SESSION 8A

REGULATORY ISSUES: CURRENT PROBLEMS AND SOLUTIONS

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EUROPEAN CHALLENGES FOR PLANT BIOTECHNOLOGY

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ABSTRACT

Plant biotechnology has evolved from early concepts of how to contribute to traditional breeding to improved products, with proven feasibility.
Along with the application of biotechnology, alliance between companies engaged in plant biotechnology, the seed and agrochemical industries are consolidating, confirming the strategic importance of plant biotechnology.
The regulatory discussion has shifted from the early phases of precaution, over "familiarity" to product acceptance. Based on this shift in the debate, it is clear that as the first products are reaching the consumer, the increasing paper-trail still creates hurdles for the application of plant biotechnology in Europe.

INTRODUCTION

Since the early development of biotechnology and genetic engineering in particular, high expectations have been raised on the potential of the technology. The technological revolution was acclaimed to be so far reaching and new that along with the promises, concerns for the environment and health were indicated. Different regulatory systems evolved addressing the issues based on a precautionary approach. During the past 2 years plant biotechnology has become a reality with the first varieties resulting from genetic engineering being planted on a commercial scale by farmers. Despite a decade of discussion, many of the contributors to the agro-food chain were taken by surprise by rapid development. In this paper the author has tried to clarify some the challenges Europe is facing dealing with the scientific and public concerns while pursuing an attractive competitive position.

PLANT BIOTECHNOLOGY AS A CROP IMPROVEMENT TOOL

The seed business has evolved around identifying and capturing the value of available genetic variability. Identification is traditionally based on screening of many combinations of lines coming from diverse origins. A trait is typically recognised as a phenotype, without any knowledge of the underlying genetic mechanism or side-effects. Capturing the value takes place through genetic stabilisation of the trait and subsequent advanced schemes of seed production. The limiting factor in many developments is the increasing difficulty to discover desired traits.
With ever more sophisticated techniques e.g. somaclonal variation and mutagenesis; genetic variability has been artificially extended. However, while certainly successful, these changes are still random and do not provide an understanding of the mechanisms or potential side-effects.

The promise of plant biotechnology resides in the potential to introduce a single desired function, at the genetic level, without any need for further identification or screening. Screening shifts to screening for genetic elements, but once a genetic element has been recognised, it can be used in different crops, despite the boundaries of sexual compatibility. Based on these forecasts, biotechnologists claim to have revolutionised plant breeding making classical breeding obsolete. However, as the first products were tested, it was realised that although the function of the genes may be known, the way they are inserted into the plant has an important effect on the phenotype. Gradually, testing schemes were developed which are comparable to what is known from traditional breeding. The role of plant biotechnology is therefore now seen as an essential source of new traits, which are then incorporated through traditional breeding in optimised varieties.

The first commercial applications of biotechnology provide us with a view of the potential. For example the first herbicide tolerant varieties have created additional opportunities for weed management schemes, involving post-emergence herbicides with improved safety profiles.
In other cases, biotechnology can make treatments become more directed. This is the case when plants protect themselves against pests which are otherwise difficult to treat: e.g. the ability of Bt-corn to withstand damage by the European corn borer (*Ostrinia spp*). Finally, solutions are offered to problems that could not be solved. These range from protection against virus mediated diseases to new applications such as changes in oil composition or the production of pharmaceutical compounds in plants.

With these applications in the commercial pipe-line, the industry is establishing a realistic position for plant biotechnology as an important tool for further crop improvement.

A REGULATORY FRAMEWORK BASED ON PRECAUTION.

While the benefits of new developments are easily recognised, it may take a while before undesirable traits are discovered. In the case of genetic engineering, the scenarios of creating "new" organisms, interfering with natural selection and crossing species boundaries, evoked sufficient questions and uncertainty to warrant a careful approach. This careful approach is usually referred to as the "precautionary approach" (Brady and Gaull 1996), meaning that nothing is permitted until a certain amount of information on safety is available. For example a genetically modified plant cannot be field tested until an assessment has been made of the potential impact based on available information. When information is lacking or specific attention is warranted then certain containment measures may be required. Only after sufficient experience has been acquired can one proceed to the next level of testing, usually with less containment requirements. This balance between containment and safety provides feedback between developers, experts and regulatory authorities.

As different products were being developed, the general attitude changed from precaution to familiarity. The scientific data accumulated showed that the modified crops were very similar to existing crops so that instead of thinking in terms of "new" organisms, the genetic modified plants could be considered "familiar", as predictable. Focus was gradually shifting

to the impact both realised and potential of the introduced trait. Based on this shift, a base was created which allowed the first product to be grown on a commercial scale.

However, while the developers and authorities were reviewing the available information, the general public were hardly involved and the perception of a high risk technology still prevailed. In addition, environmentalists continued to campaign against genetic engineering. When the first products became a commercial reality, consumer associations found themselves in a difficult position translating this sophisticated technology into everyday language.

Due to this bridging of interest, a totally new type of product communication is taking form. Usually contributors to the agro-food chain are communicating with the next link in the chain, e.g. breeders are addressing farmers, farmers talk to traders, traders to processors, processors to secondary processors, processors to retailers and retailers to consumers. As previously described , biotechnology is now well established in breeding. Whilst breeders were addressing farmers on the potential impact to agriculture (e.g. how to use herbicides), suddenly the technology communication requires developers to discuss farming issues with consumers. However, the average consumer faces the difficulties of understanding the technical aspects of a product and also the lack of knowledge of farming practice.

In reviewing the recent developments within the EU regulatory system, it is clear that the emphasis is not on the technology and particularly on risk assessment. All new regulatory developments are aimed at informing those individuals and organisations on the processing chain.

EUROPE CHALLENGED

All regulatory systems are evolving from precaution to familiarity. However, the EU has adopted a special position by creating a specific regulatory framework for genetically modified organisms (GMO's). Most other countries have chosen to incorporate review procedures within existing product regulations, which allows for a better product focus. Within the EU, GMO's have been singled out as an exclusive class. Once a GMO, the product is always considered a GMO, (whereas in the USA products can be "deregulated" or in Canada they are no longer considered a "plant with a novel trait"). With this basic difference in mind, Europe is faces several challenges :

Completing a coherent regulatory framework

Council Directive 90/220 EEC (Anonymous, 1990) on the deliberate release of genetically modified organisms provided for the first EU wide framework for the development of genetically modified organisms. This Directive focuses on the environmental impact and possible human health effects of any kind of introduction in to the environment. Whilst the Directive was published in 1990, the procedures are still under development.

On May 15th of 1997, the EU Novel Food Regulation (Anonymous, 1997) came into force, replacing a scattered set of national requirements. It may take a considerable period before the procedure and data-requirements as spelled out in this regulation become clear. Aspects of novel feed are still being developed.

In contrast, the regulatory systems of competing markets are fully established (USA, Canada, Japan), are transparent and are being streamlined to allow for shorter regulatory review processes.

Agreeing on risk assessment criteria

Most regulation is triggered in response to unwanted effects. Certain rules are defined or threshold levels are agreed to avoid problems that have been previously encountered. The previous problem/hazard becomes the condition to be avoided.

However, in a precautionary approach such clear targets are absent. Broader goals are set such that no impact on the environment is likely. It is however always a relative assessment, with no clear measurements or decision points. It is actually questionable whether biotechnology is capable of creating a plant that is truly damaging beyond what exists today in nature.

However, the uncertainty over risk assessment criteria is a matter of debate between EU-Memberstates. The choice and priority of criteria differs from country to country. The European Commission have recognised this problem and an informal expert working group has been established to formulate an EU-wide acceptable risk assessment model. Despite the commitment, this working group has become involved in political issues, and technical progress is slow.

