# SESSION 9D

# REGULATORY ISSUES: CURRENT PROBLEMS AND SOLUTIONS

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Poster Papers 9D-1 to 9D-3

# A DECISION-MAKING SCHEME FOR MANAGING THE RISK OF DAMAGE TO SUCCEEDING CROPS FROM CARRY-OVER OF PESTICIDE RESIDUES IN SOIL

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## ABSTRACT

The introduction of highly active herbicides, such as the sulfonylureas, not only led to improved weed control but also to a greater threat to sensitive following crops. A number of methods can be used to investigate the threat posed to following crops by a new herbicide. The paper proposes a decision making scheme to be used to judge the extent of testing required and the most suitable methods to use. It is the result of the work of the Efficacy Evaluation Panels of the European and Mediterranean Plant Protection Organisation (EPPO). A formal EPPO Guideline in this area will be produced at a later date. The decision-making scheme also suggests ways in which any risks to following crops identified can be managed by appropriate label warnings, such as on the intervals needed before a sensitive succeeding crop can be planted.

## INTRODUCTION

With the use of soil-acting pesticide materials there has always been a possibility that these materials might persist at levels in the soil which might cause damage when the succeeding crop is planted. The introduction of materials such as the sulfonylurea herbicides, which are active in soil at very low doses, highlighted this risk. Agrochemical companies producing these products had to develop ways to examine whether the effects were likely and their magnitude. Those who advise on the use of pesticides or research into their properties also became involved and a number of methods were developed for these purposes.

### The regulatory requirement

It is a requirement of many regulatory schemes that evidence of efficacy must be submitted to support registration of pesticides. Efficacy evidence weighs up the positive benefits of pesticide application against negative aspects, including damage to following crops. Within Europe an example of this can be seen with the harmonised controls over plant protection products, which have begun under Directive 91/414/EEC, the 'Authorisations Directive' (Anon. 1991). For product authorisation in a Member State, Commission Directive 93/71/EEC (Anon. 1993) specifies the efficacy data that are required to support authorisation of a plant protection product. In order to identify 'Impacts on succeeding crops' the latter Directive states that 'Sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops'. This means that the data submitted and the trials methods used must be acceptable to the appropriate registration authorities.

European and Mediterranean Plant Protection Organisation's (EPPO) involvement

EPPO is an intergovernmental organisation which publishes papers on all aspects of plant protection. As part of its work it produces guidelines on the biological evaluation of pesticides, these can be used for general research and development, or in the production of data to be submitted as part of a registration dossier. Their status is confirmed under the efficacy requirements of the 'Authorisations Directive' where EPPO guidelines are stated to be the acceptable standard to follow when conducting efficacy trials (Anon. 1993). The guidelines are often based on existing guidelines produced by member states. With succeeding crops a number of guidelines were available so the Efficacy Evaluation Panels drew up a guideline using common methods and it was agreed across its membership.

The guideline is intended not only to give information on the design of a particular trial but is also intended as a step-wise guide to the different types of examination that can be carried out. It also takes into account information from trials and tests conducted for other purposes, such as information on the soil persistence of the active substance. A decision-making scheme was drawn up to help agrochemical companies and other parties researching in the area to decide on the methods to follow. This paper describes the decision making part of the scheme. Detailed information on the conduct of trials will be given in the guideline to be published by EPPO.

