SESSION 3A

REGISTRATION OF PLANT PROTECTION PRODUCTS IN EUROPE: EMERGING ISSUES

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Revision of Directive 91/414

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ABSTRACT

In the European Union, plant protection products and the active substances that they contain are regulated under Council Directive 91/414/EEC. The Directive has been implemented in the Member States over the past 10 years. During this time the review of existing active substances and the evaluation of new active substances has progressed successfully via effective co-operation between the European Commission, the Member States and individual notifier companies. There is still much work to do to complete the review programme. Experience gained in implementing the provisions of Directive 91/414 has demonstrated that a number of changes are required to reflect current requirements and to clarify certain areas in order to better harmonise the operation of the regulatory system for plant protection products. This paper summarises the current progress with the EU review of existing active substances and provides an indication of some of the proposals that are being considered for a revised Directive.

INTRODUCTION

Council Directive 91/414/EEC of 15 July 1991 (EEC, 1991) concerning the placing of plant protection products on the market was required to be implemented by Member States from 26 July 1993. The main elements of the Directive are as follows:

- To harmonise the overall arrangements for the authorisation of plant protection products within the European Union (EU). This to be achieved firstly by harmonising the process for considering the acceptability of active substances at a European Community level in respect to environment and health. Secondly, even though individual product authorisation remains the responsibility of individual Member States, by establishing harmonised risk assessment criteria for Member States to use when considering the safety of those products;
- The Directive provides for the establishment of a positive list (Annex I) of active substances which have been shown to be acceptable in terms of risk to people or the environment;
- Member States are only permitted to authorise the marketing and use of plant protection products where the active substances are listed in Annex I, except where transitional arrangements apply;
- The Directive provides for a series of transitional arrangements and derogations until 25 July 2003, that have since been extended, to allow for the progressive re-evaluation of those active substances already on the market in the EU on 25 July 1993 (the "existing active substances");
- The Directive also makes provision for a system of mutual recognition, such that following the listing of an active substance on Annex I of the Directive, Member States are obliged to grant authorisations (on request) on the basis of those granted in other

Member States; subject to comparability of the agricultural, plant health and environmental conditions in the two Member States.

Ten years has now elapsed since the implementation of the Directive. During this period, Member States have worked hard in co-operation with the Commission to undertake the huge amount of work required in order to fulfil the requirements set out in the Directive.

In particular, and after a relatively slow start, the programme for the review of all of the existing active substances was firmly established. Much was learnt from the work done on those active substances included in the first stage of the review programme and this has had a direct bearing on how the subsequent stages have been handled.

During this time the various Annexes to the Directive have also been developed together with a wide range of guidance documents to enable Member States to apply common standards in conducting risk assessments.

At an early stage in the implementation of the Directive, it was acknowledged that there were particular issues which were causing difficulty for Member States and that at some point it was inevitable that there would be a need to revise the Directive. This would need to take account of changing circumstances, not least the need to reflect the extension of the timetable for the completion of the review programme until the end of 2008; the establishment of the role of the European Food Safety Authority (EFSA) and the fact that the EU was being enlarged to include a further 10 New Member States in May 2004.

ORGANISATION OF THE EU REVIEW PROGRAMME

Article 8.2 of the Directive provides the basis for the establishment of the review of existing active substances via the adoption of specific regulation. A total of 865 active substances have been identified as being on the market on that date. A progressive programme for dealing with the review of active substances has been established with a series of regulations that implement the four stages of the programme as follows:

- Stage 1 - Regulation 3600/92 (EEC, 1992);
- Stage 2 - Regulations 451/2000 (EC, 2000);
- Stage 3 - Regulations 1490/2002 (EC, 2002);
- Stage 4 – Regulation 1112/2002 (EC, 2002a).

In addition a number of Commission Decisions have been published extending the periods of authorisation for products based on existing active substances to enable the completion of the review beyond the original deadline of 25 July 2003.

The procedures under which the successive stages of the programme have been managed have been refined and consolidated to take account of the experience gained along the way, in order to stand a chance of completing the work in a timely manner. The overall procedures are similar for all stages. This involves the initial expression of interest in supporting an active substance by a notifier, followed by submission of a dossier conforming to the data requirements (Annexes II and III) of the Directive. A rapporteur Member State then conducts an evaluation of the data submitted in the dossier producing a Draft Assessment Report (also known as draft monograph). The Draft Assessment Report is then considered via a technical

peer review process in which other Member States jointly review the outcome of the evaluation conducted by the rapporteur and to identify any outstanding issues and confirm outstanding data requirements. Following peer review, the evaluation is discussed in a European Commission Working Group – Evaluation, at which all Member States have an opportunity to consider whether all the outstanding issues have been satisfactorily addressed. On some occasions either the peer review or Evaluation Group may refer a particular scientific issue to the Scientific Committee (now Scientific Panel) for an expert opinion before reaching a final judgement. Once scientific issues have been resolved the active substance is considered in the Working Group - Legislation where the Commission will seek views on a proposal for inclusion in Annex I of the Directive, or not, as appropriate. A vote based on qualified majority will then be taken by the Standing Committee on Food Chain and Animal Health (SCFA). The outcome of the vote is then reflected in a Decision adopted and then published by the European Commission in the Official Journal.

The current status of the review of existing active substances is given in Table 1.

Table 1. Summary of current progress with the European Commission review of existing active substances on the market on 25 July 1993

Stage	No. of substances	Supported awaiting decision	Inclusion in Annex I	Non-inclusion in Annex I
1	90	34	32	24
2	148	52	-	96
3	389	151	-	238
4	238	148	-	90
Total	865	385	32	448

Stage 1

All draft assessment reports have been received and the peer review procedure is almost completed. So far a total of 32 decisions have been taken for inclusion, 24 for non-inclusion. All decisions on the Stage 1 active substances will be completed by the end of 2005.

Stage 2

A total of 148 substances were included in the regulation establishing the procedure. Complete dossiers were received for 52 substances. Draft Assessment Reports are due to be delivered to the European Food Safety Authority (EFSA) during 2003 and early 2004. The peer review procedure will in future be managed by EFSA, with scientific opinions on the substances being put to the Commission in 2004/05 for consideration with the Member States for inclusion (or withdrawal). It is expected that decisions on all Stage 2 active substances will be completed by the end of 2005.

Stage 3

A total of 389 active substances were identified under Stage 3, with a total of 151 active substances notified as being supported. Notifiers were required to submit lists of the data

supporting their dossiers to rapporteur Member States in May 2003. The submission of the dossiers is to be handled in two tranches with 71 active substance dossiers due to be submitted to the rapporteur Member States in November 2003 and the remaining 80 in November 2004. It is expected that decisions on all Stage 3 active substances will be completed by the end of 2008.

Stage 4

The active substances included in the final stage of the review programme consists of a range of different compounds used for a variety of purposes, and includes:

- Micro-organisms;
- Substances authorised in human foodstuffs or animal feeding stuffs;
- Plant extracts;
- Animal products;
- Attractants/repellents/traps or dispensers;
- Rodenticides;
- Substances used on stored plants or stored plant products;
- Specified commodity chemicals.

Following a notification procedure in 2002-3, a decision for non-inclusion of 90 active substances was published in July 2003. Notifications for 148 active substances have been accepted, with the period for their evaluation extended to December 2008.

A separate paper in the proceedings to this congress provides more details of how notifications for 4th stage have been handled to date.

