SESSION 9B

REGULATORY CHALLENGES: REGIONAL ISSUES – GLOBAL SOLUTIONS?

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Papers	9B-1 to 9B-4

The Food Quality Protection Act of 1996

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ABSTRACT

The Food Quality Protection Act (FQPA) became law in August 1996. It is the most significant and complex U.S. legislation ever adopted for the regulation of pesticides. In particular, the FQPA ambitions were to establish a set of new rules for re-evaluating food tolerances for pesticides, the maximum legally permissible pesticide residues on various food products in the U.S. This paper highlights some of the FQPA's important requirements and assesses how implementation is proceeding. Some of the more significant national and international consequences of the law are also discussed.

INTRODUCTION

The main thrust of FQPA introduced in 1996 was to establish a set of new rules for reevaluating food tolerances for pesticides-the maximum legally permissible pesticide residues on various food products in the U.S. Tolerances are equivalent to Maximum Residue Levels (MRLs) in Europe. The FQPA required the U.S. Environmental Protection Agency (EPA) to reevaluate a total of approximately 9,700 food tolerances within a 10-year timeframe. One-third of the reassessments were to be completed by August of 1999 with priority given to the more hazardous pesticides. EPA selected the organophosphorus compounds, carbamates, and products classified as B2 "probable human" carcinogens for priority attention.

Initially, the law was applauded by the agricultural chemical industry because its passage coincided with the abolishment of the infamous Delaney Clause of the Federal Food, Drug and Cosmetic Act (FFDCA). [The Delaney Clause was a section of the FFDCA that created a double standard whereby residues of a "carcinogenic" pesticide that were acceptable on a raw commodity (e.g., tomatoes), were considered unacceptable (at any level) in processed products of that commodity (e.g., tomato sauce).] Public interest groups also applauded passage of the FQPA since they viewed the law as a government-sanctioned vehicle for realizing their goal of eliminating a large number of pesticide products they considered dangerous or unnecessary.

In the three years since FQPA became law, however, views have changed considerably. Registrants, along with growers and food producers, have voiced increasing concern that, as FQPA is implemented, there is a strong likelihood that critical crop protection tools may be lost or severely restricted. As EPA struggles to implement the law, the registrant and user communities are urging caution against moving forward too quickly before critical scientific and public policy issues are resolved. On the other hand, public interest groups are pressuring EPA to proceed at full speed. The debate continues and is engaging the attention of a broad spectrum of key people and organizations, including those involved in international issues such as food safety, trade, and public's right to know.

HEALTH RISK ASSESSMENT

Perhaps the most significant changes mandated by FQPA relate to the procedures to be used by EPA for conducting health risk assessment of pesticides. These will have a major impact on establishing tolerances for food-use pesticides and, indeed, on the entire pesticide registration process.

A new safety standard

Under the old safety standard required by the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), a pesticide product could be registered in the U.S. if its use caused "no unreasonable adverse effect." This clearly implied a benefits consideration which allowed some pesticides with potential risks to stay on the market because of their significant benefit to society. In contrast, FQPA now requires pesticide registrants to demonstrate that their products can be used with a "reasonable certainty of no harm." This is a new safety standard that leaves no room for consideration of benefits. It is driven entirely by potential health risks and comes close to requiring a demonstration of absolute safety. This is an unattainable goal for a pesticide chemical or, for that matter, for any other product of modern technology.

To meet the requirements of this new safety standard, the FQPA calls for EPA to adopt new and more stringent risk assessment approaches, even though neither the required data nor scientific methodology are currently available.

Aggregate exposure assessment

One of the new requirements in conducting risk assessments and establishing food tolerances, is that EPA must now take into account the total *aggregate pesticide exposure* of various subpopulations from all non-occupational sources (food, water and residential uses). Prior to FQPA, EPA estimated the potential risks of food-use pesticides only on the basis of the dietary intake of pesticide residues. While available food residue and consumption data provide reasonable estimates of pesticide intake from food, exposure data for other sources, especially for home use of pesticides, are relatively poor. This will prove to be a severe constraint on the conduct of realistic aggregate exposure assessments and will require the continued use of conservative assumptions.

Cumulative risk assessment

The other major change in risk assessment methodology mandated by FQPA is that, instead of evaluating the risks associated with exposure to individual products, as has been the case in the past, the EPA must now consider the potential cumulative risks associated with several different pesticides known to have a common mechanism of toxicity. This requirement is particularly troublesome for two reasons. First, there are difficulties in precisely defining the term "common mechanism of toxicity" and identifying appropriate groups of chemicals to be assessed together. Second, there is currently no appropriate methodology for conducting such assessments. In effect, the law requires the immediate application of undeveloped and untested techniques.

The "Risk Cup"

The total allowable level of daily exposure to any given pesticide has not changed and is defined by the Acceptable Daily Intake (ADI) or Reference Dose (RfD). This value is obtained by applying an appropriate uncertainty (or safety) factor (usually about 100) to a No-Observed-Adverse-Effect Level (NOAEL) for some toxicological endpoint obtained from an appropriate laboratory study.

The fundamental problem for both EPA and pesticide registrants is to ensure that the total aggregate daily exposures to a pesticide fall within the RfD. Under FQPA, the RfD has been colorfully analogized to the "Risk Cup." When the cup is filled to capacity for a given pesticide, it means that the total aggregate exposure to that product has attained 100% of the RfD. If the cup is less than full, EPA can consider more tolerance requests. If, on the other hand, the cup is overflowing, the registrant must make difficult decisions on how exposures to the product can be reduced. The problem is, of course, exacerbated by the requirement for cumulative risk assessment because the single *cumulative* "risk cup" must be able to accommodate the individual "risk cups" of each of the other products in the common mechanism group. From a practical standpoint, this means that, to be accommodated in the cup, the exposure contributions from each of the products in the group may have to be reduced.

While the FQPA states what has to be done, it provides no guidance on how to proceed, other than indicating that the process must be based on sound science and reliable data. At the present time, neither the required data nor appropriate scientific methodologies are available to allow EPA to conduct aggregate exposure and cumulative risk assessments as required by FQPA. Few, if any, guidelines have been provided to registrants by EPA and a variety of task forces and work groups are still attempting to interpret the law and determine how it can be appropriately implemented.

Child sensitivity and endocrine disrupters

In view of recent regulatory emphasis on protecting sensitive subpopulations, especially children, it is perhaps not surprising that FQPA requires EPA to apply an extra 10-fold safety factor to its pesticide risk assessments when children are thought to be at special risk. This factor can be applied in addition to the usual uncertainty factors (10 each for possible inter- and intra-species variability) used in deriving the RfD from the NOAEL, or can be applied to account for uncertainty in the exposure data. Child sensitivity continues to be a controversial science policy issue and remains a major topic of debate in both EPA and among registrant and user groups. Issues such as when the extra factor will be required and the needs, if any, for additional tests to identify possible effects in children are the focus of intense discussion. Application of the additional safety factor will clearly result in a more conservative risk assessment, which reduces still further the available space in the "risk cup."

The FQPA also requires the Agency to consider the potential endocrine-mediated or hormonal effects of pesticides. The law required EPA to establish a validated screening and testing program for estrogenic and "other" endocrine-mediated effects within two years of FQPA enactment and to implement the program under FIFRA in an additional year. The endocrine issue has been under active evaluation through EPA's Endocrine Disrupter Screening and

Testing Advisory Committee (EDSTAC) and, although the proposed program is still not finalized, it is already factored into every hazard assessment.

MANAGING THE PROCESS

The impact of FQPA on EPA was compounded by the fact that the law became effective immediately. The Agency was unable to accommodate the new requirements into its usual operations, because FQPA involved fundamental changes in both science policy and regulatory practice. Furthermore, there still exists significant disagreement within the scientific community as to how to interpret many of the requirements of the law and to translate them into practice.

