SESSION 5A

LEGISLATIVE CONTROL OF PESTICIDES IN THE EC: REQUIREMENTS AND CONSEQUENCES

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INVITED PAPERS 5A-1 to 5A-3

LEGISLATIVE CONTROL OF PESTICIDES IN THE EC: PRACTICAL CONSIDERATIONS

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ABSTRACT

The Directive 91/414/EEC concerning the placing of plant protection products on the market has provided the opportunity for a harmonised approach to pesticide registration throughout the EC. The previous differences between Member States over data requirements and interpretation of data should be prevented freeing the trade in plant products and plant protection products from State to State. The provisions given in the Directive provide a good basis for the construction of regulatory procedure which should benefit both agriculture and yet improve safety to the environment. However, there are many practical considerations which have been overlooked in the Directive itself. Guidance notes or rules need to be drafted to make the procedures work without adding to the bureaucratic load of the regulatory scientist and the applicant. This paper identifies some of the more important areas which will need addressing in the coming months before the Directive is implemented.

INTRODUCTION

The Council Directive concerning the placing of plant protection products on the market (91/414/EEC) was adopted on 15 July 1991. The main objective of this Directive was to harmonise the procedures used by Member States to authorise the sale and use of plant protection products. The procedures currently used by individual Member States vary considerably both in the detailed data requirements and, more importantly, in the interpretation of the data. These differences can be considered as barriers to trade. However, it has been recognised that in harmonising the assessment procedure, risks to such things as ground-water and the environment and human and animal health had to take priority over the objective of improving plant health. The intended regulation would balance the safety against the benefits to agriculture. It is envisaged that there should be benefits to the agrochemical industry in having a harmonised assessment procedure with relatively few additional data required for authorisation from one Member State to another. Also there would be a re-evaluation of older active ingredients to ensure that the supporting data were up to modern standards.

All of these aims must be considered to be desirable as the Single Market approaches. Amongst the key elements in the Directive will be the need to establish a Community list of authorised active ingredients by majority through the Standing Committee on Plant Health. Also there will be a need for a procedure for assessing whether an active ingredient can be entered onto this list. It is in the interests of the Community to allow the free movement of plant products and plant protection products between Member States and that studies conducted in one State should be recognised in another subject to regional differences which could present a risk from the intended use. It is recognised that guidance is needed for Member States to evaluate data in a uniform manner and the "Uniform Principles" will be

drafted and agreed before the implementation of the Directive. It is also necessary to maintain consistency between existing Directive and Community laws. Indeed the Directive emphasises the need for close co-operation between the Commission and the Member States.

Harmonisation can be considered on two levels; the legal framework giving the scope and provisions and the scientific assessment of the data. For practical purposes the scientific assessment can be further subdivided into the procedures required to provide and generate the most appropriate data and the interpretation of those data into recommendations (authorisations). Much of the initial understanding of pesticide registration which has formed the basis of the Directive has been based on the knowledge that there exists a high degree of harmonisation already in the provision of toxicology data. In terms of weight alone this probably comprises the majority of the data-package and would undoubtedly seem true. However, evaluation of the data in terms of risk requires interpretation and integration of items of data which often result in expert judgements which hitherto have not be harmonised.

In January 1990 a symposium was held at the University of Reading, UK, on the future changes in pesticide registration within the EC. It was clear that a system based on a scientific assessment of data was necessary and indeed was employed by many Member States (Hollis, 1990). However, there was great concern over lack of guidance on the practical aspects of the procedures envisaged for the handling and assessment of data by both the Commission and individual Member States (Tooby, 1990). Although a considerable leap forward has been made since that symposium, much of the practical guidance which will be necessary to operate the system without it becoming over bureaucratic has yet to be agreed and published. Mortensen (1990) identified a number of major problems with the, then, proposed Directive. These included the fact that the procedures would be time consuming when it is considered that both old and new products would need to be evaluated under the same system and the rules presented were difficult to interpret. The practical detail required to operate the Directive has still to be developed and agreed.

The purpose of this paper is to take a critical look at the proposed procedures and identify potential problem areas which will need addressing. It is recognised that the Commission and Member States will be discussing such matters over the next few months. Therefore, by the time that the paper is committed to print some of the concerns will have been considered and rules or guidance provided.

The procedures will be considered under the main headings as they appear in the Directive.

SCOPE (Article 1)

Many National authorities legislate for the control of pesticides for uses in both agriculture and non-cropped situations. Therefore, to have a new procedure for plant protection products but not others will add to the burden of operating procedures within each authority. Especially if the proposed active ingredient is intended for use in both sectors where procedures and decision trees could be different. This may be exacerbated if the proposed Directive on non-agricultural products is agreed and, furthermore, if the procedures are not in line with those proposed under 91/414/EEC.

