 94/37/EC
2.	Physical and chemical properties	Directive 94/37/EC
3.	Other information	Directive 94/37/EC
4.	Analytical methods	Directive 96/46/EC
5.	Toxicological and metabolism studies	Directive 94/79/EC
6.	Residues	Directive 96/68/EC
7.	Fate and behavior in the environment	Directive 95/36/EC
8.	Ecotoxicological studies	Directive 96/12/EC
9.	Summary	guidance document 1663/VI/94 rev.7.2
10.	Classification and labeling in the sense of Directive 67/548/EEC	guidance document 1663/VI/94 rev.7.2
Part B - Microorganisms and viruses		under preparation (1)

(1) Data requirements simply listed in Directive 91/414/EEC

AUTHORIZATION PROCEDURE FOR PLANT PROTECTION PRODUCTS CONTAINING A NEW ACTIVE SUBSTANCE



PROCEDURE FOR DECISION MAKING BY THE COMMISSION
(Article19 of Directive 91/414/EEC)

DRAFT OF THE MEASURES TO BE TAKEN

↓

PREPARED BY COMMISSION SERVICES

- PEER REVIEW
- EVALUATION GROUP (15 MS)
- SCP
- OTHER DG'S

↓

DISCUSSION IN WORKING GROUP LEGISLATION (15 MS)

↓

CONFIRMATION AGREEMENT OTHER DG'S

↓

DISCUSSION IN STANDING COMMITTEE ON PLANT HEALTH

- 15 MEMBERS STATES
- PRESIDENCY : COMMISSION

REQUEST FOR OPINION OF THE STANDING COMMITTEE

VOTE

DE	10	ES	8	PO	5	FIN	3
F	10	B	5	AU	4	IRL	3
IT	10	GR	5	SE	4	LUX	2
UK	10	NL	5	DK	3	COMMISSION	0
Total : 87							

FAVORABLE OPINION/VOTES FOR > 62 → THE COMMISSION ADOPTS THE MEASURE

UNFAVORABLE OPINION/VOTES AGAINST > 62 → THE COMMISSION PROPOSES MEASURES TO COUNCIL. IF THE COUNCIL DOES NOT ADOPT MEASURES WITHIN 3 MONTHS, THE COMMISSION ADOPTS THE PROPOSED MEASURES

NO OPINION →

REGULATION (EEC) N° 3600/92 - REVALUATION PROGRAM

THIS REGULATION COVERS THE REEVALUATION PROCEDURE FOR A FIRST GROUP OF 90 SUBSTANCES. THE REGIME IS BASED ON SHARED RESPONSIBILITY BETWEEN:

INDUSTRY: delivery of data according to the data requirements of Directive 91/414/EEC;

↓

RAPPORTEUR MEMBER STATES: Evaluation and preparation of recommendations for decision making

↓

COMMISSION: Coordination and decision making on active substances : Consultation of Experts (Peer Review), of SCP and of Member States (Evaluation and Legislation Working Groups, Standing Committee)

POSSIBLE DECISIONS

Sufficient data presented		No interest to present data or no sufficient data
Safety requirements satisfied, at least under certain conditions of use,	no demonstration that safety requirements are satisfied	
- Inclusion in Annex I (associated with necessary conditions)	Decision not to include[1] in Annex I and/or prohibition under Directive 79/117/EEC	Decision not to include the active substance in Annex I
1 decision taken (imazalil)	*1 decision u. final preparation (dinoterb)*	*4 decisions taken 1 decision u. final preparation*[2]

↓

MEMBER STATES: Review or withdrawal of authorizations of products containing the reviewed active substance

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1 definitivcly or provisionally (post-ponement, suspension)

2 cyhalothrin, ferbam, azinphos-ethyl, propham, fenvalerate

POSSIBLE FUTURE DEVELOPMENTS

REVIEW DIRECTIVE 91/414/EEC

1. Improvement of the **resource basis** for the implementation of Directive 91/414/EEC and in particular the reevaluation program in the Member States and the Commission

2. Amendments in Directive 91/414/EEC related to the review of the EC regime concerning the **classification/labeling/packaging** of plant protection products.

3. Development of detailed rules with regard to **microorganisms**, including **GMOs**

4. **Technical review** of Directive 91/414/EEC

   - taking into account gained experience and confidence between Member States
   - more deep going harmonisation
   - addressing particular technical questions, e.g. minor uses, commodity chemicals, fast tracks for certain categories of products

5. Harmonised rules for better **control on safe use and distribution of plant protection products**

IMPLEMENTATION OF DIRECTIVE 91/414/EEC

1. Development of guidance documents.

2. Development of Annexes II, III, VI with regard to microbial plant protection products.

3. Preparation of 2nd phase of the re-evaluation program.

MRL SETTING PROGRAM

Increased coordination of MRL setting with decision making under Directive 91/414/EEC

Annex IIa

updated revison

New Active Substances under evaluation on 02.07.98
Completeness of dossier

No.	Dev. Code	*Active substance (Main use of product)*	*Company submitting application*	*Date of application to a MS*	*Information sheet to MS*	*MS carrying out complet.ess check*	*Rapporteur MS report on completeness received by Commission*	*Confirmation of receipt of rapporteur MS report on completeness in all MSs*	*Date of Commission receipt of dossier from company*	*Confirmation of receipt of dossier in all MS*	*Date of referral of dossier to SCPH**	*Decision on completeness*
		Chemical substances										
1		**Prohexadione Calcium (PG)**	BASF	10,02,94		F	04,01,95	25,09,95	15,03,95,	25,09,95	25,09,95	positive; SCPH 14.06.96; OJ No L 220, 30,08,96, p 19 **96/520/EC**
2		**Kresoxim-methyl (FU)**	BASF	28,03,95	30,03,95	B	19,07,95	25,09,95	22,08,95	25,09,95	25,09,95	positive;SCPH 24,11,95; OJ No L 91, 12.04.96, p. 74. **96/341/EC**
3		**Flurtamone(HB)**	Rhône-Poulenc Agro France	15.02.94		F	30,10,95	23,11,95	28.11.95	24,11,95	24,11,95	positive; SCPH 20.03.96; OJ No L 130, 31.05.96, p. 20. **96/341/EC**
4		**Chlorfenapyr (AC,IN)**	Cyanamid	07,07,95	21,08,95	E	11,12,95	11.01.96	17.01.96	30.01.96.	30.01.96	positive; SCPH 14.06.96; OJ No L 220, 30,08,96, p 21 **96/521/EC**
5	DE 795	**Quinoxyfen (FU)**	DowElanco	01,08,95	08,08,95	UK	18.01.96	30.01.96	09,01,96	20.03.96	20.03.96	Positive; SCPH 22.04.96; OJ No L 189, 30,07,96, p 112 **96/457/EC**
6	ICIA 5504	**Azoxystrobin (FU)**	Zeneca Crop Protection	15,09,95	02,11,95	D	22.03.96	22.04.96	20.03.96	22.04.96	22.04.96	positive; SCPH 14.06.96; OJ No L 220, 30,08,96, p 25 **96/523/EC**
7	KWG 4168	**Spiroxamine (FU)**	Bayer	13,10,95	19.10,95	D	22.03.96	22.04.96	17.04.96	22.04.96	22.04.96	positive; SCPH 14.06.96; OJ No L 220, 30,08,96, p 23 **96/522/EC**
8	RPA 201772	**Isoxaflutole (HB)**	Rhône-Poulenc	06.03.96	14.03.96	NL	22.04.96	22.04.96	09.04.96	22.04.96	22.04.96	positive; SCPH 14.06.96OJ No L 220, 30,08,96, p 27 **96/524/EC**
9		**Alanycarbe(IN)**	Otsuka Chemical Co.	24.07.95	25.01.96	F	18,12,97	18,02,98	06,02,98	18,02,98	18,02,98	
10	DPX KE 459	**Flupyrsulfuron methyl (HB)**	Du Pont de Nemours	26,10,95	25.01.96	F	22,07,96	16,08,96	04,07,96	16,08,96	16,08,96	positive, SCPH 20,11,96;OJ No 64, 05.03.1997, p.17 **97/164/EC**
11		**Flumioxazine(HB)**	Cyanamid	02,05,94	25.01.96	F	30.05.96	14.06.96	16.06.96	12,07,96	12,07,96	positive, SCPH 11,07,97; OJ No L262, 24.9.97, p.7. **97/631/EC**

*Starting date for the maximum 6 months period for the Community completeness check

No.	Dev. Code	*Active substance (Main use of product)*	*Company submitting application*	*Date of application to a MS*	*Information sheet to MS*	*MS carrying out complet.ess check*	*Rapporteur MS report on completeness received by Commission*	*Confirmation of receipt of rapporteur MS report on completeness in all MSs*	*Date of Commission receipt of dossier from company*	*Confirmation of receipt of dossier in all MS*	*Date of referral of dossier to SCPH**	*Decision on completeness*
12	CGA 152005	**Prosulfuron(HB)**	Novartis	14,05,95	25.01.96	F	30.05.96	14.06.96	06.06.96	14,06,96	14,06,96	positive; SCPH 11,10,96; OJ No L 52, 22,2,1997,p.20. **97/137/EC**
13	CGA 329351	**Mefenoxam (new iso name proposed metalaxyl-M)**	Novartis Crop Protection AG	09.02.96	15.02.96	B	19,11,96	19,12,96	31,01,97	21,03,97	21,03,97	positive; SCPH 29,05,97; OJ No L239, 30,8,97, p.48. **97/591/EC**
14	DPX A8947	**Azimsulfuron(HB)**	Du Pont De Nemours	04.03.96	04.03.96	I	31,07,96	11,10,96	01,08,96	11,10,96	11,10,96	positive, SCPH 20,11,96;OJ No 64, 05.03.1997, p 3. **97/164/EC**
15		**Fosthiazate(NE)**	ISK Biosciences Division	05.03.96	13.03.96	UK	30,10,96	20,11,96	20,11,96	19,12,96	19,12,96	positive, SCPH 21,03,97; OJ No L 152, 11.06.1997, p.31. **97/362/EC**
16		**Cyclanilide(PG)**	Rhône Poulenc Agrochimie S.A.	27.03.96	01.04.96	EL	30.05.96	14.06.96	30.05.96	14.06.96	14.06.96	positive; SCPH 11,10,96; OJ No L 52, 22.2.1997, p.20. **97/137/EC**
17	F8426	**Carfentrazone-ethyl (HB)**	FMC Europe NV	14.02.96	28.03.96	F	25,10,96	20,11,96	21,11,96	19,12,96	19,12,96	positive, SCPH 21,03,97; OJ No L 152, 11.06.1997, p.31. **97/362/EC**
18	FOE 5043	**Flufenacet (HB) (previous name fluthiamide)**	Bayer S. A.	01.02.96	28.03.96	F	25,10,96	20,11,96	19,11,96	19,12,96	19,12,96	positive, SCPH 21,03,97; OJ No L 152, 11.06.1997, p.31. **97/362/EC**
19		**Imazosulfuron (HB)**	Urania Agrochem GmbH	27,06,96	24,07,96	D	05,05,97	11,07,97	23,06,97	11,07,97	11,07,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**
20	AEF 095404	**Ethoxysulfuron (HB)**	AgrEvo	03,07,96	04,07,96	I	22,01,97	06,02,97	10,03,97	21,03,97	21,03,97	positive; SCPH 29,05,97; OJ No L 239, 30,8,97, p.48. **97/591/EC**
21	CGA 215944	**Pymetrozine (IN)**	Novartis	04,09,96	20,09,96	D	18,03,97	29,05,97	28,05,97	29,05,97	29,05,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**
22	DPX JE 874	**Famoxadone (FU)**	DuPont de Nemours	02,10,96	02,10,96	F	26,03,97	21,03,97	03,10,96	21,03,97	21,03,97	positive; SCPH 29,05,97; OJ No L239, 30.8.97, p.48. **97/591/EC**
23	CGA 245 704	**(proposed iso name azibenzolar-s-methyl)(FU)**	Novartis	15,10,96	04,11,96	F	05,05,97	19,06,97	15,05,97	19,06,97	19,06,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**

*Starting date for the maximum 6 months period
for the Community completeness check

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24		**Flazasulfuron (HB)**	I. S. K. Biosciences	16,12,96	01,01,97	E	06,06,97	29,05,97	02,05,97	29,05,97	29,05,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**
25	L 91105D	**Carvone (PG)**	Luxan B.V.	26,03,97	05,05,97	NL						
26	MON 37500	**Sulfosulfuron (HB)**	Monsanto	24,04,97	05,05,97	IRL	11,07,97	11,07,97	07,07,97	11,07,97	11,07,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**
27	EF 1218	**Cyhalofop-butyl (HB)**	Dow Elanco	30,04,97	07,05,97	I	05,11,97	16,12,97	04,11,97	16,12,97	16,12,97	positive SCPH 16.12.97; OJ No. L 96, 28.3.98 **98/242/EC**
28	BAS 615H	**(proposed iso cinidon-ethyl) (HB)**	BASF plc.	28,04,97	08,05,97	UK	12,01,98	18,02,98	29,01,98	18,02,98	18,02,98	positive; SCPH 22,4,98; OJ. L. 176, 20.6.98 **98/398/EC**
29	KBR 2738	**Fenhexamid (FU)**	Bayer plc.	08,05,97	15,05,97	UK	16,12,97	18,02,98	10,03,98	18,02,98	18,02,98	positive; SCPH 22,4,98; OJ. L. 176, 20.6.98 **98/398/EC**
30	RP020630	**Oxadiargyl (HB)**	Rhone Poulenc	16,06,97	23,06,97	I	16,12,97	18,02,98	18,12,97	18,02,98	18,02,98	positive; SCPH 22,4,98; OJ. L. 176, 20.6.98 **98/398/EC**
31		**Pyraflufen-ethyl (HB)**	Nihon Nohyaku Co. Ltd.	16,06,97	18,06,97	B	02,12,97	16,12,97	04,12,97	16,12,97	16,12,97	positive SCPH 16.12.97; OJ No. L 96, 28.3.98 **98/242/EC**
32	DPX R6447	**Azafenidin (HB)**	Du Pont de Nemours	25,06,97	01,07,97	E	08,12,97	16,12,97	28,11,97	16,12,97	16,12,97	positive SCPH 16.12.97; OJ No. L 96, 28.3.98 **98/242/EC**
33		**S-Metolachlor (HB)**	Novartis N.V.	01,08,97	04,08,97	B	23,02,98	21,04,98	12,03,98	21,04,98	21,04,98	positive SCPH 7,7,98;OJ No.L228, 15.8.98 **98/512/EC**
34	BAS 620 H	**Tepraloxydim (HB)**	BASF	11,09,97	12,09,97	E	17,02,98	21,04,98	12,03,98	21,04,98	21,04,98	positive SCPH 7,7,98;OJ No.L228, 15.8.98 **98/512/EC**

*Starting date for the maximum 6 months period
for the Community completeness check

No.	Dev. Code	*Active substance (Main use of product)*	*Company submitting application*	*Date of application to a MS*	*Information sheet to MS*	*MS carrying out complet.ess check*	*Rapporteur MS report on completeness received by Commission*	*Confirmation of receipt of rapporteur MS report on completeness in all MSs*	*Date of Commission receipt of dossier from company*	*Confirmation of receipt of dossier in all MS*	*Date of referral of dossier to SCPH**	*Decision on completeness*
35	JV 485	**Fluazolate (HB) (formerly isopropazole)**	Twinagro	29,09,97	09,10,97	UK	08,06,98	7,7,98	22,06,98	7,7,98	7,7,98	
36	DPX-KN128	**(proposed iso name indoxacarb) (IN)**	Du Pont de Nemours	06,10,97	13,10,97	NL	18,02,98	18,02,98	15,12,97	18,02,98	18,02,98	positive; SCPH 22,4,98; OJ. L. 176, 20.6.98 **98/398/EC**
37	KIF 3535	**Mepanipyrim(proposed iso name(FU)**	Kumiai	24,10,97	03,11,97	I	28,05,98	7,7,98	25,06,98	7,7,98	7,7,98	
38	AC 299 263	**Imazamox (HB)**	Cyanamid NV/SA	02,12,97	12,01,98	F	10,06,98	7,7,98	25.06.98	7,7,98	7,7,98	
39	MTF 651	**Flusulfamide (FU)**	Mitsui Toatsu Chemical Co.	19.09.97	3.10.97	UK						
40	DE 570	**(proposed iso name florasulam) (HB)**	Dow AgroSciences	02,02,98	03,02,98	B	8,06,98	7,7,98	25,06,98	7,7,98	7,7,98	
41	CGA 279 202	**Trifoxistrobin(FU)**	Novartis Crop Protection UK Ltd.	28,01,98	06,02,98	UK	04,09,98					
42	SZX 0722	**Iprovalicarb (iso proposed)**	Bayer Plc.	30,03,98	01,04,98	IRL	06,04,98	21,04,98	08,04,98	21,04,98	21,04,98	positive SCPH 7,7,98;OJ No.L228, 15.8.98 **98/512/EC**
43	BAS 625H	**Clefoxidim (HB)**	BASF	02,04,98	03,04,98	E	11,08,98					
44		**Etoxazol (IN)**	Sumitomo Chemical Agro Europe SA	21,04,98	20,05,98	F	03,09,98					
45		**Benzoic acid(BA, FU,OT)**	Menno Chemie Vertriebs-Ges	25,05,98	27,05,98	D	28,05,98	7,7,98	29,05,98	7,7,98	7,7,98	
46	ZA 1296	**Mesotrione (HB) (iso proposed)**	Zeneca Agrochemicals	23,04,98	05,05,98	UK						
47	CGA 277 476	**Oxasulfuron (HB) (iso proposed)**	Novartis Protezione Piante S.p.A.	29,05,98	05,06,98	I						
48		**Ferric Phosphate (MO)**	W.Neudorff GmbH KG	27,08,98	09,09,98	D						
49	SAN 1367H	**Pyridafol (HB) (iso proposed)**	Novartis Crop Protection UK Ltd.	10,09,98	10,09,98	UK						
		Micro-organisms										

*Starting date for the maximum 6 months period for the Community completeness check

New Active Substances under evaluation on 02.07.98
Completeness of dossier

No.	Dev. Code	*Active substance (Main use of product)*	*Company submitting application*	*Date of application to a MS*	*Information sheet to MS*	*MS carrying out complet.ess check*	*Rapporteur MS report on completeness received by Commission*	*Confirmation of receipt of rapporteur MS report on completeness in all MSs*	*Date of Commission receipt of dossier from company*	*Confirmation of receipt of dossier in all MS*	*Date of referral of dossier to SCPH**	*Decision on completeness*
1		**Paecilomyces fumosoroseus (IN)**	Thermo Trilogy Coporation	18.05.94	21,12,94	B	14,11,95	23,11,95	18,05,95	24,11,95	24.11.95	positive, SCPH 20,11,96;OJ No 64, 05.03.1997, p.17 **97/164/EC**
2		**Pseudomonas chloroaphis(FU)**	Svenska Lantmännen riksförbund	15,12,94	19,09,95	S	22,11,95	11.01.96	15.02.96	20.03.96	20.03.96	positive; SCPH 07,02,97 ;OJ L.98, 15.04.97, p.15 **97/248/EC**
3	AQ 10	**Ampelomyces quisqualis(IN)**	Ecogen Europe sarl	12,04,96	12.04.96	F	25,10,96	19,11,96	09,12,96	06,02,97	06,02,97	positive; SCPH 29,05,97; OJ No L239, 30.8.97, p.48. **97/591/EC**
4	SE NPV	**Spodoptera exigua nuclear polyhedrosis virus(IN)**	biosys	12,07,96	24,07,96	NL	02,04,97	29,05,97	23,04,97	29,05,97	29,05,97	positive; SCPH 17,10,97; OJ No.L351, 23.12.97, P.67. **97/865/EC**
5		**Coniothyrium minitans**	Prophyta GmbH	10.09.97	15.10.97	D	05,01,98	7,7,98	19,03,98	7,7,98	7,7,98	
6		**Zucchini Yellow Mosaic Virus (ZYMV mild strain)**	Horticultural Research International	23,01,98	06,02,98	UK						
7		**Gliocladium catenulatum (FU) strain J1446**	Kemira Agro Oy	19,05,98	29,05,98	FIN						

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for the Community completeness check

Annex IIIa

updated revison

1ST STAGE OF WORK UNDER ARTICLE 8(2) OF DIR. 91/414/EEC

PROGRESS OF WORK ON 02.07.98

No	Active Substance	Rapp. MS	Date of submission of monograph	Receipt of Monographs in Com.	Receipt of summary dossier in Com	State of examination	Peer review
1	2,4-D	EL	31,10,96	17,01,97	20,05,97	7	Sept.97-Jan.98
2	2,4-DB	EL	30,04,96	17,01,97	25,07,97	7	Sept.97-Jan.98
3	Acephate	I	30,04,96	30,09,96	24,10,96	4	
4	Alachlor	E	31,10,96			4	
5	Aldicarb	UK	30,04,96	02.04.96	20,09,96	7	09-12,96
6	Amitraz	A	31,10,96	06.01.98		4	
7	Amitrole	F	30,04,96	18,07,96	06,01,97	7	01-04,97
8	Atrazine	UK	30,04,96	11,11,96	05,02,98	4	March-July 98
9	Azinphos-ethyl	D	-----			1	-
10	Azinphos-methyl	D	30,04,96	11,10,96	24,03,97	7	Sept 97-Jan 98
11	Benalaxyl	P	30,04,96			4	
12	Benomyl	D	30,04,96	21,11,97	17,02,98	4	March-July 98
13	Bentazone	D	30,04,96	13,11,96	29,11,96	7	Sept 97-Jan 98
14	Bromoxynil	F	31,10,96	18,12,97		4	
15	Carbendazim	D	31,10,96	21,11,97	10,02,98	4	March-July 98
16	Chlorothalonil	NL	31,10,96			4	
17	Chlorpropham	NL	30,04,96			4	
18	Chlorpyrifos	E	31,10,96			4	
19	Chlorpyrifos-methyl	E	30,04,96	16,09,97	19,11,97	4	
20	Chlortoluron	E	31,10,96			4	
21	Chlozolinate	EL	30,04,96	03,11,97		4	March-July 98
22	Cyfluthrin	D	30,04,96	13,11,96	13,12,96	5,7	01-04,97

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7= evaluation group examination

8= scp examination

9= decision in final preparation

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12=postponment

1ST STAGE OF WORK UNDER ARTICLE 8(2) OF DIR. 91/414/EEC
PROGRESS OF WORK ON 02.07.98

No	Active Substance	Rapp. MS	Date of submission of monograph	Receipt of Monographs in Com.	Receipt of summary dossier in Com	State of examination	Peer review period
23	Cyhalothrin					1	-
24	Cypermethrin	B	31,10,96			4	
25	DNOC	F	30,04,96	30,09,96	26,02,97	7	04-07,97
26	Daminozide	NL	30,04,96			4	
27	Deltamethrin	S	31,10,96			4	
28	Desmedipham	FIN	30,04,96			4	
29	Dinocap	A	30,04,96			3	
30	Dinoterb	F	30,04,96	18,07,96		1	01-04,97
31	Diquat	UK	30,04,96	02,04,96	29,07,96	7	09-12,96
32	Endosulfan	E	31,10,96			4	
33	Esfenvalerate	P	30,04,96	11,10,96		7	04-07,97
34	Ethofumesate	S	31,10,96			4	
35	Fenarimol	UK	30,04,96	02.04.96	26,08,96	5,8	09-12,96
36	Fenthion	EL	30,04,96	04,07,96		8	09-12,96
37	Fentin acetate	UK	31,10,96	11,11,96	27,11,97	4	March-July 98
38	Fentin hydroxide	UK	31,10,96	11,11,96	27,11,97	4	March-July 98
39	Fenvalerate	P	31,10,96			2,3,1	-
40	Ferbam	B	-----			1	
41	Fluroxypyr	D	30,04,96	27,09,96	06,01,97	6	01-04,97
42	Flusilazole	IRL	30,04,96	18,07,96	26,08,96	5,7	01-04,97
43	Glyphosate	D	31,10,96			4	
44	Imazalil	L	30,04,96	15,07,96	30,08,96	10	09-12,96

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updated revison

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45	Ioxynil	F	31,10,96			4	
46	Iprodione	F	30,04,96	18,07,96	17,12,97	4	March-July 98
47	Isoproturon	D	31,10,96			4	
48	Lindane	A	31,10,96			4	
49	Linuron	UK	31,10,96	11,11,96	04,08,97	7	Sept. 97-Jan 98
50	MCPA	I	31,10,96			4	
51	MCPB	I	30,04,96			4	
52	Maleic hydrazide	DK	30,04,96	03,09,97	04,11,97	4	
53	Mancozeb	I	31,10,96			4	
54	Maneb	I	30,04,96			4	
55	Mecoprop	DK	31,10,96			4	
56	Mecoprop-p	DK	31,10,96			4	
57	Metalaxyl	P	31,10,96			4	
58	Methamidophos	I	31,10,96			4	
59	Metiram	I	30,04,96			4	
60	Metsulfuron - methyl	F	31,10,96	25,06,97	18,07,97	7	Sept 97-Jan 98
61	Molinate	P	30,04,96			4	
62	Monolinuron	UK	30,04,96	11,11,96	04,08,97	7	Sept.97-Jan.98
63	Paraquat	UK	31,10,96	01,10,96	26,02,97	7	04-07,97
64	Parathion	I	30,04,96			4	
65	Parathion-methyl	I	31,10,96			4	
66	Pendimethalin	E	31,10,96	20,05,98		4	Sept.98-Jan.99

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1ST STAGE OF WORK UNDER ARTICLE 8(2) OF DIR. 91/414/EEC
PROGRESS OF WORK ON 02.07.98

No	Active Substance	Rapp. MS	Date of submission of monograph	Receipt of Monographs in Com.	Receipt of summary dossier in Com	State of examination	Peer review period
67	Permethrin	IRL	31,10,96	10,06,98		4	
68	Phenmedipham	FIN	31,10,96			4	
69	Procymidone	F	30,04,96			4	
70	Propham	NL	-----			1	-
71	Propiconazole	FIN	30,04,96			4	
72	Propineb	I	30,04,96	17,07,96	07,01,97	7	01-04,97
73	Propyzamide	S	31,10,96	19,05,98	19,05,98	4	
74	Pyrazophos	NL	30,04,96	14,05,98		4	Sept.98-Jan.99
75	Pyridate	A	30,04,96	18,11,96	07,01,97	7	04-07,97
76	Quintozene	EL	30,04,96	02,12,97	09,02,98	4	March-July 98
77	Simazine	UK	31,10,96	20,12,96	05,02,98	4	March-July 98
78	Tecnazene	UK	30,04,96	02.04.96	04,07,96	7	09-12,96
79	Thiabendazole	E	30,04,96	08,08,96	23,10,96	7	Sept.97-Jan.98
80	Thifensulfuron	F	30,04,96	18,07,96	09,12,96	7	01-04,97
81	Thiophanate-methyl	D	31,10,96	21,11,97	16,01,98	4	March-July 98
82	Thiram	B	31,10,96	15,01,98		4	
83	Triasulfuron	F	30,04,96	30,09,96		6	Sept 97-Jan 98
84	Vinclozolin	F	30,04,96	26,03,97	04,08,97	4	March-July 98
85	Warfarin	IRL	30,04,96	15.05.96	20,09,96	7	09-12,96
86	Zineb	I	31,10,96			4	
87	Ziram	B	31,10,96	09,06,98		4	
88	alpha-Cypermethrin	B	30,04,96			4	
89	beta-Cyfluthrin	D	30,04,96	28,11.96	28,11,96	7	01-04,97
90	lambda-Cyhalothrin	S	30,04,96	,,06,96	31,07,96	7	09-12,96

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ANNEX IV (updated revision: 2 July 1998)

1. LIST OF ADOPTED LEGISLATIVE MEASURES, FRAMEWORK 91/414/EEC

1.1 General legislation

1. Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, O.J. No L 230, 19.8.1991, p.1

2. Commission Regulation (EEC) n° 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC,OJ n°L366 of 15 December 1992.

3. Commission Directive 93/71/EEC of 27 July 1993 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, O.J. No L 221, 31.8.1993, p. 27

4. Commission Directive 94/37/EC of 22 July 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, O.J. No L 194, 29.7.1994, p. 65

5. Commission Regulation (EC) n° 933/94 of 27 April 1994, laying down the active substances of plant protection products and designating the rapporteur Member State for the implementation of Commission Regulation (EEC) n° 3600/92, OJ n°L 107 of 28 April 1994.

6. Commission Directive 94/79/EC of 21 December 1994 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, O.J. No L 354, 31.12.1994, p. 16

7. Commission Regulation (EC) n° 491/95 of 3 March 1995 amending Regulation (EC) No 933/94, in particular with regard to the integration of the designated public authorities and the producers in Austria, Finland and Sweden in the implementation of the first stage of the programme of work referred to in Article 8 (2) of Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

8. Commission Directive 95/35/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ No L172, 22.7.95, p6.

9. Commission Directive 95/36/EC of 14 July 1995 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ No L172, 22.7.95, p6.

10. Commission Regulation (EC) N° 2230/95 of 21 September 1995 amending Regulation (EC) No 933/94, laying down the active substances of plant protection products and designating the rapporteur Member States for the implementation of Commission Regulation (EEC) N° 3600/92, OJ N° L225, 22.9.95, p.1.

11. Commission Directive 96/12/EC of 8 March 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ No L65,15.3.96, p 20.

12. Commission Directive 96/46/EC of 23 August 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ No L214, 23.8.96, p. 18.

13. Commission Directive 96/68/EC of 21 October 1996 amending Council Directive 91/414/EEC concerning the placing of plant protection products on the market, OJ No L277, 30.10.96, p. 25.

14. Commission Regulation (EC) n° 1199/97 of 27.6.1997 amending Regulation (EEC) n° 3600/92 of 11 December 1992 laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC,concerning the placing of plant protection products on the market, OJ N° L170, 28.6.1997, p. 19.

15. Council Directive 97/57/EC of 22 September 1997 establishing Annex VI to Directive 91/414/EEC concerning the placing of plant protection products on the market, O.J. No L 265,27.9.1997, p. 87.

1.2 Measures with regard to individual active substances

1. Commission Decision 94/643/EC of 12 September 1994(OJ n°L249 of 24 September 1994) concerning the withdrawal of authorisations for plant protection products containing cyhalothrin as active substance.

2. Commission Decision 95/276/EC of 13 July 1995(O.J L170, 20.7.95, p.22), concerning the withdrawal of authorisations of plant protection products containing ferbam and azinphos-ethyl as active substances.

3. Commission Decision 96/586/EC of 9 April 1996(O.J. L 257, 10.10.96, p. 41) concerning the withdrawal of authorisations for plant protection products containing propham as an active substance.

4. Commission Directive 97/73/EC of 15 December 1997 (O.J. L 353, 24.12.97, p. 26) including an active substance (imazalil) in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

5. Commission Decision 98/269/EC of 7 April 1998 (O.J. L 117, 21.04.1998 p 13) concerning the withdrawal of authorisations for plant protection products containing dinoterb as an active substance.

6. Commission Decision 98/270/EC of 7 April 1998 (O.J. L 117, 21.04.1998 p 15) concerning the withdrawal of authorisations for plant protection products containing fenvalerate as an active substance.

7. Commission Decision 98/ /EC of June 1998 (O.J. ...) including an active substance (azoxystrobin) in Annex I of Directive 91/414/EEC concerning the placing of plant protection products on the market.

1.3. Measures concerning the completeness of dossier for new active substances

Active substance	Decision	O.J.
Kresoxim-methyl	96/266/EC	L 91 of 12.4.96, p. 74
Flurtamone	96/341/EC	L 130 of 31.5.96, p. 20
Quinoxyfen	96/457/EC	L 189 of 30.7.96, p. 112
Prohexadione Calcium	96/520/EC	L. 220 of 30.8.96, p. 19
Chlorfenapyr	96/521/EC	L 220 of 30.8.96, p. 21
Spiroxamine	96/522/EC	L 220 of 30.8.96, p. 23
Azoxystrobin	96/523/EC	L 220 of 30.8.96, p. 25
Isoxaflutole	96/524/EC	L 220 of 30.8.96, p. 27
Cyclanilide	97/137/EC	L 52 of 22.2.97, p. 20
Prosulfuron	97/137/EC	L 52 of 22.2.97, p. 20
Flupyrsulfuron-methyl	97/164/EC	L 64 of 5.3.97, p. 17
Azimsulfuron	97/164/EC	L 64 of 5.3.97, p. 17
Paecilomyces fumosoroseus	97/164/EC	L 64 of 5.3.97, p. 17
Pseudomonas chloroaphis	97/248/EC	L 98 of 15.4.97, p. 15
Fluthiamide	97/362/EC	L 152 of 11.6.97, p.31
Carfentrazone-ethyl	97/362/EC	L 152 of 11.6.97, p.31
Fosthiazate	97/362/EC	L 152 of 11.6.97, p.31
Mefenoxam	97/591/EC	L.239 of 30.8.97, p.48
Ethoxysulfuron	97/591/EC	L.239 of 30.8.97, p.48
Famoxadone	97/591/EC	L 239 of 30.8.97, p.48
Ampelomyces quisqualis	97/591/EC	L 239 of 30.8.97, p.48
Flumioxazine	97/631/EC	L 262 of 24.9.97 p.7
CGA 245 704	97/865/EC	L 351 of 23.12.97 p. 67
Flazasulfuron	97/865/EC	L 351 of 23.12.97 p. 67
Spodoptera exigua	97/865/EC	L 351 of 23.12.97 p. 67
Polyhedrosis virus	97/865/EC	L 351 of 23.12.97 p. 67
Imazosulfuron	97/865/EC	L 351 of 23.12.97 p. 67
Pymetrozine	97/865/EC	L 351 of 23.12.97 p. 67
Sulfosulfuron	97/865/EC	L 351 of 23.12.97 p. 67

Active substance	Decision	O.J.
Cyhalopfop-butyl	98/242/EC	L 96 of 28.3.98
Pyraflufen ethyl	98/242/EC	L 96 of 28.3.98
Azafenidin	98/242/EC	L 96 of 28.3.98
BAS 615H	98/398/EC	L 176 of 20.6.98
KBR 2738 (fenhexamide)	98/398/EC	L 176 of 20.6.98
Oxadiargyl	98/398/EC	L 176 of 20.6.98
DPX-KN 128 (indoxacarbe)	98/398/EC	L 176 of 20.6.98

2. MAIN WORKING DOCUMENTS FOR GUIDANCE IN USE BY MEMBER STATES OR INDUSTRY

2.1 Finalised documents submitted to standing committee

1. Doc. 7109/VI/94 rev. 6.c1 : Applicability of Good Laboratory Practice to data requirements according to annexes II, part A and III, part A of Council Directive 91/414/EEC.