The role of the EU in biotechnology

When Mr. Delors announced the White Paper for Europe's economic future, biotechnology was recognised as a leading technology for the next century. Europe is lagging behind in many economic areas, but at least in biotechnology the requisite scientific expertise and funding are available. However, as one proceeds through the next steps of application the regulatory aspects are becoming increasingly burdensome and unpredictable, thereby discouraging investors, developers and manufacturers.

The fact that large areas are being planted with products of plant biotechnology confirm that the technology has come to maturity. These products will inevitably enter the food chain and will reach European consumers. The political arena is reacting to this "forced" consumption. However, the true debate should be on how Europe can gain a position of competitive advantage and establish itself as a leading developer of products of biotechnology.

Coping with trade implications

When the first genetically modified soyabean and corn shipments reached Europe in late 1996, international trade organisations faced problems because of delays in Europe's decision making. The processing chain and consumers were unprepared for the questions and uncertainties that arose. The fight for the basic freedom of consumer choice took precedence over any environmental and/or health issues. The European infrastructure, both regulatory and commercial was not ready to handle the targets which had been set long before. In fact, comparing the list of clearances between North-America and Europe confirms that this will not be an occasional event. Due to the deficiencies in the European regulatory process there is no simple way of ensuring that products will be cleared in a timely fashion in both continents..

The reaction so far has been the finalization of the Novel Food Regulation and further development of labelling rules. While this may apparently solve part of the deficiency, the net effect is even more worrying :

- Procedures for Novel Food authorisation are still under development. It is unlikely that a fast decision making process will result.
- The guidance on labelling may be acceptable where crops are cultivated in the EU, however it will almost certainly prove impossible for imported commodities. The North-American authorities do not agree on the necessity to segregate genetically modified products and this issue may need to be referred to a higher level e.g. The World Trade Organisation.

Creating a true information platform.

Considering the developments in Europe, the critical factors have been the lack of information and the need for transparency. Biotechnology is perceived as a new, high technological field, controlled by a few multi-national companies. Whilst both developers and authorities have been concerned with the scientific issues, particularly safety, public opinion has hardly changed on the perceived risk. The public is hardly aware of the regulatory framework and public opinion surveys show a general distrust of experts. Despite the precautions that were taken, in a difficult regulatory climate, Europe is still not in a position to make politically, sound decisions on the application of biotechnology.

On the other hand, plant biotechnology has been in the public eye since the first plant transformation. Instead of bringing the viewpoints closer, a hollow debate has resulted long before any actual product was under review.

Yet, a true information platform is the only solution to this impasse. This information needs to be multifaceted covering agriculture, the food/feed processing chain and the technological aspects. The product needs to be concisely specified and the basis for the regulatory decisions must be transparent.. Such a platform requires different industrial inputs which span the range of this new communication chain, from seed and agro-chemical companies to

consumers. Some initiatives to organise this platform are being taken by officials and industry, as the first products are being introduced.

The establishment of such an information platform, may signify a new approach where the internal standards and stewardship of the entire food industry in response to global consumer demand outpaces the development of regulatory guidelines.

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GENETICALLY MODIFIED PLANTS - THE EUROPEAN UNION REGULATORY SYSTEM

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ABSTRACT

The regulatory system in place for the deliberate release and placing on the market of genetically modified plants is described along with indications of future developments in the regulatory regime. The range of experimental releases and marketing consents is given.

INTRODUCTION

Recognising the importance of ensuring the safe development of modern biotechnology and producing a harmonised approach throughout the E.U., in 1988 the European Commission proposed two horizontal directives. The aim of these directives was to protect human health and the environment from any risks associated from activities involving genetically modified organisms.

The two Directives were Directive 90/219/EEC on the contained use of genetically modified micro-organisms and Directive 90/220/EEC on the deliberate release of genetically modified organisms (GMOs). They were adopted in April 1990 and came into force in October 1991. Directive 90/220/EEC is of most relevance to release of genetically modified plants.

LEGISLATION

Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms

This Directive harmonises the laws, regulations and administrative provisions of the Member States and protection of human health and the environment when carrying out deliberate releases of GMOs. It also regulates the placing on the market of products containing or consisting of GMOs intended for subsequent deliberate release into the environment.

This Directive does not apply to releases or products regulated under specific sectorial legislation e.g novel foods, pharmaceutical products which foresee a risk assessment similar to that described in Directive 90/220/EEC.

Research and development - deliberate releases

Before a release is undertaken a notification must be submitted to the Competent Authority designated by the Member State within whose territory the release is planned to take place.

The notification includes a technical dossier evaluating the risks likely to be posed by the release to human health and the environment. The dossier must include relevant information on the GMOs, the release and the environment exposed. Information on monitoring of the release, control measures, waste treatment and emergency response plans must also be included as appropriate.

The Competent Authority acknowledges the notification and evaluates any risks posed by the release to human health and the environment. When the Competent Authority is satisfied with the notification for the proposed release, it circulates a Summary Notification Information Format describing the release to other Member States and considers their comments. After this procedure the Competent Authority grants a consent for the release to take place.

The whole process for approval of experimental releases must be completed by the Competent Authority within 90 days of receipt of the notification.

Applications for placing on the market

Before a product containing a GMO, or combinations of GMOs, is placed on the market, a notification has to be submited to the Competent Authority of the Member State where the product is to be placed on the market for the first time. The applicant can only proceed with the marketing of the product when they have the written consent of the Competent Authority.

The notification should contain the information which is required for an experimental release and the results of previous experimental releases, if any. In addition to this, information is required on the product, manufacturer/distributor, estimated production/import, conditions and type of use with details of any instructions, labelling and packaging for the product and any measures to be taken in case of unintended release.

The Competent Authority reviews the information supplied, including the risk assessment and recommended precautions for the safe use of the product, and if in agreement, forwards the dossier to the Commission. The Competent Authority should reach an opinion within 90 days of receipt of the notification.

The Commission forwards the dossier to the other Member States which have 60 days to consider the dossier and raise any issues. If the issues cannot be resolved, and the Competent Authority of a Member State raises an objection with stated reasons, the Commission prepares a Proposal with the measures to be taken which is considered by a committee composed of representatives of the Member States and chaired by a representative of the Commission as set out in Article 21 of the Directive.

The members of the Committee vote on the Commission Proposal according to the qualified majority vote arrangements set out in the Treaty establishing the EEC and subsequent modifications thereof. There are 87 votes to be cast and at least 62 have to be in favour to obtain a vote in favour of the placing on the market of the product - the Commission does not vote in this process. If the vote is in favour, then the Commission adopts the measures as a Decision and the Member State which received the dossier from the manufacturer issues a consent in accordance with the Commission Decision. If the Committee cannot deliver an opinion, then the Commission submits the proposed measures to the Council of Ministers. The Council votes on the Commission's proposal and can either vote to adopt the Commission Proposal by qualified majority or reject the Proposal unanimously. If after a three month period the Council has not acted, the Commission adopts the proposed measures.

Under Article 16 of the Directive, Member States can restrict or prohibit a product issued with a consent, where they have justifiable reasons to believe it constitutes a risk to human health and the environment. If a Member State takes this action it must inform the Commission and the other Member States, and then a decision on the matter is taken in accordance with the procedure set out in Article 21 of the Directive.

Adaptations of the Directive to technical progress

The Directive has been twice modified to take account of technical progress. This was done in;

- Commission Decision (94/15/EC) adapting to technical progress for the first time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms; and

- Commission Decision (97/35/EC) adapting to technical progress for the second time Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms.

The adaptations to technical progress in Commission Decision (94/15/EC) amended annex II to produce an annex with questions relevant for genetically modified plants, whereas Commission Decision (97/35/EC) makes provision for a confidential register of modifications introduced into organisms and specified labelling requirements for products consisting of or containing GMOs.