INCLUSION OF ACTIVE SUBSTANCES IN ANNEX I (Articles 5, 6, 19 and 20)

The procedures under this heading can be divided into two parts. Firstly the procedures for new active ingredients and secondly the procedures for the review of older products already on the market. The precise procedures for the review of older products are being discussed at present with the Commission and are clearly identified as being of high priority. From the date of the implementation of the Directive those products already on the market will have a derogation for a period of not greater than 10 years (Article 8). It is the intention that these products are reviewed to meet modern requirements and are included in Annex I. Clearly this process will take the full 10 years to undertake and will stretch most authorities. The work will be shared throughout the Member States and priorities will need to be agreed.

This will mean that certain products will not be assessed until the very end of the 10 year period. For products containing those active ingredients not included in Annex I, no freedom of trade can exist under the terms of mutual recognition until such time as the active ingredient has been included in the Annex. This could result in the registration of old products in certain Member States as if they were new products in order to gain entry into another State. Thus the review programme envisaged by the EC could be tackled from more than one point. There will be more than enough work for most authorities with a structured review programme without the added confusion of older products being processed as if they were new active ingredients. Clearly this scenario is a worst case but some thought should be given to the mutual recognition of the older products not included in the Annex I.

For new active ingredients the intended procedures are clearer. The Member State receiving the first application will inform the Commission. It is assumed that the Member State will become the rapporteur and prepare a risk assessment and will handle all of the data. It is also assumed that this Member State will organise the data to be "peer reviewed" by a subcommittee of the Standing Committee on Plant Health. This subcommittee will comprise five Member States on a rolling membership. It would be easy to envisage disagreements between this subcommittee and the main committee if certain Member States were not involved with the earlier discussions. Clearly the detailed procedures must be carefully drafted to reduce what could easily become a second tier of bureaucracy. The Commission should draft rules for the procedures to be adopted in due course.

During the earlier discussions on the Directive the misunderstanding that risk could be assessed from the active ingredient data alone in order to include the chemical in Annex I was dispelled. Article 6 clearly states that some data from Annex III will also be needed to assess the risks. However, no guidance exists on the principles which should be adopted by the Standing Committee on Plant Health or by the Member States preparing the dossier for scrutiny. Much has been speculated over the "Uniform Principles" to be used by individual Member States assessing information under the rules for mutual recognition but nothing has been said about the assessment of new products. It is assumed that the decision trees and trigger points to be adopted for the "Uniform Principles" will also be used for this stage of the evaluation. Any alternative approach could result in two sets of standards.

GRANTING, REVIEW AND WITHDRAWAL OF AUTHORISATIONS (Articles 4, 10 and 13 and Annex VI)

The general provisions under this section of the Directive cover the authorisation of products from one Member State to another once the active ingredient appears in Annex I. This could be of considerable benefit to all concerned in the registration process. However, the rules will have to be carefully written to cover such procedures. At present it has been suggested that the active ingredients in the Annex I will also have conditions attached to them. For example, a chemical could be acceptable for inclusion in Annex I but only under the condition of use in cereals. Such a condition would restrict other uses in other Member States. At present it is uncertain that if the manufacturer wished to extend the use in the same or, indeed, in another Member State such a new use would have to be assessed as if it was a new product. This clearly would be unnecessarily complicated and bureaucratic and the rules would need to carefully written on this aspect.

It is important to recognise that the data required by the Member States when assessing the application for authorisation under the provisions of the mutual recognition, includes some data provided under Annex II.

At first the idea that the major part of the data package would not be evaluated by the Member State because of the need to accept active ingredients on the Annex I list seemed to be a stumbling block for acceptance among regulatory scientists. In practice this will not happen because the first evaluation will be discussed at the Standing Committee on Plant Health. Although this Committee adopts a voting procedure, provided that each active ingredient is voted upon there will be an opportunity to express agreement or reservations at that stage. Thus accepting Annex III data for mutual recognition will be relatively straightforward.

In cases where the data do not support a use in the Member State, the discussions with the Commission following such a decision could be time consuming. Guidance on the procedure to adopt would be of value in this area. It remains to be seen whether a Member State would be forced to accept a chemical against its National wishes.

TRANSITIONAL MEASURES AND DEROGATIONS (Article 8)

The provisions under this Article cover the initial period from the receipt of the application to the inclusion of the active ingredient onto the list in Annex I. There will be considerable difficulty for some Member States to meet this period without some restructuring and increased resources. The UK is by no means immune from this criticism. Another aspect of this transitional derogation might be the possibility that a product could enter the first Member State supported by a less than complete data package. Clear rules should be drafted to guide the authorities in this area. For the period of the review of older products the derogation is entirely sensible.

