SESSION 9A

ADVANCES IN THE FORMULATION, PACKAGING AND APPLICATION OF PESTICIDES

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CONTROLLED RELEASE TECHNOLOGY: SAFETY AND ENVIRONMENTAL BENEFITS

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ABSTRACT

The primary objectives of controlled release technology applied to crop protection are improved efficiency and targetting of bioactive materials. This is an approach to formulating which covers a range of release profiles that are appropriate to the target pest and its environment. The trends in the development of practical controlled release systems for use in crop protection are reviewed by highlighting significant examples considering micro-encapsulation, thermoplastic granules, microbial pesticides and cellular methods. Benefits of controlled release additional to those above include safer mammalian toxicology, improved environmental properties compared to conventional formulations and the opportunity for increased exploitation of active agents with better environmental behaviour. These aspects are discussed in qualitative and quantitative detail.

INTRODUCTION

The concern of controlled release formulations is to optimise the delivery of pesticides and related bioactive agents following the process of application. Whether applied by spray or granule/dust methods the formulation functions after retention by certain parts of the cropping environment. From then on, the availability over time to the biological target is determined by the nature of the formulation and by the delivery pathway in the environment. The availability of the bioactive agent can thus be influenced by the rate of release from the formulation. The approaches to achieve this manipulation that are currently practically available will be considered here with relevant comments to their additional benefits of environmental and toxicological safety.

Scope of controlled release

Time-related release from a formulation is only part of the overall delivery process. Apart from the obvious step of physical placement (application by spraying or granule/dust treatments) the delivery process includes the availability to or movement towards the target organism, in a variable environment. This is complicated by the time-concentration requirements for effective management of the target pest (Hartley and Graham-Bryce, 1980). Thus this needs to be defined before the parameters of formulation design and delivery can be conceived. The longer the delivery pathway in time and space the less influence the release rate can have on the uptake by the target pest. Thus greater efficiency would be obtained with the closest pesticide placement and so controlled release will be more obviously effective in these situations. An example relevant to crop protection is seed treatment (Graham-Bryce, 1988; Nevill and Burkhard, 1988).

Controlled release can be considered as technology of formulation which provides the active agent at a rate appropriate to control the pest. This rate is not exclusively defined and can include examples such as;

a steady continuous release, independent of time, over the period of control (zero order),
a decreasing rate either exponential (first order) or square root of time based,
rapid release for a short period, or
rapid release after a time delay (delayed or timed release).

Alternatively, the release could be target initiated through target specific properties. In analogous pharmaceutical applications modified release (delayed release, targetted release and extended release) has been defined (Peterson, 1983). In this definition extended release was based on performance in the patient and it must allow at least a doubling of the treatment interval, to be so defined.

SOME EXISTING EXAMPLES OF CONTROLLED RELEASE TECHNOLOGY

For crop protection agents controlled release formulation has been traditionally divided into chemical and physical methods. However, the disadvantages of chemically-bound agents (polymeric propesticides) of high registration costs and costly production methods have proscribed their application to agriculture. Physical methods, e.g. micro-encapsulation, laminates, matrices, inclusions and osmotic devices, are the most common and some specific examples are considered later. These methods can be divided into reservoir systems, with or without a rate-controlling membrane, and matrix or monolithic systems. Of these, micro-encapsulation, consisting of a small reservoir bounded by a thin plastic membrane, is the most popular.

To these categories of controlled release formulations there is a more recent addition: biological. This could include the extension of physical methods covering polymer formulations of biopesticides or of living organisms. However, an approach more clearly described as biological controlled release systems is the use of cells, either living or dead, for encapsulation and delivery to the target (Barnes and Cummings, 1987). Cells evolved, after all, to protect sensitive bio-active molecules and to regulate their release (and uptake). Ready-made cells are available easily, for example from bacteria, algae and yeasts.

The ultimate in delivery and targeting is to locate the pesticide within the crop plant to be protected. This may be achieved through endophytes (bacteria living within the plant) or alternatively, through transgenic crop plants. However, to be effective, these methods must be in place, whether or not there is a pest problem and in many circumstances in the absence of pests could exert an energy drain on the plant.

Micro-encapsulation

Micro-encapsulation has been the most successful of the controlled release technologies to reach commercial adoption. This has been aided by application methods using conventional spraying equipment and the general benefit in formulation of standardising the surface properties of the particles. Although environmental benefits are conferred on a pesticide by encapsulation, environmental regulations are likely to be the greatest barrier

to its utilization as regulatory requirements cover not only the active agent but every combination of polymers used in the formulation.

Modification of the particle surface properties by micro-encapsulation allows the variable properties of many active agents to be treated as one, i.e. those of the encapsulating polymer itself. This is a benefit long recognised in other industries where micro-encapsulation has applications in improving the handling of finely divided materials. Thus a wettable powder or suspension concentrate for spraying can be prepared from a liquid active ingredient or even from a compound where a phase change may occur at or near ambient temperatures (Beestman and Deeming, 1981).

Of the various approaches to prepare microcapsules (Kondo and van Valkenburg, 1979) the method most generally applicable to crop protection uses interfacial condensation polymerization, with its advantages of low cost and high active ingredient loading. This process forms a thin capsule wall which then controls the release by diffusion (Baker and Lonsdale, 1975).

The first agricultural micro-encapsulated pesticide to be marketed, "Penncap-M", appeared in 1974. Benefits realized by this formulation included increased safety to operators and to the treated crop and also extending the use of the active agent (methyl parathion) to crops for which conventional formulations have proved phytotoxic (Kydonieus, 1980). Since then many other micro-encapsulated formulations of crop protection agents have appeared (for listing, see Wilkins, 1990).

Applications to agriculture can be typified by foliar spraying (e.g. "Penncap-M" above), spraying onto soil surfaces e.g. "Dyfonate MS" containing fonofos insecticide; "Capsolane" containing the thiocarbamate herbicide EPTC and the protectant R25788) and as a seed treatment. Seed treatment of winter wheat with a water-based micro-encapsulated formulation of the insecticide fonofos ("Capfos") gives good and long-lasting protection against wheat bulb fly and frit fly attacks. A similar formulation of the pyrethroid insecticide tefluthrin ("Tefluthrin CS") incorporated into pelleted sugar beet seed provided many advantages over conventional formulations (Marrs and Seaman, 1978) and controlled a range of soil arthropod pests. Control was as good as a separate soil granule application at a much higher application rate, and thus reduced any potential hazards to the environment.

Thermoplastic based granules

The withdrawal of the residual organochlorine insecticides is causing a gap in the control of soil arthropod pests. Unlike foliar spraying situations there is no possibility of using repeat applications for placing further doses of short lived insecticides within soil. Thus, there has been a clear need for soil applied controlled release formulations which has been satisfied in the case of sugar cane pests by the introduction of thermoplastic granules ("suSCon"). These are monolithic (matrix) granules produced by incorporation of the active ingredient with pore-producing inert powders in a plastic matrix (McGuffog *et al.*, 1984). The ingredients are compounded, extruded and pelletized. Release occurs from the granule (dimensions from 0.6mm x 0.6mm to 3mm x 3mm) by leaching. The release rate is sustained by gradual dissolution of the inert powder leading to an advancing pore structure.

Application of these formulations has been initially aimed at control of white grubs attacking the roots of sugar cane. In the absence of

persistent organochlorine insecticides these pests are difficult to control as sugar cane is normally grown as a semipermanent crop (4-5 years) with several harvestings during this period. Pest attack can occur every year. A controlled release formulation based on the organophosphate insecticide chlorpyrifos ("suSCon Blue") was introduced in Australia in 1985. This granule is applied at planting of the sugar cane sets and is effective against cane grubs for three years. Registration of this formulation has since been extended to a number of other countries.

As chlorpyrifos is of low mobility in most soils its effectiveness depends on movement of the target insect pest. Control of sugar cane borer requires a systemic insecticide and a thermoplastic granule formulation of phorate has been recently introduced into China for this application. This product ("suSCon Fu Ming") applied at planting at 1.8 to 3.6kg AI/ha provides control for 1 year. Similarly a 10% thermoplastic formulation of carbosulfan provides commercial control of termite attack in young trees in Africa for 2 years (Boehm and Anderson, 1990).

Microbial pesticide controlled release: cellular formulations

Living microbial pesticides can be formulated under mild conditions to enhance their survival and extend the period of infectivity and thus control. Gel-forming polymers, such as alginate (Connick, 1988) are employed. Another approach is the use of preformed capsules as in cells of yeasts, bacteria and algae. The difficulties of entrapping the pesticide in these cells can be overcome through transferring the genes for the production of pesticidal protein toxins to a suitable "carrier" micro-organism. This micro-organism can be chosen to optimize the targetting of the pest as well as to improve the persistence.

An example of this is the transfer of biotoxin genes from *Bacillus thuringiensis* to the bacterium *Pseudomonas fluorescens*. This is expressed in the formation of the endotoxin crystals within the *P. fluorescens* cells (Gaertner, 1990). In practice the cells are killed and fixed following fermentation to provide an effectively encapsulated fully active biotoxin (Cellcap™). This formulation has given good foliar control of lepidopteran pests (e.g. diamondback moth) and development of similar *P. fluorescens* formulations of other biotoxins has given good activity against other insects.

As the toxin is protected, the use of a wide range of formulating materials for dispersing, wetting, suspending and sticking properties is available which were not acceptable with the spore and crystal preparations of conventional *B. thuringiensis* products. Other advantages include circumvention of public concern on release of genetically engineered organisms, no spreading from site of application, excellent shelf-life and field stability, and ease and reproducibility of production.

Encapsulation in living cells offers other advantages, especially in delivery to, and controlled availability in, the root zone, mediated through presowing seed treatment but these active cells may lack competitive ability in the micro-environment. However, one approach to avoid this is based on the endophytic bacterium (able to grow within plants) *Clavibacter xyli* subsp. *cyanodontis* which have been genetically engineered to express *B. thuringiensis* δ-endotoxins. Seeds are then treated with this bacterium to establish the endophytes in the vascular system of the subsequent plant and to provide long-term protection against insect attack (Gaertner, 1990).

ENVIRONMENTAL AND SAFETY BENEFITS

General benefits of controlled delivery include;

better targetting,
use of soil applications in place of spraying,
elimination of solvents,
decreasing odour, irritation or toxic exposure to user,
choice of more environmentally safe active agents,
safety to crop,
increased bioselectivity,
reduced pest repellency and improved bait acceptance,
coformulation of incompatible pesticides,
improved physical handling or other formulation properties.

Environmental safety

Increased efficiency in delivery to target pests implies less environmental contamination and reduced application rates. The reduced intrinsic hazards to various non-target organisms can be demonstrated more directly. In aquatic areas toxicity hazards to fish are important both ecologically as well as for food production. Micro-encapsulation can reduce toxicity to fish; this can be shown for cypermethrin as in Table 1 (Marrs, 1990).

Table 1. Toxicity of cypermethrin emulsifiable concentrate (EC) and micro-encapsulated (CS) to rice fish (flowthrough test)

formulation	concentration mg/l	number of dead fish at 48 h (out of 5)
100g/l EC	0.05	0
	0.05	4
	50	-
100g/l CS	0.05	0
	0.5	0
	50	5

For micro-encapsulation the ratio of wall thickness to capsule diameter influences fish toxicity. Table 2 compares the toxicity of fenvalerate, another pyrethroid insecticide, in micro-encapsulated (CS) and technical grade (TC) forms.

Table 2. Toxicity of fenvalerate to killifish (*Oryzias latipes*)

mass median diameter μm	wall thickness μm	LC50 of CS* / LC50 of TC
50	0.113	862
52	0.011	22
31	0.002	12
23	0.051	119
4	0.038	32
5	0.011	7
5	0.002	3

* as active ingredient, after 48 hours
(after Tsuji, 1990)

Mammalian toxicity

A change in formulation from conventional spray concentrates to micro-encapsulation generally results in the use of more benign inert ingredients, with consequent reduction in irritancy problems. The reduced availability of the active agent usually also decreases the mammalian toxicity of the product. For example, Table 3 compares the acute toxicities of tefluthrin micro-encapsulation (CS), emulsifiable concentrate (EC) and technical grade (TC) forms.