Simplified procedures

The Directive foresees that when Competent Authorities have obtained sufficient experience with releases of certain GMOs, they can propose simplified procedures for releases of such types of GMOs.

There have been two Commission decisions on simplified procedures;

- Commission Decision (93/584/EEC) of 22 October 1993 establishing the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC, (O.J. L279 of 12/11/1993) and

- Commission Decision (94/730/EC) of 4 November establishing simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC.

The simplified procedures in decision 94/730/EC provided the ability for notifiers to include connected programs of work for releasing a number of genetically modified plants from the same recipient crop plant species, on a number of release sites, in one application.

Applications under Directive 90/220/EEC

Since October 1991 to June 1997 there have been over 1000 part B notifications concerning experimental releases. A breakdown of the experimental releases for plants is given in Table 1. There have been eleven consents for placing on the market issued under part C of the Directive, given in Table 2.

Review of Directive 90/220/EEC in the context of the Commission's communication on Biotechnology and the White paper.

Directive 90/220/EEC has been reviewed to determine how well it has been operating throughout the European Community. The review of the operation of Directive 90/220/EEC has identified the following weaknesses;

- insufficient clarification concerning the objectives for risk assessment, which has hindered full harmonisation between Member States at the research and development stages and which has led to disagreements between Member States at the stage of placing on the market of products;

- absence of a risk classification as well as of a link between administrative procedures and identified risk, which may result in cumbersome procedures for low risk releases;

- weak link between parts B and C of the Directive, which means that experimental releases under part B do not always provide the relevant data for the environmental assessment necessary for the placing on the market under part C;

- cumbersome administrative procedures and approval system for placing on the market of products, which have led to delays in approving products;

- absence of an active role for the Commission on a number of aspects, including the right to propose simplified procedures and to acknowledge part C dossiers and objections, which has led to delays in exploiting existing possibilities for simplification and to problems in implementing part C;

- absence of a possibility to resolve controversy through consultation of independent Scientific Committee(s), which has caused problems in implementing part C;

- absence of sufficient flexibility for technical adaptation, which prevents regular updating of the Directive to scientific and technical progress;

- absence of clear current labelling requirements which creates unease with members of the public.

Recognising the above-mentioned points and the need for a regulatory horizontal framework sufficiently flexible and specific to ensure a high level of environmental and human health safety and transparency, while facilitating the development of this important technology, the Commission intends to adopt a Proposal for an amendment of Directive 90/220/EEC in the course of 1997.

The Interplay between Regulation 258/97 on Novel Foods and Novel Food Ingredients and Directive 90/220/EEC

The Regulation came into force on the 15 May 1997, under the regulation foods and food ingredients which contain or consist of GMOs and which on the date of its entry into force have not been used for human consumption to a significant degree within the Community, may not be placed on the market in the absence of an authorisation granted under the Novel Foods Regulation.

The Commission intends to publish a guidance document detailling the interplay between Regulation 258/97 on novel foods and novel food ingredients and Directive 90/220/EEC on the deliberate release of genetically modified organisms.

Table 1. Releases involving plants

African violet	1
Alfalfa	2
Apple	1
Barley	2
Beet (including fodder- and sugar-)	151
Carnation	3
Carrot	2
Cauliflower	5
Chicory	35
Chrysanthemum	1
Cotton	8
Egg Plant	2
Eucalyptus grandis	3
European Plum	1
Grapevine	2
Lettuce	4
Maize	246
Marigold	8
Melon	8
Norway Spruce	1
Petunia	2
Poplar	7
Potato	117
Rape (including oilseed-, fodder- and swede)	220
Scotch Pine	1
Silver birch	2
Soybean	8
Squash	6
Strawberry	1
Sunflower	6
Sweet Orange	1
Thale Cress	1
Tobacco	38
Tomato	62
Wheat	9
TOTAL	**967**

Table 2. PRODUCTS APPROVED UNDER DIRECTIVE 90/220/EEC AS OF 15 JULY 1997

Product	Notifier	Date of Commission Decision
1. Vaccine against Aujeszky's disease	Vemie Veterinär Chemie GmbH	18.12.92
2. Vaccine against rabies	Rhône-Mêrieux	19.10.93
3. Tobacco tolerant to bromoxynil.	SEITA	08.06.94
4. Vaccine against Aujeszky's disease (further uses)	Vemie Veterinär Chemie GmbH	18.07.94
5. Oilseed rape resistant to glufosinate ammonium	Plant Genetic Systems	06.02.96
6. Soybeans tolerant to glyphosate	Monsanto	03.04.96
7. Male sterile chicory tolerant to glufosinate ammonium	Bejo-Zaden BV	20.05.96
8. Bt-maize tolerant to glufosinate ammonium	Ciba Geigy	23.01.97
9. Oilseed rape resistant to glufosinate ammonium	Plant Genetic Systems	06.06.97
10. Oilseed rape resistant to glufosinate ammonium	Plant Genetic Systems	06.06.97
11. Test kit to detect antibiotic residues in milk	Valio Oy	14.07.97

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THE REGISTRATION OF PLANT PROTECTION PRODUCTS AND THE IMPLEMENTATION OF THE DIRECTIVE 91/414/EEC IN PORTUGAL

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ABSTRACT

The Direcção-Geral de Protecção das Culturas (DGPC) of the Ministry of Agriculture is the competent and designated authority for the registration of plant protection products and for the implementation of Directive 91/414/EEC in Portugal. Within the DGPC, the Plant Protection Products Service (PPPS) is responsible for national and EU evaluation of plant protection products. It is a centralized service with several Specialist Teams with expertise in different areas. As a result of the implementation of Directive 91/414/EEC and Regulation EEC 3600/92, Portugal was designated rapporteur for the reevaluation of five existing active substances but, is as yet not acting as rapporteur for any new active substance although some companies have requested us to be so. However, as a result of recent recruitments we are now in a better position to be involved in the evaluation of new active substances, and to participate in ECCO and EU experts meetings. Taking into account the specific agricultural and climatic conditions of Southern Europe, we feel it is very important to improve the level of cooperation between Southern Member States in order to contribute to agronomic solutions to problems characteristic of the Southern countries.

THE REGISTRATION OF PLANT PROTECTION PRODUCTS IN PORTUGAL

The registration of plant protection products began in Portugal in 1967 with the publication of law nº 47 802 on 19th of July. Until 1994, this law was complemented with several other laws and regulations. On November 11th 1994 and on June 12th 1995 the "Decreto-Lei" nº 284/94 and the "Portaria" nº 563/95, were published and these implement Directive 91/414/EEC into Portuguese legislation.

In Portugal the competent and designated authority for the registration of the plant protection products is the Direcção-Geral de Protecção das Culturas (DGPC) which is part of the Ministry of Agriculture. Within the DGPC, the Plant Protection Products Service (PPPS) is the service responsible for the evaluation and registration of all plant protection products and prepares the decisions to be taken by the DGPC directorate.

The PPPS is organised into four Divisions:

- Registration
- Toxicology, Environment and Ecotoxicology
- Formulations and Residues
- Biological Evaluation

The Divisions are split into Specialist Teams (Figure 1). The Biological Evaluation Division includes four teams dealing with insecticides, fungicides, herbicides and growth regulators, respectively. The Formulation and Residues Division contains two teams; one dealing with the physical and chemical aspects of active substances and formulations and the other with the analysis of pesticide residues. The Toxicology, Environment and Ecotoxicology Division includes two teams; one for mammalian toxicology and the other for ecotoxicology and fate and behaviour. The Registration Division, includes a team whose responsibility is the establishment of maximum residues levels (MRL's) for pesticides in crops.

The Registration Division manages the applications, coordinates advice from Specialist Teams and prepares the decisions to be submitted to the DGPC directorate.