EXTENSION OF THE FIELD OF APPLICATION (Article 9)

Both official and scientific bodies can apply for an extension of the field of use of a product when it is in the public interest to do so. The Member State will assess the relevant documentation provided by the applicant. However, no guidance in this area has been provided.

CONFIDENTIALITY (Article 13)

The procedures are clearly laid out in the Directive. However, the practical implementation for review and "me-too" products still remains a potential minefield.

CONTROL MEASURES (Article 17)

The provisions under this Article lay down the need to check products for compliance with the requirements of the authorisation and are already undertaken in many Member States. In the UK this will mean a reorganisation and the required funding to be found for the competent laboratory to undertake such checking. Member States will need to report annually on results of inspections.

EXPERIMENTAL PERMITS AND TRIALS (Article 22)

Applications can be made to Member States in much the same way as currently undertaken.

UNIFORM PRINCIPLES (Annex VI)

Although the Uniform Principles will be presented by another speaker in this session, the content of this Annex will be central to the procedures and timing of programmes by both the applicants and the authorities. It will have a major impact on the practical aspects of regulatory science. The proposed decision trees and, more importantly, the trigger points will shape the policy to be adopted throughout the Community. If they are too rigid the registration procedure will be fossilised for a long period. On the other hand if they are too flexible they might allow differences in the interpretation of data to occur and differences over decisions to remain. The decisions and consequent policy must be based on the best available science as at present.

The early timetable for the completion of the Uniform Principles is welcomed in one respect but may reduce the usefulness in another because good decision trees and study selection procedures are currently being developed under a joint Council of Europe/EPPO initiative. These will not be available until the end of 1992. It will be essential to harmonise as far as possible the interpretation of data and the trigger points. This will assist the agrochemical industry in designing their development programme to meet the detailed requirements not specified in the Annexes II and III but implied in the speculation over the Uniform Principles.

GENETICALLY MODIFIED ORGANISMS

This is an extremely important area and one which has apparently become confused because of the wording used in the existing deliberate release Directive 90/220/EEC. It is hoped that rules can be drafted which are acceptable to all concerned in this area. It should be possible to cross refer to the Directive 90/220/EEC to adopt the environmental impact assessment approach outlined in the Annexes to that Directive. With this two tier approach the release of the GMO will have had an environmental assessment under the deliberate release Directive before it is assessed at the first marketing level of authorisation under the pesticide Directive. This system is operating in the UK at present and works extremely well.

CONCLUSION

By the time that this paper is presented many discussions will have taken place with the Commission. Furthermore, the first drafts of the Uniform Principles and the rules for the procedures to be adopted for the review of older chemicals and for application of new active ingredients will have been at least discussed if not prepared. Member States and the Commission recognise the need to work hard in this area to achieve the necessary deadlines. The information given in this paper is derived from earlier discussions on the Directive but without the opportunity for further clarification by the Commission and may be out of date by the time the paper is presented.

REFERENCES

Hollis, G. A. (1990) The United Kingdom View. Proceedings of a symposium organised by the BCPC. Future changes in pesticide registration within the EC. Monograph No. 44: 19 - 21.

Mortensen, L. (1990) A view of the EC proposed registration directive on plant protection products from a government regulatory agency standpoint. Brighton crop protection conference - pests and diseases - 1990: 1071 - 1078.

Tooby, T. E. (1990) The likely impact on national regulatory authorities. Proceedings of a symposium organised by the BCPC. Future changes in pesticide registration within the EC. Monograph No. 44: 111 - 115

THE OBJECTIVES AND IMPACT OF THE EC UNIFORM PRINCIPLES

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ABSTRACT

Uniform principles for the evaluation of data for risk assessment and risk management within the process of authorization are now under development. The scope, objectives and content of these principles are described from the point of view of German experiences.

INTRODUCTION

The establishment of Uniform Principles (UP's) supporting legal measures within the EC is up to now without any example. The justification comes from the following sources:

i) after adoption of Directive 91/414/EEC (O.J. 1991) the authorization of plant protection products (PPP) remains a task of the Member States

ii) structure and evaluation processes within the competent authorities are quite different between the Member States

iii) the mutual acceptance of authorizations will only work if authorization within the Member States will be done in a quite similar way

Therefore the UP's are part of the system now established in the EC and included in the Directive 91/414/EEC as Annex VI.