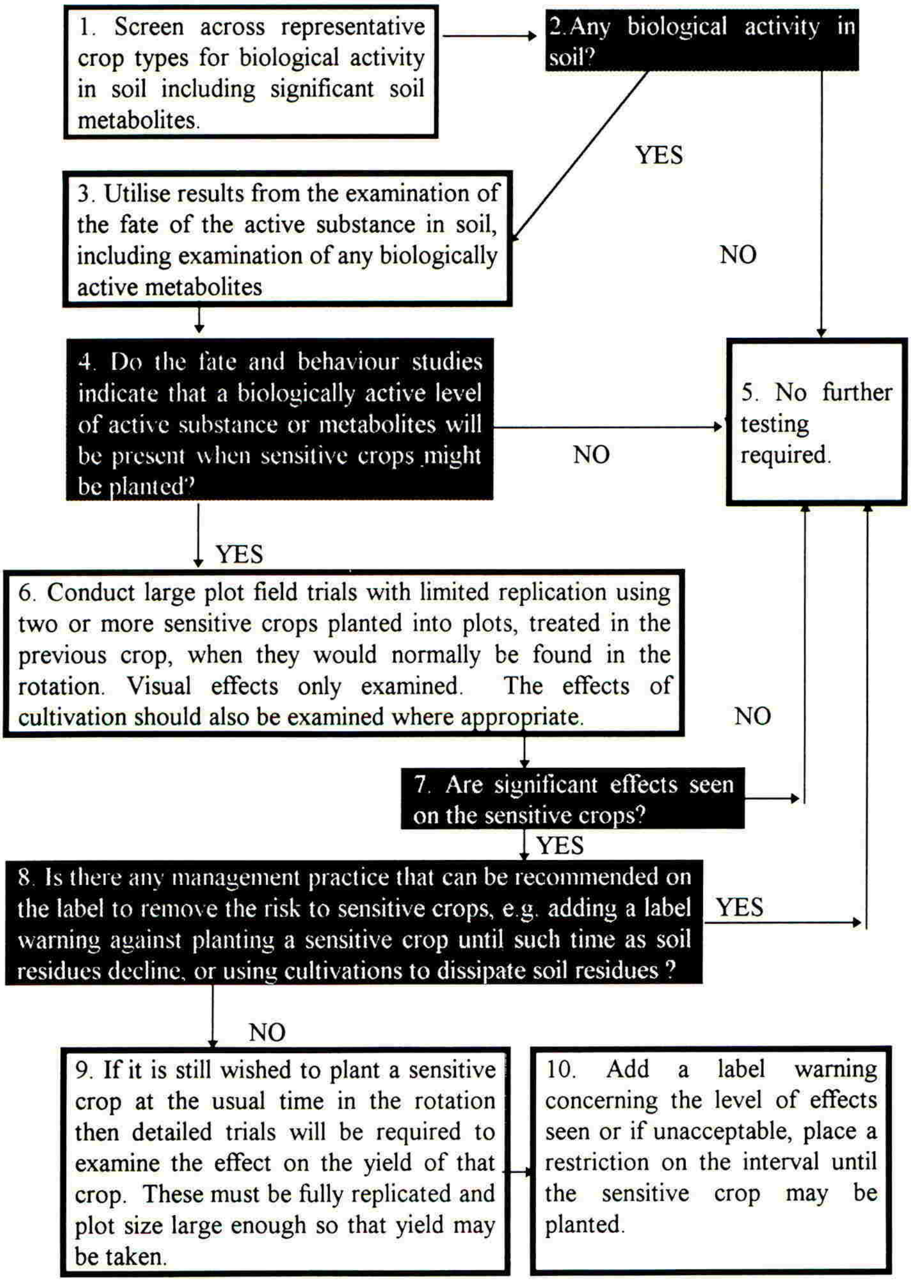
## INVESTIGATION OF THE PROPERTIES OF THE ACTIVE SUBSTANCE

It can be seen from the decision-making scheme (Figure 1) that the investigation of the properties of the active ingredient is the first step. This is important as it may show that in many cases no further tests are required, where further testing is required the guideline will help in the planning process. Normally, only the active substance is considered, with a representative formulation being used in tests. If product formulation, such as granular or slow-release formulations, may affect the rate of dissipation of the active substance in the soil, then these formulations will need to be tested. The active substances that normally pose the highest risk to following crops are herbicides, but these methods should be followed for all pesticide types to demonstrate whether effects can occur. Two main aspects must be investigated.

### Studies on fate and behaviour of the active substance in soil

The persistence and biological availability of the active substance in soil must be examined in a specifically designed set of trials, the conduct of which is outside the scope of this guideline. Information on these studies is given in the EPPO Decision-Making Scheme for the Environmental Risk Assessment of Plant Protection Products - Chapter 3, Soil (Anon. 1993). The dissipation of the active substance in a range of soil types and conditions relevant to use in the field must be determined in these trials. If an active substance breaks down to form metabolites that are persistent in soil, then these should be included in the screening for biological activity.

Figure 1. A decision making scheme for deciding on the extent of testing needed to examine effects on succeeding crops and for dealing with the results.



Biological activity of the active substance

A test on representative rotational crop types should be made to examine if there is any effect on germination in, and growth through, soil containing the active substance. Even if the active substance is normally only effective via the foliage of plants, screening must still take place as some uptake from the soil may occur. A range of representative, relevant, crop species are tested in either, or both, glass-house or field conditions. They are planted into soil or growing medium into which a range of doses of active substance have been incorporated. The doses tested should be selected to represent the target dose to be applied to the treated crop and, when necessary, a range of decreasing doses in order to determine the dose that gives no significant effects on the most sensitive plant species tested. If an active substance is likely to accumulate in the soil, an appropriate higher dose of the active substance should be screened for activity.

## DECIDING ON THE NEED FOR TESTING

The results of soil behaviour tests and screens of biological activity must be taken together to see if the active substance poses a risk to succeeding crops. The nature of succeeding crops and the likely interval between application and planting of these crops must be considered. If the active substance has no activity against plants in soil at the highest doses screened, then field trials are unnecessary. Where the active substance has soil activity, the dose likely to be present in the soil at the time a sensitive succeeding crop will be planted, must be compared to the dose which will significantly affect that crop. This will depend on the persistence of the active substance and the sensitivity of possible succeeding crops.

If it is likely that damaging levels of the active substance will be present in the soil when a sensitive crop will be planted, then field testing will be necessary to examine the extent of effects. All likely succeeding crops should be considered, not only those that are planted the soonest after harvest, as very sensitive crops planted some time after normal harvest may be at greater risk.

If tests indicate that the active substance degrades to form metabolites that are themselves persistent and testing indicates that these metabolites have biological activity against plants in soil, then the same decisions are required on the need for field testing. This means that, if active levels of metabolites will be present in soil when sensitive plants will be planted, then field trials must be conducted.

## DESIGN OF FIELD TRIALS

In the first instance it is suggested that large plot trials are conducted. In these a range of sensitive crops are planted into land which where the previous crop was treated with the active substance under investigation. Plot size should be at least $40m^2$ and can be with limited replication. If it could influence the carry-over of the active substance, and is likely to occur under local conditions, different cultivations can be applied to different parts of the plots. Trials should be conducted over two seasons with the active substance being applied at the recommended dose and, if relevant, particularly for herbicides and plant growth regulators, at double dose. If there is a suitable reference product with similar properties this can also be applied, primarily to determine if conditions were conducive to the carry-over of the active substance. In these trials only visual effects are assessed on the crops planted. Conditions under which the trials are conducted, such as soil type, time of application and time of planting of the crop should be those which are expected to pose the greatest risk to succeeding crops.

If required, further replicated, smaller plot trials can be conducted, with plots at least $12m^2$, in which the effect on yield of sensitive crops is examined as well as visual effects.

Other additional types of trial

There are other types of trials that can be conducted to provide additional information. If effectiveness and crop safety trials can be marked out until the succeeding crop is sown or planted then assessments can be made of any effects seen on the succeeding crop.

Soil cores can be removed from trial plots and examined using chemical or bioassay methods to determine the presence of residues in the soil. This can be done at times when a succeeding crop was not planted, to determine if damaging levels were present at that time. Alternatively, tests can be done when crops were planted so that the levels detected can be compared to the level of damage seen. This means that predicted levels of the active substance in soil in other situations can be better correlated with expected levels of damage.

A further type of trial is the incorporation of predicted levels of active ingredients into the soil of larger plots and planting sensitive crops to assess the effects on yield of these active substance levels. This removes the problems of conducting trials over two or more years, but may not provide a true picture of effects, as metabolites may not be at the levels normally seen in a succeeding crop situation. However all three types of trials can provide useful extra information.

## MANAGING THE RISKS IDENTIFIED

If effects are seen on succeeding crops a number of courses of action are possible. It may be possible to state that these crops should not be planted for an interval after use of the active substance. Evidence may need to be sought to demonstrate that the interval recommended is sufficient so that unacceptable effects are no longer seen. It may be possible to warn against planting a sensitive crop in certain conditions, such as soil types where dissipation of the active substance is slower, or following periods of dry weather. If soil residues can be dissipated by cultivation it may be possible to state on the product label that these cultivations must be conducted prior to planting or sowing a sensitive succeeding crop. To develop these management practices the evidence must be provided from a range of trials to support the advice to be given.