In the Registration Division there are two "registration bureaus" one for national and the other for EU procedures and evaluation. Each bureau is responsible for processing the dossiers, submission to the Specialist Teams, preparation of information and correspondence to firms, notifiers, national and EU Member States departments. The Registration Division also maintains the registration data base, prepares publications (lists and guidelines) to be issued and information to be exchanged between Member States and the Commission according to article 12 of Directive 91/414/EEC.

The PPPS has a staff of 75 distributed throughout the four Divisions and includes 28 graduates including Agronomists, Chemists, Biologists and Pharmacists. Each Specialist Team includes 3 or 4 graduates.

The dossiers are evaluated by the different teams according to subject. Experimental studies on biology, degradation, residues monitoring and formulation quality are also evaluated by the specialists.

The evaluation of dossiers and the authorisation of plant protection products (PPP) follows the scheme shown in Figure 2. The plant protection products containing active substances new to Portugal, are considered by a Toxicology Committee (CATPF) made up of representatives from the Ministries of Agriculture, Health and Environment. This Committee provides to the DGPC, advice on the toxicological classification of the PPP and the choice of suitable risk and safety phrases for the purpose of labelling.

For plant protection products containing existing active substances (Anon. 1996a) but which are not included in Annex I of Directive 91/414/EEC, national legislation allows a period of five years for full authorization. However the existing authorizations are all provisional, renewed annually, since some difficulties did not allow for full authorization.

Prior to 1993 there was no review programme in Portugal. However, certain plant protection products were withdrawn from the market particularly those containing DDT, mercuric compounds, aldrin, endrin, dieldrin, HCH, heptachlor, thalium sulphate, arsenic anhydride, arseniate, "Dimetilan", strychnine, sodium fluoride, chlordane, hexaclorobenzene, nitrofen or ethyl parathion.

DIRECÇÃO-GERAL DE PROTECÇÃO DAS CULTURAS

EVALUATION AND REGISTRATION OF PPP

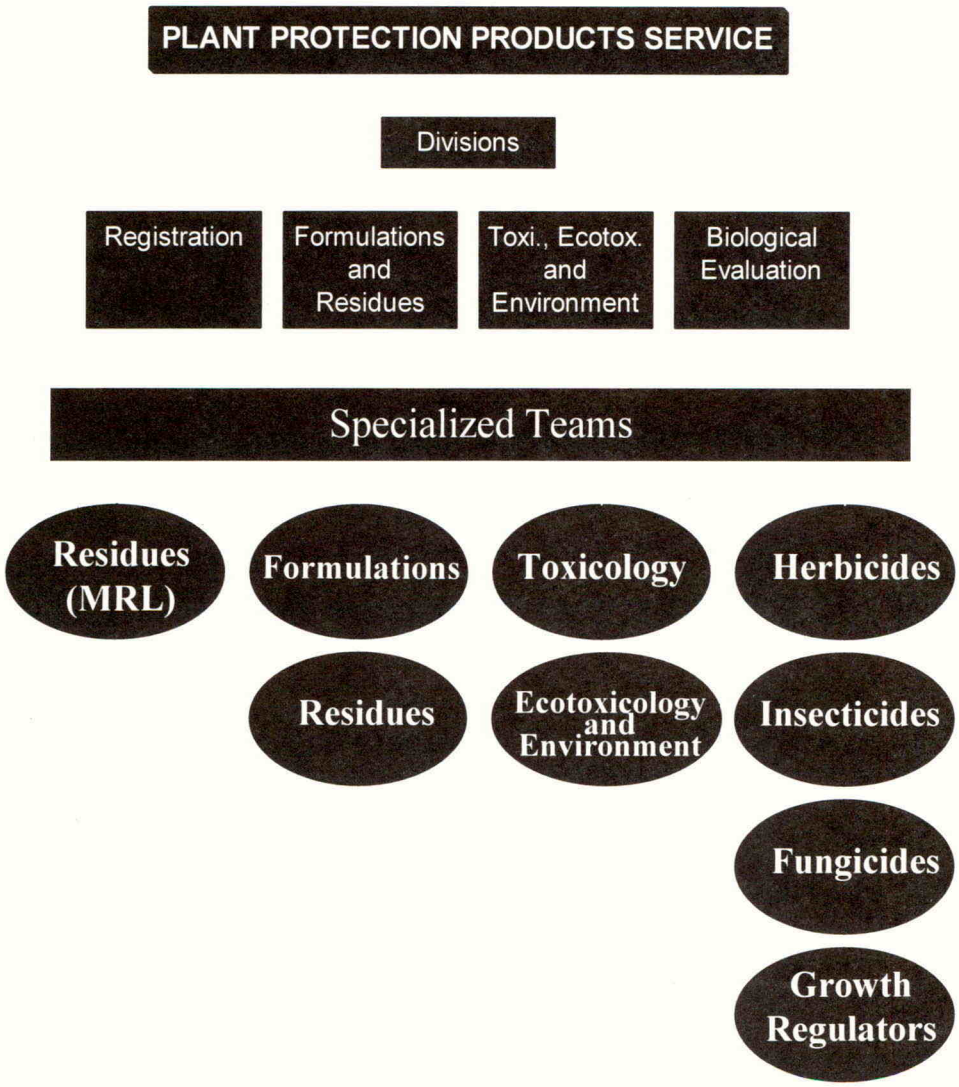

Fig. 1 - Diagram of the Plant Protection Products Service

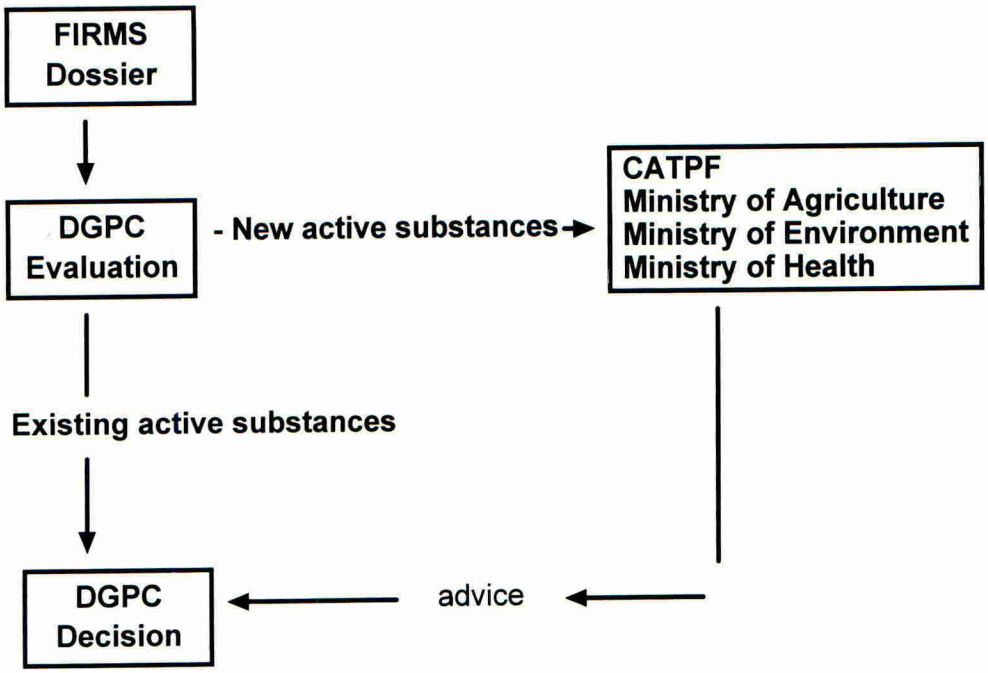

Fig. 2 - Scheme of the procedure for the registration of plant protection products in Portugal

IMPLEMENTATION OF DIRECTIVE 91/414/EEC IN PORTUGAL

The main differences between the "old" national registration regime and the "new" one, implementing Directive 91/414/EEC, are the introduction of changes in procedures for applicants; how the dossiers are organised; scientific staff organization; evaluation and decision making criteria (Uniform Principles); exchange of information between Member States and the Commission (Information System) and written reports (monographs) on the active substances.