NEW ACTIVE SUBSTANCES

A total of 94 new active substance dossiers have been received for consideration under the Directive, comprising 85 chemical substances and 9 micro-organisms. There are currently 51 dossiers under consideration. Decisions on inclusion and non-inclusion on Annex I have been taken for 43 and 2 active substances respectively.

AMENDMENTS TO DIRECTIVE 91/414 TO EXTEND TRANSITIONAL MEASURES

The Directive has now been in force for just over 10 years. The fact that the review of existing active substances has taken longer than the period allowed for completion has required that the transitional measures allowed for in Article 8.2 have had to be extended. In the case of the remaining decisions for Stage 1 and for decisions for Stage 2 of the EU review the extension has been granted until December 2005. And for Stages 3 and 4 the extension has been granted until December 2008. The Directive has therefore had to be amended by way of Standing Committee Decision and the introduction of new Commission Regulations; transitional measures still apply for those active substances still to be assessed for Annex I inclusion and will continue to do so pending completion of EU review programme.

THE PROCESS TO AMEND DIRECTIVE 91/414

Ten years of experience of implementing the provisions of the Directive have demonstrated certain shortcomings in both its scope and transparency. In addition various other developments on a political level have reinforced the need to take a fresh look at how the Directive operates. Furthermore, May 2004 sees the enlargement of the EU to include an additional 10 Member States. It therefore makes sense to introduce a proposal for revision at a time when these countries are able to make a contribution to the development of proposals.

By way of preparation for producing a proposal for the amendment of the Directive the European Commission held a wide-ranging stakeholder workshop in Corfu in July 2002 involving a broad cross-section of stakeholders, including regulatory authorities, industry, grower and industry trade associations, consultants and non-governmental organisations.

The outcome of the workshop identified various key issues which the Commission has been using as the basis for preparing a draft proposal. At the time of preparation of this paper the proposal is still in the form of an internal Commission document and has yet to be made more widely available. This is largely due to the fact that there are a number of unresolved political issues under consideration within the Commission services that have to be addressed before a draft proposal can be circulated.

It is envisaged that a stakeholder consultation will take place in October 2003. In the light of comments received from the consultation exercise the proposal will be amended as appropriate and then submitted for inter-service consultation within the European Commission, with a view to the possible adoption of the proposal towards the end of 2003.

MAIN ELEMENTS OF PROPOSAL

Political issues

Centralised evaluation of products and decision making

The enlargement of the European Union in May 2004 to include an additional 10 Member States raises the prospect that work post-Annex I listing of active substances will be duplicated many times. It is already clear that the current 15 Member States are facing a massive task in handling product re-registration in accordance with Annex III data requirements and uniform principles (Annex VI). (See paper on Re-registration elsewhere in this session).

In order to address this situation the Commission has made a proposal to establish some form of centralised body that would act to co-ordinate the registration process at the product level post-Annex I listing. Member States have been asked to offer their opinions on the establishment of such a body and to suggest what form it might take. A centralised product-evaluation body (with subsequent centralised or decentralised decisions) may also provide an easier route for applicants to obtain mutual recognition of authorisations within the EU (see below). In addition such a centralised body would improve the consistency of decision making.

Data protection

Data protection is mainly an issue for Member States and industry at the product authorisation stage. Representations have been made to the Commission from all sides expressing their own particular views on how data protection should be applied. The Commission acknowledges that this is an area where an acceptable solution must be devised. It is proposed that there should be a system of compulsory data sharing in respect of vertebrate studies, which could also be extended to other areas.

Obtaining a satisfactory solution would help eliminate the current problems which Member States have in determining whether approval holders have the necessary access to protected studies following Annex I listing of existing active substances.

Finance

Following new rules that entered into force in 2003, there is currently no legal basis to allow the Commission to spend money to enter into contracts or to otherwise fund work in support of the further development of the Directive. This would include work such as the commissioning of studies, preparation of guidance documents, review of problem areas and the like. This situation will be addressed in the proposal.

Technical issues

Scope

It is proposed that the scope of the Directive will be extended to include safeners and synergists. In addition scope will also extend to include co-formulants, however it is expected that this will be done via a negative listing proposal.

Technical guidance documents

At present guidance documents are simply adopted by Member States, they have no legal status. It is proposed that these will in future become Annexes to the Directive and be legally binding upon Member States. This will help to avoid the situation in which Member States make their own interpretations of whether, how and when particular guidance should be applied. This has sometimes lead to unfruitful discussion at Working Group level and delayed decision taking. The status of guidance documents has also been an issue for a number of the countries due to join the EU in 2004 in terms of how they frame their plant protection product regulations in order to conform with the Directive.

Comparative assessment

The principles of comparative assessment and the substitution principle are already in place in the Biocidal Products Directive. The application of these principles was discussed at the Corfu meeting, where comparison at the product level commanded most support. Sweden has successfully operated a system of comparative assessment of products for a number of years and this may provide a useful model for other Member States to adopt.

Mutual Recognition

Mutual Recognition in accordance with Article 10 of the Directive is one of the main planks of a harmonised system at the product level. If operated effectively it has the potential to provide many benefits to growers and the agricultural industry and to reduce the amount of work required to be done by the regulatory authorities in the Member States. Until now Mutual Recognition has been of limited applicability due to the relatively low numbers of active substances listed on Annex I and the reluctance of industry (for various reasons) to request that Member States apply it. However it is clear that there are certain political and technical impediments to the operation of a successful system of mutual recognition. Not least of which is the desire on the part of Member States to maintain the right to conduct a full evaluation of product approval in accordance with their own agricultural, climatic and geographical situations and to refuse approval of certain products.

Discussion in Corfu raised the possibility that some form of zonal or regional Mutual Recognition might find favour with the majority of Member States. This proposal has been examined further in an Expert Meeting hosted by Germany and Member States have been asked to provide comments to the Commission in September.

Role of the European Food Safety Authority (EFSA)

EFSA is responsible for managing the peer review of the Draft Assessment Reports produced following evaluation of the dossiers from the 2nd stage of the review programme onwards and providing a report to the Commission on whether on active substance should be included on Annex I or not. In addition EFSA will have a similar role in respect of the procedures for new active substances. The revisions to the Directive will need to take account of the separation of risk assessment from risk management and the respective roles of EFSA and the Commission in the revised procedure.

CONCLUSION

The size of the task defined in Directive 91/414 must not be underestimated, and the amount of progress that has been achieved is a credit to the stakeholders involved. Progress was particularly difficult during the early years because the Directive was incomplete at the time of adoption and it is only subsequently that Annexes II, II, IV, V and VI have been established. In addition guidance documents have been developed over time to clarify the way in which particular technical issues should be approached. Other frustrations and stumbling blocks encountered have had to be resolved in discussions between those involved. It is important that a revised Directive should consolidate the excellent work done so far, however it is clear that certain aspects of the implementation of the Directive could be greatly improved by better defining the procedures required to put in place a more harmonised approach. This is particularly the case in the areas of data protection and mutual recognition.