Before Council adopted the Directive there has been a discussion between the Member States and the Commission concerning scope and purposes of the UP's. Whilst the Commission, supported by several Member States, adhered to a very narrow scope, more or less related only to Article 4 of the Directive and to adopt only by a Standing Committee, some Member States, including Germany felt that it would be better to include more articles and that the UP's should be adopted by Council. Of course, Article 4 must be the core of the principles but the same way of acting is necessary also when evaluating new or old substances (Article 8 para 1 and Article 8 para 2) or as far as the mutual acceptance is concerned (Article 10). The different positions were resolved by a compromise. The first draft of UP's has to be adopted by Council in one year's time, i.e. a deadline of 15 July 1992 and would be limited closely to Article 4, the requirements of authorization. Amendments would be done by the Standing Committee on Plant Health and decided by majority. So everybody is happy, up to now! But this may change, when the Commission has sent its proposal to Council and the Member States have to decide about the acceptance of this proposal.

THE OBJECTIVES

UP's should be aimed at harmonizing the decision-making process between the results of data produced by the tests described in the Annexes II and III and the granted authorization. Therefore the UP's are directed to the competent authorities as far as Article 4 is concerned but they are very important for the applicants too.

Granting authorizations for plant protection products has become very expensive and time consuming so that every chance for reduction without being less careful should be taken. Transparency in the decision-making process is one of these chances, because this will lead to a better judgement about necessary data, justification of additional trials and tests, as well as to improve the possibilities for companies to judge the success of their applications. Furthermore UP's offer the chance to make clear to the public the way in which decisions are made about such sensitive products as plant protection products, under which circumstances applications would be refused and which cut-off criteria exist expressed in simple terms. UP's will open the "black box" for all involved parties. However it would be unfair to state that a black box exists without having mentioned all the existing efforts between authorities and applicants to establish rules, guidelines and memoranda of understanding. In reality principles for decision making in the process of authorization exist in mostly all Member States. Often however they are not stated, they differ at which level these discussions are taken or how compulsory they are. For some issues they are well established, for others they grew up in the past by experience. Therefore no systematic approach exists, to say nothing of harmonization.

THE CONTENT

As for everything in life the troubles occur when looking into details. To get a real chance for adoption the draft has to score a bull's-eye with regard to generalization on one hand and efficient detailed specifications on the other.

Some preliminary work exists. For example that done by FAO, the Danish and Swedish authorities and, last but not least, in the Member States of the EC. A new initiative related to the UP's is taken by EPPO and the Council of Europe with the Joint Panel of Environmental Risk Assessment of plant protection products. The honourable task is now to find a way out of the jungle and, in this context, the following considerations may be helpful:

1) Establish basic principles as part of the uniform principles

Basic principles should outline the principles of authorization in a very general way. For example the following five basic principles could be taken:

i) High quality
Examination and evaluation of the data package are done carefully, with sound knowledge based on scientific principles and the current status of knowledge and techniques; international collaboration with regard to the process of evaluation is fostered.

ii) Transparency

The actual status of the application is apparent and available at any time; a main dossier exists; the data which are not confidential and the summary are retrievable with modern information techniques.

iii) Appropriateness of measures

Refusal of authorization should be discussed only after having checked all possibilities to set conditions or to restrict the use; intrinsic properties are not sufficient to take appropriate decisions.

iv) Balanced decisions

If a decisions has to be taken, whether or not a plant protection product has unacceptable impacts on the environment, the following factors shall be considered:

- probability of the occurrence of the impacts,
- weight of disadvantage of the impacts,
- possibility to replace the product,
- the disadvantages, if the product is not used

v) Inclusion of external knowledge

Before the decisions regarding the authorization is taken, the proposal should be discussed with a Scientific Advisory Committee.

2) Establish specific principles

Specific principles could initially be defined with regard to Article 4 para 1(b). This would mean the establishment of a separate principle, and if applicable a subprinciple, for each requirements of authorization.

Specific principles and subprinciples would be as follows:

i) efficacy
ii) phytotoxicity
iii) animal protection
iv) human health including fate on and in plants and plant products, residues, toxicity (mutagenic, embryotoxic and carcinogenic effects).
v) environment including chemical and physical properties, soil (behaviour in soil, microflora), water (penetration into groundwater, aquatic organisms, aquatoxicity), air (entry and fate), side effects (beneficial organisms, honey bees, birds and free-living mammals, earth worms), tendency to accumulation, waste disposal.

3) Each principle should follow a master structure

This master structure would include a description of the issue (for instance efficacy), existing harmonized or agreed guidelines, warning criteria, cut-off criteria (if applicable), a flow chart, remarks and references.

As an example let us consider the issue of residues for which one must establish two subprinciples, namely degradation and residues.

i) Degradation

Necessary data would be required on:

- degradation, transformation and metabolism in/on plants; uptake, distribution and mode of action.