In response to the introduction and requirements of Directive 91/414/EEC, the DGPC has taken on more staff and made organisational changes. New graduates admitted to the DGPC during 1993 and 1994 are now trained after three years of working alongside senior staff and a training programme involving visits to other countries.

Portugal have been contacted by some companies to undertake the initial examination and evaluation of dossiers for inclusion of new active substances in Annex I. However priority has been given to national evaluation and it has been a challenge for Portugal to meet its obligations to evaluate new active substances. Significant progress is being made and Portugal is now participating in the third round of ECCO meetings.

Under the first review list of Commission Regulation No. 3600/92 (Anon. 1992) Portugal was designated rapporteur for five existing active substances (benalaxyl, esfenvalerate, fenvalerate, metalaxyl and molinate). At October 1996 the draft report on esfenvalerate had been completed. The molinate report is nearing completion. Support for fenvalerate has been discontinued, the evaluation will cease and products with this active substance will be withdrawn from the EU. During 1998 draft reports on benalaxil and metalaxyl will be prepared.

The DGPC has under preparation new national guidelines for the preparation and presentation of dossiers based on the Annexes of Directive 91/414/EEC and in document 1663/VI/94 (Anon. 1996).

The introduction of new legislation, regulations and procedures means it is necessary to have urgent improvements to laboratories, to meet the requirements of good laboratory practices (GLP), as well as the increase in dossier storage capacity and improvement of information/communication systems.

SOME PORTUGUESE STATISTICS ON THE REGISTRATION AND SALES OF PLANT PROTECTION PRODUCTS

In the period 1967 to July 1997, 3307 applications for registration of plant protection products have been made to the DGPC. At July 1997, 785 authorized plant protection products, containing 231 active substances, were registered in Portugal.

Currently there are 250 applications for registration with DGPC. Forty eight of these are plant protection products containing 40 active substances new to Portugal and these includes 14 plant protection products containing eight active substances new to the EU.

Portugal covers a total of 89,060 square kilometres, and 38,799 (44%) is used for agriculture and 32,080 (36%) is occupied by forests (Ministério da Agricultura, 1995).

During 1995 sales of pesticides in Portugal amounted to 11,818 tons of active substances (77% fungicides, 14% herbicides, 6% insecticides and 3% others) (Chaby Nunes & Silva, 1996), representing an usage of approximately 3kg active substance per hectare of cultivated area.

THE PARTICIPATION OF SOUTHERN MEMBER STATES IN THE EU EVALUATION AND AUTHORIZATION PROCESS

In the Southern Member States (SMS - France (part), Greece, Italy, Portugal and Spain) agriculture is an important social and economic activity . The SMS are important producers and exporters of fruit and vegetables to Northern Europe. The agriculture of the region is characterized by specific edapho-climatic conditions, a great variety of crops and diversity of pests and diseases.

Plant protection is based on the following main principles:

. sustainable agriculture
. good agricultural practice
. reduction in the use of pesticides
. risk reduction in the use of pesticides
. use of alternative methods of control

The application of these principles is not an easy task in the SMS because of the need for frequent use of pesticides.

In Table 1 is presented the major quantity of active substance (in tons) sold per year in each Member State over the last five years (Eurostat, 1996), (Silva, in press). The data is presented separately for the Northern and Southern Member States in decreasing order. In this Table is also presented the number of votes for each EU Member State in the Standing Committee on Plant Health.

Table 2 gives the number of active substances on the market in each Member State. A total of 839 active substances are on the market in the EU. The figures are presented separately for the Northern and Southern Member States, in decreasing order.

In the reevaluation programme the five SMS were designated rapporteurs for 39 (43%) of the 90 active substances included in the first reevaluation list.

As rapporteurs for new active substances, until July 1997, companies chose the SMS for carrying out the completeness check on dossiers for 18 active substances (51%) in a total of 30 (France 11; Italy 4; Spain 2; Greece 1; Portugal 0).

The programme for the ECCO Meetings to July 1997 includes the participation of 66 (28%) experts from the SMS in a total of 234 experts from all member states.

In line with article 8 of Directive 91/414/EEC, to July 1997, in the SMS, nine (30%) provisional approvals have been granted to products with new active substances in a total of 30 authorizations in the EU (Anon. 1997).

AN APPROACH TO COOPERATION AMONGST THE SOUTHERN MEMBER STATES

The data provided shows the importance of plant protection products in the SMS, representing 75% of the total sales of active substances in the 15 Member States. Four of them (Spain, France, Greece and Italy) have most active substances registered, in the whole of the EU. However this importance is not expressed at evaluation and decision making levels. In fact at July 1997 only 28% of the experts participating in the ECCO Meetings were from the SMS and only nine of the 30 provisional approvals have been granted to SMS. At the decision level the five SMS represented 44% of the votes of the Standing Committee on Plant Health.

Table 1 - Number of votes and quantity of active substance (in tons) of plant protection products sold in each EU Member State.

	North		South	
Member State	**sales**	**votes**	**sales**	**votes**
SPAIN			111.539	8
FRANCE			103.434	10
ITALY			91.686	10
GERMANY	36.944	10		
UNITED KINGDOM	28.746	10		
NETHERLANDS	17.306	5		
PORTUGAL			11.818	5
BELGIUM	10.426	5		
GREECE			8.595	5
DENMARK	4.628	3		
AUSTRIA	4.489	4		
SWEDEN	1.961	4		
IRELAND	1.942	3		
FINLAND	1.742	3		
LUXEMBOURG	253	2		
total	**108.437**	**49**	**327.072**	**38**

% of sales	25	75
% of votes	56	44

Table 2 - Number of active substances in the market in each EU Member State by decreasing order (October 1996) (Anon. 1997)

Member State	**North**	**South**
SPAIN		542
FRANCE		537
GREECE		410
ITALY		397
IRELAND	359	
BELGIUM	348	
UNITED KINGDOM	332	
NETHERLANDS	293	
AUSTRIA	282	
PORTUGAL		258
GERMANY	233	
LUXEMBOURG	220	
DENMARK	159	
SWEDEN	133	
FINLAND	120	
Total number of active substances		**839**

The data presented emphasizes the urgent need for cooperation between the SMS in order to achieve a harmonized approach bearing in mind their characteristics, specificity and agronomic importance in the EU. Efforts must be done between SMS at administrative and private company level.

At administration level coordinated regional agreements must be developed for a uniform position in the North/South dialogue. Will, knowledge about "who is who", dialogue capacity, identification of the subjects concerned and definition of strategies are the steps to be implemented in order to reach that goal. Greater attention must be given to the improvement of the exchange of information between Member States at administrative and private levels. Coordinated programmes must be established to generate and use data in the SMS or in other regions of the world with similar agronomic and edapho-climatic conditions.

By these procedures data on efficacy, residues, fate and behaviour and ecotoxicology could be useful for the evaluation of new and old active substances namely for the establishment of MRL's, authorizations of plant protection products on minor uses, mutual recognition and other agronomical solutions considering the specificity of the agriculture of the South. A harmonized approach to the review of authorization of plant protection products, using a common Annex III dossier, after inclusion of the active substance concerned in Annex I, could also be an important area of cooperation between Southern Member States representing a great advantage for companies and national authorities.