EPA's challenge, therefore, was how to accommodate the new requirements of FQPA while continuing to handle an already heavy work load of evaluating and approving new products and addressing a wide variety of other issues. This has proved extremely difficult and, to the frustration of all concerned, regulatory progress on all fronts has slowed considerably. Implementation of FQPA has been aided by the Tolerance Reassessment Advisory Committee (TRAC). Through TRAC, EPA has worked with the United States Department of Agriculture (USDA) to facilitate the resolution of several FQPA science policy issues and to ensure transparency in the process. EPA has adopted a formal process whereby draft polices are published for public comment and subsequently refined based on feedback received from registrant, user and public interest groups.

Although the process for addressing these science policy issues is now in place it is likely to take a few more years to conclude. Protecting children from unnecessary exposure to pesticides, for example, is a goal with which everyone can concur. Reaching a consensus among politicians as to how this can be achieved, however, is much more difficult and is a major reason why most food safety legislation leaves such critical public policy choices to government officials. This complicates and delays the decision making process and is a constant source of frustration to those with direct interests in the outcome. The public interest groups expect conservative interpretations and aggressive implementation of the law, while the registrant and user communities want policies that assure the continued availability of most of their preferred products.

PROGRESS TO DATE

On the third anniversary of the FQPA, EPA announced that it had completed 3,290 tolerance reassessments, surpassing the target required by the law. The Agency also pointed out that two-thirds of the reassessments involved high-priority pesticides and many involved crops consumed by infants and children. According to the Agency, all assessments were based on current, sound science and the latest scientific methods and data. Although the EPA clearly met the requirement of the law, it should be pointed out that some 45% of the reassessments were accomplished by simply removing from the books old tolerances for uses that were canceled many years ago. Furthermore, some of the most recent reassessments (e.g., those with methyl parathion and azinphos methyl), completed just prior to the FQPA deadline of August 3, were quite controversial and were characterized as decisions made by deadline

rather than by data. Moreover, the recent tolerance decisions were made with single pesticides with emphasis on dietary exposures. Dissatisfied and frustrated with the progress to date, a public interest group celebrated the third anniversary of FQPA by filing a law suit against the Agency for failing to meet the requirements of the law.

CONSEQUENCES

It is still too early to predict the likely consequences of FQPA on the agrochemical and agrobusiness communities. There is no question that, as implementation proceeds, many tolerances may be canceled and a number of well-established "essential" uses of older products may be lost. There will be more pressure to reduce or eliminate tolerances when the Agency fully implements the FQPA requirements of aggregate exposure and cumulative risk assessment. In cases where no effective replacements are available, the consequences to agriculture could be substantial. This is likely to be particularly true for many minor crop uses where pesticide sales are relatively small. To ensure a smooth transition as product uses are phased out, close cooperation will be necessary between the agrochemical and user communities.

There are also international implications of implementing FQPA. Potentially serious trade irritants and barriers will be created if EPA cancels tolerances for pesticide products used on crops grown in other countries and imported to the U.S. since, without a tolerance, the commodities will not be allowed into the country. Efforts over the last few years to harmonize guidelines, MRLs and other aspects of the pesticide regulatory process are presently stalled as other countries struggle to understand the FQPA and wait to see how it might affect their activities.

The current focus on synthetic chemicals may be advantageous for those companies investing heavily in biotech products and "safer" pest management tools are among the only new products being actively solicited, evaluated and registered by EPA. These advantages are countered, however, by international concerns, particularly from Europe, regarding the safety and public acceptability of genetically modified plants and products. Consequently, it is not yet clear what role, if any, FQPA might have in the development of pesticide products based on biotechnology.

OPPORTUNITIES

While there are a myriad thorny issues and problems to resolve, opportunities also exist. These include incentives for the industry to develop new and safer pesticide products and to generate new toxicology and exposure data to more clearly demonstrate the safety of existing products. There also will be incentives for affected groups (users, processors and registrants) to join forces and form coalitions and task forces to develop creative solutions to the issues raised by the FQPA. By working together, they can promote a more balanced and workable implementation of the new law that should ultimately be beneficial to the industry as a whole.

Further information on the FQPA can be obtained from the web-site www.fqpa.com.

Pesticide registration in Europe – current status and future developments

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ABSTRACT

Council Directive 91/414/EEC established procedures for the regulation of new and existing active substances in plant protection products within the European Community (EC). Considerable progress has been made in implementing the requirements of the Directive, although the programme for the re-evaluation of existing active substances is way behind schedule. A new regulation, intended at overcoming the current problems and putting the review programme back on track is in preparation. Implementation of this new review regulation will provide the main challenge to both industry and regulatory authorities in the immediate future.

INTRODUCTION

Prior to 1991, all Member States of the European Community (EC) operated their own registration regimes for plant protection products, with very little co-operation between the individual members. This resulted in a duplication of work for both industry, in terms of submissions, and the authorities in terms of data evaluation and granting authorisations. The different standards being applied in the different Member States were also considered to constitute a barrier to trade in plant protection products within the internal market, in direct contravention of one of the fundamental principles behind the establishment of the community.

Council Directive 91/414/EEC

In order to establish a harmonised procedure for the regulation of plant protection products in the EC, Council Directive 91/414/EEC (Anon., 1991) concerning the placing of plant protection products on the market was adopted and has now been implemented in all Member States. This Directive sets out the basic principles and procedures to be adopted for the authorisation of plant protection products, whilst the annexes provide the basis for the harmonisation of data requirements and regulatory decisions.

Through the implementation of Directive 91/414/EEC a European wide regulatory process for determining the acceptability of active substances with regard to their safety to humans and the environment was established, whilst leaving the responsibility for the authorisation of plant protection products to the individual Member States. Annex I to the Directive lists those active substances that have been deemed acceptable in accordance with the criteria set out in Article 5 of the Directive, that is that their use and their residues, consequent on application consistent with good plant protection practice, do not have any harmful effects on human and animal health or on ground water or any unacceptable influence on the environment.

The data requirements to establish the safety of the active substance and products containing it are set out in Annexes II and III of the Directive respectively. The so called 'uniform

principles' to be used in the evaluation of the safety of plant protection products are laid out in Annex VI. Under the terms of the Directive, an authorisation for a plant protection product may only be granted at Member State level once the active substance has been included in Annex I. Obviously it will take some time to reassess the 800 or so active substances already on the market at the time of adoption of the Directive with respect to their acceptability for inclusion in Annex I. Article 8 (2) of the Directive, therefore, established transitional measures for 'existing' active substances and provided the basis for the EC review programme.

Commission Regulation (EEC) No 3600/92 (Anon. 1992) established a collaborative programme for the review of existing active substances. It listed the first 90 active substances for review in Europe, and set out a timetable for the provision by industry of dossiers to support the inclusion of the active substance in Annex I and the preparation of reports of the evaluations (monographs) by the rapporteur Member States. In principle, one year was given for each of these stages.

