SESSION 10

IMPLICATIONS OF MODERN REGULATORY REQUIREMENTS FOR CROP PROTECTION

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INVITED PAPERS 10-1 to 10-4

THE EUROPEAN COMMUNITIES' PESTICIDE REGISTRATION REGIME: THE ROLE OF SCIENCE, CHALLENGES AND OPPORTUNITIES

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ABSTRACT

The fundamental principles underlying the EC pesticide registration regime, enshrine science and sound scientific judgement as the basis for decision making. While many subsidiary elements of the regime have yet to be published, significant progress has been achieved. The adoption of the Directive has prompted the development and validation of many additional experimental protocols, models and risk assessment schemes. There is an urgent need to accelerate the pace of that work. It is apparent that many benefits will accrue on its implementation. A high level of protection for man, animals and the environment will be achieved. Among the practical benefits that will accrue, are clarity as to data requirements, rationalization of data requirements, reduced costs for industry, on an overall basis, a much improved data base for decision making, and consistency in decision making based on good science.

INTRODUCTION

The need for international harmonization in the field of pesticide regulation has been recognized for many years. That recognition prompted the development, by the Food and Agriculture Organization of the United Nations (FAO), by the Council of Europe, and by the Organization for Economic Co-operation and Development (OECD), of recommendations for the harmonization of data requirements, and of guidelines as to methodologies for generating data. Although many of the recommendations and guidelines adopted were implemented by most member countries, many significant differences remain in national requirements as to the studies required and the methodologies to be used in generating data.

Differences in the data requirements of various countries and in the methodologies accepted by them for the generation of data, result in very significant additional costs for industry in generating data to address issues that often have already been fully investigated. The additional data thus generated add little to knowledge as to the fate, behaviour and impact of the pesticide concerned, while the costs arising necessarily are passed on, ultimately to

consumers. Differences in approach to the interpretation of data and in risk assessment (Clegg, 1990) continue to cause grave concern, add significantly to costs, result in different decisions being made, and serve to increase the growing scepticism with which science and scientists are regarded (Mohr 1990).

All pesticide regulatory regimes, as well as the decisions taken under such regimes with respect to individual pesticides, necessarily take account of and reflect, to a greater or lesser extent, the various and often conflicting demands of economic, social, political and scientific considerations (Johnson 1990).

THE NEW EC AUTHORIZATION REGIME

The regime adopted in 1991 by the European Communities (Council Directive 91/414/EEC), provides a legal framework for the elaboration of relevant procedures, for the harmonization of data requirements and methodologies, for the interpretation of data submitted, and for decision making, with respect to pesticides used for plant protection. The Commission of the European Communities, is expected to submit a similar proposal to Council for other pesticides, before the end of 1992.

Basic principles

The Directive adopted recognizes the essential role of pesticides in food production as well as the risks for man animals and the environment associated with their use. The balance achieved as between the social and political constraints arising, and scientific principles and uncertainties, in addition to ensuring the removal of many remaining technical barriers to trade, resulted in:

- the elimination of confidentiality with respect to the results of testing (summary form);
- provisions to minimize the amount of testing involving vertebrate species;
- an obligation to ensure that vertebrates to be controlled are caused no unnecessary pain of suffering;
- an obligation to ensure a high standard of protection for man, animals and the environment, that obligation to take precedence over the improvement of plant production;
- an obligation to ensure that real benefits accrue from use as authorized; and
- an obligation to ensure use in accordance with the principles of good plant protection practice and when possible the principles of integrated control.

A fundamental principle contained in the Directive is that decisions with respect to individual pesticides, be made *in the light of current scientific and*

technical knowledge following evaluation of the relevant data and information. Thus, science is enshrined as the basis for decision making. Through specifying that data be generated in accordance with the Principles of Good Laboratory Practice (GLP), through reliance on validated experimental protocols, through the elaboration of scientifically sound criteria to determine the circumstances under which particular studies are required, and through the adoption of scientifically sound evaluative and decision making criteria, the central role of good science in pesticide regulation will be assured.

Under the terms of the Directive, and with a view to eliminating barriers to trade, studies conducted in one Member State must be accepted in others, where the results obtained are relevant *viz.*, *agricultural, plant health and environmental (including climatic) conditions in the regions concerned*, are comparable. Applicants are obliged to justify claims made as to comparability as between two or more regions. Where it is accepted that comparability exists with respect to conditions in a Member State that has already authorized a product, following receipt of the data other Member States are obliged to authorize the product concerned, without undertaking a further evaluation of the data package. Those provisions are expected to eliminate much unnecessary testing and to streamline the regulatory decision making process.

Selected specific issues

The Community procedure for the evaluation of active substances *inter alia* envisages the estimation of acceptable exposure levels for those workers using preparations containing them. It is likely that for each substance, an acceptable operator exposure level (AOEL) will be established (Lynch, 1992). In the context of the nature and duration of exposure likely to occur, and the risks arising, AOEL values should be based on the no observed adverse effect levels (NOAEL) determined in short-term toxicity studies, and reproductive toxicity, including teratology, studies.

It can be anticipated that the provisions of the Directive, relating to extensions in the field of application of particular products, will facilitate their authorization at minimal cost for minor uses, because of the exemption from data requirements relating to performance. An unintended effect may be that the authorization of many, if not most, tank mixes will be achieved through that same means, with the result that manufacturers may be able to avoid liability in the event of damage.

Following implementation of the Directive and pending the examination of the active substance concerned under the Community review programme, applications for authorization of new preparations, or new uses of preparations, containing active substances present in formulations which were marketed prior to July 1993, will be evaluated by the competent authorities of the relevant Member State, under national rules as to data requirements and the Community rules as to evaluative and decision making criteria. Where existing national

rules as to data requirements are deficient (*viz.*, certain data not required), the Community rules as to data requirements take precedence, to the extent that the national rules are deficient.

It seems unlikely that it was intended that active substances which were not registered or used commercially, but which were supplied and used under experimental permits prior to July 1993, should qualify to be treated in the same manner as substances used commercially in formulations that had been properly registered or cleared. The definition of *placing on the market* contained in the Directive, requires that substances used under experimental permits be treated in the same manner as those which had received registration for commercial use.

The arrangements for experimental use and testing of products envisage exemption from an obligation to obtain authorization for such uses being made available to appropriate persons and possibly institutions, subject to appropriate conditions, which can be expected in include the availability of appropriate facilities and equipment, appropriately trained personnel and restrictions on the marketing of produce from experimental plots. Such measures will permit a streamlining of procedures for granting authorizations for experimental use.

It is likely that the task of elaborating the data requirements and criteria to determine when particular studies are required for those plant protection products which are micro-organisms or viruses or are preparations containing them, will commence once the requirements for chemical based products have been elaborated. Necessarily, that work must include the requirements for organisms that have been genetically modified.

DETAILED REQUIREMENTS

Although many papers concerning the requirements of the Directive and the implications arising for industry and regulatory authorities, have been published (Mortensen, 1990; Thomas, 1990; McMinn and Thomas, 1991; Petzold, 1991; Tooby, 1991), detailed and informed comments and assessments necessarily must await the adoption and publication of the various subsidiary instruments to complete the Annexes to the Directive and the publication of the documents to specify *inter alia* the format for the presentation of dossiers (Table 1).

Data requirements

It is envisaged that in the drafting of proposals for Annexes II and III, a stepwise or sequential approach (tiered), will be taken in specifying the programme of testing and experimentation required, the results of basic tests or studies determining the need for further testing. It can be anticipated that in the interests of realizing the objective of achieving economy in the use of

resources necessary for the generation of information and data, and of the objective of the minimization of the extent of testing involving vertebrate species, the approach specified will involve testing of active substance, rather than of formulated product, where the data thus generated is of value, and precludes testing of the various preparations containing the active substance.

TABLE 1. Anticipated timetable for the adoption of subsidiary instruments and documents necessary for the authorization of plant protection products in the European Communities.