Table 3. Acute toxicity of tefluthrin formulations to rats

formulation	oral LD50 mg/kg	dermal LD50 mg/kg	skin irritation (rabbit)
200g/l CS	>2000	>2000	slight
50g/l EC	321	>1800	severe
technical	35	200-1000	none

(after Marrs and Scher, 1990)

Reductions in skin and eye irritation are also seen (from irritant to non-irritant and from moderate irritant to non-irritant, respectively, to the rabbit) when comparing "Eradicane EC" with the micro-encapsulated "Capsolane" referred to before. Encapsulated fonofos, used as a seed treatment, had the following acute toxicities:

Oral rat LD50 2370 mg/kg
Dermal rabbit LD50 1500 mg/kg,

which were 100 times (oral) or 10 times (dermal) less than the values for technical grade material (Scher, 1985).

In the case of another organophosphate insecticide, fenitrothion, encapsulation with a polyurethane, gave very low acute toxicity (Table 4). This formulation, intended for protection of timber against termites, is easily decomposed by sunlight and causes little environmental pollution (Tsuji, 1990).

Table 4. Acute toxicity of fenitrothion microcapsules ("Kareit") LD50 mg/kg

	rat	mouse
oral	>2000	>200
dermal	>5000	>5000

(after Tsuji, 1990)

In the case of thermoplastic controlled release granules the improvements in mammalian safety are equally significant. The reductions in toxicity by this method of formulation are indicated in Table 5.

Table 5. Acute toxicity LD50, comparing technical grade with thermoplastic granules

Product	Acute oral LD_{50} (rats)	Acute dermal LD_{50} (rabbit)
suSCon Blue 140 kg^{-1} chlorpyrifos	1000mg/kg	>2000mg/kg
Technical chlorpyrifos	135-165mg/kg	2000mg/kg+
Marshal* suSCon 100g kg^{-1} carbosulfan	>1000mg/kg	>2000mg/kg+
Technical carbosulfan	185-250mg/kg	>2000mg/kg
suSCon Fu Ming 100g kg^{-1} phorate	319mg/kg	>2000mg/kg+
Technical phorate	1.6-3.7mg/kg	2.5-6.2mg/kg+ (rat)
G22001 140g kg^{-1} parathion	578mg/kg (male)	>2000mg/kg+
Technical parathion	3.6mg/kg (female) 13mg/kg (male)	6.8mg/kg (female rat)+ 21 mg/kg (male rat)+

+ Acute percutaneous LD50
* Registered trademark
(after Boehm and Anderson, 1990)

Environmental benefits

An important environmental benefit of controlled release is the facility to use crop protection agents of limited intrinsic duration, i.e. to separate bio-activity from persistence. This can allow the replacement of materials such as organochlorine insecticides with short persistence organophosphates and others (McGuffog et al, 1984), with reduced environmental impact. Indeed, the successful uptake of pheromones with controlled release formulations for insect pest monitoring and control is an excellent example of this concept (Kydonieus and Beroza, 1982), replacing some insecticides which have a greater environmental impact and which through resistance are less effective. However, in spite of the technical advantages of this approach the commercial success is not yet beyond doubt (Weatherston, 1990), a situation typifying slow acceptance of the new technology. Controlled release formulations can also improve uptake by the target pest and thus increase biological activity and control. When the polar juvenile hormone inhibitor, compactin, was formulated in liposomes (small lipid spheres) a much enhanced activity was demonstrated in insects (Belles *et al*, 1988). This method may also be of value in the application of improved efficiency of other newer polar pesticides, such as insect growth regulators and insecticidal peptides and proteins.

Release mechanisms based on environmental factors may also be used to improve delivery to target pests. The chewing of insects to release capsule contents is used to target termites (Tsuji, 1990). In the open environment, daily fluxes in temperature (Greene and Stewart, 1989) and in light (Lohmann and Petrak, 1989) could stimulate a pulsed release to match the pest's behavioural cycle or to supply an active agent synchronised with physiological changes. The use of formulations that are site-specific in releasing into a unique micro-environment may have applications. These could be specific in terms of pH or enzymatic properties, for example, the low pH of the molluscan gut or the high pH of the lepidopteran gut (Bohm *et al*, 1990). Selectivity between plants can also be achieved by exploiting pH-dependent release from formulations sprayed onto the leaf surface (Lohmann and D'Hondt, 1987).

The current environmental pressure on soil application of pesticides which are potential hazards for groundwater pollution could lead to withdrawal of many otherwise acceptable control agents. With controlled release formulations their effective life could be enhanced. One consequence of ground water problems has been a trend towards foliar applied pesticides, especially post-emergence herbicides. This foliar mode of application places the pesticide in a more exposed, less sorptive location which increases the hazard of loss to the atmosphere. Here again, the role of controlled release to reduce evaporative losses from leaf surfaces could be critical in the environmental safety of these pesticides.

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THE SPRAY DRIFT TASK FORCE: DEVELOPMENT OF A DRIFT STUDY DATABASE FOR REGISTRATION PURPOSES

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ABSTRACT

The Spray Drift Task Force has been formed as a joint venture among companies in the United States to produce a generic spray drift database to satisfy the conditional registration requirements of the United States Environmental Protection Agency pertaining to spray drift. Membership is open to any present or potential registrant of agricultural chemicals. Cost are shared equally. Testing is expected to begin in 1991. Current activities include protocol development, identification of subcontractors, and finalization of the overall testing scheme. Activities are expected to proceed for at least four years.

INTRODUCTION

In order to assess pesticide exposure in the environment, the United States Environmental Protection Agency (EPA) promulgated "Spray Drift Data Requirements" at 40 CFR 158.440, issued a document entitled "Pesticide Assessment Guidelines Subdivision R Pesticide Spray Drift Evaluation" dated 1984, and "Hazard Evaluation Division Standard Evaluation Procedure Pesticide Spray Drift Evaluation: Droplet Size Spectrum Test and Drift Field Evaluation Test" dated June 1986. The Pesticide Assessment Guidelines allow the use of generic data to evaluate the spray drift of pesticides in place of individual studies. Satisfactory generic data do not already exist because the number of studies available to the EPA which can reliably contribute to an overall understanding of pesticide spray drift is limited.

The EPA has requested separate spray drift studies for many pesticide products through data call-ins, re-registration actions and new product registrations.

Since the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) permits registrants to share the cost of developing additional data required under paragraph 3(c) (2)(B) and paragraph 4(d)(3), a joint venture called the "Spray Drift

Task Force" was formed and officially constituted on April 17, 1990 to generate the data requirements of its members.

PURPOSE

The purpose of the Spray Drift Task Force is to develop, acquire, own and defend and assert rights to compensation for the use of pesticide spray drift data required by EPA or other comparable registration authorities worldwide. The Spray Drift Task Force activities include, but are not limited to, acquiring or developing generic spray drift data applicable broadly to different formulations used by its members.

MEMBERSHIP

Membership in the Spray Drift Task Force is open to any company or person having a prospective or existing pesticide registration subject to spray drift data requirements by the EPA. As of July 30, 1990 the Task Force membership stood at 22:

American Cyanamid Company
Amvac Chemical Corporation
Atochem North American
BASF Corporation
Ciba-Geigy Corporation
DowElanco
E.I. du Pont de Nemours and Co. Inc.
Fermenta ASC Corporation
FMC Corporation
Helena Chemical Company
Hoechst-Roussel Agri-Vet
ICI Americas, Inc.
Makhteshim-Agan (America)
Mobay Corporation
Monsanto Corporation
Nor-Am Chemical Company
Platte Chemical Company
Rhone Poulenc Ag Company
Sandoz Crop Protection
Sostram Corporation
Uniroyal Chemical Company
Valent U.S.A. Corporation

Membership in the Task Force will remain open to any registrant wishing to join. Likewise, a member can withdraw from the Task Force at any time.

Very specific guidelines exist defining exactly who has access to the database as a result of an individual membership. These guidelines, too detailed to discuss here, address circumstances involving company affiliates and end-use (formulator) registrants.

DATA REQUIREMENTS

Spray drift data requirements are conditionally required by the EPA for products intended to be applied by aerial (rotary and fixed wing), mist blower, overhead chemigation, high clearance ground sprayers or other methods of ground application.

The purpose of the data requirement is to determine the movement of the active ingredient to and from the intended target site.

The determination of a pesticide's potential to move off target (deposition versus distance) is made from information gathered from atomization and field evaluation studies conducted with commercial equipment and "worst case" scenarios.

The generic database produced by the Spray Drift Task Force is not expected to contain all types of information on every "test substance" or active ingredient. It is expected to contain sufficient information to support the respective registration obligations for current and future products of the members within the selected scope of formulation types and use patterns.

CONFIDENTIALITY OF DATABASE

All data generated by the Spray Drift Task Force will be confidential to the Task Force. The joint venture is funded entirely by the members. The database will be used for registration purposes only. For the data to be compensatable under FIFRA, The Task Force must retain ownership of all raw data. The Task Force intends to defend this right to compensation. Within these constraints, however, recognizing the pressures on academic and government researchers to publish, and the likelihood of involvement of some of these public sector individuals as consultants, the Task Force is willing to pursue confidentiality agreements permitting publication of summary information.

COST

The cost of the Spray Drift Task Force will be shared equally by each member. The membership fee during the initial 75 day signup period ending July, 1990 was $10,000. A late-joining member is subject to all required payments plus an interest adjustment. Additionally, members joining after testing data has been generated are subject to a testing risk assessment fee.

TEST SUBSTANCE

All testing, and therefore all data, conducted by the Spray Drift Task Force will be on the "test substances", which are the spray tank mixtures consisting of the particular formulation, diluted according to product label requirements, and including any recommended spray additives. A "test substance" which contains a tracer material, rather than an active ingredient, may be selected for use in field drift studies.

TASK FORCE ORGANIZATION

The Task Force is organized into two main committees and several subcommittees. The Administrative committee is composed of representatives from each member company and is the governing body of the Task Force. The Technical Committee is also composed of representatives from each member company and is responsible for the general supervision and management of the acquisition or development of

the generic spray drift data. Subcommittees of the Technical Committee have been formed along the lines of expected data collection and testing activites, and are generally responsible for establishing specific, standardized protocols.

Literature Search and Database Format Subcommittee

This subcommittee is responsible for compiling existing studies and data which may be useful as primary bridging or supplemental data for the generic database. This subcommittee also is responsible for establishing the format for entering data into the database.

Physical Properties Testing Subcommittee

This subcommittee is responsible for identifying the physical properties of the test substances which may correlate to relative amount of off-target movement. This subcommittee is also responsible for identifying the testing methods, establishing the testing protocol and potential contract sites to do the testing.

Atomization Subcommittee

This subcommittee is responsible for establishing a standardized protocol for wind tunnel and static atomization testing to generate droplet spectra for test substances which indicates their relative potential for off-target movement. It is also responsible for identifying instrumentation and potential contract testing locations.

Field Study Subcommittee

This subcommittee is responsible for establishing standardized protocols for conducting field tests. These protocols will determine the impact of test substance, equipment, weather and other variables on off-target movement. Items requiring standardization include:

Application equipment selection and adjustment
Site selection and justification
Calibration methods and verfication
Weather monitoring equipment and data requirements
Collection devices and sample handling procedures
Analytical methods

This subcommittee is also responsible for selection, verification and general use of mathematical models that may be used to analyze various application scenarios and their impact on off target movement.

TIMETABLE

The development and submission of generic spray drift by the Spray Drift Task Force will involve several phases over four or more years. In response to data call-ins under FIFRA paragraph 3(c) (2)(B), where members have cited participation in the Spray Drift Task Force as their substantive response, the EPA has, on a case-by case basis, granted

extensions until 1994. The Task Force plans on keeping the EPA informed of its progress in compiling the generic drift database through periodic reports demonstrating its diligence.

Test plans call for atomization and field tests to begin in 1991. Tests in 1992 and 1993 will fill in data gaps remaining after 1991 testing and after full review of existing data.