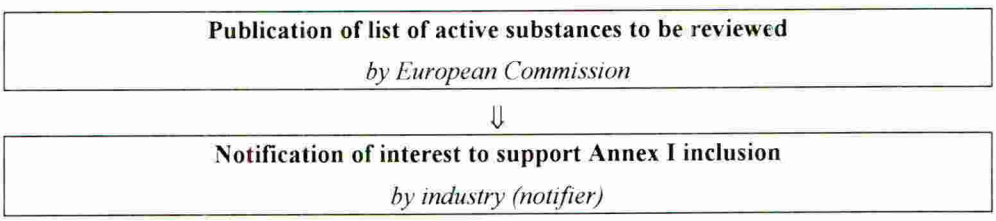
The registration procedure

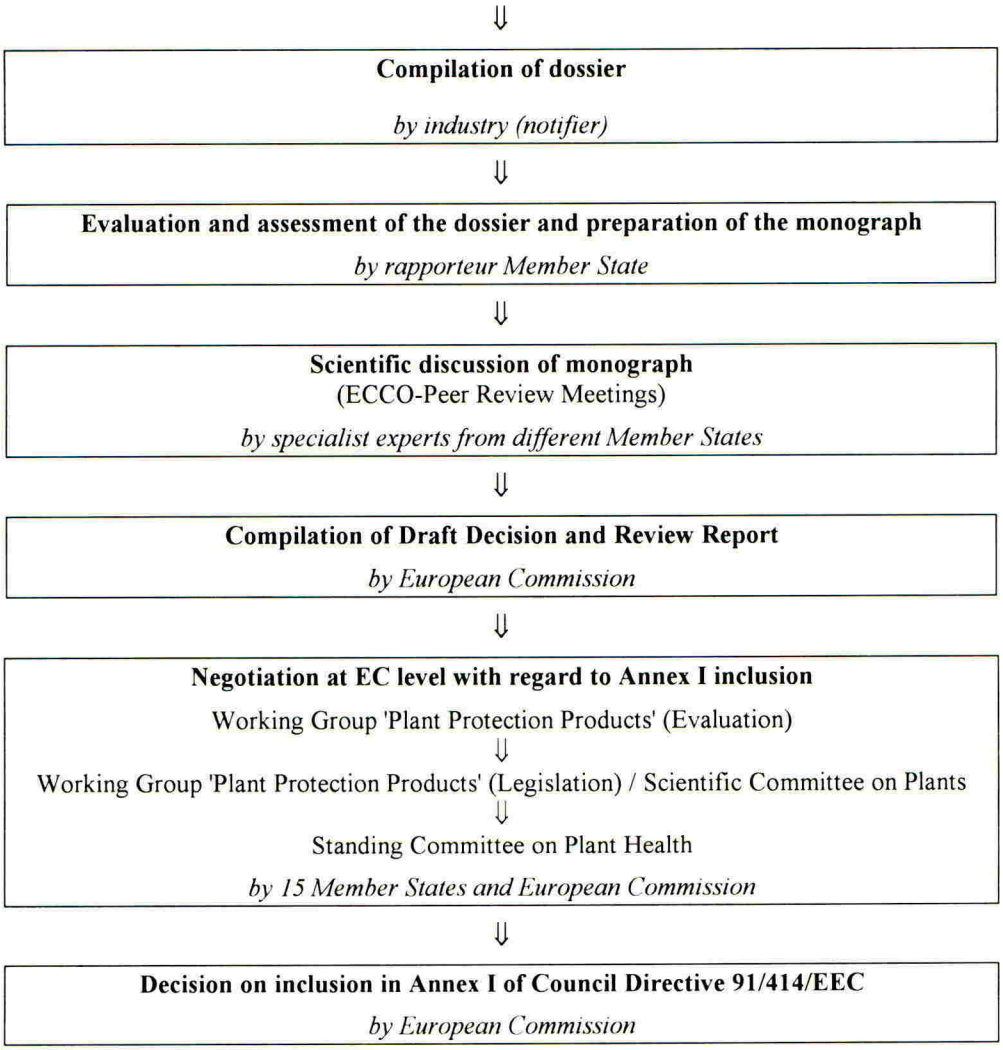
A flow diagram illustrating the current procedure for the re-evaluation of existing active substances is presented as Fig. 1.

The first step, following the publication by the European Commission of the list of active substances to be reviewed, is for companies to notify their intention to seek inclusion of an active substance in Annex I and then to provide a dossier to the Member State that is to undertake the evaluation of the data, the rapporteur Member State (RMS). The RMS then evaluates the data and prepares a report of the evaluation, or monograph, which is the forwarded to the Commission. The monograph is then peer reviewed by experts in the ECCO Peer Review programme, prior to consideration by all Member States within the framework of the Standing Committee on Plant Health (SCPH). Currently, this consists of a detailed technical consideration at the Working Group 'Evaluations', followed by consideration at the Working Group 'Legislation', which considers the wider aspects of the evaluation. At the same time the evaluation is also considered by the independent Scientific Committee on Plants (SCP), which also expresses an opinion on the acceptability for Annex I inclusion. Taking into account the views of the Member States and the SCP, the Commission then takes a decision with respect to inclusion, or not, of the active substance on Annex I.

For new active substances the procedure is essentially the same, although there is an additional step in the procedure where the completeness of the dossier is agreed at EC level.

Fig. 1: Procedure for the review of existing active substances in plant protection products within the European Community under Article 8 (2) of Council Directive 91/414/EEC.





CURRENT STATUS – ACHIEVEMENTS TO DATE

As of 1 August 1999, 58 dossiers for new active substances have been agreed as complete and are, therefore, under evaluation. Monographs for 24 of these have been peer reviewed, with six more scheduled for consideration in the next round of peer review meetings. Four new active substances, azoxystrobin, kresoxim-methyl, spiroxamine and azimsulfuron have been included in Annex I.

For existing active substances, 66 monographs have been prepared by the rapporteur Member States, of which 52 have been peer reviewed with a further eleven to be considered in the next round of peer review meetings. As a result, one existing active substance, imazalil, has been included in Annex I. For seven others (cyhalothrin, ferbam, azinphos-ethyl, propham, dinoterb, fenvalerate and DNOC) decisions not to include the compound in Annex I have

been taken, and products containing them have been withdrawn from the market. In addition, decisions relating to the non-inclusion of a further two active substances (pyrazophos and monolinuron) have received a favourable opinion in the SCPH and are being finalised by the Commission.

Although decisions relating to Annex I inclusion have only been taken for a total of 12 new and existing active substances, a number of other important initiatives have been developed, which should be numbered among the achievements so far.

Several guidance documents have been prepared, including guidelines for the preparation and presentation of complete and summary dossiers for inclusion of active substances in Annex I (Anon. 1998a) and guidelines for the preparation of "monographs" by the rapporteur Member States (Anon. 1998b). The CADDY project (Computer aided dossier and data supply) has been developed and introduced to provide an electronic format for the preparation and submission of dossiers. Other guidelines relate to carrying out residue trials, Good Laboratory Practice, the preparation and presentation of data concerning efficacy and the modelling of fate and behaviour of plant protection products in the environment (groundwater, surface water, soil).

A key element of the strategy for improving procedures developed by the European Commission is the development of guidance on the criteria for Annex I inclusion. This document is now being developed by an expert working group, and should be available in early 2000. In addition, guidance documents on mutual recognition, data protection, the establishment of AOELs, the setting of an acute reference dose (ARfD), dermal absorption, relevant metabolites, persistence in soil and aquatic and terrestrial ecotoxicology are currently being prepared.

The development of these guidance documents is seen as essential for improving the efficiency of the system and harmonising the evaluation standards across the community. Furthermore, two of the afore mentioned initiatives, the dossier and monograph guidelines and CADDY, are also of particular importance with respect to the global harmonisation of pesticide registration.

The EC guidelines on the preparation of dossiers and monographs for active substances formed the basis for the development of similar equivalent documents that have been formally adopted at OECD level. This is an important step towards harmonisation and work-sharing on a wider international level, since industry now has a standard format for the preparation of a dossier for submission in all OECD countries.

The aim of the CADDY project is to facilitate the provision of dossiers for active substances to regulatory authorities through the development of a suitable electronic format for the compilation and submission of dossiers in an efficient and economic manner. As a result, the long-term archiving of dossiers and the increased accessibility of information contained therein will also be facilitated.