2. Doc 1694/VI/95, 4952/VI/95, 6476/VI/96 and 7617/VI/96: 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 (in groundwater, surface water and soil).

3. Doc. 7017/VI/95 rev.4: Guideline developed within the Standing Committee on Plant Health with regard to the acceptability of data, whether or not performed in accordance with the principles of Good Laboratory Practice (GLP).

4. Doc. 1663/VI/94 rev. 8 of 22 April 1998: Guidelines and criteria for the preparation and presentation of complete dossiers and of summary dossiers for the inclusion of active substances in Annex I of Directive 91/414/EEC (Article 5.3 and 8.2)

5. Doc. 1654/VI/94 rev.7 of 22.April.1998: Guidelines for preparation of monographs by rapporteur Member States.

2.2 Guidelines under progressive development

1. Doc. 1614/VI/95 rev.7: Working document for guidance to the Member States with regard to the implementation of Articles 6 and 7 of Regulation (EEC) n° 3600/92, developed in the working group "plant protection products - legislation" of the SCPH.

2. Doc. 1663/VI/95 rev.2 16.6.1996: Working document for guidance to the Member States with regard to the implementation of Article 6 of Directive 91/414/EEC for new active substances, developed in the working group "plant protection products - legislation" of the SCPH.

3. Doc. 7600/VI/95 rev.6 of 14.7.1997 - Guidelines and Criteria for the preparation and presentation of data concerning efficacy as provided in Annex III, parts A and B, section 6 of Directive 91/414/EEC concerning the placing of plant protection products on the market (biological assessment dossier.)

4. Doc. 1607/VI/97 rev. 1 of 22.7.1997 which contains further guidance for carrying out residue trials containing the following parts:

- 7028/VI/95 rev.2: Appendix A
  Metabolism and distribution in plants

- 7029/VI/95 rev.4: Appendix B
  General recommendations for the design, preparation and realisation of residue trials
- 7524/VI/95 rev.1: Appendix C
  Testing of plant protection products in rotational crops

- 7525/VI/95 rev.1: Appendix D
  Comparability, extrapolation, group tolerances and

- 7035/VI/95 rev.4: Appendix E
  Processing studies

- 7030/VI/95 rev.2: Appendix F
  Metabolism and distribution in domestic animals

- 7031/VI/95 rev.3: Appendix G
  Livestock feeding studies

- 7032/VI/95 rev.4: Appendix H
  Storage stability of residue samples

- 7039/VI/95: Appendix I
  Calculation of Maximum Residue Levels and Safety intervals e.g. Pre-harvest Intervals

EU-Guidelines for the Preparation of Dossiers and Monographs

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A 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) (Document 1663/VI/94, rev 7.6 of 31 October 1997)

The version of the guidelines currently being used by industry is rev 7.2 of 25 July 1996. Revision 7.6 (31 October 1997) was considered by the Working Group "Legislation" during its meeting of 16 and 17 December last. It is envisaged that rev 8 will be finalised in coming weeks by the Standing Committee on Plant Health and will then be issued and commended for use in preparing future submissions. It is not envisaged that a further revision will be necessary for some time.

A1 The purpose for which the guidelines were developed can be summarized as being to:

- ensure the quality and consistency of the documentation submitted;
- facilitate efficiency and economy in the use of resources necessary for the preparation of that documentation;
- facilitate applicants in checking the completeness and quality of the documentation prior to its submission;
- facilitate the use of electronic media for the submission, archiving and retrieval of the documentation submitted; and
- facilitate efficiency and economy in the use of resources necessary for its evaluation.

A2 The main changes in revision 8 of the document (as compared to rev 7.2) are as follows (minor changes of an editorial nature and/or relating to points of fine details are not listed):

a) a text to reflect developments with respect to the electronic submission of dossiers will be included in the General Introduction (CADDY). In addition the need to present information such as GAP, MRL and reference lists in table or spread sheet format is now emphasized;

b) guidance for the preparation of individual test and study reports is no longer included;

c) the numbering system for Tier I checks as to the acceptability of the quality of test and study reports has been amended to re-establish internal consistency,

d) Tier I checks as to the acceptability of the quality of reports relating to analytical methods, are no longer required;

e) applicants will now be required to conduct a literature search and are required to include all relevant papers identified in the reference lists to be submitted;

f) applicants are to be required to certify the accuracy of information submitted in support of claims for data protection in accordance with Article 13 of the Directive;

g) minor additions to the text have been introduced to specify that Tier II summaries should be concise but comprehensive and to require that the significance of results obtained, effects and observations reported be highlighted;

h) the need to submit efficacy overviews is emphasised in situations where an Annex III dossier is submitted in support of an application for the authorization of a plant protection product, for use by the competent authority for the purposes of the consideration of an authorization - it would not be used for the purposes of any inclusion of an active substance in Annex I;

i) a text to require the inclusion in the Tier III overall summary and assessment of a diagrammatic representation of metabolic pathways - animals, plants, soil and water - has been introduced;

j) a requirement that a list of end points be prepared and be appended to the Tier III overall summary and assessment has been introduced;

k) many of the examples included in the Appendices to the document have been upgraded or corrected; and

l) a number of corrections to the forms for checking dossiers for completeness have been made, in order to ensure compliance with the current requirements of Annex II and Annex III.

A3 Possible procedural changes for future consideration

It was inevitable that there would be inefficiencies in the system developed to give effect to Council Directive 91/414/EEC, while new procedures were being developed and while the

Commission, the competent authorities of the Member States and applicants were all becoming proficient in the implementation of those procedures. Since the system is operational for some time, it is appropriate that we now examine it with a view to identifying mechanisms that could be used to improve its efficiency and that could be used to reduce the time periods necessary between submission of dossiers and decision making with respect to inclusion of active substances in Annex I of the Directive.

In the case of 12 of 28 new active substances for which applications were submitted it took 10 months or more from the date of submission of the dossier by the applicant until the date on which all Member States confirmed the receipt of the dossier. In the case of 15 of the 22 new active substances for which a decision on completeness has been made, the period between the date of submission of the dossier by the applicant and the date of the decision was 12 months or longer. Accordingly, a series of suggestions are proposed in this paper with a view to reducing the period necessary for taking decisions in accordance with Article 6 (3) - that dossiers submitted are complete.

Suggestion 1 In each case that a company requests that a Member State receiving a dossier for a new active substance, act as Rapporteur and prepare the draft monograph for the compound, a representative of the company should personally present the dossier to the relevant competent authority. The representative of the company should be the person responsible for ensuring that the dossier is compiled in the appropriate format and is complete. The representative of the company should be prepared to spend at least two full working days with the competent authority. On the day of receipt of the dossier (extending if necessary into the following day) the competent authority, with the assistance of the company representative) should conduct the check for completeness - a process that must not involve evaluation of the acceptability of data, information and justifications provided.

During the process, the competent authority should complete the column which is intended for official use, on Evaluation Forms 1 through 4.

Suggestion 2 Once the completeness check has been finished, the representative of the company should, before leaving the premises, be informed (in writing) of the contact points for the submission to the competent authorities of other Member States and the Commission of copies of complete and summary dossiers, the number of copies required and information concerning submission in hard copy and electronic format.

The representative of the company should be asked for an estimate of the time necessary to achieve circulation of the dossier to all relevant contact points - it should not be more than 12 days.

The representative of the company should be required to ensure that a receipt for each dossier submitted to the competent authorities of the other Member States and the Commission is obtained at time of delivery (to specify the number of copies and whether complete or summary dossier, hard copy and/or electronic form) and be required to send the original version of those receipts to the competent authority of the Rapporteur Member State.

Suggestion 3 Within 7 days of the receipt of a dossier for a new active substance, the competent authority of a Member State (Rapporteur) should circulate the required information concerning the dossier received and at the same time should circulate the completed Forms for checking dossiers for completeness.

Suggestion 4 Within 14 days of the receipt of a dossier for a new active substance, the competent authority of a Member State (Rapporteur) should send a copy of the receipts signed by the competent authorities of the other Member States, to the Commission.

Such procedures if adopted and followed, would ensure that the period between submission of a dossier for a new active substance and the date on which the Working Group "Legislation" confirms that the dossier has been received by all Member States, could be reduced to one or at most two months.

Suggestion 5 The competent authorities of other Member States in evaluating completeness checks conducted by the proposed Rapporteur Member States, must ensure that the process does not involve evaluation of the acceptability of data, information and justifications provided. If they chose to conduct their own completeness check, the competent authorities of other Member States should be given no more than 21 days to complete the process.

Suggestion 7 The Commission should seek the opinion of the Standing Committee on Plant Health with respect to proposed decisions concerning the completeness of dossiers received, within two months or at most three months of the date of submission of the dossier by the applicant.

Such procedures if adopted and followed, would ensure that the period between submission of a dossier for a new active substance and the date on which the Standing Committee on Plant Health gives its opinion on the completeness of the dossier could be reduced to two or at most three months.

B Guidelines and Criteria for the Evaluation of Dossiers and for the Preparation and Presentation 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 (Document 1654/VI/94, rev 6.4 of 31 October 1997)

The version of the guidelines currently being used by the competent authorities of the Member States is rev 6 of 25 July 1996. Revision 6.4 (31 October 1997) was considered by the Working Group "Legislation" during its meeting of 16 and 17 December last. It is envisaged that rev 7 will be finalised in coming weeks by the Standing Committee on Plant Health and will then be issued and recommended for use in preparing future draft monographs. It is not envisaged that a further revision will be necessary for some time.

B1 The purpose for which the guidelines were developed can be summarized as being to:

- ensure a consistently high standard in the documentation prepared; and
- facilitate efficiency and economy in the use of resources necessary for the preparation of that documentation.

B2 The main changes in revision 7 of the document (as compared to rev 6) are as follows (minor changes of an editorial nature and/or relating to points of fine details are not listed):

a) changes necessary to maintain consistency with the amended format of the dossier guidelines have been introduced;

b) an amendment has been introduced to indicate that in addition to the monograph, other documents (e.g. peer review reports, evaluation meeting reports etc.) will be available to interested parties;

c) a text has been developed and included to emphasise that the Level 2 reasoned statement of conclusions should not contain details of risk assessments included in Annex B. In addition, a text to require the inclusion of a diagrammatic representation of metabolic pathways identified or proposed - animals, plants, soil and water - has been introduced;

d) a requirement to append a list of end points to Level 2 has been included; and

e) the guideance for preparation of the detailed summary, evaluation and assessment (Annex B) has been made more explicit with respect to toxicological studies. In addition guidance has been developed and included for the preparation of summaries, evaluations and assessments of environmental fate and behaviour data and information and ecotoxicological studies.

B3 Possible procedural changes for future consideration

The harmonized regulatory system introduced by means of and to give effect to Council Directive 91/414/EEC, has resulted in the introduction of a science based system which provides for a very high level of protection for man, animals and the environment.

That system has to-date included the peer review of draft monographs by experts from each of the key disciplines and has involved experts from up to 7 Member States attending each European Commission Co-ordination (ECCO) meeting. In addition to the draft monograph for compounds being considered, ECCO meetings also consider comments on the draft monograph provided by the applicant or main notifier and comments provided by other Member States. Following the completion of the peer review process and with the benefit of information provided through informal contact with the applicant or main notifier, an overview meeting involving the Commission, the Rapporteur Member State, and the ECCO Group Chairmen is held on the basis of which the ECCO report, which is sent to the Commission, to the Member States and to the applicant or main notifier, is prepared.

Where necessary and in the light of the response of the applicant or main notifier, a tripartite meeting between the Commission, the Rapporteur Member State and the Commission is convened, after which the matter is referred to the Working Group "Evaluation" and subsequently to the Working Group "Legislation" and the Standing Committee on Plant Health.

The system that has been developed has helped assure the quality of decisions taken. That same system and in particular the peer review part of it has been of particular benefit in ensuring that standards are maintained. It has also served to develop consistency in the standard to which draft monographs are prepared and has resulted in there being a dramatic increase in the level of confidence placed in evaluations completed by the competent authorities of other Member States. The system has proved to be a very useful training and confidence building vehicle for experts form the competent authorities of all 15 Member States.

However, the resources necessary to operate the system, in terms of numbers of experts and the time taken to make decisions, is excessive. It therefore is necessary that a simplified and streamlined process be developed, retaining those elements of the process which are essential in order to ensure the quality of decisions taken.

Suggestion The ECCO peer review system cannot be sustained - the number of experts necessary to conduct peer reviews for some 60 or more compounds per annum, are not available. It therefore is suggested that it be replaced with a Co-rapporteur system. The organizers of the ECCO meetings (currently BBA and PSD) should provide experts to work with those of the Rapporteur

Member State and act in the capacity of Co-rapporteurs. It is proposed that BBA serve as Co-rapporteur for half the compounds reviewed each year and that PSD serve as Co-rapporteur for the other half.

Rapporteur Member State experts should be in regular telephone and e-mail contact with their Co-rapporteur counterparts. In addition, Co-rapporteur experts should attend all relevant evaluation meetings held by the Rapporteur Member State competent authority.

Draft monographs should where achievable, reflect the views of the experts involved from the competent authority of the Rapporteur Member State and the those of the Co-rapporteur experts. In cases where a consensus is not achieved the views of the experts from the Rapporteur Member State should be those contained in the draft monograph (the views of the Co-rapporteur will emerge in due course when all Member States are invited to comment on the draft monograph).

Such procedures, if adopted, should result in a significant increase in the capacity of the regulatory system to process applications for both existing active substances and new active substances while at the same time reducing the period between submission of application and decision making by some six months or more.

Role of ECCO-Peer Review Meetings and Responsibilities of ECCO Teams (BBA/PSD)

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Introduction

ECCO stands for European Commission Co-Ordination and the ECCO Peer Review Programme has been developed as part of the joint evaluation process for new and existing active substances of plant protection products in accordance with the requirements of Council 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 Standing Committee on Plant Health (SCPH).

In general, an active substance must be included in Annex I of the Directive before any plant protection products containing that active can be authorised in any Member State. Under Article 8(2) of Directive 91/414/EEC, the 825 existing active substances that were already on the market in the Member States when the Directive was implemented on 26 July 1993 must be examined to establish their eligibility for inclusion in Annex I of the Directive. In addition, any new active substances not on the market at the time of implementation of the Directive must also be considered for inclusion in Annex I.

The data provided in support of applications for inclusion of active substances in Annex I are evaluated by a 'Rapporteur' Member State, which produces a report, or monograph, of the evaluation. This is submitted to the European Commission which must then decide on inclusion in Annex I after seeking the opinion of the SCPH, on which all Member States are represented.

Evaluation procedure at Community level

Chemical manufacturers and interested parties are required to notify the European Commission of their intention to support a certain active substance with regard to its inclusion in Annex I. These notifiers, in general companies manufacturing active substances and plant protection products, compile a dossier to support their notification for inclusion of the active substance in Annex I of the Directive. The dossiers are prepared to a standard format, as laid down in a European Commission guidance document, and include the data required by Annex II and III of Directive 91/414/EEC.

The Member State to which the dossier is submitted for evaluation, the rapporteur Member State nominated by the European Commission, then prepares a monograph setting out the details of its evaluation of the dossier.

A monograph consists of a number of sections, reflecting the different sections of the dossier dealing with particular areas of evaluation and assessment such as physico-chemical properties, methods of analysis, fate and behaviour in the environment, effects on non-target species (ecotoxicology), mammalian toxicology, and residues. It also contains a list of the studies relied upon in the evaluation and a proposal from the rapporteur Member State regarding inclusion in Annex I.

Once a monograph has been completed by a rapporteur Member State, it is sent to the European Commission for consideration within the framework of the SCPH, the first stage of which involves the discussions at the ECCO-Peer Review Meetings.

Following the ECCO meetings, the monograph and Peer Review Reports are considered by two European Commission Working Groups and then the SCPH, which delivers its opinion by qualified majority voting, prior to the final decision on inclusion being taken by the European Commission. All 15 Member States attend the Working Groups, the first of which, the WG - Evaluations, discusses the more technical aspects of the review, and the second, the WG - Legislation, which considers the wider implications of the recommendations arising from the evaluation. At the same time as the evaluation is being considered within the framework of the SCPH, it will also be considered by the Scientific Committee on Plants, the opinions of which will also be taken into account by the European Commission before finalising the decision on inclusion in Annex I.

Forming a pan-European view on a monograph

Although one Member State is responsible for the evaluation of the dossier and the preparation of the monograph, the principle objective of the process is to obtain the agreement of all 15 Member States on the inclusion, or not, of an active substance on Annex I. It was considered, therefore, important to obtain a wider, pan-European view on any monograph as soon as possible in the process.

The original proposal was that the rapporteur Member State would liaise with one or more other Member States, or co-rapporteurs, during the evaluation phase of the process. This system was provided for under Article 7(2) of Regulation 3600/92:

'... rapporteur Member State shall (during the evaluation) consult with experts from other Member States accepted by the Commission on a proposal from the Member State concerned with regard to the whole or certain parts of the dossier.'

The main aims of the proposed co-rapporteur system were to build a community view into the evaluation, and to facilitate decision making in the Community through the harmonisation of evaluation standards which would lead to increased confidence in the assessments of other Member States.

Although the co-rapporteur system was provided for in the original Review Regulation, it soon became apparent that following the receipt of the dossiers the rapporteur member States were not liaising with each other during the evaluation and preparation of the monographs. Instead, for a number of reasons, the rapporteurs prepared the monographs independently. The UK experience was that it was not possible to liaise as proposed within the timetable for evaluation laid down by the Commission.

It was agreed that some form of wider review of the monographs would be required prior to their full consideration in the 15 Member State Working Groups, and that this should take the form of a detailed, technical review.

A Pilot Project programme was established by the Commission in 1995 to initiate discussion on the harmonisation of evaluation and reporting procedures among the Member States.

A series of ten meetings involving the Commission and experts from all Member States were organised by the BBA, Germany and PSD in the UK. The meetings considered in detail three monographs that had been prepared by BBA and PSD - cyfluthrin, fluroxypyr and fenarimol. The meetings were organised so that each one covered a different specialist area of the monograph, i.e. physical/chemical properties, fate and behaviour, ecotoxicology, residues and mammalian toxicology.

At these meetings, PSD and BBA explained the evaluation and problems that had been encountered in the preparation of the draft monographs. A further 5 meetings were subsequently organised to facilitate an exchange of views between all Member States following actual 'hands-on' experience with the dossiers they had received and started to evaluate.

As well as allowing for an exchange of views with regard to the detailed scientific principles arising from the evaluation, the Pilot Project meetings were used to develop guidelines for the evaluation of dossiers and preparation of reports, or 'Monograph Guidelines' (Document 1654/VI/94) and to review the 'Dossier Guidelines' (Document 1663/VI/94). The latest revisions of both of these documents are currently being circulated by the Commission.

The ECCO Peer Review Programme

On 1 August 1996, the ECCO-Team was founded, consisting of two groups situated at the BBA in Braunschweig and at the Pesticides Safety Directorate (PSD) in York/United Kingdom.

The ECCO-Team (BBA) is part of the Co-Ordinating Group within the Department of Plant Protection Products and Application Techniques at the BBA (Federal Biological Research Centre for Agriculture and Forestry) which is part of The Federal Ministry of Food, Agriculture and Forestry. The ECCO-Team (PSD) is part of the Pesticides Safety Directorate, which is an Executive Agency of The Ministry of Agriculture, Fisheries and Food in Great Britain. Both teams share the work undertaken as part of the ECCO-project equally, and are comprised of both technical and administrative support staff.

The ECCO-Team organises the Peer Review Programme on behalf of the European Commission, liaising as necessary with the Member States and other interested parties. This involves co-ordinating the review and evaluation programme together with the European Commission and the preparation and organisation of ECCO-Peer Review Meetings.

At these meetings, invited experts from different Member States and representatives of the European Commission discuss specific parts of the monographs for several active substances with a view to formulating an opinion on inclusion in Annex I of Council Directive 91/414/EEC.

It is important to note that it is the invited experts that discuss the monographs and formulate opinions on the recommendations, not the ECCO-Teams who are responsible for the organisation and servicing the meetings only.

In addition to the organisation of the ECCO-Peer Review Meetings the aim of the ECCO-Team is to support the European Commission in the development of procedures for the standardisation of evaluation and assessment criteria. This, in turn, should lead to the harmonisation of the authorisation and use of active substances of plant protection products in all 15 Member States of the European Union.

The work of the ECCO-Teams

The ECCO process begins when the European Commission selects the monographs to be considered during a particular round of meetings and agrees the timetable. On behalf of the European Commission, the ECCO-Teams send copies of the relevant monographs to the 'Designated National Authorities' of the Member States as well as to the main data holders, giving them the possibility to comment on the monographs.

A call for the nomination of relevant experts is then sent to all Member States and on receipt of nominations the European Commission selects those to be invited to the appropriate ECCO-Peer Review Meetings. The participants, invited to attend as private experts, are chosen mainly for their expert knowledge in the section considered. An expert from each of the rapporteur Member States for the monographs being considered is always invited.

Prior to the meeting the experts receive a formal invitation letter from the ECCO-Teams, on behalf of the European Commission, as well as the invitation pack including a complete set of monographs. Comments from Member States and/or data holders concerning the monographs are collected by the ECCO-Teams and tabled at the meeting for consideration.

The ECCO Teams then organise and service the meetings. Up to seven experts from the 15 Member States as well as representatives of the European Commission (DG V, DG VI, DG XI, DG XXIV) take part in the meetings. The working language for all the meetings is English and the chairperson is a scientific expert in the relevant field provided by the BBA or PSD. At the meeting, the participating scientist from the ECCO-Team acts as a report writer, taking notes of the discussions and assisting the chairperson, ensuring that all items which need to be discussed are covered during the meeting.

As well as organising and servicing the meetings, the ECCO-Teams are responsible for the reimbursement of expenses to those attending on behalf of the European Commission, and for producing the various reports of the meetings that are required.

Documentation produced

The notes taken at the meeting provide the basis for a meeting report which reflects in an objective way the important discussions and results of each meeting. This 'Concise Outline Report' consists of a main text and several appendices ('list of end points', 'list of data requirements', 'list of studies relied upon for which data protection has been claimed' and 'suggested classification and labelling', as appropriate).

It is the aim of each meeting to agree on the key issues. The main text explains the changes in the 'list of end points' proposed during the meeting, substantiates the data requirements identified and points out areas of concern which, in the opinion of the experts, may influence any inclusion in Annex I.

The 'list of end points' is prepared by the rapporteur Member State and summarises the end points which will later be used by the Member States in making decisions on the authorisation of individual plant protection products in accordance with the Annex VI of Council Directive 91/414/EEC. Where the meeting agrees on the existence of data gaps in the dossier a 'list of data requirements' will be compiled during the meeting.

The data holder may claim data protection for individual studies in the dossier. If the claim is substantiated and the meeting agrees that during the re-evaluation process these studies were considered as essential for the evaluation with a view to Annex I inclusion, a 'list of studies relied upon for which data protection has been claimed' will also be compiled.

As appropriate, a 'suggested classification and labelling' proposal for the active substance may also be agreed at the meeting to assist DG XI which is responsible for this area.

The finalised report of each meeting is sent to the European Commission DG VI (for further consideration) and to the participants of the meeting (for information only).

At the end of each round, the ECCO-Teams are responsible for preparing a full report for each active substance considered at the meetings. This is a compilation of the relevant section of each of the individual meeting reports. An evaluation table is also produced, to facilitate decision making within the framework of the SCPH.

Details of work so far

Between September 1996 and January 1998, 50 ECCO-Peer Review Meetings have been organised in four separate rounds. Two further rounds will be organised under the current, second ECCO contract before February 1999.

Example of an ECCO round

Each round consists of a series of meetings, and an example of the timetable for a round of meetings is provided in Table 1 below.

Table 1 shows that during the fourth round of meetings, from 15 September to 21 November 1997, five meetings were organised at each centre relating to the five main scientific sections of the monographs. During this round, six monographs were reviewed at the meetings organised by the BBA and five at PSD. A total of 69 nominated experts from the rapporteur and other Member States were invited by the ECCO-Teams on behalf of the European Commission to attend the meetings.

Table 1: Timetable for Round 4 of ECCO-Peer Review Meetings and the active substances (as) discussed.

Round 4				
Meeting	**Date 1997**	**Monograph section**	**as** *)	**Location**
ECCO 40	15 - 18 September	Phys Chem properties	31-36	BBA
ECCO 41	23 - 26 September	Phys Chem properties	26-30	PSD
ECCO 42	29 Sept. - 2 October	Fate and Behaviour	31-36	BBA
ECCO 43	7 - 10 October	Mammalian Toxicology	26-30	PSD
ECCO 44	13 - 16 October	Ecotoxicology	31-36	BBA
ECCO 45	21 - 24 October	Residues	26-30	PSD
ECCO 46	27 - 31 October	Mammalian Toxicology	31-36	BBA
ECCO 47	4 - 7 November	Fate and Behaviour	26-30	PSD
ECCO 48	10 - 13 November	Residues	31-36	BBA
ECCO 49	18 - 21 November	Ecotoxicology	26-30	PSD
ECCO 50	26 - 30 January 1998	Overview Meeting	26-36	BBA

*) **Active substances to be discussed during the meeting:**

26 - azinphos-methyl (EAS)
27 - bentazone (EAS)
28 - triasulfuron (EAS)
29 - azimsulfuron (NAS)
30 - metsulfuron (EAS)
31 - 2,4-D (EAS)
32 - 2,4-DB (EAS)
33 - linuron (EAS)
34 - monolinuron (EAS)
35 - thiabendazole (EAS)
36 - flurtamone (NAS)

(NAS) = new active substance
(EAS) = existing active substance

After the last technical meeting of the round in November, a nine week break was scheduled before the final Overview meeting (ECCO 50). This was to provide sufficient time for the rapporteur Member States time to clarify open questions and data requirements with the main data holders and others. At the Overview meeting the conclusions from all the meetings at both the BBA and PSD will be considered and a draft Review Report prepared for each active substance.

Achievements to date

During the first four ECCO rounds, a total of 36 monographs have been discussed of which 7 were for new active substances. The main criteria for selection of an active substance for consideration was the availability of the monograph, the category or relatedness of the active

substance and the involvement of as many rapporteur Member States as possible. The European Commission have also treated monographs for new active substances as a matter of priority. All the monographs submitted to the Commission to date have been scheduled for consideration.

The monographs considered so far represent all main categories of active substances, with 18 of the 36 being herbicides (three of which were new active substances), nine being fungicides (four of which were new active substances), eight insecticides and one rodenticide.

In terms of Member State representation by experts at the meeting, the 50 ECCO-Peer Review Meetings scheduled until January 1998 will have been attended by a total of 352 experts from all 15 Member States (see Figure 1). Each meeting can only be attended by up to seven experts and, therefore, no Member State can be represented in all meetings. All Member States have contributed significantly to the meetings and all regions in Europe have been represented. The larger Member States such as Germany and France have contributed more experts to the meetings than the other States (43 and 40 respectively) but even the smallest Member State Luxembourg provided experts for 6 of the 50 meetings.

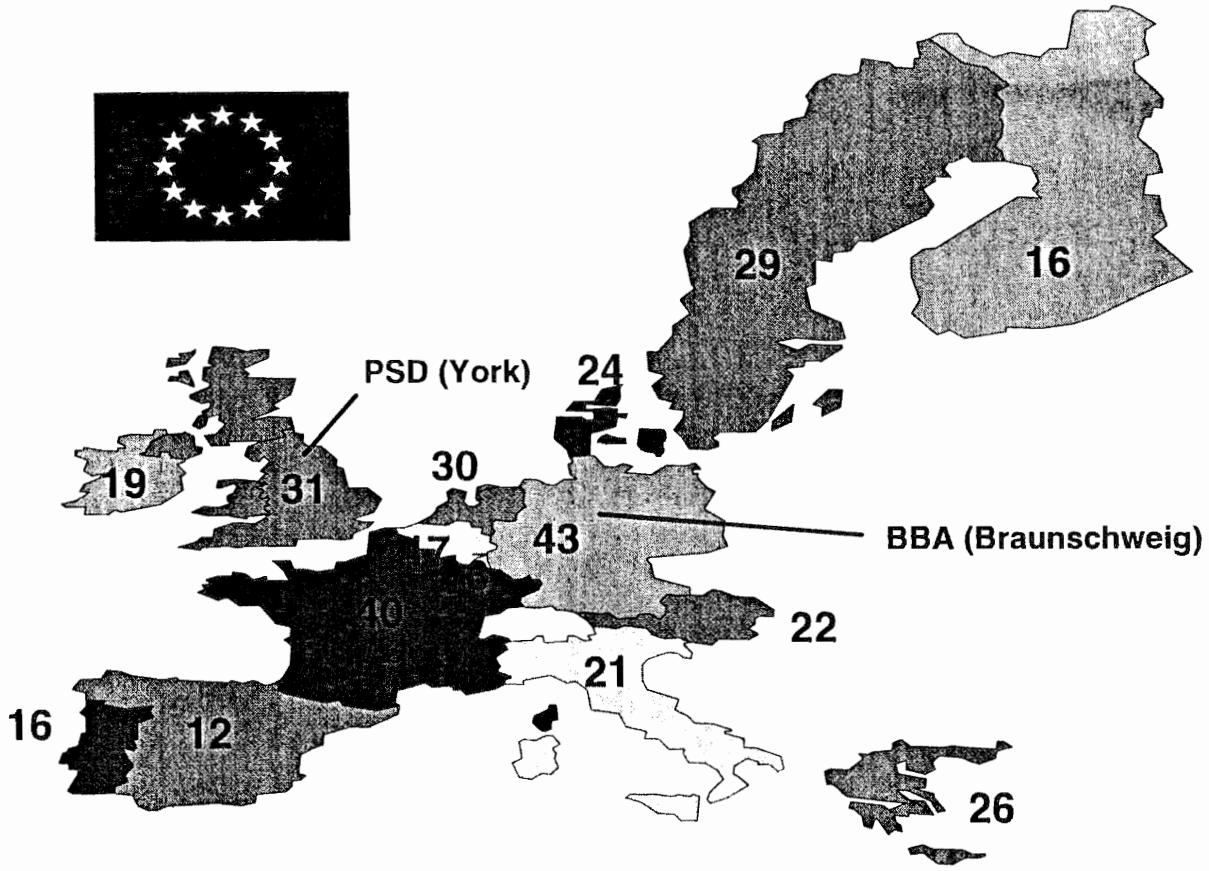
Progress and developments so far

Considerable effort has been devoted to seeking ways of improving the evaluation process in order to maximise efficiency. In particular, attention has been paid to the procedures for consultation with notifiers, to the establishment of common standards for risk assessment and to the harmonisation of authorisation arrangements.

It has become apparent that there is considerable variation in the amount of consultation occurring between notifiers and rapporteurs during the evaluation and preparation of the monograph, ranging from regular liaison to no communication at all. The whole point of the Peer Review meetings is to facilitate the decision making process within the framework of the SCPH. This requires that all the data available have been evaluated and that the notifiers have been consulted over the proposed decisions arising from the evaluation of the data.

Based on experience gained in the first three rounds, the procedures for Round 4 have been amended in order to accommodate improvements in liaison between notifiers and rapporteur Member States. Evaluation tables are now produced following each meeting, which detail all the outstanding data requirements and unresolved points that have been identified. These are sent to the notifier and rapporteur as soon as possible after the meeting in order that the notifier can address the concerns that have been raised prior to the final 'Overview' meeting in each round.

Figure 1: Number of experts from respective Member States attending the first 50 ECCO-Peer Review Meetings, round 1-4



Also, compared with the first three rounds, more time is scheduled between the last technical meeting and the 'Overview' meeting to allow for more detailed consultation on the issues that have arisen. With improved liaison between notifiers and rapporteurs to resolve as many outstanding issues as possible during the ECCO Peer Review process, the decision making process in the framework of the SCPH should become more efficient.

The establishment of common standards in risk assessment through the exchange of views between experts from several Member States attending the meetings and the development of Guidance documents as part of the contract (e.g. AOEL, aquatic toxicity, persistence) is also an important function of the programme. This should again lead to increased efficiency in the decision making process through better understanding and co-operation between the Member States, and will be of particular importance when notifiers begin to seek authorisation via mutual recognition as provided for in Article 10 of Directive 91/414/EEC.

Authorisation procedures have been enhanced through the improvements to the system, the documentation in particular making the decision making process more transparent and efficient. The development of 'end point sheets' and 'evaluation tables' have already demonstrated their worth in helping to focus discussions on the key issues of the risk assessment.

Based on experience gained from the first three rounds, it is also now apparent that in many cases experts from five Member States can adequately discuss the technical aspects of an evaluation and represent the different regions of the European Union. For the fifth round onwards, therefore, only five experts will routinely be invited to the meetings, although there is provision within the contract to invite up to seven experts where necessary. Again, the efficiency of the meetings should be improved with the involvement of fewer experts, while at the same time freeing up resources within the Member States for the evaluation of dossiers and preparation of monographs.

Conclusions

The ECCO-Teams and the European Commission have been extremely busy organising the first four rounds of meetings. The European Commission had originally only planned for the consideration of 18 monographs during the first three rounds, or the first year of ECCO-Peer Review Meetings. Even though the structure and procedures for the ECCO-Peer Review Meetings were developed in a very short space of time, with the help of the experts involved in the meetings and the European Commission, the ECCO-Teams were able to arrange for the consideration of an additional seven active substances. This was a considerable achievement.

The success of the first round led to a backlog of work for the European Commission in terms of producing Review Reports for all the active substances that had been considered. This

situation is now being addressed by the ECCO-Teams through the retrospective drafting of evaluation tables for those active substances considered during the first three rounds of meetings. This measure, together with the amendments adopted for the current series of ECCO meetings, with the drafting of Review Reports following the 'Overview Meeting' as part of the Peer Review Programme, should ensure that such backlogs do not occur in the future.

Experts from across the community have all contributed significantly to the ECCO-Peer Review Meetings. Scientific advice was given to the European Commission which in turn was able to facilitate the preparation of regulatory decisions in the Standing Committee on Plant Health - the most important of which to date is that for the inclusion of imazalil in Annex I of the Directive. Further, the meetings have contributed significantly towards the establishment of common standards for risk assessment and the harmonisation of authorisation procedures.

The Peer Review Programme is a dynamic and evolving process, and significant improvements have been incorporated into the procedure for the next three rounds of meetings in order to make the system more efficient. It is clear that further improvements will be required in order to deal with the numbers of monographs required under the Directive. Initiatives such as the participation of only 5 experts and the development of evaluation tables should aid the process.