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Re-registration of plant protection products in Europe

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ABSTRACT

With the implementation of Council Directive 91/414/EEC, a two stage regulatory system was introduced for the evaluation and authorisation of both active substances and plant protection products. Active substances are assessed for acceptability at the Community level, while the safety and efficacy of products and uses are evaluated at the Member State level at re-registration. Until recently the main focus has been on the effort needed to take decisions on inclusion or non-inclusion on Annex I of the Directive, but consideration also needs to be given to the amount of work now falling to the Member States after Annex I inclusion.
For the older active substances being considered under the review programme, only a limited number of uses are being considered as the basis for Annex I inclusion. This means that the consideration of the safety and efficacy of all the remaining uses being supported is being put back to the Member States at re-registration, with substantial workloads envisaged and plenty of scope for duplication of effort.
An expert group has been commissioned to look at the possibilities for harmonisation of deadlines and procedures post-Annex I inclusion, to facilitate the sharing of the workloads envisaged. This will also involve looking at the possibilities for increasing the uptake of mutual recognition as a route for approval.

INTRODUCTION

Council Directive 91/414/EEC, concerning the placing on the market of plant protection products, was adopted in July 1991 and entered into force on 25 July 1993 (EEC Council, 1991). This provided the framework for a harmonised European regulatory system for the evaluation and authorisation of plant protection products and the active substances contained in them.

A two-stage registration process has been established through the Directive, with the consideration of the acceptability of active substances being done at community level while the authorisation of specific products and uses is dealt with by the individual Member States. Thus, Annex I to the Directive, the list of active substances deemed acceptable and which may be included in pesticide products for use in the community, has become the prime focus of the European regulatory system.

In order to demonstrate acceptable uses in terms of risks to users, consumers and the environment, a considerable amount of data must be provided by the manufacturer. The data requirements relating to active substances and plant protection products are specified in

Annexes II and III of the Directive respectively, and relate to six discrete areas of the risk assessment; physical and chemical properties, environmental fate and behaviour, ecotoxicology, mammalian toxicology, residues and (Annex III only) efficacy.

The registration process, at least in terms of the consideration of active substances for Annex I inclusion, has been standardised. In general terms, a dossier containing the data referred to above is submitted by the applicant/notifier to support the inclusion of an active substance in Annex I. These data are then evaluated by a single *rapporteur* Member State on behalf of the others and a draft assessment report (previously referred to as the draft 'monograph') is prepared. The draft assessment report summarises the evaluation of the data and includes a proposal for a decision in relation to Annex I inclusion. This is then submitted to the European Commission, where the evaluation is further considered by the Commission and all 15 Member States prior to a decision on Annex I inclusion, or not, being taken by the Commission.

In the same way that the regulatory procedures relating to the assessment of active substances needed to be harmonised at Community level, so too did the decision making processes relating to the assessment of safety and efficacy of products at the national level. The basic criteria for conducting risk assessments for plant protection products are established by way of Article VI of the Directive, which sets out the so-called 'uniform principles' for the assessment of the acceptability of products. The details of the uniform principles were published in Directive 97/57/EC (EC Council, 1997). The authorisation of products at Member State level is known as re-registration.

The Directive applies to both new and existing active substances, the latter being defined as those that were already on the market as of 25 July 1993, the date of the entry into force of the Directive. The basic principle behind the Directive is that products should not be authorised unless they have been assessed against the standards laid down in Annexes II, III and VI. It was clear, however, that thousands of products containing over 800 active substances had already been authorised in the different Member States. In order that these, too, should meet the requirements of the new standards defined in the Directive, provision was made for the re-assessment of all those active substances via a structured programme of re-evaluation.

Article 8.2 of the Directive provides a derogation that allows Member States to continue to regulate products containing existing active substances in accordance with existing national legislation for a period of ten years from the date of the Directive coming into force, i.e. until 25 July 2003. During this period, a review programme was to be established for the re-assessment of the existing active substances. The original plan was to publish annual lists of active substances for review and the first review regulation, Regulation 3600/92, listed the first 90 active substances to be reviewed and detailed the procedure to be followed (EEC Commission, 1992).

This procedure involved an organised work programme, with a single *rapporteur* Member State being assigned for each active substance to undertake the evaluation of the dossier on behalf of all the other Member States and the European Commission. The data supplied in the dossiers for the first list substances included information relating to all authorised uses of the active substance across the Community and data to demonstrate the safety of all those uses.

Progress with the evaluation and decision making for the first list of actives for review was not as rapid as originally anticipated. This is hardly surprising given the diverse range of regulatory systems in place across Europe at the time of the adoption of the Directive, and the complexity of the risk assessment for pesticides. Six years elapsed before the first positive decision relating to Annex I inclusion was taken, with a total of 60 decisions relating to Annex I inclusion or non-inclusion for active substances on the first list having been taken to date.

It was clear that urgent measures were required in order to get the programme back on track and a new approach was adopted with the second review Regulation. Regulation 451/2000, which came into force on 1 March 2000, was split into two parts (EC Commission, 2000). The first part provided details of the second list of 148 active substances for review, and the deadlines and procedures to be adopted. The second part of the Regulation initiated the review of all the remaining active substances on the market in the third phase of the review programme, setting a deadline for commitments to support the active substances in future reviews. For both the second list and the third phase of the programme, the Regulation made it clear that all active substances not supported would be withdrawn from the market by 25 July 2003.

Due to the slow progress with the review, the timeframe for completion of the programme has been extended past the original ten-year period specified. The review as a whole is to be completed by the end of 2008, but decisions on the first and second list substances are to be taken by the end of 2005.

Other radical changes introduced under Regulation 451/2000 included limiting evaluation for Annex I inclusion to a small range of uses, supported by available data. It was clear that a large number of the uses included in the dossiers for active substances on the first list were not actually supported by data, such that decisions on their acceptability could not be made. For one of the first list active substances, 28 uses were covered in the dossier but only two of those were eventually considered with regard to Annex I inclusion. It was agreed, therefore, that limiting the assessment to only those uses actually supported by available data would expedite the decision making process. All the remaining uses would be evaluated for safety and efficacy during re-registration at the Member State level.

Whilst possibly facilitating the decision making process, this change in emphasis for the review programme will lead to substantially increased workloads for the individual Member States at re-registration. With all the remaining uses not considered in relation to Annex I potentially being evaluated by all 15 Member States at the same time, there is clearly considerable scope for duplication of effort.

THE RE-REGISTRATION PROCESS

Once a decision is taken to include an active substance in Annex I, the including Directive requires that relevant authorisations are granted, withdrawn or varied in accordance with the Directive within a prescribed period. For existing active substances, this marks the transition between national and Community rules. In Great Britain, this equates to an approval under the Control of Pesticides Regulations 1986 being superseded by an approval under the Plant Protection Products Regulations 1995 (UK, 1986, 1995).

There are two key steps in the process. The first, Step 1, is to meet conditions of the Annex I inclusion, in terms of the technical specification of the active substance and any restrictions required, and to demonstrate access to a complete Annex II dossier. The second, Step 2, involves the submission and assessment of a full Annex III (product) data package in accordance with Annex VI of the Directive, the Uniform Principles.

Associated with these two key steps are three key dates:
i) The 'entry into force' date specified in the Directive.
ii) The 'compliance deadline' or 'bringing into force' date, by which Member States are required to have completed Step 1, the compliance check and, where necessary, to have amended or withdrawn existing authorisations. This is usually six months after the first 'entry into force' date.
iii) The 'final deadline' for amending or withdrawing national authorisations as a result of the full, Step 2 assessment. This is usually four years after the first 'entry into force' date.

RE-REGISTRATION IN PRACTICE

With only limited experience of the re-registration process to date, it is clear that the move to a more de-centralised process for the authorisation of plant protection products is leading to different decisions in different Member States. To date, only 13 active substances have been through the Step 1 compliance check stage, and only one has been through the complete re-registration process. Although similar submissions were received by the different Member States, the conclusions drawn have varied.