It may be that after carrying out large plot trials with limited replication it is predicted that some visual effects will occur but the significance of the damage may not be known. An agrochemical company may still wish to recommend the planting of a sensitive crop in this situation. This is where small plot replicated trials taken to yield will help determine the practice required. These can be in a true following crop situation and also in the alternative type of trial using known levels of active substance incorporated into soil, as described earlier.

If it is found that unacceptable effects on yield occur then an interval between application and planting these crops may still need to be recommended. Where unacceptable effects on yield are not seen then the label may be amended to warn that any visual effects seen do not produce a reduction in yield. It may also be possible to warn that under certain conditions unacceptable yield affects are likely to be seen.

## CONCLUSION

The methods suggested are intended to build up the knowledge of the properties of an active substance, starting with both biological and physical and chemical properties. This information is used to determine the extent of work required, if indeed it is needed at all, and then to plan further tests. Where effects are seen in succeeding crops, then a management strategy can be drawn up. This may include recommendations on the intervals before sensitive crops may be planted and possibly using cultivations to dissipate soil residues. This is to ensure that unacceptable effects will not be seen in succeeding crops following application of the active substance.

## ACKNOWLEDGEMENTS

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# REDUCTION OF EXPOSURE TO PESTICIDES WITH PROTECTIVE CLOTHING: IMPLICATIONS TO RISK ASSESSMENT FOR REGISTRATION PURPOSES

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## ABSTRACT

Risk assessment for registration purposes is aimed at the evaluation of both exposure to and hazard of an active substance. As a tier in this process, reduction of potential dermal exposure resulting from protective clothing is considered. Registration authorities may use default reduction factors (ranging from 0.01 to 0.25) for the reduction of potential and actual dermal exposure. The results of a field study on the efficiency of (protective) clothing for the reduction of exposure to the insecticide propoxur indicates less reduction of internal exposure than would be expected from a reduction of the external (dermal) exposure. A more conservative default reduction factor of 0.4 for each layer of clothing is proposed.

## INTRODUCTION

Risk assessment for registration purposes is aimed at the evaluation of exposure to an active substance and evaluation of its hazardous properties. In the first tier of this process, potential exposure has to be assessed or estimated by predictive models (van Hemmen & Brouwer, 1997). Potential exposure is determined by factors that determine the source strength of emission of the pesticide, *e.g.* application method, dosage and application rates, and other factors that influence the transmission of the pesticide to the worker, *e.g.* environmental conditions, engineering controls (cabs). Secondly, the reduction of the potential exposure to actual exposure has to be estimated. Actual dermal exposure, *i.e.* the amount of active substance coming into contact with the skin and the fraction transferring through protective and work clothing or via seams to the underlying skin, is determined by the distribution of potential exposure over the body related to covered and uncovered skin (clothing modality), and the rate of penetration or permeation of the active substance through clothing. Since the process of transfer of a contaminant through impermeable protective clothing is limited to permeation, generally this will result in increased reduction of transfer compared to penetration through permeable textiles. Finally, the amount of active substance present on the skin and can be absorbed by the body has to be estimated. Skin absorption is influenced by the physico-chemical properties of the compound, concentration, and vehiculum. In addition, work and environmental factors also influence dermal uptake, *e.g.* blood flow, skin temperature and skin moisture. Various predictive models have been developed in North America and Europe. Recently, the EUROPOEM expert group reviewed the underlying data supporting these models and have proposed generic surrogate potential exposure values for different methods of application (EUROPOEM, 1997). For skin penetration no theoretical reasons exist to establish generic data. However, without knowledge on the dermal absorption of a pesticide 'worst case' assumptions are often used, ranging from 10 % to 100 % (van Hemmen & Brouwer, 1997). Default values for the protective capacity of normal work clothing and of specially designed protective clothing have been derived from laboratory or field studies. The results of laboratory studies indicate a high reduction of actual skin exposure. However, for the purpose of risk assessment the overall effectiveness of protective measures should be based on the reduction of the absorbed amount under field conditions. In this paper the results of a field study aimed at determining exposure reduction of protective clothing by biological monitoring will be discussed in view of these default values.

## MATERIALS AND METHODS

The study was conducted in nine commercial greenhouses for the cultivation of carnations in the Greenhouse district of Zuid Holland in the Netherlands. The absorbed dose of propoxur was determined for applicators (n=9) and harvesters (n=18) using biological monitoring in two trials. In the first trial, workers wore their normal working clothes, followed by a trial where the same workers wore additional protective clothing. The minimum period between the two trials was 5 days. Work clothing was defined as the clothing which was normally worn by the workers. For the applicators this was jeans with a long sleeved shirt and for re-entry workers jeans and a T shirt or short-sleeved shirt. Protective clothing consisted of Tyvek coverall with hood and nitrile rubber gloves, and cotton coveralls and stretch-cotton gloves for applicators and harvesters, respectively. The test substance Undeen®[*1] (active ingredient propoxur 200 g/L) was applied by hand-held high-volume spraying equipment at a minimum dosage rate of 25.g a.i./ 1000 $m^2$ and an application rate of approximately 100 L /1000 $m^2$.

### Dermal exposure assessment

Actual exposure of the hands was assessed for applicators after mixing, loading and application, and for harvesters following re-entry. Workers were asked to wash their hands twice with a hypoallergic soap for 15 s with consecutive rinsing with tap water. During the hand washes the water was collected in a 5 L polyethylene bottle.

### Respiratory exposure assessment

Measurements were carried out using an IOM-sampler. The sampling head was attached to a constant-flow pump operating at 2 L/min, containing two glass fibre filters. One filter operated as a back-up filter to capture any propoxur breaking through from during sampling.
The total respiratory exposure (µg) during the application or harvesting periods was estimated by adjusting the concentration in the breathing zone (µg/$m^3$) to the pulmonary ventilation (1.9 and 1.25 $m^3$/hr for applicators and harvesters, respectively (Brouwer *et al.*,1997), and multiplying by the duration of the tasks.

### Biological monitoring

The absorbed dose of propoxur was measured by determining the total amount of 2-isopropoxyphenol (IPP) excreted in the urine, and collected over a period of 24 hr from the start of exposure as described in detail in previous studies (Meuling *et al.*, 1991, Brouwer *et al.*, 1993). Kinetics studies with volunteers revealed a one to one relationship between absorbed propoxur and excreted IPP on a mole basis. Pulmonary retention of 40 % was used

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1 Registered Trademark of Bayer AG, Leverkusen, Germany

to calculate the relative contribution of the respiratory exposure to the internal exposure. To estimate the contribution of the dermal exposure, the calculated respiratory portion was subtracted from the total amount of IPP excreted in urine.