It is also clear that communication is crucial to the whole programme. With notifiers and rapporteurs liaising throughout the evaluation process some of the problems currently being experienced with the first monographs to go through the system should be alleviated. It is important that the notifiers are consulted as soon as possible to resolve any potential problems at an early stage in the evaluation, thus ensuring that resources are used as efficiently as possible. Notifiers, however, must realise that they can help the process by improving the quality of the dossiers submitted. Uses must be rationalised, such that only those that are supported by data are included in the dossier submission.

Other ongoing developments and initiatives within the OECD Pesticide Forum and elsewhere (e.g. revision of the EU and development of the generic dossier and monograph guidelines, development of systems for the standardised submission of data on CD-ROM,) will also help to ensure that the considerable workloads foreseen for the next few years are achievable by increasing world-wide co-operation in the evaluation and authorisation process.

Practical Implications for the Regulation of Plant Protection Products Following the Transfer of Certain Responsibilities to DG XXIV - Directorate General Consumer Policy and Consumer Health Protection

M. WALSH

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The European Commission system of Scientific Committees was overhauled in 1997 in order to separate the committees from the services responsible for the corresponding policy and legislation. This resulted in the eight scientific committees being relocated in the Directorate General XXIV – 'Consumer Policy and Consumer Health'. The Directorate General was also given responsibility for inspection and control in relation to food safety matters. The overall guiding principles governing the establishment and functioning of the Committees have been, independence, excellence and transparency. One of the eight Committees created by Commission Decision 97/579/EC was the Scientific Committee on Plants (SCP). This Committee supercedes the former Scientific Committee for Pesticides but the role has been widened to cover plants more generally and to include, for example, new and developing areas such as certain aspects of biotechnology. The future functioning of the newly created SCP is discussed in detail with particular emphasis on the possible means for maximizing the desired objectives, whilst minimizing delays in the regulatory process.

Practical Implications for Regulation of Plant Protection Products following the Transfer of Certain Responsibilities to DG XXIV

Michael Walsh,

European Commission
Directorate-General XXIV
Consumer Policy & Consumer Health Protection

Introduction

- Speech in three parts
  - Background to changes
  - Actual changes
  - Practical implications

Background to changes

- Mr Santer's Statement to European Parliament - 18 February 1997 regarding Parliament's Committee of Inquiry and report on the BSE Affair
- Recognition of certain shortcomings, such as, lack of transparency, lack of co-ordination and lack of rigour
- Necessity to make changes evident.

Actual Changes

- Legislation
  - Article 100a of the Treaty to be used particularly in animal and plant health area involving co-decision between the Council of Ministers and the European Parliament.
  - Article 129 - revision to increase community powers in the field of health.
- Separation of services responsible for legislation from inspection and scientific advice

Scientific Advice
Scientific Steering Committee
Commission Decision 97/404/EC

- Role
  - Co-ordination role
  - Identify committees for multi-disciplinary
  - deal with differences of opinion between committees
  - deliver opinions on matters not covered by existing mandates
  - draw attention to emerging consumer health problems

Scientific Advice
Scientific Committees
Commission Decision 97/597/EC

- 8 Scientific Committees established
  - Food
  - Animal Nutrition
  - Animal Health and Welfare
  - Veterinary Measures - Public Health
  - **Plants**
  - Cosmetics
  - Medical Products and Devices
  - Toxicology, Ecotoxicology and Environment

Scientific Committee on Plants

- Replaces Scientific Committee for Pesticides
- Role enlarged to fill certain gaps and allow greater flexibility
- In addition to plant protection products wider aspects of plants covered
- Maximum of 19 members
- Current membership 15
- Mandate 3 years renewable once

Formation of the SCP

- Open call for expression of interest
- Members chosen from 103 applicants on the basis of their proven scientific ability
- Balance of disciplines and backgrounds
- Possibility to supplement committee with necessary expertise
- Selection independent of nationality

Mandate of Scientific Committee on Plants

- Commission's Communication of 30.4.1997 consumer health and food safety
- Scientific advice in matters relating to health of consumers critical at all stages of legislation preparation
- Communication stressed international dimension and necessity for Communities position to be based on sound science.

SCP Agenda
Second Plenary Meeting

- Genetically Modified Organisms
- Plant Protection Product Active Substances
- Risk Assessment for Pesticide Residues in Food
- Data Requirements for micro-organisms to be used as plant protection products
- Adequacy of current testing requirements to detect endocrine toxicity in plant protection products.

Future SCP Work

- Criteria for assessment of plant protection products for persistence
- Criteria for assessment of operator exposure to plant protection products
- Criteria for the assessment of plant protection products for aquatic toxicity
- Pesticide residue legislation in preparation

Conclusion

SCP should:

- be complementary to existing systems
- not increase delays to an already complex system
- increase transparency in the process
- show initiative and provide leadership

Verfahrensablauf der EU-Wirkstoffprüfung in Deutschland aus der Sicht des Ministeriums

K. WEISSLEDER

Bundesministerium für Ernährung, Landwirtschaft und Forsten
Bundesrepublik Deutschland

Herr Präsident, Herr Vorsitzender, meine sehr verehrten Damen und Herren!

Mit der Ratsrichtlinie 91/414/EWG über das Inverkehrbringen von Pflanzenschutzmitteln wurde vor dem Hintergrund der Schaffung des gemeinsamen Binnenmarktes ein ehrgeiziges Programm aufgelegt, die in Pflanzenschutzmitteln enthaltenen Wirkstoffe zu überprüfen, ob sie nach dem Stand des Wissens grundsätzlich geeignet sind, in Pflanzenschutzmitteln verwandt zu werden. Ein ehrgeiziges Programm zum einen im Hinblick auf den Umfang der zu überprüfenden Stoffe, genauer gesagt zirka 800 Altwirkstoffe, d.h. Wirkstoffe in Pflanzenschutzmitteln, die vor dem 26. Juli 1993 in einem Mitgliedstaat der Europäischen Union im Handel waren, und Wirkstoffe in nach dem 26. Juli 1993 in den Handel gekommenen Pflanzenschutzmitteln, die sogenannten neuen Wirkstoffe. Ehrgeizig zum anderen aber auch im Hinblick auf die Zeitspanne. Die Überprüfung soll im Prinzip innerhalb von 10 Jahren, d.h. im Jahr 2003 abgeschlossen sein.

Die Mitgliedstaaten haben mit ihrer Zustimmung zu diesem arbeitsteiligen Verfahren die Arbeitsbelastung ihrer zuständigen Stellen erhöht. Neben die Erledigung des "normalen" Zulassungsverfahrens trat die Aufgabe der anteiligen Überprüfung der alten Wirkstoffe und das Verfahren bei neuen Wirkstoffen.

Obwohl eine gewisse Erfahrung mit der gemeinsamen Überprüfung von Wirkstoffen von Pflanzenschutzmitteln durch die Richtlinie 79/117/EWG vorlag, wurde mit dem Arbeitsprogramm der Richtlinie 91/414/EWG Neuland betreten. Neuland weniger aus der Sicht der Entscheidungsprozesse sondern vielmehr im Hinblick auf die systematische Aufarbeitung der Datengrundlagen und die Transparenz im Entscheidungsverfahren. Aber gerade dieses Vorgehen versprach für den stets aufmerksam beobachteten Bereich des Pflanzenschutzes den, zugegeben nicht einfachsten, aber auf breiter Basis akzeptierten Weg hin zu einem Binnenmarkt frei von Handelshemmnissen bei einer gleichzeitig gemeinschaftsweiten Wahrung eines hohen Schutzniveaus bei der Zulassung von Pflanzenschutzmitteln.

Bis zum heutigen Tage ist bereits die Hälfte der oben genannten 10-Jahresfrist verstrichen, aber mit Imazalil erst ein Wirkstoff in den Anhang I der Richtlinie 91/414/EWG aufgenommen worden. Aus meiner Sicht besteht jedoch kein Grund zum Pessimismus, sondern vielmehr Anlaß für Zuversicht in die zukünftige Entwicklung des Arbeitsprogramms. Ich

möchte Ihnen dazu im folgenden die EU-Wirkstoffprüfung aus Sicht des Bundesministeriums für Ernährung, Landwirtschaft und Forsten als einem am Verfahren Beteiligten nahebringen.

Einführend werde ich Ihnen eine Übersicht über den Aufbau und die Aufgabenorganisation der in Deutschland auf Bundesebene an den Arbeiten im Rahmen der Richtlinie 91/414/EWG beteiligten Organisationseinheiten geben.

Die Exekutive der Verfassungsorgane in der Bundesrepublik Deutschland wird von der Bundesregierung wahrgenommen (Abb. 1). Sie setzt sich aus dem Bundeskanzler und den Bundesministerien zusammen. In der Bundesregierung der Bundesrepublik Deutschland liegt der Pflanzenschutz und damit auch die Federführung für die Richtlinie 91/414/EWG beim Bundesministerium für Ernährung, Landwirtschaft und Forsten.

Meine Damen und Herren, ich habe gesagt:
die Federführung für die Richtlinie 91/414/EWG liegt beim Bundesministerium für Ernährung Landwirtschaft und Forsten. Es wäre falsch zu denken, Federführung hieße alleinige Zuständigkeit. Vielmehr hat das federführende Ressort nach der Geschäftsordnung der Bundesregierung diejenigen Ministerien zu beteiligen, deren Zuständigkeiten berührt sind. Im Rahmen der Richtlinie 91/414/EWG sind dies vorrangig das Bundesministerium für Wirtschaft, das Bundesministerium für Gesundheit und das Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit. Durch das Bundesministerium für Gesundheit werden bei der Wirkstoffprüfung vor allem die Bereiche Gesundheit von Mensch und Tier sowie Trinkwasser und durch das Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit vorrangig die Prüfbereiche Wasser, Boden und Abfall abgedeckt. Fachliche Unterstützung erfahren die Bundesministerien durch die ihnen nachgeordneten Bundesoberbehörden (Abb. 2). Im Falle des Bundesministeriums für Ernährung, Landwirtschaft und Forsten ist dies die Biologische Bundesanstalt für Land- und Forstwirtschaft, die BBA, die gleichzeitig die nach dem Pflanzenschutzgesetz zuständige Behörde für die Zulassung von Pflanzenschutzmitteln und von der Bundesregierung benannte Behörde zur Koordinierung der EU-Wirkstoffprüfung ist. Die BBA ist zudem eine der zehn zum Geschäftsbereich des Bundesministeriums für Ernährung, Landwirtschaft und Forsten gehörenden Forschungseinrichtungen. Beratende Behörde für das Bundesministerium für Gesundheit ist das Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin und für das Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit das Umweltbundesamt, beide nachgeordneten Behörden mit Sitz in Berlin.

Das Bundesministerium für Ernährung, Landwirtschaft und Forsten (Abb. 3), unter der Leitung von Herrn Bundesminister Borchert, unterstützt durch den Staatssekretär Herrn Dr. Feiter und den neuen Parlamentarischen Staatssekretär Herrn Hinsken, zeigt die klassische Struktur einer Stablinienorganisation. Das Bundesministerium für Ernährung, Landwirtschaft und Forsten gliedert sich in 8 Abteilungen, genauer gesagt einen Leitungsstab und 7 Fachabteilungen mit derzeit rund 950 Mitarbeitern.

Innerhalb eines Bundesministeriums ist die Federführung wiederum einem Referat zugeordnet. Beim Bundesministerium für Ernährung, Landwirtschaft und Forsten liegt diese Zuständigkeit bei dem für den Pflanzenschutz zuständigen Referat 313, angesiedelt in der Fachabteilung 3 "Agrarische Erzeugung, Veterinärwesen". Wie auf Ressortebene bedeutet Federführung auch innerhalb eines Ministeriums die Prüfung und Sicherstellung der Beteiligung anderer, in der Sache beteiligter Fachreferate. Lassen Sie mich im Falle der Richtlinie 91/414/EWG als zu beteiligende Referate exemplarisch das Rechtsreferat, das Tierschutzreferat und das Referat für Verbraucherschutz und Lebensmittelqualität nennen, letzteres als zuständiges Referat für den Bereich der Rückstände von Pflanzenschutzmitteln in Lebensmitteln.

Vor Erstellung eines Kommentares gegenüber der Europäischen Kommission, sei es eine Stellungnahme zu einem Entwurf der EU-Kommission oder eine nationale Vorlage, bedeutet dies somit nach der Prüfung der notwendigen Beteiligung eine Abstimmung innerhalb der Ressorts und nachfolgend die Abfassung einer abgestimmten Stellungnahme zwischen den Ressorts. Änderungswünsche zu beteiligender Ressorts sind vom federführenden Referat zu berücksichtigen. Laut Geschäftsordnung der Bundesministerien sind die Bundesministerien zudem zur Einbeziehung beteiligter Wirtschaftskreise und, wenn die Durchführung den Pflanzenschutz berührt, zur Beteiligung der Länder verpflichtet. Zur Einbindung der Länder möchte ich exemplarisch die Kontrollmaßnahmen nach Artikel 17 der Richtlinie 91/414/EWG nennen, die in Deutschland von den Ländern durchgeführt werden.

Das Bundesministerium für Ernährung, Landwirtschaft und Forsten, als federführendes Ressort für die Richtlinie 91/414/EWG hat allerdings nicht nur die umfassende Einbindung aller Beteiligten zu garantieren, sondern auch die rechtzeitige Erledigung der notwendigen Aufgaben sicherzustellen.

Das federführende Ressort vertritt die abgestimmten Stellungnahmen der Bundesregierung durch schriftliche Kommentare und die Teilnahme an den verschiedenen Gremien der Europäischen Gemeinschaft im Rahmen der Richtlinie 91/414/EWG und in weiteren internationalen Gremien. Diese Arbeiten umfassen zum einen die administrativen Verfahrensschritte der EU-Wirkstoffprüfung von der Abstimmung über die Vollständigkeit eines Dossiers bis zu den Verhandlungen über die Aufnahme eines Wirkstoffs in den Anhang I der Richtlinie und zum anderen die Mitarbeit an der Erarbeitung der Vielzahl notwendiger Leitlinien, Verordnungen, Entscheidungen und Ergänzungsrichtlinien zur Richtlinie 91/414/EWG. Schließlich liegt beim federführenden Ressort die Verantwortung, die gemeinschaftliche Rechtsetzung in nationales Recht zu implementieren.

Meine Damen und Herren, nach dieser groben Übersicht über Struktur und Arbeit des Ministeriums lassen Sie mich Ihnen nun zwei Beispiele aus dem Bereich der Richtlinie 91/414/EWG vorstellen. Und zwar möchte ich zum einen die Einbindung des Bundesministeriums für Ernährung, Landwirtschaft und Forsten in die EU-Wirkstoffprüfung selbst

darstellen und zum anderen in aller Kürze auf den Stand der nationalen Umsetzung der Richtlinie 91/414/EWG selbst eingehen.

Das nachfolgende Schema (Abb. 4) skizziert den bekannten Ablauf der EU-Wirkstoffprüfung. Ich möchte Ihnen anhand dieser Graphik die Einbindung des Bundesministeriums für Ernährung, Landwirtschaft und Forsten aufzeigen. Dabei werde ich mich auf die wichtigsten Aufgaben beschränken, die vom Bundesministerium für Ernährung, Landwirtschaft und Forsten selbst ausgeführt werden und nicht im Auftrag durch die BBA erledigt werden. Letzteres wird Gegenstand des nachfolgenden Beitrages sein.

Bei der EU-Wirkstoffprüfung können wir in Abhängigkeit davon, ob ein Mitgliedstaat als Rapporteur benannt ist oder nicht und ob es sich beim zu bewertenden Wirkstoff um einen alten oder einen neuen Wirkstoff handelt, insgesamt vier Fälle unterscheiden.

Im Rahmen der Vorprüfung, dem ersten Schritt des Verfahrens, ist das Bundesministerium für Ernährung, Landwirtschaft und Forsten beteiligt, wenn in der Arbeitsgruppe "Pflanzenschutzmittel / Gesetzgebung" im Falle neuer Wirkstoffe Beschlüsse zur Vollständigkeit der Unterlagen bzw. bei Altwirkstoffen Beschlüsse über die Unvollständigkeit der eingereichten Unterlagen vorbereitet werden und nachfolgend im Ständigen Ausschuß "Pflanzenschutz" über einen entsprechenden Entscheidungsentwurf der Europäischen Kommission abgestimmt wird.

Im Rahmen der Hauptprüfung übernimmt das Bundesministerium für Ernährung, Landwirtschaft und Forsten, in den Fällen, in denen Deutschland als Rapporteur benannt ist, die abschließende Ressortabstimmung der von den nachgeordneten Behörden erarbeiteten Wirkstoffmonographie und übersendet diese schließlich an die Europäische Kommission. In den anderen Fällen übernimmt das Bundesministerium für Ernährung, Landwirtschaft und Forsten die abschließende nationale Abstimmung der Stellungnahmen zu den Monographien anderer Mitgliedstaaten.

Nach der Bewertung der Monographien in den Mitgliedstaaten und den ECCO-Meetings wirkt das Bundesministerium für Ernährung, Landwirtschaft und Forsten in den Sitzungen der Arbeitsgruppe "Pflanzenschutzmittel / Evaluierung" mit. Die Hauptaufgabe in diesem letzten Abschnitt der Wirkstoffprüfung liegt jedoch in der Teilnahme und Delegationsleitung für die Bundesrepublik Deutschland in den Sitzungen der Arbeitsgruppe "Pflanzenschutzmittel / Gesetzgebung" und der Federführung bei der ressortübergreifenden Erarbeitung von schriftlichen und mündlichen Kommentaren in der oben beschriebenen Form. Schließlich vertritt das Bundesministerium für Ernährung, Landwirtschaft und Forsten die Bundesrepublik Deutschland in den Sitzungen des Ständigen Ausschusses für "Pflanzenschutz", um hier die deutsche Haltung zu den erarbeiteten Review-Reports und Entscheidungsvorschlägen einzubringen.

Durch den letzten Punkt dieser Graphik möchte ich nun zum zweiten, nicht minder interessanten Punkt, der Implementierung der Richtlinie 91/414/EWG in nationales Recht überleiten. Diese wird in Deutschland durch das "Erste Gesetz zur Änderung des Pflanzenschutzgesetzes" erfolgen. Ich werde Ihnen nun in gebotener Kürze den Fortgang dieser Gesetzesinitiative bis zum heutigen Tag schildern (Abb. 5).

Der vom Bundesministerium für Ernährung, Landwirtschaft und Forsten erstellte Referentenentwurf wurde nach Anhörung der zu beteiligenden Wirtschaftskreise und -verbände, in Deutschland sind dies ca. 70 Verbände, mit den zu beteiligenden Bundesministerien abgestimmt und durch das Bundesministerium der Justiz rechtsförmlich geprüft. Da die neuen Vorschriften die Zuständigkeit der Länder stark berühren werden, war der Gesetzentwurf nach dem Grundgesetz der Bundesrepublik Deutschland als sogenanntes zustimmungsbedürftiges Gesetz als erster parlamentarischer Schritt der Ländervertretung, d.h. dem Bundesrat zuzuleiten. Die Zuleitung erfolgte im Mai 1997. Nach Beratungen in den Ausschüssen des Bundesrates (Landwirtschaft, Gesundheit, Umwelt, Europäische Angelegenheiten und Wirtschaft) verabschiedete der Bundesrat seine Entschließung mit den Änderungswünschen zu dem vorgelegten Gesetzentwurf im Juli letzten Jahres. Nach dem bereits beschriebenen regierungsinternen Prozedere fertigte daraufhin die Bundesregierung unter Federführung des Bundesministerium für Ernährung, Landwirtschaft und Forsten ihre Stellungnahme zum Beschluß des Bundesrates, die sogenannte Gegenäußerung. Diese wurde mit dem Gesetzentwurf und dem Beschluß des Bundesrates im August 1997 dem Bundestag, also dem Parlament, zur Beratung zugeleitet. Hier wurde der Gesetzentwurf in drei Beratungen, den sogenannten drei Lesungen behandelt. Das Gesetz wurde am 25. November 1997 mit den Stimmen der Koalition vom Bundestag beschlossen. Nach der deutschen Verfassung ist jedes zustimmungsbedürftige Gesetz nach Verabschiedung durch den Bundestag, erneut den Ländern, mit anderen Worten dem Bundesrat zuzuleiten. Dieser prüft, ob er dem Gesetz in der beschlossenen Form zustimmen will oder einen Vermittlungsausschuß anrufen will. Der Bundesrat hat im vorliegenden Fall beschlossen, den Vermittlungsausschuß einzuberufen, allerdings aus Gründen, die nichts mit der Umsetzung der Richtlinie 91/414/EWG zu tun haben. Es steht zu erwarten, daß trotz dieser Verzögerung das Gesetz planmäßig am 1. Juli dieses Jahres in Kraft treten kann.

Meine Damen und Herren, Sie werden sich jetzt vielleicht fragen, warum die Umsetzung der Richtlinie 91/414/EWG in deutsches Recht so lange gedauert hat. Zum einen hat der erste Entwurf (von 1993) aufgrund der Bundestagswahl 1994 die parlamentarischen Gremien nicht mehr erreicht. Zum anderen hat die Bundesrepublik Deutschland stets die Auffassung vertreten, daß die Richtlinie einschließlich des Anhangs VI, die einheitlichen Grundsätze, vorliegen müsse, bevor das Parlament entscheiden kann, weil erst beide Texte zusammen Klarheit verschaffen, welches Schutzniveau für Mensch, Tier und Naturhaushalt mit den Regelungen verbunden ist. Zur Erinnerung, die Bundesrepublik Deutschland hat 1994 gegen die Fassung des Anhangs VI gestimmt, eben weil das Schutzniveau nicht ausreichte.

Neben dem nationalen Verfahren bestand zudem die Verpflichtung, das Gesetz nach der Richtlinie 83/189/EWG zu notifizieren, weil das Gesetz über die Umsetzung der Richtlinie 91/414/EWG hinausgehende Vorschriften enthält (z. B. über das Inverkehrbringen von Pflanzenstärkungsmitteln). Dazu wurde der regierungsinterne Gesetzentwurf über das Bundesministerium für Wirtschaft der Europäischen Kommission zur Notifizierung zugeleitet. Die Frist für Stellungnahmen läuft noch, bisher sind allerdings keine Einwände der anderen Mitgliedstaaten eingegangen.

Die Anhänge II, III und VI der Richtlinie 91/414/EWG werden durch eine Novelle der Pflanzenschutzmittelverordnung in nationales Recht überführt. Die Umsetzung erfolgt durch Verweis auf die Anhänge selbst. Abgerundet wird die Implementierung durch eine Änderung der Kostenverordnung und eine allgemeine Verwaltungsvorschrift über die Identität von Pflanzenschutzmitteln mit dem Arbeitstitel "Allgemeine Verwaltungsvorschrift über den Rahmen der akzeptablen Abweichungen der in den Verkehr gebrachten Pflanzenschutzmittel von den in der Zulassung erfaßten Inhaltsstoffen". Diese drei Rechtssetzungsvorhaben sollen zeitgleich mit dem neuen Pflanzenschutzgesetz zum 01.07.1998 in Kraft treten.

Meine Damen und Herren, nachdem ich Ihnen, nennen wir es das "Tagesgeschäft" des Bundesministeriums für Ernährung, Landwirtschaft und Forsten vorgestellt habe, erlauben Sie mir nun abschließend einige Worte zur Bewertung des Verfahrens der EU-Wirkstoffprüfung.

Das Arbeitsprogramm ist, wie wir gesehen haben, aufwendig, langwierig und verlangt von allen Beteiligten einen großen Einsatz nicht nur an Know-how sondern auch an Arbeitskraft. Um gleiche Wettbewerbsbedingungen zu schaffen und gleichzeitig ein hohes Schutzniveau zu wahren, gibt es jedoch keine Alternative zur gründlichen Bewertung aller Wirkstoffe. Der auf den ersten Blick aufwendige Abstimmungsprozeß ermöglicht, die Sachkunde und Erfahrungen aller beteiligten Stellen nutzbar zu machen und garantiert eine ausgewogene Entscheidung. Auf eine Kurzform gebracht:

"Vielfalt im Innern und Einheit nach außen!"

Wie jedes dynamische System, bedingt oder vielleicht besser gesagt, erlaubt die EU-Wirkstoffprüfung einen Lernprozeß, der eine schrittweise Optimierung des Systems ermöglicht. In der Wirtschaft wurde dafür der Begriff des "Kontinuierlichen Verbesserungsprozesses" geprägt. Und meine Damen und Herren, seit Beginn des Programms wurden ständig Verbesserungen vorgenommen. Leitlinien wurden erstellt, um Vorgaben zu präzisieren und zu standardisieren. Interne Arbeitsabläufe in den Reihen aller Beteiligten wurden verbessert. Es ließen sich weitere Beispiele aufführen, doch lassen Sie uns in die Zukunft schauen. Niemand kann zum jetzigen Zeitpunkt versprechen, daß in fünf Jahren die "restlichen" Wirkstoffe in Anhang I aufgenommen sind. Doch das bestehende Verfahren bestätigt mit der Aufnahme des ersten Wirkstoffs, daß es lebensfähig ist, und die in der Vergangenheit erreichten

Optimierungen lassen uns diesbezüglich optimistisch in die Zukunft blicken. Wir haben meines Erachtens drei wichtige Bereiche, in denen wir entsprechend weiter ansetzen sollten:

1. Verschlankung des Verfahrens,
2. Transparenz des Verfahrens und
3. Feedback des Erreichten und Abbau dabei identifizierter Probleme.

Als jüngste Ansätze zu diesen drei Punkte lassen Sie mich exemplarisch das CADDY-Programm, das Pesticide Information System, die fortschreitende Erarbeitung von Guidance-Dokumenten und die ständige Optimierung der ECCO-Meetings nennen. Nicht zuletzt steht die Novellierung der Richtlinie 91/414/EWG bevor.

Meine Damen und Herren, das bisher Erreichte sollte uns ermutigen, auch weiterhin an einem Strang zu ziehen, selbst wenn dies für den einen oder anderen eine gewisse Durststrecke bedeuten mag. Lassen sich mich dazu mit Dante schließen, der sagte:

"Der eine wartet, daß die Zeit sich wandelt,
der andere packt sie kräftig an und handelt!"

Ich danke für Ihre Aufmerksamkeit.

Figure 1: **Structure of the Federal Government of the Federal Republic of Germany**

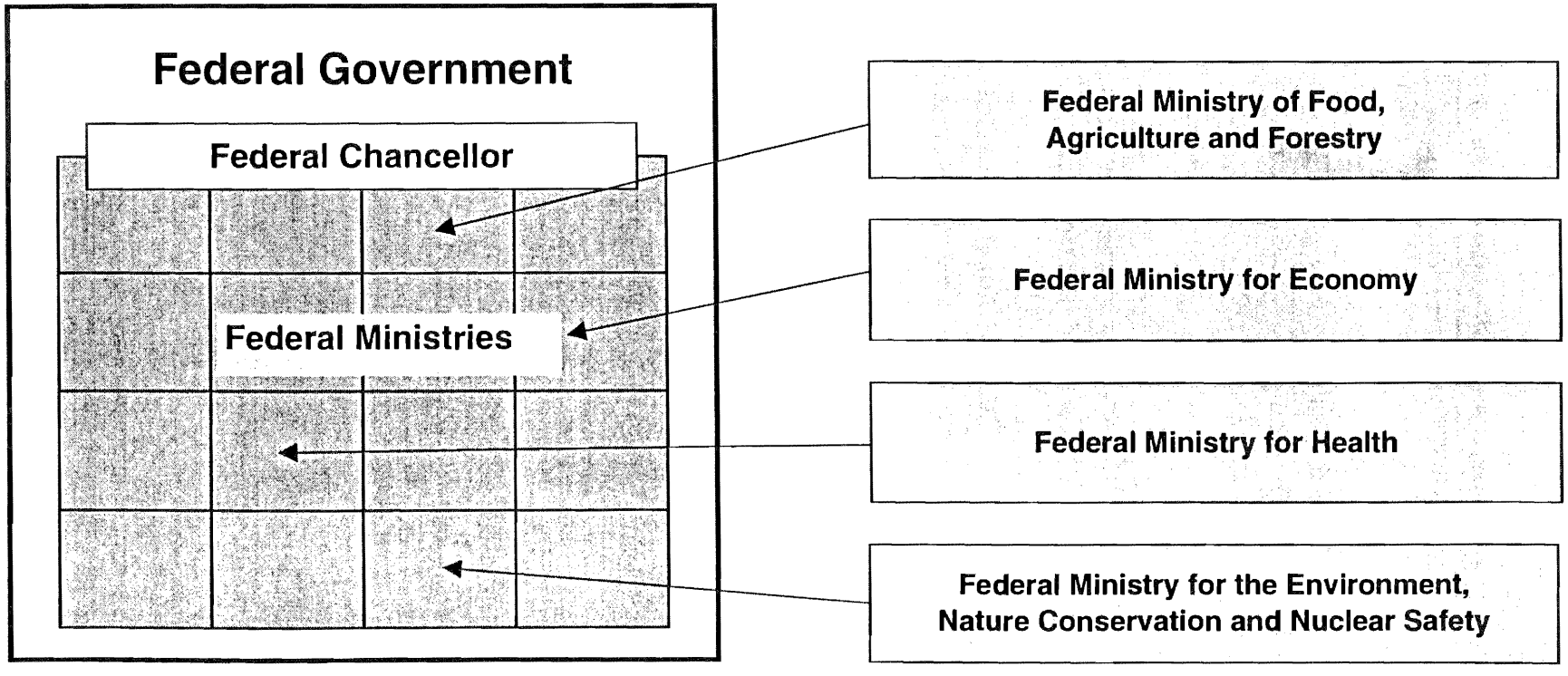


Figure 2: **Ministries and competent authorities**

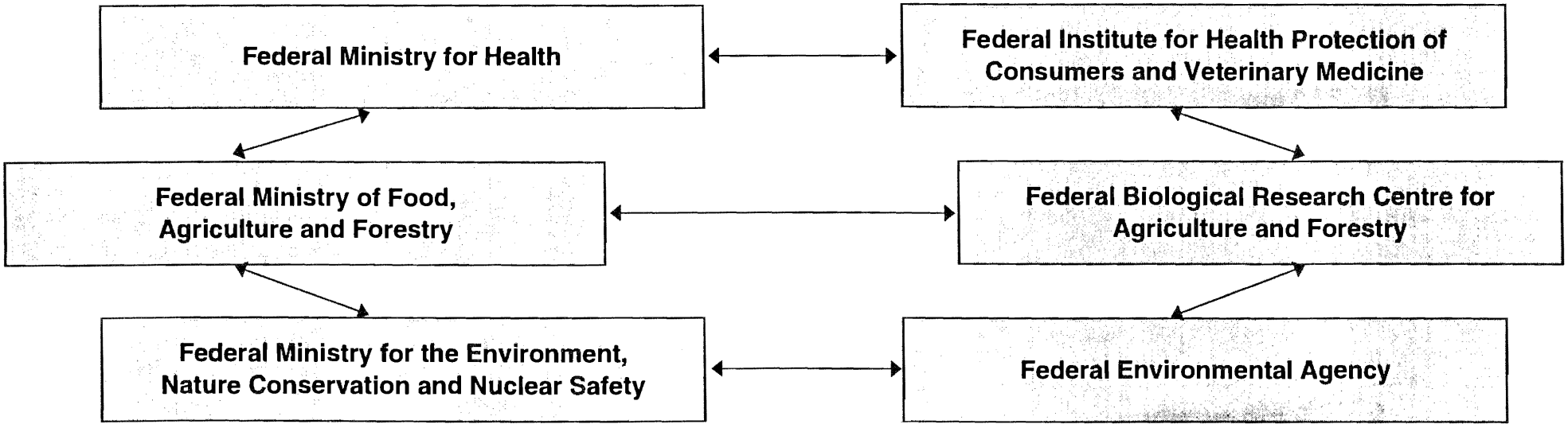


Figure 3: **Organization scheme of Plant Protection in the Federal Republic of Germany**