Subject	Surmised Date of Adoption
Annex II - Data requirements for active substances[1]	1993
Annex III - Data requirements for preparations[1]	1993
Annex VI - Uniform Principles for evaluation and authorization of plant protection products	1992/3
Rules of the Standing Committee on Plant Health with regard to evaluation and inclusion of active substances in Annex I	1993/4
Commission Regulation specifying the rules for the review of existing active substances	1992
Data requirements for authorization for experimental use	1993
Explanatory Notes relating to the presentation and format of dossiers	1993

[1] to specify relevant methodologies, and include criteria to determine when particular studies and information are required.

Through the elaboration of appropriate criteria, much unnecessary testing involving different formulations of the same active substance should be eliminated, particularly, but not exclusively, relating to testing as to fate and behaviour in the environment, and as to impact on non-target species. The maximization of the extent to which that objective will be achieved, depends on the timely availability of comparative data that can be used to establish principles for extrapolation of results from active substance to formulated product and from one formulation to others. Such comparative data if made

Evaluative and decision making criteria

As in the case of data requirements, informed comments as to the detail of the evaluative criteria to be used in decision making with respect to active substances (Community decision) and preparations (Member State decision), must await the publication of relevant documentation (Table 1). Nevertheless some general and preliminary observations can be made, as many aspects follow directly from the text of the Directive as adopted, and since the consultative process undertaken by the Commission in drafting its proposals with respect to the Uniform Principles to be used by the Member States in the evaluation of applications for the authorization of preparations, is now completed.

To a considerable extent, the criteria adopted will follow from those currently used in the Member States. The criteria adopted will be based on sound scientific principles and practices, and will be chosen to achieve a high level of protection for man, animals and the environment. It is likely that the criteria to be used in the evaluation of applications relevant both to active substances and to preparations, will involve or include:

- decision making on the basis of sound scientific judgement;
- risk management forming an integral part of the evaluative and decision making process;
- conditions and restrictions imposed being appropriate to the severity of the risks arising;
- formulations being of the required quality;
- analytical methods being sufficiently robust;
- amounts used being the minimum necessary to achieve the desired effect;
- performance being judged primarily on the basis of a comparison with reference products and on the basis of yield response and quality;
- assessment of risks for man being based on consideration of dose response relationships, the mechanisms involved, no observed adverse effect levels (NOAEL) and the application of appropriate safety factors to permit estimation of acceptable daily intake (ADI) levels and acceptable operator exposure levels (AOEL);
- residues at harvest being the minimum necessary consistent with authorized use;
- the significance of levels remaining in soil or water being assessed through field studies to demonstrate risks for non-target species; and
- assessment of impact on non-target species being based on consideration of impact on the abundance and diversity of species.

CONCLUSIONS

The adoption of Directive 91/414/EEC represents a breakthrough and a milestone in the harmonization of pesticide regulatory systems and requirements. Through the new European system, science is enshrined as the basis for decision making with respect to pesticide registration. On its implementation, a firm basis will exist for responding to the many misleading, often uninformed, comments and reports as to the impact of pesticides.

There are many challenges still to be met to ensure the smooth and effective operation of the new system, among them, the development of the Annexes, experimental guidelines, models and risk assessment schemes required. The greatest challenge is to recognize the remarkable achievement already made through adoption of the Directive and to recognize the benefits and opportunities that will accrue from its implementation. Such recognition has already taken place, to some extent, as evidenced by the resources made available by governments, academia and industry, for the development of guidelines, models and risk assessment schemes (Table 3). It is necessary, however that the pace at which the work concerned is being completed, be increased.

Among the practical benefits that will accrue from implementation of the Directive, are clarity as to data requirements, rationalization of data requirements, reduced costs for industry, on an overall basis, a much improved data base for decision making, and consistency in decision making based on good science. Such benefits should greatly increase opportunities for the development of more effective plant protection products, at reduced cost, while ensuring that the risks for man, animals and the environment are minimized. If availed of, the end result should be better quality and cheaper food.

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THE USE OF MODELS IN THE REGULATORY DECISION MAKING PROCESS

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ABSTRACT

Models can be used in various ways for regulatory purposes. At every stage of the registration process computer simulation models can assist with interpretation of measured data and in elucidation of parameter values. The choice of model must match the application. Care needs to be exercised when applying models to predict site-specific chemical behaviour, as in these situations the repercussions of incorrect assumptions and field variability will be greatest. Regardless of the model or application, there is no substitute for an appreciation and understanding of the physical, chemical and biological processes which determine chemical fate, and experimental data which confirm or refute the results of computer simulations.

INTRODUCTION

Regulation of the use of agricultural chemicals is becoming more stringent as evidence grows of the widespread effect that these chemicals have in the environment. However the complexity of the pathways through which chemicals dissipate from their point of original application has led to much controversy about the manner in which chemical fate should be assessed, the nature of the experimental work which should be conducted, and how the knowledge about chemical behaviour obtained should be applied to the diversity of environmental conditions experienced in agriculture. Field measurements of chemical dissipation are extremely time-consuming, expensive, and subject to soil and sampling variabilities, and it is often difficult to draw firm conclusions from experimental observations. Computer simulation models appear to make these tasks easier than before, since they have the capability of integrating so many of the processes which occur simultaneously in crops and soils, and can be executed rapidly for many different scenarios. Multiple executions of these models, using input parameters representative of the variability experienced in the field allows the uncertainty to be encompassed.

Simulation models must be used correctly if they are to be a useful scientific tool, and not fall into disfavour because they do not deliver what was perhaps mistakenly thought possible. When used as part of the regulatory procedure there is a special need for sound scientific reasoning behind the choice and application of simulation models.

During the past few years there has been increasing criticism of models and the way in which they are developed and used. Philip (1991) warns against the trend towards using speculative models in place of the traditional scientific methods of observation, experimentation, and deduction. While these doubts are justified, there are applications for models which cannot be met easily by any other means. But models and their predictions, as with any other scientific procedure, should be subject to

careful and rigorous examination.

Users of models often have only a vague understanding of their nature and content. This, more than any other factor, leads to inappropriate applications and invalid conclusions. There are many chemical fate models available today, at all levels of complexity. Unfortunately, interactive user interfaces, help screens, default data values, and on-screen colour graphics makes computer models appear more reliable and accurate than is justified. Models do not contain any inherent knowledge which enables them to predict chemical fate more accurately than can be measured in the laboratory or field. What they do provide is a means of tying together various pieces of knowledge so that various scenarios and interactions can be explored, other than the few it is possible to measure directly.

The National Research Council (1990) in the United States produced a detailed evaluation of the current status of groundwater models and their regulatory applications. They concluded that there are conceptual problems concerning water and solute flow in unsaturated systems, and for more complicated chemical and microbial processes. They concluded that properly designed models are useful tools to assist in problem evaluation, design of remedial strategies, and conceptualization of flow processes. Models can provide additional information for decision making, identify limitations in data, and guide collection of new data. They warned against the approval of particular models by regulatory agencies, which could lead to inappropriate applications and stifle the development of better approaches. Instead, model selection should depend upon the type of problem and level of understanding required.

Zubkoff (1992) summarized some of the uses of simulation models by the United States Environmental Protection Agency during the pesticide registration process. These include: determining the necessity for additional studies when full chemical characterization of the chemical is incomplete; integrating data submissions of laboratory and field observations; estimating the probable fate and distribution after a severe runoff event; comparing alternative chemical application rates and methods for different soil-crop-environment combinations; comparing different soil-crop-environmental combinations representing different geographic regions with the same chemical; evaluation of preliminary designs of proposed field experiments; and gaining insight into the environmental fate of modern chemicals which are applied at very low rates. A wide range of models, data bases, expert systems and GIS-based techniques are used in these evaluations.

In this paper computer simulation models are discussed in relation to their suitability for various applications. I will attempt to outline what I perceive as their limitations and benefits.