The development of the CADDY retrieval software commenced in 1995 at the European level with the establishment of a joint EU Member States/ECPA Data Transfer Steering Group and quickly advanced to become an international project through the participation of US-EPA, PMRA Canada, ACPA and Canadian Industry. Industry has already started to compile

dossiers using the CADDY software, with 11 dossiers for new active substances having been submitted on CD-ROM so far, and several member states have already gained experience of using the retrieval software. More detailed information on CADDY may be found on the Internet on the Global Crop Protection Federation (GCPF) Home Page (www.gcpf.org).

FUTURE DEVELOPMENTS

With only one existing active substance included in Annex I and decisions relating to a further seven having been taken, the real challenge for the immediate future will be the review of the remaining (700 or so) existing active substances. Directive 91/414/EEC provides for transitional measures for existing compounds for ten years only, with the current derogation for national authorisations due to end in July 2003. The European Commission has, therefore, developed a strategy to expedite the review programme prior to reporting on progress to the European Parliament and the Council in 2001. At the time of writing, the draft review regulation is at an advanced stage of development, although imminent changes in the Commission structure may result in some changes to the latest proposals, which are described below.

New review regulation

The next phase of the EC review programme is to be implemented by way of a new Review Regulation. This will establish the procedures for the second and subsequent rounds of reviews and is split into two sections. The first sets out the procedures for dealing with the second list of active substances for review, whilst the second sets out the procedures for the notification of all of the remaining existing active substances. The new Regulation will also establish provisions for the charging of fees to cover the work involved in undertaking the reviews.

Annex I of the current draft Regulation lists over 140 active substances that will form the second review list (see Table 1). These include all the organophosphate and carbamate active substances on the market, together with a number of active substances of concern, a number of active substances for which complete dossiers are thought to be available, and a number that are unlikely to be supported. In order to facilitate the notification procedure, the new list will also identify the RMS for each active substance.

A relatively tight timetable has been laid down for this next phase of the programme, with notifiers being given nine months to submit their notifications of support for the active substances included in the next list. These notifications consist of a commitment to submit a complete dossier and the payment of a fee to cover the work involved in handling the notification and undertaking the completeness check following the subsequent receipt of the complete dossier. The rapporteur Member States then have three months to report on the notifications, following which the European Commission has a further three months to report the results of the exercise to the SCPH. Another regulation will then be published, giving details of the active substances that have been supported and establishing a deadline of 12 months for the submission of the complete dossiers to the rapporteur Member States. Following receipt of the dossier and the check for completeness, which should take no longer

than three months, the rapporteur will have 12 months to prepare a draft report of the evaluation of the dossiers that have been deemed complete for submission to the Commission.

Table 1 Active substances included in the draft second review list

PART A: Anticholinesterase active substances		**PART B:**	**PART C**
Organophosphates	phosalone	1,3-dichloropropene	barban
Azamethiphos	phosmet	1,3-dichloropropene (cis)	bromocyclen
Ampropylfos	phosphamidon	captan	bronopol
Bromophos	phoxim	folpet	chloral-semi-acetal
Bromophos-ethyl	pirimiphos-ethyl	clodinafop	chloral-bis-acylal
Cadusafos	pirimiphos-methyl	clopyralid	chlorfenprop
Carbophenothion	profenofos	cyanazine	chlorobenzilate
Chlorfenvinphos	propetamphos	cyprodinil	chloroxuron
Tetrachlorvinphos	prothiofos	dichlorprop	p-chloronitrobenzene
Chlormephos	prothoate	dichlorprop-P	DADZ(Zinc-diethyldithiocarbamate)
Chlorthiophos	pyraclofos	dimethenamid	di-allate
demeton-S-methyl	pyridaphenthion	dimethomorph	difenoxuron
demeton-S-methyl-sulphone	quinalphos	diuron	(2-(dithiocyanomethylthio) - benzothiazol
Oxydemeton-methyl	sulprofos	fipronil	fluorodifen
Dialifos	sulfotep	fosetyl	furfural
Diazinon	temephos	glufosinate	isocarbamide
Dichlofenthion	terbufos	haloxyfop	naphthylacetic acid hydrazide
Dichlorvos	thiometon	haloxyfop-R	noruron
Dicrotophos	thionazin	metconazole	pentachlorophenol
Monocrotophos	tolclofos-methyl	methoxychlor	4-t-pentylphenol
Dimefox	triazophos	metolachlor	propazine
Dimethoate	trichlorfon	metribuzin	sodium diacetoneketogulonate
Omethoate	trichloronat	prometryn	sodium dimethyldithiocarbamate
Formothion	vamidothion	pyrimethanil	2,4,5-T
Dioxathion	**Carbamates**	rimsulfuron	
Disulfoton	bendiocarb	terbutryne	
ditalimfos	benfuracarb	tolylfluanid	
Ethephon	carbofuran	tribenuron	
Ethion	carbosulfan	triclopyr	
ethoate-methyl	furathiocarb	trifluralin	
Ethoprophos	butocarboxim	trinexapac	
Etrimfos	butoxycarboxim	triticonazole	
Fenamiphos	carbaryl		
Fenitrothion	dioxacarb		
Fonofos	ethiofencarb		
Isazofos	formetanate		
Isoxathion	methiocarb		
Heptenophos	methomyl		
Iodofenphos	thiodicarb		
Isofenphos	oxamyl		
Malathion	pirimicarb		
Mecarbam	promecarb		
Mephosfolan	propamocarb		
Methidathion	prothiocarb		
Mevinphos	propoxur		
Naled	thiofanox		
Phorate	triazamate		

The new regulation will also set out a schedule for the review of all the remaining existing active substances (around 600) not covered by the first or second review lists, with the exception of those active substances covered by Annex II. This lists those active substances, or groups of active substances, that are not considered to be of high priority for review. The industry will be required to provide a declaration of their intention to support the active substance in the review programme within three months. These so-called pre-notifications will allow those involved in the process of examining the actual notifications to determine the likely workloads to be dealt with. The actual notifications will then be received six months later, and will comprise an undertaking to submit a complete dossier for the review, details of the data available, a completeness check and completed lists of end-points for the active substance involved. The information provided in this more detailed notification, compared to that required for those actives substances included in the second list, will be used to establish the priorities for review when preparing subsequent lists of actives substances for review.

The notifications will be checked and those that are considered acceptable will be reported to the European Commission. A report from the Commission will be considered by the SCPH, following which a new regulation will establish the third and subsequent lists of active substances for review and the deadlines associated with that work. The deadlines established for the consideration of the notifications have been set with a view to ensuring that the consideration of the report by the SCPH will take place early in 2001. The results of this phase of the programme and the Regulation issued as a result would then be included in the Commission report that is required to be made to the European Parliament and the Council, in July 2001, on the progress to date with the implementation of the Directive.

Based on experience from the first round of reviews, two fundamental changes to the current system will be introduced through the new Regulation. The first relates to the recommendations that can be made by the rapporteur in the draft report following the assessment of the dossier and the second relates to the number of uses considered at EC level during the evaluation of the dossier.

The original review regulation allowed for four possible outcomes following the assessment of a dossier; inclusion in Annex I, non-inclusion in Annex I, postponement of a decision on Annex I inclusion pending the receipt and evaluation of further data, or suspension from the market pending the same information. For various reasons, not least the adoption of the precautionary principle with regard to matters concerning human exposure to pesticides, the latter two options have been removed from the new regulation. In future, therefore, the only recommendations available to the RMS following the assessment of the information in a dossier will be inclusion or non-inclusion in Annex I.

The dossiers submitted for the actives covered by the first review regulation tended to cover all of the existing uses in the EC, and trying to evaluate these with respect to Annex I inclusion has proved to be extremely resource intensive and a major factor in delaying the decision making process. The new Regulation specifically requires that only a limited number of uses representative of EC conditions are included in the dossiers. Annex I inclusion will be based on this limited number of uses, with all the other uses that might be required throughout Europe being evaluated at Member State level following Annex I inclusion.