TEST PLAN

A phased testing approach has been adopted as the best way to meet the challenges of limited field and laboratory testing resources, EPA deadlines, potentially changing membership and statistical validity. Each phase represents one year's testing and may include all types of data determination: field tests, atomization tests, and physical property tests. The phased testing concept calls for an investigative approach that will rank physical properties contribution to the atomization process. Each physical property found to have significant correlation to atomization will be used to group test substances into categories which reflect their potential to generate drift prone droplets, eg. < 150 microns.

Plans call for this grouping to proceed from literature basis to physical property testing to atomization studies to field studies. However, uncertainties about physical property testing methods appear to make atomization tests the initial grouping method, with physical properties to be correlated to these results afterward. Field test in Phase I will begin in 1991 on at least one of the three use patterns (aerial, chemigation, ground). After data has been obtained and evaluated, other use patterns or test substances will be identified for the following year's (phase) testing to fill in potential data gaps. This process will be repeated again, as necessary, to arrive at a solid database.

TECHNICAL CHALLENGES

The central challenge to generation of this generic database is development of a test design which clearly identifies the relative impact of the independent variables upon spray drift. Standardizing protocols and identification of variables is absolutely imperative. While this is sometimes obvious, it is not when the test subtance has not been characterized by Physical Property and Atomization tests. Identification of field tests required for sufficient database cannot be complete until the interaction between physical property and atomization is understood. Specific challenges for each subcommittee follow.

Physical Property Challenges

Atomization of liquids is reported to be a funciton of the liquid's viscosity, surface tension, and density. However, when trying to rank various agricultural spray solutions by their tendency to form relative proportions of small droplets from a standard nozzle and set of conditions, these three parameters often fail to be predictive. When trying to differentiate among aqueous spray solutions in particular, one experimental

challenge is the relatively narrow segment of the range of viscosities, surface tensions, and densities that are typical. Observed proportions of fine droplets formed could be the result of random scatter expected from the nozzles and techniques used or that the physical properties and testing techniques may not include all the appropriate ones.

High speed photography has shown that primary atomization and secondary breakup occurs within 10 milliseconds. Also, the shear rate experienced by a spray solution at the orifice is extremely high, in the 25,000 - 100,000 sec^{-1} range. Identifying test procedures that reflect these conditions is a challenge.

The Physical Property Subcommittee will first do instrument evaluation and then range-finding studies on the following properties, based upon the aforementioned physical limits: for primary atomization - dynamic surface tension, high shear viscosity, elongational viscosity; for secondary breakup - dynamic surface tension, low shear viscosity, elongational viscosity. Additionaly, methods and equipment must be identified to evaluate evaporation rate of a droplet. Test substances that represent the limits of the mentioned physical properties will be identified and measured. These test substances will then advance to Atomization testing to determine if correlation with concentration of drift prone droplets can be established. If correlation is established, physical properties may be considered an indication of a drift potential for a test substance.

Atomization Challenges

Two goals of the Atomization Subcommittee are: (1) establish the correlation between field drift study results and spray droplet spectra, and (2) establish the correlation between these droplet profiles and physical properties of the spray solution. Because ground, aerial, and chemigation techniques are required by EPA, both static and wind tunnel atomization tests will be necessary. Critical nozzle selection will be based upon a correlation with the product use-pattern matrix generated by the Field Study Committee.

Only two wind-tunnel facilities have been identified in North America which will be capable of testing active chemical products: New Mexico State University and the University of New Brunswick. Both sites have Particle Measurement Systems and have plans to update their facilities. A round robin test protocol is being developed to compare results from these two facilities, as well as facilities that may surface.

A study using a range of formulation types, or test substances spanning a wide range of measurable physical properties, will be run in 1991 to demonstrate the relationship of physical properties to droplet distribution. Primary interest will focus upon drift prone droplets, although the entire spectrum will be recorded.

Field Study Challenges

The Field Study Subcommittee has a number of challenges that must be overcome. These include:

Product Use Matrix Development - EPA requirement for spray drift data generally specified consideration of aerial, mist blower, chemigation and high clearance ground sprayer use patterns, ie. application methods. Subsequent communication with EPA and further interpretation of EPA guidance documents confirmed that spray drift data is required for practically all outdoor use patterns. Obviously, this scope requires significant organization and clarification. A "Use Pattern Matrix" was developed to address this problem. The matrix approach allowed a systematic organization of three basic use patterns: aerial, chemigation and ground. The first dimension of the matrix describes use patterns which were divided into more descriptive subgroups. For example, ground use patterns specifically include orchard/vineyard air blast sprayers, field crop sprayers, vector (mosquito) control, lawncare sprayers and right of way sprayers. The second dimension of the matrix specified the application volume per unit area. Volumes per unit area were subdivided into four categories which result in general application types of equipment and methods.

The matrix approach creates a broad view of the application practices that are common. Identification of "Worst Case" practices, as required by EPA, as well as typical or best cases is facilitated by this approach.

Typical Nozzle and Equipment - Each of the resulting "blocks" in the Product Use Matrix must be represented by a nozzle type and operation practice. This is a challenge because of the vast number of combinations that are possible. The "worst case" selection criteria is applied, however, consideration of "reasonable and customary" logic is also applied. Once again, the matrix approach results in a broad spectrum of nozzle types and equipment arrangements that span from worst case to best case. Atomization and field studies will use the identified nozzles.

Product Lists - The Use Pattern Matrix also offers an excellent approach for organizing the vast number of active ingredients, formulations and tank mixes that were presented by the member companies for the defense effort of the Task Force. Each "block" of the matrix was assigned a descriptive code. Member companies compiled lists of products requiring spray drift data and assigned a descriptive code for each labeled use pattern. The product lists for all members will be entered into a database that will allow sorting by descriptive code. This method will provide insight into the relative importance of each matrix block.

Protocol Development - A major challenge is to develop a protocol that will permit uniform data collection across a broad range of use patterns, weather conditions and geographical locations. Of particuliar importance is selection of collection devices.

many types and configurations of collection devices are possible. This abundance of options is confounded by numerous references of variable collection efficiency that is influenced by droplet size and weather conditions. Current plans are to use several collection devices which may include: High volume air samplers, horizontal flat plates and rotating target devices.

Model Development - Analysis and future value of the Task Force database is dependent upon the development of empirical models and employment of existing mathematical models. Models allow the predictive power that is important for exploring data gaps resulting from changing field conditions or consideration of untested use patterns.

Parameters necessary for model operation are being identified so that protocols will assure proper collection when field studies are conducted. Existing mathematical models are being reviewed to determine their relative predictive accuracy of off target movement, as well as consideration of the relative "ease" of providing input parameters and user friendliness. Five models which have been identified are:

U.S. Forest Service's FSCBG and AGDISP (Barry and Ekbald, 1990).
PKB Model from University of New Brunswick. (Picot and Wallace, 1987).
David Smith Model from Mississippi State University (Smith, 1990).
DowElanco Model. (Patel and Gaidos, 1989).

Plans are being made to compare the inputs and outputs of these models by evaluation using an existing data set.

CONCLUSION

The purpose and scope of the Spray Drift Task Force presents a tremendous organizational and technical challenge. These challenges are greatly overshadowed by the great opportunity to understand the many factors that influence spray drift. Many obstacles must be overcome, however, the potential for success of the Spray Drift Task Force in accomplishing the described purpose are excellent when one considers the committment of resources that have been made by member companies.

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DEVELOPMENTS IN PESTICIDE PACKAGING

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ABSTRACT

The 1980s have witnessed major changes to packagings used for pesticides. This has been influenced by increased availability and choice of high barrier plastics and by demands from regulatory authorities and end users for high performance, safe and convenient to use containers.

The 1990s will continue to see developments in container design, particularly to meet requirements for easy rinsing, no-contact dispensing and marine pollution prevention. A most important problem to be addressed is the used container disposal issue which will require the introduction of industry-wide container management programmes.

INTRODUCTION

As with all other goods, the quality of a pesticide may be measured by the extent to which it fulfils the expectations of the end user. In this respect, the formulation and the package are totally interrelated and must be acceptable as a whole to the farmer. The pesticide packaging industry's objective must be to deliver the pesticide to the consumer in packaging that is legal, safe, convenient and of high quality, and to do so as economically as possible.

The 1980s have seen major changes in the way in which crop protection products are packaged. These have been determined by a number of factors including:

- imposition of the United Nations package performance tests, which require all package systems containing hazardous goods to meet certain minimum performance standards. These tests have highlighted the deficiencies of a number of traditional pesticide packages such as glass and tinplate containers.

- pressure from regulatory authorities and farmers for containers which are specifically designed for the safe and convenient handling and dispensing of pesticide formulations.

- advances in plastics materials and moulding technologies which have allowed the widescale employment of user-friendly plastics containers that are compatible with aromatic hydrocarbon solvents as well as water-based crop protection formulations.

- introduction of high activity pesticides which have dramatically increased the requirement for smaller packs and the need for accurate dispensing.

- increased co-operation amongst pesticide manufacturers in using new technologies to produce packages designed so that they are immediately recognisable as pesticide containers to minimise the risk of inadvertent reuse for food and drink.

HIGH BARRIER PLASTIC MATERIALS

Plastic containers offer a number of advantages for pesticide packaging, including improved durability, increased possibilities for design modifications at relatively low offtakes and, in some cases, lower costs. Only the limited spectrum of solvent compatibility has restricted their use as pesticide containers. However, during the last 10 years a number of barrier materials and technologies have emerged that have revolutionised pesticide packaging. Some of these are summarised below.

Single Materials

A number of polymers commonly used by the plastics industry have solvent resistant properties but are not really suitable for standard monolayer extrusion blow moulding due to high cost (ethylene vinyl alcohol - EVOH), production difficulties (polyamide - PA) or because containers produced from them are brittle, particularly at low temperatures (polyacrylonitrile - "Barex"). However, some of these polymers are used as barrier layers in co-extrusions (see below). Glycol-modified polyethylene terephthalate (PET-G) has practically no hydrocarbon solvent resistance and relatively poor impact strength when extrusion blow moulded, but when bottles are manufactured from un-modified PET using the injection-stretch-blow moulding technique, the resulting biaxial orientation yields containers of pleasing appearance resembling glass, with good neck definition, good impact strength and high permeation resistance to aromatic hydrocarbons. Unfortunately, resistance to ketonic solvents is not particularly good and the polymer has a high water vapour transmission rate compared to high density polyethylene (HDPE).

Co-extrusion

Multilayer plastic containers can be produced by co-extrusion blow moulding different polymers together. Normally, high density polyethylene (HDPE) is used to provide the mechanical properties and either PA, "Barex" or EVOH is used to provide the barrier layer. An adhesive is also extruded to bond the support and barrier layers together in a typical three layer co-extrusion. Four and five layer co-extrusions are also used. The major advantage of co-extrusion is the ability to tailor the barrier to suit a particular product.

Fluorination

This technique relies on the reaction of fluorine gas with polyethylene to produce a solvent resistant fluoro-carbon barrier on the container surface. Fluorine treatment may be carried out either during the container moulding process, in which case only the inner surface is fluorinated, or as a post-moulding operation when the outer container surface is also fluorinated. Obviously the processes require extensive environmental and safety controls to avoid escape of fluorine and also of hydrogen fluoride which is a by-product of the process.

Laminar Technology

A fundamental problem with the technologies described above is the high cost of the complex machinery and/or environmental controls required to produce solvent resistant containers. Therefore, to make the processes cost effective, large quantities of containers must be produced, yet the offtake of containers by the crop protection products industry is small compared to other industries eg. the beverage and oil industries. Considerable progress has been made in Europe in making our business more attractive to potential suppliers by standardising the range of packs used within individual companies and by Company grouping to adopt standard package designs and materials, e.g. the Bayer, BASF, Hoechst, Schering range of co-extruded containers and the Dow, ICI, Shell range of PET containers.