Step 1 – compliance checking

Although the three key dates are specified in the including Directives, the internal deadlines for submissions set by the Member States can differ. For the Step 1 compliance check, many Member States set a deadline for submission of the required information of the date of entry into force of the Directive, allowing a full six months for the assessment of the submission. Other Member States, however, set later deadlines for the submission of the required information, allowing less time for the evaluation and checking of compliance.

The level of checking for compliance also differs between the Member States, with some conducting a very limited check of the information provided, leaving the full detailed assessment to the Step 2 evaluation. Other Member States, however, are conducting detailed evaluations of the information provided, checking that the data provided match the regulatory end-points established during the review.

Data protection is afforded to new Annex II data used in the risk assessment to support specific regulatory end-points. The most complicated aspect of the compliance check is the assessment of whether or not the applicant has demonstrated access to a complete Annex II data package. This can be done through either the provision of letters of access to the original submission evaluated for Annex I inclusion, or the provision of an equivalent data package. Where a data package is provided, it can consist of newly generated studies or references to older studies that are claimed to be equivalent to those from the original applicant that have received data protection as a result of the review. It is often a matter of scientific judgement whether the cited studies are equivalent or not.

Furthermore, all Member States are conducting the same assessment within the same six-month period, sometimes reaching different conclusions on the same submissions for the reasons given above.

Step 2 – full re-registration

With only a limited range of representative uses being considered for Annex I inclusion, the workloads facing the Member States in terms of the assessment of the safety and efficacy of all the remaining uses on the label has increased dramatically.

Different deadlines are applied in different Member States for the receipt of the full Annex III submissions, again allowing different periods of time for the assessments. The shorter the time for the assessment, the greater the risk that it will not be completed by the final deadline, at which point all national approvals must be revoked regardless of whether a new authorisation under Directive 91/414/EEC has been issued.

A further problem is that there is no standard format for Annex III submissions, or for the report of the assessment conducted by the Member States. This is in contrast to the pre-Annex I active substance evaluation process, where standard formats for company dossiers and Member States draft assessment reports have been developed.

The extent to which the risk assessment already undertaken with respect to Annex I inclusion of the active substance varies between the Member States, with some relying totally on the original assessment while others require further data / models to address national issues. The potential for the requirement for further data post-Annex I inclusion will only be compounded by the fact that only a limited range of uses are considered for Annex I inclusion.

The risk assessment for plant protection products is extremely complex and continually evolving, and several guidance documents have recently been developed in an attempt to further harmonise procedures. Whilst these documents have resulted in significant improvements in the standards of the risk assessments, it is clear that there are still differences in interpretation of the guidelines. Newly identified areas of concern are also being addressed in different ways in the Member States, pending the development of guidance documents in these areas.

POSSIBILITIES FOR IMPROVEMENT

An organised programme of work-sharing exists for the active substance assessments pre-Annex I, with a *rapporteur* Member State undertaking the assessment on behalf of the Community. Similar procedures must be adopted for the post-Annex I re-registration assessments, in order to reduce the duplication of effort and increase consistency in decisions. The European Commission has established an expert working group to consider the issues and develop proposals for a more harmonised procedure.

Step 1 – compliance checking

Following each inclusion in Annex I, a common six-month period is specified for the Member States to undertake the compliance checks for products approved in their countries. It is

likely, therefore, that many (if not all) Member States will be conducting the same assessment at the same time.

It is proposed that the *rapporteur* Member State undertakes the compliance check on behalf of all Member States, particularly in view of the knowledge and experience of the active substance gained from the original risk assessment undertaken in relation to Annex I inclusion. This should be possible at least for checking compliance of the active substances, ensuring the technical material is within the specification considered for Annex I inclusion. Assessment of the access to an Annex II package may be more difficult, as justifications for non-provision of data may be Member State specific, but the possibility for doing this should be examined.

A standard submission deadline of the date of entry into force could be adopted by all Member States to simplify the procedure. A standard format for the report of the compliance check should also be developed, to increase transparency and facilitate the acceptance of the opinion of the *rapporteur* by other Member States.

Step 2 – full re-registration

Again, the adoption of a standard (latest) submission deadline, 18 months or two years prior to the final deadline, would simplify the procedure and reduce the potential for confusion and missing deadlines. It would also ensure that sufficient time was available for the full assessment. This would, of course, be the latest deadline for submission, and earlier applications for re-registration would be accepted.

Article 10 of Directive 91/414/EEC provides for a system whereby the authorisations granted in accordance with the Directive in one Member State should be accepted by other Member States, subject to the establishment of comparable conditions. This is commonly known as 'mutual recognition'. Although there is limited experience of the system to date, it is one of the fundamental principles of the Directive and must be made to work if the workloads now envisaged at re-registration are to be successfully managed.

Ideally, the *rapporteur* Member State would undertake the assessment of the Annex III dossiers for all products and uses, making the best use of the experience of the active substance gained through the original assessment. Other Member States would then mutually recognise the authorisations granted by the *rapporteur*. Given the range of climatic conditions across Europe, however, it is probably more realistic to think in terms of three Member States (North, Middle, South) performing the lead risk assessment on behalf of other countries in that region.

Individual Member States may have specific requirements to be addressed on a national basis, as in the UK. Even though the authorisation may not be simply accepted, and additional information may be required, the resource savings would still be significant as the majority of the risk assessment will not need to be repeated.

Standardised formats for the company submissions, for the re-registration evaluation reports and possibly even the authorisation documentation would facilitate the uptake of the system, making the process more transparent.

Sell-out periods for withdrawn products

Different approaches to wind-down periods or sell-out periods are being adopted in different Member States. Although the including Directives specify the compliance deadline and the final date for amending or withdrawing authorisations, what happens after that date, in terms of sell-out periods, is not prescribed and is left to the Member States to decide. Different approaches are being adopted in different countries, ranging from immediate revocation of all approvals with no withdrawal periods, to approval for use of stocks already in the supply chain only, through to continued approval for all.

This is leading to difficulties, with the Industry unsure of sell-out periods applying in different Member States. This could lead to surplus stocks being left on farms with the associated retrieval and disposal problems. It also creates an unlevel playing field for growers, with certain products /uses available to growers in certain Member States and not to others.

Adoption of a standard sell-out period could alleviate these potential problems, and a 12 month sell-out period for stocks in the supply chain from the compliance deadline or the final deadline is being considered.

CONCLUSIONS

Council Directive 91/414/EEC introduced a two-stage regulatory process for the evaluation and authorisation of plant protection products, with the active substances being considered at Community level and the products being authorised at Member State level. Over the last ten years, the main focus has been on the initial assessment of the acceptability of the active substances, although progress has been slow. A new approach, considering only a limited number of uses in relation to the assessment for Annex I inclusion, has been adopted to expedite the review programme. These changes in the review procedures now mean that more work, in terms of the evaluation of the safety and efficacy of plant protection products and their uses, is being transferred from the Community level to the individual Member States.

An organised programme of work-sharing has been established for the pre-Annex I consideration of active substances, although there are no similar measures for the evaluation of products and uses at re-registration, which will be a considerably larger task. The limited experience gained thus far in the programme has shown that, under the current arrangements, there is considerable potential for duplication of effort and for inconsistency in decision making.