CONCLUSIONS

Significant progress has been made with the implementation of the Directive 91/414/EEC, but there is still a very long way to go. The EC review programme in particular is considerably behind schedule, with only one active substance included in Annex I so far. As a robust and effective review programme is an intrinsic part of providing public reassurance on the safety of pesticides, there is a clear need to expedite the review programme.

The proposed new regulation establishing the next phases of the EC review programme is, therefore, necessarily ambitious. It could be argued that it is too ambitious, especially when viewed against the background of progress to date with the first list of reviews. However, it is a step in the right direction, and the improvements that have been incorporated to overcome the problems encountered with the first review list together with initiatives such as the development of criteria for Annex I inclusion should see the review programme make good progress.

Such progress will inevitably be resource intensive for both industry and regulatory authorities. One possible way in which this burden can be shared to everyone's advantage is through wider international co-operation involving all those countries currently re-assessing the safety of existing active substances. To this end the initiatives being undertaken by the OECD are to be welcomed.

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International co-operation and harmonization in pesticide registration: the work of the OECD

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ABSTRACT

Since 1992, OECD countries have been working to harmonize regulatory approaches to pesticide registration and to co-operate in sharing the work of pesticide review. Harmonized regulatory approaches increase efficiencies for governments and industry. In 1998, harmonized formats for data submissions by industry and fo country data review reports were agreed. Harmonized formats for industry submissions should enable companies to submit largely the same package to all OECD countries without having to reformat the information. Harmonized formats for country data review reports make it easier for countries to use each other's reports to help them in their own review. Work is also being done to harmonize data requirements, testing methods and risk assessment procedures. At the same time, discussions between OECD and non-OECD countries on ways to extend co-operation in pesticide review have begun.

REASONS TO CO-OPERATE

OECD counties[1] all invest significant resources in evaluating agricultural pesticides before they are marketed to ensure that they do not pose unacceptable risks to human health and the environment. They are also re-evaluating pesticides that have been in use for many years to be sure they meet modern scientific and safety standards. Over time therefore, each country has developed its own regulatory procedures, practices and programmes for evaluating pesticides.

Since many pesticides used in OECD countries are the same, governments recognised the substantial benefits that could be gained if the task of pesticide evaluations for registration and re-registration were shared - rather than duplicating each others' work. OECD countries therefore created the Pesticide Programme, in 1992, to harmonize regulatory approaches. Harmonized regulatory approaches allow countries to conduct evaluations more efficiently. More efficient evaluations can: (1) advance the protection of public health and the environment; (2) result in more timely, less burdensome decisions for industry; and (3) facilitate international trade of agricultural commodities.

This paper describes OECD's efforts to increase international co-operation and harmonization in pesticide registration. However, it should be noted that the Pesticide Programme also includes activities to promote the development and implementation of agricultural pesticide

[1] OECD currently has 29 Member countries: Australia, Austria, Belgium, Canada, Czech Republic, Denmark, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Japan, Korea, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Spain, Sweden, Switzerland, Turkey, UK, US.

risk reduction policies and practices in OECD countries, and a range of activities to promote co-operation and harmonization in the regulation of non-agricultural pesticides (biocides).

MANAGING THE WORK

The Working Group on Pesticides (formerly the Pesticide Forum) oversees the OECD Pesticide Programme. The Working Group is comprised primarily of government regulators from the Member countries but also includes representatives from the European Commission (EC), from other international organisations (e.g. IPCS, UNEP, FAO, CoE, EPPO), and from industry, agricultural worker and environmental groups. The Working Group meets in Paris every 9 months to review progress and plan further work. The current Chair and Vice Chair of the Working Group is Vibeke Bernson (Sweden) and Bill Murray (Canada) respectively.

SHARING THE WORK OF PESTICIDE REVIEW

Assessing the potential

At the beginning of the Pesticide Programme, countries believed that significant resources could be saved if they could use each other's pesticide data review reports on the same pesticide rather than each country having to perform a separate evaluation. This is not as simple as it sounds since it requires countries to accept others' approaches to evaluating chemical hazards. However, through the Pilot Project to Compare Pesticide Data Reviews (OECD, 1995)[2], countries found that: (1) despite considerable differences among the reports reviewed, countries were largely arriving at the same conclusions with respect to hazard; and (2) many existing data review reports could already complement another country's independent review, or even replace it in areas where study results are straightforward (e.g. acute toxicity). The use of each other's reports was therefore a real possibility and it was agreed that a mechanism should be established to enable the exchange of data review reports among countries to begin straightaway.

Although the results from the Pilot Project were very optimistic regarding the sharing of review reports, countries felt that they would gain more from the procedure if, in future, the reports were written to a common format. The purpose would be to ensure that reports were clearly organised, easy to read, and contained all information that might be needed by another country. The reports examined in the Pilot Project represented a wide variety of document types and styles. They included long, detailed documents and short, summary reviews which might be organised in a variety of ways. These differences made the reports difficult to compare and, in some cases, to read. But most important was that, in many of the reports, key information was lacking or unclear. High priority was given to developing harmonized formats for government review reports, although countries agreed that the lack of agreed formats should not stand in the way of initiating work sharing activities.

[2] The Pilot Project compared pesticide data review reports for seven pesticides (amitraz, diazinon, dicofol, dinocap, endosulphan, iprodione and pyridate) known to have been reviewed by multiple countries and/or international organisations.

Starting to share the work

Following the recommendations of the Pilot Project, a database of pesticide reviews was created in 1995 for governments to use to find out who else has reviewed, or plans to review, a particular pesticide. The database now lists more than 2,000 evaluation reports on hundreds of pesticides and government evaluators are using it actively to locate reports of interest and to contact colleagues in other countries. Around 700 reports have been exchanged in the last 4 years.

Now OECD countries are trying to do more than use one another's evaluation reports to support their own pesticide registration decisions - they are actually beginning to work together in a more systematic way. The 15 European Union countries have been carrying out joint pesticide evaluations for several years (under Directive 91/414/EEC). Canada and the US are now routinely dividing up the work (e.g. the US may review information related to human health, and Canada the environmental information). And Australia, Canada, the US, and Ireland (on behalf of the EU) recently took part in a work sharing exercise to evaluate a new active ingredient. Currently most co-operation among countries is in the evaluation of new pesticides, but the Pesticide Programme hopes soon to identify ways of also sharing the work to reassess old pesticides.

This more systematic approach to sharing the work of pesticide reviews has been helped by the development of a common format for the data review reports, as recommended by the Pilot Project. OECD countries agreed to the format in February 1998 (OECD, 1998a). The format, based on and compatible with that of the EU, should assure that reports written by different countries are structured in the same way, contain the same level of detail, and are "transparent" in discussing the study results and the authors' observations. Also agreed in February 1998 was a common format for the data submissions prepared by pesticide manufacturers (OECD, 1998b). Until recently, pesticide manufacturers had to submit data in different formats for different OECD countries. Now it should be possible for companies to submit largely the same package of information to different countries without having to reformat the information. At a meeting of the Working Group on Pesticides in June 1999, virtually all countries indicated that they would accept data submissions in the OECD format.

Systematic work sharing of pesticide reviews is not easy, particularly at the beginning. It requires considerable planning. It requires evaluators to be open to different approaches and to have confidence in other's abilities. And it requires co-operation from the pesticide companies. However, the potential efficiency gains are great and countries remain committed to proceeding, albeit with caution, in this direction. A workshop to develop ideas for the type of activities that could develop further trust and confidence among countries and promote work sharing will be held during 2000.

The long-term goal?