Three warning criteria could be:

- the larger metabolite fraction has not been characterized
- completely different fates depending on the various crops investigated
- high persistence of the active ingredient in and on the plant

Three cut-off criteria could be:

- the type and quantity of metabolites are not acceptable from the viewpoint of human toxicology
- the type and quantity of metabolites are not acceptable from the viewpoint of ecotoxicology
- the active ingredient is persistent in and on plants and all other environmental compartments

ii) Residues

Necessary data would be required on:

- Behaviour and fate of residues in foodstuff of plant origin, animal fodder of plant origin, rotational crops, processed food of plant origin and foodstuff of animal origin, after the animals have been fed with fodder containing residues

Three warning criteria could be:

- Exceeding the Maximum Residue Level (MRL) in the target crop is possible.
- Exceeding the MRL in rotational crops is possible
- Exceeding the MRL in foodstuffs of animal origin is possible

Four cut-off criteria could be:

- Residues were not acceptable from the viewpoint of toxicology
- Residues were not acceptable from other viewpoints (e.g. ecotoxicology)
- application prohibited (by regulation)
- active ingredient tends to accumulate in the food chain

The warning criteria and the cut-off criteria have to be specified. For example persistence by fixing an acceptable turnover rate and rate of formation of carbon dioxide.

This paper has attempted to present the German impression of the Uniform Principles. We are well aware of the importance of this work and await the Commission's draft with curiosity.

REFERENCES

Official Journal No L230, 19 August 1991, p.1, Council Directive concerning the placing of plant protection products on the market.

THE IMPACT OF COMMUNITY REGULATIONS ON THE FUTURE DEVELOPMENT OF NEW COMPOUNDS: AN INDUSTRY VIEW

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ABSTRACT

The implementation of the 'Registration' Directive in 1993 will bring about major changes to the regulatory control of crop protection products throughout the Community. Further important changes will follow when agreement is reached on the Uniform Principles, although the key technical details will undoubtedly take longer to emerge than the much broader approach currently envisaged for the 'Framework' Directive. Any attempt to implement the Directive without having reached agreement on the harmonization of data requirements, etc., would, in Industry's view, be a retrograde step as would any Review Programme which concentrated on the consideration of 'old' compounds to the detriment of the Community evaluation of new active ingredients. Initiatives, at both Member State and Community level, to reduce the use of crop protection products are viewed with considerable concern as such initiatives often seem to confuse different objectives, namely reduction in environmental impact and reduction in agricultural production. These political and regulatory factors combine to create an environment which is less than friendly towards the development of new compounds. Despite these perceived negative factors it is suggested that the Directive and the Uniform Principles offer an opportunity for real progress towards effective harmonization but only if the issues are approached on a pragmatic and scientific basis.

INTRODUCTION

The adoption of the 'EC Registration Directive' (O.J. 1991) in July of 1991 foreshadows one of the most significant changes that the Crop Protection Industry has ever seen. Its implications within the European Community are both extensive and comprehensive and clearly effects all Agrochemical Companies operating within the Community, large or small, European, American or Japanese. Once the Directive is implemented in 1993 regulatory procedures will change dramatically and many new systems and procedures will need to be learnt by Government Regulators and Industry alike. Whereas the details of these systems are known from the Directive itself the actual practical operation of the Directive leaves much to speculation and to questions which may only be answered on the basis of the practical experience gained during the first, possibly tentative, steps into this largely unknown territory. At present other areas closely associated with and stemming directly from the requirements of the Directive are also clouded by areas of considerable doubt or ignorance. Most notably these areas are the Uniform Principles which will define more precisely the data requirement and the evaluation of these data and the Review Programme which will establish the way in which the Community will evaluate those active ingredients on the market at the time of

implementation of the Directive.

This enormous regulatory change is concurrently accompanied by changes of a more politically orientated nature aimed clearly at reducing agricultural production in the Community and apparently at minimising the environmental impact of modern day farming methods. Incorporated within this initiative is an unequivocal policy declaration by both the Commission and by some individual Member States, to reduce the use of crop protection chemicals by up to 50% (Commission of the EC 1988).

Against this background of future regulatory changes and ongoing and developing political trends, one must seriously consider the impact on the research and development of new crop protection chemicals and the continued marketing of some products currently on the market.

THE REGISTRATION DIRECTIVE

Details of the Registration Directive are well known and, to the extent that the Directive has now been adopted, it is no longer possible to foresee any circumstances under which the details of the Directive are likely to change, at least in the short term. Whereas it is understood that an Amendment to the Directive is currently being drafted by the Commission, it is further understood that changes included in this Amendment are of a technical/linguistic nature or else are concerned with extending the scope of the Directive to include those active ingredients used in agriculture but not necessarily for crop protection, e.g. the use of insecticides in controlling flies in animal houses.