Harmonisation of procedures, including submission deadlines and standardised documents, could facilitate an organised work programme for re-registration, based on the concept of mutual recognition. The expert working group established by the European Commission is considering the issues and developing a guidance document to introduce more harmonised procedures.

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Progress with resolving minor use crop protection issues in Europe

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ABSTRACT

The European Commission (EC) has recognised the need for authorised minor uses of plant protection products in both minor crops and for minor problems in major crops. The number of pesticides available for minor uses has always been limited because of the high cost of development and registration, relative to potential sales of the products. The lack of authorised crop protection products creates pest, disease and weed problems on farms, sometimes leading to illegal use, toxicological concerns and environmental pollution. In order to address the situation the EC has established an Expert Group on Minor uses. This Expert Group consists of members from UK, FR, DE, PO, BE and NL and COM. Two co-ordinators have been appointed in the Expert Group on Minor Uses: France for Southern Europe, and the Netherlands for Northern Europe. Several activities are ongoing, and one primary target is to obtain more plant protection solutions for minor crops through co-ordinating research (chemical, non-chemical and integrated control), and through better EU oriented harmonisation at ground level of the national designated authorities in the Member States. This technical work is done in close collaboration with national co-ordinators from all Member States of the EU, including all central and eastern European accession countries. The EU co-ordinators organise the work through a Technical Group. Although the Technical Group itself mainly consists of government officials, the group works closely with the farmers' organisations, plant protection industry and other stakeholders. The paper describes the approach taken and the state of the art of the progress made.

INTRODUCTION

Minor uses relate mainly to horticultural crops, that are grown on small areas, but where the produce has a high value. There are also minor uses for crops grown on large areas, and for novel crops. Markets for minor uses of plant protection products (PPP) are in general too small to recover the high costs of authorisation and therefore few uses are sought by the crop protection industry. In addition, the fact that crops tend to be high value also adds to the potential stewardship costs for approval holders, particularly where there are claims for crop damage. The cost of residue studies needed for authorisation of uses in minor edible crops is a major contributing factor to this general lack of commercial interest in authorisation. The widespread lack of authorisations/approvals creates problems with regards to crop protection situations on farms, sometimes leading to illegal use, environmental pollution and both real and perceived toxicological concerns.

At the European level the European harmonisation process and its registration requirements are aggravating this problem. It is critical that specific actions are taken to alleviate minor use problems, at both national and international levels.

NATIONAL APPROACHES

In the European Union of today we experience a range of approaches in the field of minor use authorisation and organisation, which are too complicated to describe in one paper. Some of these individual approaches are described in papers by Meijer (2003), Wise and Chapman (1997) and Pallutt and Schmidt (1996).

It is interesting to note that the awareness of the minor use problem has increased in recent years, and that national governments and the EU Commission are increasingly willing to play a more active role in finding solutions to support the minor use sector. The original approach of the strict division of tasks between crop protection industry (application for authorization), governments (granting authorization) and farming community (users) has now largely been replaced. Farmers' organisations, such as the Horticultural Development Council and the Dutch Agriculture and Horticulture Organisation (LTO) take an active role, and some Member State governments are very active in supporting stakeholders in finding and executing solutions. In addition, the European Crop Protection Association (ECPA) has stated that a more active role of industry in alleviating the minor use problem is desirable.

EXPERT GROUP ON MINOR USES

The EC has recognised the need for authorized minor uses of PPPs in both minor crops and for minor problems in major crops.

In 2002 the EC established an Expert Group on Minor Uses in order to address this situation. This Expert Group consists of members from the United Kingdom, France, Germany, Portugal, Belgium, the Netherlands and the Commission.

The terms of reference have been stated as follows:

- Oversee the EU minor uses programme.
- Oversee the work of the technical group and validate technical priorities.
- Devise criteria and principles for various aspects of the programme.
- Liase with stakeholders (ECPA, ECCA, COPA) on minor uses policy issues.
- Liaise with international organizations (OECD, EPPO) on this subject; attend international meetings and study possible co-operations (for example with US EPA) as advisers for the Commission.
- Make proposals and reports of their activities to the Working Group (Legislation) and the Commission.

Efforts are directed towards obtaining more plant protection solutions for minor crops through co-ordinating research and through better EU oriented harmonisation at ground level between the national designated authorities in the Member States. Co-operation with stakeholders such as the farmer's organisation COPA, the industrial organisations ECPA and ECCA, and other stakeholders is seen as essential in obtaining success. It is considered that the Expert Group

will obtain practical ideas for the improvement of the Directive 91/414 through their exposure to the many practical minor use problems.

TECHNICAL GROUP

The newly established Technical Group is crucial to co-ordination at the EU level. This group consists of two EU co-ordinators (from France and the Netherlands) plus national co-ordinators from all participating Member States.

Terms of reference

The terms of reference for the Technical Group have been stated as follows:

- Co-ordinate Member State residues trials programmes to reduce overlaps;
- Consider proposals for co-ordinated research, potentially involving EU funding;
- Monitor progress on the development of alternatives to the essential uses;
- Develop ideas for necessary harmonisation at ground / national level in authorisation processes;
- Liase with the major companies to encourage support for minor uses;
- To report to the Expert Group on Minor Uses.

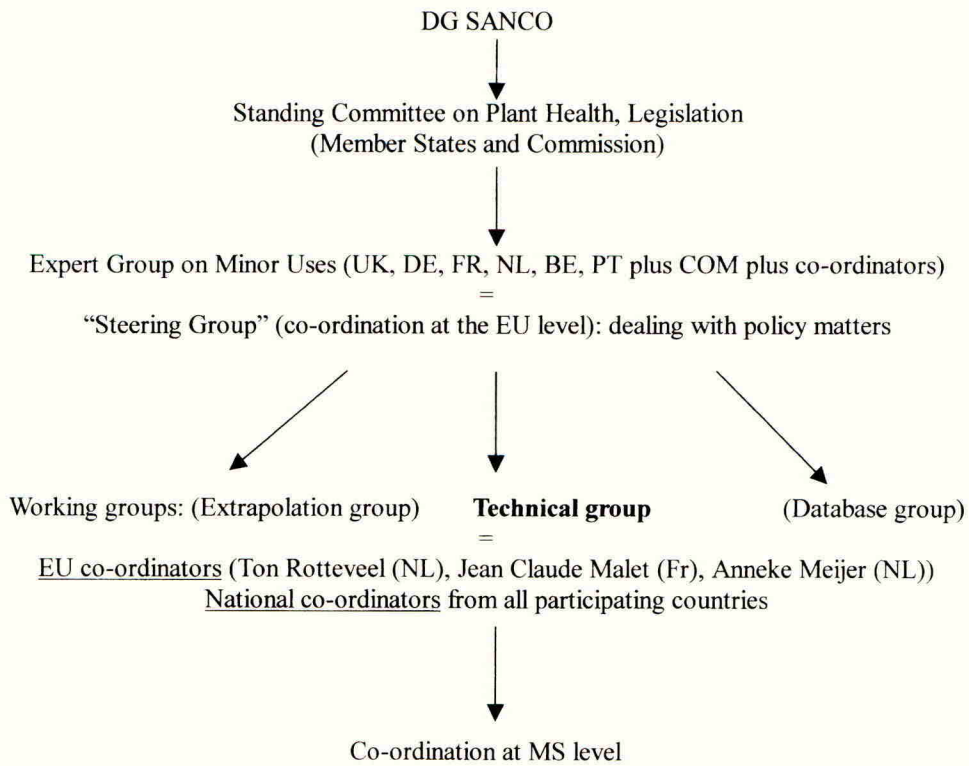

Figure 1. Place of the technical group within the EU-structure

The Technical Group on minor uses is the "workhorse" of the Expert Group on Minor Uses and faces the task of securing a great number of extensions of authorisations of Plant Protection Products in the European Union.