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DIRECTIVE 91/414/EEC: RECENT PRACTICAL EXPERIENCE AND A LOOK TO THE FUTURE

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ABSTRACT

Following the adoption of the Directive by Member States, two major tasks were immediately presented. Firstly, data requirements had to be agreed to cover all specialist areas of risk assessment and new procedures had to be developed to process applications. Secondly, the review programme had to be started, the scale of which was totally underestimated. Both tasks have taken up a considerable amount of time and resources. Although much has been achieved in harmonising data requirements and even in the development of scientific decision-making, it is time to take stock of the situation and discuss options for the future.

INTRODUCTION

Pesticides regulation in the UK and elsewhere in the European Community is in a transitional period due to the implementation of Council Directive 91/414/EEC, concerning the placing of plant protection products on the market, and the proposed Biocidal Products Directive.

In the UK, Directive 91/414/EEC was implemented in 1995 by means of The Plant Protection Product Regulations (PPPR), 1995 (S1 1995, No 887), made under section 2(2) of The European Communities Act, 1972, and the accompanying Plant Protection (Fees) Regulations, 1995 (S1 1995, No 888). Two further statutory instruments have come into force: The Plant Protection Products (Amendment) Regulation (PPP(A)R), 1996 (S1 1996, No 1940) and The Plant Protection Products (Basic Conditions) Regulations (BCR), 1996 (S1 1997, No 189). The reason for these two further instruments was to formally implement the Commission Directives amending Parts A of Annexes II and III of 91/414/EEC and to enable a style of control and enforcement to be applied to plant protection products, similar to that found under the Control of Pesticides Regulations (COPR), 1986 (SI 1986, No 1510), which would allow consistent controls over the use of pesticides.

In due course legislation will be needed to implement the regulation of non-agricultural pesticides covered by the Biocidal Products Directive. For those registrations already in existence and not immediately subject to either Directive, the COPR will continue to be applied.

Blending the new legislation on Plant Protection Products into an existing well-established national framework covering all pesticide uses has been challenging and has required considerable change in the organisation of the Pesticides Safety Directorate (PSD) and to the supporting regulatory procedures involving committees and Government Departments

responsible for pesticide regulation. This change has had to be managed at the same time as developing procedures and mutual understanding in Europe.

91/414/EEC contained only skeletal information at the time of adoption. However, since that time, data requirements have been fleshed out and adopted as a number of amending Commission Directives issued between 1993 and 1996 (Table 1). In addition, guidance aimed at notifiers (Anon. 1996a) has been developed and amended several times and complementary guidance for Member States has been prepared on the preparation of monographs (Anon. 1996b). As a greater understanding of the problems facing each Member States has been reached, it has become clear that these initiatives were essential to assist in the harmonisation process. This has meant that the regulatory requirements and some of the procedures have had to be continuously amended to reflect these changes.

Table 1. Commission Directives amending 91/414/EEC

Commission Directive	Subject
93/71/EEC	Introduction and efficacy
94/37/EC	Physico-chemical properties
94/79/EC	Mammalian toxicology
95/35/EC	GLP requirements
95/36/EC	Fate and behaviour
96/12/EC	Ecotoxicology
96/46/EC	Analytical methods
96/68/EC	Residues
draft?	Parts B of Annexes II and III on micro-organisms

Alongside all of this has been the review programme. This task was never going to be easy, as the UK found from experience with its own review programme. To have asked for this task to be undertaken by 15 Member States (originally 12 when the decision was taken), all struggling to implement 91/414/EEC and with widely differing abilities and experiences of risk assessment and monograph preparation, was, to say the least, over-ambitious in scale and timing. Nevertheless, the review programme has been useful in identifying many problems in both risk assessment and regulatory procedures which needed to be resolved. One of the clear messages to emerge from discussions between Member States is that agreement is only possible after developing experience with real, live issues. Attempting to plan ahead is very difficult because of the tendency for regulators to use worst-case scenarios as if they were the most likely events and, furthermore, as if these events were likely to occur with equal frequency across all regions of Europe.

Given this tendency, those Member States with national policies to reduce the number of pesticidal products or severely restrict uses in certain areas have developed the most stringent line, which has been the case, for example, in Denmark and Sweden (Emmerman, 1996,

Jørgensen, 1996). It is only when critical GAPs are identified and a complete understanding of the likely operator and environmental impact at the time of application that the hazard can be put into perspective and the risk assessment carried out.

It is the intention of this paper to identify the changes that have occurred since the adoption of 91/414/EEC; to consider the decision-making process using experiences from the review programme; and to offer some thoughts on the future. The discussion will be confined only to the scientific and technical aspects of risk assessment and to the regulatory procedures.

THE APPROVALS PROCESS

Changing Patterns of Work

Applications for pesticide approval can be categorised under three main headings; New Substances and Reviews, which are processed through committees, and Non-Committee, which are processed through the Technical Secretariat. As an Agency, the Pesticides Safety Directorate was organised to process all three types of application and has targets set for each stream. However, work is demand-driven and the numbers of applications received under each of these categories has varied in composition and scope markedly since the adoption of the Directive. Initially the approvals work was dominated by substances new to the UK, but already on the market elsewhere in the Community, and by Technical Secretariat applications. As time progressed, the EC review programme became the dominant component, together with a change in the type of application for new substances. The latter change was expected as more applications for substances new to the Community were received. It was notable because for most of these applications the UK was not required to be rapporteur. Nevertheless a full "Evaluation" document was prepared in each case which was equivalent to a monograph. Currently, approvals work is dominated by Technical Secretariat applications and this demand is growing dramatically. The continuous change in the pattern of work has required some careful management and flexible deployment of scientific staff.

Other Member States have been faced with similar problems of shifting workloads but only the larger authorities have had the opportunity to exercise a flexible approach. For these reasons the rate of change, to adopt new procedures and be able to rapidly process the work at the same pace across the 15 Member States, has been very variable indeed. Early in the review programme many Member States requested that priority be given to new actives substances rather than work exclusively on the review compounds. Difficulties were experienced in the UK; but this problem had been foreseen and the resources organised to process all three streams. Nevertheless, new active substances were processed in a shorter time frame than some review compounds.

Re-designing Procedures

Not only has PSD had to utilise its resources flexibly to meet the changing demands, the regulatory procedures have also had to be re-designed. Whilst this change was being undertaken in readiness for the new procedures, the EC regulatory system emerged and evolved, requiring some fine tuning of the national processes. Even the implementation of the Directive into UK legislation did not take place without some difficulty and some other Member

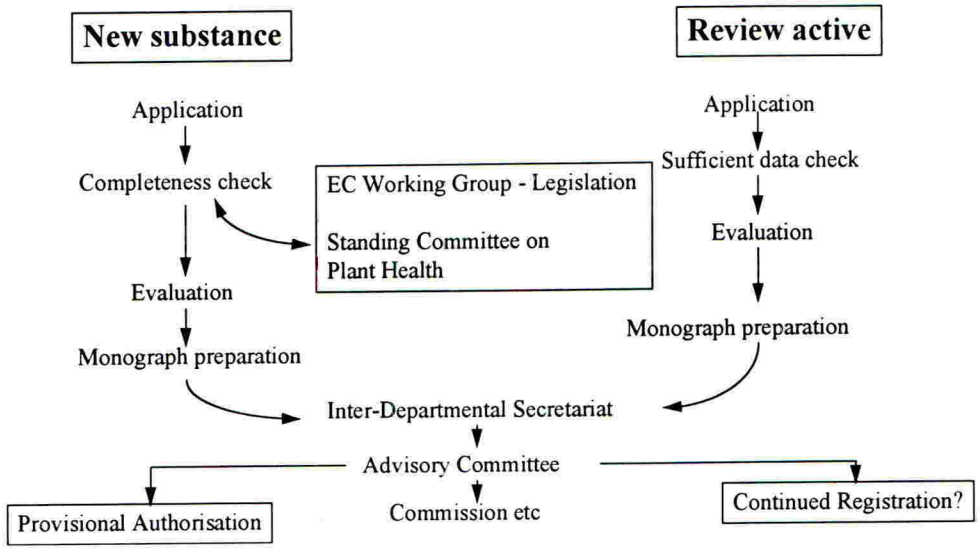
States have found similar difficulties. Indeed, such difficulties still exist for at least one Member State.