However, outside Europe and the US the development of these technologies has been patchy and consequently the du Pont de Nemours "Selar" technology was received with great interest. This method of conferring solvent resistance involves the use of a mixture of polyamide and a 'compatibiliser' developed by du Pont which when mixed at between 8% and 15% with polyethylene produces solvent resistant containers on only slightly modified extrusion-blow-moulding machinery. The improved resistance derives from a laminar barrier of polyamide established within the container walls. From an economic viewpoint imported product content is low, existing blow-moulding machinery can be used and there is no handling risk as with fluorination technology. Unfortunately, the parameters involved in routinely obtaining a good laminar structure under non-ideal conditions have not been fully resolved.

CONTAINER DESIGN

Studies carried out in the USA (Akesson, 1988) and also by the British Agrochemical Association (BAA) in the UK indicated that a major cause of farm worker contamination occurred during dispensing the concentrate from traditional containers into the spray tank. This was caused mainly by 'glugging' and splashing during pouring, but also due to container handles being too small for gloved hands and positioned too close to the container neck. Poor design also allowed significant product hold-up in the 'empty' containers, particularly in the hollow handles of blow-moulded containers.

Since 1983, UK users were encouraged through the Chem-Ag procedure to report unsatisfactory pack designs. This subsequently led to the issue of guidelines for pesticide container design (MAFF 1983) initially only for liquids. Based on these guidelines, modern plastics pesticide containers are now designed to improve drainage, have wide necks to minimise glugging and include large pinched-off handles to improve handling and dispensing. Work carried out at MAFF's Harpenden laboratory (Gilbert et al, 1988) on some new 'low exposure' containers indicated that spillage during dispensing could be reduced by a factor of ten for five litre containers compared to traditional pesticide packs.

CLOSED SYSTEM DISPENSING

The first steps towards closed transfer and mixing systems were taken by the California Department of Food and Agriculture during the mid-1970s in an attempt to reduce pesticide contamination amongst those who mix pesticides. Unfortunately, universal use of such systems was limited partly because of the lack of standardisation of container designs, particularly neck forms with which the system must be compatible (Jacobs, 1988). In order to facilitate the introduction of closed systems at the request of the major European-based crop protection companies, a GIFAP Packaging Task Force was formed this year with an objective of proposing a minimum number of standard thread forms for new plastics pesticide containers. The Group has already agreed that one standard should be a modified ASTM 63mm thread and an increasing number of containers in Europe are now being moulded with this neck finish.

MARINE POLLUTION

In January 1991, Annex 3 of the International Maritime Organisation's Marine Pollution Convention comes into force. This annex states that packages destined to be internationally transported by sea and contain products which have been classified as marine pollutants must be adequate to minimise the hazard to the marine environment. Although the exact definition of 'adequate' has yet to be established, it is obvious that packages must be sufficiently robust to remain intact after immersion in sea water for long enough to allow salvage attempts to be made. This will probably mean that unprotected paper-based packaging will not be permitted for pesticides classified as marine pollutants.

DISPOSAL

Probably the most important issue to be faced by the Agricultural Chemical Packaging Industry during the 1990s will be the safe and environmentally acceptable disposal of used pesticide containers. Although it is estimated that less than one per cent of all blow-moulded plastics packaging is used by the crop protection agrochemical industry, the public perception of used packaging is increasingly negative, compounded by the real or perceived toxicity of the products involved.

A number of surveys have been carried out aimed at determining the residues remaining in 'empty' containers and current methods of disposal. A typical survey carried out in the Departement of Marne (France) in 1986 yielded the following results:

- About 1.4 million pesticide containers were disposed of as follows:

  48% by on-farm burning

  40% by burial on private or municipal dumps

  7% by uncontrolled dumping

  5% by recycling

Observations during container sorting revealed considerable amounts of residual product remaining in used containers; on average 70 grams per 10 litre container. Thus, a large quantity of product could be dispersed into the environment in an uncontrolled manner.

It is inevitable that environmental legislation will increasingly prohibit on-farm burning or burial and dumping of contaminated containers on municipal dumps is already illegal in many countries.

Faced with such pressures, industry-wide integrated pesticide container management programmes will need to be developed. Such programmes are already being evaluated on a pilot scale in some US and Canadian States and have been in operation for some years in Denmark. Elements in such programmes must include:

Disposal Minimisation

Probably the most elegant solution to the container disposal problem is to package the formulation in a water soluble film such as polyvinyl alcohol (PVOH). In this manner the packaging is dissolved in the spray tank alongside the formulation and can be considered as a closed system unit dose pack. PVOH sachets have been used for over 20 years for packaging wettable powders but recently Rhône-Poulenc introduced an EC packaged in PVOH sachets.

Significant reductions in the numbers of pesticide containers have been achieved in the USA, particularly by the introduction of returnable multi-trip drums of around 50 litres capacity and by the supply of products to larger users in so-called minibulk tanks (500 to 2,000 litres capacity).

The weight of packing material used for pesticides has recently been reduced mainly by replacement of metal and glass by plastics. Further improvements may be achieved by reducing the weight of polymer in existing plastics containers and by increased use of flexible plastics packaging such as bag-in-box systems. Extensive evaluation will be necessary before the introduction of such systems. Use of smaller containers by, for example, increasing the active ingredient content in the formulation will reduce packaging material but moves in this direction may not only require product re-registration but also introduce the need for more accurate measurement and dispensing into the spray tank.

Container Decontamination

Effective rinsing of the empty container is a pre-requisite for disposal. The effectiveness of container decontamination is dependent upon a number of factors, as listed below.

Formulation properties

High viscosity liquids, particularly those likely to 'cake' on container walls such as some SCs will obviously present greater decontamination problems than solutions, particularly those based on low viscosity solvents. Non-dusty granular formulations will leave less residue than WPs.

Container design

The design of pesticide containers to improve drainage has previously been discussed. However, the concern to remove as much product as possible from containers is not limited to the Pesticide Industry. The West German Chemical Industry Association has demanded that steel and plastic drum design be improved to reduce residues remaining in 200 litre drums down to less than 100 millilitres. under 'standard' conditions.

Container rinsing

Wherever possible, containers must be rinsed with water immediately after emptying and the rinsate added to the spray tank. US Federal and some State regulations now demand triple rinsing as a minimum requirement and, preferably, high pressure rinsing with a lance should be used.

Recognising that triple rinsing is time consuming and its efficiency highly operator dependent and that lance pressure rinsing is not ideal for some container types, the Dutch crop protection industry funded the development of a container rinsing machine (Haghuis et al, 1986, Klomp, 1987), designed to be installed on the water inlet to the spray tank. It was agreed that containers for both solids as well as liquids should be capable of being rinsed on this machine to a residue level below 0.01% of the original contents after 30 seconds.

Such containers may then be treated as normal farm refuse. Un-rinsed containers must be returned to a special chemical waste dump for disposal. The covenant between industry and government has been in operation for less than one year but is seen as a model by other European countries to ensure that the toxicity risk posed by used containers is substantially reduced.

Obviously any closed dispensing system should include a rinse cycle that must achieve the same 0.01% standard.

Disposal of rinsed containers

Although rinsing can remove most of the product residue, it has been shown (Donegan, 1986) that some pesticide residues are retained by the walls of metal (aluminium and lacquer-lined steel) and plastics containers and therefore could still pose a potential additional environmental and safety risk. The degree of such risk is still subject to assessment by the major crop protection companies, co-ordinated by the GIFAP Packaging Task Force. A Canadian toxicology group is also investigating product residues in used containers (Davreux, 1990).

Until product/container sorption characteristics have been fully defined, it is premature to discuss material recycling, particularly for plastics, apart from using the calorific value of the polymer as energy. Metal and glass containers can be recycled via smelting and glass furnaces respectively.

Safe collection, segregation, shredding and disposal schemes will need to be developed on an industry-wide basis involving crop protection companies, distributors, authorities, disposal companies, and, most importantly, the end users.

CONCLUSION

As stated in the introduction, the package is an integral part of the product and, as such, must be treated as part of the total product stewardship approach. This paper has highlighted some of the facets involved in ensuring that pesticide packages are safe, convenient and environmentally acceptable.

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SESSION 9B

CURRENT AND PROPOSED EUROPEAN COMMUNITY LAWS: EFFECT ON REGISTRATION OF PESTICIDES IN MEMBER STATES

CHAIRMAN M J. THIAULT

SESSION ORGANISER MR N. PUNJA

A VIEW ON THE EC PROPOSED REGISTRATION DIRECTIVE ON PLANT PROTECTION PRODUCTS FROM A GOVERNMENT REGULATORY AGENCY STANDPOINT

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ABSTRACT

The bearing principles of the EC Commission's proposed Directive on the registration of plant protection products are outlined, comprising a Community list of data requirement, a Community procedure for the establishment of a Positive List of active ingredients, authorization by the Member States of preparations containing active ingredients, and mutual recognition. Comment is made on difficulties with the implementation of each of these principles by the Member States, such as the lack of guidelines on the conditions of acceptability of products, authorization by Member States of preparations for use in their own territories for three years even if the active ingredient is not yet on the Positive List, and uncertainty with mutual recognition as to whether National level of protection will be maintained.

INTRODUCTION

At this point in time the final outcome of the discussion on the EC legislation on registration of plant protection products is not known. This paper therefore outlines a comment on the EC Commission's Proposal for Placing of EEC-Accepted Plant Protection Products on the Market [COM(89)34]. This proposal has now been discussed for more than one and a half years. Although I have participated in all the meetings on the proposal but one, I dare not guess on the final directive, but it seems that the present principles of the Commission's proposal will remain unchanged.

The Commission's proposal is rather complex and covers many aspects and I only want to comment on the bearing principles of the proposal which in my opinion are the following:-

1. A Community list of data which may be required by the applicants to fulfil. The data requirements are not final but are to be decided for each active ingredient and preparation. A Community procedure will decide whether an application satisfies the requirements for the active ingredient.

2. A Community procedure for the establishment of a Positive List of active ingredients the use of which may, a priori, be considered safe to human health and to the environment.

3. Member States judge the acceptability based on local conditions, safety, efficacy and environmental impact of individual preparations containing active ingredients authorized at Community level.

4. Mutual recognition of National acceptance. A Member State must authorize the marketing of a product approved in another Member State to the extent that the agricultural, plant health and environmental conditions relevant to the use of the product are comparable in the regions concerned.

These four principles are to be used for both new and old products.

DATA REQUIREMENT

I believe that all Member States are very much in favour of harmonized data requirement. It is a great advantage, at least for the smaller countries, that the data requirements are harmonized within the Community considering the costs to produce the data. It becomes easier for Member States to persuade the applicant to produce data when you have common EC-data requirement.

The data requirement in Annex II for the active ingredient and Annex III for the preparation are described in very broad terms, in fact only as headlines. A number of details e.g. which species should be used are not specified in the proposed Directive. The data requirements in Annexes II and III are more like a list of data which may be required.

Detailed guidelines or principles for the data requirement will be worked out either in the two year period from the adoption of the Directive to the implementation of the Directive or before the adoption of the Directive.

There is a Community procedure for decision as to whether data submitted on the active ingredient satisfies the data requirement or not and as to which tests should be carried out on a particular active ingredient. The legal basis for a decision is given in the Directive. The decision is taken by the Commission after consultation with the Standing Committee. There may be many very difficult discussions among representatives of the Member States in the Standing Committee since there are different attitudes in the different Member States on data requirements. Provisional approvals are currently granted in at least three Member States on a limited data package. In other Member States applications are accepted for examination only if all data necessary to evaluate the effects of the relevant field of use of a preparation are submitted. It might be very difficult for the Standing Committee to advise the Commission. As the Commission shall take the utmost account of the opinion delivered by the Committee it might also find itself in a very difficult position.

This conflict is put into focus when considering the ability of each Member State to authorize a preparation for use in its own territory for a period of up to three years even if the active ingredient is not on the Positive List.

There is some concern in certain Member States that this three year authorization will be used as a sort of provisional approval based on a limited data package. This is considered a major drawback and is very difficult to accept for these Member States.

POSITIVE LIST OF ACTIVE INGREDIENTS

The decision to include an active ingredient on the Positive List is taken by the Commission in accordance with the opinion of the majority in the Standing Committee. This is a well known procedure.

But the conditions given in Article 5 of the proposed EC Commission Directive for inclusion of an active ingredient on the list are not easy to use when deciding.