Current structure and activities

The Technical Group operates in two sub-groups: one for Southern Europe, co-ordinated by France (Jean Claude Malet: e-mail jean-claude.malet@agriculture.gouv.fr), which consists of the southern European zone as delimited in the Residue Directive: southern France, Spain, Portugal, Italy, Greece and the accession states; Slovenia, Malta, Cyprus, and Hungary.

The Northern subgroup is co-ordinated by the Netherlands and consists of Austria, Belgium, Denmark, Finland, Germany, Ireland, Luxembourg, the Netherlands, Sweden, United Kingdom and the accession states; Estonia, Czech Republic, Latvia, Lithuania, Poland and Slovakia.

In order to keep processes in North and South from diverging, and to improve co-ordination, the co-ordinators participate in each other's meetings and develop common procedures for co-ordination. In the future the co-ordinators will also be responsible for the co-ordination of an extrapolation group (residue data and efficacy) and a database group. These additional areas are considered central to future prioritisation of work and are both urgently required, but unfortunately in both cases the funding, which is critical to establishing procedures, has not been obtained to date.

The principal function of the Technical Groups is to facilitate and stimulate co-ordination and co-operation. Individual Member States are too small to secure minor use authorisations on the wide range of crops and problems on a stand-alone basis. Economy forces them to co-operate in obtaining the necessary data for authorisation, which is for the larger part residue data. The Technical Group will help to identify relevant information and the right partners where research is needed. It is considered that provided bureaucratic and national legal hurdles are removed, the process of Mutual Recognition will be an essential component of Minor Use authorisations in the European Union of the future. Authorisations will almost always be in the form of extensions of use, and by the process of extrapolation from the dossier, which has been prepared in support of approvals on major crops, although it is accepted that for individual crops residues data may be required.

In many cases it might be two states co-operating on a use, which has been identified as being mutually important. Such co-operation has already been established between the United Kingdom and Germany. They established successful co-operation some years ago, which has contributed to the start of the Expert Group on Minor Uses.

Interestingly in this case it is a government institution in Germany (the Biologische BundesAnstalt, BBA) co-operating with the grower funded Horticultural Development Council in the UK. This proves that such private/official co-operation can work well.

Sharing of information and sharing of data is a key success factor for the Technical Group. Before co-operation can begin, it is critical that each Member State can identify what approvals or authorisations of interest to their own country, exist elsewhere in Europe. The network of national co-ordinators in the Technical Group can provide this information. More

difficult is the sharing of data. Obtaining data is expensive and the use of data is therefore not usually free, which is logical. On the other hand however, exchange of data on different crops between interested parties can be used rather than payment towards the original cost of data generation. This approach has the benefit of increasing the range of approvals for crops in both participating countries. It is a task of the Technical Group to facilitate as much data sharing as possible. It should be clear to all participants in the process that all partners should also bring in their own data to be shared.

Gap determination

All Member States have their gaps for crop protection situations; such gaps do not refer to good agricultural practice here but to missing authorisations for crop protection situations. The French call this an empty use and the Germans call it "Lücke". The Technical Group is currently conducting an exercise to provide an inventory of priority gaps in each Member State. This exercise is important because these priority gaps will be the focus of central co-ordination efforts and also the centre of co-operation with industry where any new chemistry promises to fill the gap. Industry (agrochemical manufacturers) has expressed its interest in European minor use gap priority setting. In this way the Technical Group have already prioritised fly problems in vegetables and fruits as a critical gap for the EU, and are actively seeking solutions with an industry partner.

Example: the fly problem in vegetable and fruit crops

Within the Expert Group on Minor Uses one of the projects for the six participating Member States was to prepare a "five wishes list" with their major minor use gaps (= ranked combinations of crop and pest or disease problems) for which no, or very few solutions exist. In comparing these lists the Technical Group found that most countries have a fly problem in vegetables/fruits and all countries mentioned the same active substance as a potential solution for this problem. The group agreed on handling this common problem first as a pilot project.
The next step was to approach the approval holder of this active substance. This company was prepared to give a presentation during the Technical Group meeting in March 2003 on the possibilities of this active substance for the control of fruit and vegetable flies in the EU. All non-governmental delegates participating in this meeting were asked to leave the meeting during this agenda point. The meeting discussed the confidential information presented and concluded that one of the ways forward is through co-operation with companies.

The company was interested in need analysis and in creation of a uniform data package suitable to all MS. It was made clear where the company was going to apply for which authorisation and for which cases there was scope for authorisation but no company action to be expected. This is the situation where the co-ordinators of the Member States have the possibility of jointly developing an additional data package for these minor use fields. In order to make exchange of information easier the co-ordinators are developing formats to present information in the Technical Group meetings.

Confidentiality issues

In many cases the Technical Group will deal with confidential information concerning (intended) dossiers for the authorisation of plant protection products. This requires a

guaranteed level of confidentiality, which is obtained through the Technical Group comprising of civil servants only, and the signing of a declaration of confidentiality.

However, wherever necessary, others will be invited to the Technical Group meetings for specific agenda points, e.g. industry representatives discussing their own active substances.

Selection criteria for issues

Criteria have been identified for the evaluation of proposed research plans and co-operation. These criteria will be used for future European co-ordination of research aimed at obtaining extensions of authorisations for minor uses. The following have been identified:

- The use is meant for more than 1 Member State.
- The (new or old) active substance has an authorization in the relevant North/South EU zone.
- The (old) active substance has been notified.
- The owner agrees to the intended extension of use, and intends to keep the formulation of the active substance needed for the intended minor use on the market.
- Concerning uses in food crops: an accepted MRL exists in at least one relevant crop, and sufficient space in the ADI is available.
- The intended extension of use replaces an "EU essential use".
- Generated data will be freely shared among Member States.
- Sufficient indication of efficacy exists.
- The use is necessary for reasons of agricultural efficiency (economic prevention of loss of quantity and/or quality) and/or necessary for the continuation or development of integrated crop protection in the relevant crop.
- The use allows resistance risk management absence of which would otherwise endanger the sustainable use of an existing integrated crop protection in the relevant crop.

Non-chemical solutions

Pesticide products for minor uses are needed because there is a problem in crop protection. If alternative solutions can be identified in order that the problem may be solved effectively and efficiently without the application of a plant protection product (for example using Integrated Pest Management Techniques), then that would be equally helpful. The Technical Group will also evaluate the possibilities for the development and application of non-chemical crop protection solutions in minor crops.

DATABASE OF USES IN ALL MEMBER STATES

The co-ordinators have concluded that there is a considerable need for a database, which includes approvals for all Member States. It has been decided that the national database held by France provides a good basis for this development. Plans are in place to translate the database into English, and at the same time expand it with the uses from all Member States during the co-ordination process.