Discussed, but not agreed among countries, is the goal to *"facilitate sharing the work of registration and re-registration among countries as a routine way of doing business, and specifically to work toward the situation where data on a new active ingredient would be reviewed once for all OECD countries"*. It should be possible given the accomplishments to date and the ongoing work but it might take some time.

HARMONIZATION ACTIVITIES TO UNDERPIN WORK SHARING

Harmonized formats for industry data submissions and country data review reports need to be underpinned by harmonized data requirements, testing methods and risk assessment procedures to maximise efficiency gains from sharing the work of pesticide reviews. For governments, differences in data requirements and risk assessment procedures limit the extent to which they can use each other's evaluations. For industry, differences in data requirements and testing methods lead to redundancy in product testing by industry which costs a great deal of money and wastes animals' lives.

Data requirements

A survey of data requirements for the registration of ***chemical pesticides*** performed during 1993 revealed a high degree of similarity in data requirements among countries for most test areas; the major differences were in the areas of efficacy and ecotoxicology (OECD, 1994). Because of the high degree of similarity, further work to harmonize data requirements for chemical pesticides was postponed. However, now that a common format for pesticide data submissions has been agreed and countries are beginning to work together, the fact that data requirements differ among countries becomes more apparent. Work to harmonize data requirements is therefore back on the agenda.

The pesticide industry is currently developing a proposal for a common core data set that will be used as a basis for further discussion among countries. The industry proposal will comprise those requirements that are largely common in OECD countries and would constitute the minimum set of studies required to make a registration decision on the active substance in a pesticide product. The existence of a common core data set, would not, however, preclude countries requesting additional data important to their own circumstances.

OECD is also working closely with the EU and with CODEX to develop minimum data requirements for establishing ***Maximum Residue Limits***. The current areas of focus at present are: (a) guidance on geographical/climatic regions for residue trials, (b) criteria for determining the minimum number of residue trials, and (c) acceptable extrapolations/mutual support of residue trials data among crops. It is anticipated that minimum requirements could be agreed by the end of 2000.

The development of common data requirements for registering ***biological pesticides*** is more advanced. Following a survey of data requirements for biological pesticides (OECD, 1996)[3], work continued on the development of common core requirements for micro-organisms and pheromones. It is expected that harmonized requirements will be agreed during 2000.

Test guidelines

The OECD countries have been working together for two decades to develop guidelines for testing chemicals (OECD, 1993). Nearly 100 guidelines have been developed over this period, but many more are required, particularly for pesticides. Priorities for work on OECD Test

[3] The survey focused on data requirements for micro-organisms, but also collected information on pheromones, insect and plant growth regulators, plant extracts, macro-organisms and transgenic plants.

Guidelines to cover pesticide registration requirements were first identified in 1993. Of the 40 high priority activities identified, 16 have been completed and a further 16 are underway. Good progress has been made, but much work remains to be done.

The advantage of OECD guidelines over methods of other international organisations (e.g. ISO) or individual countries, is that the results from tests performed according to OECD Test Guidelines and to OECD principles of Good Laboratory Practice, are accepted by all OECD countries. Pesticide manufacturers therefore should not have to perform different studies for different countries.

Risk assessment

The harmonization of approaches to pesticide risk assessment has not had high priority within the Pesticide Programme to date. During the Pilot Project, referred to above, the scientists involved reported that the biggest problem when comparing assessment reports was not lack of familiarity with each other's assessment approaches, or lack of harmonized approaches, but lack of clarity and transparency in the reviewers' written evaluation reports. Higher priority was therefore given to developing the common reporting format referred to earlier. Never-theless work has begun in a limited way with the development of Guidance Notes for the Analysis and Evaluation of (1) Repeat-Dose Toxicity Studies, and (2) Chronic Toxicity Studies. Guidance for the former is almost complete. The Pilot Project showed that different approaches in assessment approaches among countries in both these areas could cause problems in mutual use and acceptance of reviews. No new work is planned until the current projects are completed.

CO-OPERATION BETWEEN OECD AND NON-OECD COUNTRIES

Although the principal focus of the Pesticide Programme is on harmonization activities that help OECD Member countries, there is a strong interest to help and co-operate with others in pesticide assessments. A first step was taken in this respect at a consultation among OECD and non-OECD countries hosted by the US EPA and the Swedish Chemicals Inspectorate and held in Washington in October 1998. Participants included representatives from agencies/institutions responsible for pesticide registration and assessment from seven OECD countries (Australia, Belgium, Canada, Germany, the Netherlands, Sweden and the US), eight non-OECD countries (Brazil, Bulgaria, Columbia, Egypt, the Gambia, Jamaica, Israel and Malaysia), the EC, IPCS, FAO, CCPR, the pesticide industry and the OECD Secretariat.

The non-OECD countries present expressed considerable interest in the co-operation occurring among OECD countries and in the possibility of gaining access to data review reports from OECD countries to help them with their own reviews. The meeting therefore recommended that the Working Group on Pesticides consider making the Database of Pesticide Reviews available to non-OECD countries to help them locate reports of interest. In addition, the pesticide industry was asked to consider ways to facilitate the flow of information from agencies in developed countries to those in developing countries, and, when applying for registration, to indicate in which countries registration has already been granted. It was also recommended that, when applying for registration, pesticide companies should provide copies of other countries' reviews whenever possible.

While some of the non-OECD countries present felt that they would be able to use data review reports done according to the OECD format, some thought that they might be rather complicated. Another recommendation therefore was that FAO and IPCS develop a guidance document on how to use the complex information contained in developed countries' risk assessment reports. Industry was also asked to consider developing " fact sheets" (e.g. expanded Material Safety Data Sheets) suitable for regulatory authorities in developing countries.

The Working Group on Pesticides has received a report of the consultation and will consider the recommendations for further co-operation with non-OECD countries at their meeting in February 2000.

SAVINGS TO GOVERNMENTS AND INDUSTRY

An estimation of the savings to governments and industry resulting from OECD's work on chemicals and pesticides was published in 1998 (OECD, 1998c).

For pesticides, potential conservative yearly cost savings were estimated based on the assumption that 10 new active ingredients enter the global market each year. Savings that might accrue to industry through not having to perform repeat testing and in being able to submit largely the same data submission package to all OECD countries are in the order of 107 million French francs. Savings to governments from being able to use each other's reviews were in the order of 13 million French francs. Some benefits are not readily quantifiable, and the value of bringing together governments, industry, other ngos and international organisations to discuss and resolve issues and to learn from each other should not be underestimated.

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Global regulatory developments - sensible regulation or strangulation?

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ABSTRACT

The marketing and sales of crop protection products is governed by stringent regulatory requirements. These requirements have increased and become more complex over the past two to three decades. The crop protection industry has always welcomed demanding regulations as long as they are sensible, provide a "level playing field" and are based on sound science. This paper discusses, whether these conditions are still holding true or the balance is tilting from sensible regulation towards the strangulation of crop protection product development and sales and an undue reduction in freedom of operation. In this context, the paper concentrates on examining harmonisation of registration requirements, the EU Registration Directive, data protection and stewardship, the precautionary principle and residues in food.

INTRODUCTION

There is little doubt that the crop protection industry today is probably the most heavily regulated industry. Its activities are governed by a plethora of national and regional laws and regulations as well as International Codes and Conventions, such as the International Code of Conduct on the Distribution and Use of Pesticides and the International Convention on Prior Informed Consent. The industry has always welcomed stringent requirement for the registration of its products, provided these requirements are science-based and the evaluation of the concomitant studies is based on a balance of benefits and risks. Indeed, the crop protection industry has been actively involved in helping establishing national or regional registration schemes as well as voluntary instruments such as the Code of Conduct. The products provided by the crop protection industry are, and have to be, biologically active in order to achieve their desired effects. Recognising that these desired effects could also be associated with undesirable side-effects, which may not be acceptable, the industry carries out exhaustive testing to demonstrate the safety of its products prior to sale. These tests are also designed to meet the requirements for registration stipulated by Governments. In some countries, voluntary schemes (such as the UK Pesticide Safety Precaution Scheme) preceded legislation. Although effectively self-regulating, such schemes proved effective at the time, their inherent flexibility being one major advantage in dealing with changing circumstances such as nature of chemicals, new scientific advances etc.