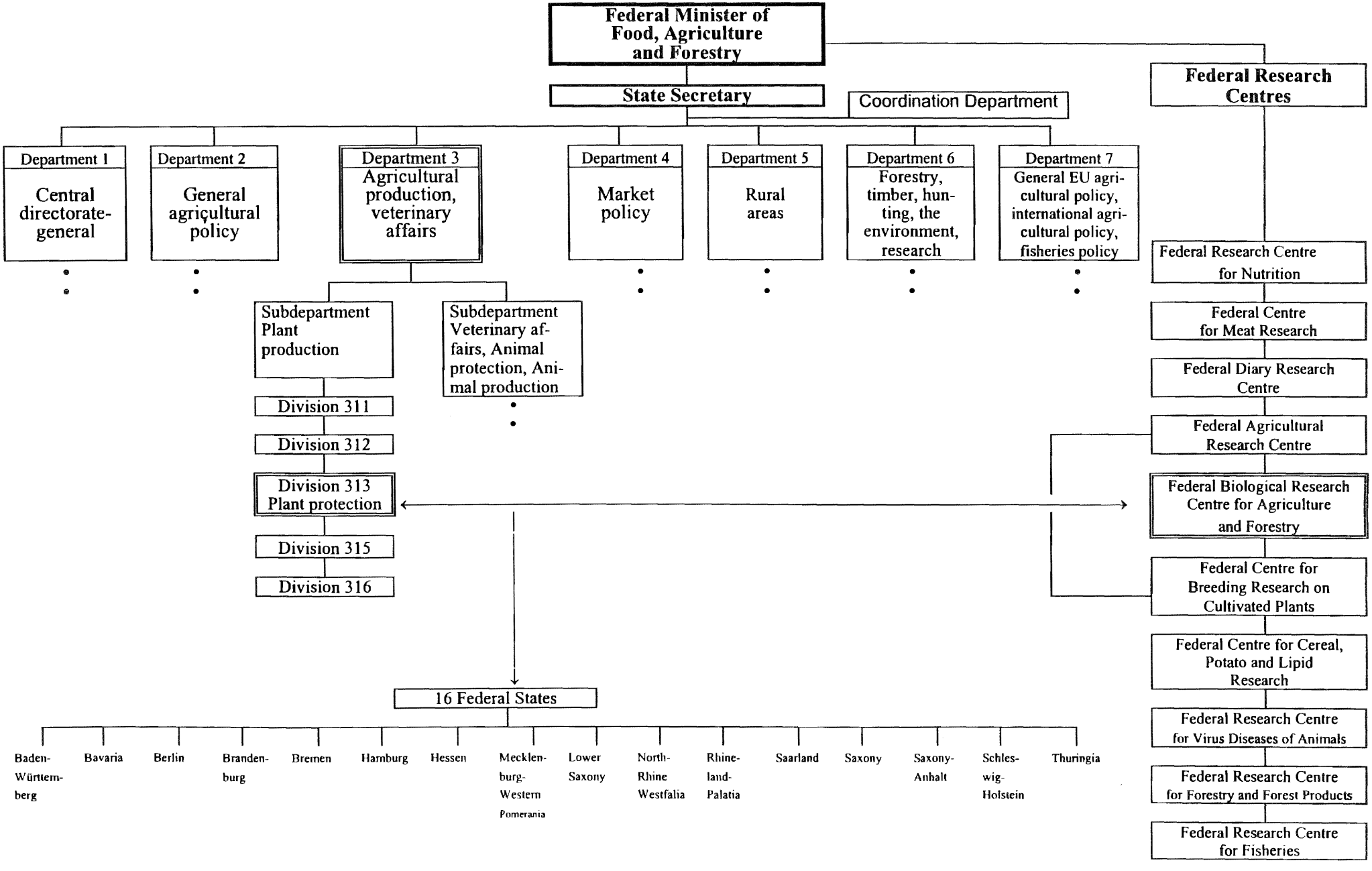


Figure 4: **EU-Peer Review of active substances**

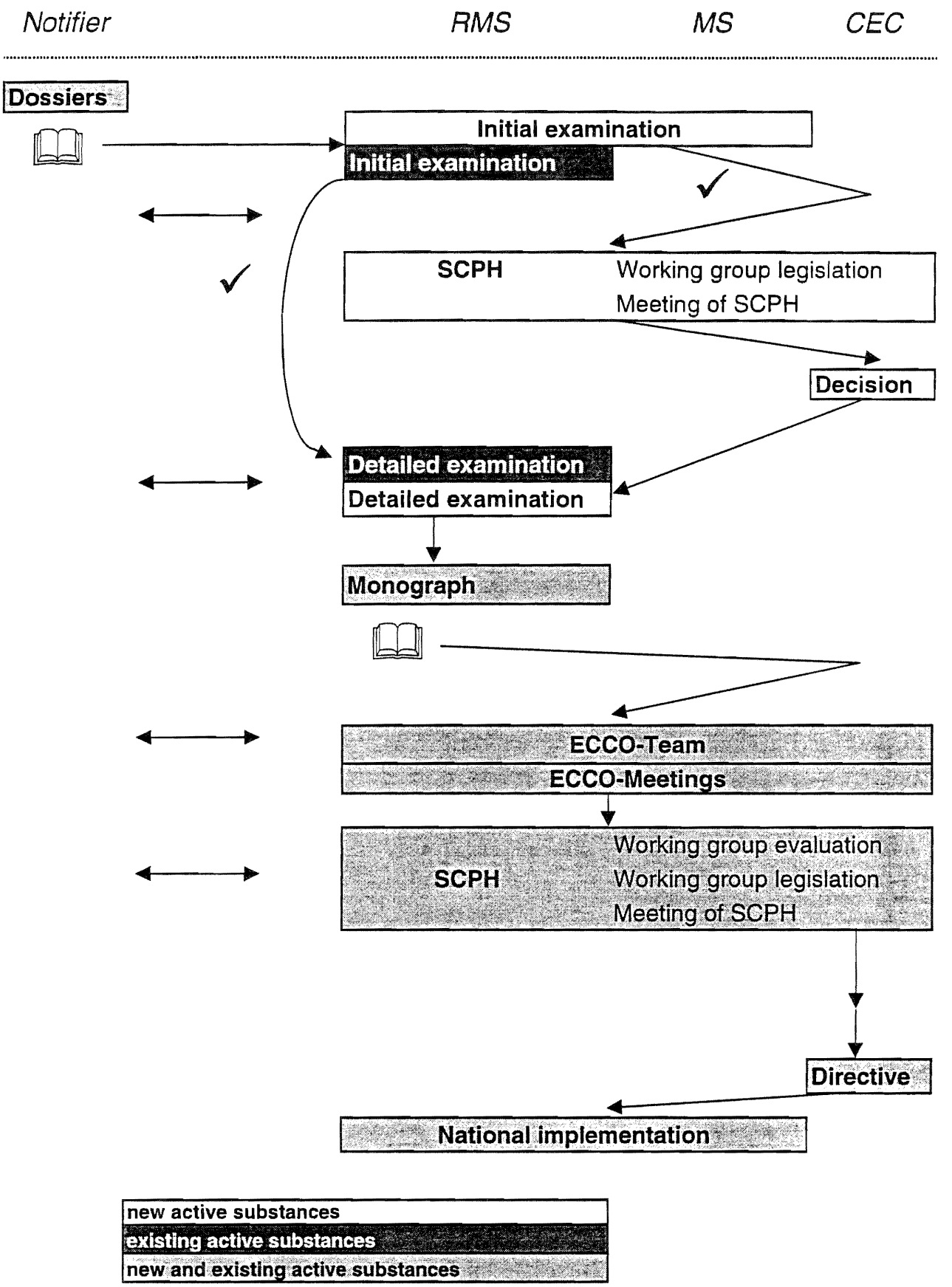
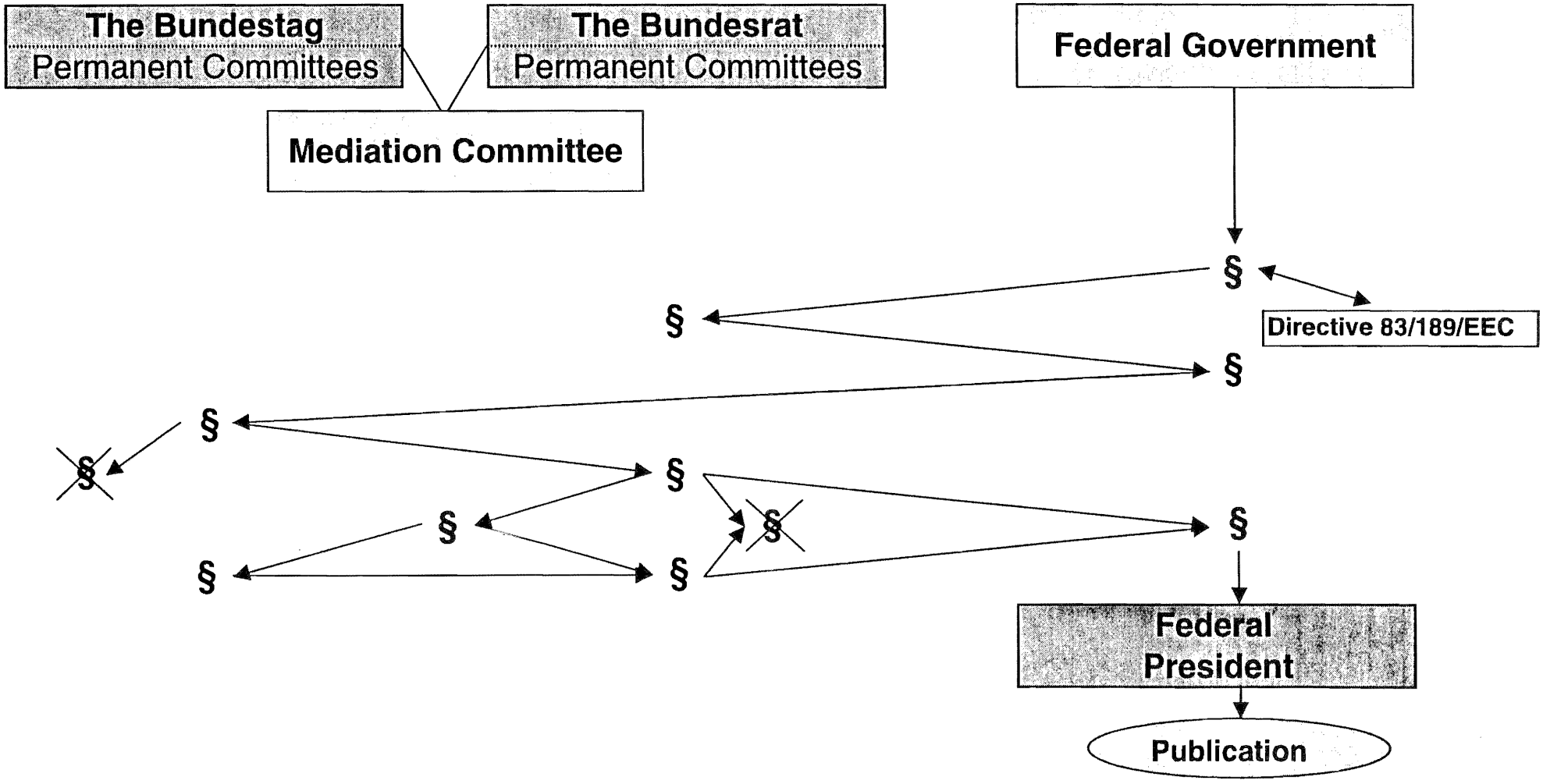


Figure 5: **Legislation in the Federal Republic of Germany**



The EU Re-evaluation of Active Substances in Germany, from the Point of View of the Ministry

K. WEISSLEDER

Federal Ministry of Food, Agriculture and Forestry
Germany

Dear President, dear chairman, dear ladies and gentlemen!

With Council Directive 91/414/EEC, concerning the placing on the market of plant protection products, and the creation of the Single European Market in the background, an ambitious programme was imposed for examining active substances in plant protection products to see whether they are fundamentally suitable, according to current knowledge, of being used in plant protection products. This is an ambitious programme, considering first of all the amount of substances to be examined, to be more exact around 800 existing active substances, i.e. active substances in plant protection products which were on the market in a Member State of the European Union before 26 July, 1993 and active substances in plant protection products which appeared on the market after 26 July 1993, so-called new active substances. Ambitious also regarding the amount of time given. The evaluation should in principle be completed within 10 years, i.e. by the year 2003.

By agreeing to participate in this procedure based on the division of labour, the amount of work for the competent authorities increased. Apart from being responsible for the "normal" authorisation procedure, they took on an additional share in the evaluation of the existing active substances and the procedure for new active substances.

Although the authorities already had some experience in the joint examination of active substances in plant protection products through Directive 79/117/EEC, the work programme of Directive 91/414/EEC meant treading on new ground; not so much as far as the decision processes were concerned, but rather with regard to working systematically through the data bases and with regard to the transparency in the decision procedure. But it was precisely this procedure which promised a way for the constantly scrutinised area of plant protection to an internal market freed from trade barriers, whilst at the same time maintaining a common high level of protection with regard to the authorisation of plant protection products, admittedly no easy way, but at least a broadly acceptable one.

To this day, half of the 10-year deadline has already been reached, but as yet, only one active substance, Imazalil, has been listed in Annex I of Directive 91/414/EEC. However, I do not believe that there is any reason to be pessimistic; on the contrary, we should look positively towards the future development of the work programme. In this regard, I would now like to

tell you something about the EU evaluation procedure for active substances from the point of view of the Federal Ministry of Food, Agriculture and Forestry as a party involved in the procedure.

As an introduction, I will give you a general view of the structure and the organisation of duties of the organisations in Germany involved in the work within the framework of Directive 91/414/EEC on a national level.

The executive power of the constitutional bodies in the Federal Republic of Germany is the Federal Government (fig. 1). It is composed of the Federal Chancellor and the Federal Ministries. In the Federal Government of the Federal Republic of Germany, plant protection, and therefore also Directive 91/414/EEC, is under the supervision of the Federal Ministry of Food, Agriculture and Forestry.

Ladies and Gentleman, I repeat:
the supervision of Directive 91/414/EEC lies with the Federal Ministry of Food, Agriculture and Forestry. It would not be correct to think that supervision means sole responsibility. According to the Standing Orders of the Federal Government, the supervisory ministry must involve those ministries whose competency are concerned. Within the framework of Directive 91/414/EEC, these are mainly the Federal Ministry for Economy, the Federal Ministry for Health and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety. The Federal Ministry for Health covers mainly the areas of human and animal health and drinking water in the evaluation procedure for active substances and the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety the examination areas of water, soil and waste. The Federal Ministries receive expert advice from the subordinate Superior Federal Authorities (fig. 2). In the case of the Federal Ministry of Food, Agriculture and Forestry, this is the Federal Biological Research Centre for Agriculture and Forestry, the BBA, which, in accordance with the Plant Protection Act, is at the same time the competent authority for the authorisation of plant protection products and the authority named by the Federal Government for the co-ordination of the EU evaluation procedure for active substances. In addition, the BBA is one of the ten research institutions under the jurisdiction of the Federal Ministry of Food, Agriculture and Forestry. The advisory authority for the Federal Ministry for Health is the Federal Institute for Health Protection of Consumers and Veterinary Medicine, and for the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety the Federal Environmental Agency, both subordinate authorities with headquarters in Berlin.

The Federal Ministry of Food, Agriculture and Forestry (fig. 3), under the leadership of the Federal Minister, Mr. Borchert, supported by the Undersecretary of State, Dr. Feiter, and the new Parliamentary Undersecretary of State, Mr. Hinsken, demonstrate the typical structure of a hierarchical organisation (in German: Stablinienorganisation). The Federal Ministry of Food, Agriculture and Forestry is divided into 8 departments, or to be more exact, a co-

ordination department and 7 specialist departments comprising at present around 950 employees.

Within a Federal Ministry, supervision is delegated to a division. For the Federal Ministry of Food, Agriculture and Forestry, this competency lies with division 313, responsible for plant protection, to be found in Department 3 which is specialised in agricultural production and veterinary affairs. As on ministry level, supervision within a ministry also means examining and ensuring the participation of other specialised divisions involved. As divisions involved in Directive 91/414/EEC, please allow me to mention, for example, the law division, the division for animal protection and the division for consumer protection and food quality, the latter being the competent division concerning the area of residues from plant protection products in food.

Before a comment is prepared for submission to the European Commission, be it a comment on a draft from the EU Commission or a national draft and after checking to see whether their participation is necessary, a vote is taken within the ministries, and following this, the preparation of a comment approved by the ministries. Desired changes to the ministries participating must be taken into account by the supervisory division. According to the Standing Orders of the Federal Ministries, the latter are in addition obliged to involve participating industrial circles and if the procedure touches on plant protection, the participation of the Federal States. As an example of the Federal States' involvement I would like to mention the control measures in accordance with Article 17 of Directive 91/414/EEC which are performed by the Federal States.

As the supervisory ministry for Directive 91/414/EEC, the Federal Ministry of Food, Agriculture and Forestry is however not only responsible for guaranteeing the involvement of all parties concerned, but also for making sure that all the necessary work is completed on time.

The supervisory ministry represents the comments submitted by the Federal Government, in the form of written comments and participation in various forums of the European Community within the framework of Directive 91/414/EEC, and in other international forums. This work includes on the one hand the administrative procedure of the EU evaluation procedure for active substances, from the decision on the completeness of a dossier to negotiations as to whether an active substance should be listed in Annex I of Directive 91/414/EEC, and on the other hand co-operation in compiling the numerous necessary guidelines, regulations, decisions and supplementary directives for Directive 91/414/EEC. Finally, the supervisory ministry has the responsibility of implementing common law-making into national law.

Ladies and gentleman, after giving you a general view of the structure and work of the Ministry, please allow me to present two examples concerning Directive 91/414/EEC. First of

all, I would like to describe the involvement of the Federal Ministry of Food, Agriculture and Forestry in the EU evaluation procedure for active substances and then to touch briefly on the present situation of national implementation of Directive 91/414/EEC.

The following diagram (fig. 4) shows the normal procedure for evaluating active substances. With the help of this diagram, I would like to explain the role of the Federal Ministry of Food, Agriculture and Forestry. I will limit my explanation to the most important items of work which the Federal Ministry of Food, Agriculture and Forestry does not delegate to the BBA but which it performs itself. The BBA will be the subject of my next contribution.

We can differentiate between four different types of cases in the EU evaluation procedure for active substances, regardless of whether a Member State is named as rapporteur or not and whether the active substance involved is an existing or a new one.

The Federal Ministry of Food, Agriculture and Forestry is involved in the initial examination, the first step in the procedure, if in the working group "Legislation" decisions as to the completeness of the documentation on new active substances or decisions as to the incompleteness of the submitted documentation on existing active substances, are prepared, and subsequently also in the Standing Committee for Plant Health when a corresponding draft decision of the European Commission is voted on.

Within the framework of the detailed examination, and in those cases where Germany is named as rapporteur, the Federal Ministry of Food, Agriculture and Forestry takes the final vote on a ministerial level regarding the active substance monograph compiled by the subordinate authorities and sends this to the European Commission. In all other cases, the Federal Ministry of Food, Agriculture and Forestry takes the final vote on a national level regarding comments on monographs from other Member States.

After assessing the monographs in the Member States and the ECCO-Meetings, the Federal Ministry of Food, Agriculture and Forestry is active in the meetings of the working group "Evaluation". The main task in this final stage of the evaluation procedure for active substances is participation and heading the delegation for the Federal Republic of Germany in the meetings of the working group "Legislation", and supervising the interministerial compilation of written and spoken comments in the form described above. Finally, the Federal Ministry of Food, Agriculture and Forestry represents the Federal Republic of Germany in the meetings of the Standing Committee for Plant Health, in order to present Germany's opinion on the Review Reports and proposed decisions.

Using the last item in the diagram, I would like to move on to the second point of no less interest; the implementation of Directive 91/414/EEC in national law. In Germany, this will be the "First law to change the Plant Protection Act". I will now present to you briefly the progress of this legislation initiation to the present day (fig. 5).

The draft of the official report (in German: Referentenentwurf) compiled by the Federal Ministry of Food, Agriculture and Forestry was voted on together with the federal ministries concerned, after a hearing in front of the industrial circles and associations concerned - in Germany these amount to around 70 associations, and then examined legally by the Federal Ministry of Justice. Since the new regulations will effect the competence of the Federal States, the bill required the approval of the *Bundesrat* (Federal Council), in accordance with the Basic Law of the Federal Republic of Germany, and had to be passed on to the Federal States' representative, i.e. the *Bundesrat*, as a first parliamentary step. This transmission occurred in May 1997. Following debates within the *Bundesrat* committees (for agriculture, health, the environment, European affairs and the economy), the *Bundesrat* approved its decision, including the desired amendments to the draft bill submitted, in July of last year. After the procedure described above, the Federal Government produced its comment on the decision of the *Bundesrat*, the so-called counterstatement, under the leadership of the Federal Ministry of Food, Agriculture and Forestry. This was directed to the *Bundestag* (Federal Parliament), together with the draft bill and the *Bundesrat's* decision, in August 1997 for deliberation. The draft bill was treated in three readings. The bill was voted on by the coalition and passed on 25 November, 1997 by the *Bundestag*. According to the German constitution, each law which requires the approval of the Federal Council must be passed on to the Federal States again, in other words the *Bundesrat,* after it has been adopted by the *Bundestag*. The *Bundesrat* checks to see whether it agrees with the bill in its current form or whether it wishes to call a mediation committee. As far as the case in hand is concerned, the *Bundesrat* has decided to call for the mediation committee, although for reasons which have nothing to do with the implementation of Directive 91/414/EEC. The bill is nevertheless expected to come into force as planned on 1 July of this year.

Ladies and gentlemen, you may now ask yourselves why the implementation of Directive 91/414/EEC has taken such a long time. First of all, the first draft (of 1993) did not reach the parliamentary forums due to the *Bundestag* elections in 1994. Secondly, the Federal Republic of Germany was always of the opinion that the Directive, including Annex VI (the Uniform Principles), must exist before Parliament can make a decision, since clarity cannot be achieved on what sort of protection level for humans, animals and the natural balance the regulations will mean until both texts are present. As a reminder, the Federal Republic of Germany voted against the drafting of Annex VI in 1994 because the level of protection was insufficient.

Apart from the national procedure, it was also compulsory to notify the bill in accordance with Directive 83/189/EEC, because the law on the implementation of Directive 91/414/EEC moreover contains other regulations (e.g. on the placing on the market of plant resistance improvers). In this regard, the Government's internal draft bill was passed on for notification to the European Commission via the Federal Ministry for Economy. The period of time is still running in which comments can be submitted, but up until now, no objections have been received from other Member States.

The Annexes II, III, and IV of Directive 91/414/EEC are being transferred to national law by an amendment to the Plant Protection Product Ordinance. They are being implemented by reference to the annexes themselves. This implementation is rounded off by an amendment to the BBA-Ordinance of Costs and a general administrative provision regarding the identity of plant protection products with the title, "General administrative provision concerning the framework of acceptable deviations of plant protection products placed on the market from the ingredients included in the authorisation". All three of these legal projects are to come into force simultaneously with the new Plant Protection Act on 1 July, 1998.

Ladies and gentlemen, after having described to you the daily work of the Federal Ministry of Food, Agriculture and Forestry, I would now like to close by saying a few words on the general assessment of the EU evaluation procedure for active substances.

The work programme, as can be seen, is complicated, tedious and demands a great input not only of know-how but also of work from those concerned. In order to create similar conditions of competition and at the same time maintain a high level of protection, there is however no alternative to the thorough assessment of all active substances. The decision making procedure which at first sight seems very complicated, enables the exploitation of expert knowledge and experience in all institutions concerned and guarantees a balanced decision. In short:

"Diversity on the inside and unity on the outside!"

As every dynamic system, the EU evaluation procedure for active substances calls for, or perhaps rather allows a learning process which makes a step by step optimisation of the system possible. In trade and industry, the phrase "continuous improvement process" has been coined for this. Ladies and gentlemen, since the very beginning of the programme, improvements have constantly been made. Guidelines were established to specify and standardise the various tasks. Internally, work routines were improved by all concerned. I could name more examples, but let us instead look to the future. Nobody is in the position at the moment to be able to promise that in five years' time the remaining active substances in Annex I will have been listed. However, the present procedure has proved with the inclusion of the first active substance that it is viable and the optimisations achieved in the past allow us to look optimistically into the future. In my opinion, there are three important areas in which we should concentrate on making improvements:

1. Slimming down the procedure,
2. Transparency of the procedure and
3. Feedback on what has been achieved and resolving problems identified through this.

As most recent examples of attempts at the above, I would like to mention the CADDY Programme, the Pesticide Information System, the progressive work on guidance documents,

the continual optimisation of the ECCO-Meetings and last but not least, the forthcoming amendment to Directive 91/414/EEC.

Ladies and gentlemen, that which has already been achieved should help to motivate us to join forces, even if this means a period of reduced circumstances for some of us at times. I would like to close with a quotation from Dante who said,

"Whereas one man waits for time to change,
the other tackles it energetically and acts!".

Thank you for listening.

Verfahrensablauf und Stand der EU-Wirkstoffprüfung in Deutschland aus der Sicht der Benannten Behörde

A. WILKENING

Biologische Bundesanstalt für Land- und Forstwirtschaft
Bundesrepublik Deutschland

Sehr geehrter Herr Präsident, meine Damen und Herren.
Ich werde Ihnen nun Informationen über den Stand der EU-Wirkstoffprüfung in Deutschland und die dafür entwickelten Verfahrensabläufe aus Sicht der Benannten Behörde geben.

Einleitung:

In Deutschland sind folgende Ministerien und Behörden mit der Prüfung und Zulassung von Pflanzenschutzmitteln und der EU-Wirkstoffprüfung befaßt.

Abb. 1: Responsibilities 1

Für offizielle Stellungnahmen z.B. an die Europäische Kommission ist die Bundesregierung zuständig, die sich im Falle der EU-Wirkstoffprüfung auf die Zuarbeit folgender Ministerien stützt: Gesundheitsministerium, Ministerium für Umwelt, Naturschutz und Reaktorsicherheit sowie das Ministerium für Ernährung, Landwirtschaft und Forsten. Diese Ministerien können jeweils auf Ihre Fachbehörden zurückgreifen. Es sind dies das Institut für den gesundheitlichen Verbraucherschutz und Veterinärmedizin (BgVV), das Umweltbundesamt (UBA) und die Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA).

Die Biologische Bundesanstalt für Land- und Forstwirtschaft ist die von der Bundesregierung gemäß Artikel 3 der Verordnung (EWG) Nr. 3600/92 benannte Behörde zur Koordinierung der EU-Wirkstoffprüfung. In Anlehnung an die Zuständigkeiten im nationalen Verfahren sind Umweltbundesamt und BgVV an der EU-Wirkstoffprüfung beteiligt. Sie sind aber im Gegensatz zum nationalen Verfahren keine Einvernehmensbehörden.

Abb. 2: Responsibilities 2

In der BBA sind an der EU-Wirkstoffprüfung die Abteilung für Pflanzenschutzmittel und Anwendungstechnik (AP) mit ihren Fachgruppen Biologische Mittelprüfung und Chemische Mittelprüfung beteiligt. Die Fachgruppe Anwendungstechnik steht hier nur der Vollständigkeit halber, sie hat aber direkt nicht mit der Wirkstoffprüfung zu tun. In der Fachgruppe Biologische Mittelprüfung werden die Auswirkungen auf Nichtzielorganismen (Regenwürmer, Bodenmikroflora, Nutzarthropoden außer Bienen, Wirbeltiere und Wasserorganismen), die Wirksamkeit und Kulturpflanzenverträglichkeit von Insektiziden und Akariziden im Hopfen

sowie Wirksamkeit (von Insektiziden, Akariziden und Rodentiziden) im Vorratsschutz bearbeitet. Die Fachgruppe für chemische Mittelprüfung ist zuständig für die Prüfung und Bewertung der physikalischen und chemischen Eigenschaften der Wirkstoffe und Mittel, für das Rückstandsverhalten, den Verbleib im Boden, im Wasser und in der Luft, jeweils einschließlich der entsprechenden Analytik, sowie für die Abfallbeseitigung.

Neben den Fachgruppen der Abteilung sind auch die Institute für Ackerbau und Grünland, Pflanzenschutz im Forst, Pflanzenschutz im Gartenbau, Integrierten Pflanzenschutz, Unkrautforschung und Pflanzenschutz im Weinbau an der Prüfung beteiligt. Ihre Zuständigkeiten liegen in den Prüfbereichen Wirksamkeit, Pflanzenverträglichkeit und Auswirkungen auf Bienen.

Weiter Einzelheiten entnehmen Sie bitte dem Ihnen ausgehändigten BBA-Berichtsheft Nr. 37.

Das Umweltbundesamt nimmt Stellung zu den Prüfbereichen Wasser, Luft und Abfall und das Institut für gesundheitlichen Verbraucherschutz und Veterinärmedizin zur Gesundheit von Mensch und Tier sowie zum Trinkwasser.

Abb. 3: Active Substances; Germany is not RMS - Initial Evaluation

Grundsätzlich sind 4 verschiedene Fälle der EU-Wirkstoffprüfung zu unterscheiden:

- alter Wirkstoff; Deutschland ist berichterstattender Mitgliedstaat
- alter Wirkstoff; Deutschland ist nicht berichterstattender Mitgliedstaat
- neuer Wirkstoff; Deutschland ist berichterstattender Mitgliedstaat
- neuer Wirkstoff; Deutschland ist nicht berichterstattender Mitgliedstaat

Alle Verfahren laufen nach einem ähnlichen Schema ab, wobei die Fälle

- Deutschland ist Berichterstatter und
- Deutschland ist nicht Berichterstatter

natürlich größere Unterschiede aufweisen. Diese beiden Verfahrensabläufe möchte ich Ihnen vorstellen, wobei ich also auf die kleineren Unterschiede im Verfahrensablauf zwischen alten und neuen Wirkstoffen nicht eingehe. Betrachten wir zunächst den Fall "Deutschland ist nicht berichterstattender Mitgliedstaat":

Nachdem der berichterstattende Mitgliedstaat den check for completeness abgeschlossen hat, beginnt die Vorprüfung in Deutschland. Zunächst wird eine kurze Eingangsprüfung durchgeführt, d.h. die vom Antragsteller, der Europäischen Kommission oder vom berichterstattenden Mitgliedstaat eingereichten Unterlagen (Dossiers, check for Completeness, ggf. Nachlieferungen und ergänzende Stellungnahmen) werden auf formale Vollzähligkeit (Sprache: Anschreiben in deutscher Sprache, ansonsten werden alle Dokumente in englisch akzeptiert, Anzahl

Kopien) überprüft und registriert. Die in der Abbildung skizzierte Eingangsbestätigung erhält nur der Antragsteller. Gleichzeitig wird ihm die von der BBA vergebene Kenn- Nummer mitgeteilt. Das alles geschieht in max. 2 Wochen. Innerhalb einer weiteren Woche werden die Unterlagen verteilt. Für die eigentliche Vorprüfung wird eine Frist von 5 Wochen gesetzt. Das UBA beteiligt sich nicht an der Vorprüfung. Die Vorprüfung wird in Abhängigkeit von den jeweiligen Bearbeiterinnen und Bearbeitern und von dem zu prüfenden Wirkstoff unterschiedlich intensiv durchgeführt. Zumindest werden aber im check for completeness aufgeführte Datenlücken betrachtet. Teilweise geben wir auch Hinweise zu Datenlücken, die normalerweise erst in der Hauptprüfung zu identifizieren sind. Dies geschieht dann nur in kommentierender Form zur Arbeitserleichterung und Information für berichterstattenden Mitgliedstaat und Antragsteller. Bei neuen Wirkstoffen, für die in Deutschland schon ein Antrag auf vorläufige Zulassung eingereicht worden ist, kann auf die bereits national getroffenen Bewertungen und Kommentare zurückgegriffen werden. Das Ergebnis der Vorprüfung in Deutschland wird gleichzeitig an die CEC, den RMS, die Ministerien, BgVV und UBA versendet. Der Zeitbedarf beträgt insgesamt 9 Wochen.

Es schließt sich die Entscheidung über die Vollständigkeit des Dossiers auf EU-Ebene an. Anschließend erstellt der RMS die Monographie.

Abb. 4: Active Substances; Germany is not RMS - Main Evaluation

Der RMS legt die fertige Monographie der CEC vor. Diese veranlaßt die Verteilung durch das ECCO-Team (European Commission Co-ordination) an alle Mitgliedstaaten. Damit beginnt die Hauptprüfung in Deutschland. Die eingehenden Monographien werden registriert, vervielfältigt und wie üblich verteilt. Für die Überprüfung der Monographien und die Mitteilung über das Ergebnis stehen 5 Wochen Zeit zur Verfügung. Der Zeitbedarf insgesamt beträgt im Regelfall mindestens 8 Wochen. Die BBA erstellt den Entwurf eines Berichtes mit Entscheidungsvorschlag, den ersten oder in unserem internen Sprachgebrauch gelben Entwurf. Dieser wird wieder an BgVV, UBA und innerhalb der BBA verteilt und ggf. erneut diskutiert. Die Erfahrungen haben aber gezeigt, daß die in Abb. 4 erwähnten Autorentreffen in der Regel nicht durchgeführt zu werden brauchen und oftmals eine schnelle Einigung auf einen zwischen den Behörden abgestimmten Vorschlag möglich ist. Es resultiert der zweite oder rote Entwurf, der im Falle unterschiedlicher Bewertungen von BBA einerseits und UBA oder BgVV andererseits ggf. noch auf Ressortebene abgestimmt werden muß. Auch diese Stufe war bisher nur ausnahmsweise erforderlich. Die Endversion der deutschen Kommentare zur Monographie des berichterstattenden Mitgliedstaates wird an CEC, ECCO, RMS, BML, BgVV, UBA versendet und in der BBA verteilt. Soweit die Beschreibung der Mitarbeit Deutschlands an der EU-Wirkstoffprüfung, wenn andere Mitgliedstaaten Berichterstatter sind.

Wenn Deutschland die Berichtspflichten übernommen hat, wird das Verfahren prinzipiell in gleicher Weise durchgeführt. Natürlich ist der Prüfaufwand ungleich höher.

Abb. 5: Active Substances; Germany as Rapporteur Member State - Check for Completeness

Zunächst müssen wir als Berichterstatter für die anderen Mitgliedstaaten und die Europäische Kommission den Check for Completeness durchführen. Dazu wird der Antrag nach Eingang wieder einer kurzen Eingangsprüfung unterzogen (Prüfung der Sprachrichtigkeit und Anzahl der Kopien (4 complete und 2 summary dossiers)). Diese Prüfung ist nach einer Woche abgeschlossen. Es wird eine Kenn.-Nr. vergeben, die dem Antragsteller oder Notifizierer mit der Eingangsbestätigung mitgeteilt wird. Wenn bereits hier erkennbar ist, daß Unterlagen fehlen, werden sie ebenfalls mit diesem ersten Schreiben nachgefordert. Falls der Antrag formal vollzählig ist, wird er an UBA, BgVV und innerhalb der BBA verteilt. Für den eigentlichen check for completeness und die Zusammenstellung der Ergebnisse stehen max. 10 Wochen zur Verfügung. Es hat sich als nicht ganz einfach erwiesen, für den check for completeness die richtige Bearbeitungstiefe zu finden. Wie detailliert sollte man sich das Dossier im Verlauf dieser Vorprüfung ansehen? Als Fazit hat sich ergeben, daß nicht bis auf die Stufe der Originalstudien hinabgegangen werden sollte. Es besteht sonst die Gefahr, einer vorgezogenen Detailprüfung. Es soll lediglich festgestellt werden, ob der Antrag in der vorliegenden Form formal vollständig und damit prüffähig ist. Andererseits können bei neuen Wirkstoffen nach der Entscheidung des Ständigen Ausschusses Pflanzenschutz vorläufige Zulassungen ausgesprochen werden. Dies verbietet eine zu oberflächliche Prüfung. Oftmals wird die Vorprüfung auch von Wissenschaftlerinnen und Wissenschaftlern durchgeführt, die aus ihren Erfahrungen im nationalen Verfahren und der Arbeit mit anderen Wirkstoffen auch unbedeutendere Datenlücken relativ schnell aufspüren. In Deutschland besteht der Grundsatz, daß alle Unzulänglichkeiten, die bei dieser Vorprüfung festgestellt werden, berichtet werden. Wird der Antrag als unvollständig eingestuft, ergehen entsprechende Nachforderungen an der Antragsteller, der 4 Wochen Zeit für eine ergänzende Stellungnahme erhält. Auch bei als vollständig erachteten Dossiers geben wir Hinweise auf ev. Unzulänglichkeiten des Dossiers, damit der Antragsteller möglichst frühzeitig informiert ist. Es bleibt aber festzustellen, daß die Grenze zwischen Vor- und Hauptprüfung nicht immer leicht zu ziehen ist. Der Zeitbedarf für den check for completeness beträgt bei vollständigen Dossiers 3 Monate. Bei den 5 bisher in Deutschland geprüften Dossiers betrug der Zeitbedarf 3, 5, 2mal 6 und 8.5 Monate, jeweils gerechnet vom Eingang des Dossiers bis zur Versendung des Berichtes an die CEC.

Unabhängig von dem sich nun anschließenden Verfahren auf EU-Ebene zur Feststellung der Vollständigkeit des Dossiers beginnen wir sofort mit der Hauptprüfung, wenn aus deutscher Sicht der Antrag vollständig ist. Selbstverständlich können auch während der Hauptprüfung noch Datenlücken identifiziert werden.