Additional observations and measurements

Dislodgeable foliar residue sampling was conducted during re-entry. Skin moisture was assessed in triplicate prior to work and immediately after sampling at five different locations of the skin. Measurements were performed using a Corneometer CM820. Skin moisture was expressed in arbitrary units (AU) representing the electrical capacity of the skin.

Chemical analyses

The handwash solution was analyzed by a HPLC system with a fluorescence spectrometer. The limit of quantification (LOQ) for hand rinsing liquid was 20 µg/L at an injection volume of 20 µL. 2-Isopropoxyphenol was determined using gas chromatography and mass-selective detection as described by Leenheers *et al.*, (1992).

RESULTS

Comparison of determinants of exposure for both exposure scenarios

Applications were performed at an average dosage rate of 36.8 g a.i./ 1000 $m^2$ and an average application rate of 113.5 L/1000 $m^2$. The treated area ranged from 1000 to 5100 $m^2$ and the period of mixing/loading/application ranged from 12 to 77 min. Mixing and loading represented less than 10% of the total working period. For none of the application variables were significant differences observed between the two exposure scenarios. For dislodgeable foliar residues no significant differences were observed between the exposure scenarios.

Dermal exposure

Actual exposure was significantly lower during the use of protective gloves. Median level of propoxur observed in the wash water after mixing/loading and application without protective gloves was 348 µg, whereas 16, was the median for the scenario with protective gloves The relative contribution of mixing and loading decreased substantially in the situation where protective gloves were worn. After harvesting the figures were 164, and 8 µg, respectively. Reduction of external exposure of the hands is expressed as 100 % - (exposure protective clothing/ exposure working clothing)* 100 %. Median efficiency of gloves in field practices was 95 % and 87 % for applicators and harvesters, respectively.

Respiratory exposure

Respiratory exposure to propoxur showed no significant differences for exposure scenarios with and without protective clothing. The estimated mean contribution of the respiratory exposure to the IPP-excretion was about 4 %.

IPP excretion

IPP excretion while wearing normal work clothes ranged from 128 to 1505 nmol and from 83 to 2189 nmol for applicators and harvesters, respectively. The amount of IPP excreted after working in protective clothing was significantly reduced to 70 - 926 nmol and 16 - 917 nmol for applicators and harvesters, respectively. Median reduction of the internal exposure was 42 % and 38 % (reduction factor of approximately 0.4), respectively.

Skin moisture

Skin moisture ranged from 45 to 147 AU (arbitrary units) for different parts of the body. For the applicators all body parts, except the palm of the hands, revealed higher skin moisture during application with protective clothing. Similar results were observed for the harvesters. In this case only the back of the hands showed no significant increase of skin moisture during harvesting with protective clothing.

Relation between external exposure, skin moisture and internal dose

The differences between the two trials were examined for IPP excretion, propoxur contamination of the hands and skin moisture as independent variables. For applicators this resulted in a significant contribution of hand contamination to the model ($p= 0.03$, $R^2=0.4$). Addition of the skin moisture variable resulted in considerable increase of the $R^2$ (up to 0.8), although without a significant contribution of the independent variables.

## DISCUSSION

Conclusions on the reduction of external exposure by protective clothing in the present study can only be given for exposure of the hands, *i.e.* comparison of actual exposure of the hands with and without gloves. Median protecive efficiency of gloves in field practice, *i.e.* 95 % and 87 % for applicators and harvesters respectively, fit well with other investigators (Brouwer *et al.*, 1997). Prior to the present study, whole body monitoring was performed in a feasibility study to determine within-worker variances of exposure, distribution of potential exposure and degree of penetration through cotton clothing. For applicators potential exposure of the hands was approximately 15% of the total exposure, about 60 % was located at the legs. For harvesters approximately 25 % of the exposure was located at the torso and another 25 % at the hands. Median penetration was 9.5 % and 6.6 % for applicators and harvesters, respectively. In the present study a good correlation is observed between hand-wash data and IPP excretion for harvesters without protective clothing ($R^2=0.87$), but this correlation decreased in the situation where protective clothes including cotton gloveswere worn ($R^2=0.25$). These observations indicate a relative increase in the contribution of percutaneous absorption of other exposed skin areas to IPP excretion. The same holds for applicators. However, it can be argued that a linear relationship exists between external dose and absorption, *i.e.* a fixed percentage of absorption which forms the underlying assumption of the linear regression analyses.
The discrepancy between the observed 'overall' efficiency of protective clothing (based on the reduction of the absorbed amount) indicates that the use of percentage reduction may well oversimplify the processes of reduction, especially for dermal exposure and absorption. Bos *et al.* (1996) stated that the both dermal dose ($D_A$ = mass per uni skin area) and the exposed surface area ($A$) are determinants of dermal absorption. Two approaches were offered to describe the process of absorption. Firstly, a generally accepted approach of percentage

absorption. Percentage absorption is considered to be a compound-specific but dose-independent value. In the second approach the absorption rate is limited by a compound-specific maximum flux $J_{max}$. In this approach $D_A$ affects the elapsed time to reach the maximum flux (lag-time). In addition (micro) environmental factors, *e.g.* skin temperature and moisture will affect the level of $J_{max}$ for different parts of the body. The consequences of the latter approach for the evaluation of reduction of skin contamination would be that the effectiveness for reduction of dermal absorption depends on the level of $J_{max}$ . In cases where $J_{max}$ is high, reduction of the actual skin exposure might be reflected proportionally in decreased dermal uptake, whereas if $J_{max}$ was low, reduction of the actual skin exposure would only decrease the lag-time, but possibly and not very substantially the overall skin absorption. Moreover, if the reduction of actual exposure, for instance by protective clothing, affects the level of $J_{max}$ the overall effect of this reduction might be reversed, however, the area exposed *(A)* where $J_{max}$ is reached, might be decreased. Fick's first law of diffusion implies a maximum flux, so a further increase in the dermal area dose will not result in a higher rate of uptake (Bos *et al.*, 1996). The actual hand exposure of the applicators is largely influenced by mixing and loading activities which form only a small part of total exposure period (approximately 5%). The lag-time necessary to reach a steady-state flux, although not known for propoxur, may exceed the short period of exposure during mixing/loading. In addition, the steady-state absorption flux is influenced by several conditions such as temperature and skin moisture. In a recent volunteer study by Meuling *et al.*, 1997, the increase of IPP excretion was associated with an increase of skin moisture contents over a similar range as observed in the present study. The results of the regression analyses presented an association between the difference of skin moisture, due to protective clothing and the differences between IPP excretion between the clothing modalities. Observations in the present study support the hypothesis that the change of skin variables under the conditions of protective clothing result in an enhancement of dermal uptake. Actual dermal exposure may be reduced by protective clothing, but the resulting dermal area dose will be absorbed more extensively. Table 1 gives default values for dermal protection that may be used by several national authorities for registration purposes. (van Hemmen & Brouwer, 1997). Beelen *et al.*, (1995) have thoroughly reviewed the published literature to evaluate the effectiveness of clothing in reducing exposure to pesticides for different exposure scenarios, *i.e.*