The procedures initially were straightforward and could be dealt with under COPR. As the pattern changed it was clear that the review programme would be very resource intensive and could easily have swamped the system to the detriment of other applications. The substances new to the Community brought their own problems, as Member States, including the UK, began to issue Provisional Authorisations in advance of the monographs becoming available.

National Regulatory Procedures

Implementation of the Directive has required a complete reassessment of the original procedures put in place under COPR. The most obvious change has been the recognition that, for active substances new to the Community and those under the review programme, the final stage of the approval process, granting a product approval, cannot take place until the active substance has been included in Annex I. Therefore, although the Advisory Committee on Pesticides continues to evaluate data, provide scientific advice and recommend regulatory action, it now also advises on the UK line to take in subsequent working group discussions and to advise Ministers on the suitability for Provisional Authorisation under Article 8.2 in the case of new substances. The new procedures for dealing with full dossiers through the Committees is presented in diagrammatic form in Figure 1.

Figure 1. UK Regulatory Procedures



With the increased in-house scientific expertise in PSD, the need for the original Sub-Committee on Pesticides (SCP) diminished and in the interests of efficiency it was wound up. Involving the other Government Departments much earlier in the registration process then became a priority and to meet this important need, a new Committee, known as the Inter-Departmental Secretariat

(IDS), was set up. All of these changes had to be implemented without adversely affecting targets.

Other Member States have had to re-organise their regulatory procedures to bring them into line with the requirements of the Directive and, indeed, to implement the Directive.

One new experience has been the need to seek agreement from the 15 Member States on dossier completeness (Article 6.3). This has caused unnecessary work and has introduced a potential delay in the procedure, as many Member States have used this step in the procedure to commence an evaluation and have criticised study reports. It was never intended to carry out an evaluation at this stage. The purpose was to check that all of the data requirements had been met by the inclusion of study reports or a scientific case. To overcome this delay, several Member States, including the UK, have started the evaluation of the dossiers as soon as they satisfied themselves of completeness. Although no Provisional Authorisation could have been granted until agreement had been reached and voted upon by the Standing Committee on Plant Health, in practice, this has not proved to be a problem. The procedure would improve if there was a greater understanding of what was required at the completeness check stage.

On the other hand, the review programme does not require a completeness check to be carried out and voted upon. The rapporteur is required to assess the situation and report to the Commission that there are sufficient data for an evaluation to be carried out. This, of course, has brought its own problems at the expert working group stage of assessment with so many data gaps being identified. If the same stringent check had been employed with the reviews as with the new substances, there would not have been any review dossiers evaluated.

Another difficulty emerged with the preparation of monographs. Many Member States had not had experience of preparing written reports or summaries to support their regulatory decisions. As a result, there has been a sharp learning curve for all participants to include all relevant data and present hazard and exposure data in a format that can be used by other Member States for their own risk assessment. This has been as equally challenging to the UK who are perhaps quite used to drafting reports for the ACP to evaluate and estimating exposure using mathematical models and, for example, UK wildlife species as examples. Of course, it was recognised that such scenarios might not be appropriate elsewhere in Europe. Furthermore, there has been a tendency, perhaps, to play down some studies if they represented a scientific thinking which was opposed by the evaluator.

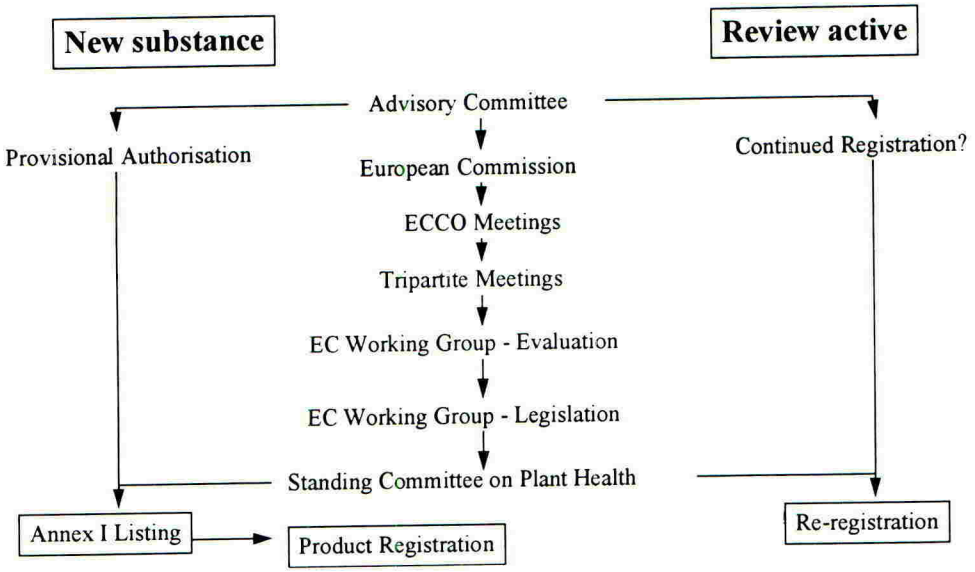
The diagram in Figure 1 has not included any reference to the Technical Secretariat work which, currently, is continuing its work under COPR. No product registrations can be granted under PPPR until active substances are included in Annex I. No consideration of mutual recognition or re-registration of products containing active substances from the review programme has been possible yet. However, PSD has expressed a view on how this would be achieved in the future (Anon. 1996c, 1996d, 1997).

European Regulatory Procedures

The procedures following those carried out at national level have been dictated almost entirely by the review programme. This was inevitable as the first monographs received were on review compounds. The structure of the European procedures is given in Figure 2. It was quite clear

that there had to be a peer review of the monographs to check on consistency and scientific quality. A programme of expert groups were set up, known as ECCO (EC CO-ordination) meetings, and have been jointly organised by the UK and Germany under a contract from the EC. Up to seven Member States meet to discuss each scientific specialism and give an opinion on the risk assessment.

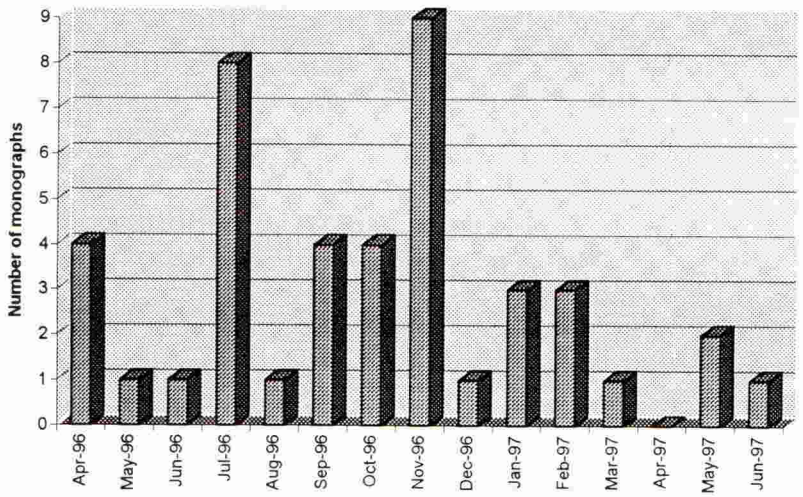
Figure 2. European Regulatory Procedures



The rate of development has depended largely on the rate of receipt of draft monographs from Member States and on the range of regulatory problems that have been identified. The ECCO meetings were set up and began the task of assessing the early batch of monographs received. At the time of preparing this paper, 43 monographs have been received (7 new active substances and 36 review compounds) with the greatest number being submitted during the last quarter of 1996 (see Fig. 3)

It was clear from the outset that although the ECCO meetings were successful, there needed to be a wider discussion with all Member States before considering any regulatory proposal. Also, as most of the monographs had been prepared on review compounds with many data gaps, it became clear that the rapporteur would need to discuss the proposed decisions with the notifier before formulating regulatory decisions. Initially, a Tripartite meeting was proposed between the rapporteur, the notifier and the Commission (DG VI) to satisfy this requirement. In future, this will almost certainly be reduced to a bilateral meeting between the rapporteur and the notifier and will take place at the end of the specialist discussions during the ECCO round of meetings.