Abb. 6: Active Substances; Germany as RMS; Main Evaluation

Die Hauptprüfung erfolgt wieder parallel in den drei Behörden. Die Zeitvorgabe für die Anfertigung der Kommentare für die Monographie beträgt 6 Monate. Zu dem angekündigten Termin wird eine erste Fassung der Monographie aus unserem EDV-System herausgezogen.

Zu diesem Zeitpunkt liegt erstmals eine komplette Version der Monographie vor. Für die redaktionelle Durchsicht und insbesondere für die Formulierung eines Entscheidungsvorschlages wird jeweils ein Redaktionskomitee gebildet. Diese Redaktionskomitees bestehen aus 3 Personen (je ein Vertreter/in von FB, FC und der Koordinierungsgruppe (KG)). Spätestens 5 Wochen nach dem Ende der Hauptprüfung ist der gelbe Entwurf fertiggestellt. Der gelbe Entwurf wird dem Antragsteller und dem deutschen Sachverständigenausschuß zur Kenntnis gegeben. Der Antragsteller erhält Gelegenheit zur Stellungnahme. Es schließt sich ein Treffen der Autoren an, auf dem die komplette Monographie einschließlich Nachforderungen und Entscheidungsvorschlag diskutiert werden. Die auf dem Autorentreffen vereinbarten Änderungen fließen in den roten Entwurf ein, der ca. 10 Wochen nach dem gelben Entwurf fertigstellt sein sollte. Die roten Entwürfe stellen die Grundlage für die Abstimmung auf Ressortebene dar. Diese Abstimmung kann in unstrittigen Fällen sehr schnell erfolgen. Nach Einigung auf Ressortebene wird die weiße Fassung als deutsche Stellungnahme an die CEC versendet. Der Antragsteller wird aufgefordert aktualisierte Dossiers an alle Mitgliedstaaten zu versenden. Bei den bisher in Deutschland fertiggestellten Monographien betrug der Zeitbedarf für die Hauptprüfung 11 bzw. 13 Monate, gerechnet ab der Feststellung der Vollständigkeit im Ständigen Ausschuß sogar jeweils nur 7.5 Monate.

Es schließt sich nun das Verfahren auf EU-Ebene mit Diskussionen in der ECCO-Runde, der Arbeitsgruppen Evaluation und Legislation sowie im Wissenschaftlichen Ausschuß an.

Abb. 7: Comments from Germany on monographs of other MS

Deutschland ist mit 10 Wirkstoffen an der ersten Stufe des Programms zur Überprüfung der Wirkstoffe als berichterstattender Mitgliedstaat beteiligt. Für die Wirkstoffe Azinphos-methyl, Benomyl, Bentazon, Carbendazim, beta-Cyfluthrin, Cyfluthrin, Fluroxypyr und Thiophanatmethyl wurden Monographien erstellt und der Europäischen Kommission zur Einleitung des Entscheidungsverfahrens zur Aufnahme dieser Wirkstoffe in Anhang I der Richtlinie 91/414/EWG übermittelt. Die Monographien für Glyphosat und Isoproturon liegen im Entwurf vor. Weiterhin haben wir bisher Kommentare zu 24 Monographien anderer Mitgliedstaaten erstellt und an die Europäische Kommission weitergeleitet. Sieben Stellungnahmen sind z.Z. in Bearbeitung - 44 Monographien stehen noch aus.

Abb. 8: Evaluation of new active substances in the EU

Mit Stand vom 13. Januar 1998 waren 43 neue Wirkstoffe in den verschiedenen Mitgliedstaaten der Europäischen Union in Prüfung. Fünf Dossiers wurden in Deutschland eingereicht. Für Azoxystrobin und Spiroxamine wurde die Prüfung in Deutschland abgeschlossen. Für Pymetrozin und Imazosulfuron liegen erste Entwürfe der Monographien vor. Coniothyrium minitans befindet sich noch im Stadium der Vorprüfung, die in Deutschland aber schon abgeschlossen ist.

Abb. 9: Authorization of Plant Protection Products in Germany - check for completeness

Eine Entscheidung über die Zulassung neuer Pflanzenschutzmittel mit Wirkstoffen, die in Anhang I der Richtlinie 91/414/EWG aufgenommen worden sind, soll gemäß Anhang VI der Richtlinie im Regelfall in spätestens einem Jahr nach Vorliegen des kompletten Antrages getroffen werden. Auch im Entwurf des neuen Pflanzenschutzgesetzes ist eine entsprechende Frist für die Bearbeitung aller nationalen Anträge vorgesehen. Aus diesem Grund ist der hier vorliegende Verfahrensvorschlag entwickelt worden. Neu gegenüber dem bisherigen nationalen Zulassungsverfahren ist die Einführung eines check for completeness in Anlehnung an die EU-Wirkstoffprüfung und die Einführung von Terminkontrollen. Der Ablauf wird Ihnen nun vertraut vorkommen.

Nach Eingang der Unterlagen erfolgt wieder die formale Eingangskontrolle mit Eingangsbestätigung. Der Antrag wird registriert und es wird eine Kenn-Nr. vergeben. Die erste Terminüberwachung D1 erfolgt nach 3 Wochen. Falls keine gravierenden Mängel festgestellt werden, wird die Vorprüfung gestartet und der Termin D2 auf 9 Wochen nach D1 festgelegt. Bei der Vorprüfung erfolgt eine grobe Durchsicht auf Prüffähigkeit einschließlich der Fragen der Verwertung von Unterlagen in Anlehnung an die EU-Wirkstoffprüfung.

Abb. 10: Authorization of Plant Protection Products in Germany - main evaluation

Ist das Ergebnis der Vorprüfung negativ, wird die Hauptprüfung erst gestartet, wenn die noch bestehenden Forderungen erfüllt worden sind. Ist das Ergebnis der Vorprüfung positiv, wird die Hauptprüfung gestartet und dadurch die nächsten Termine D3 und D4 vorgegeben. Für die fachliche Prüfung, die Hauptprüfung, werden 32 Wochen eingeplant. 4 Wochen vor Ablauf dieser Frist liegt der Zeitpunkt D3. 28 Wochen nach dem Beginn der Hauptprüfung wird eine Liste der unerledigten Anträge erstellt, die den an der Prüfung Beteiligten eine Hilfestellung bei der Prioritätensetzung sein soll. Die Liste soll einmal wöchentlich automatisch per EDV erzeugt werden. Zum Zeitpunkt D4, 36 Wochen nach dem Beginn der Hauptprüfung, erhält der Antragsteller eine Mitteilung über das Ergebnis dieser Hauptprüfung. Das entspricht in etwa der heutigen 2. Zwischenmitteilung. Wird die Hauptprüfung mit einer negativen Bewertung abgeschlossen, sind 2 Fälle zu unterscheiden:

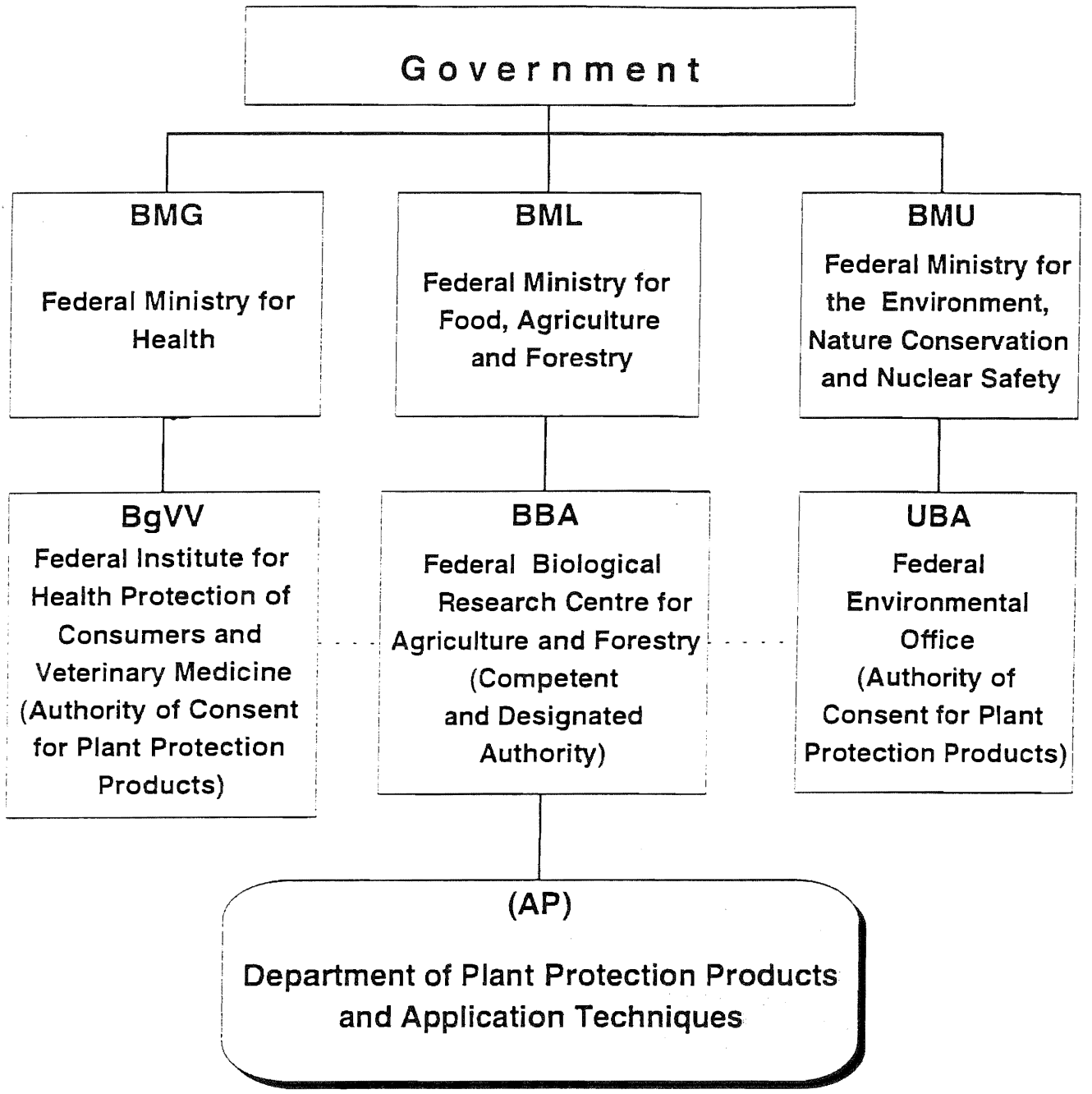
1.) Ankündigung der Abweisung
Der Antragsteller wird angehört. Die betroffene Firma erhält für die Abgabe der Stellungnahme eine Frist von 4-6 Wochen. Die SVA-Vorlage erfolgt hiervon unabhängig. Zum Termin D5 muß entschieden werden, ob der Antrag abgelehnt wird oder die weitere Antragsbearbeitung als Hemmung weiterläuft.

2.) Hemmung
Dem Antragsteller wird ohne Fristsetzung mitgeteilt, daß Unterlagen fehlen und der Antrag gehemmt wird. Es versteht sich, daß die Hemmungszeiten nicht als Bearbeitungszeiten gerechnet werden können. Die Bearbeitungsfrist läuft erst weiter, wenn die letzte Nachlieferung

bearbeitet und die letzte Hemmung aufgehoben ist. Der Antrag wird dann dem Sachverständigenausschuß (SVA) zur Anhörung vorgestellt.

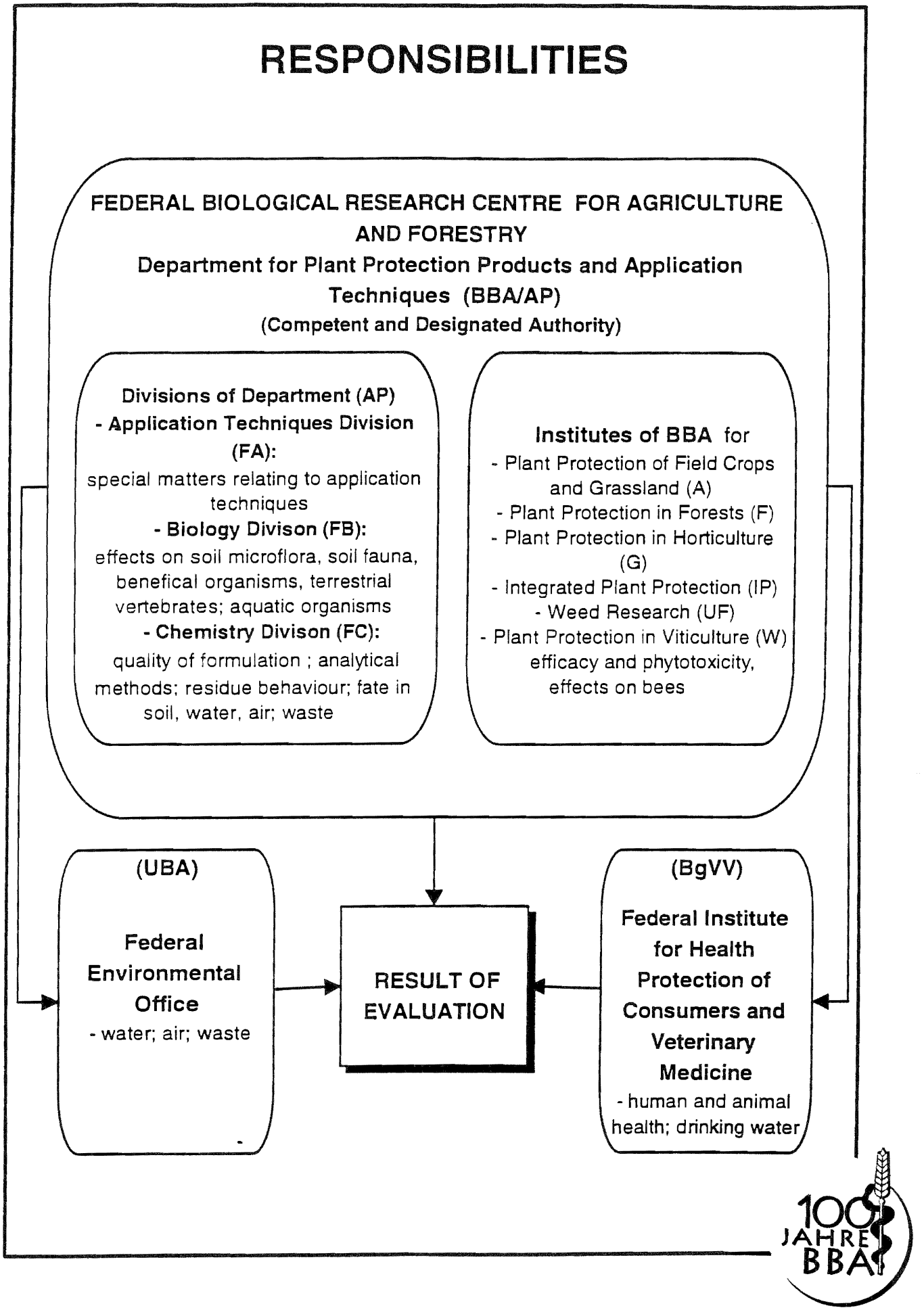
Ein Mittel soll für den ersten SVA-Termin nach Ende der Hauptprüfung (32 Wochen) vorgesehen werden. Die SVA Anhörung ist das Referenzdatum für D5 (8 Wochen später). Insgesamt ist die Planung auf eine maximale Bearbeitungszeit von 52 Wochen ab Beginn der Hauptprüfung abgestellt.

EU-EVALUATION OF ACTIVE SUBSTANCES AND AUTHORISATION OF PLANT PROTECTION PRODUCTS IN GERMANY (Responsibilities)

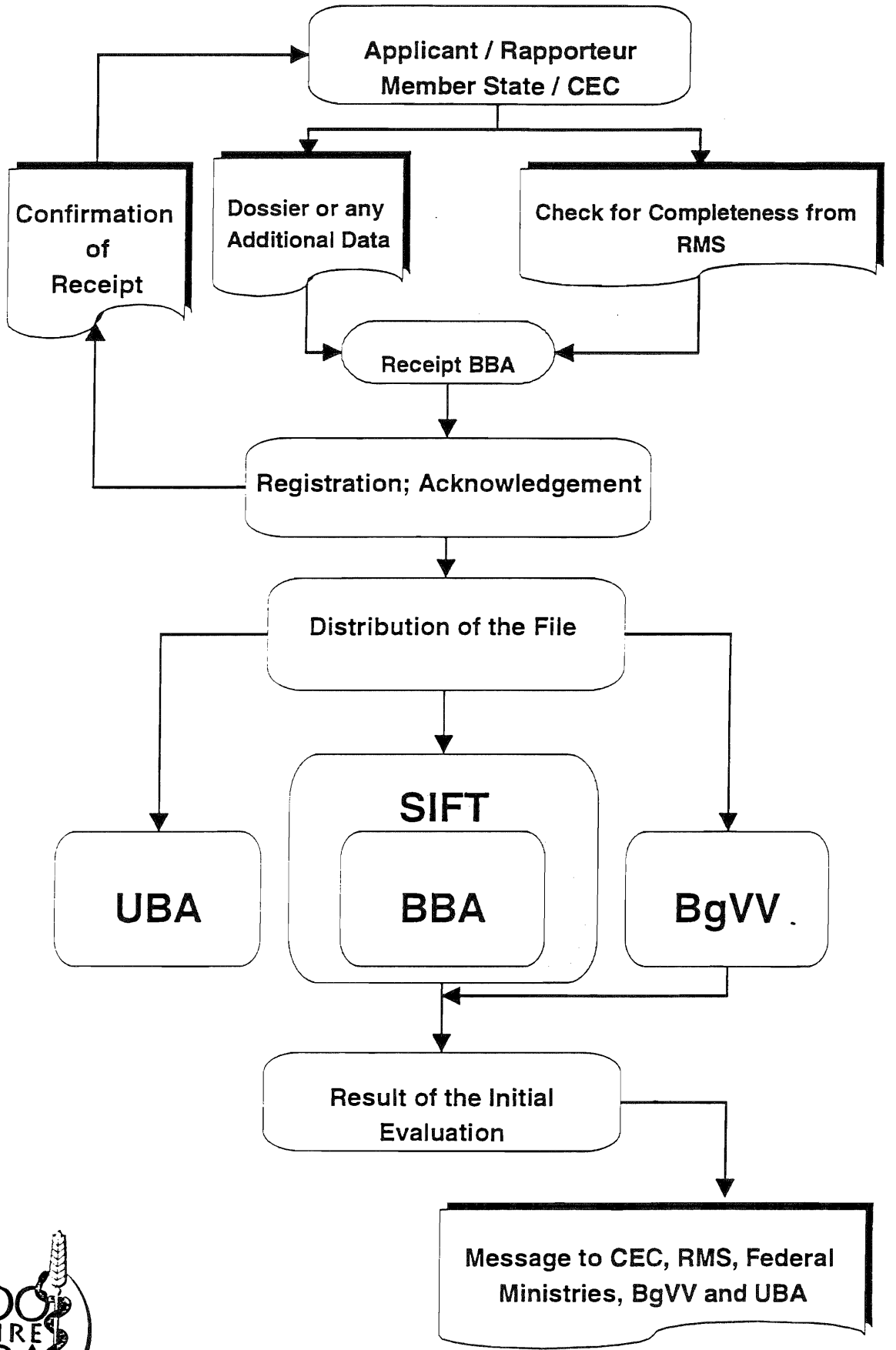


100 JAHRE BBA

Figure 2


RESPONSIBILITIES
FEDERAL BIOLOGICAL RESEARCH CENTRE FOR AGRICULTURE AND FORESTRY
Department for Plant Protection Products and Application Techniques (BBA/AP)
(Competent and Designated Authority)
Divisions of Department (AP)
- Application Techniques Division (FA):
special matters relating to application techniques
- Biology Divison (FB):
effects on soil microflora, soil fauna, benefical organisms, terrestrial vertebrates; aquatic organisms
- Chemistry Divison (FC):
quality of formulation ; analytical methods; residue behaviour; fate in soil, water, air; waste
Institutes of BBA for
- Plant Protection of Field Crops and Grassland (A)
- Plant Protection in Forests (F)
- Plant Protection in Horticulture (G)
- Integrated Plant Protection (IP)
- Weed Research (UF)
- Plant Protection in Viticulture (W)
efficacy and phytotoxicity, effects on bees
(UBA)
Federal Environmental Office
- water; air; waste
RESULT OF EVALUATION
(BgVV)
Federal Institute for Health Protection of Consumers and Veterinary Medicine
- human and animal health; drinking water
100 JAHRE BBA

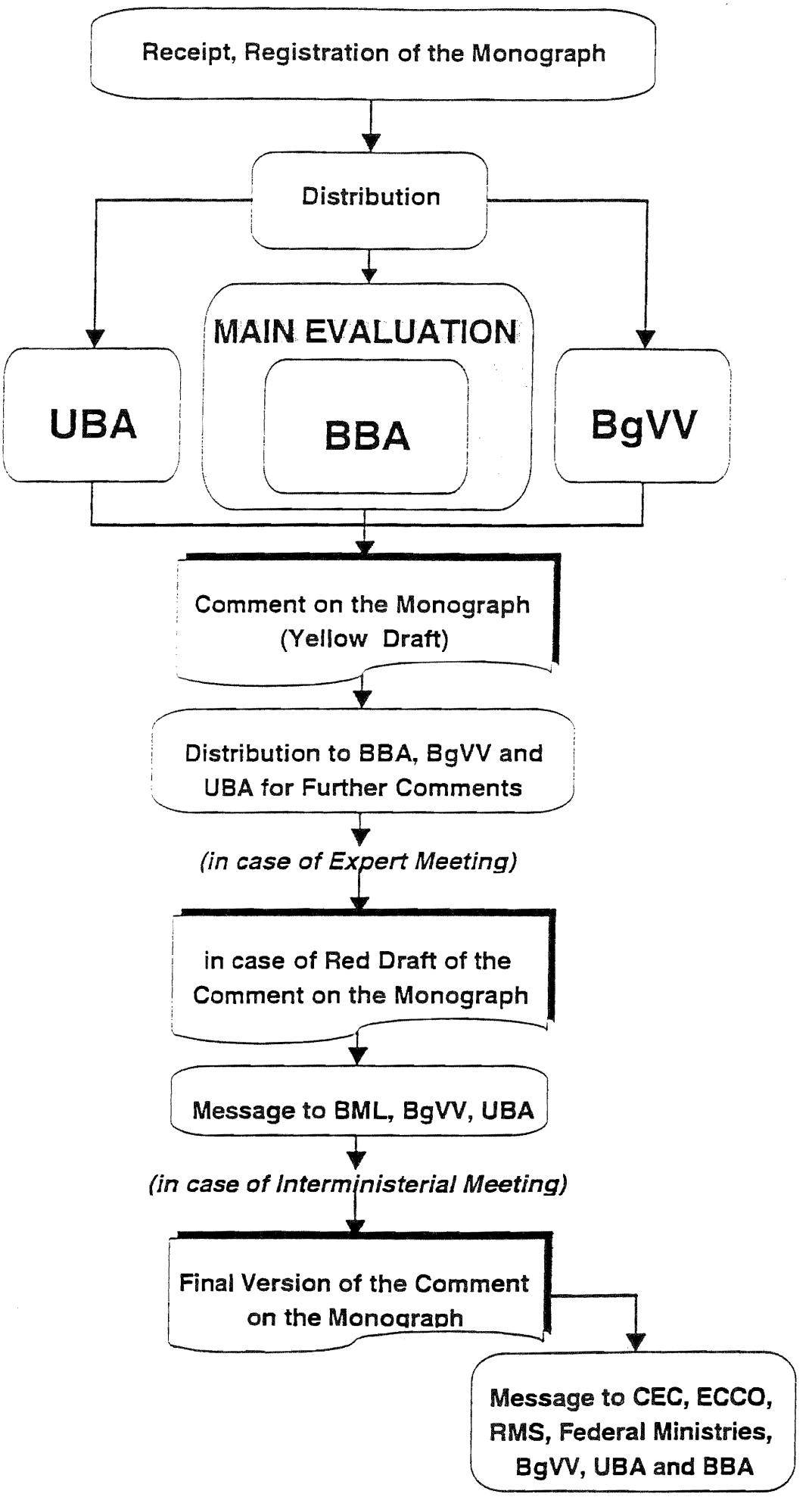
Active Substances; Germany is not Rapporteur Member State
Initial Evaluation



100 JAHRE BBA

Figure 4

Active Substances; Germany is not Rapporteur Member State - Main Evaluation



ACTIVE SUBSTANCES; GERMANY AS RAPPORTEUR MEMBER STATE; CHECK FOR COMPLETENESS

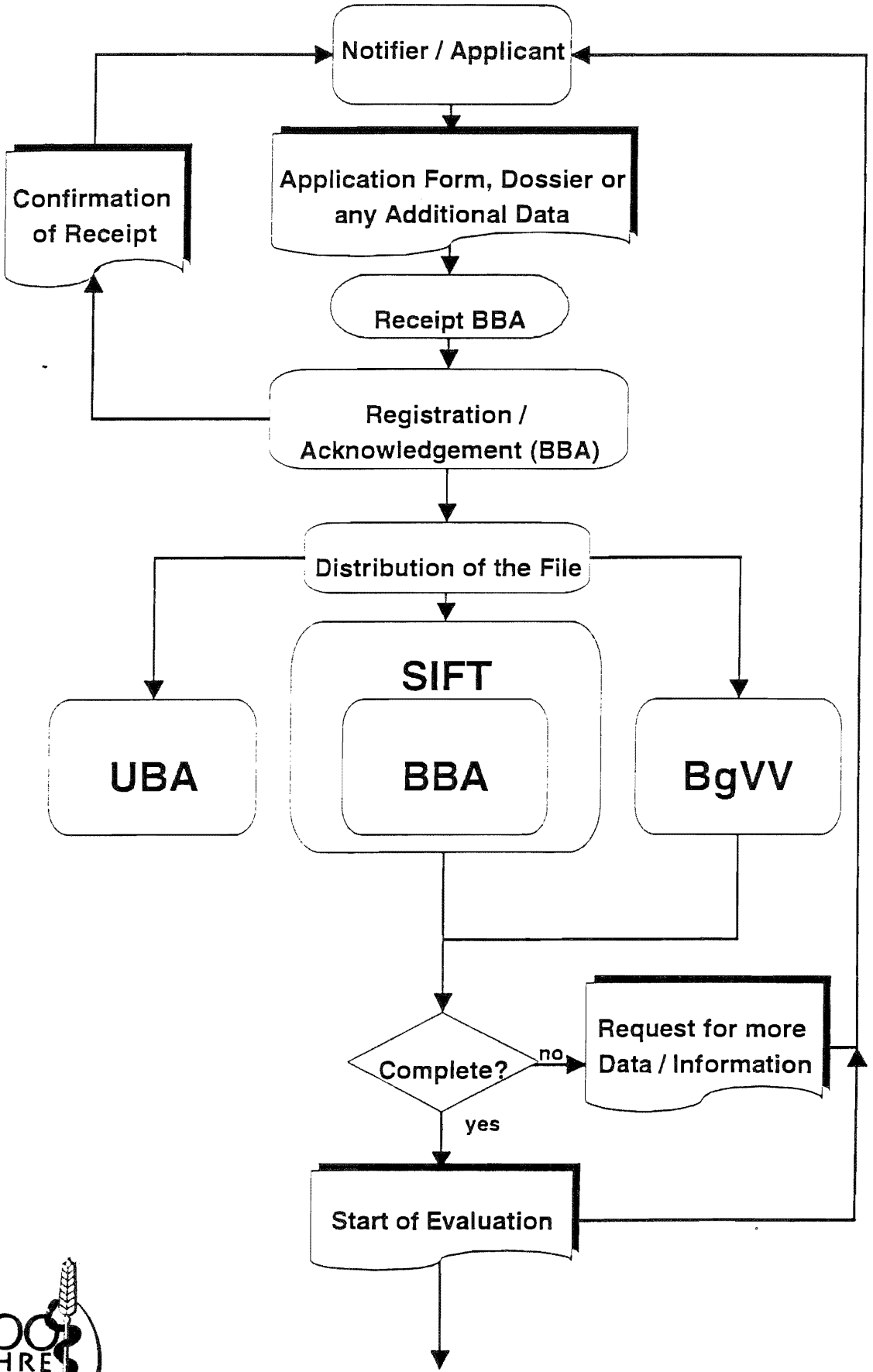
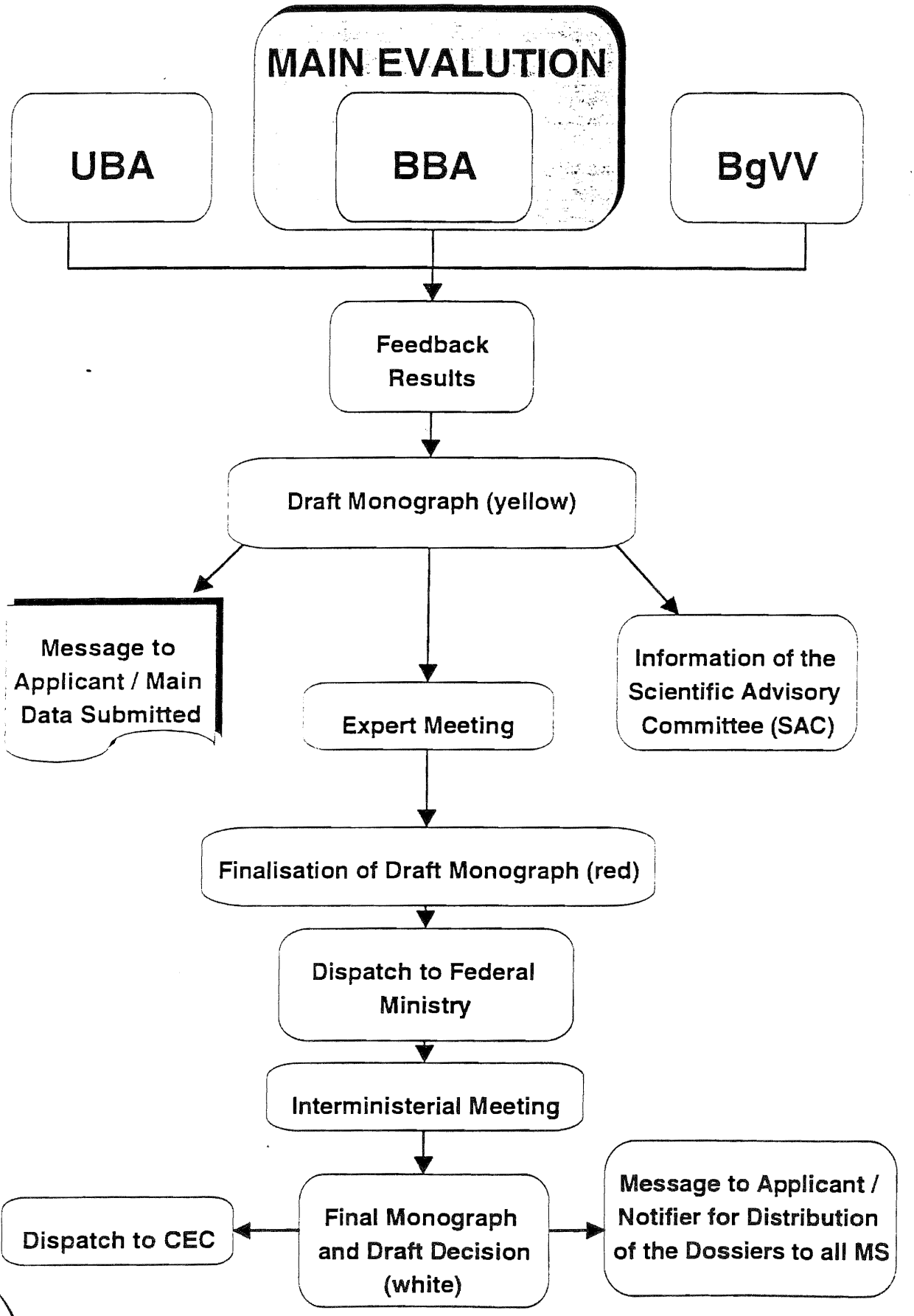
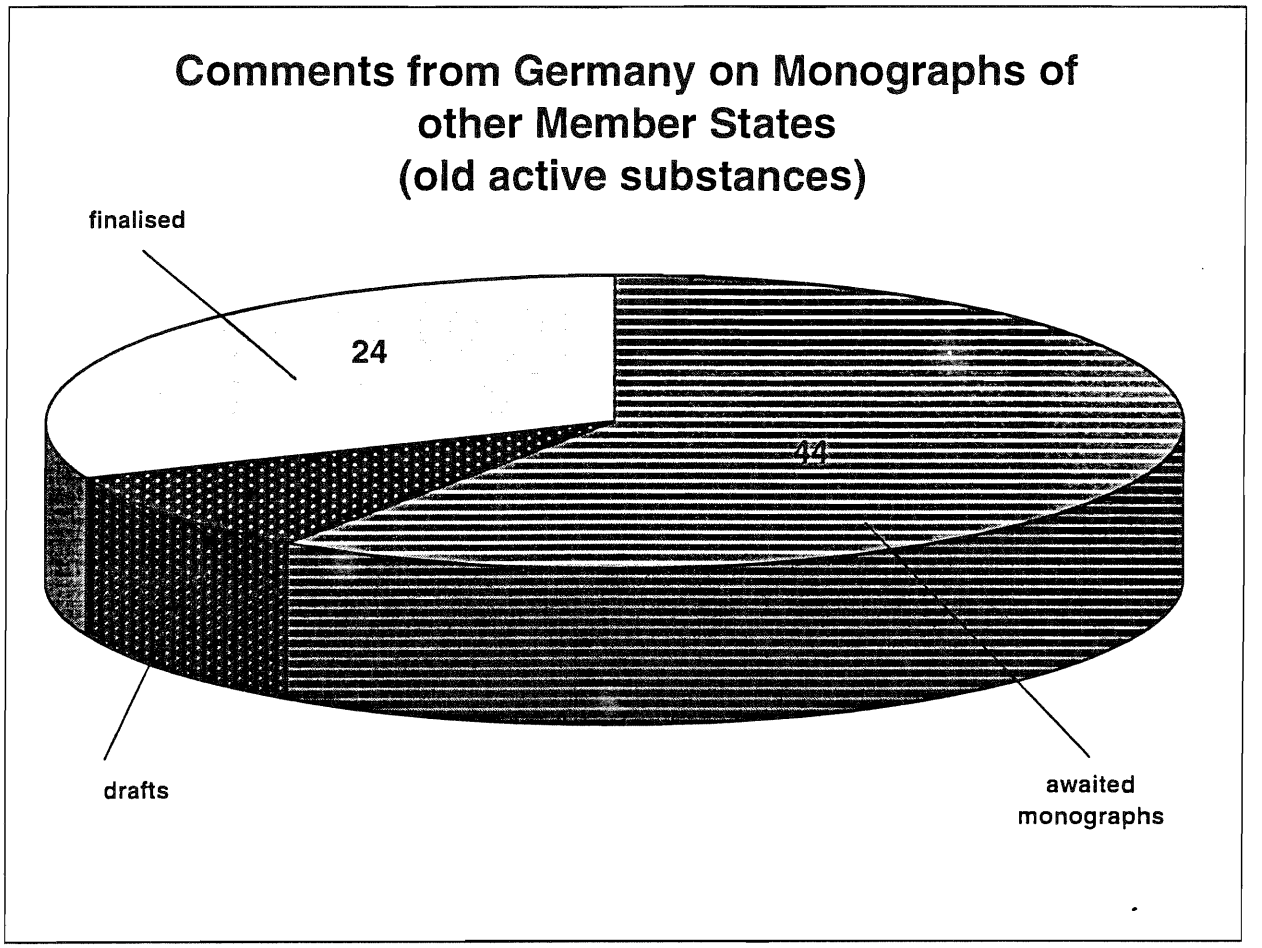