Table 1 Default values of reduction coefficients for exposure to pesticides using protective clothing (van Hemmen & Brouwer, 1997)

| Protective clothing | Germany | UK | California | EUROPOEM |
|---|---|---|---|---|
| Protective gloves | 0.01 | | 0.1 | 0.1 |
| application | | 0.1 | | |
| mixing/loading | | 0.01-0.1 | | |
| Normal clothing | | Variable | | 0.5 |
| application | | | 0.1 | |
| re-entry | | | 0.25 | |
| Coverall | 0.05 | | 0.1 | 0.1 |
| Protective clothing | 0 | | 0.05 | |

mixing/loading, application and re-entry. Briefly, they observed that most studies have focussed on the ability of fabrics or devices (gloves, clothing) to prevent penetration or permeation into or through the material and relatively few studies have been performed to evaluate the reduction of actual exposure under field conditions. Most of the latter studies drew conclusions on the effectiveness of exposure reduction by comparing 'potential' exposure (exterior clothing or pads) with 'actual' exposure (interior pads or underwear). Since the characterization of exposure, *e.g.* distribution of dermal exposure over the body and droplet size distribution, may determine the effectiveness of exposure reduction under actual conditions, the authors concluded that effective exposure reduction can not be considered to be a inherent property of the material or device. However, since for most scenarios exposure characteristics are lacking they proposed defaults to estimate resulting actual exposure from the transmission of contaminants through clothing (non-fabric specific) and protective devices, *e.g.* chemical resistant coveralls and gloves. They proposed a default reduction factor for one layer of 0.4 for workers wearing a one- or a two layer work clothing modality, and a default reduction factor of 0.15 for chemical resistant gloves.

In conclusion, it can be stated that for risk evaluation of pesticide exposure for registration purposes it is necessary to generate reliable estimates of the actual exposure and the distribution over the body. If no data on actual exposure are available or can be generated, generic exposure level estimates can be used as a first tier. To estimate actual dermal exposure of workers data on the 'normal' work clothing are needed or different clothing modalities can be taken into consideration. For clothing the default reduction factor of 0.4 (Beelen *et al.*, 1995) for each layer seems useful as a first estimate. The results of the present study, based on the reduction of internal exposure, support this approach.

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# COMPETITION AND ENVIRONMENTAL REGULATION IN THE US MARKET

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## ABSTRACT

The US regulatory regime for herbicides and other pesticides is an intricate set of requirements that attempt to balance many competing interests. This balancing is apparent in the process for obtaining "me-too" pesticide registrations, which allow manufacturers of generic pesticides to enter the US market while still protecting the ownership interests of the original registrants. A me-too registration applicant can choose the selective method of support or the cite-all approach in applying for a me-too registration. A me-too registration applicant must offer to compensate the owners of the data on which the application relies. The parties may reach agreement on data compensation through negotiation, or they may embark on binding arbitration. Applicants using the selective method of support may face petitions filed by the primary registrants asking the US Environmental Protection Agency (EPA) to deny the applications. An applicant may also be required to provide additional safety data, which can sometimes be satisfied by becoming a member of a data-development task force. With the me-too registration process, EPA balances the goals of protecting human health and the environment, promoting competition in the pesticide market, and encouraging the development of new pesticide products and data to support them.

## INTRODUCTION

The federal government agency primarily responsible for ensuring that the manufacture, sale, and use of pesticides in the US are conducted with proper regard for human health and the environment is the US Environmental Protection Agency (EPA). Statutory law, implementing regulations, policy documents, and case law combine to define this regulatory program, making it extremely complex, especially to a newcomer to the US market. This complexity, however, is surmountable, and newcomers have entered the US pesticide market with great success.

US environmental regulation of pesticides attempts to balance many competing interests. It promotes the development of new pesticides, in part by protecting ownership interests in data on these pesticides, while also facilitating a market for generic products, in part by allowing generic manufacturers to rely on data others developed regarding the product. It balances the need to protect public health and the environment with the economic benefits of effective pesticides.

One of the newest US environmental laws, the Food Quality Protection Act, signed into law in August 1996, illustrates how the US Congress addresses these competing interests in pesticide regulation. Among other things, the new law places heightened emphasis on the need to protect the sensitive sub-population of children from the health risks posed by pesticides and gives EPA the explicit authority to consider the benefits of a pesticide in establishing tolerance levels, *i.e.*, the amount of the pesticide that may remain on food. Another important development regarding the protection of human health is the law's emphasis on "cumulative risk" or the overall health risk posed by several agents that have a similar health effect.

In reconciling the many compelling and competing interests, the pesticide regulatory program has become increasingly complicated over the history of its development. This complexity itself is a major obstacle to both the introduction of new pesticide products to the US market and the entrance of newcomers to existing US pesticide markets. This paper examines a specific example of how the US regulatory system balances the need to protect human health and the environment with the desire to promote economic competition: the "me-too" registration process.

## THE "ME-TOO" REGISTRATION PROCESS

### Application process

In order to market a pesticide in the US, one must obtain authorization in the form of a pesticide registration from EPA. EPA will not grant a registration unless it has adequate data on the pesticide's characteristics and potential effects. Consequently, the databases supporting pesticide registrations can be very large and diverse. They can include physical and chemical characteristic data, residue chemistry data, environmental fate data, animal toxicity studies (acute, subchronic, chronic, teratogencity, reproduction, mutagenicity, and metabolic studies), re-entry protection studies, spray drift evaluations, nontarget organism data, and product performance data.