The history of crop protection product legislation and regulations is one of continuous development. This is not surprising given the changing nature of the products and the advancement of science. Furthermore, the market for these products and the agricultural commodities treated with them is global. Regulatory developments have to take account of this important aspect, in particular in the light of the move to global free trade.

Where is global regulatory development today? Are the regulations still sensible or are we moving towards a state where an industry may be strangulated by a maze of "red-tape" legislation no longer designed to assure the safety of crop protection products, but blatantly established to reduce or eliminate their use? Looking at a few examples and activities may provide, at least, a partial answer to the questions posed.

INTERNATIONAL HARMONISATION

Early initiatives by FAO

By the early 1970's it was recognised that having national legislative or other provisions requiring the registration of pesticides prior to sale was leading to divergence in requirements and consequently, to increased costs and/or a limit on the availability of pest control agents (Anon, 1997). However, it was also recognised that uniformity of requirements should be possible. Efforts concerning international harmonisation of pesticide registration requirements, initially led by the Food and Agriculture Organisation (FAO) of the United Nations, were started.

On the positive side, the FAO efforts established a number of principles which are still valid today, though not necessarily practised in all circumstances:

1. The principle that the registration process is essentially predictive both with regard to the fate as well as the effect of pesticides and thus is based on the concept of extrapolation. There was consensus that "experience has shown this to be a valid concept although it is clearly more reliable with closely related species".

2. The principle of "transportability of data", eg that laboratory data are universally applicable (and thus, that there should be no duplication of experimental work) and that field tests are, at least, regionally applicable and in some circumstances can be more widely applicable, eg temperate climate field dissipation tests can be applicable to tropical regions, because the effect of higher temperatures and humidity are well understood.

3. The principle of step-wise registration or phased approach to registration, ie registration is granted to an extent that is commensurate with the availability of data. Whilst this principle is still followed today in respect of experimental use permits or emergencies, it is by and large no longer applied when it comes to registration for commercial sales.

4. The principle of risk mitigation, ie the registration process is not an 'all or nothing' process. If the risk from use of a pesticide as proposed in the original registration submission is judged to be too high, measures to reduce the risk to an acceptable measure may be agreed and introduced rather than the petition being outright rejected.

5. The principle of proprietary data protection, ie that the data of the original submitter should not be used for the purpose of evaluating and registering a product of a

submitter who neither owns the data or is given access to the data by the rightful owner. Unfortunately, this principle has not yet been implemented universally.

Ultimately, for a number of reasons, the FAO harmonisation work yielded few tangible results. Although embracing the notion of harmonisation in principle, there was little evidence that steps towards international harmonisation were adopted at national level. Issues of national sovereignty, well-entrenched positions on registration, differing work priorities, lack of seeing a real need for harmonisation, and rejection of "foreign" ideas may all have contributed to this. There were also too many organisations involved, who had their own agenda, for real progress to be made. Nevertheless, the early work still effects present harmonisation work.

Recent initiatives by OECD

More recent harmonisation initiatives such as the Organisation of Economic Co-operation and Development's "Pesticide project" differ in their motivation for harmonisation. Increase in cost of or lack of availability of pesticides have been replaced by the need to facilitate free trade, the lack of regulatory resources and scientific expertise, the recognition that duplication is a waste of resources and that harmonisation actually makes sense.

In the context of harmonisation, the OECD activities pertain to test guideline development, establishing common/core data requirements (including defining minimum residue data requirements), harmonisation of submission and data review formats, and worksharing.

For harmonisation to make sense, it must satisfy three fundamental principles:

1. It must reduce time from submission of a registration package to decision;

2. It must provide measurable financial benefit in data generation, eg by eliminating unnecessary duplication of testing;

3. It must permit increased co-operation amongst regulators.

On this basis, the OECD pesticide project has the full support of the crop protection industry, because, if successful, it will influence global regulatory developments towards sensible regulation and avoid strangulation: Common/core data requirements form the basis and define the scope for harmonisation. The requirements will be supported by common guidelines and study protocols. The data developed are mutually acceptable, since they are based on common quality criteria. This being the case, data reviews can be shared by different regulatory authorities. These reviews, in turn, are accepted by all Governments involved in this harmonisation and form part of the basis for taking individual national regulatory decisions.

THE EU REGISTRATION DIRECTIVE

The European Single Market legislation with its requirement for free trade necessitated harmonisation of registration legislation and procedures across the EU Member States. This has resulted in Directive 91/414/EEC, the "Registration Directive". What has this Directive done in the context of sensible regulatory developments? At this point, the balance tilts towards "strangulation". The split system of active ingredient and product registration (with, in practice, only some vague requirement for "mutual acceptance") has considerably lengthened time to registration. 'Political' considerations of what may be nationally acceptable in terms of product registration greatly impinge on the scientific/technical data review. Data requirements and their evaluation have been harmonised essentially at the "highest common factor". In some respect, the precautionary principle has taken a foothold (see below), although the registration process produces adequate data for risk assessment. This is "an example of the trend towards the politicisation of science" (Anon, 1999). Nonetheless, the Directive still includes some, though not all, the principles for registration and harmonisation established during the FAO harmonisation days. However, it is also a considerable distance away from the pragmatism advocated by the industry during the drafting stages. There is a need for continued discussion between the European Commission, Member States and industry to overcome most, if not all the implementation problems.

INTELLECTUAL PROPERTY

The development of plant protection products is an increasingly expensive business. A main amount of the expenditure is devoted to developing safety data and demonstrating that the new product does not have any undesirable side-effects. This data must be protected from use for third party (other registration applicant) purposes, if the rightful owner is not to be denied the fruits of his scientific endeavours. In addition, it encourages more and continued research in the field of crop protection. Ever since the 1977 FAO *Ad hoc* Government Consultation on International Standardization of Pesticide Registration Requirements (Anon, 1977), the crop protection industry has emphasised the importance of the protection of intellectual property (and registration data in particular). The results of this activity have, at best, been mixed. Whilst some progress towards better data protection has been made over the years in some parts of the world, data protection has more or less continually been eroded in the important North American and European markets. Whilst the data protection system in the USA appears to have been stable for some time now, the situation in the EU is far from satisfactory. The EU Registration Directive has tried to harmonise data protection provisions across the member states. In some cases this has led to some improvement of data protection, in others it had the opposite effect.

On the whole, however, data protection has been eroded. This trend continues for reasons of misrepresentations of "the public's right to know", concerns - real or perceived - about duplication of tests with mammals, and political pressure to "protect" small and medium sized enterprises. If this trend is not reversed or, at least, halted, the consequences could be far reaching. Registrants may elect to limit their research only to data that are specifically required by the Regulatory Authorities. They may not continue to act in accordance with the principles of good stewardship and develop data beyond the need of registration, because such data will not be protected. Less stewardship-conscious "players" will get a "free ride"

and, consequently, will never see the need for them to contribute to stewarding crop protection products. Thus, the erosion of data protection could, inadvertently, undermine the stewardship of crop protection products.