Figure 3. Number of monographs received by the European Commission



Opening the discussions to the full 15 Member States at the Working Group on Evaluation has the effect of opening the scientific debate from first principles. So there has been a tendency to replicate effort. This has been to some extent inevitable, as Member States with different philosophies and experience exchange views on risk assessment within a scientific understanding still undergoing development. This highlights one problem in that agreement is not always achieved when there are doubts over the science. Debate over the acceptable degree of risk will continue whilst the science supporting the arguments continues to evolve.

The Working Group on Legislation looks at the wider implications and prepares the draft Directives or Regulations for the Standing Committee on Plant Health to consider and vote upon. At this level of European debate, the discussion is very similar to that which occurs in the UK at the ACP and Departmental agreement stage of regulatory affairs. The aim is to distil the science, prepared at the ECCO meetings and agreed at the Working Group on Evaluation, and propose regulatory decisions. The main discussion centres on the restrictions or conditions to be included in the listing on Annex I.

The next stage of the process will depend more on the individual Member States and their ability to implement the relevant parts of 91/414/EEC and their willingness to accept scientific evaluation and regulatory decisions carried out by another Member State.

EXPERIENCE AT THE ECCO MEETINGS

These meetings have been a tremendous success. They have allowed each Member States to build up expertise to the same level in each of the scientific specialisms and has allowed the experts to meet and exchange views on specific and general scientific topics. It is only through such meetings that the necessary regulatory experience will be gained. The scientific principles

behind the experimentation are generally agreed by all participants and as such the study reports are all evaluated in a similar manner. At present there is some variation in the format and content of the monograph but this should become more harmonised with time and experience. The main differences of opinion emerge over the interpretation of the data and the significance of the findings. This is not a new phenomenon and will occur whenever a number of experts meet. The challenge is to find common ground and propose a text that will be acceptable to all.

To understand the problem facing the participants at these meetings it has to be recognised that each Member State may have developed a different philosophy to operator, consumer and environmental safety. Therefore, the supporting legislation may also differ markedly. Interpretation of data in some cases may be difficult if it puts the expert in a position that would be difficult to defend. Of course, it could be said that the purpose of the ECCO meetings is not to discuss matters related to policy. However, it is often very difficult to propose restrictions, for example, without some reference to overall policy.

The absence of agreed decision-making schemes which can be used in all regions has made a consensus very difficult to achieve. Although the data requirements and the original Uniform Principles gave general guidance over some of the key trigger values identifying the next tier of study requirements, differences of opinion still occur. These differences together with the tendency to adopt a worst-case scenario as if it was the most likely event, has resulted in a very stringent line taken in some cases. This often expresses itself in the need for further data usually from the next tier of studies. So a tendency is developing for higher tier studies to be required as a part of the core data set.

Further data requirements are inevitable with any application. However, the greatest difficulty has been identifying whether the requirements fall under Annex II or III. If they are the latter, the requirement can be carried out at the Member State level. Similarly restrictions are often regionally related but it has been difficult to arrive at a consensus when some Member States have clearly been opposed to some uses.

It has to be said that the notifiers have often made the task of evaluating the data very difficult indeed by not providing all of the core data and by submitting data on usage in such a confused and complex state that it has been impossible to define what uses are critical. This applies to the review programme chemicals more than the new active substances. Nevertheless, it is the review compounds that have defined the principle procedures to be adopted and are influencing opinion.

It is clear that compounds persistent in the soil are being scrutinised very carefully indeed and unless there is a full characterisation of the degradation products made with a full assessment of the fate and distribution of the compounds in the environment, the regulatory decision will be made with very severe restrictions. The consequences of a persistent substance or degradation product will be to require biological data in one or more environmental compartments. Data might be required in aquatic and terrestrial species and consideration of dietary uptake also might be needed.

One procedural point to emerge which will need some careful management has been the inevitable decisions that seem to be emanating from each of the specialist meetings which in isolation may not be the most appropriate in the overall regulatory decision. Also depending on

which Member States have attended, there might not be a set of proposals necessarily relevant to all regions of Europe. Hopefully these issues will be sorted out at the final meeting of the chairmen of each of the specialist meetings. Further progress with each application will rely heavily of the rapporteur to arrange the bilateral meetings required to develop a timetable for the generation of further data or to decide whether the notifier will continue with the support for the registration.

LOOKING AHEAD

Two main problems still exist. They are the review programme and the lack of progress over agreement at the stage of Annex I listing. At the time of writing this paper the Community is exactly half way through the time-table adopted in the Directive to complete the review of all existing active substances. Clearly this objective cannot be met without some further consideration of how to prioritise further work or to amend the Directive. It is essential to start to discuss the way ahead at high level throughout the Community as soon as possible and not wait until it is too late.

The difficulties experienced at the Expert Working Group on Legislation over the drafting of the proposed Directive listing an individual active substance on Annex I will also need careful consideration in the future. Some Member states have difficulties with the acceptance of some compounds which have already been banned from use. If an unrestricted listing is made in Annex I, under Article 10 on mutual recognition it would be possible to seek a market use in those countries which do not want to accept a registration. For this reason. worst case scenarios have been used in the risk assessment and very stringent restrictions on use have been proposed to prevent such uses being listed. In developing the arguments there has been a tendency for the more developed Northern authorities to ignore uses in the Southern States which could continue without risk.

The expectations from the Agrochemical Industry were that the system would have dramatically improved, allowing them access to markets in many Member States. The stark reality has been that even for the larger, well-organised regulatory authorities such as PSD, there have been difficulties implementing the legislation and changing procedures to meet new requirements. For those Member States without a well-structured regulatory authority, it has been impossible to keep up with the timetable.

It has always been recognised that the system would only work well once sufficient experience had been gained by all Member States working together. Through the exchanges of views at both scientific and policy levels, mutual trust would emerge. However, this takes time which, in terms of the original Directive, is now running out. In future it has to be recognised that the science has not been developed sufficiently for unequivocal decisions to be made. They will have to be judged on the most appropriate risk management techniques available in each Member State. It has to be understood that decisions have to be made now regarding the registration of active substances in the absence of a complete scientific understanding. This will need scientific judgement which may vary across Europe. It also has to be recognised that public perception and expectation will probably play a big part in the future. The enlargement of the Community and the work of DG XXIV will almost certainly influence the future direction and operation of 91/414/EEC.

Experience with the evaluation of new substances compare with review compounds has shown that complete and modern dossiers are much easier to evaluate and interpret. The review programme has been made much more difficult because of multiple data holders. In many cases the uses across Europe varied between countries. This made the identification of critical GAPs impossible. Without these, the evaluation of the rest of the dossier could not be completed. Whatever criticisms have been levelled at the authorities over the time taken to implement 91/414/EEC and to improve procedures, the quality of the regulatory outcome has been directly proportional to the quality of the data submitted.

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