The perceived impact of the Directive on the registration process has been discussed elsewhere (Thomas, 1990 a) and the next few years will clarify the accuracy of this perception. Despite the provisions within the Directive for a 3-year Provisional Approval at the Member State level for new active ingredients, it seems almost inconceivable that the registration of a new active ingredient in any Member State will not take longer to achieve. All the available evidence, experience and plain common sense point to this conclusion. Delays in achieving registrations for new active ingredients and therefore new products results in a direct loss of income to the manufacturer with consequent effects on cash-flow and reinvestment in Research and Development. Notwithstanding all other implications of the implementation of the Directive, we would suggest that this delay in achieving registration is likely to be the single most significant effect of the Directive and by association, the development of new molecules.

THE UNIFORM PRINCIPLES

Since the early days of discussion on the Registration Directive, Industry has frequently expressed the view that the whole concept of Community harmonization of pesticide registration was approached from the wrong direction (Thomas, 1990 b). Industry felt that the 'science' of registration, i.e data requirements and data interpretation, should have been harmonized as the first priority followed by the harmonization of registration procedures and mutual recognition between Member States of national registrations.

Despite some tacit approval from some Member States (van Eck 1990) this view was not supported and the Community preferred to deal with the 'scientific' issue through the concept of Uniform Principles.

The Uniform Principles were initially aimed at providing the 'technical' support for the Directive by defining, against the background of the 'broad-brush' approach of the data requirement specified in Annex II and Annex III of the Directive, more precise details of data requirements, experimental protocols and of data evaluation. Strictly speaking the Uniform Principles relate only to product data, but as the distinction between active ingredient and product is somewhat artificial from a registration point of view, then clearly these Uniform Principles would also play a role in defining criteria for the evaluation of the active ingredient.

This original concept was however to change relatively late in the day when, as a compromise within the context of Member States discussion, it was decided to include in the Directive the provision that Uniform Principles had to be adopted within 1 year of the adoption of the parent Directive, i.e. by July 1992. Clearly this would be an impossible task given the complexity of the data requirements and the scope for protracted discussion and it has therefore been decided that the Uniform Principles will appear as a 'Framework' Directive aimed at defining general issues and the philosophy of approach but excluding any detailed guidelines on data requirements. These will follow subsequently in the form of Annexes to the Framework Directive and may be adopted in sections by rapid Commission procedures. This approach causes Industry considerable concerns which may be considered under the following broad heading:

1. Basic approach to harmonization

Any registration system has inter alia two key elements, namely procedure and data requirements. One cannot operate without the other. How then is a truly harmonized registration system within the Community to operate successfully in the absence of any Community agreement on data requirements and, of equal importance, a harmonized Community approach to the evaluation and interpretation of these data? We would suggest that the system will simply not work and that individual Member States will continue to operate much as they do now but with the additional burden to Industry of having to obtain Community Approval for the active ingredient. This is not true harmonization.

2. Diversity of approach in Member States

Whilst the Uniform Principles are currently being drafted, it seem most incongruous that additional data requirements continue to be added to the national registration systems in many Member States. Most notably in Germany and the Netherlands data requirements are being extended on a regular basis to include the need for such tests as field volatility studies, modified requirements for lysimeters, etc. Additionally we are seeing the introduction of an increasing number of different computer based models for predicting environmental fate and behaviour - again without any apparent thought towards the goal of harmonization. Would it be unreasonable to expect Member States to stop introducing new requirements at this time or are such requirements being introduced now so as to ensure their inclusion in the Uniform Principles

or at least to provide Member States with 'bargaining' position in future discussions on the Uniform Principles?

3. Highest-common factor approach

Industry has previously (Thomas 1991) expressed its concern regarding the possibility of a 'highest common factor' approach being adopted within the Uniform Principles, i.e. the Uniform Principles would be based on a compilation of the most demanding requirements in all Member States rather than to rationalise requirements into a truly harmonised approach based on scientific principles. Given the diversity of national trends referred to above, Industry remains concerned.

4. Registration criteria

Over recent years the regulatory area has seen the increasing use of 'tier-testing' in the acquisition of registration data. This approach is characterised by the need for further tests or a series of tests once a 'trigger value' is exceeded in a preliminary study of the specific property of the pesticide under investigation. Industry fully supports this approach although it would not necessarily agree with all the trigger-values currently in use in various Member States. The concept has however been adopted by some Member States, notably Denmark and the Netherlands, so as to set quantitative cut-off values, which if exceeded precludes the registration of the pesticide. In a purely administrative sense this aids the registration decision-making process in that the registration stands or falls on a simple arithmetic conclusion. This approach is scientifically unsound and ignores the basic philosophy of a weight-of-evidence approach to risk assessment. Nevertheless the approach is highly favoured by some Member States and it seems more than likely that these Member States will wish to see a similar approach incorporated into the Uniform Principles and thereby applied throughout the Community. Industry would strongly oppose such a move but in doing so recognizes that registration criteria have a certain attraction to 'administrators' and 'politicians'. Efforts to exclude such criteria from the Uniform Principles may therefore not be easy.