STEWARDSHIP

Stewardship is defined as the responsible and ethical management of all we do from invention to ultimate use of the product and beyond (Johnen and Wilks, 1997). The principle of stewardship is all-embracing, it is a "cradle to grave" philosophy. It entails the obligation to ensure that a company's activities derive maximum benefit for society with least risk to human health, wildlife and the environment. It is a voluntary activity, a type of self-regulation, which goes beyond legislative requirements. For the crop protection industry, the principle activities of stewardship are covered in the International Code of Conduct on the Distribution and Use of Pesticides (1986). Whilst it may well be illusionary to call for more self-regulation (instead of continually producing new, often ill-conceived legislation in response to demands by pressure groups), legislation should at least not get in the way of acting in accordance with good stewardship. An infamous example of legislation impeding stewardship is the so-called 6.a.2 legislation in the USA, which covers the notification of 'adverse effects' observed with crop protection products. Whilst good stewardship requires to look out for such effects (and deal with them appropriately), the wording and interpretation of the law by the US Environmental Protection Agency could be seen as encouraging registrants "to look the other way" and rather not know.

PRECAUTIONARY PRINCIPLE

Crop protection product registration has always been based on the principle of risk assessment. Having assessed the risk, this has been contrasted with the benefit side of the equation. Products would be registered, if the benefit-risk equation (with or without risk management) was positive. Recently (Anon, 1999), this risk analysis process has been described as involving three stages: Risk assessment being the scientific phase; risk management, which seeks to control the risk to an acceptable level, being the political phase; and risk communication, which is the exchange of information between decision makers, scientists and other stakeholders, being the communication phase. Our apparent inability to communicate the real risks arising from the use of crop protection products adequately and dispel subjective perceptions of these risks, a general trend of risk aversion, in particular to so-called involuntary risks, and concerted efforts by anti-pesticide pressure groups have all contributed to the precautionary principle gaining momentum in pesticide registration at the expense of risk assessment. One example being the 0.1 µg/l limit on pesticides and pesticide residues in water in the Uniform Principles of the EU Registration Directive.

In the context of the precautionary principle, Avery (1997) has warned "that the environment cannot afford regulation by emotion". Whilst there is no argument that pesticides should be used judiciously and, preferably, in accordance with Integrated Crop Management (and Integrated Pest Management within ICM), it is more than questionable, if Governments react by stipulating crude (eg 50%) use reduction targets, often euphemistically called risk reduction programmes. At stake here is the fundamental principle of proportionality, ie the

cost (or other effect) of the measure should be proportional to the benefits gained from a reduction in risk. The USA Food Quality Protection Act (FQPA) could well violate this principle, dependent on its implementation by the Environmental Protection Agency.

Conversely, it is just as questionable, when reputable organisations such as the World Bank suggest to practically wave the registration process for some types of crop protection products, whilst at the same time call for bans of others by branding these latter ones as "more dangerous broad spectrum poisons" (Anon, 1976). If such a move took hold and led to new legislation, it would be inequitable and a threat to consistency between legislation.

RESIDUES IN FOOD

Residues in food have, quite rightly, always been an important part of the safety assessment of crop protection products. The amount of data required has substantially increased over the years and does cover raw commodities as well as process food, where applicable. To accommodate world-wide free trade, the safety and acceptability assessment of residues goes beyond national requirement and requires data on a global scale for evaluation by the Joint Meeting on Pesticide Residues within the Codex Alimentarius Commission system. In addition to industry generating residue data, pertinent data are generated by national or other official or public institutions in the course of their regulatory or food monitoring activities. All these data show, that pesticide residues in food do not constitute a problem (Anon, 1992). In the vast majority of cases, residues are not detectable at all. In only a few percent of cases do residues exceed established maximum residue limits (MRLs) without this equating to any harm to consumers. This situation was already summarised by Bates (cited in Anon, 1992) in 1990 as follows: "The lesson to be learned from the existing data base on pesticide residues in commodities and diets is, that health hazards from residues do not exist for the vast majority of situations. Speculation on possible health problems is not a valid reason for the commitment of scarce valuable resources".

Nevertheless, although problems with food production are almost without exception microbiological, it is chemicals such as pesticides in food that appear to cause anxiety (Berry, 1999). This is not surprising, when, for example, Friends of the Earth published findings of analyses of pesticides in food under the heading "Dangerous Agrochemicals in Food", which on re-analysis proved to be incorrect and false (Berry, 1998). In contrast to the original story, the correction attracted little attention.

In the context of "sensible regulation or strangulation" let me quote Berry (1999): "It is evident that we should be cautious with compounds we have ground to believe are dangerous, and that we should take precautions where our information is incomplete. However, it is far from clear that a system could be devised which will guard against all contingencies, or that such a system would be desirable".

Trying to indemnify against all possible harm may lead to unjustified or ineffective allocation of limited funds. This has recently been discussed by Ritter and Ripley (1999). "Recent data from Canadian, US, European and Asian regulatory authorities suggest that dietary residues, when present at all, are present only at very low levels.....Sources of synthetic chemicals, such as dietary pesticide residues, are likely to be responsible for only a small percentage of

all cancer incidence, if at all, and diet, lifestyle and tobacco use continue to represent the most important factors in overall cancer risk world-wide. Moreover, the important benefits associated with a diet rich in dietary fibre as a cancer risk reduction strategy far outweigh any insignificant risk which may be associated with intake of extremely low levels of dietary pesticide residues". These conclusions should lead to the rational decision that public money spent on health education etc would generate a far more positive results in terms of improving public health than the present (over-) emphasis on residue monitoring. The authors, however, expressed the opinion, that for reasons of a negative public perception concerning pesticides and the emotive nature of cancer, this emphasis on pesticide regulation and control would not change.

The US FQPA is likely to become a classical example of legislation and regulatory decision making tilting towards strangulation rather than being sensible regulation. Scarce public and private technical and financial resources will be expended for little, if any, gain in maintaining or improving public health.

CONCLUSIONS

The marketing and sales of crop protection products is governed by stringent regulatory requirements. These requirements have increased and become more complex over the past two to three decades. The crop protection industry has always welcomed demanding legislation and regulations as long as they are sensible, provide a "level playing field" and are based on sound science. Recent global regulatory developments such as the EU Registration Directive and the US Food Quality Protection Act could be regarded as no longer meeting these conditions. The discussion of the examples and activities chosen to test the question posed in the title leads to the following conclusions:

1. Harmonisation of regulatory requirements is, in principle, the right way to go to avoid overburdening a global industry. The early harmonisation efforts by the FAO established some important principles, but ultimately did not achieve the goal of global harmonisation. The present OECD led harmonisation initiatives are welcomed, but may not be able to meet expectations in respect of harmonising actual data requirements.

2. The EU Registration Directive cannot be regarded as successful with regard to having achieved a pragmatic solution in respect of harmonising data requirements. On the contrary, it is a prime example of harmonising at the "highest common factor" and thus moving away from sensible regulation.

3. Data protection is by-and-large inadequate to provide a level playing field. Consequently, R&D companies suffer from the increased cost of tighter regulations, whereas secondary registrants are increasingly in a position to reap the benefits from others' research.

4. Regulations can, most probably inadvertently, get in the way of good stewardship. This, of course, provides more of a dilemma to those who actively engage in stewardship of their activities than those who are not.

5. The potential indiscriminate application of the precautionary principle constitutes the greatest threat to sensible regulation. There is a great danger that real science will be left behind and be replaced by the politicisation of science and political, emotional decisions.

6. Residues in food have always been a major aspect of the safety assessment of crop protection products. However, there is now ample evidence that dietary exposure to pesticide residues does not cause harm to consumers. Whilst not advocating that residue studies and residue monitoring are unnecessary, it should be clear, that some of the resources could be put to better effect in terms of improving public health. Instead, as exemplified by the US FQPA, legislation and regulations are strongly pushed towards strangulation and reducing the freedom to operate without an equivalent concomitant benefit to public health.

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