There are two options for providing the necessary data for a pesticide registration. First, the manufacturer can generate the data, a process that easily could take five or more years and millions of dollars. A manufacturer of any new pesticide must go through this lengthy and expensive process to obtain the initial registration for the product.

If a generic manufacturer wishes to register a molecule that is already registered, it has a second option as well. If the existing pesticide registration is older than ten years and there are no patent constraints, the manufacturer can simply generate appropriate product chemistry data and indicate that the applied-for registration will rely on the data supporting the existing registration. A registration obtained by this second route, citing data that support another registration for the same pesticide, is known as a "me-too" registration.

It is difficult to predict how long it takes EPA to grant a me-too registration. The timing depends on the complexity of the application, the data supporting the application, and the availability and experience of the EPA staff assigned to review the application. EPA recently processed and granted a technical-grade me-too application in ten months. Prospective applicants, however, generally should expect the application period to last somewhat longer.

### Data-citation options

A me-too registration applicant has two options for citing safety data that has already been submitted to EPA: the selective method or the cite-all method. With the selective method, the applicant provides EPA with a matrix of the data requirements that must be fulfilled in order to obtain a registration for that pesticide. The applicant then identifies the specific studies it is citing to meet those requirements.

The cite-all approach is simpler. The applicant simply informs EPA that it is relying on data supporting the existing registration for the pesticide. The applicant need not identify specific requirements or studies that fulfill these requirements. Generally, EPA can process cite-all applications in significantly less time than it processes selective-citation applications.

Data compensation for existing studies

Whether a me-too applicant opts for the selective method or the cite-all approach, the applicant must agree to compensate the owners of the data upon which the registration application relies. Data compensation can be a major component of a generic registrant's start-up costs. Depending upon the pesticide, these costs can amount to millions of dollars. It is important to note, however, that during data compensation negotiations or arbitration, EPA will continue to process the registration application. Once EPA issues the registration, the generic manufacturer may begin selling its product in the US, even if the data compensation issue is not yet resolved. Also, a pesticide manufacturer may be able to reduce data compensation costs by entering into a joint venture with another company to share these costs. Possible joint venture partners might be companies that already have established US distribution systems or those that have access to the necessary data.

A me-too registration applicant's compensation commitment extends to the owners of all data that was submitted within fifteen years prior to the me-too registration application. The applicant need not offer to compensate owners of data older than fifteen years. A selective-citation applicant must offer to compensate the owners of each of the individual studies the applicant cites as fulfilling an identified data requirement. A cite-all applicant must offer to compensate all of the entities on EPA's data owners list for that specific pesticide.

Once the relevant data owners receive the applicant's offer to pay, the parties may begin a negotiation process to identify appropriate compensation. The relevant statutes and regulations leave the parties tremendous latitude for determining that compensation. The regulatory scheme simply establishes some broad confines (*e.g.*, data is not compensable if it is older than fifteen years) and establishes procedures for determining the level of compensation.

With the data compensation process, Congress and EPA have attempted to balance competing goals. On the one hand, the pesticide program promotes competition through the development of a generic pesticide market. On the other hand, it encourages the development of new pesticide products by protecting the investment of companies that discover new molecules and generate data to support initial registrations. Thus, the regulatory scheme allows me-too registration applicants to cite data they did not generate, but they must compensate the data owners in order to do so.

Arbitration procedures

The pesticide statute and relevant regulations require that the parties attempt to reach a compensation agreement once the registration application has been filed and an offer to pay has been made. After ninety days, either party may invoke binding arbitration, or the parties may continue trying to reach settlement through negotiation or other means. The pesticide statute charges the Federal Mediation and Conciliation Service with the responsibility for overseeing data compensation arbitrations. This service has in turn delegated much of the responsibility to the American Arbitration Association, which has developed rules that appear in the US Code of Federal Regulations. If the parties embark on binding arbitration, they may use the arbitration rules or they may agree on their own set of arbitration rules. In any case, the arbitrators' decision is binding. The parties may appeal the decision to the courts only on grounds of misconduct by one of the parties or arbitrators.

The arbitrations are private proceedings and the results need not be released publicly. There are no established principles for how to resolve the substantive issues underlying data compensation disputes and previous arbitration decisions need not serve as precedent for subsequent arbitrations. The handful of decisions that have been released publicly are interesting in terms of understanding what issues might be raised and how they might be resolved. They also may be useful in formulating positions. This usefulness is limited, however, because arbitrators need not adopt positions that are consistent with earlier decisions.

For example, in determining how the data compensation costs should be shared, arbitrators have reached different conclusions. One early decision utilized a *per capita* approach by which the arbitrators simply counted the number of registrants for the pesticide in question (in that case two) and then assigned compensation costs based on that number (50%) (Stauffer, 1983). A later decision used a market share approach whereby the arbitrators ordered the me-too registrant to pay compensation that reflected that registrant's market share (Ciba-Geigy, 1994). Arbitrators also have used approaches that blend aspects of the two approaches (American Cyanamid, 1989; DuPont, 1988).

It can take quite a long time to reach a data compensation arbitration decision. In a recent dispute resolved through arbitration, the primary registrant invoked arbitration sixteen months after the generic manufacturer submitted its registration application and seven months after EPA actually granted that application, and the arbitration proceeding itself lasted twenty-one months (Abbott, 1991). In another proceeding, the primary registrant initiated arbitration four years after one generic registrant had received its registration and five and a half years after the second generic registrant had received its registration, and the arbitration lasted thirty-three months (DuPont, 1988).

Petition to deny a selective-citation pesticide registration application

Except for the requirement that the generic registration applicant informs EPA that it has made appropriate compensation offers, EPA will remain uninvolved in the data compensation dispute. Normally, EPA is not even informed of the status of negotiations or arbitration. The pesticide regulations, however, do provide a process for involving EPA, but only with regard to a set of limited questions. The primary registrant can petition EPA to deny the me-too registration application or cancel the registration on the basis that the applicant refuses to comply with (1) the agreed-upon procedures for reaching a settlement, (2) the binding arbitration procedures, (3) the compensation agreement, or (4) the arbitration decision. EPA will resist becoming involved in substantive disputes.