CLASSIFICATION OF MODELS

Regulation of chemicals covers all aspects of their development, registration, use and disposal. These include the determination of properties related to their environmental impact, evaluation of the relative importance of different dissipation pathways (leaching, degradation, volatilization, uptake by plants, ingestion by fauna, erosion and runoff), comparison and evaluation of different soil, environmental and management situations, explanation of experimental observations, determination of the

conditions under which a chemical may be used safely, assessment of the probability of long-term environmental contamination, and procedures for remediation of contamination. Simulation models have a role in each of these areas. The wide range of possible applications is often the source of much of the confusion and controversy that surrounds the use of models, because a model suited to one application is not necessarily suited to another. Also, the way in which simulations are interpreted and the level of accuracy and detail required varies among these applications.

Computer simulation models consist of numerical solutions to a set of quantitative equations, each of which describes some aspect of the behaviour of a chemical. In addition, they may include processes which cannot be quantified or which may apply to a limited range of situations. Typically, each of the processes has been studied or observed under carefully-controlled conditions in order to obtain values for the constants in the equations, or to develop 'rules' of behaviour. A model attempts to extend the utility of the process equations by solving them for less-than-ideal field conditions, where transient flow predominates and processes occur simultaneously, leading to interactions which are not present in controlled experiments. It is important to recognize that, in any one model, all processes are not included, process descriptions are usually simplified, there are bounds to the applicability of a model, and that other equations and concepts are usually available to describe many of the processes.

To choose a model appropriate for a specific problem requires some knowledge of the range of models available. Model classification can be approached in several different ways. Addiscott and Wagenet (1985) classified models into categories depending upon the concepts and nature of the processes used. They identified a broad classification into analytical, stochastic and deterministic models. The deterministic, or process-based models, were further subdivided as functional, which are capacity-based, and mechanistic, which include dynamic processes and which are thus more complex. Wagenet and Rao (1985) identified models as having research, screening or management applications depending upon the amount and nature of the input data required and the level of process detail that they included. Simple models are ideal for educational and demonstration purposes because they require little input data or prior knowledge and understanding by the user. At the other extreme, research models include much process detail but also demand much data which are often difficult to obtain. Somewhere between these two extremes we could expect to find the ideal 'regulatory' model, which would include sufficient process detail to make it useful but which does not require too much data or subjective judgement on the part of the user. In practice however, regulatory models come from anywhere in the range, depending upon the problem to be solved.

There are usually several options for mathematically describing each process involved in chemical dissipation and degradation. There are thus many possible combinations of process description, which is one reason for the large number of models that we have to choose from. Many users, when faced with the task of choosing a model, embark upon a fruitless exercise of comparing model predictions. Time would be better spent determining exactly which processes are included in each model, choosing one which appears to have the capability of performing the desired simulations, and verifying the code by means of some well-defined simulations which can be compared with analytical solutions or manual calculations. Such a procedure identifies the basic scientific concepts which can in turn be linked to measured data which

may be provided as part of the registration procedure.

SELECTION OF MODELS FOR REGULATORY PURPOSES

Table 1 lists some of the processes included in several popular one - dimensional pesticide fate models. These models were selected because they cover the spectrum of one-dimensional models currently available. BAM (Behavior Assessment Model) (Jury, *et al.*, 1983) is an analytical solution to the steady-state flow convection dispersion equation. CMLS (Chemical Movement in Layered Soils) (Nofziger and Hornsby, 1986) is a simple capacity model which predicts the position of the chemical concentration peak in field soils. CALF (Nicholls, *et al.*, 1982) is a mobile-immobile phase capacity model. PRZM (Pesticide Root Zone Model) (Carsel *et al.*, 1985) is a widely-used transient flow model developed by the United States Environmental Protection Agency. LEACHM (Leaching Estimation and Chemistry Model) (Wagenet and Hutson, 1989) is a suite of transient flow, convection-dispersion models for predicting the fate of several classes of chemical compounds. RZWQM (Root Zone Water Quality Model) (Ahuja *et al.*, 1991) was developed under the auspices of the United State Department of Agriculture, and is probably the most sophisticated one-dimensional chemical fate model currently available. There are many others not listed here. Most models are in a continual state of evolution, either in terms of their content, expansion into two or three dimensions, or links with other models, expert systems and geographic information systems.

TABLE 1. Features of some one-dimensional pesticide fate model.

	BAM	CMLS	CALF	PRZM	LEACHM	RZWQM
Water flow						
Steady state	*					
Capacity		*		*		
Capacity (mobile/immobile)			*			
Richards equation					*	*
Green-Ampt infiltration						*
Solute transport						
Retardation calculation		*				
Mobile/immobile mixing			*			
Convection-dispersion	*			*	*	*
Sorption						
Linear	*	*	*	*	*	
Curvelinear						*
Sorption kinetics					*	*
Degradation						
First-order	*	*	*	*	*	*
Other					*	*
Erosion/runoff				*		*
Volatilization	*				*	*
Crop growth				*	*	*

How should a model be selected? The first task is to outline the processes thought to play a role in the problem under study, and to identify

those which are to be emphasized or varied in the modelling exercise. A user who cannot do this, at least on a qualitative basis, should not be attempting to use a model as he or she will not be capable of evaluating the model output. A model is chosen or adapted which included the required processes.

Comparing models is best done by comparing the processes used to simulate chemical fate. Models which use the same equations for describing a dominant fate pathway are likely to give the same predictions. For example, leaching is related primarily to the net downward water flux. This in turn is determined by the difference between infiltration and evapotranspiration. Regardless of how water fluxes within the soil profile are simulated, predictions of average drainage flux over the long-term are likely to be similar by all models. Thus all of the transient flow models in Table 2 are likely to predict similar displacement of the chemical concentration peak, provided that sorption and degradation behaviour are described in the same way. The models may differ in the next level of detail. LEACHM, PRZM and the RZWQM predict the distribution of chemical in the profile, but these distributions depend upon the parameter values and methods used to describe dispersion. In the case of CALF, the threshold between mobile and immobile water influences the vertical distribution of chemical. Only LEACHM and the RZWQM model simulate volatilization, but this in turn depends upon assumptions about boundary layers, diffusion of the chemical in the gas phase and enhancements of diffusion owing to factors such a barometric pressure fluctuations.

Although more complex models often appear to produce more detailed simulations, these may not be based on a firm footing, since the parameters which determined the outcome of the simulation may have been estimated in the first place. A regulatory model should be free of such assumptions, or should be used in a way that enables the sensitivity to uncertain parameters to be judged.

REGULATORY APPLICATIONS

Because there is a wide variety of possible model applications during the regulatory procedure there is no single model which can be used for all purposes. In this section some of the considerations involved when choosing models for specific purposes are discussed.

Determination of chemical and soil properties

There is increasing recognition that the input parameters used in models should be determined under dynamic conditions similar to those experienced in the field, rather than in equilibrium batch-type experiments. Experimentally, this is most easily done by analyzing steady-state column breakthrough data (for example, Gamerdinger *et al.*, 1990). Both analytical and numerical solutions to the convection-diffusion equation can be used to optimize multisite kinetic sorption parameters, dispersion, etc. The extent to which these parameters are unique, and transferable among models which may use different flow and transport descriptions is unknown.

Chemical screening

Chemical screening procedures compare the likely behaviour and dissipation pathways of different chemicals under the same conditions.

Because this is a ranking procedure, high accuracy regarding field behaviour is not required. These models use well-defined, commonly-measured chemical properties as input and only require approximate soil and environmental data, if any. The models range from simple empirical indices to more sophisticated techniques which attempt to define the predominant dissipation pathways.

Evaluation of field and lysimeter data

As part of the registration procedure a number of field dissipation experiments are usually conducted. Before any predictions can be made about chemical behaviour in other soils and environments we have to be able to explain the measured data in terms of our knowledge of chemical properties, soils and boundary conditions. This is an important modelling application because it integrates much of the available knowledge about the behaviour of a chemical. Input data are usually well-defined, and comparisons between simulations and field data are done by scientists who have sound hypotheses and sufficient intuition to recognize gaps in our knowledge and limitations of the models. This application requires the use of transient flow models, and serves as a validation procedure for these models before they are used for prospective simulations.

Pinpointing sites and situations for further field experimentation

Field experimentation is expensive. To obtain the greatest benefit from a limited number of experiments it is important that the sites and design of these experiments chosen carefully. Models are useful for screening soils and climate as well as chemicals. Simulations can also aid the design of sampling and monitoring procedures. The possibility that some processes may operate in the field that are not included in the model should never be overlooked.