Figure 6

ACTIVE SUBSTANCES; GERMANY AS RAPPORTEUR MEMBER STATE
MAIN EVALUATION





100 JAHRE BBA

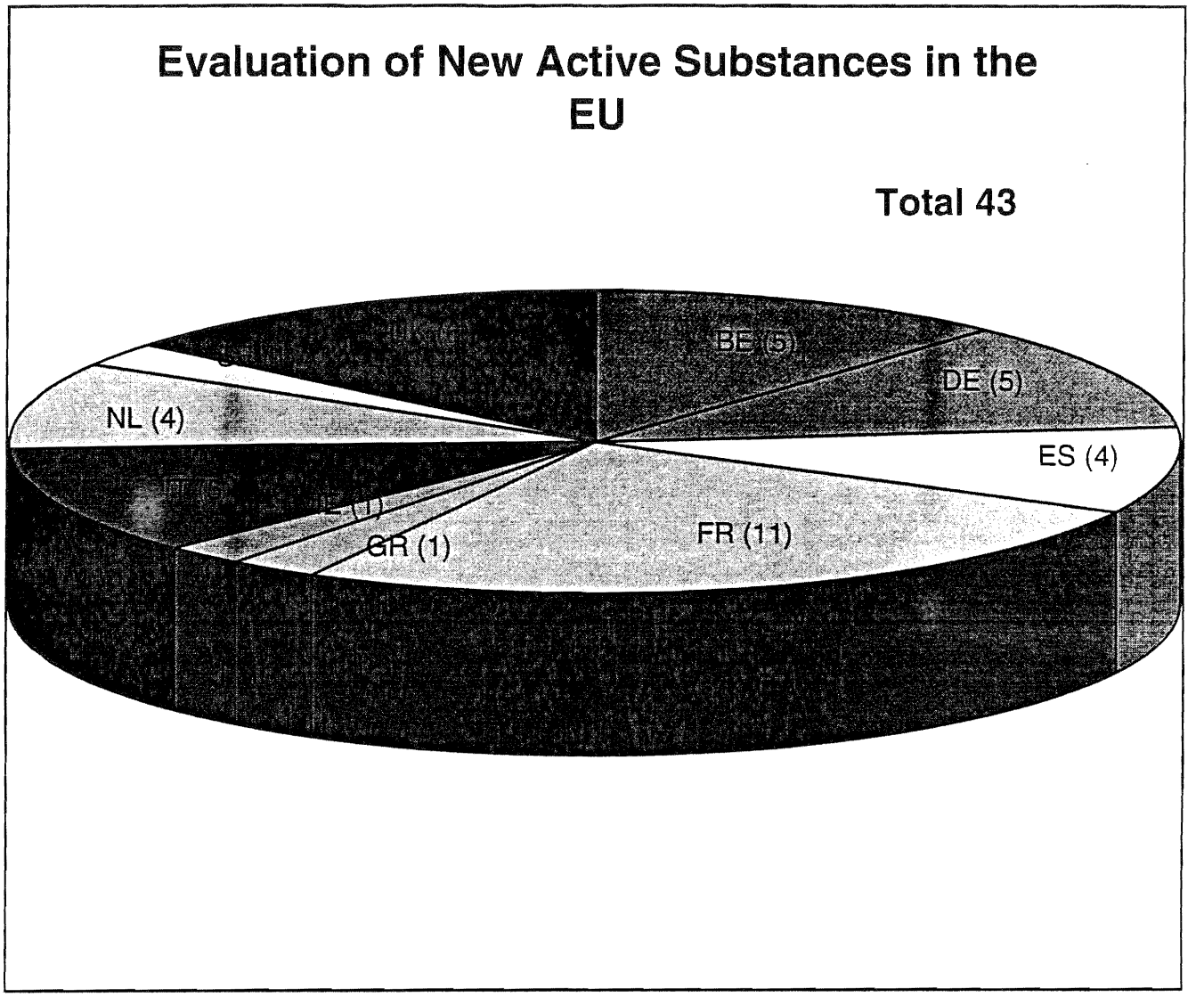

Evaluation of New Active Substances in the EU
Total 43
BE (5)
DE (5)
ES (4)
FR (11)
GR (1)
NL (4)

Figure 9

AUTHORIZATION OF PLANT PROTECTION PRODUCTS IN GERMANY
PROPOSAL FOR A NEW PROCEDURE - CHECK FOR COMPLETENESS

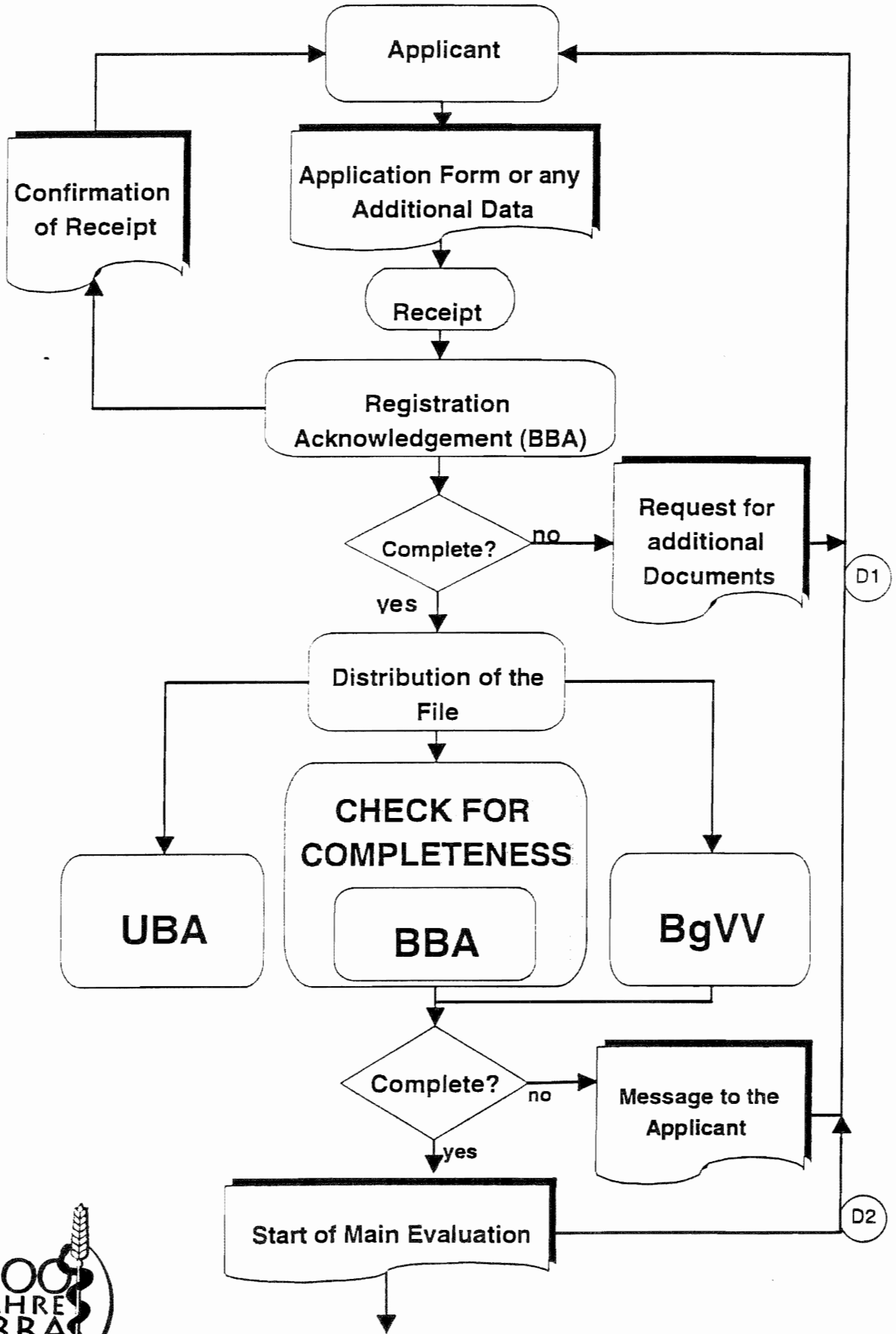
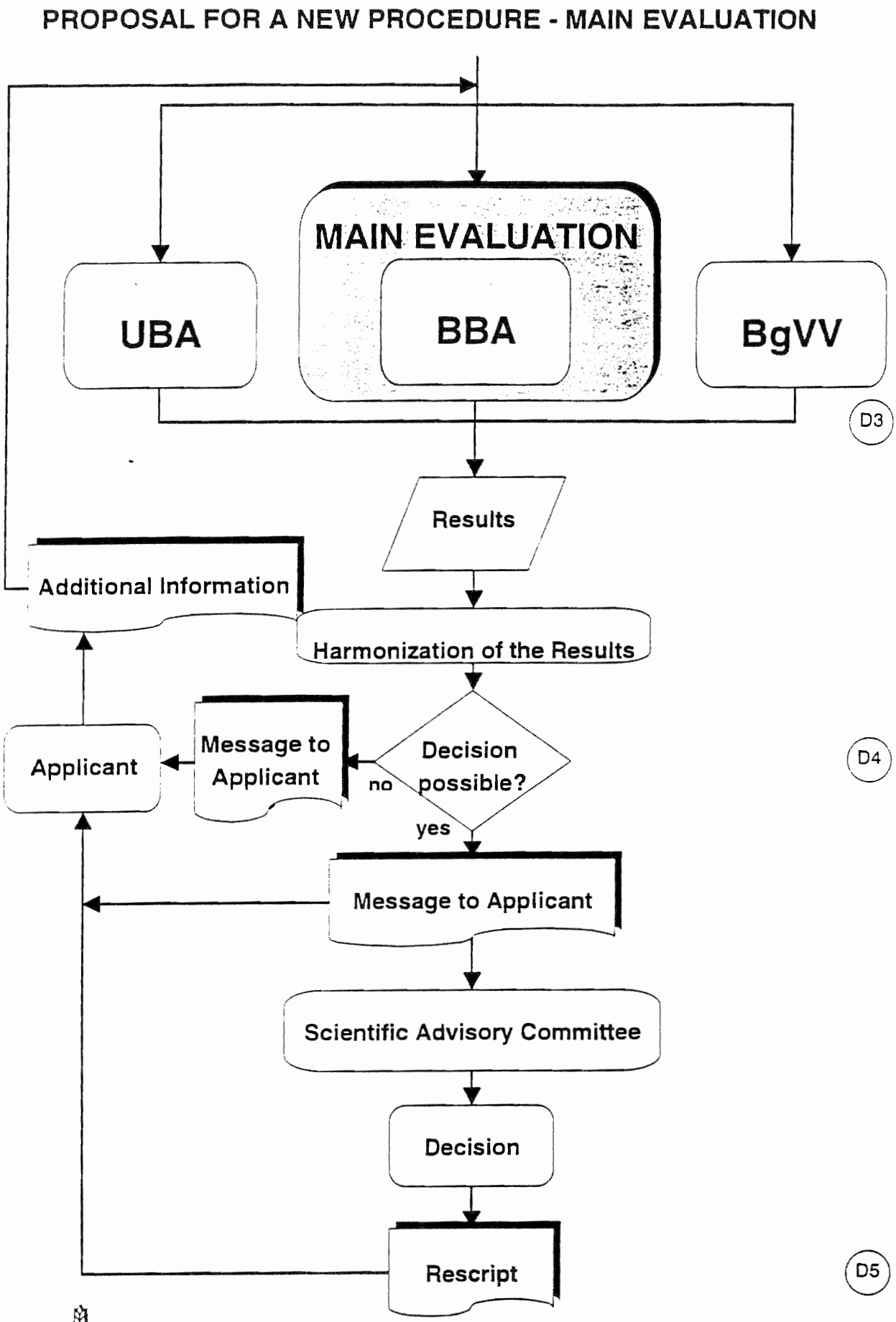


Figure 10


PROPOSAL FOR A NEW PROCEDURE - MAIN EVALUATION
MAIN EVALUATION
UBA
BBA
BgVV
D3
Results
Additional Information
Harmonization of the Results
Applicant
Message to Applicant
Decision possible?
no
yes
D4
Message to Applicant
Scientific Advisory Committee
Decision
Rescript
D5

Procedure and Present Situation of the EU-evaluation of Active Substances in Germany, from the Point of View of the Designated National Authority

A. WILKENING

Biologische Bundesanstalt für Land- und Forstwirtschaft
Bundesrepublik Deutschland

Dear Mr. President, dear Ladies and Gentlemen,
In the following 20 minutes I would like to inform you on the present situation of the EU-evaluation of active substances in Germany and the procedures developed for this purpose, from the point of view of the Designated National Authority.

Introduction:

In Germany the following ministries and authorities are concerned with the evaluation and authorization of plant protection products and the EU-evaluation of active substances.

Figure 1: Responsibilities 1

The Federal Government is in charge of making official comments, for example for the European Commission. It is supported by the following ministries who are doing the preliminary work in the EU-evaluation of active substances: the Federal Ministry of Health, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Ministry for Food, Agriculture and Forestry. These Ministries can recourse to their respective specialized authorities which are namely the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV), the Federal Environmental Office (UBA), and the Federal Biological Research Centre for Agriculture and Forestry (BBA).

The Federal Research Centre for Agriculture and Forestry is the authority designated by the Federal Government, according to Article 3 of EEC-Regulation No 3600/92, to co-ordinate the EU-evaluation of active substances. In conformity with the competencies in the national procedure, the Federal Environmental Office and the BgVV are involved in the EU-evaluation of active substances. Contrary to the national procedure however, they are not functioning as authorities of consent.

Figure 2: Responsibilities 2

Within the BBA the Department for Plant Protection Products and Application Techniques (AP) with its Divisions for Biology and Chemistry is partaking in the EU-evaluation of active substances. The Application Division is only listed here to complete the picture but does not deal directly with the evaluation of active substances. The Biology Division is investigating the effects on non-target organisms (earthworms, soil microflora, beneficial arthropods except

honey bees, vertebrates and aquatic organisms), the compatibility of crops with insecticides and acaricides in hops, their efficacy, and the efficacy (of insects, acaricides and rodenticides) in storage protection. The Chemistry Division is responsible for the evaluation and assessment of physical and chemical properties of active substances and plant protection products, for residue behaviour, fate in soil, water and air, including the respective analytical methods, and for waste disposal.

In addition to the departmental divisions, the Institutes for Plant Protection of Field Crops and Grassland, Plant Protection in Forests, Plant Protection in Horticulture, Integrated Plant Protection, Weed Research and Plant Protection in Viticulture are partaking in the evaluation procedure. They are in charge of the three test areas: efficacy, crop compatibility and effects on honey bees.

For further details, please refer to BBA report no. 37 which has been surrendered to you before the meeting.

The Federal Environmental Office takes a view on the test areas: water, air and waste, whereas the Institute for Health Protection of Consumers and Veterinary Medicine comments on human and animal health and drinking water.

Generally, a distinction has to be made between four different cases in the EU-evaluation of active substances:

- existing active substance; Germany acts as rapporteur Member State
- existing active substance; Germany does not act as rapporteur Member State
- new active substance; Germany acts as rapporteur Member State
- new active substance; Germany does not act as rapporteur Member State

All procedures are similar, whereas a greater difference exists of course between

- Germany acting as rapporteur Member State and
- Germany not acting as rapporteur Member State.

I would like to introduce these two procedures to you, however, I will not defer to minor differences in procedure between existing and new active substances. Firstly, let's suppose "Germany is not acting as rapporteur Member State":

Figure 3: Active Substances; Germany is not RMS - Initial Evaluation

After the rapporteur Member State has concluded the Check for Completeness, the initial examination starts in Germany. To begin with, a brief examination on receipt is carried through, that means, the documents (dossiers, Check for Completeness, and if needed,

additional supplements and comments) submitted by the notifier, the European Commission or the rapporteur Member State, are examined as to their completeness (language: covering letter in German, all other documents are accepted in English, number of copies) and subsequently registered. Only the applicant receives a confirmation of receipt, as outlined in the chart. At the same time he is informed about the allocated BBA registration number. The whole matter takes 2 weeks at the most with the documents being distributed within the following week, and a time limit of 5 weeks is fixed for the actual initial evaluation. The UBA has no share in the initial evaluation. The degree of intensity at which the initial evaluation is conducted varies, depending on the respective staff members and the active substance under evaluation. At least data gaps discovered during the Check for Completeness are investigated. Partly, we even point out data gaps which will normally be identified only during the main evaluation. Indications are made by way of comments in order to facilitate working processes for the rapporteur Member State and the applicant, and also for their information. In the case of new active substances for which an application for authorization has already been submitted in Germany, previous evaluations and comments already made on a national level can be fallen back upon. The result of the initial evaluation is simultaneously send to the CEC, the RMS, the Ministries, the BgVV and the UBA. A total of 9 weeks is required for this procedure. The decision on the completeness of the dossier on EU-level is due next, followed by the preparation of the monograph by the RMS.

Figure 4: Active Substances; Germany is not RMS - Main Evaluation

The RMS presents the finalized monograph to the CEC. The CEC initiates the distribution to all Member States through the ECCO-Team (European Commission Co-ordination), marking the begin of the main evaluation in Germany. The received monographs are registered, duplicated and distributed as usual. Five weeks are available for the evaluation of the monograph and the subsequent announcement of the result. The time requirement on the whole amounts usually to at least 8 weeks. The BBA prepares the draft of a report together with a decision proposal, the first, or as we call it, the yellow draft. This draft will be again distributed to the BgVV, the UBA and within the BBA, being discussed once more if the need arises. Experience shows however, that the author meetings illustrated on chart 4 don't usually have to be held, as often conformity can be reached quickly on agreed proposals between authorities. The second or red draft is drawn up consequently. In case of differing evaluations between the BBA on the one hand and the UBA or BgVV on the other hand, the red draft has to be concerted on the departmental level. Yet, up to now this step was only necessary in exceptional cases. The final version of German comments on monographs of the rapporteur Member States is send to the CEC, ECCO, the RMS, the BML, the BgVV and the UBA, and is also distributed within the BBA. So much to the description of Germany's partaking in the EU-evaluation of active substances with other Member States as rapporteur.

If Germany itself has taken on the obligation as rapporteur, the procedure is generally handled in the same way. Of course, the amount of evaluation work is incomparably higher.

Figure 5: Active Substances; Germany as rapporteur Member State - Check for Completeness

As first step, we as rapporteur Member State have to perform the Check for Completeness for the other Member States and the European Commission. Therefore, the application is subjected to a brief evaluation on receipt (examination of the correctness of language and number of copies, i.e. 4 complete and 2 summary dossiers) which takes one week. A registration number is allocated of which the applicant or notifier is informed in the confirmation of receipt. If it is already obvious at this stage that documents are missing, they are subsequently claimed in this first letter. If the application is complete it is distributed to the UBA, BgVV and within the BBA. For the actual Check for Completeness and the compilation of results a maximum of 10 weeks is envisaged. It has proved to be quite difficult to find out the appropriate depth of evaluation. Just how much should one go into detail when looking at a dossier in the course of the initial evaluation ? The upshot is that one should not go as deep as to the stage of original studies. Otherwise the danger of a possible early evaluation of details arises. Merely the completeness of the application in its existing form and thus its readiness for evaluation should be determined. On the other hand transitional authorizations can be granted for new active substances, according to a decision of the Standing Committee for Plant Health. This prevents evaluations from becoming too superficial. Very often the initial evaluation is conducted by scientists who detect even insignificant data gaps relatively fast, due to their experience in the national procedure and their work on other active substances. Germany established the principle that all shortcomings found during the initial evaluation have to be reported. If the application is classified as incomplete, respective subsequent claims are made to the applicant who gets 4 weeks time for his supplementary comment. Also, for dossiers we regard as complete, indications as to possible shortcomings of the dossiers are given, to inform the applicant as early as possible. It should however be noted, that there is a very fine line between initial and main evaluation. The time required for the Check for Completeness amounts to 3 months for complete dossiers. For each of the 5 dossiers already evaluated in Germany it took 3, 5, two times 6 months and 8.5 months respectively counted from receiving the dossiers up to mailing the reports to the CEC.

Independently of the follow-up procedure on EU-level for the determination of completeness of the dossier, we start immediately with the main evaluation if Germany regards the application as complete. Of course, data gaps may still be identified during the main evaluation.

Figure 6: Active Substances; Germany as RMS; Main Evaluation

Once more the main evaluation takes place concurrently in the three mentioned authorities. Six months are required for preparing comments on a monograph. At the fixed deadline an initial version of the monograph is extracted from our EDP-system. At this point a complete version of the monograph is available for the first time. A respective editorial committee is

established for editorial review and especially for the wording of a decision proposal. These editorial committees consist of three people (one representative each of the Biology Division (FB), the Chemistry Division (FC), and the Co-ordinating Group (KG)). At the latest 5 weeks after the conclusion of the main evaluation the yellow draft is finished. The applicant and the German Expert Committee are informed about the yellow draft. The applicant gets an opportunity to comment, followed by a meeting of authors where the complete monograph including additional claims and the decision proposal are discussed. The modifications agreed on by the meeting of authors are incorporated in the red draft which should be completed 10 weeks after the yellow draft. The red drafts are building the basis for co-ordination on the departmental level. An agreement can be reached very quickly in non-contentious cases. After an agreement is reached on the departmental level the white version, representing the German comment, is dispatched to the CEC. The applicant is requested to send the updated dossiers to all Member States. The monographs finished in Germany up to now required 11 to 13 months for the main evaluation, and if counted from the time of determination of completeness by the Standing Committee it took only 7.5 months for each main evaluation.

Consequently, the procedure on EU-level follows with discussions in ECCO-meetings, in the Working Group Evaluation and Legislation and in the Scientific Committee.

Figure 7: Comments from Germany on monographs of other MS

Germany is involved in the first step of the programme for the evaluation of active substances as rapporteur Member State with 10 active substances. Monographs have been prepared for the active substances azinphos-methyl, benomyl, bentazone, carbendazim, beta-cyfluthrin, cyfluthrin, fluroxypyr and thiopanate-methyl, and handed over to the European Commission in order to initiate the decision procedure on the inclusion of these active substances in Annex I of Directive 91/414/EEC. The monographs on glyphosate and isoproturon are available as a draft. Furthermore, until now we prepared comments on 24 monographs of other Member States and forwarded them to the European Commission. Seven comments are under preparation at the moment - 44 monographs are awaited.

Figure 8: Evaluation of new active substances in the EU

As of January 13, 1998, forty-three new active substances are under examination in the various Member States of the European Union. Five dossiers have been submitted to Germany. The evaluation of Azoxystrobin and Spiroxamine has been concluded in Germany. For Pymetrozine and Imazosulfuron initial drafts of the monographs are available. Coniothyrium minitans is still in the process of initial evaluation which has been already completed in Germany though.

Figure 9: Authorization of Plant Protection Products in Germany - Check for Completeness

A decision on the authorization of new plant protection products containing active substances included in Annex I of Directive 91/414/EEC, shall as a rule be made at the latest one year after the complete application has been submitted, according to Annex VI of the Directive. The new Plant Protection Act also provides for a respective time limit for the preparation of all national applications. That is the reason why the present draft procedure has been developed. New in comparison to the previous national authorization procedure is the introduction of a Check for Completeness in line with the EU-evaluation of active substances, and the introduction of progress control. The following procedure will be familiar to you now.

After receiving the documents, the evaluation on receipt is executed, followed by a confirmation of receipt. The application is registered and a registration number is allocated. The first progress control D1 takes place after three weeks. If no significant shortcomings are found, the initial evaluation is started, and the deadline D2 is fixed 9 weeks after D1. At the initial evaluation a rough inspection as to readiness for evaluation including questions on the use of documents is conducted, in line with the EU-evaluation of active substances.

Figure 10: Authorization of Plant Protection Products in Germany - main evaluation

If the result of the initial evaluation is negative, the main evaluation starts only after additional claims have been met. If the result of the initial evaluation is positive, the main evaluation is started, also the next deadlines D3 and D4 are set. For the technical examination, the main evaluation, 32 weeks are scheduled. Four weeks before the deadline the time limit D3 is fixed. Twenty-eight weeks after the beginning of the main evaluation a list of pending applications is made up which shall support the parties involved in the evaluation process in regard to assignment of priorities. The list shall be generated automatically once a week by EDP. At the deadline D4, 36 weeks after the beginning of the main evaluation, the applicant receives a message on the result of the main evaluation. The message is approximately equivalent to the presently applied second intermediate message. If the main evaluation finalises with a negative assessment, two different incidents have to be distinguished:

1.) Announcement of the Dismissal
The applicant is heard. The respective company gets a time limit of 4-6 weeks for the submission of its comment. The submission of the Expert Committee is independent of the company's. When meeting deadline D5, a decision has to be taken on whether the application will be dismissed or whether further processing of the application is suspended.

2.) Suspension
The applicant is informed about missing documents and the suspension of the application without setting a deadline. The time of suspension can, of course, not be regarded as processing time. The processing time starts again after the last supplement has been handled and after the last suspension has been reversed. The application is then presented to the Expert Committee (SVA) for a hearing.

One plant protection product is envisaged for evaluation on the first Expert Committee meeting after the end of the main evaluation (32 weeks). The hearing of the Expert Committee is at the same time the reference date for D5 (8 weeks later). On the whole the schedule is aiming at a maximum processing time of 52 weeks from the beginning of the main evaluation.

Industry Views on Implementation of Directive 91/414/EEC and Suggestions for Process Improvements

B. G. JULIN

European Crop Protection Association (ECPA)
Belgium

Introductory Remarks

It is a pleasure to again visit the Biologische Bundesanstalt für Land- und Forstwirtschaft (BBA) and to participate in the second BBA Notifier Conference on behalf of the European Crop Protection Association (ECPA).

I want to take this opportunity to congratulate the BBA Organization which in less than two weeks' time (January 28th) celebrates 100 years of existence. This is an outstanding accomplishment and a tribute to the vision of those who founded the organization and the excellence of its scientific contributions.

(Transparency No 2)

The start of 1998 marks more than six years, since Council Directive 91/414/EEC on the Placing of Plant Protection Products on the Market was adopted. It also marks more than four years since the implementation of the Directive. The Crop Protection Industry supports the objectives of the Directive and has a vital interest in sound scientific and efficient implementation of this Directive which seeks to harmonize the authorization for crop protection products across the European Union. Because of its importance a Working Group of ECPA has carried out a detailed evaluation of the EU Registration process and timelines for approvals, with special attention to new active substances. and products based on these substances.

(Transparency No 3)

Before going into the main part of my talk, I want to acknowledge that an impressive amount of work has been done by the Commission and the Member States to make Directive 91/414 into a workable registration process for PPPs. This huge amount of work is obvious to anyone who has read the hundreds of pages of Regulations and secondary Directives adopted under 91/414, not to forget the thousands of pages of guidelines, study documents and working documents which have been prepared.

An EU regulatory system for PPPs is now in place, it is functioning, and is beginning to produce results. The first active substance - Imazalil -, an established active substance , was recently included in Annex I, the so-called positive list. During 1998, we expect that several

more, both new and established active substances, will be added to the positive list. In addition, a considerable number of provisional authorizations for PPPs based on new active substances have been granted by the Member States.

Nevertheless, in spite of this progress, ECPA strongly believes that the EU regulatory process is too slow, duplicative, resource intensive, and costly for Member States, Commission and Industry alike. We believe that there is considerable scope for optimizing the EU regulatory process in the very near term without amending Directive 91/414.

Implementation problems and suggested solutions.

(Transparency No 4)

With these objectives in mind, i.e. to develop improvements in the registration process, which can be put in place in the near term without the need to amend Directive 91/414, an ECPA Working Group has carried out a detailed analysis of the process and timelines for EU Registrations. We focused our attention mainly on the process for approving new active substances and their products, keeping in mind that whatever improvements were identified, would likely also be beneficial for established substances. I want to take this opportunity to thank my colleagues, all of whom are present, for their many contributions.

Transparency No 5: Depicts the EU Registration Process and timelines starting with dossier submittal leading to Annex I inclusion as well as provisional authorizations by MSs. (To be explained in detail).

Transparency No 6: During our review of the Registration Process we identified problems with each step of the process; i.e. dossier completeness check, evaluation by the RMS and preparation of the monograph, the ECCO Peer Review Process and the Evaluation Working Group, and the Provisional Approval Procedure.

The next several transparencies contain our main proposals for improving the efficiency of the EU Process. The ECPA proposals have two objectives; gaining time and improving industry participation and consultation in the Registration Process. (Each transparency will be explained in detail).

Transparency No 7: Time required for Dossier Completeness Check.

Transparency No 8: Dossier Completeness Check; Background information.

Transparency No 9: ECPA Proposal for improving Completeness Check Procedure.

Transparency No 10: RMS Evaluation of Dossier and Monograph Preparation.

Transparency No 11: ECCO Expert Peer Review / Evaluation Working Group.

Transparency No 12: Provisional Authorizations; Background Informaton.

Transparency No 13: Provisional Authorizations; Economic Arguments.

Transparency No 14: Provisional Authorizations; ECPA Proposal.

Concluding Remarks

In conclusion, I want to make several observations :

(Transparency No 15)

- The improvements in the EU Registration Process already identified by ECPA can all be seen as normal, evolutionary changes in light of experiences with the present system. Indeed, several improvements have already been put in place by the Commission and Member States based on need to adapt the process.

- In our view, these proposed improvements can readily be implemented by the Commission in the near term without the need to amend the Directive. However, some of the changes, such as, eliminating the double completeness check, first by RMS and then by all MSs, would necessitate amending the Directive, and should, in our opinion, be part of the Omnibus Amendments to Directive 91/414 now under discussion.

- We believe the suggested process improvements would benefit all parties involved by :

(Transparency No 16)

  * Reducing unnecessary duplication.
  * Make better use of scarce scientific and administrative resources.
  * Improving quality of monograph via consultation.
  * Earlier resolution of perceived defects in the Dossier could avoid unnecessary follow-up work in the ECCO process.
  * Bringing new products to the market faster is an obvious benefit to EU agriculture, as these are a tool to improve the competitiveness of EU agriculture on the world market as well as providing consumers with products developed according to the latest quality standards.

(Transparency No 17)

We do not claim to have an exclusive on ideas for improving the Registration Process. We would welcome ideas from all parties.

- And lastly, we believe that our analysis of the EU Registration process and proposed improvements are an industry contribution to the objectives of the Single Market Review begun in 1996 and further elaborated in the Single Market Action Plan of June 1997. Under this action program, initiated by the Commission, European leaders have made the political commitment to make Single Market legislation, such as Directive 91/414, more efficient.

- As one of the main stakeholders in Directive 91/414, the Crop Protection Industry has decided to take the initiative to look for ways to optimize how the Directive works. To that end, we want to consult with the Commission and Member States to see how near-term improvements in the day-to-day functioning of the registration process can be achieved. ECPA invites regulators from the Commission and Member States to join this initiative for the benefit of all involved.

(1)

INDUSTRY VIEWS ON THE IMPLEMENTATION OF DIRECTIVE 91/414/EEC AND SUGGESTIONS FOR PROCESS IMPROVEMENTS

Bruce G. JULIN
Chairman
ECPA Registration Expert Group

(2)

BACKGROUND

- MORE THAN FOUR YEARS SINCE DIRECTIVE 91/414 WAS IMPLEMENTED.
- ECPA SUPPORTS THE SOUND SCIENTIFIC AND EFFICIENT IMPLEMENTATION OF THE DIRECTIVE.
- AN ECPA WORKING GROUP HAS CARRIED OUT A DETAILED EVALUATION OF EU REGISTRATION PROCESS AND APPROVALS TIMELINES.

(3)

BACKGROUND

- AN EXTENSIVE AMOUNT OF WORK DONE TO MAKE 91/414 INTO A WORKABLE REGISTRATION PROCESS FOR PPPs.
- THE PROCESS IS FUNCTIONING - BEGINNING TO PRODUCE RESULTS
- IN SPITE OF PROGRESS, ECPA BELIEVES THE EU REGISTRATION PROCESS IS TOO SLOW, DUPLICATIVE, RESOURCE INTENSIVE, AND COSTLY FOR MEMBER STATES, COMMISSION AND INDUSTRY.
- THE EU REGULATORY PROCESS CAN BE OPTIMIZED IN THE NEAR TERM WITHOUT AMENDING DIRECTIVE 91/414.