Primary manufacturers recently have objected to me-too registration applications that use the selective method of support by filing with EPA petitions to deny these applications on the grounds that the applicant did not cite all necessary studies. Although to the authors' knowledge EPA has not ruled on such a petition, the availability of this petition process may have the practical effect of making the selective-citation registration process more burdensome.

Data compensation for ongoing or future studies

If EPA determines that there is a gap in the database supporting a registration, EPA often will issue a data call-in (DCI) to fill the gap. An outstanding DCI will not block an applicant from obtaining a me-too registration. EPA still can issue a me-too registration even though the product might be the subject to a DCI. The me-too registrant simply must commit to fulfilling the DCI, just like the other registrant(s) of the product.

For several DCIs, it is common for affected registrants to form task forces designed to generate generic data to satisfy the DCIs. EPA supports the formation of such task forces and, to a limited degree, participates in the development of task force data in order, the Agency says, to avoid unnecessary duplication of data-generation efforts (and consequent increase in the work EPA must perform in evaluating these data). For pesticide manufacturers, task forces may have the additional benefit of minimizing the possibility of generating conflicting data.

A me-too registrant has various options for fulfilling a DCI. The registrant can generate its own data, which can be quite costly and time consuming. Alternatively, if a task force has been formed for the DCI, the me-too registrant can join the task force. As a late-joining member, the registrant will not only have to pay the membership fees and assessments that the original members paid, but also may have to pay interest on those amounts and an additional amount, called a "risk assessment fee," of up to 50% or more of the sum of the membership fees and assessments. (Risk assessment fees encourage early membership in task forces.)

In order to comply with a DCI, the me-too registrant can also invoke a process similar to the data compensation process of a me-too registration; it can cite the work being performed by the task force or primary registrant and commit to negotiating compensation for this reliance. Indeed, most of the publicly available data compensation arbitration decisions involved, in whole or in part, compensation for data generated pursuant to a DCI (Ciba-Geigy, 1994; Abbott, 1991; American Cyanamid, 1989; DuPont, 1988). Because of the possibility of significant transaction fees and the uncertainty regarding the compensation amount, however, a registrant may opt for joining the task force (and paying any necessary late membership fees) rather than entering data compensation negotiations with it.

A final option for gaining access to DCI data being generated by a task force is to reach some kind of teaming arrangement with an existing member of the relevant task force. A pesticide manufacturer might be able to avail itself of task force data without becoming a member by entering into some kind of joint venture with an existing task force member. As noted above, such an arrangement also might allow the manufacturer to reduce the amount it might pay in data compensation for existing studies.

## CONCLUSION

With its me-too regulations, EPA has tried to balance the goals of protecting human health and the environment, promoting competition in the pesticide market, and encouraging the development of new pesticide products and data to support them. In doing so, EPA has created a very complex system. Although EPA will continue to fine tune the balance it has struck, and in doing so undoubtably make the system even more complex, the current system works; generic pesticide manufacturers can and do access the US market, some with great success.

## REFERENCES

Arbitrations are private proceedings. The cases cited below are not reported but have been released publicly by the parties. They can be obtained by contacting the parties or the authors.


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# SESSION 10A

# PRODUCT STEWARDSHIP: PRACTICAL EXAMPLES ON WATER ISSUES

| | |
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| Chairman | DR A COCKBURN<br>*AgrEvo UK Limited, Chesterford Park, UK* |
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| Papers | 10A-1 to 10A-5 |

# STEWARDSHIP OF CROP PROTECTION PRODUCTS - THE EMPTY PROMISE?

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## ABSTRACT

Under the headline "The empty promise - the idea of product stewardship is unlikely ever to work", a Financial Times writer recently challenged the viability of the concept of product stewardship. This paper addresses this challenge as far as the crop protection industry is concerned. Stewardship in the context of this paper is defined as 'the responsible and ethical management of activities, concerning products and processes, from innovation to ultimate use and beyond'. It therefore extends to all stages of the life-cycle of a product, ie R&D, manufacture/formulation, distribution, marketing, use and disposal. As defined, the concept of stewardship covers the traditional area of safety and health of employees and environmental impact from operations (ie SHE) as well as product stewardship, usually associated with activities outside a company's direct control. This holistic approach to the management of product and process related activities befits the nature and use of crop protection products particularly well. Drawing on a number of examples of selected elements of company stewardship programmes it is concluded that stewardship is not 'the empty promise' as far as the crop protection industry is concerned. It does not only help in maintaining the industry's licence to operate, but also makes good business sense by improving the companies' 'bottom line'.

## INTRODUCTION

On 5.6.1996 The Financial Times carried a 'viewpoint' article by Peter Knight, a specialist writer on business and the environment, entitled "The empty promise - the idea of 'product stewardship' is unlikely ever to work" (Knight, 1996). Knight argued that "product stewardship is a wonderful idea, but it is unlikely ever to work. There are three big problems. First, the word "stewardship" oozes the sort of morality that business hates. Second, the idea only half-works in practice. Third, it is all based on empty promises."

Knight's viewpoint derives from looking at product stewardship across industry, but in particular the chemical industry. He welcomes the reader to "the wacky world of 'product stewardship' where manufacturers promise to take full responsibility for their products from start to finish, but fall far short of their goal". He concludes that "companies will never be able to fulfil their stewardship responsibilities when there are no police - whether real people or fully-primed markets that demand accountability. Until then, product stewardship will be about empty promises".

Knight provides a hard-hitting and uncompromising viewpoint. It constitutes a challenge to the crop protection industry which in the form of the FAO Code of Conduct on the Distribution and Use of Pesticides (Anon, 1986) as well as in related Industry and Company Guidelines has embraced the principle or concept of stewardship. Is 'stewardship' in the crop protection industry all based on empty promises? Or is it well-founded and integrated into the business? Does it make business sense?

## DEFINITION OF THE CONCEPT OF STEWARDSHIP

The concept of stewardship is not an invention of recent years or decades. It is already described in the Bible in the parable of the dishonest steward who was dismissed by his master for not taking sufficient care of the master's estate. The word stewardship comes from the Greek word *oikonomos*, 'a superior house slave of tried character who looked after the house-hold accounts'. The steward was the slave who had all the qualities necessary to enable him to be elevated to a position of trust. He never owned anything, but had to make sure that everything ran smoothly and all accounts were balanced. (The modern word 'economy' is, of course, derived from this Greek origin indicating that stewardship should make business sense.)