Prediction of temporal variation of leaching patterns

Rainfall variability is often as important as soil variability in determining long-term leaching patterns. Field experiments are performed under a limited range of rainfall patterns. A model allows the impact of long-term variability to be explored. Multiple executions of a deterministic model, using historic rainfall data may be employed, or a stochastic approach may be adopted, using generated rainfall distributions (Jury and Gruber, 1989).

Predicting the behaviour of a chemical on a regional basis

This is a common application but one which is subject to much uncertainty owing to spatial and temporal variability in climate, soil and processes. It usually requires a sophisticated model, but often the outcome of the simulations is determined by very few input parameters, such as the distribution of soil organic carbon.

Assessing remedial action

Walsh (1988) outlined the problems faced by regulatory agencies in using models for assessing remedial action at hazardous waste sites. The use of overly simple models, merely because they do not require site-specific data, usually tends to overestimation of exposure risks, and could reduce public health protection because funds available for cleanup of waste sites could be

misallocated. Walsh concluded that regulatory policy and regulatory laws should have a firm foundation in good science.

DISCUSSION

The use of models as part of the regulatory process is not merely a matter of selecting a model which is popular or which appears to be endorsed by certain organizations. A model has to be selected for specific applications. Much of the educational value of modelling lies in the process of defining the system to be modelled and in the definition of the processes and assumptions which used in the model. Passioura (1972), in a critique of crop simulation modelling, wrote: 'Given the frame of mind that a person has when creating a model..., a week's non-modelling thought would probably lead him to the same conclusions that a year's modelling would.' To blindly use a model to obtain numbers which cannot be measured is an inappropriate and stultifying process. Thinking about the processes which influence the fate of a particular chemical, identifying gaps in our knowledge, and weighing up the relative importance of the various dissipation pathways is as important as the execution of the model itself.

There has been a trend towards multiple executions of models, especially of large complex models which require many parameters. Lack of data has been replaced with Monte Carlo type simulations, where real data are replaced with values chosen at random from an assumed population distribution of values. This is a procedure which appears sophisticated and statistically well-founded, but closer examination of the basic premises often shows that there were no good data bases from which the input parameter distributions could be derived. The temptation to embark upon large sensitivity studies and regional simulations is great, and occasionally justified, given the increasing computer resources at our disposal. Sometimes, however, far more is gained from a smaller exercise, studying the interaction between two or three processes, rather than trying to interpret the results of a very complex model.

Walsh (1988) stated: 'modelers must contend with the practical reality that computer models by their very nature, have a unique capacity to appear more certain, more precise, and more authoritative than they really are.' Modelling is undoubtedly a useful tool for evaluating chemical fate but the recognition that they are necessarily simplifications of the real world must precede their adoption as a regulatory tool. Such acceptance by industry, regulatory agencies and environmental organizations will help make modelling a useful, respected and less controversial tool in environmental impact studies.

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SOME LESSONS FROM THE UNITED STATES REREGISTRATION PROGRAM

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ABSTRACT

The development of the pesticide reregistration program in the United States and changes in the program over the last 20 years are discussed, and some suggestions are made about lessons other governmental organizations can learn about pesticide reassessment programs.

INTRODUCTION

For several years the United States Environmental Protection Agency (EPA) has been conducting a program to "reregister" pesticide chemicals that were first registered in the United States before 1984. The European Community (EC) is now initiating a similar program under which chemicals that have been registered in one or more member nations will be reviewed and either placed on a Positive List or banned from the market. This paper will attempt to draw lessons from the United States experience that may be helpful in the EC effort.

THE REREGISTRATION PROGRAM IN THE UNITED STATES

Brief history of the program for regulating pesticides in the United States

If one seeks to avoid some of the problems that EPA has experienced with its reregistration effort it is useful to examine the context in which the program began and developed. In the United States there has been a pesticide regulatory program at the federal level since 1910. However, for many years the main role of that program was to combat fraud by sellers of ineffective products. Federal "registration" of products (licensing as a precondition of marketing) was not required at all until 1947, and until 1964 the federal registration system had no effective enforcement component. This licensing program was operated by the Department of Agriculture until 1971, when EPA was established. By then, about 40,000 products were registered, containing one or more of several hundred active ingredients.

Until 1978 each individual state was authorized to register pesticides for sale and use within that state, whether the product was federally registered or not, and many states did issue these "intrastate" registrations. For the past several decades, many of the states' pesticide laws have been quite similar, because they were based on model legislation drafted that was by an interstate commission and was designed to complement the federal law. The implementation of these laws by the various states varied considerably, however, with respect to the level of scrutiny of products, the extent of concern about safety issues as opposed to consumer fraud prevention, and the amount of resources made available to support the programs.

Until the 1970's, to the extent that these federal and state licensing programs were concerned with safety issues, the main emphasis was on safety to those who applied pesticides or worked or lived in or near treated areas. However, in addition to the licensing of pesticides for sale, since the early 1950's the federal government has also regulated the level of pesticide residues on food commodities in interstate commerce, and thus focusing on dietary risk. This program for setting residue "tolerances" was administered by the Food and Drug Administration until 1971. Most state governments also regulated pesticide residues to some extent, but the federal system has been predominant; most state laws simply applied federal standards to food that was produced and consumed within an individual state. Again, many of the state laws on pesticide residues were based on model legislation and thus were quite similar.

In the early 1970's the EPA was formed, and the two federal programs--product licensing and residue regulation--were combined and placed under its jurisdiction. At about the same time the potential for adverse ecological effects of some pesticides became widely recognized. Under the 1972 amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), Federal licensing of all products was required (a phase-out period for state licenses was provided). The statute directed EPA to balance all risks and benefits of the use of a pesticide in deciding whether a new product may enter the market and whether previously registered products should be banned from the market, registered for "restricted use" only by certified applicators, or made available for "general use." State governments have an important enforcement role under the 1972 FIFRA; they also are entitled to register products for uses that serve "special local needs" as long as the products' ingredients are federally approved and any needed residue tolerances were in place.

The reregistration program

The 1972 FIFRA amendments also required the EPA to "reregister" all previously-registered products in accordance with the new law's criteria. The 1972 law did not define reregistration, specify criteria by which the EPA would decide what could be reregistered, or specify what was to become of products that were not reregistered. Moreover, the legislative history reflects no expressions of concern by the EPA at this lack of direction. Congress and the EPA apparently both thought at first that reregistration, whatever it was, would be an easy job; the law allowed four years for the EPA to complete the task.

EPA began its reregistration task assuming that it had a fairly usable data base, and devised ambitious criteria for sorting products into three categories: those that should be taken off the market, those that could be retained with restrictions on who could use them, and those that were essentially non-problematic. But by 1977 it had became clear that the early assumptions had been totally unrealistic. The studies that supported the existing registrations were found to be hopelessly inadequate, and entire new categories of studies were needed in order to allow evaluation of the potential hazards with which regulators had come to be concerned. Moreover, disputes with registrants about trade secrecy, data compensation rights, and market entry for look-alike products had tied the registration and reregistration processes in knots. The lack of progress toward reregistration and the discovery that a major laboratory had falsified many independent toxicity studies gave rise to persistent political criticism of the program.

In 1978 Congress removed the reregistration deadlines, gave the EPA new authority to require submission of data on old chemicals, and enacted compromises on the "business" issues concerning rights in data and market entry for "me-too" products. Although the 1978 law still provided no explicit criteria or procedural rules to govern reregistration, it recognized the existence of the risk criteria and procedures that the EPA had devised administratively in 1975 for identifying products whose potential risks required special regulatory attention and possible restriction or banning.