(4)

ECPA WORKING GROUP PROGRAM

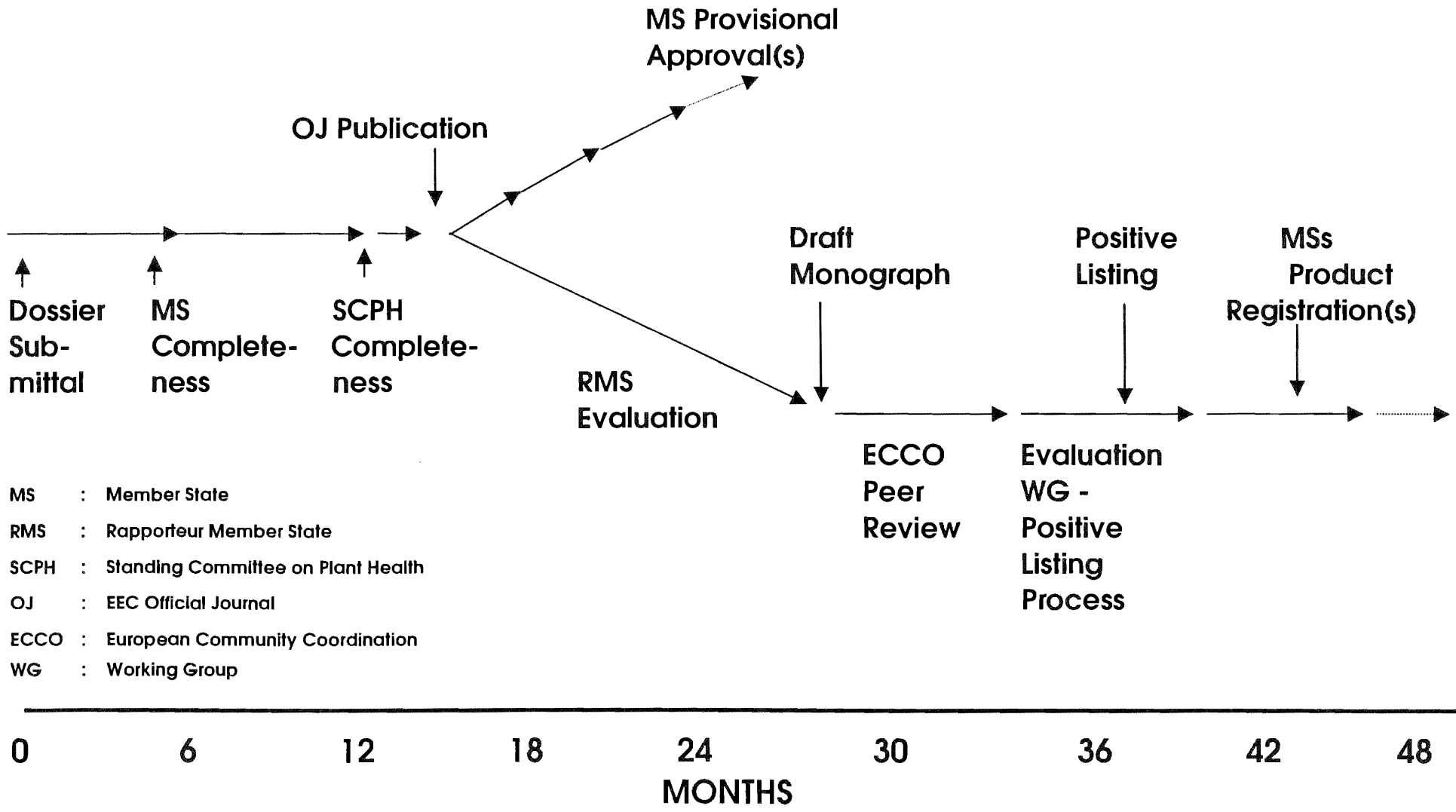
- ANALYSIS OF EU REGISTRATION PROCESS.

- DEVELOP NON-LEGISLATIVE WAYS TO IMPROVE EFFICIENCY OF PROCESS.

- FOCUS ON PROCESS FOR APPROVING NEW ACTIVE SUBSTANCES.

- H. MATTAAR, RHONE-POULENC
  F. MEIER-MANZ, NOVARTIS
  R. VAN PEER, AMERICAN CYANAMID
  R. ROWE, DOW ELANCO
  B. JULIN, DUPONT

PROCESS / TIMELINES FOR EU REGISTRATIONS



(6)

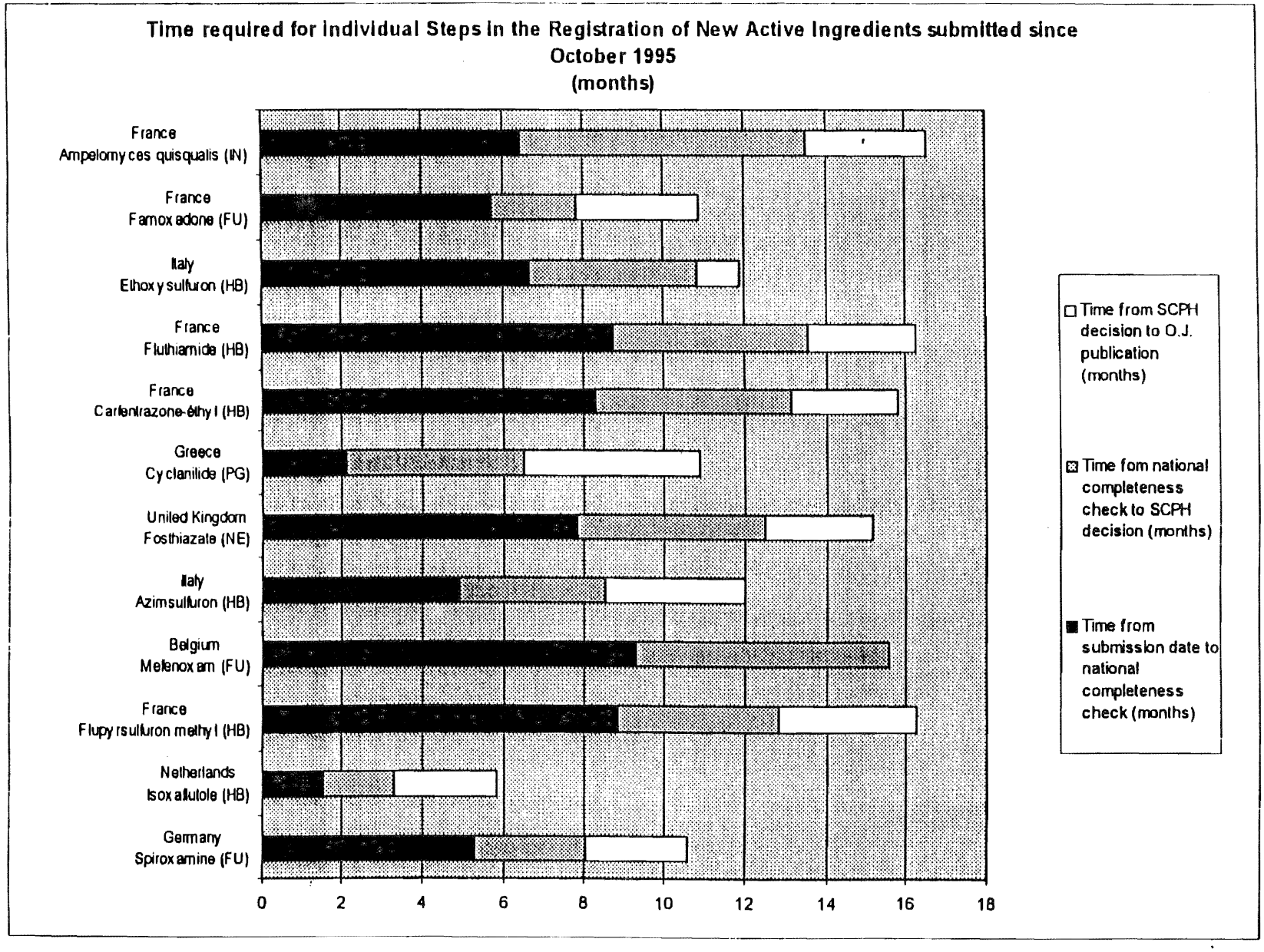
91/414 IMPLEMENTATION PROBLEMS

- ❑ **DOSSIER COMPLETENESS CHECK (MS AND EU LEVEL) AND PUBLICATION IN OFFICIAL JOURNAL.**

- ❑ **RMS EVALUATION AND MONOGRAPH PREPARATION.**

- ❑ **ECCO PEER REVIEW PROCESS/EVALUATION WORKING GROUP.**

- ❑ **PROVISIONAL AUTHORIZATIONS.**


Time required for individual Steps in the Registration of New Active Ingredients submitted since October 1995
(months)
France
Ampelomyces quisqualis (IN)
France
Famoxadone (FU)
Italy
Ethoxysulfuron (HB)
France
Fluthiamide (HB)
France
Carfentrazone-éthyl (HB)
Greece
Cyclanilide (PG)
United Kingdom
Fosthiazate (NE)
Italy
Azimsulfuron (HB)
Belgium
Mefenoxam (FU)
France
Flupyrsulfuron methyl (HB)
Netherlands
Isoxaflutole (HB)
Germany
Spiroxamine (FU)
0
2
4
6
8
10
12
14
16
18
Time from SCPH decision to O.J. publication (months)
Time fom national completeness check to SCPH decision (months)
Time from submission date to national completeness check (months)

(8)

MAIN PROPOSALS FOR IMPROVEMENTS

❑ DOSSIER COMPLETENESS CHECK AND OJ PUBLICATION.

- PRESENT AVERAGE TIMELINE IS 6+4+3 = 13 MONTHS.
- BEST TIMELINE TO DATE 1.5+1.5+2 = 5+ MONTHS.
- MSs NOW HAVE EXPERIENCE IN DOING COMPLETENESS CHECK - TIME TO KNOW EACH OTHER'S WORKING METHODS.
- UNDER 91/414 A DOUBLE COMPLETENESS CHECK IS REQUIRED, BUT A COMPLETENESS CHECK BY ONE MS (RMS) SHOULD SUFFICE.

(9)

MAIN PROPOSAL FOR IMPROVEMENTS

❑ DOSSIER COMPLETENESS CHECK AND OJ PUBLICATION.

- ONE OR TWO MSs TO DO INITIAL CHECK ON CONTRACT FOR ALL MSs WITHIN ONE MONTH.
- EXPEDITED CHECK BY ALL MSs
  FOLLOWED BY SCPH COMPLETENESS DECISION WITHIN TWO MONTHS.
- FASTER INTERNAL COMMISSION
  PROCEDURES FOR OJ PUBLICATION. PUBLISH WITHIN ONE MONTH AFTER SCPH DECISION.
- TOTAL ELAPSED TIME - NO MORE
  THAN 4 MONTHS. *

* (ASSUMES SUBMITTAL OF A COMPLETE HIGH-QUALITY DOSSIER).

(10)

MAIN PROPOSAL FOR IMPROVEMENTS

- ❑ RAPPORTEUR MS EVALUATION OF DOSSIER AND MONOGRAPH PREPARATION.

- CONSULTATION WITH APPLICANT DURING EVALUATION OF DOSSIER.
- APPLICANT TO REVIEW MONOGRAPH BEFORE IT ISSUES.
- "PROBLEM AREAS" TO BE HIGHLIGHTED FOR ECCO REVIEW.
- MONOGRAPH COMPLETED WITHIN 12 MONTHS OF RMS DESIGNATION.

(11)

MAIN PROPOSAL FOR IMPROVEMENTS

- ❑ ECCO EXPERT PEER REVIEW PROCESS / EVALUATION WORKING GROUP.

- NEW SCIENTIFIC ISSUES TO BE RAISED SHOULD BE CIRCULATED TO ALL PARTIES BEFORE MEETING.
- APPLICANT (SCIENTIFIC EXPERT) TO BE PRESENT OR ON CALL.
- IMPROVE COMMUNICATION BETWEEN APPLICANT AND ECCO EXPERT MEETINGS.
- IMPROVE FINAL ECCO REPORT - CLEAR RATIONALE FOR ADDITIONAL STUDY REQUESTS.
- IMPROVE COMMUNICATION DURING LATER STAGES OF POSITIVE LISTING PROCESS.

(12)

MAIN PROPOSAL FOR IMPROVEMENTS

❑ PROVISIONAL AUTHORIZATION (PA)

- PA PROCESS IS WORKING. HOWEVER, AS PRESENTLY APPLIED, EACH MS DOES THEIR OWN EVALUATION AND DECISION. SAME AS PRE-91/414.

- MSs HAVE DIFFERENT APPROACHES INTO PAs.

  * BE, GY, UK, NL
  * FR, IT, SP, GR, IRE
  * SW, DK, FIN

(13)

MAIN PROPOSAL FOR IMPROVEMENTS

❑ PROVISIONAL AUTHORIZATIONS (PA)

- PAs ARE CRITICAL TO COMPANIES. A DELAY CAN RESULT IN THE LOSS OF AN ENTIRE SEASON'S SALE, WHICH CANNOT BE RECOVERED.

- A YEAR'S DELAY IN APPROVAL OF A NEW PRODUCT WITH ESTIMATED PEAK ANNUAL SALES OF 160 MM ECU WOULD MEAN THE LOSS OF 28 MM ECU PROFIT

(14)

MAIN PROPOSAL FOR IMPROVEMENTS

- ❑ PROVISIONAL AUTHORIZATION (PA)

- REDUCE DUPLICATE REVIEWS BY MSs OF SAME INFORMATION.
- AFTER FIRST PA IN ANY MS, SUPPORTING DECISION DOCUMENT OR MONOGRAPH TO BE DISTRIBUTED TO ALL MSs.
- OTHER MSs TO MAKE USE OF THIS DOCUMENTATION TO EXPEDITE PAs.

(15)

CLOSING COMMENTS

- ❑ THE ECPA PROPOSALS ARE NORMAL EVOLUTIONARY CHANGES BASED ON EXPERIENCE.
- ❑ THE IMPROVEMENTS CAN BE IMPLEMENTED IN THE NEAR TERM WITHOUT AMENDING DIRECTIVE 91/414.
- ❑ ELIMINATION OF THE DOUBLE COMPLETENESS CHECK SHOULD BE PART OF THE 91/414 OMNIBUS AMENDMENTS UNDER DISCUSSION.
- ❑ PROCESS IMPROVEMENTS WOULD BENEFIT ALL PARTIES, COMMISSION, MEMBER STATES AND INDUSTRY.

(16)

CLOSING COMMENTS

BENEFITS

- REDUCE DUPLICATION.
- BETTER USE OF RESOURCES.
- IMPROVE QUALITY VIA CONSULTATION.
- EARLIER RESOLUTION OF "DOSSIER PROBLEMS".
  LESS FOLLOW-UP WORK.
- BRINGING NEW PRODUCTS TO MARKET FASTER BENEFITS EU AGRICULTURE.

(17)

CLOSING COMMENTS

- WE WOULD WELCOME IDEAS FOR PROCESS IMPROVEMENT FROM ALL PARTIES.
- WE BELIEVE OUR PROPOSED IMPROVEMENTS ARE AN INDUSTRY CONTRIBUTION TO THE SINGLE MARKET REVIEW AND SINGLE MARKET ACTION PLAN.
- AS ONE OF THE MAIN STAKEHOLDER IN DIRECTIVE 91/414, ECPA WANTS TO START A CONSULTATION TO ACHIEVE IMPROVEMENTS IN THE FUNCTIONING OF THE REGISTRATION PROCESS.
- WE HOPE ALL PARTIES WILL TAKE PART IN THIS INITIATIVE.

Information on CADDY (Computer Aided Dossier and Data Supply)

J. WENZELBURGER

Bayer AG
Germany

In 1993, Council Directive 91/414 came into force in the European Commission establishing a new pesticide registration regime and a requirement for industry data submission to be supplied in a standardised dossier format.

The problem for authorities would be a threat of paper overload and the lack of storage capacity (108 m storage capacity for about 24 active ingredients).

For industry this would mean immense cost for printing, copying, assembling and transporting of paper mass = about 200.000 DM per a.i. = 4.800.000 DM.

The solution for these problems was the identification of electronic means to compile and submit regulatory dossiers for plant protection products in an efficient and economic manner which lead to the development of CADDY (Computer Aided Dossier and Data Supply).

The strategic goal of the CADDY project is to facilitate the provision of dossiers for pesticides to regulatory authorities, the long-term archiving of such dossiers and the accessibility of information contained in such dossiers in a cost-effective manner using electronic media.

In **1995** the work on the CADDY program was started. The ECPA Data Transfer Working Group was formed, later the Joint EU Member States/ECPA Data Transfer Steering Group.

In **June 1996** US EPA, PMRA Canada, Canadian Industry and ACPA became members of the latter which lead to the foundation of the Joint Data Transfer Steering Group. In **November 96** CADDY was presented to the OECD Pesticide Forum in Paris. In **January 97** the GRIT Group (Global Regulatory Information Technology Group) was formed with the goal to consider developments and make strategy plans for electronic data submissions, while ensuring good corrdination at international level. Members of the GRIT Group are: US-EPA, PMRA Canada, EC, ACPA, ECPA, Canadian Industry, OECD, BBA, PSD-GB, NRA Australia.

In **November 1997** the Joint Data Steering Group was renamed in CADDY Steering Group.This group consists of participants of PMRA Canada, Canadian Industry, US-EPA, ACPA, EC, EU Member States and ECPA.

Steps of the CADDY Development:

January 1996: Completion of the Format Specification, Version 0.7.

February 1997: Completion of the Standard Retrieval Software Specification, Version 0.3.

April 1997: Request for tender.

June 1997: Decision for PSI to develop the Retrieval Software.

October 1997: Beta Test.

November 1997: Acceptance of the Software.

November 1997: First Trainings.

December 1997: Software ready to be distributed.

In due course information on CADDY will availabe on the GCPF homepage of the World Wide Web.

Joint Caddy Steering Group

chaired by: A. Scharpé / J. Wenzelburger

PMRA Canada:	Mrs. Krogh	
Canadian Industry:	Mr. McCully	
US EPA:	Mrs Martin	
ACPA:	Mr. McAllister	
EC	Mr. Scharpé	
EU Member States:	Mr. Bruno	DE
	Mr. Dobson	UK
	Mr. Sobreiro	PT
	Mrs. Bouneb	FR
	Mr. Witting	NL
ECPA	Mr. Lacey, DowElanco	
	Mr. Mattaar, Rhone-Poulenc	
	Mr. Meier-Manz, Novartis	
	Mr. Rittig, BASF	
	Mr. Wenzelburger, Bayer	

Scope: Data Transfer Steering Group is responsible for basic decisions on:
- Development of CADDY Step I
- Discussion and decision of next CADDY steps

The following documents will be available on the GCPF Homepage of the WWW by the end of February 1998 (www.gcpf.org):

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Info Brochure	**Dr. Falk R. Rittig** BASF AG **Phone:** (49) 621 6027 377 **Fax:** (49) 621 6027 701 **E-Mail:** falk.rittig@apd.x400.basf-ag.de
Application Guide	**Michael Groß** Hewlett Packard **Phone:** (49) 6172 161 563 **Fax:** (49) 6172 161 568 **E-Mail:** michael_gross@hp.com
Order Forms a) EU Retrieval Software/ Training b) US Retrieval Software c) US Training	**Horst Schneberger** PSI **Phone:** (49) 6021 366 613 **Fax:** (49) 6021 366 112 **E-Mail:** hschneberger@abg.psi.de **David J. Godfrey** Universal Systems Inc. (USI) **Phone:** (001) 703 222 1255 **Fax:** (001) 703 222 0543 **E-Mail:** dave_godfrey@usiva.com

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ANHANG (ZUSÄTZLICHE INFORMATIONEN) / ANNEX (SUPPLEMENTAL INFORMATION)

Doc. 1606A1-4/VI/95 rev. 21 (05.08.98): List of Contact Points

C.A. Landsmann, J.M. von Kietzell, J.-R. Lundehn and D.J. Flynn (1998):
The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: background, present situation, aims (part one).
In: Nachrichtenbl. Deut. Pflanzenschutzd., **50** (3), S. 49-52.

J.M. von Kietzell, C.A. Landsmann, J.-R. Lundehn and D.J. Flynn (1998):
The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: facts, dates, numbers (part two).
In: Nachrichtenbl. Deut. Pflanzenschutzd., **50** (3), S. 53-57.

1606A1/VI/95 rev.21
05.08.98

CONTACT POINTS

This document provides a list of contact points for:

1. the application of Directive 91/414/EEC
2. the re-evaluation programme of existing active substances
3. the evaluation of new active substances
4. the exchange of information according to Art.12

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L	Mr Aschman	352 457172 340	352 457172 218
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S	Mrs Bernson	46 8 7357 698	46 8 7306768
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ANNEX I

1. Number of Summary Dossiers to be submitted for existing active substances

	Normal No. of Copies	
	Paper	CD-ROM sets
B	1	6
DK	1	3
D	4(5)*	3 (complete doss.)
EL	4	
E	4	
F	2	6 (1 complete doss.)
FIN	2	
S	1	
A	3	3 (complete doss.)
IRL	2	
I	1	
LUX	2	
NL	1	4
P	1 (only if no cd-rom is available)	1
UK	2	
Commission**		4
Total	40	

* number in parenthesis refers to submissions without CD-ROM sets.
** 1 summary dossier each for DG VI, DG XI, DG XXIV and for ECB/JRC Ispra

2. In addition 1 summary on disc should be submitted to each Member State and the Commission (only if files are not provided on CD-ROM.

3. A full dossier has to be sent to:

- the Rapporteur Member State
- the Member States requesting explicitly a full dossier
- ECCO (BBA) Braunschweig for the active substances as soon as they are peer reviewed.

3. CONTACT POINT IN THE DESIGNATED AUTHORITY TO WHICH DOSSIERS FOR THE NEW ACTIVE SUBSTANCES SHOULD BE SENT

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1606A3/VI/95 rev.20
08.06.98

ANNEX II

Number of summary dossiers and complete dossiers
requested by Member States for **new** active substances

	When Rapporteur Member State				**When Member State in Standing Committee**			
	Complete dossiers including summary dossier		Additional Summary dossiers		Complete dossiers including summary dossiers		Additional Summary dossiers	
	Paper	CD-ROM	Paper	CD-ROM	Paper	CD-ROM	Paper	CD-ROM
B	4	6	0	0	1	6	3	
DK	1	3	1	3	1	3	0	3
D	3(4)	3	1(2)		3(4)	3	1(2)	
EL	2		3		1		3	
E	2		4		1		2	
F	3	6			2	6		
FIN	2		2		1		2	
S	1		3		1		3	
A	3	3	0	0	1	3	2	0
IRL	1	4(1con)	2		1	1	1	
I	1[(a)]		1		1		1	
LUX	1		1			1	2	
NL	2	4	3	4	1	4	3	4
P	1	1	0	0	1a (only if no cd-rom availab le)	1	0	0
UK	2		0		1		0	
Comm.**						1		4

\+ in each case 1 Summary on disk for each Member State (5 disks for IT, 3 disks for AU).

* number in parenthesis refers to submissions without CD-ROM sets.

** 1 summary dossier each for DG VI, DG XI, DG XXIV and for ECB/JRC Ispra
1 complete dossier for DG XXIV
2 disks for DG VI

[(a)] certain parts of dossier may need to be sent to different addresses - verify with contact name before sending.

4. CONTACT POINT IN THE MEMBER STATES FOR THE EXCHANGE OF INFORMATION ACCORDING TO ART.12 of DIRECTIVE 91/414/EEC

	Contact	Fax Number	Telephone Number
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B	Mr Houins	32 2 208 38 66	32 2 208 38 25
D	Mr Holzmann	49 531 299 3003	49 531 299 3452
DK	Mrs Bennekou	45 32660 479	45 32 66 0576
ESP	Mr Martinez	34 1 3478248	34 1 3478274
F	Mr Vernede	33 1 4955 5949	33 1 4955 4955
FIN	Mr Blomqvist	358 9 1342 1421	358 9 1342 1537
GR	Mr Ziogas	30 1 3617 103	30 1 5291 412
I	Mr Marabelli	39 6 5994 3217	39 6 5994 3780
IRL	Mr Lynch	353 1 820 42 60	353 1 6072613
LUX	Mr Aschman	352 457172 340	352 457172 218
NL	Mr Meijs	31 317 471 899	31 317 471 810
P	Mr Seabra	351 1 4420 616	351 1 4435 712
S	Mrs Bernson	46 8 7357 698	46 8 7306768
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The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: background, present situation, aims (part one)

Die Aufgaben des ECCO-Teams (BBA) und (PSD) im Rahmen der Umsetzung der Richtlinie des Rates 91/414/EWG: Hintergrund, aktuelle Situation, Ziele (Teil 1)

3. Mitteilung zur EU-Wirkstoffprüfung (Pflanzenschutzmittel)[2]

Von Cornelia A. Landsmann, J.M. von Kietzell, J.-R. Lundehn (BBA) und D.J. Flynn (PSD)

Abstract

Details of the co-ordinating work undertaken by the ECCO-Team (European Commission Co-Ordination) in Braunschweig and York/United Kingdom as part of the Peer Review Programme of the European Commission for the evaluation of existing and new active substances of plant protection products within the framework of Council Directive 91/414/EEC are presented. The role of the ECCO-Team in facilitating the decision making process for the inclusion of active substances of plant protection products in Annex I of Council Directive 91/414/EEC during the first 4 rounds of ECCO-Expert Group Meetings is described.

Key words:

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

Zusammenfassung

Es erfolgt die Darstellung von Details der koordinierenden Arbeit des ECCO-Teams (European Commission Co-Ordination) in Braunschweig und York/Vereinigtes Königreich als Teil des 'Peer Review' Programms der Europäischen Kommission zur Überprüfung und Bewertung alter und neuer Pflanzenschutzmittelwirkstoffe im Rahmen der Richtlinie des Rates 91/414/EWG. Die Rolle des ECCO-Teams bei der Unterstützung des Entscheidungsprozesses für die Aufnahme von Wirkstoffen in Anhang I der Richtlinie des Rates 91/414/EWG während der ersten 4 Runden der ECCO-Expertensitzungen wird beschrieben.

Stichwörter:

Pflanzenschutzmittel, Alt-Wirkstoff, neuer Wirkstoff, Prüfung und Bewertung, Zulassung, 'Peer Review' Programm, ECCO, Richtlinie des Rates 91/414/EWG

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[2] 2. Mitteilung siehe KULA, H., 1997: Zweite BBA-Notifizierer-Konferenz, Braunschweig, 15./16. Januar 1998 (Informationsveranstaltung zur EU-Wirkstoffprüfung). Nachrichtenbl. Deut. Pflanzenschutzd. **12**, 317.

Background and objectives of the work

On 1 August 1996, the ECCO-Team was founded, consisting of two groups situated at the BBA in Braunschweig and at the Pesticides Safety Directorate (PSD) in York/United Kingdom. This European Commission Co-Ordination (ECCO) Team carries out work on behalf of the European Commission, Directorate General (DG) VI (Agriculture) on the basis of a time-limited contract. The European Commission has provided for a Peer Review Programme as part of the joint evaluation process for the inclusion of existing and new active substances of plant protection products in Annex I of Council Directive 91/414/EEC (LUNDEHN, 1997). The inclusion of an active substance in Annex I will in future be prerequisite for any further authorisation of plant protection products containing that active substance in the Member States and the basis for mutual recognition of authorisations. The final decision on the inclusion of an active substance in Annex I will be taken by the European Commission within the framework of the 'Standing Committee on Plant Health' in Brussels (Fig. 1). The aim of the ECCO-Team is to support the European Commission in the development of procedures for the standardisation of evaluation and assessment criteria in order to harmonise the authorisation and use of active substances of plant protection products in all 15 Member States of the European Union.

The ECCO-Team (BBA) is part of the Co-Ordinating Group within the Department of Plant Protection Products and Application Techniques at the BBA (Federal Biological Research Centre for Agriculture and Forestry) which belongs to The Federal Ministry of Food, Agriculture and Forestry. The ECCO-Team (PSD) is part of the Pesticides Safety Directorate, which is an Executive Agency of The Ministry of Agriculture, Fisheries and Food in Great Britain. Both groups share their tasks within the ECCO-project equally. They consist of scientists with the administrative support of, for example, foreign language secretaries.

The ECCO-Team organises the Peer Review Programme on behalf of the European Commission. This implies liaising with the Member States and, where necessary, with other interested parties. Its main task is the organisation of ECCO-Peer Review Meetings and the associated work before, during and after a meeting. At these meetings attended by invited experts from different Member States and representatives of the European Commission, a scientific review of evaluation reports, or monographs, for several active substances is carried out. The details of the ECCO-Team's work are co-ordinated with the responsible services in the European Commission (VI.B.II.1) at monthly co-ordination meetings held in Brussels. When necessary certain aspects are also discussed with the Member States in the meetings of the Working Group 'Plant Protection Products' (Legislation) of the 'Standing Committee on Plant Health'.

Details of the evaluation process

Under Article 8 (2) of Council Directive 91/414/EEC, the 825 existing active substances (including organisms) which were on the market in the Member States before the deadline of

25 July 1993 must be examined with respect to their suitability for inclusion in Annex I. The first list of 90 active substances prioritised for re-evaluation was published in Annex I of Regulation (EEC) No. 3600/92. Producers then notified the European Commission of their intention to support a certain active substance. These notifiers, which were in general companies manufacturing active substances and plant protection products, compiled a dossier to support their notification for inclusion of the active substance in Annex I of the Directive. This dossier consists of studies which have been submitted by a company for that purpose. Subsequently a monograph on each active substance was prepared by the Member State to which the dossier was submitted for evaluation, referred to as the rapporteur Member State. The active substances were distributed among the Member States for evaluation according to a quota (for details see Regulations (EC) No. 933/94 and (EC) No. 491/95), requiring between 1 - 11 monographs to be prepared by each Member State. To date (11 November 1997), an additional 43 monographs on new active substances, which were not yet on the market at the time of implementation of the Directive, have been or are being prepared.

A monograph consists of different sections, dealing with the different areas of evaluation and assessment: physico-chemical properties, methods of analysis, further information, fate and behaviour in the environment, effects on non-target species (ecotoxicology), mammalian toxicology, and residues. It also contains lists of studies relied on for the evaluation and a proposal from the rapporteur Member State regarding inclusion in Annex I. Once a monograph has been completed by a rapporteur Member State, it is sent to the European Commission for consideration within the framework of the Standing Committee on Plant Health. The ECCO-Peer Review Meetings could be considered as the first stage of this process.

ECCO-Peer Review Meetings (1996 - 1997)

These meetings took place in Braunschweig and York and were organised in rounds. Each round consisted of 11 - 14 meetings, with each meeting dealing only with a specific section of a monograph for each of the active substances scheduled to be considered during the round. The meetings were organised in such a way that experts in a particular scientific discipline could examine that specific section of the dossiers and monographs for consideration, i. e. section I (physico-chemical properties, methods of analysis, further information), section II (fate and behaviour in the environment), section III (effects on non-target species/ecotoxicology), section IV (mammalian toxicology), section V (residues), and section VI (regulatory questions). The meetings in round 1, 2 and 3 (September 1996 until July 1997) lasted approximately 3 days and examined 4 to 5 active substances. It is expected that the fourth round of meetings (September 1997 until January 1998) will last 4 days and consider 5 to 6 active substances. For further details on all meetings see Table 1 of the following publication "The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: part two".

Fig. 1: Steps of the joint review process for existing active substances in plant protection products within the European Union according to Article 8 (2) of Council Directive 91/414/EEC (action level of the ECCO-Team in dark colour)

Publication of active substance to be reviewed

by European Commission

⇓

Notification of interest to support Annex I inclusion

by industry (notifier)

⇓

Compilation of dossier

by industry (notifier)

⇓

Evaluation and assessment of active substance

Compilation of monograph

by rapporteur Member State

⇓

Scientific discussion of monograph and preparation of decision
(ECCO-Peer Review Meetings)

by experts of 7 different Member States per meeting

⇓

Compilation of Draft Decision and Review Report

by European Commission

⇓

Negotiation on EU level with regard to Annex I inclusion

Working Group 'Plant Protection Products' (Evaluation)

⇓

Working Group 'Plant Protection Products' (Legislation)

⇓

Standing Committee on Plant Health

by 15 Member States and European Commission

⇓

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

by European Commission

Additionally, 3 'Guidance Document Meetings' involving experts from all 15 Member States were organised as part of the ECCO work. The aim of these meetings was to provide guidance to the European Commission and the Member States on how to deal with problematic areas in the evaluation and assessment of active substances through the preparation of a guidance document on, for example, operator exposure or aquatic ecotoxicology.

The ECCO-Team's work includes: co-ordinating the review and evaluation programme together with the European Commission, the preparation and organisation of ECCO-Peer Review Meetings, the provision of technical and scientific support to the meetings, and the preparation of reports after the meetings.

Organisational procedures

The ECCO-process begins when the European Commission selects the monographs to be considered during a particular round of meetings and agrees on the timetable. The ECCO-Team sends, on behalf of the European Commission, copies of the relevant monographs to the 'Designated National Authorities' of the Member States as well as to the main data submitters, giving them the opportunity to comment on the monographs. Then, a call for nomination of experts is sent to all Member States and on receipt of nominations the European Commission selects the experts from the different Member States to be invited to particular ECCO-Peer Review Meetings. The participants are chosen for their expert knowledge in the section for consideration. One expert from the rapporteur Member State for the monographs under consideration is always invited. Prior to the meeting the experts receive a formal invitation letter from the ECCO-Team, on behalf of the European Commission, as well as the invitation package including a complete set of monographs. Comments from Member States and/or data submitters concerning the monographs are collected by the ECCO-Team and tabled at the relevant meeting. Up to 7 experts from the 15 Member States as well as representatives from the European Commission take part in the meetings. The working language is English. The chairperson is provided by the BBA or PSD depending on the venue of the meeting. At the meeting, the participating scientist from the ECCO-Team takes notes and assists the chairperson, ensuring that all items which need to be discussed are covered during the meeting.

Immediately after the meeting the ECCO-Team prepares a meeting report which reflects the important discussions and results of each meeting in an objective way. This 'Concise Outline Report' consists of a main text and several appendixes ('list of end points', 'list of data requirements', 'list of studies relied upon for which data protection has been claimed' and 'suggested classification and labelling'). It is the aim of each meeting to agree on the key issues. The main text explains the changes in the 'list of end points' proposed during the meeting, substantiates the data requirements identified and indicates the areas of concern which may influence any decision on inclusion in Annex I. The 'list of end points' is prepared by the rapporteur Member State which is required for the evaluation and assessment of active

substances according to Annex II of Council Directive 91/414/EEC. Where the meeting agrees on the existence of data gaps in the dossier a 'list of data requirements' is compiled during the meeting. The data submitter may claim data protection for individual studies in the dossier. A 'list of studies relied upon for which data protection has been claimed' is compiled by the rapporteur Member State. Should the claim be substantiated during the re-evaluation process and these studies were considered as essential for the evaluation with regard to Annex I inclusion, data protection may be granted in accordance with Article 13 (3) of Council Directive 91/414/EEC. Normally, in the case of new active substances, all studies that have been relied on when preparing the monograph can be granted data protection by Member States because it is assumed that all these studies which are essential for the evaluation, are new, unpublished, and have not been used in support of a previous authorisation. As appropriate, a 'suggested classification and labelling' proposal for the active substance may also be agreed on at the meeting to assist DG XI which is responsible for that area. The finalised report of each meeting, sometimes consisting of more than 100 pages, is sent to the European Commission DG VI (for further consideration) and to the participants of the meeting (for information only).

At the end of each round, a 'Full Report' is sent to Member States and the main data submitters which also includes the conclusions of an ECCO-Round. This report, sorted by active substance, consists of all 'Concise Outline Reports' and all relevant documents considered at the meetings and referred to in the reports (comments from Member States, other interested parties and/or data submitters as well as documents tabled at the meetings).