Two conditions should be fulfilled:-

(i) Residues of an active ingredient in edible plant products, edible livestock or in the environment do not have any harmful effects on human or animal health or on the environment.

(ii) It may be expected that preparations manufactured from the active ingredients will meet the requirements for the preparations.

No one of course would oppose the first condition. No Member State would vote for the inclusion of an active ingredient if its residues have any harmful effect on man or the environment. We might have some very interesting discussions to decide what residues cause no harm.

The second condition, however, reflects the main problem created by the separation of the decisions on the active ingredient and on the preparations manufactured from it.

The registration authorities of Member States authorize preparations and not active ingredients. These authorizations are granted on the basis of information on, among other things, the use of the preparations. It is very difficult to take the decision on the inclusion of an active ingredient on the Positive List without information on the effects of the preparations manufactured from it.

This is of course the reason for having the second condition. But the expression "it may be expected that the preparation meets the requirements for the preparation" gives no operational guidelines for decision making.

You could imagine that the Standing Committee in fact examined the preparation in order to take the decision on the inclusion of an active ingredient on the Positive List.

The consequence of the second condition might therefore be that the decision on the inclusion of an active ingredient on the Positive List in fact is an authorization at the Community level of a preparation for a particular field of use in certain regions within the Community.

So the Positive List could be considered not only as a list of active ingredients but as a list of active ingredients with certain restrictions, such as the field of use, in which regions they can be used etc.

JUDGEMENT BY MEMBER STATES ON THE PREPARATIONS

When judging the preparations the Member States shall provide that a preparation may be accepted only if:-

(a) Its active ingredient is listed in Annex I and any conditions laid down therein are fulfilled.

(b) It is established that:-

I. It is sufficiently effective.

II. It has no unacceptable effects on plants or plant products.

III. It has no harmful effect on human or animal health.

IV. It has no unacceptable advserse influence on the environment.

I believe that all 12 Member States can agree on the above mentioned conditions. But there are no guidelines on how to interpret the general wording of the conditions. There might be as many as 12 different interpretations of the conditions.

This makes it very difficult to judge the consequence of the Directive on the level of protection. Guidelines for interpretation will be worked out before or during the period of two years from the adoption of the Directive until implementation, to ensure that there is a Community interpretation of the general conditions. The lack of guidelines on interpretation makes it very difficult for certain Member States to take a final position on the proposed Directive.

A special problem with the conditions on the preparation is related to the Positive List.

No Member State can authorize a preparation for a field of use which is not mentioned on the Positive List. An extension of a field of use requires a Community decision that the field of use in question should be included on the Positive List for the active ingredient in question.

The decision on the inclusion of further fields of use on the Positive List has to take the conditions for inclusion of active ingredients into account including conditions for preparations, which means that you expect that a preparation fulfils the requirements for preparations. This could mean that there is a Community procedure for the first authorization of the first extension of the field of use.

The decision on the extension of the field of use could therefore be a rather time consuming process. A Member State might therefore choose to use the derogation option given in Article 8 and authorise the extended field of use for a period of three years in its own territory.

MUTUAL RECOGNITION

A Member State must authorize the marketing in its territory of a plant protection product which is already accepted in another Member State unless some agricultural, plant health and environmental conditions relevant to its use are not comparable in the regions concerned.

This leaves the Member State with a very difficult task, the decision as to whether agricultural, plant health and environmental conditions are comparable in the regions concerned. There are no guidelines on how to carry out this camparison. The decision of a Member State can, however, be overruled.

Since there are no guidelines for decisions on plant protection products there is an uncertainty in certain Member States whether their National level of protection can be maintained, for instance the level of protection of groundwater. Some Member States do have some difficulties in accepting the Directive without knowing what the consequence on their own National level of protection will be.

CONCLUSION

Although there are advantages with the proposal for the Directive on EC-Accepted Plant Protection Products, e.g. the common data requirements, there are major problems that are unsolved, e.g. the level of protection has not been decided, the procedures to be used are very time consuming and sometimes the rules given are very difficult to interpret.

Since the principles of the Directive are to be used for both new products and for re-evaluation of all the old products a tremendous burden of work is put upon the Member States. With the unanswered questions which will have to be discussed in connection with many preparations I find it very difficult to see how this proposal in the short run at least can ensure free circulation of safe products.

The scenario I consider the most probable is that each Member State will take decisions in its own territory for periods of three years while we at the Community level will be busy trying to solve all the unanswered questions.

AN INDUSTRY VIEW OF THE EC REGISTRATION DIRECTIVE

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ABSTRACT

The European Commission's Proposal for a Directive aimed at harmonising pesticide registration has been discussed at length by the Council Working Party on Agricultural Questions and an Amended Proposal has been drafted. This Amended Proposal is now under consideration by Agricultural Attachés and is understood to have been assigned a high priority by the Italian Presidency. These new proposals contain a number of significant changes, some of which are welcomed by Industry, particularly those relating to the protection of proprietary data. Major issues which are identified for future attention are proposals for Uniform Principles and Explanatory Notes which will provide detailed guidance on data requirements and procedures. Despite these improvements the basic structure of the Directive is unaltered and Industry remains concerned as to the impact of the Directive once implemented.

INTRODUCTION

Following the publication of the European Commission's proposals for the harmonisation of pesticide registration within the Community (O.J. 1989), this topic has been the subject of much discussion in a variety of fora. Most recently the British Crop Protection Council Symposium at Reading in January 1990 (Thomas, 1990 a) provided the opportunity for an extensive review of the proposals on the basis of political, scientific and regulatory considerations as viewed by the Commission, National Governments and Industry. In the six months since that time we have seen an almost unprecedented number of meetings of the Council Working Party on Agricultural Questions, under the Irish Presidency, to consider the Commission's Proposal. These discussions culminated in the drafting of an Amended Proposal which, under the Italian presidency, was submitted to the Committee of Agricultural Attachés for resolution of outstanding areas of disagreement between Member States.

It is understood that the Italian Presidency is committed to assigning a high degree of priority to this topic. Thus, whereas the following remarks relate to the Council Working Party's Amended Proposal, it must be recognized that changes may well ensue from future discussions at the various stages of consideration within the Community procedures.

THE AMENDED PROPOSAL

Essentially the basic structure of the Draft Directive remains intact and continues to be based on a two-tiered approach with active substances being approved at Community level and plant protection products being approved by individual Member States. Despite Industry's reservations regarding this approach it was perhaps unrealistic to expect any significant changes in this basic approach given the difficulty of the problem and the historical background of proposals for the Community harmonisation of pesticide registration.

The major changes are summarised in Table 1, but it should be noted that these changes have not necessarily been agreed by all Member States or accepted by the Commission. Rather they reflect a compromise of various national positions which remain to be agreed, or indeed further amended, at the Agricultural Attachés or COREPER (Committee of Permanent Representatives) levels and ultimately by the Council of Agricultural Ministers. It should also be noted that even if agreement is eventually reached on the Draft Directive, final adoption can only be achieved when the Council has received the Opinion of the European Parliament. Progress within the Parliament has, in contrast to the Council Working Party, been slow and at times confused. For example, at one stage the Parliament's Environmental Committee was faced with some 180 Amendments to the Commission's Proposal which, had these Amendments proceeded to a formal vote, would have represented a formidable task in drafting the Opinion. At the time of writing this paper the Parliament is investigating a more pragmatic means of arriving at this formal Opinion.

ADDITIONAL CONSIDERATIONS OF THE COUNCIL WORKING PARTY

During its discussions on the Commission's Proposal, the Council Working Party identified a number of other areas of considerable importance to the final adoption of the Directive or to relationships with other Directives. Thus:

Scope of the Directive

In response to a request from a number of Member States to extend the scope of the Directive so as to include such uses as wood preservatives, safeners, ectoparasiticides and animal husbandry, the Council Working Party has formally requested the Commission to submit proposals for a further Directive to cover these uses.

Relationship with EC Maximum Residue Limits (MRLs)

The Council Working Party recognized that data submitted under the provisions of the Registration Directive should be of assistance in accelerating the process by which Community MRLs

TABLE 1. Major changes in the Amended Proposal for harmonisation of pesticide registration in the EC

	Commission Proposal	Amended Proposal
1.	No allowance for Provisional Approval as traditionally utilized in France, UK, Ireland	Possible allowance of Provisional Approval if data 'can be expected to satisfy' requirements, particularly in the field-based environmental area [Article 8(1)]
2.	Derogation allowing MS to authorize for up to 3 years products containing a.i. not in Annex I	Extension of 3 year period if no decision yet taken [Article 8(1)]
3.	10 years to review 'existing' a.i.s	Progress report after 8 years and possible prolongation beyond 10 years [Article 8(2)]
4.	Protection of proprietary data limited to 15 years for data on new a.i. included in Annex I from first authorisation in a MS	10 year data protection for a.i. and product data; 5 year protection of review data and and re-registration data from date of inclusion of a.i. in Annex I [Article 12]
5.	Applicant can only appear before Standing Committee at invitation of the Commission	Applicant will be asked to appear before the Committee if there is a possibility of an unfavourable decision. [Article 6(4)]
6.	Lack of definition of 'comparable' agricultural, plant health and environmental conditions with respect to mutual recognition of registrations	Documentation to support claim of comparability to be submitted by the applicant [Article 10(1)]
7.	Criteria of mutual recognition of registrations	Registration in a 'second' MS subject to the adoption of Uniform Principles [Article 10(1)]

TABLE 1 continued:

8.	Criteria for inclusion in Annex I	Where relevant additional requirements for the establishment of an ADI, acceptable operator exposure, fate and distribution in the environment and impact on non-target species. [Article 5(2)]
9.	5 year period for re-inclusion of a.i. in Annex I	10 year period for re-inclusion in Annex I [Article 5(5)]
10.	Data requirements for inclusion of a.i. in Annex II	Annex III data also required on at least one preparation containing the a.i. [Article 6(2)]
11.	Annex IV (Standard phrases of nature of special risks) and Annex V (Standard phrases of safety advice)	Both Annexes are deleted

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are established - a view which the Commission would seem to have accepted. (Walsh, 1990)

Uniform principles

Article 17(1) of the Commission's Proposal provides for the adoption of Uniform Principles aimed at ensuring harmonisation of the authorization of plant protection products by individual Member States. The Council Working Party has defined more clearly the content of these Uniform Principles which will provide guidelines to ensure that Member States apply the following in an equivalent manner:

- the need for specific studies or information
- the assessment of studies and the consequences of particular findings
- a risk/benefit analysis leading to the granting or rejection of approval

- the imposition of restrictions or conditions to any approvals granted

These considerations will apply to the areas of efficacy, risks to operators, bystanders, consumers and animals, environmental fate and ecotoxicological impact.

In addition to these Uniform Principles, criteria and requirements will be defined so as to provide guidance regarding the inclusion of an active ingredient in Annex I.

Whereas the importance of these Uniform Principles is undisputed (see also further comments below), there is some disagreement between Member States as to their relationship with the Directive itself. Thus some Member States would wish to see the Uniform Principles adopted as an integral part of the Directive, others would be agreeable to their adoption by the Standing Committee on Plant Health prior to the implementation date of the Directive.

Explanatory notes

The Draft Directive defines data requirements for the active ingredient (Annex II) and for the plant protection product (Annex III), and Article 17(2) provides for the adoption of 'Explanatory Notes' relating to these data requirements. In its discussion, and as with the Uniform Principles, the Council Working Party defined these 'Explanatory Notes' more clearly. Thus the 'Explanatory Notes' are seen as providing applicants with information and guidance on the content of the Directive and the procedures to be followed regarding the submission of applications and their assessment with respect to:

- inclusion of the active ingredient in Annex I and any subsequent renewal or review of inclusion

- authorization of plant protection products and any subsequent renewal, review, modification or cancellation of authorizations.