During the next 10 years the EPA devoted considerable resources to the reregistration process, and reviewed almost 200 of the most important active ingredients, primarily those used on food crops. The EPA decided that the resources available to it would allow the introduction of approximately 20-30 chemicals per year into the multi-year process. For many of these chemicals, the initial reregistration activity consisted mostly of cataloging the chemicals' uses, determining the kinds of data needed for the chemicals, and requiring the registrants to generate and submit new studies concerning mammalian toxicity, plant and animal metabolism, crop residues, environmental fate, and ecotoxicity if no such studies had been submitted previously. Up to 4 years were allowed for the registrants to supply the missing data. In most cases the EPA decided to require only the outright data gaps to be filled immediately, instead of first evaluating the studies it had to determine whether old studies were so inadequate that they would have to be replaced as well. Because of this postponement of the review of existing studies, a second round of review was conducted for chemicals once the first round of required data had been submitted. This round consisted of reviewing all the old and new studies, deciding which studies were acceptable, deciding what further studies were needed, and reaching tentative conclusions about the hazard potential of the chemicals. In several cases, these reviews resulted in the commencement of special review proceedings or other adverse actions against the chemicals.

However, by the mid-1980s the Agency was being criticized severely by some for its lack of progress in reregistration actions. Environmental and consumer groups, as well as Congressional committees,

complained that perceived hazards were not being ameliorated and claimed that the lack of progress proved that the EPA was a tool of industry. But the registrants were also unhappy with several aspects of the reregistration process. Industry members complained that after they had completed the many studies required by the initial round of data call-ins, they found the process had just begun. The EPA not only was requiring the replacement of old studies recently found to be inadequate, but also was imposing entirely new types of study requirements, and finding the newly completed studies to be inadequate using criteria adopted only after the studies had already been started. The industry began to realize that the costs of testing in the modern era would exceed the future profit potential for some products, and for minor uses of other products. Registrants increasingly needed to know how much reregistration would really cost, so that they could decide whether to drop products or budget for their continued support. Finally, the "moving target" for data requirements was prolonging the completion of reregistration unacceptably. The delays gave some credence to claims by pesticide critics that pesticides posed unknown and therefore unregulated dangers, claims that hurt the credibility of both EPA and the pesticide industry.

Meanwhile, EPA had a complaint of its own: it found that it would need a lot more money--hundreds of millions of dollars more than previously budgeted--to fund the governmental component of a reregistration effort that would be sufficiently rigorous, understandable, and rapid to minimize criticism of the Agency. There was a danger that the reregistration program would come to be perceived as a sort of regulatory black hole that would absorb data, dollars, and expectations at an ever-increasing rate, but would emit nothing of substance. In fairness, the EPA had managed to gather reasonably comprehensive information on about 100 of the most important pesticides and was nearing the time when major regulatory decisions could be reached; but there were still some 300 more active ingredients that had hardly been examined at all.

In 1988 Congress again amended FIFRA. This time it directed the EPA to follow a strict schedule for beginning and ending the reregistration process for the ingredients that the EPA had not yet begun to examine. Congress also established a financial incentive for the EPA to stay on the schedule and to complete the reviews already underway by allowing the EPA to collect fees from registrants for a 9-year period ending in 1997 and directing that these revenues be used only for reregistration activities. The 1988 amendments also required registrants to facilitate EPA's reviews of data by evaluating existing studies and summarizing those thought to be valid and usable.

Since 1988 the EPA has again issued a large number of data call-ins. In response to the need to pay fees and commit resources to generate studies, registrants have abandoned about one third of the 600 active ingredients subject to reregistration and have decided to support only the most profitable uses of many others, to the great dismay of growers who had relied on the abandoned products.

Only a few active ingredients, mostly inconsequential ones, have progressed to the point of reregistration eligibility decisions, although many more ingredients will reach this stage in the next few years. Recently, the EPA stated that it again needs substantial additional financing to operate the program, and is talking openly about completing the process of reregistration in the year 2002 rather than 1997. The "moving target" problem has continued to trouble registrants, who still complain that the EPA continues to add new data requirements to the list of required studies and is judging recent studies by even more recent acceptability criteria.[1]

For many chemicals an additional complication has been the relatively short schedules that the EPA has set for test completion, especially in areas where tests that should logically be performed sequentially must be run in parallel because of the tightness of the schedules. In the residue chemistry area, for example, the EPA says that the proper approach is to first determine qualitatively which metabolites are present in food commodities as a result of pesticide use and develop analytical methods for detecting and measuring all the

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[1] EPA has acknowledged this problem in the residue chemistry area. In a very recent paper (EPA 1992) it listed recently adopted criteria for study acceptability, and promised (p. 25) to apply them only to studies that it received in the future. To solve the problem, however, EPA should have said that it would apply the new criteria only to studies commenced after the criteria were announced; studies begun in 1990, 1991, or early 1992 will still be judged by retroactive standards.

metabolites of concern, and then for EPA to review the data and decide what residues need to quantified. Only then should the registrant use that knowledge to determine quantitatively the residue levels that result from use. But the EPA has set schedules for residue chemistry testing that often preclude use of this sequential process and instead require the qualitative work to be done in parallel with the qualitative residue measurements, before the EPA has decided whether the qualitative testing is adequate. Registrants also have sometimes found it extremely difficult to develop satisfactory analytical methods for measuring residues of all relevant metabolites in all relevant food commodities. These problems threaten to cause the disqualification of a number of recently completed, very expensive quantitative studies.[2]

One result of the perceived slowness of the federal reregistration process that should be of interest in Europe is the renewed interest in the independent regulation of pesticides at the state and local levels in the US. California and New York, among others, now have active registration programs that independently evaluate pesticides and often impose requirements that go beyond those of the federal government. Some cities and other localities have attempted to ban certain pesticides or regulate their use very stringently, and a number of cases asserting or challenging the right of states and localities to regulate pesticides are working their way through the court systems. Supporters of renewed state and local regulation routinely justify these programs by arguing that the EPA is not proceeding quickly enough on its own.

EPA has undertaken what has proven to be an incredibly complicated and resource-intensive reregistration project, and while it has made a great deal of progress, there also have been several disappointments. The experience of the EPA should be very useful to the EC in its upcoming effort to reconsider the status of all crop-protection chemicals.

LEARNING FROM THE UNITED STATES PROGRAM

Many lessons no doubt could be learned from an examination of the United States reregistration program, but for the purposes of this paper, we will focus on three: the need for realism in setting goals, the need for clear program definition and prospective rules, and the need to avoid undue rigidity. As an overall point, those in charge of establishing the European reassessment of crop protection chemicals obviously should take the time to learn where problems arose in the United States program and to consciously takes steps to avoid those problems.

Be realistic about the project's goals

A lack of realism about the goals and likely effects of the United States reregistration program--on the part of both the legislators who called for the program and the EPA, which is implementing it--has caused great problems for the EPA and the regulated industry. Pesticide regulation is a highly complex and controversial business, and this will not change. Governmental programs like these are easy to criticize and hard to run. In response to calls for reform, legislators and regulators often are tempted to declare that they have put into place a program that will solve the problems and remove the controversies, but they should resist

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[2] In its 1992 analysis of the rejection rate of residue chemistry studies (EPA 1992), EPA acknowledges the proper sequencing (pp. 6-7): "Using the results of plant and animal metabolism studies, EPA determines which metabolites are of concern and need to be included in the tolerance expression. . . Once the metabolism data indicate what to look for, and methods are developed to measure the [relevant metabolites], field experiments are conducted to determine the magnitude of the pesticide residue. . ." Industry commenters had said (p. 24) that "There should be an intermediate step in the registration process in which the Agency will quickly review the registrant's metabolism data, and the Agency and the registrant can agree on what should constitute the total toxic residue, so that work on an appropriate method can proceed. If this type of procedure cannot be accomplished in an expedient fashion, then clear 'trigger values' for toxicity of metabolites should be developed, so that the registrant and the Agency use the same criteria in deciding if a metabolite should be included in the analytical method [and subsequent residue determinations] or not." But EPA refused (p. 25) to apply this approach, saying without explanation "For chemicals undergoing reregistration the Agency is not willing to delay field trials while metabolism studies are being reviewed."

the temptation. Successful completion of a relatively modest program to increase knowledge somewhat and ameliorate the worst problems is much more valuable than a grander program that promises to yield comprehensive, current information and eliminate all problems but that does not produce demonstrable results in a reasonably short time.