RESIDUES DATABASE PROJECT

Currently there is an initiative established by HDC in the UK to establish a database indicating where residues data have already been generated in support of pesticide products on minor crops. Efforts are ongoing to expand this databank for use across Europe, although currently only Germany and UK have provided data to populate the database. Belgium has now agreed to participate. This database urgently requires European funding to enable widespread expansion. In the short term it is considered that this database will include reference to residues data only, but in the longer term the intention is that details of efficacy and crop safety trials should be included.

Already Germany and the UK have identified areas of duplication, where both countries have generated residues data for the same use. In addition, the HDC have found that by using the database, it has been possible to fill minor use gaps by requesting access to trial reports from Germany, and using these residues data to support approvals in the UK.

It is considered that the use of such a database could save considerable time, funds and reduce duplication of effort and that it would be a most useful tool in the EU co-ordination process for minor uses.

EXTRAPOLATION PROJECT

Authorisation of minor uses almost always depends on the extrapolation of data from other uses. In the most positive case this will lead to the possibility of granting authorisation without the need for new (and expensive) data. A European extrapolation system does exist for residue work, and at the various national levels extrapolation rules exist for efficacy.

However, there seems to be scope for more extrapolation possibilities with residue work, and there is certainly a need to couple residue extrapolation to efficacy extrapolation. Such a system would show clearly which crops should be used to conduct research, in order to obtain the maximum from a MRL setting point of view. In future the European Food Safety Authority will be the only MRL setting authority, with Member States no longer able to set National MRLs, and it is certain that many old, existing uses will not stand up to the new system. This will cause many new gaps or empty uses, and will again create a great need for additional research, and a risk of future illegal use. A proposal to set all MRLs at a level of 0.01mg/kg (where not supported by data) on 1 January 2005 is currently being discussed within the EU, and it is considered that potentially some crops could no longer be produced within the EU because of a lack of authorisations or approvals. If this proposal is implemented within its proposed time frame, there will be insufficient time for approval holders and interested parties to generate additional residues data to support the minor uses sector.

CONCLUSIONS

The creation of the Expert Group on Minor Uses and its Technical Groups is a step forward towards achieving proper solutions for minor use problems in Europe and towards practical harmonisation of plant protection product authorisation. Key factors to its success will be the

constructive co-operation between all parties concerned: European Commission, governments, crop protection industry, research institutions and farming industry.

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The UK perspective on comparative assessment

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ABSTRACT

The question of introducing comparative assessment for pesticides is being addressed in the revision of Council Directive 91/414/EEC which governs the European pesticides authorisation system. This paper outlines current UK thinking on taking comparative assessment and substitution on board in the registration process either at the active substance level or the pesticide product level. Two alternative approaches are also considered, first to adopt a semi-regulatory system requiring farmers and growers to select lower risk products, and second to provide more information to farmers enabling them to make an assessment at the point of selection for use.

INTRODUCTION

Pesticide regulation is a very complicated business. Typically now 200 studies and 50,000 pages of data are reviewed in the evaluation of a new active substance. The object of this complex process is to establish that the substance meets the standards of Directive 91/414/EEC (EEC Council, 1991) which require that it should have "no unacceptable effect" on human health or the environment. What is "unacceptable" is a matter for scientific and political judgement. But at any point in time there is a standard against which all active substances and products are judged.

This means that new pesticides or older pesticides undergoing review must meet the safety standard if they are to be approved. However, beyond this there are commercial drivers of efficacy and cost. Once authorised a product will succeed in the market if it works better and is cheaper than its rivals. But what about safety? This should also be a driver. Comparative assessment aims to meet this objective.

COMPARATIVE ASSESSMENT

What do we mean by comparative assessment of pesticides? In essence it is the comparison of any two active substances or products against certain criteria, such as health or environmental effects, and the substitution of the higher risk substance or product. How comparative assessment should operate is still very much a matter for debate. To be worthwhile, any proposed scheme should:

- have sufficient impact on patterns of use to justify the administrative effort involved;
- be transparent to the pesticide industry and others, and be defensible in law;
- be reasonably simple for those involved to use;

- be compatible with the European (EU) regulatory system;
- be sufficiently flexible to cater for products continuously entering and leaving the market;
- encourage innovation and development of safer products.

AMENDING DIRECTIVE 91/414/EEC

Comparative assessment is not part of the current Directive 91/414/EEC. Both the European Parliament and the Council have debated the possibility of the introduction of comparative assessment into the Directive. This was in the context of the report that the Commission published in 2001 on the operation of Directive 91/414/EEC during the previous 10 years. The Parliament was quite clear that they wanted to see comparative assessment become part of the revised Directive. The Council's conclusions were less clear cut but they did call on the Commission to study the issue and this process is now in train. Three key questions need to be addressed:

- At what level should the comparisons be made?
- How should comparisons be made?
- What happens to substituted substances or products?

At what level should comparisons be made?

The two-tier nature of the EU authorisation system makes this a fundamental issue in the design of the future regulatory framework. First, comparative assessment could operate at the active substance level, as it will for biocidal products. However, whether the system of comparative assessment in the Biocidal Products Directive (98/8/EC) (European Parliament and EC Council, 1998) is the right one for plant protection products is a matter for debate. For biocidal products, active substances will be compared, but with the proviso that substitution can only occur within the same product type. There are 23 such product types, such as 'wood preservative' or 'film preservative', thus breaking down the area of use under consideration to a reasonably manageable scale.

Comparative assessment at the active substance level fits best with the structure of Directive 91/414/EEC. In negotiating terms this is the most likely development to succeed since the precedent has been established in EU law. The approach would be relatively simple to operate and would apply to all member states. However, unlike biocides, an active substance within the scope of Directive 91/414/EEC will normally have uses on a wide range of crops. There is unlikely to be a complete overlap of uses of any two active substances given the wide variety of uses of most. We can after all only substitute like for like. So the risk of this approach is that its practical impact would be marginal. Taking account only of major uses could have a significant impact on the pesticide armoury available for minor crops.

Second, the approach could operate at the product level. The current practice in Sweden, which is the main "working model" for comparative assessment, is to compare products rather than active substances. The philosophy behind the Swedish system is essentially that hazard/risk cannot be quantified in absolute terms but that the hazard or risk posed by different products can be ranked. The Swedish system operates around cut-off criteria, which constitute a traffic light system. Products with similar uses are ranked using key end points, such as mobility in soil. Substitution only operates in the amber zone and generally only

towards the top end of this zone. The Swedes estimate that only about 10-15% of withdrawals under their review programme were due to substitution. The rest occurred for commercial reasons or because the product was in the red zone and hence unacceptable. Comparison at the product level greatly reduces the overlap problem. Products have fewer uses and comparison and substitution become simpler and more likely to bite. It would be more meaningful in terms of product and use details. It would also allow for special circumstances which may justify using a product that carried a higher risk - such as special provisions for minor uses, or a need to prevent resistance, or for use in Integrated Pest Management.

In addition to these difficulties, there is the hazard versus risk argument. When comparing active substances, the intrinsic properties of the substances can be compared. But if products are compared, application rate, formulation type and other properties which determine risk can be factored in. A more reliable comparison can be made. Hence it appears that the technical arguments favour comparison at the product level. But this approach does not sit so comfortably within the EU two-tier authorisation system. The acceptability of active substances is decided at EU level and the acceptability of products by member states. Directive 91/414/EEC is designed to bring about something approaching a "common market" in plant protection products. If comparative assessment is applied on products at member state level it might act against this objective.

How should comparisons be made?