THE REVIEW PROGRAMME

Clearly the introduction of a new Community registration system must involve not only an evaluation of new active ingredients and products but also a review of those active ingredients on the Community market at the time of the introduction of the new system. The Directive accommodates this requirement and in doing so sets a highly ambitious, some might say impossible, task of completing such a review for these existing active ingredients within a ten year period. Full details of how this Review Programme will operate are yet to be published but it is known that requirements for the Reviews will be implemented in the form of a Commission Regulation, the implementation date of which will coincide with that of the Parent Directive. Active ingredients will be reviewed on a priority basis with the responsibility for the reviews being allocated to individual Member States on a weighted basis.

The exact number of active ingredients 'registered' throughout the

Community is not known but is certainly in excess of 450 and may be as high as 600. Completion of the Review Programme within the 10 year period is thus highly questionable and Industry's concern stems from a fear that scarce scientific resources, both within Government and Industry, will be disproportionably directed toward reviews of 'old' compounds at the expense of the evaluation of 'new' compounds. This concern arises from a consideration of the effort currently being spent on re-registration programmes in various Member States and the vociferous complaints from some quarters that 'old' pesticides should be withdrawn from the market until their data bases have been confirmed as complying with modern-day standards. Here again, as with so many current aspects of the regulatory scene, political influences cannot be discounted. Industry hopes that a sensible balance will be established between the evaluation of 'old' and 'new' pesticides.

REDUCTION IN PESTICIDE USAGE

Individual Member States have already declared their intention to introduce measures and legislation to reduce the extent of pesticide use within their territories. Some have gone so far as to set specific targets (e.g. in the Netherlands the objective is a 50% reduction by the year 2000). In others the aim is less specifically defined (e.g. in the UK the objective is to reduce levels of pesticide use to levels commensurate with the needs of Good Agricultural Practice). In a recently published Communication (Commission of the EC, 1991a) the Commission has proposed that a system of financial aid should be provided to farmers so as to encourage the use of "production methods with low risk of pollution and damage to the environment. This would involve significant reduction in the use of potentially polluting inputs (fertilizers, pesticides, herbicides) in the case of crop production." It is significant that this proposal is part of a package of reforms aimed at introducing fundamental changes to the Community's Common Agricultural Policy and one must question whether the alleged increase in environmental risk posed by crop protection chemicals is merely an 'excuse' to support the objective of reduced productivity and hence reduced production. It seems ironic that Industry continues to invest heavily in the development of technologically advanced compounds (i.e. in terms of increased safety, increased efficacy and decreased environmental impact) whilst the Commission may be perceived by some as actually discouraging such advancement. This could be regarded as both short-sighted in terms of the need to maintain an effective Agrochemical Industry and parochial in terms of the situation regarding global food supplies in relation to a continually expanding world population.

OTHER MEASURES

Although not strictly relevant to the specific issue of the registration of crop protection products one cannot ignore a number of activities in related areas of legislative control. Thus:

The non-agricultural pesticides directive

A proposal to introduce a Directive to harmonize the registration of pesticides used in the non-agricultural area (e.g. public health, wood preservation, industrial and masonry biocides) is currently at the preliminary

discussion stage (Commission of the EC, 1991b). This Proposed Directive follows very closely the format, structure and content of the Registration Directive. Its scope in terms of areas of use is considerably wider than the Registration Directive and in some cases, e.g. registration of public health products in Germany and France, the Proposal would impose regulatory control where it does not exist at present. The development of this Proposal will be viewed with interest but one major concern which has already been identified by Industry is the absence of any formal link between the two Registration Directives. A significant number of, for example, public health insecticides are derived from uses originally developed for agricultural application. The need to gain Community approval for the same active ingredient under two separate Directives seems a classic example of wheel re-invention and an unnecessary waste of scientific resources.

Notification of existing substances

This Commission Proposal (O.J. 1990) is aimed at providing extensive data packages on chemicals which are used within the Community on a large scale, e.g. in excess of 1000 t/pa. As currently drafted, this Proposal includes pesticides which meet the extent of use criteria although there is an understanding that, because of the existing regulatory control at Member States level and the future control under the Registration Directive, the evaluation of the data submitted on pesticides will assume a low priority. Given this tacit acknowledgement of the existing evaluation procedures what then, one might ask, is the point of Industry submitting the data in the first place? The compilation of these data, in accordance with specific formats, is both time consuming and expensive and would seem to serve little purpose. Industry sincerely hopes that the Commission and Member States can be persuaded to exclude pesticides from the requirements of these two impending legislative initiatives.