Amendments to the procedures in Round 4

Based on the experience gained in Rounds 1 to 3, the procedure for Round 4 has been amended in order to accommodate improvements in the liaison between the notifiers and the rapporteur Member States. During each meeting an 'Evaluation table' will be prepared by the report writer consisting of all data requirements and unresolved points and questions which will be sent to the rapporteur Member State. By contacting directly the main data submitter to resolve the open issues immediately after the meeting, the rapporteur Member State will hopefully be in a position to deal with these points at the last meeting of that round. This 'Overview Meeting' has replaced the former 'Regulatory Questions Meetings' of Rounds 1 to 3. Its role is to consider the results of the ten previous meetings and to provide advice to the European Commission to assist in the preparation of a decision in the 'Standing Committee on Plant Health' relating to the inclusion of the active substance considered in Annex I. The 'Overview Meeting' should ensure consistency within and between active substances and basically quality control the underlying scientific basis of decisions and resolve issues raised at earlier meetings. The result of the 'Overview Meeting' will include a 'Draft Review Report' with complete lists of proposed data requirements, end points, studies relied upon for which data protection has been claimed, and suggestions for classification and labelling of all active substances dealt with in the round. The complete lists of proposed data requirements and

studies relied upon for which data protection has been claimed will supersede those in the monograph. Any critical areas which should receive particular attention will also be forwarded to the European Commission.

Post Peer Review procedures

On the basis of the outcome of the ECCO-Peer Review Meetings (and, if appropriate, tripartite meetings between the European Commission, the rapporteur Member State and the main data submitter to consider unresolved points, unclear items or questions which arose from the 'Overview meeting') a revised 'Draft Review Report' will be compiled. The next step is a technical discussion with all 15 Member States in the European Commission's Working Group 'Plant Protection Products' (Evaluation) followed by a more general discussion in the Working Group 'Plant Protection Products' (Legislation). In the end, a draft Directive on Annex I listing (or where necessary a decision on suspension, withdrawal or postponement) is submitted to the 'Standing Committee on Plant Health' for its formal opinion (Fig. 1). On the basis of the favourable opinion given by the 'Standing Committee on Plant Health', the European Commission will adopt the decision. Any restrictions or conditions associated with that inclusion, as detailed in the amending Directive and 'Review Report', would be implemented by all Member States in accordance with Article 8 (2) of Council Directive 91/414/EEC. Subsequently, all plant protection product authorisations relating to that active substance would need to be reviewed by Member States and the plant protection products re-registered as appropriate, in accordance with the inclusion in Annex I and the uniform principles set out in Annex VI of that Directive. Once plant protection products have been authorised under Council Directive 91/414/EEC, Article 10 of the same Directive can also be applied. This Article provides for the mutual recognition of authorisations granted under the conditions specified in Council Directive 91/414/EEC. This means that, at the request of an applicant, a Member State to which an application for the authorisation of a plant protection product, already authorised in another Member State, is made, must also authorise the placing of that product on the market in its territory, to the extent that agricultural, plant health and environmental conditions relevant to the use of the product are comparable in the regions concerned. However, Member States still have the possibility, taking into account restrictions and conditions related to the inclusion in Annex I, of imposing, with the agreement of the applicant, their own restrictions or conditions for use of specific plant protection products, reflecting their special geographical or ecological features.

Review and aims

The first active substance, imazalil, should soon be listed in Annex I. A favourable unanimous opinion was given by the 'Standing Committee on Plant Health' on 11 July 1997 in Brussels.

Funds for the next rounds of peer review meetings have been made available by the European Commission and a second contract has been awarded to BBA and PSD. Round 4 of the

ECCO-Peer Review Meetings has begun in mid September 1997 and will end in January 1998. Two further rounds of meetings are planned for 1998/1999.

Preceding the ECCO-project a workshop was held in 1994 and a pilot project of the European Commission was organised in 1995. The first meeting of all national authorities for the approval of plant protection products took place in June 1994 at the BBA in Braunschweig ('Joint Meeting of Competent and Designated Authorities' or JMCDA). The results included agreements on draft monographs, on monograph guidelines and on dossier guidelines. Based on the experience gained and recommendations made at the JMCDA, the BBA and PSD organised a pilot project. In the course of this ECPPM-project (European Community Pilot Project Meetings) three examples of dossiers and monographs were compiled, procedures and guidelines were developed further. In a series of 13 expert group meetings (ECPPMs) held between February and November 1995, participants from all Member States and the European Commission gathered in Braunschweig. With the ECCO-project, another step has been made in the direction of co-operation and harmonising of evaluation and assessment of active substances and plant protection products within the 15 Member States of the EU. Without the continuous help, close co-operation and support of the Member States, the European Commission and the notifiers, this work would not have been achieved. A great deal of effort has been made to ensure that Member States and notifiers participate as fully as possible. The ECCO-Team will endeavour to ensure that the decision making process remains transparent and strive for simple and efficient procedures within the evaluation process.

Acknowledgements

The ECCO-project has been financed by the European Commission and special thanks are due to the services of DG VI, and in particular, A. SCHARPÉ, L. SMEETS and M. WALSH. We would also like to thank everyone who has been involved in the meetings, and in particular, ANJA HEISSNER and KERSTIN KOCH of the ECCO-Team (BBA) and AGNES COSTA-CORREA of the ECCO-Team (PSD).

Reference

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The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: facts, dates, numbers (part two)

Die Aufgaben des ECCO-Teams (BBA) und (PSD) im Rahmen der Umsetzung der Richtlinie des Rates 91/414/EWG: Fakten, Daten, Zahlen (Teil 2)

4. Mitteilung zur EU-Wirkstoffprüfung (Pflanzenschutzmittel)[3]

Von J.M. von Kietzell, Cornelia A. Landsmann, J.-R. Lundehn (BBA) und D.J. Flynn (PSD)

Abstract

The ECCO-Peer Review Programme is part of the joint evaluation of existing and new active substances within the framework of Council Directive 91/414/EEC and Regulation (EEC) No. 3600/92.

Specific information on the first 50 ECCO-Peer Review Meetings held in 4 rounds from September 1996 to January 1998 by the BBA (Braunschweig) and PSD (York) is given which can be summarised as follows: 36 active substances have been reviewed of which 7 were new (i.e. not on the market before 25 July 1993). 18 of the 36 reviewed active substances are herbicides, the other 18 include all main categories of active substances. The monographs were prepared by 13 Member States. Experts from all 15 Member States of the European Union (EU) have attended the meetings, representing all regions in the EU. Scientific advice was given to the European Commission which assisted in the preparation of the regulatory decisions in the Standing Committee on Plant Health of the European Commission in Brussels.

Key words:

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

Zusammenfassung

Das "ECCO-Peer Review Programm" ist Teil der gemeinsamen Prüfung und Bewertung alter und neuer Pflanzenschutzmittelwirkstoffe im Rahmen der Richtlinie des Rates 91/414/EWG und Verordnung (EWG) 3600/92. Es wird über die ersten 50 ECCO-Expertensitzungen informiert, die in 4 Runden von September 1996 bis Januar 1998 in der BBA (Braunschweig) und dem PSD (York) organisiert wurden. Diese Information wird wie folgt zusammengefaßt: 36 Wirkstoffe wurden geprüft, davon 7 neue (das heißt nicht vor dem 25. Juli 1993 im Verkehr). 18 der 36 geprüften Wirkstoffe sind

[3] 3. Mitteilung siehe LANDSMANN, C.A., J.M. VON KIETZELL, J.-R. LUNDEHN UND D.J. FLYNN: The work of the ECCO-Team (BBA) and (PSD) in the implementation of Council Directive 91/414/EEC: background, present situation , aims (part one). Nachrichtenbl. Deut. Pflanzenschutzd. 50 (30), 1998, S. 49-52.

Herbizide, die anderen 18 umfassen alle wesentlichen Wirkungsbereiche. Die Monographien wurden von 13 Mitgliedstaaten erstellt. Experten aus allen 15 Mitgliedstaaten der Europäischen Union (EU) waren an den Sitzungen beteiligt. Sie repräsentierten alle Regionen der EU. Die Europäische Kommission wurde wissenschaftlich beraten, und somit wurde ein Beitrag für die Vorbereitung der Entscheidungen im Ständigen Ausschuß Pflanzenschutz bei der Europäischen Kommission in Brüssel geleistet.

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

Introduction

The ECCO-Peer Review Programme is part of the joint evaluation of existing and new active substances of plant protection products within the framework of Council Directive 91/414/EEC and Regulation (EEC) No. 3600/92.

Existing active substances are defined as already being on the market on 25 July 1993 in the EU. New active substances were not authorised in any EU Member State up to this date and are presently in different stages of evaluation on EU level. Some of them are now already on the market in provisionally authorised plant protection products in certain Member States.
The background and objectives of the ECCO project have been outlined in the preceding publication (part 1). In this publication (part 2), the organisation of a round of ECCO-Peer Review Meetings is described and specific information on the four rounds of meetings which have been organised already is provided, including the names of the active substances considered and the rapporteur Member States and experts involved.

Documentation of ECCO-Peer Review Meetings, Rounds 1-4

Until now, 50 ECCO-Peer Review Meetings have been scheduled in four rounds, from September 1996 to January 1998. Two further rounds will be organised under the current ECCO contract until February 1999. The timetables of rounds 1- 4 are presented in table 1.

The timetable of the 4. round of meetings is explained as follows: from 15 September 1997 to 21 November 1997 ten meetings related to the five specific scientific sections of the monographs, ECCO 40 and 41 (identity, physical/chemical properties, methods of analysis, further information), ECCO 42 and 47 (fate and behaviour in the environment), ECCO 44 and 49 (effects on non-target species), ECCO 43 and 46 (mammalian toxicity), and ECCO 45 and 48 (residues) have been organised in the two centres BBA (Braunschweig) and PSD (York). Six monographs are being reviewed at BBA, five at PSD. 69 nominated experts from the

Tab. 1: Timetable for the ECCO-Peer Review Meetings of rounds 1 - 4 and the active substances (a.s.) discussed

Round 1					
Meeting	**Date 1996**		**Monograph section**	**as** *)	**Location**
ECCO 1	17 - 19	September	Phys Chem properties	1 - 4	PSD
ECCO 2	24 - 26	September	Phys Chem properties	5 - 8	BBA
ECCO 3	1 - 3	October	Ecotoxicology	1 - 4	PSD
ECCO 4	8 - 10	October	Fate and Behaviour	5 - 8	BBA
ECCO 5	15 - 17	October	Fate and Behaviour	1 - 4	PSD
ECCO 6	22 - 24	October	Ecotoxicology	5 - 8	BBA
ECCO 7	29 - 31	October	Mammalian Toxicology	1 - 4	PSD
ECCO 8	5 - 7	November	Mammalian Toxicology	5 - 8	BBA
ECCO 9	12 - 14	November	Residues	1 - 4	PSD
ECCO 10	19 - 21	November	Residues	5 - 8	BBA
ECCO 11	26 - 28	November	Regulatory questions	1 - 4	PSD
ECCO 12	3 - 5	December	Regulatory questions	5 - 8	BBA

*) **Active substances discussed during the meeting:**

1 - fenthion (EAS)
2 - imazalil (EAS)
3 - lambda-cyhalothrin (EAS)
4 - warfarin (EAS)
5 - aldicarb (EAS)
6 - diquat (EAS)
7 - tecnazene (EAS)
8 - fenarimol (EAS)

Round 2					
Meeting	**Date 1997**		**Monograph Section**	**as *)**	**Location**
ECCO 13	7 - 9	January	Phys Chem properties	9 - 12	PSD
ECCO 14	14 - 16	January	Phys Chem properties	13 - 16	BBA
ECCO 15	21 - 23	January	Fate and Behaviour	9 - 12	PSD
ECCO 16	21 - 23	January	Mammalian Toxicology	13 - 16	BBA
ECCO 17	28 - 30	January	Ecotoxicology	9 - 12	PSD
ECCO 18	4 - 6	February	Residues	13 - 16	BBA
ECCO 19	11 - 13	February	Mammalian Toxicology	9- 12	PSD
ECCO 20	18 - 20	February	Fate and Behaviour	13 - 16	BBA
ECCO 21	25 - 27	February	Residues	9 - 12	PSD
ECCO 38	3 - 4	March	Guidance Doc. Meeting		BBA
ECCO 22	4 - 6	March	Ecotoxicology	13 - 16	BBA
ECCO 23	11 - 13	March	Regulatory questions	9 -12	PSD
ECCO 24	18 - 20	March	Regulatory questions	13 - 16	BBA

*) **Active substances discussed during the meeting:**

9 - amitrole (EAS)
10 - beta-cyfluthrin (EAS)
11 - cyfluthrin (EAS)
12 - fluroxypyr (EAS)
13 - flusilazole (EAS)
14 - propineb (EAS)
15 - thifensulfuron(-methyl) (EAS)
16 - dinoterb (EAS)

Round 3					
Meeting	**Date 1997**		**Monograph section**	**as** *)	**Location**
ECCO 25	15 - 17	April	Phys Chem properties	17 - 21	PSD
ECCO 26	22 - 24	April	Phys Chem properties	22 - 25	BBA
ECCO 27	29 - 1	May	Fate and Behaviour	17 - 21	PSD
ECCO 28	6 - 8	May	Ecotoxicology	17 - 21	PSD
ECCO 29	13 - 15	May	Fate and Behaviour	22 - 25	BBA
ECCO 30	20 - 22	May	Mammalian Toxicology	17 - 21	PSD
ECCO 37	23	May	Guidance Doc. Meeting		PSD
ECCO 39	30	May	Guidance Doc. Meeting		BBA
ECCO 31	27 - 29	May	Ecotoxicology	22- 25	BBA
ECCO 32	3 - 5	June	Mammalian Toxicology	22- 25	BBA
ECCO 33	10 -12	June	Residues	17 - 21	PSD
ECCO 34	17 - 19	June	Residues	22- 25	BBA
ECCO 35	25 - 27	June	Regulatory questions	17 - 21	PSD
ECCO 36	1 - 3	July	Regulatory questions	22 - 25	BBA

*) **Active substances discussed during the meeting:**

17 - azoxystrobin (NAS)
18 - kresoxim-methyl (NAS)
19 - spiroxamine (NAS)
20 - isoxaflutole (NAS)
21 - DNOC (EAS)
22 - quinoxyfen (NAS)
23 - pyridate (EAS)
24 - esfenvalerate (EAS)
25 - paraquat (EAS)

Round 4					
Meeting	**Date 1997**		**Monograph section**	**as** *)	**Location**
ECCO 40	15 - 18	September	Phys Chem properties	31-36	BBA
ECCO 41	23 - 26	September	Phys Chem properties	26-30	PSD
ECCO 42	29 Sept. - 2 October		Fate and Behaviour	31-36	BBA
ECCO 43	7 - 10	October	Mammalian Toxicology	26-30	PSD
ECCO 44	13 - 16	October	Ecotoxicology	31-36	BBA
ECCO 45	21 - 24	October	Residues	26-30	PSD
ECCO 46	27 - 31	October	Mammalian Toxicology	31-36	BBA
ECCO 47	4 - 7	November	Fate and Behaviour	26-30	PSD
ECCO 48	10 - 13	November	Residues	31-36	BBA
ECCO 49	18 - 21	November	Ecotoxicology	26-30	PSD
ECCO 50	26 - 30 January 1998		Overview Meeting	26-36	BBA

*) **Active substances to be discussed during the meeting:**

26 - azinphos-methyl (EAS)
27 - bentazone (EAS)
28 - triasulfuron (EAS)
29 - azimsulfuron (NAS)
30 - metsulfuron (EAS)
31 - 2,4-D (EAS)
32 - 2,4-DB (EAS)
33 - linuron (EAS)
34 - monolinuron (EAS)
35 - thiabendazole (EAS)
36 - flurtamone (NAS)

(NAS) = new active substance
(EAS) = existing active substance

rapporteur and other Member States have been invited by the ECCO-Team on behalf of the European Commission to attend the meetings.

After the tenth meeting, a 9 week break has been scheduled to give the rapporteur Member States time to clarify open questions and data requirements with the main data submitters and others. In this period the ECCO-Team documents the results of the ten meetings in a draft review report and prepares the last meeting of the round.

The meeting ECCO 50 (Overview Meeting) is scheduled from 26-30 January 1998. In this meeting the discussions of the ten meetings are summarised and the draft review report is revised.

In table 2, a list of all active substances which have been dealt with in first 4 ECCO-rounds is presented. In total, the monographs of 36 active substances have been discussed of which 7 were new (i.e. not on the market before 25 July 1993). The main criteria for selection of an active substance was the availability of the monograph, the category or relatedness of the active substance and the integration of as many Member States as possible. The European Commission has treated monographs on new active substances as a matter of priority.

Additionally to the 36 monographs already discussed, 7 monographs which had been finalised in the meantime have been sent to all Member States by the ECCO-Team (tab. 3). The small number of only 7 finalised monographs yet to be discussed shows that the current organisation of the ECCO-Peer Review Meetings is able to cope with the speed in which monographs are being prepared.

Tab. 2: Alphabetical list of all active substances discussed in rounds 1-4 of ECCO-Peer Review Meetings

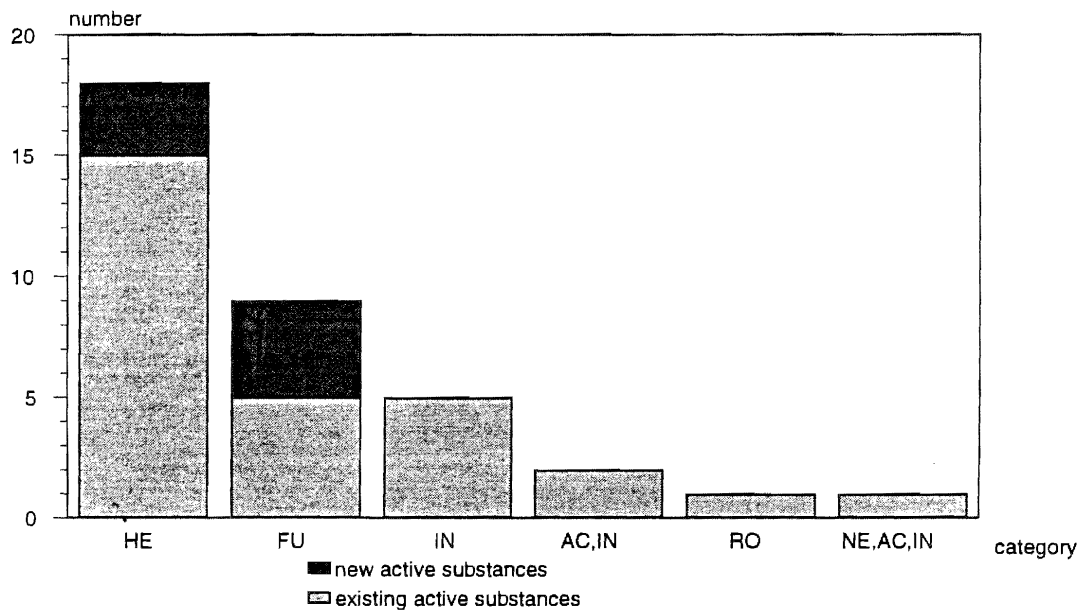
active substance	existing or new	category	rapporteur Member State	discussed in centre	discussed in round
2,4-D	existing	herbicide	Greece	BBA	4
2,4-DB	existing	herbicide	Greece	BBA	4
aldicarb	existing	nematicide/ acaricide/ insecticide	United Kingdom	BBA	1
amitrole	existing	herbicide	France	PSD	2
azimsulfuron-methyl	new	herbicide	Italy	PSD	4
azinphos-methyl	existing	acaricide/ insecticide	Germany	PSD	4
azoxystrobin	new	fungicide	Germany	PSD	3
bentazone	existing	herbicide	Germany	PSD	4
beta-cyfluthrin	existing	insecticide	Germany	PSD	2
cyfluthrin	existing	insecticide	Germany	PSD	2
dinoterb	existing	herbicide	France	BBA	2
diquat	existing	herbicide	United Kingdom	BBA	1
DNOC	existing	acaricide/ insecticide	France	PSD	3
esfenvalerate	existing	insecticide	Portugal	BBA	3
fenarimol	existing	fungicide	United Kingdom	BBA	1
fenthion	existing	insecticide	Greece	PSD	1
fluroxypyr	existing	herbicide	Germany	PSD	2
flurtamone	new	herbicide	France	BBA	4
flusilazole	existing	herbicide	Ireland	BBA	2
imazalil	existing	fungicide	Luxembourg	PSD	1
isoxaflutole	new	herbicide	The Netherlands	PSD	3
kresoxim-methyl	new	fungicide	Belgium	PSD	3
lambda-cyhalothrin	existing	insecticide	Sweden	PSD	1
linuron	existing	herbicide	United Kingdom	BBA	4
metsulfuron	existing	herbicide	France	PSD	4
monolinuron	existing	herbicide	United Kingdom	BBA	4
paraquat	existing	herbicide	United Kingdom	BBA	3
propineb	existing	fungicide	Italy	BBA	2
pyridate	existing	herbicide	Austria	BBA	3
quinoxyfen	new	fungicide	United Kingdom	BBA	3
spiroxamine	new	fungicide	Germany	PSD	3
tecnazene	existing	fungicide	United Kingdom	BBA	1
thiabendazole	existing	fungicide	Spain	BBA	4
thifensulfuron	existing	herbicide	France	BBA	2
triasulfuron	existing	herbicide	France	PSD	4
warfarin	existing	rodenticide	Ireland	PSD	1

Tab. 3: Alphabetical list of finalised and distributed monographs which have yet to be discussed in a round of ECCO-Peer Review Meetings

active substance	existing or new	category	rapporteur Member State
acephate	existing	insecticide	Italy
atrazine	existing	herbicide	United Kingdom
fentin acetate	existing	herbicide/ fungicide	United Kingdom
fentin hydroxide	existing	herbicide/ fungicide	United Kingdom
iprodione	existing	fungicide	France
simazine	existing	herbicide	United Kingdom
vinclozolin	existing	fungicide	France

The monographs considered so far represent all main categories of active substances. 18 (50 %) of the 36 active substances reviewed are herbicides (3 of which are new active substances), 9 are fungicides (incl. 4 new active substances), 5 insecticides, three additional insecticides which have additional effects on mites and/or nematodes, and one rodenticide (fig. 1).

Fig. 1: Distribution of categories of active substances reviewed in ECCO-Peer Review Meetings rounds 1-4



HE: herbicide, FU: fungicide, IN: insecticide, AC: acaricide, RO: rodenticide, NE: nematicide

In rounds 1-4, 29 of 825 existing active substances (including organisms) were reviewed in ECCO-Peer Review Meetings, in addition to 7 of the 43 (date 11 November 1997) new active substances which are currently in the system (fig. 2 a and b).

Fig. 2 a: Total number of active substances registered in the EU on 25 July 1993 compared to the number of existing active substances reviewed in round 1-4

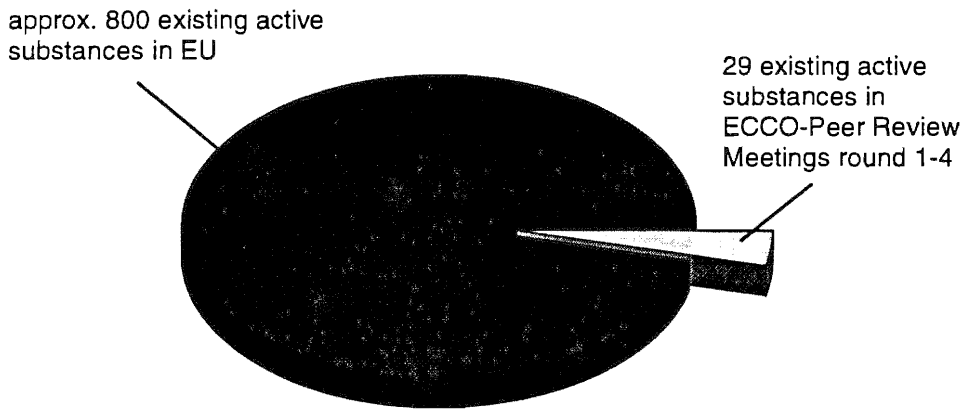
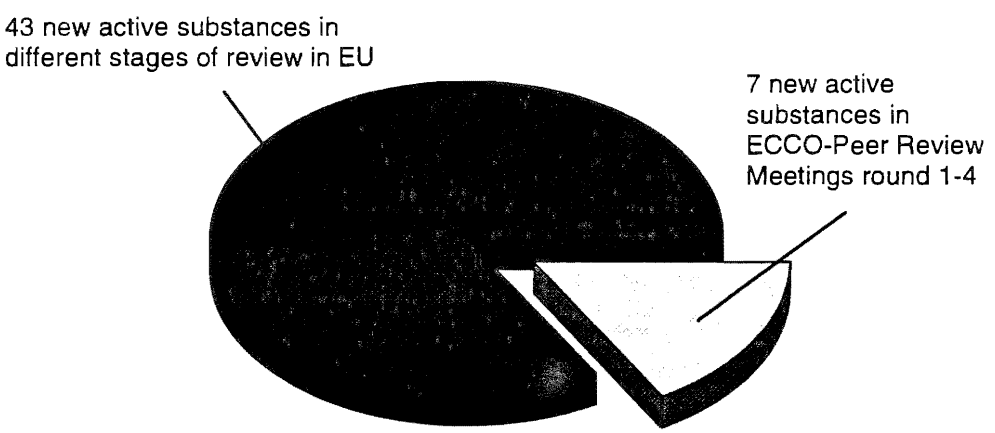
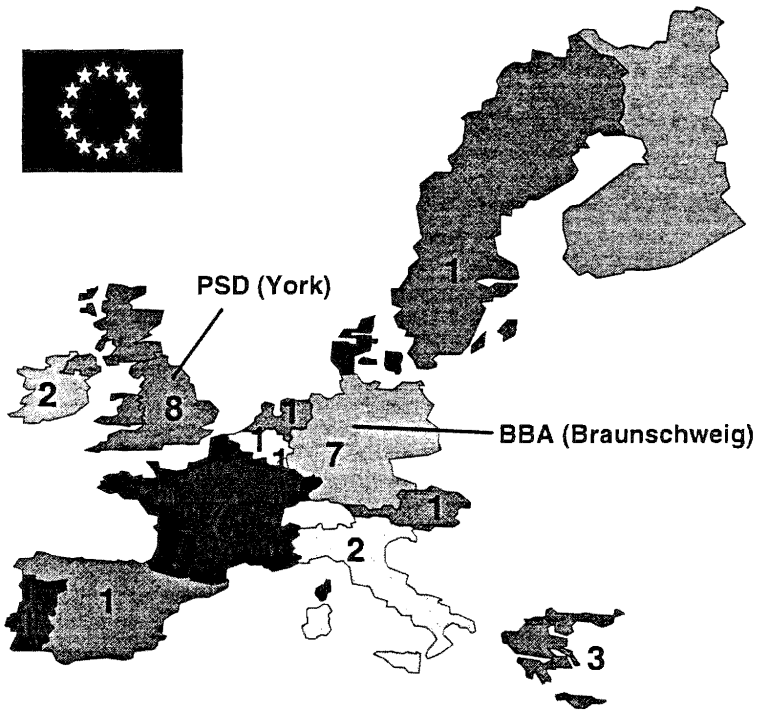


Fig. 2 b: Total number of new active substances in different stages of evaluation (date 11 November 1997) compared to the number of new active substances reviewed in round 1-4



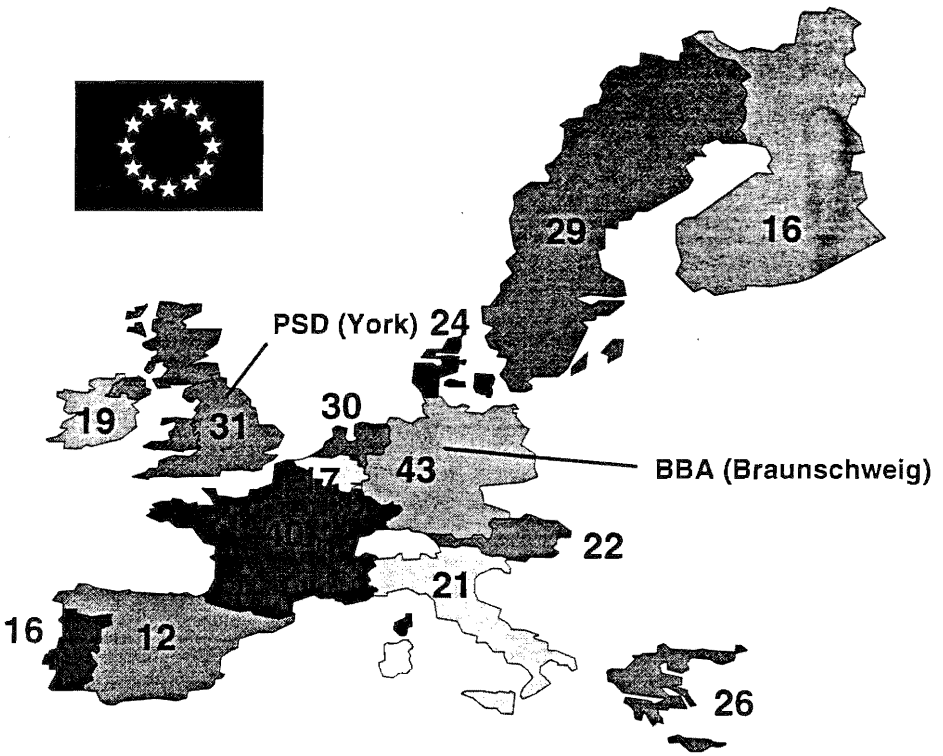
Out of the 36 monographs dealt with so far, eight have been prepared by the United Kingdom and seven by France and Germany respectively. Several other Member States have contributed monographs, with only two Member States yet to have a monograph considered by the Peer Review Meetings (figure 3).

Fig. 3: Number of monographs prepared by respective rapporteur Member States for ECCO-Peer Review Meetings, rounds 1-4



The 50 ECCO-Peer Review Meetings scheduled until January 1998 will be attended by 352 experts from all 15 Member States (figure 4). Each meeting can only be attended by up to 7 experts and therefore, no Member State can be represented in all meetings. All Member States have made significant contributions to the meetings where, generally, all regions in Europe were represented. The bigger Member States such as Germany and France contributed more experts (43 and 40 respectively) to the meetings than the other States but even the smallest Member State Luxembourg sent experts to 6 of the 50 meetings.

Fig. 4: Number of experts from respective Member States attending the first 50 ECCO-Peer Review Meetings



Conclusions and Outlook

For the first year of ECCO-Peer Review Meetings the European Commission had originally scheduled the review of only 18 monographs. From the very start of the ECCO-programme the expert groups immediately worked in a constructive and positive manner, even though the structure and procedures for the ECCO-Peer Review Meetings had been developed in a very short space of time. For this reason, ECCO-Peer Review Meetings for 25 instead of 18 active substances could be organised.

Experts from throughout the EU have all contributed significant input to the ECCO-Peer Review Meetings. Scientific advice was given to the European Commission which facilitated discussions in the Working Groups 'Plant Protection Products' (Evaluation) and (Legislation) and the preparation of regulatory decisions in the Standing Committee on Plant Health in Brussels.

Under the current ECCO-contract it is envisaged that two additional rounds with 26 more meetings will review further 21 active substances. If organisational and financial conditions allow, more active substances may be reviewed.

Clearly the procedures will have to be developed to allow for the Peer Review of almost 800 existing active substances yet to be reviewed and many new active substances within the given time frames. At the moment, the regulatory experiences and practices of 15 Member States with different cultures, history and geographic conditions are being amalgamated and a harmonised plant protection product regime is gradually developing which integrates the conditions and needs of all 15 Member States.

Certain ongoing developments within the EU-Member States and the European Commission as well as in the OECD Pesticide Forum (e.g. submission of data on CD-ROM, generic dossier and monograph guidelines) may help to overcome the foreseeable workload in the next years by increasing world-wide co-operation.

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Aktuelle Informationen über das ECCO-Team und die ECCO-Peer Review Meetings (Zeitpläne, Liste der behandelten Wirkstoffe, ECCO Working Documents, Statistik) sind jederzeit über die Homepage der Biologischen Bundesanstalt für Land- und Forstwirtschaft im Internet abrufbar:

Current information about the ECCO-Team and the EU-Peer Review Meetings (timetables, list of active substances discussed, ECCO Working Documents, statistics) can be obtained anytime via the Federal Biological Research Centre for Agriculture and Forestry's Internet homepage:

http://www.bba.de/ap/ap_ecco/ap_ecco.htm

Berichte aus der Biologischen Bundesanstalt für Land- und Forstwirtschaft
erscheinen seit 1995 in zwangloser Folge.

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Heft 20, 1996: Rechtliche Regelungen der Europäischen Union zur Prüfung und Zulassung von Pflanzenschutzmitteln und Wirkstoffen. (Richtlinien, Verordnungen, Entscheidungen und Protokolle), Stand: 1. September 1996. 2. Auflage. Bearbeitet von Dr. Jörg-Rainer Lundehn, 347 S.

Heft 21, 1996: Arbeitsschutz und Arbeitssicherheit im öffentlichen Dienst (Stand: August 1996). Dirk Altewein, 21 S.

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Heft 34, 1997: Europäische und nationale Regelungen für gentechnisch veränderte Organismen (GVO) (Richtlinien, Entscheidungen, Gesetze und Verordnungen) Stand: 1. Juli 1997. Dr. Günther Deml, Dr. Joachim Schiemann und Dr. Jörg Landsmann, 180 S.

Heft 35, 1997: Rechtliche Regelungen der Europäischen Union zu Pflanzenschutzmitteln und deren Wirkstoffen (Band A: Richtlinie 91/414/EWG und diesbezüglicher Protokolle) 3. Auflage, Stand: 1. November 1997. Bearbeitet von Dr. Jörg-Rainer Lundehn, 322 S.

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Heft 38, 1997: Inhaltsverzeichnis Amtliche Pflanzenschutzbestimmungen N.F. Band 1, Heft 1 bis Band 63, Heft 5. Bearbeitet von Sigrid von Norsinski, Elke Vogt-Arndt und Richard Voigt, 74 S.

Heft 39, 1998 Wirkstoffdatenblätter zur arbeitsmedizinischen Vorsorgeuntersuchung - Pflanzenschutzmittel -, 1. Folge, Stand: Dezember 1996. Bearbeitet von Dr. Hans-Hermann Schmidt, Dr. Eberhard Hoernicke, Marion Fathi, Rudolf Pfeil, 241 S.

Heft 40, 1998: Liste der zugelassenen Pflanzenschutzmittel (Stand: 1. Januar 1998). Bearbeitet von Dr. Achim Holzmann und Andreas Spinti, 69 S.

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