In 1972, almost as an afterthought, Congress required the EPA to reregister all products. The EPA initially interpreted this mandate very broadly, without realistically assessing the work needed or the resources available, and thereby inadvertently fostered an unrealistic perception of what could and would be accomplished. Ever since then, the Agency has been subjected to demands for a level of regulatory oversight that would require resources greatly exceeding those available. In 1988 Congress, responding to environmentalists' urgings, amended FIFRA to require that reregistration culminate in a detailed, use-by-use, risk/benefit evaluation of each product containing any of the hundreds of ingredients subject to the reregistration program. Not until this year did the EPA finally state publicly what has been obvious for some time: a reregistration program that must scrutinize several hundred ingredients over a period of a few years and absorb thousands of new studies cannot be expected to do much more than yield a relatively current database and identify those ingredients that may pose risks serious enough to warrant further risk/benefit evaluation and eventual regulatory action.[3]

Those who are planning a new reregistration program thus should give careful concern to the difficulties that can be caused by too grand a set of initial goals. We strongly recommend that planners not create (or allow) too high a level of public and political expectation of what can be accomplished quickly and easily. If there are several areas to be addressed, do not attempt to design one program to address them all, but instead set up several smaller, more manageable and understandable projects. The EC has made a good start in this direction by limiting its "positive list" program to crop protection chemicals.

Above all else, the designers of a reassessment program must remember that the program must be affordable. If the program is to include a substantial governmental review component, then an adequately skilled staff must be assembled and trained before the reviews are scheduled to occur. The EPA experience shows that it is easy to underestimate resource needs, difficult to anticipate the extent of problems that will occur, and easy to increase both governmental and industry costs dramatically by making even relatively small changes in the program, if the changes are made only after the program is already well underway.

Define the requirements for data production and the process for data review carefully, and do not impose requirements retroactively

This may appear to be simply a restatement of the first recommendation, but we think it is a separate and important concept. Designers of a program for reassessing pesticide chemicals should keep firmly in mind the following facts:

- The reassessment program will focus inevitably on generation and review of data.
- Data generation is very expensive and studies often take years to complete. A study has to be designed before it can be performed. It is unrealistic to assume that registrants will be able to predict future policy changes by regulators and design their studies accordingly, and it is unfair and counterproductive to punish registrants for not anticipating these changes.

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[3] A May 1992 memorandum issued by the Director of the EPA's Office of Pesticide Programs (Campt, 1992) made two important points. First, it recognized that "a moving target of constantly changing [data] requirements makes it difficult to establish objective and consistent criteria for reregistration" and announced EPA's decision to establish a fixed target data base for reregistration and fixed, prospective criteria for those studies. Second, it said that the Agency's reregistration review would focus on a review of the target data base and an assessment of any risks shown by that data, and suggested strongly that if the risk assessment for an ingredient indicated "a potential for unreasonable adverse effects," the further evaluation needed for final risk/benefit decisions would not be made as a part of the reregistration program, thus eventually allowing EPA to declare that the reregistration process is complete even if some questions are left to be dealt with later.

- Thus, if the goal is that data are to be generated, evaluated, and used for decision making in a reasonably short time, the rules must be established in advance and not changed retrospectively. Requiring a four-year program of studies to start in year 1 and then announcing in year 3 that entirely new criteria for evaluating the studies will be used will produce chaos. Announcing that the program will take 20 years instead of the projected 10 will produce public contempt for regulators. The fact that scientific advances give rise to new questions about pesticides does not change this.

- A reassessment program will be both unnecessarily expensive and needlessly complicated if it asks unnecessary questions, and will be challenged if it lacks internal logic. Regulators should not require a study unless they have a good understanding of what regulatory steps or assumptions will flow from unfavorable study results, nor unless the study is designed to answer specific questions that need answering.

- Registrants may have fair questions about the need for particular studies and should have an opportunity to have these questions considered and answered before they are required to commit massive amounts of resources. Registrants' testing budgets are not limitless, and they may react to rigidity in testing requirements by choosing to abandon products instead of commencing the testing. The increasingly vociferous complaints by United States producers of "minor use" crops about the abandonment of pesticides that are vital to them—if only marginally profitable to registrants—has come to have a major unbalancing influence on the United States reregistration program.

Avoid unneeded rigidity

Our final suggestion is to avoid unnecessary rigidity or strictness in the design and management of the reassessment program. There is a clear need for rules in any program of such scope, both to guide registrants and to protect regulators from endless entanglement in *ad hoc* decisionmaking. But there is still a need for the careful exercise of discretion in designing and implementing the program, in areas such the following:

- deciding whether studies that do not comply with every requirement or guideline nonetheless provide sufficient information to answer the relevant questions.

- setting schedules that permit normal sequencing and review of studies, taking into account potential scientific difficulties that may be associated with particular chemicals (e.g., analytical method development for metabolites).

- recognizing that good laboratory practice requirements and other such rules are not ends in themselves but rather are intended to encourage the careful conduct and proper documentation of studies in order to obtain useful regulatory information.

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THE IMPLICATIONS OF MODERN REGULATORY REQUIREMENTS FOR CROP PROTECTION - A CONSUMER VIEW

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ABSTRACT

As more is known about pesticides, more regulation is needed to control their effects in the interests of good agricultural practice. The main regulatory burden falls on farmers and growers in the industrialised countries of Europe. An increase in regulation requires a corresponding clarity in decision making. The confidence of consumers and users in pesticides would be improved if regulators could agree what the health risks of particular chemicals are and if international standards of occupational health, and water, soil, and air quality could be agreed in the same way that Codex has begun to harmonise food residue standards. The main concerns of consumers and users are the cost of regulation, the need for a comprehensive policy of reduced pesticides usage, and a sustainable agriculture that pays farmers for environmental stewardship rather than over-production.

REGULATORY REQUIREMENTS WILL INCREASE IN THE UK

The increasing regulatory framework surrounding pesticides means that users can no longer simply apply the pesticide according to the label directions. As well as crop health, pesticides affect soil, air and water quality, human health and wildlife. Although pesticides today tend to be more species specific, and effective at lower dose rates than previously, they are in consequence more biologically active: pesticides in parts per billion affect water quality, and have been shown to affect human immune systems; and in parts per trillion, marine fauna.

Until the passing of the Food and Environment Protection Act 1985 (FEPA), there was very little legislative control over pesticides. Now, in addition to statute law and the regulations made under it, users must be mindful of Codes of Practice, Approved Codes of Practice, and the contractual specifications imposed by wholesalers, retailers and distributors. Regulation from other areas including food safety, health and safety at work, and water quality also applies to pesticides. Regulatory requirements will in due course cover even wider areas in even more detail - including container design and disposal, personal protective equipment standards, biocides or non-agricultural pesticides and genetically modified organisms.

The trade and environmental aspects of pesticides use mean that wider, regional, laws and policies have also to be considered. EC Directives and Regulations have a direct impact on pesticides users; so also do OECD programmes; and information, trade, waste, and transport agreements are handled by a number of different UN and intergovernmental agencies.

The direct result of increasing regulatory requirements is that the use of pesticides becomes an increasingly demanding task. In the UK, the generally mandatory certificate of competence should increase user skills, but the time may be approaching when many categories of pesticides may be used only by professional applicators. As much of our food is imported, another consequence is that UK consumers will expect similar competence in the use of pesticides from users elsewhere.

REGULATION FURTHER AFIELD

There may be a case for farmers in northern European industrialised economies complaining of too much regulation. But in the Third World, the chances are there is little or none. An FAO survey found that more than 50% of developing countries have no legislation enabling government to restrict the pesticides that can be marketed or to limit their availability to particular areas or users; in Africa the proportion is 76% (FAO, 1989). In spite of the best efforts of the international agencies, a recent report of the joint WHO/UNEP Working Party, enquiring into the impact of pesticide poisoning on human health (WHO, 1990) estimates that there are 3 million cases of acute severe pesticide poisonings worldwide per year, including 220,000 fatalities. Particular emphasis was laid by the report on the situation in developing countries where the majority of poisonings occur, and where information is hardest to come by.