- presentation of applications including format and language

THE INDUSTRY VIEW OF THE CURRENT POSITION

General issues

The Industry's general and specific concerns regarding the Commission's Proposal have previously been discussed in some detail (Thomas, 1990b) and it is gratifying to record that at least some of these concerns have been addressed in the Council Working Party's Amended Proposal. These include the extension of the time period for renewal of inclusion in Annex I from 5 to

10 years, the tacit acceptance that the review of existing active ingredients will take longer than 10 years and the acceptance that the applicant be given an automatic opportunity to be heard by the Standing Committee in the case of an initial negative decision regarding inclusion in Annex I.

The protection of proprietary data

Of possibly greater importance are the Amended Proposal's provisions regarding the protection of proprietary data. The Commission's original Proposal included provisions which protected only those data submitted on the active ingredient. Industry strongly contended that such protection should extend to cover data relating to the plant protection product, data submitted to support product label extension, and data to support re-registration or a review of an existing active ingredient. Whereas the length of data protection proposed for these various classes of data are open to debate, Industry welcomes the acceptance of the need for such data protection so as to ensure the continuation of the significant financial investment necessary to maintain a viable and technologically advanced agrochemical industry.

This is a highly complex area and it is understood that the Council Working Party spent much time in discussing this issue before the compromise included in the Amended Proposal was reached. However, whereas it is understood that the majority of Member States have apparently agreed to this compromise, Industry is concerned that some Member States would still wish to see data derived from animal experiments subject to different provisions.

Provisional approval

Despite Industry's support for the continuation of the system of Provisional Approval as traditionally practised in such countries as France, UK and Ireland, it is perhaps not surprising that Member States failed to reach an agreement on this issue. Those Member States who opposed any amendments to the Commission's Proposal apparently felt that a derogation which allowed Member States to operate such a system on an optional basis would give farmers in such Member States a commercial advantage over those in Member States not availing themselves of the derogation. Whereas Industry would still defend the pragmatic approach to registration offered by the application of Provisional Approval, it nevertheless recognizes that in reality France is the only commercially significant country within the Community which currently operates a 'real' Provisional Approval system. (Although Provisional Approval is nominally still part of the UK system, registration delays in the UK are such that 'full' data packages are invariably available before new active ingredients are considered for approval.) Therefore it seems that in the event of this issue being resolved on the basis of a qualified majority vote it is unlikely that there would be sufficient support to include this provision in the Directive.

This would be a pity because the benefits to the farmer, industry and the regulatory authorities of a system of Provisional Approval in the Member States is considerable.

Data requirements, Uniform Principles and Explanatory Notes

It seems clear to Industry that the data requirements specified in Annex II and Annex III have received less attention by the Council Working Party than the procedural elements contained in the 'body' of the Directive. This is regrettable. Industry has constantly maintained that true harmonisation of pesticide registration would be more easily achieved by establishing the harmonisation of data requirements and data interpretation before attempting to harmonise registration procedures. Furthermore it is of considerable concern to Industry that Annex III requirements (i.e. product data) have been significantly expanded in the Amended Proposal, particularly in the environmental area where it would appear that West German requirements have been added without any real critical discussion.

Both Annexes II and III have been described by some informed sources as merely a 'shopping list' to cover all eventualities and that the Introduction to both Annexes clearly allows applicants the opportunity to justify not including any specific item(s) of data which are felt not to be relevant. Whereas such views are reassuring, experience indicates that detailed lists of data requirements favour a 'check-list' approach to the submission of actual data and omissions are often difficult to defend.

Against this background, and in the realisation that there now seems little or no opportunity to amend Annexes II and III, Industry views the Uniform Principles and Explanatory Notes as being of vital importance. The objectives defined by the Council Working Party and described above are therefore to be welcomed and it is hoped that Industry, as a key participant in the generation of the data, will be given full opportunity to contribute in the preparation of the Uniform Principles and Explanatory Notes.

Notwithstanding the comments made above regarding Industry's satisfaction at the improvements which have been made to the Commission's Proposal, such comments should not be taken as approbation for the Directive as a whole. Industry remains extremely concerned that implementation of the Directive will lead to considerable difficulties to all concerned, not least because of the administrative problems and registration delays which will inevitably follow implementation.

THE FUTURE

The considerable effort of the Council Working Party, acting

under the impetus of the Irish Presidency, is fully recognized but it is perhaps worthy of note that some significant issues of principle remain unresolved despite this degree of effort. This, I believe, reflects the complexity of the issues involved, the difficulties in reaching compromises against the background of National Registration Systems which have been operating for some 30 years, the degrees of 'political' pressure operating in Member States and an innate 'parochial' attitude of Member States to pesticide registration. Despite these difficulties I personally believe that Community needs will overcome National reservations and that a Directive will be adopted in due course. Having risked the prediction of such an outcome however it would be even less judicious to predict when such an outcome might be achieved.

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RESIDUES AND MAXIMUM RESIDUE LEVELS

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ABSTRACT

Although European Community pesticide residue legislation has existed for many years it is very incomplete. The coming of 1992 and the completion of the internal market together with the considerable attention pesticides are receiving at the moment has led the European Commission to propose new legislation to extend Community control over pesticide levels and set up a system whereby maximum residue levels can be agreed more rapidly. This paper describes the proposal in detail and goes on to explain how MRLs are likely to be fixed in the future. It concludes by looking at the relationship between the Community and its trading partners and also with the Codex Committee on Pesticide Residues.

DRAFT PROPOSAL FOR MRLs FOR CERTAIN PRODUCTS OF PLANT ORIGIN INCLUDING FRUIT AND VEGETABLES.

Although there has been pesticide residue legislation in the European Community since 1976 the Commission have never considered this to be entirely satisfactory. There are three main reasons for this. First there are the Community trade problems which can arise where third Countries are exporting to the Community. Member States still have a considerable amount of freedom to set national MRLs. The UK itself has national MRLs which came into effect in 1989. Importers are faced with considerable differences in MRL standards between Community Member States. Secondly, there are problems of trade within the Community. The current situation of a whole range of different MRL standards cuts across the Community's aim for a free market by the end of 1992. It is not surprising that the new MRL proposals feature in the annex to the Commission's White Paper, "Completing the Internal Market". Thirdly the Commission have been concerned about the length of time that it takes to agree MRLs and aim to speed up the procedure considerably.

Early in 1989, therefore, the Commission published a new proposal for MRLs on certain plant products including fruit and vegetables. The proposal is essentially a framework proposal which determines how MRLs are to be fixed in the future. It does not actually set any MRLs. This will be done at a later date. The aim of the Commission was to see the proposal adopted by the Council of Ministers by the end of June 1989. However, adoption cannot take place until the European Parliament have delivered an opinion. At the time of writing, in July 1990, this is still being awaited. However, it is hoped adoption will take place before the end of 1990.

The Commission's proposal was debated by a Committee of the House of Commons in May 1989.

The main features of the proposal are as follows:-

1. Scope

The proposal applies to all fresh fruit and vegetables as well as frozen or dried products. Certain plant products not previously covered by Community MRL legislation also come under the proposal. These are pulses, oilseeds, potatoes, tea and hops. MRLs will not be set for processed products. Some products have been excluded eg cocoa and coffee because current opinion is that these do not give rise to significant residues when consumed. However the scope of the proposal can be extended by the Standing Committee for Plant Health. Cereals and products of animal origin are outside of this proposal and covered by their own directives which are due to be reviewed in 1991.

2. Classification of Products

The annex of the proposal subdivides the various fruit and vegetables into groups and sub-groups. The classification, although less detailed, is based on the system used by Codex. The idea is that when MRLs are set for a particular pesticide they are set for all uses. In this way it is easier to ensure that the Acceptable Daily Intake (ADI) of a pesticide is not exceeded. The annex also describes which part of the product the MRL is to apply to. Again this follows Codex procedures.

3. Mandatory MRLs

MRLs set under the proposals will be mandatory in all Member States. Indeed the proposal is currently drafted as a Regulation and MRLs set under it would be directly applicable to the Member States of the Community. The current Fruit and Vegetable Directive (76/895/EEC) is optional in the sense that while Member States must not set MRLs lower than those set out under this directive they can set higher MRLs or no MRLs at all if they wished. More recent directives on cereals and products of animal origin set mandatory MRLs and the new proposal follows suit. However, the old Fruit and Vegetable Directive is to continue for the time being and MRLs will be transferred to the new proposal over a period of time.

One feature of the old 1976 directive which has been carried over into the new proposal is the so-called "safeguard" clause. If a Member State considers that new information shows that a Community MRL endangers human or animal life it may temporarily reduce that level within its own territory. This action is reported to the Commission and the other Member States and the Standing Committee on Plant Health then decide whether the Community MRLs should change. The Member State taking safeguard must abide by the decision of the Standing Committee.

4. Standing Committee Procedure

MRLs set under the old residues directives have to be adopted by the Council of Ministers. The Commission have never been happy about the time this can take. Originally under the 1976 directive unanimity had to be achieved at the Council before proposals could be adopted. However under the Single European Act majority voting now applies and Council decisions tend to be made more quickly. Even so, Council procedure, in the Commission's view at least, is a long and time consuming one. The new proposal therefore gives the responsibility for setting MRLs together with the various other powers such as amending the annexes to the proposal, to the Standing Committee for Plant Health. This is a committee of national experts from Government Departments and regulatory authorities chaired by a Commission representative. The Committee vote on Commission proposals using qualified majority voting. This is a weighted voting procedure and requires at least three Member States to abstain or vote against the proposal to block it. Such a system has been used successfully in many other areas including the veterinary medicines and animal feedingstuffs areas. There is provision for the Commission to take the matter to the Council if a proposal is blocked, but in other sectors this procedure is seldom if ever used.

5. Community Monitoring Programmes

The proposal requires annual reports to be produced by Member States on the monitoring work that they have carried out as is already the case in the directive for cereals and products of animal origin. These reports must be submitted to the Commission by 1 August each year and may be debated by the Standing Committee's Sub-group on Pesticide Residues. The new proposal also requires programmes for future monitoring work to be submitted at the same time. Each November and after consultation at the Sub-group for Pesticide Residues, the Commission will recommend to Member States a co-ordinated programme of monitoring for the following year. In particular, priority areas will be identified. Five years after the adoption of the proposal the Commission is required to forward to the Council a report on the Community monitoring work and may also make appropriate proposals.

The UK has long carried out extensive monitoring work on pesticide resides through the Working Party on Pesticide Residues and published reports of its results and conclusions at regular intervals. It also publishes a booklet describing Government food surveillance.

6. Methods of Sampling and Analysis

Sampling methods for monitoring fruit and vegetables are already set out in a Council Directive 79/700/EEC. Community sampling procedures for other products and Community methods of analysis do not yet exist but there is provision in the new proposal for these to be established. Member States are free to use valid scientific methods of analysis other than Community methods, even if Community

methods have been established, provided these are reported to the Commission and other Member States. However, where there are differences in the interpretation of results between national methods and Community methods then Community methods shall prevail. Sampling and methods of analysis shall be established through a Commission Committee, probably the Standing Committee for Plant Health.

7. Exports

The original proposal published by the Commission excluded exports. This will almost certainly change and produce exported from the Community will be required to meet the MRLs set under the proposal. However there are two important exceptions to this. The first is where a third country requires a particular treatment and the second is where treatment of produce is necessary during transportation and subsequent storage.

8. Animal Feedingstuffs

Produce used as feedingstuffs was also excluded from the original proposal and again it is almost certain it will be included in the final adopted proposal. Any produce listed in the annex and used for food (and drink) and feedingstuffs will be subject to the MRLs set under the proposal. If listed produce is used for any other purposes it will not be subject to any of the MRLs set.

9. Post-harvest Treatments

The proposal requires that for fruit and vegetables an indication should be given if produce has been treated post-harvest with pesticides. The indication should bear the words "treated with" followed by the common or scientific name of the pesticide used. For wholesalers the information should be on the invoices and external packaging and for retailers it must be clearly visible to the consumer. There is also provision for subsuming the labelling and other provisions of certain post-harvest preservatives on fruit currently covered by Directive 74/65/EEC into this proposal. This part of the proposal has tended to attract most discussion which is a pity since it deflects attention away from the proposal's main aims. I do not intend to comment on it further since it has nothing to do with the fixing of MRLs. Suffice it to say that there is disagreement among Member States as to whether this labelling requirement is acceptable in its present form, and at the time of writing there is a strong likelihood that this particular part of the proposal will be withdrawn with the requirement that it be considered for possible coverage in a separate proposal.