The second question is how should the comparison be made? Each active substance or product will exhibit different risks to humans and to different components of the environment. Which of the two substances or products is safer may therefore not be clear-cut. So we need clear criteria as a basis for comparisons which are capable of being defended against legal challenge.

What happens to substituted substances or products?

A further question must be what happens to substituted substances or products? For obvious reasons the crop protection industry is nervous about these potential developments. They fear that the operation of comparative assessment could lead to the loss of important substances in which they have invested a great deal of money, because of the chance emergence of a safer substance soon afterwards. We have to recognise that this is a reasonable concern. It may be that substituted substances should enjoy a longer phase out period than those which are removed because they are not commercially supported. We must remember that these substituted substances would be fully supported by data and have been judged acceptable by the system. They are just less acceptable than others.

It seems likely that comparative assessment will be introduced in the registration process for pesticides - the question is how? We need a system that is simple but fair. Regulators should have the powers to discourage less favourable products from remaining on the market. There should also be the flexibility for regulators to enable products to remain on the market for a limited period when no alternatives are available. However we must recognise that comparative assessment of pesticides is a complex issue and are watching the practical implementation of the Biocidal Products Directive with interest.

Comparison of active substances already operates to a limited extent via the "essential use" provision in Directive 91/414/EEC. This allows member states to seek derogations for a limited range of crops if an active substance is unsupported or fails to gain Annex I inclusion. In support of an application for essential use, the member state must submit a dossier including evidence of research programmes and financial support for the development of alternative control measures. One way forward might be to develop a more formal mechanism for encouraging the authorisation of safer alternatives to replace withdrawn active substances and products. Linked to this we could consider a range of EU-wide incentives to stimulate the innovation and development of such alternatives.

IMPACT ON FARMERS AND GROWERS

The review of existing active substances is central to Directive 91/414/EEC. This review programme is resulting in the withdrawal of many of the older, generally higher-risk products that are not being supported for commercial as well as safety reasons. The review programme will have a significant impact on agriculture. The impact will be most severe in the horticultural sector because the relatively small area of individual horticultural crops sometimes does not justify the investment required to support the substance. A projection of the current review trends forwards to 2008 (the planned completion date for the review) suggests that only about 50% of the 420 or so supported active substances will survive the review programme. Although we anticipate continuing developments in integrated crop management, the bulk of the EU's 130 billion Euro per year crop production industry will only be supported by a relatively small number of active substances. Farmers and growers are concerned that the introduction of comparative assessment and substitution into the regulatory process could lead to a further reduction in product diversity.

SEMI-REGULATORY APPROACH

Rather than taking comparative assessment on board in the registration process, a semi-regulatory approach could be adopted, such as some form of grading scheme requiring farmers to select the lower risk products in most situations. This approach could be based around differential labelling that would inform the farmers' decision-making process when choosing a product for a particular application. The system might operate similarly to the UK's current COSHH (Control of Substances Hazardous to Health) Regulations. Under these Regulations, those who use hazardous substances are required to conduct an assessment of all risks to health before starting work. They are then required to record the assessment and review it regularly.

To investigate this approach further, the Pesticides Safety Directorate (PSD) carried out a comparative assessment of the environmental risk for the use of several products and two crop/pest combinations using the University of Hertfordshire's "pesticide Environment Management for Agriculture" (pEMA) software (Table 1). The comparison was based on pEMA scores for birds, mammals, honeybees, non-target arthropods, aquatic life and earthworms. The pEMA system assesses the risk at a field and farm level using appropriate toxicity and exposure data. The products were graded as A, B or C depending on their overall score. Aggregate scores in the range 0 to -20 are classified as good practice. Scores in the range -21 to -60 should alert the user to review their pesticide strategy. "Safer" products could

be available or practices could be modified to improve the overall performance. Scores below -60 indicate a serious problem with choice of product or practices. From the assessment, seven products were classified in category A, five in category B and two products were graded in the higher risk group C. However, it is important to emphasise that this was an exploratory study and that much more work needs to be done to develop robust systems.

Table 1. Comparative assessment of environmental risk using pEMA scores

Crop (pest)	Product (active substance)	Overall pEMA score	Proposed grade based on pEMA score
Cereals (powdery mildew)	'Product i' (epoxiconazole)	-7	A
	'Product ii' (quinoxyfen)	-18	A
	'Product iii' (prochloraz)	-32	B
Potatoes (blight)	'Product iv' (chlorothalonil)	-43	B
	'Product v' (fentin hydroxide)	-62	C
	'Product vi' (maneb)	-48	B
	'Product vii' (dimethomorph + mancozeb)	-3 + -16	A
	'Product viii' (zoxamide + mancozeb)	-14 + -23	B

There are some good scientific arguments for this semi-regulatory model. It would offer a risk-based approach, which could take into account product and use details and the intended site of application. Higher risk products need not be substituted entirely, but could be reserved for situations in which there was no alternative. However, there are also practical arguments against the approach. In particular, the need for record keeping would make the approach potentially bureaucratic and it would be difficult to enforce. It would also be very difficult to apply such an approach evenly across member states. Some might apply it vigorously and others less so.

However, we may find that a semi-regulatory approach to comparative assessment has an important role to play on an EU-wide basis. One application might be in achieving the reduction in use of priority substances required under the Water Framework Directive. Products could be graded, for example A, B or C as described above, in accordance with key environmental end-points. National authorities could then advise on the use of these products as appropriate in local River Basin Management Plans.

MORE INFORMATION FOR FARMERS AND GROWERS

A third option could be to encourage schemes that will make more information available to farmers and growers to make an assessment at the point of selection for use. This option

would offer the same advantages as the semi-regulatory model, in that it would be a meaningful risk-based approach, encompassing product and use details and site of application. However, as with the previous option, the impact of this approach may be limited.

However, there is no reason why this approach should not operate in addition, rather than as an alternative, to a regulatory scheme. As part of the "Voluntary Initiative" an industry led UK initiative which aims to deliver environmental benefits over and above a pesticide tax, companies are developing "Environmental Information Sheets" to provide a basis on which farmers and growers can take locally based decisions on product choice. Another key element of the Voluntary Initiative is a commitment from farmers and growers to draw up a "crop protection management plan" (CPMP). A CPMP must address the farm's crop protection policy, detail water protection measures taken, indicate a commitment to improve competency and consider how the direct and indirect impact of pesticide products on non-target species can be mitigated. Those farmers who took part in a pilot programme in 2002 on drawing up a CPMP felt it helped them manage the use of pesticides on their farm better. More generally there are advisory software packages which allow farmers to compare their environmental performance in pesticide use with "best practice". So, in summary, initiatives in this area provide useful support to what might be called the "comparative assessment approach".

CONCLUSION

There are difficulties in turning an apparently simple and sensible idea into a practical policy. Regulators should have the powers to encourage the introduction of safer products and phase out less desirable ones. It may be that additional approaches to farmers and growers such as those described in this paper are also needed. Providing more information would allow farmers and growers to make more informed choices, for example on products suitable for use in particular water catchment areas. Making a comparison of products at the farm level increases farmers' responsibilities and awareness of issues and fits with programmes such as the UK's Voluntary Initiative.

We need a system or systems that are proportionate, as well as providing incentives to the crop protection industry and to farmers to deliver continuous improvement. We must aim for a competitive commercial market and to maintain reasonable armoury of pesticides for minor crops to respond to range of pests and diseases and potential resistance problems and at the same time be compatible with EU policy for harmonised pesticide approvals.

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