Of the estimated 3 million acute severe poisonings, 2 million are thought to be suicide attempts, of which 200,000 are thought to be fatal. The estimated incidence of unintentional acute severe poisonings, at 1 million, has doubled since 1972. This is linked to a doubling of pesticide production from 1.5 million tonnes of pesticides in 1970 to about 3 million tonnes in 1985. In the next ten years, pesticide use in developing countries is expected to double. The Working Party calculates that the poisoning rate is set to increase at a similar pace.

The Pesticides Trust's own research (Pesticides Trust, 1992) indicates that few Third World countries systematically monitor acute or chronic pesticide poisoning, or environmental quality. Increasingly, consumers are realising that they cannot expect other countries to produce food for the industrialised First World using hazardous products and technologies we have rejected.

HARMONISING INTERNATIONAL STANDARDS

The more complicated the regulation, the greater is the need to try and agree internationally the interpretation of data. The results of different views by regulators can only lead to confusion among users and consumers - Alar and the EBDCs are the obvious examples. Only last year, the International Agency for Research on Cancer concluded: "The spraying and application of non-arsenical insecticides entails exposures that are probably carcinogenic to humans" (IARC, 1991) - a verdict that flies in the face of the views of many other regulatory bodies. One of the tasks of national and international regulators is to agree how to agree.

Progress has been made in harmonising data registration packages, and it is hoped that procedures such as the draft Uniform Principles being discussed at the moment within the EC will help to harmonise interpretation of data (EC, 1992b). A conference in Sweden this year organised by KEMI, the Swedish National Chemicals Inspectorate, addressed these issues within the OECD (KEMI, 1992). The conference underlined the urgent need to agree on harmonised principles or guidelines for the assessment of risks, particularly in the difficult areas of carcinogenesis and ecotoxicology.

There has been considerable international emphasis in trying to set standards for residues of pesticides in food and produce, particularly through the Codex procedure. What consumers and users are now concerned about is that there has so far been no comparable international effort in other important areas - including occupational health standards for those who produce and work with pesticides, and environmental quality standards for air, water, and soil. Proposals are made in UNCED's Agenda 21 for a new intergovernmental mechanism for this purpose.

Consumers and users are also particularly interested in the GATT negotiations: what measures of environmental protection and rural support will be permitted to remain in the "Green Box"? What measures will producer and importer nations be able to take to safeguard their own food security in the face of dumping?

CLARITY IN DECISION MAKING

An increase in regulatory requirements needs to be accompanied by clarity in decision making. In the UK, FEPA establishes the Advisory Committee on Pesticides as a body to advise Minsters, but says little about any policy of pesticides use. It is not clear what regulatory decisions about pesticide use are political and what decisions are scientific or administrative. It is not clear what risks, benefits, and costs are to be considered in registration of pesticides, and decisions over their use; nor how alternative methods of pest control are evaluated; nor how risks, benefits and costs should be weighed and balanced; nor whose job it is to make the calculation.

The data requirements listed by MAFF and HSE for registration of new products do not indicate how the data are to be interpreted, nor what the criteria of interpretation are. The "acceptable" risks for cancers, or dietary or skin exposure, by way of examples, are not clear. The job of identifying hazard and risk is clearly one for the ACP as an independent expert committee. However, decisions about the acceptable levels of risk, and the management of risk are decisions where the public and different interest groups representing consumers, users, conservationists, environmentalists and the community at large have a stake. Greater clarity is called for to distinguish between scientific and political decision.

ONE CHEMICAL AT A TIME

The Alar affair demonstrated the power of consumers and the media, in the absence of clear decisions and guidance by regulatory agencies. It also highlighted the increasing difficulties in clearing or reviewing pesticides on a chemical-by-chemical basis. In many cases, banning or restricting the use of a pesticide may result in simply replacing one chemical by another. Increasingly it is necessary to look at the role of pesticides in each sector of production or use.

The voluntary withdrawal in the UK of Alar may well have reduced cancer risks to children from exposure to daminozide and UDMH. However, it was just as important to look at the safety of other chemicals that might have been used instead; and at non-chemical alternatives in orchards. Everyone needed to know whether Alar was safe, but the issue for growers, retailers and consumers was could enough apples be grown more safely without it.

The restriction of triazine herbicides is another example. In order to help meet EC drinking water standards and to reduce the levels of atrazine and simazine in drinking water, non-crop uses of atrazine and simazine have been revoked. No advice has so far been offered to users as to what alternative products or non-chemical methods of pest control they should use, or how water pollution by other pesticides can be avoided.

This is a familiar problem. Advising how not to control pests can be easier than advising how to control pests. The joint UN Environment Programme/Food and Agriculture Organisation Prior Informed Consent scheme is successfully making information available to regulators and users on particularly hazardous chemicals that have been banned or severely restricted for health or environmental reasons: but does not recommend what form of pest control to use instead. This is a nettle that

has to be grasped.

TRAINING IN PEST CONTROL

The Control of Pesticides Regulations have introduced certificates of competence, which must go to improve the safe use of pesticides. However, it is the Control of Substances Hazardous to Health (COSHH) Regulations, made under health and safety legislation, rather than FEPA, that have made a difference in everyday use.

The emphasis on the safe use of pesticides is understandable: but training should be on safe pest control. This involves making choices about chemicals, but also what methods of pest control, chemical or not, are appropriate. The point was made at last year's BCPC Conference, in the context of pesticides and water policy: "Voluntary agreements to reduce the use of certain herbicides like atrazine and simazine in the non-agricultural sector have already taken place. There is, however, cause for concern with regard to the alternatives being chosen which in some cases have greater potentials to contaminate water sources and have worse toxicological profiles. At present there is no comprehensive advice available to agricultural or non-agricultural users concerning pesticide choice and the preservation of water quality. Certificates of competence for pesticide application are now required but the health and safety of operatives are the main focus in the training programme" (Carter, Hollis, et al., 1991).

The Royal Commission on Environmental Pollution recently published its report on freshwater quality (Royal Commission on Environmental Pollution, 1992). It criticised the MAFF Code of Practice on Pesticides (MAFF/HSE 1990): "...it places the burden of decision on the pesticide user, who, though familiar with local conditions and experienced in crop management, weed or infestation control, is unlikely to be able to make such an assessment unaided."

FREEDOM OF ACCESS TO INFORMATION

The increasing regulation of pesticides means users need to know more about pesticides. In order to know more, access to information is required. The need for such information was well expressed by the Memorandum submitted by the Campaign for Freedom of Information in its submission to the House of Commons Select Committee on Agriculture: ".....access to such (safety test) data is needed:

a) so that there may be informed public discussion of the risks of pesticides and the adequacy of controls
b) so that those who have experienced or observed unexplained ill-effects can assess the likelihood that these result from pesticide exposure
c) so that pesticide users can make informed choices from amongst the pesticides available to them" (House of Commons Select Committee on Agriculture, 1987).

MAFF published at the beginning of this year its consultation document on the subject. The Pesticides Trust and many others welcomed the proposals, and MAFF's recognition of the importance of the debate. In particular, we welcome the Evaluation documents now released, the prompt appearance of the ACP's Annual Report, and the increasing consultation in regulation and policy. Such a welcome cannot, however, be extended to the new MAFF Fact Sheets.

It is important that users and professional advisors have access to up to date

information about pesticides: data summaries or fact sheets are the only practical means of providing this information. The COSHH Regulations, which apply to most pesticides, impose on pesticide users, whether employers or self-employed, the duty of making a risk assessment before using a pesticide. Label information is a start, together with product data sheets from manufacturers, but users need independently produced and accessible information to help make decisions about use or alternative products to use, or possible medical treatment.

The U.S. EPA publishes its series of "Pesticide Fact Sheets" summarising the toxicology and registration status of pesticides, together with advice on health and safety and conditions of use. The Fact Sheets list data gaps where the Agency has no information from the manufacturers, has inadequate data, or has particular concerns.