COMMUNITY WORK PROGRAMME

Once the framework legislation has been adopted the Commission will present proposals for MRLs to the Standing Committee on Plant Health. Discussions on these proposals will take place at the Standing Committee's Sub-group on Pesticide Residues. The

Commission's work programme is likely to be as follows.

1. Set MRLs on pesticides not yet subject to Community legislation.

2. Set MRLs for potatoes and hops and perhaps the other products coming under Community legislation for the first time (pulses, oilseeds and tea).

3. Review those MRLs already in the 1976 Fruit and Vegetables Directive and transfer as many of these as possible to the new proposal thereby making them mandatory.

4. Review the Cereals and Animal Products Directives and probably make proposals for these to be subject to Standing Committee procedure. The Animal Products Directive will almost certainly be extended to cover eggs and possibly fish. Work is also likely to take place on contact organophosphorus insecticides for cereal storage.

5. Examine the monitoring information received from Member States and draw up Community programmes for monitoring.

6. Start work on establishing Community procedures for sampling and analysis.

The aim is to have Community MRLs for most pesticides used on traded produce by the end of 1992. Some work has already been carried out and proposals for a range of "priority" pesticides could be ready within a month or two of the adoption of the framework proposal. These pesticides are likely to include some of the pyrethroids, the dicarboximides, the benzimidazoles, the dithiocarbamates, chlorpyrifos ethyl and methyl, acephate and methamidiphos. None of these pesticides is yet covered by Community legislation. A second list of priority pesticides is currently being drawn up and MRLs for these could be agreed during 1991.

THE SETTING OF COMMUNITY MRLs

The Commission has very limited resources available to collect data and examine MRL proposals and relies heavily on Member States to do the bulk of the work for them. Also the Commission are only able to hold a limited number of full meetings of the Sub-group on Pesticide Residues. Expenses, especially for simultaneous translation, are considerable. Generally the full Group are unlikely to meet more than six times a year. Detailed consideration can, however, be given to MRLs by small ad hoc groups of five people from the Sub-group being appointed to look at each pesticide. The likely plan is that two rapporteurs will be appointed, one to do the initial evaluation and the second for commenting on the work. The two reports would then be examined by the ad hoc group and reported to the main Sub-group on Pesticide Residues. Once the Sub-group have commented the Commission will make proposals for the Standing

Committee on Plant Health. Under this system all Member States would be given the opportunity to submit information to the Commission and the rapporteurs of their good agricultural practice (GAP) and on any trial data they may have. Likewise, manufacturers would be asked to submit a full residue dossier.

A problem that has occurred in the past is that Community MRLs have been set on a somewhat ad hoc basis. The process is likely to become more formal and more scientific in the future. Information will have to be provided in much the same way as it is to the FAO/WHO Joint Meeting on Pesticide Residues. Patterns of use will be required as well as trials data and information on crop variety, rates of application, pre-harvest intervals and residues will all be required. Information will also be needed on the effects of washing, cooking and processing and any transfer of the pesticide into beverages or processed products. Details of metabolites will be required too. Information will be needed on analytical methods, results of monitoring and existing Codex and national MRLs. Although this seems a formidable amount of information to collect together, there will be many instances where much of it is readily available through information submitted to national registration authorities and the JMPR.

The general idea is to consider all uses of a pesticide together. There may be some exceptions to this eg for hops and potatoes where there is an urgent need for Community MRLs. Where there is no known use or inadequate data for a particular crop, the MRL will be set at the limit of determination. However, where a pesticide is currently being used, there would be a danger that agricultural producers could be denied valuable plant protection uses while new residues trials are being carried out. It is likely that the Commission will defer setting MRLs for three to four years for any products where data are inadequate provided there are no toxicological problems and trials are either underway or an undertaking is given to carry out the work.

Trials studies, of course, can be expensive and, clearly, it would be unreasonable to expect detailed studies on every individual crop. There may be a certain amount of flexibility to extrapolate data for one crop to another where the crops are very similar (eg peaches to apricots and nectarines, and carrots to parsnips). The Sub-group on pesticide Residues is currently drawing up guidelines on the extrapolation of data which should not be too different to those currently used by the UK when granting registrations.

MRLs must be set giving due regard to the toxicology of the pesticides, and little useful progress can be made in setting MRLs until an Acceptable Daily Intake is known. Where a pesticide is reassessed and its ADI changes then MRLs may also have to be reassessed. Likewise, existing MRLs may have to be reassessed if the use of a pesticide is extended. The Sub-group can get advice on toxicological problems from the Scientific Committee on Pesticides. Whereas the Sub-group is made up of officials representing their departments or registration authorities, the SCP is made up of

individuals invited to serve by the Commission because of their own professional knowledge and expertise in a subject. The SCP can be asked by the Commission to investigate any matter concerning pesticides but the Committee has a large number of toxicologists serving on it and is particularly suitable for investigating safety problems.

In the future there is also likely to be an important relationship between the EC Pesticide Residues legislation and the proposed pesticide Registration Directive. The Registration Directive seeks to establish an EC approved list of pesticide active ingredients and is fully described in the BCPC monograph No. 44. In order to appear on the approved list a safety level must be established for the pesticide active ingredient which involves setting an ADI. The intention of the Commission is to discuss proposals for MRLs in the Sub-group on pesticide residues as soon as the pesticide is entered on the approved list. Since the use of pesticides are likely to be extended at various stages after approval and since pesticides will have to be reviewed from time to time then MRLs set in Community legislation will also have to change. That is why it is essential that a rapid system of setting and amending MRLs must be established by the Community.

Much of the Commission's methodology on evaluating pesticide residues is very similar to our own UK approach which is set out in our pesticide residue - technical policy paper and is contained in an appendix to the 1990 annual report of the Advisory Committee on Pesticides.

RELATIONSHIPS WITH COUNTRIES OUTSIDE THE COMMUNITY

Community MRLs will apply to imports from third countries as well as Community produce. There has been a tendency in the past to discuss MRLs only taking account of European Community data. Now that all new MRLs are to be mandatory and with many new pesticides and crops being covered by MRLs, then it is essential that agricultural practices of third countries are taken into account when discussing MRLs and these are consulted at an early stage and given the opportunity to comment on proposals and provide trial data.

The FAO and WHO Codex Committee on Pesticide Residues is the main means whereby all countries discuss data and agree international MRLs for pesticides, and it is through Codex that the European Community can best keep in touch with their trading partners. Member States of the Community attend the CCPR meeting in their right and, in addition, the European Commission also attends. The CCPR is now in its 23rd year and has set or proposed MRLs for over 130 pesticides. The technical work on both toxicology and residue evaluations is carried out by the Joint Meeting on Pesticide Residues (JMPR) who publish their reports and evaluations each year.

There has been some debate about whether the European Community should be setting MRLs when there are readily available Codex

standards to follow. It seems very likely from the Commission's comments at the 1990 CCPR meeting that the Community, on some occasions at least, will be setting lower MRLs than Codex. However there are often good reasons for the Community taking such action. First of all, some products may in the main, only be traded within the Community. There is little point in taking account of agricultural practices in countries who do not trade with us. Secondly, the Community does in some cases possess more up to date information than would have been considered by Codex especially for pesticides that have not been reviewed by the JMPR recently. Thirdly, it has to be borne in mind that very few of the major trading countries accept all the Codex standards and many have their own MRL legislation. The Community likewise may have good reasons for departing from Codex standards.

There is no point in the European Community re-inventing the wheel and repeating all the work carried out by the JMPR. The starting point in any European Community assessment of pesticide residues will always be the Codex standards and JMPR evaluations where these are available and in some cases, especially where the JMPR work is recent, little else need be done. Where the European Commission does decide to make proposals different from existing Codex standards, clear explanations must be given to our trading partners explaining why the Community find it necessary to set a different level.

Member States of the European Community are precluded from accepting Codex standards. This has contributed to the decline in Codex acceptances in recent years. Until recently the Community itself was also unable to accept Codex standards since the Codex rules did not allow trading blocks to accept standards. In 1989 Codex altered their rules and the European Community in turn have drawn up proposals for a directive which will allow them fully to accept Codex standards in the future. This should increase the number of Codex acceptances and strengthen the work of the CCPR and JMPR.

Differences in the approach to the assessment of pesticides in various countries of the world have received considerable publicity over the last two years. Much comment has been made over the different scientific approaches used. However, quite often it is differences in legislation rather than a different scientific approach that leads national registration authorities to take different courses of action on pesticides. These problems have been particularly apparent in the United States. Two things are essential for the future. First, there must be far more regular meetings on pesticide issues with the Commission representatives and US officials so that we understand one another's problems better. There are signs that this is happening and one good thing that may come out of the recent procymidone in wine problem is that it has led to the Commission and EPA/FDA officials talking to one another. Secondly, it is essential that the European Community can react quickly to any pesticide crisis that may hit us from time to time. Again matters seem to be improving and the Scientific Committee on Pesticides were

very quick to examine and report on the daminozide problem. But once again the need to legislate quickly is also needed and this will soon be possible.

The considerable advantages to our trading partners,especially the developing countries, of the Commission's new proposals should not be overlooked. On many occasions at CCPR meetings, developing countries have said that they are less concerned about what MRLs are actually set, within reason, but more concerned that there is not a greater uniformity of MRLs throughout the world. At the moment most Community Member States set their own MRLs and these vary considerably. By harmonising these MRLs the Community will be helping growers in third countries and, in particular, those in the developing countries.

5. CONCLUSION

The new Commission proposals for pesticide residues have tended to be somewhat overshadowed by the more publicised and highly complicated pesticide Registration Directive. However the residues proposal is also very important and has considerable work implications for the Member States of the Community. As yet the full implications of the proposal are little understood. We badly need the proposal to be adopted so that preparatory work that has already been done by the Sub-group on Pesticide Residues can be used to set new MRLs on a wide range of important pesticides. Apart from the need to harmonise MRL legislation in the context of 1992 and the need to have a Community system of MRLs that will facilitate trade with third countries, a greater coverage of MRLs at Community level may go some way towards giving greater assurances to consumer groups and the public at large that pesticide usage is adequately controlled and that their food is safe to eat.

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IMPACT OF EC LEGISLATION ON THE DEVELOPMENT OF BIOTECHNOLOGY IN AGRICULTURE

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ABSTRACT

It is argued that Europe is in danger of missing a major opportunity because it does not have a coherent framework for the regulation of biotechnology. The planned introduction into the environment of genetically modified organisms has reopened the debate on the regulation of biotechnology. European countries and the European Community are wrestling with a problem complicated by the introduction of concepts such as environmental harm, whether the technique or the organism should be regulated and the relationship to existing legislation. To obtain the benefits of agricultural biotechnology for Europe we need to develop a system of risk assessment which characterises types of releases into degrees of concern, clearly defines and assigns regulatory responsibility, regulates products on the basis of their inherent characteristics and does not apply economic criteria for product marketing authorisation.

INTRODUCTION

At the 1986 BCPC conference Dr K Heusler presented a paper "Biotechnology: Regulating the Unknown" in which he discussed the challenge facing society in regulating this "new" science. On the one hand biotechnology offers clear benefits for our society while on the other hand it is seen by some as a journey into an unknown full of imaginary dangers. As Heusler said this has always been the case. The man who drew a map of the world several hundred years ago wrote in areas of terra incognita in bold letters: HERE ARE THE DRAGONS.

There is little doubt that biotechnology is the next driving force in agricultural research. In this paper we review the developing regulatory situation in Europe and examine where there are still areas of terra incognita.

BACKGROUND

European experience with the regulation of recombinant DNA (rDNA) technology, certainly in the 1970's and early 1980"s, has been analogous to that in the USA with many countries setting up "Recombinant DNA Advisory Committees" and working to the guidelines issued by the US National Institutes of Health or equivalents to these. Examples are France, Netherlands, West Germany, Sweden, Ireland and the UK. Most of these countries set up non-mandatory notification and review systems to oversee laboratory-based research work involving recombinants.