These two examples serve to illustrate a significant trend towards greater and greater regulatory control of pesticides irrespective of the control which already exists and which will be further increased over the next few years. It must be acknowledged at some time that the Agrochemical Industry is one of the most heavily controlled industries in the world and one must recognize that merely extending this control has little or no benefit to society, but merely serves to deprive it of the advantages associated with technological advances.

IMPACT ON NEW COMPOUND DEVELOPMENT

There can, we believe, be no doubt regarding the advances made in crop protection chemistry over the last thirty years or so; dramatic reductions in rates of application and increased target specificity are but two examples of the areas where significant improvements have been achieved. This period of intensive development has been accompanied by an equally intensive escalation of the regulatory control of pesticides, an escalation which indeed still continues. Many of the changes in data requirements have resulted from science-based developments in the relevant areas, e.g. toxicology, environmental science, analytical chemistry and risk assessment. In more recent years however parallel, but equally important, influences have arisen from non-scientific areas such as political, socio-economic and lobbying

organizations. All these, and other factors have combined to make the discovery, development and marketing of a successful new crop protection product, increasingly more difficult and also more expensive. This is most dramatically demonstrated in the decreasing number of innovative companies active in this area of business and in the fact that such companies must synthesize some 25,000 active ingredients so as to obtain any chances of success in finding that elusive new compound.

One might argue that the future implementation of the Registration Directive is merely another step along the regulatory path and that Industry will adapt to its impact and implications, much as it has done with similar changes in regulatory control at the National level. Whereas there is an element of truth here inasmuch as Industry will learn, perhaps somewhat painfully, to cope with the Directive in a mechanistic sense, it would be over-simplistic in the extreme to underestimate the future impact of the Directive. This is no mere change, however significant, at the Member State level but rather a change which will apply to the whole Community and to the very large Western European crop protection market. Because of the difficulties and financial risks inherent in the development of a new compound, this development must be aimed at a world market or at least at those major parts of that market, i.e. USA, W. Europe, Japan. Regulatory barriers to the registration of new compounds within the Community could therefore preclude the development of a new compound on a broader global basis.

The views presented above may be regarded by some as being somewhat pessimistic, although experience would indicate that they reflect realism rather than pessimism. It would however seem appropriate to conclude this discourse on a more positive note and, in this context, we would wish to stress one key concept, namely 'opportunity'. Whereas the Registration Directive may not be entirely in line with what Industry would have wished, the Directive is, nevertheless, now a fact of life. The Development of the Uniform Principles offers a unique opportunity to harmonize data requirements and data interpretation throughout the Community. At the risk of appearing over-optimistic one might ask whether these Uniform Principles might then be used as the basis for harmonization with the world's other two major regulatory bodies in the USA and Japan.

The opportunity for a pragmatic, scientific approach is there to be grasped - let us hope that all those concerned will take full advantage of this opportunity.

REFERENCE

Commission of the European Communities (1988), Environment and Agriculture, Communication of the Commission, COM(88)338 Final.

Commission of the European Communities (1991a), The development and future of the Common Agricultural Policy, Communication of the Commission to the Council and to the European Parliament, COM(91)258 Final.

Commission of the European Communities (1991b), Proposal for a Council Directive concerning the placing of non-agricultural pesticides and the

active substances thereof on the market. DOC XI/III/563/91.

Official Journal No. C276, 5 November 1990, 33, p.1. Proposal for a Council Regulation (EEC) on the evaluation and the control of the environmental risks of existing substances.

Official Journal No. L230, 19 August 1991, p.1. Council Directive concerning the placing of plant protection products on the market.

Thomas, B. (1990a), An industry view of the EC Registration Directive, 1990 Brighton Crop Protection Conference - Pests and Diseases 3, 1079 - 1086.

Thomas, B. (1990b), The GIFAP view of European Registration of Pesticides. In: Future Changes in Pesticide Registration within the E.C. B Thomas (Ed). BCPC Monograph No 44, Thornton Heath : BCPC Publications, pp. 43-48.

Thomas, B (1991) : Requirements for Registration - An Industry Viewpoint. In : Pesticide Chemistry : Proc. Seventh International Congress of Pesticide Chemistry (IUPAC), H Frehse (Ed). Weinheim, Germany, VCH, pp. 475-484.

Van Eck, W.H. (1990). Status of the Proposed Registration Directive and the Views of Some Member States - The Dutch View. In : Future Changes in Pesticide Registration within the EC. B. Thomas (Ed). BCPC Monograph No. 44, Thornton Heath, BCPC Publications, pp 29-32.