MAFF indicated in March 1989 that data sheets would be prepared and made available to the public. The Saltsjobaden International Meeting on Pesticides, organised by the Swedish National Chemicals Inspectorate, in October 1991, recommended that "as a minimum, sufficiently detailed summaries of health and safety (including environmental) data be available to the public, taking into account the protection of proprietary rights". Unfortunately, the first set of Fact Sheets recently issued by MAFF are very disappointing. There is nothing in the very basic information they contain that is not already available in a number of other publications. They list only the name and structure of the active ingredient, its review category, MRLs if any, and a summary of approved uses, usage, and formulations. It is difficult to see who they would assist and why they have been produced.

THE COSTS OF REGULATORY REQUIREMENTS

Increasing regulation means increasing costs. As taxpayers, we all pay for the pre-market and post-market control of pesticides by regulatory authorities. The costs of water privatisation and the need to comply with the EC Drinking Water Directive mean that consumers - who are generally not polluters - will have to pay. Many different shades of opinion agree that pesticide regulation is under-resourced. Industry pays the registration levy: and has offered to pay more for a faster service. Environmentalists, consumers, unions, and industry together pressed for more resources for pesticide registration, and an increased Agricultural Inspectorate at HSE (Green Alliance et al., 1989). There is insufficient encouragement towards good agricultural practice when HSE has only 100 or so inspectors who may only visit a farm once every ten years; when MAFF is under-resourced; and when users have to pay for advice from ADAS under its new agency status.

A consequence of the increasing costs to industry is that there may be a withdrawal by companies of products from smaller, less profitable markets. Although the markets may be small, the number of users may not be. Off-label approvals, specialist horticultural products, and local authority amenity products are the obvious examples. In these cases, help from the public purse may be needed to sustain research and development of alternative pest control methods, and to maintain jobs.

The first recourse to pay for environmental pollution is to make the polluter pay. This is often easier said than done. A number of countries are investigating fiscal instruments to share the burden equitably between users, producers, and the public - permits, quotas, levies, a sales tax, or an income tax are all under review. In addition, strict liability, environmental insurance, and a Superfund-style compensation scheme are all likely to be in place within the next few years.

REGULATORY REQUIREMENTS AND POLICY

It is not only the pre-market and post-market controls of pesticides that everyone pays for, but also agriculture. What are we using pesticides for? No one wants to see pesticides used simply to increase unnecessary EC produce mountains or intervention stocks. Farmers need to know what they should be growing - what are the goals of agricultural policy? How are producers to be kept on the land, and how are they to be rewarded?

The CAP Reform agreement, including set-aside, is generally unpopular, and may not curb over-production (Agra-Europe, 1992). However, the accompanying measures, which will shortly be produced and form part of the Agri-Environment package may benefit the environment by supporting water protection, the reconversion of arable land to pasture, and organic farming and environmentally friendly production practices. The Fifth Environmental Programme was announced by the Commission in March 1992 (EC, 1992a). In agriculture, the Programme will aim for "significant reduction of pesticide use per unit of land under production and conversion of farmers to methods of integrated pest control, at least in all areas of importance for nature conservation".

The objectives of pesticide policy in the UK are, according to the White Paper "This Common Inheritance" (HMSO, 1990):

* the amounts of pesticides used should be limited to the minimum necessary for the effective control of pests compatible with the protection of human health and the environment;
* in making decisions on the use of pesticides, the government will take into account efficacy, human health, and environmental factors;
* the government will review all approvals at regular intervals and will withdraw them if significant new information about harmful effects on man or the environment comes to light;
* subject to essential commercial confidentiality, the information supporting decisions on the use of pesticides should be available for public scrutiny; and
* procedures for approving the use of pesticides must be fully independent of sectoral interests.

Is a policy of minimum use enough? A wide variety of bodies have expressed concern about the overuse of pesticides. The recent report of the British Medical Association (BMA, 1992) has called for reduced pesticide usage. The National Farmers Union, the Cooperative Wholesale Society, and the National Rivers Authority have issued policy statements about reducing pesticides usage. The Sixteenth Report of the Royal Commission on Environmental Pollution also recommends "...a national strategy (including a timetable) for reducing pesticides use should form part of the UK's water quality plan" (Royal Commission on Environmental Pollution, 1992).

PESTICIDE REDUCTION POLICIES

A number of agricultural nations are introducing reduction programmes. Denmark developed a plan in 1985 to reduce the use of pesticides by 50% before 1997. In Sweden, a programme was put forward in 1988 to reduce pesticide use by 50% in 5 years. The Netherlands has developed the most comprehensive, sector-by-sector policy. Similar plans are also being examined the USA (Pimentel, 1991): the aim is to reduce pesticide use with minimal reduction in crop yields. Lower input costs will protect profit margins. Indeed the UK government has, for example, undertaken in the Third North Sea Conference, to reduce the discharge of the Red

List pesticides to the North Sea to half their 1985 levels by 1995.

What, therefore, is to be understood by reduction? It is not a question simply of replacing an active ingredient with another of less weight, or dispensing with sulphuric acid treatments. Neither is it a question of copying blindly ideas from another country. The Netherlands, for example, uses far more pesticides than other European countries. A comparison of the elements of the policies of Denmark, Sweden, and the Netherlands suggests that pesticide reduction includes reducing dependence on chemicals in agriculture; reducing risks to operators, consumers, and the environment; and reducing the use of pesticides.

Part of the process of reducing dependence on chemicals involves examining the costs and benefits of pesticide use. Regulatory authorities generally investigate the quality, efficacy, and safety of pesticides. It may now be necessary for them to consider the question of the need for a product; and what are the costs, risks, and benefits of use.

The costs and benefits of pesticides have traditionally been assessed in terms of their ability to reduce pest loss, compared with the cost of pesticides. In those terms, pesticide use was worthwhile. More recently, however, researchers have started to include the indirect environmental and social costs of pesticides in the calculation. These previously hidden costs may help to argue the case for a reduction of pesticide use, and in some cases may lead to consideration of whether synthetic chemical pesticides should be used at all.

The Pearce Report (Pearce et al., 1989) draws attention to the importance of the concept of sustainability, in maintaining environmental resources and ecological functions upon which the agricultural system depends. The report was a government-funded study, and its conclusions were welcomed by the then Secretary of State for the Environment. The ideas of environmental accounting it sets out introduce the calculation of the future costs of present use.

The second element of pesticides reduction policy should be the reduction of risk - both to the health and the environment. There is a need to develop methods of comparing risks. A number of countries are now developing the notion of "cut-off" criteria. The Swedish National Chemicals Inspectorate (KEMI) has published a set of principles for identifying unacceptable pesticides used in agriculture (Andersson, Gabring, et al,. 1992). The purpose of the report is to provide information describing when KEMI considers a pesticide to be unacceptable from the standpoint of health and environmental protection on the basis of its intrinsic properties.

There are a number of approaches to reducing pesticides input in agriculture - these include the use of more selective chemicals, reduced dosage and reduced application frequency, spot treatments, inter-row applications, patch spraying, seed treatment, slow release granules, low volume sprays with minimal drift, and more careful timing of applications (Jordan 1990). Pest and disease forecasting, and the development of spray or pest "thresholds" will also be helpful. Pesticide input reductions of 36% (in terms of kg active ingredient/ha) have been achieved in Federal Germany, and 60-90% in the Netherlands in experiments over several seasons while maintaining quality production without economic loss.

Some nations, as part of their pesticides policy, have tackled the problem of inaccurate or poorly-maintained spray equipment by requiring regular testing of application machinery. Retesting of equipment is mandatory every two years, and subsidies are available to cover the cost of the test. This has been taken on board by the Danish and Swedish programmes, and a similar scheme is about to be introduced in the Netherlands, and is seen as the most important single measure

next to operator training to reduce overuse of pesticides.

The Pesticides Trust supports the calls for a coherent policy on pesticides use. The brevity and generality of the White Paper need to be given substance and translated into achievable targets. Those who work with pesticides and those who are exposed to them need clear guidance on the costs, benefits, controls, and alternatives to pesticides. At present the burden of deciding how pesticides should be used falls entirely on the user: instead of a policy of minimal pesticides use, there is only a minimal policy for pesticides.

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