The European Community accepted in 1982 a Recommendation on the regulation of DNA activity. So the pattern was clear at this stage of predominantly laboratory-based work with national advisory committees, generally non-mandatory notification requirements and guidelines. As experience gathered and none of the conjectured hazards materialised these committees and supporting agencies relaxed their guidelines again; this also happened in the USA. Most countries then moved into a relatively quiet period until the mid 1980's.

PLANNED INTRODUCTION

It is axiomatic that for many products in the agricultural sector to reach the market they will have to be released into the environment during their development stage. Planned introduction or use in the environment of recombinant organisms reopened the debate on the regulation of genetically modified organisms. This debate has many complicating features compared to the initial discussions in the 1970's and 1980's.

Initially many European countries added a mechanism for reviewing planned introductions to their existing advisory committee structures. But this is not straight forward because:

- Whereas before the focus was primarily on human health, it is now also about environmental harm and this is by no means such a clear concept. This has often been part of a general review of environmental legislation e.g., the Green Bill in the UK.

- It is widely recognised that it is the nature of the organism not the technique of genetic modification that matters. This has meant that many agencies are struggling not to focus on rDNA and are therefore wrestling with issues of definition.

- There is, in some European countries, intense publicity, public interest and political involvement. Also pressure groups e.g., environmentalists, consumers, animal rights and farming lobbies are taking a keen interest.

- Several different government departments and regulatory agencies are involved because of environmental issues and the fact that the so called "new biotech" is nearer the market place. This in turn has led to product legislation review.

OECD

An OECD Ad-Hoc Group of National Experts on Safety and Regulations in Biotechnology was set up in 1983. The Group's main task was to identify scientific criteria for the safe use of rDNA organisms in industry, agriculture and the environment.

Underlying the specific recommendations in the subsequent report (OECD, 1986) were the following fundamental points:

- Any **risks** raised by rDNA organisms are expected to be of the **same nature** as those associated with conventional organisms. Such risks may, furthermore, be assessed in generally the same way as non rDNA organisms.

- Although rDNA techniques may result in organisms with a combination of traits not observed in nature, rDNA techniques will often have inherently **greater predictability** compared to conventional methods of modifying organisms.

- There is no **scientific basis to justify specific** legislation for rDNA organisms - although the report recommended an examination of existing oversight mechanisms to ensure that adequate control may be achieved.

The principal recommendation in the report for environmental and agricultural applications was that the final establishment of internationally agreed safety criteria was at that time premature. A provisional approach was recommended incorporating independent case-by-case review of such proposals prior to application. The report gave the factors that should be taken into account during risk assessment.

The **underlying points** for planned introduction were:

- **Considerable data** on environmental and human health effects of living organisms exist and should be used to guide risk assessments.

- Developments should be encouraged in a **stepwise** fashion Lab --> growth chamber/greenhouse --> limited field testing --> large scale.

The emphasis is on a **careful approach**, learning as experience accumulates.

The OECD report also makes the point that "case-by-case" "...is not intended to imply that every case will require review by a national or other authority since various classes or proposals may be excluded".

A draft OECD report is now being circulated which examines the development of the scientific basis for a concept to be known as "Good Development Practice". This attempts to develop further risk assessment ability and to begin to rank concerns over particular releases, in this case by suggesting the features that allow small scale field trials of low or negligible risk to be identified.

Since the 1986 report several European countries have used its recommendations and conclusions in framing national guidelines and approaches to regulation. Examples are UK, Denmark, Netherlands and France, while others are considering the report's implementation. The European Commission has also made use of the report in proposed directives. An important point is that the report has been able to influence the way regulations are applied, irrespective of the "severity" of those regulations.

EUROPEAN COMMISSION

The Commission are confronting us with a series of confusing and often conflicting draft directives (TABLE 1) which are in danger of vastly over regulating biotechnology and inhibiting its development in Europe.

One Directive (Council Directive, 1990) deserves a closer examination because of the way it is affecting other legislation:-

A COUNCIL DIRECTIVE ON THE DELIBERATE RELEASE OF GENETICALLY MODIFIED ORGANISMS TO THE ENVIRONMENT

This directive provides for a case-by-case notification and endorsement procedure by a competent national authority. A distinction is made between the procedures for introductions carried out as part of research and development activity, and introductions involving finished products. In the latter case, the endorsement procedure involves consultation with the Commission and other Member States as well as national authority endorsement. The product section of the directive does not apply to organisms already covered by certain Community product legislation, but only if these contain risk assessment similar to that envisaged in the Deliberate Release Directive.

TABLE 1. **EEC REGULATORY INITIATIVES ON BIOTECHNOLOGY**

	COMMISSION	COUNCIL	PARLIAMENT
DG's III/XI: Contained Use	Adopted		
DG XI: Deliberate Release	Adopted		
DG VI: Pesticides	X*		
DG III: New Foods	X (Drafting)		
DG V: Protection of Workers	X	X	X
DG III: Intellectual Property Protection	X	X	X
DG VI: Plant Breeders Rights	X		
DG VI: Marketing Transgenic Animals	X (Drafting)		
DG III: Food Labelling	X (Drafting)		
DG III: Harmonisation Food Additives	X (Drafting)		
DG VI: Productivity	X (Drafting)		

* X = Stage reached

Our concerns with the Deliberate Release Directive can be summarised as follows:

- **The Directive will involve duplication of both Testing and Data Review Processes for products.**

Under the directive's product approval requirements, there is considerable overlap with existing product approval mechanisms and, therefore, duplication in generation of product test data. There is also a burdensome requirement for triple review of notification at national, Member States and Commission level.

This will lead to increase in uncertainty for product approvals and, therefore, increased cost of product development.

- **The Directive takes a type of Technology as its scope irrespective of the nature of the Product.**

There should be no technology-specific "horizontal" Community rules at the stage of product regulation. The correct approach is to determine the category into which any product of biotechnology falls for regulatory purposes (e.g., pesticide, food, pharmaceutical), and to apply those sectorial rules on a non-discriminatory basis. As it stands, the directive will seriously distort product legislation. The same type of product may as a result be dealt with under different rules simply because of the techniques used and not because of any safety criteria.

- **The Directive will adversely affect Competitiveness and Jobs**

The Directive proposals, rather than providing a clear and positive climate for biotechnology in the Community, serve to create confusion and discouragement.

In our view, the Commission and Member States have missed a major opportunity to put in place a coherent framework for the regulation of biotechnology. Rather than establish or review existing general legislation to ensure that the new techniques of biotechnology can be dealt with, these directives impose a major legislative burden for industry and academia on certain types of technique. The consequences of this become acute when considering that the scope of the deliberate release directive extends to marketable products. In the European Community we are as a result in danger of:-

developing different regulations for rDNA biopesticides than for other biopesticides,

different requirements for foods containing rDNA micro-organisms than for foods with micro-organisms modified in less precise ways

different rules for rDNA live vaccines than for other live vaccines.

This is a direct result of focusing on techniques as a trigger for regulation. In commercial terms, it leads to dual approval systems or discrimination against the newer products of biotechnology and fragmentation of the regulatory picture. In turn this involves increased cost and regulatory uncertainty, both of which threaten investment, benefits and jobs. This also has upstream consequences for research and development in academia. The consequences of not having a coherent policy for biotechnological competitiveness in Europe have been pointed out by the industry (SAGB, 1990a, b)

THE WAY FORWARD

We see a variety of positions in Europe - some more restrictive than others. The EC directive will of course impose a case-by-case review system on the 12 Community countries.

But what lies beyond the literal case-by-case approach? There will be a rapidly increasing number of field trials (now over 200 world-wide, with about 80 within Europe). This experience plus the outcome of risk assessment research and information exchange activities will enable us to develop **systems of risk assessment** such that we **characterise** types of releases into degrees of concern.

For planned release in particular - the need is to move off the baseline of just having a comprehensive list of points to consider (as in the 1986 OECD report) to a position where we can think about each release within a consistent framework that allows us to discriminate better between releases of minimal concern and those of greater concern. In other words, a system of ranking to increase our ability to predict effects, categorise releases, increase the speed and confidence of reviews and hence to assist in learning which is an all important part of the process. This type of development has clear parallels to rDNA regulatory developments in the 1970's, where ability to assess risk in a systematic way and accumulation of experience allowed greater discrimination over what experiments required detailed prior review.

Several important scientific reports point us in this direction. For example, the US Office of Technology Assessment (OTA, 1988) report on planned release states:-

- "Adequate pre-release safety review of planned introductions is now possible, even though some scientific uncertainties remain that will be resolvable only with practical experience".

- "None of the small scale field-tests proposed or probable within the next several years are likely to result in an environmental problem that would be widespread or difficult to control".

- "In many cases realistic small-scale field tests are likely to be the only way potential risks from commercial scale uses of genetically engineered organisms can be evaluated".

- "Because the critical issues differ with application, a flexible review process, founded in critical scientific evaluation and adaptable to the requirements of particular cases, can serve industry and the public interest well without being unduly burdensome".

And finally, and most importantly for regulation,

- "It should be possible now, or become possible in the near future, to sort planned introductions into broad categories for which low, medium, or high levels of review are appropriate".

A similar message is to be found in the recent reports by the National Research Council (NRC, 1989) and the Ecological Society of America (Tiedje, 1989) .

THE SENIOR ADVISORY GROUP ON BIOTECHNOLOGY

Against the background of an increasingly confused regulatory picture, industry is expressing its concern. 1989 saw the establishment of a Senior Advisory Group on Biotechnology (SAGB) under the umbrella of the European Chemical Industry Federation (CEFIC).

The SAGB provides a senior industrial forum for debating policy issues affecting biotechnology in the European Community. Its purpose is to promote a supportive climate for biotechnology in Europe. The founding members of SAGB are: Feruzzi Group, Hoechst AG, ICI PLC, Monsanto Europe S.A., Rhone-Poulenc, Sandoz Ltd. and Unilever PLC. Each of these companies is represented at board level on the SAGB.

The SAGB has set out its agenda in a series of reports (SAGB 1990a,b,c), which express a number of requirements that are essential if Europe is to become competitive in the use of biotechnology and thus to benefit in terms of products, jobs and investment, while at the same time protecting both man and the environment.

On regulations the SAGB makes a number of points:

CLEARLY DEFINE AND ASSIGN REGULATORY RESPONSIBILITY - Given the variety of overlapping regulatory initiatives taking shape, there is an urgent need for co-ordination and the development of a policy framework for regulations. There must also be a mechanism for the oversight of such a policy.

APPLY EXISTING, NON DISCRIMINATORY APPROACHES FOR SAFETY IN RESEARCH AND INDUSTRIES PROCESSES - The tendency within the European Commission is to focus on certain biotechnological techniques as regulatory triggers. This is not scientifically justified as techniques themselves are not indicators of safety or risk. The correct approach is to accommodate new technology within existing general legislative frameworks coupled as necessary with specific and detailed guidelines. These in turn can be adjusted and modified with experience. Good European examples of this were France and the UK, particularly in the research phases of rDNA technology.

REGULATE PRODUCTS ON THE BASIS OF THEIR INHERENT CHARACTERISTICS AND INTENDED USE - This is essential if we are not to distort the way products are regulated before reaching the market.

DO NOT APPLY ECONOMIC CRITERIA FOR PRODUCT MARKETING AUTHORISATION - A further worrying trend is the introduction of the so called "fourth hurdle" into market authorisation legislation. So far marketing authorisation has been based quite properly on the criteria of quality, safety and efficacy. The products of biotechnology, as with other new developments, such as information technology, will have social and economic consequences. But it is not the role of the regulatory authority to consider these when judging a product's safety and quality prior to marketing. Questions of social impact and "market need" for products must be judged separately by other political processes and by the market place.

CONCLUSION

It is our hope that at future conferences there will not be the need for another paper concerned with the regulation of Biotechnology, terra incognita and debates about dragons. Instead, it is hoped, we will be seeing a regulatory climate that is clearer, co-ordinated between the various Commission services and which gives a sense of confidence for industry, academia and the public. We can then expect Europe to harness the benefits of biotechnology on a par with the other major trading blocs, USA and Japan.

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