Nowadays the word 'stewardship' or 'product stewardship' is used in a variety of ways with sometimes substantially differing meaning - and this may have contributed to Knight's rather negative view of it. For example, the 'Responsible Care' initiative of the chemical industry limits the scope of stewardship more or less to safety, health and environmental aspects of products. In the crop protection industry the scope is usually substantially wider.

ZENECA defines stewardship as the "responsible and ethical management of activities, concerning products and processes, from innovation to ultimate use and beyond". The concept, consequently, extends to all stages of the life-cycle of a product, from R&D through manufacture/formulation, distribution, marketing/sales to use and disposal, and its associated activities.

As defined, the concept of stewardship covers the traditional area of safety and health of employees and environmental impact of manufacturing operations as well as product stewardship, usually associated with activities outside a company's direct control. This holistic approach to the management of product and process related activities befits the nature and use of crop protection products (CPP's) particularly well. For example, choice of appropriate formulation and packaging, including robust and lasting labels are as critical to the safe and effective use of the products as education and training at distributor, retailer, adviser and farmer level; these latter activities usually being more readily associated with stewardship in crop protection than the former.

## APPROACH TO STEWARDSHIP

The concept as described requires a change of approach in manufacturing activities well beyond considerations for the traditional areas of employee health and safety and impact on the immediate environment. It extends, for example, to issues such as labelling, packaging and transport. What does this mean?

A plant manager is not only accountable for the traditional SHE issues, he is also accountable for the product leaving the factory and arriving at its destination in a fit state to do its job. This encompasses having the correct label (type, language etc) fixed to the container in such a way that it will not fall off; having packed the individual product as well as the entire consignment using materials and means that ensure that it reaches its destination without any damage to or deterioration of packaging, product container or label.

Given this accountability, it should be a thing of the past, that re-labelling has to be carried out at the port of destination, because the labels have been "eaten" by mould as a consequence of the failure to think through the problems generated by using wet, animal-based glue to fix the label and immediate packaging, palleting and shrink-wrapping, which create the continuous moist atmosphere required by microorganisms present in the glue to do their devastating work.

The concept of stewardship, therefore requires a proactive rather than reactive approach. It is about managing all activities properly, rather than about correcting mistakes (which, of course, needs also to be done, if the proactive approach has broken down).

The proactive approach helps both the customer and the company. The customer receives the goods as required and the company benefits from not having the expense of taking corrective action. In other words the concept has internal (company) and external (customer) focus.

Those who are familiar with the quality approach to R&D, manufacture and formulation etc, will see a strong association between "quality work" and the concept of stewardship for the activities that are largely under a company's control. The concept of stewardship probably requires even broader thinking and outlook than the quality approach.

The proactive nature of stewardship requires a *"questioning culture"*, in which questions like:

"Is there a better, safer, environmentally more acceptable way of doing this?"
"Are our labelling, packaging and transport and storage adequate in all respects?"
"Are we abiding in our marketing/sales/promotion by accepted standards?"
"Is everything being done as we can reasonably be expected to do it?"
"Are we protecting our licence to operate?"

are common place.

## STEWARDSHIP GUIDELINES

In the concept discussed in this paper, stewardship is a responsibility of all staff:

- The principle of stewardship encompasses a "cradle to grave" philosophy.
- Business conduct, ethics and day to day activities must be beyond reproach.
- All staff have an obligation to ensure that a company's activities derive maximum benefit for society with the least risk to human health, wildlife and the environment.
- A questioning culture must be developed, in which everybody asks: "Is there a better/safer etc way of doing this?".

Ultimately every individual in the organisation is responsible for maintaining the business's licence to operate. Truly effective stewardship depends on leadership. Therefore stewardship principles should form an integral part of job remits and individual staff objectives.

To assist staff with bringing the concept of stewardship to life throughout the organisation ZENECA, for example, has developed a series of "Stewardship Guidelines". These Guidelines are fully compatible with the requirements of the "FAO Code of Conduct on the Distribution and Use of Pesticides" (Anon, 1986). Divided into 18 separate pieces of guidance, they cover all activities along the stewardship continuum from R&D to Disposal: Product Information; Research and Development; Regulatory Affairs; Environmental Issues; Health and Safety; Manufacturing, Formulation and Filling; Packaging; Labels; Transport; Storage; Marketing, Sales and Purchasing; Advertising and Promotion; Product Application and Personal Protective Equipment; Education and Training; Waste Disposal; Emergency Procedures; Public Affairs and Monitoring and Auditing.

The Guidelines are what the original meaning of the word guidelines stands for: they are guidance, not instructions or prescriptions, for staff to carry out their job in accordance with the principles of stewardship.

If stewardship is to work, it is critical that measurements and formal control mechanisms are established and that there is full commitment to these at the highest level in the organisation. Therefore, a system of general auditing on the basis of guidelines such as described above (supported by specialist audits, eg engineering, transport, fire, environmental etc audits) should be operated. This helps to assess the state of compliance with stewardship principles at a given time, in a given place and part of the organisation and provides the basis for corrective action, where appropriate. But more importantly, it provides the information required to develop plans for improvement and prioritise the (limited) resources and allocate them to areas of most need.

## STEWARDSHIP PROGRAMME

The space available does not allow painting a complete picture of stewardship programmes along the chain from invention to use and ultimate disposal. A few examples must suffice. It goes without saying that compliance with legislation is a fundamental principle of stewardship. Thus, the research, studies and dossiers required to obtain product authorisation and registration are not discussed here, although it would be intriguing to elaborate on stewardship in product registration and regulatory affairs. There are examples where good stewardship and registration requirements do not go hand-in-hand; legislation and regulation concerning crop protection registration in the widest sense can be counterproductive to good stewardship, eg over-prescriptive reporting requirements which remove professional, scientific judgement; over-restrictive testing protocols which limit the scope of the applicability of the research; inflexible approach concerning test data, which disregards the individual nature of different chemicals/products. It is also not helpful that similar or virtually identical products appear in the same market with different hazard classification.

### Formulation research and development

In the past, maximum efficacy and ease of use have been the primary aims of formulating an active ingredient into a crop protection product. As a consequence emulsifiable concentrates (ECs), which easily disperse on and penetrate into plants and at the same time readily dilute in the spraying equipment, have enjoyed great popularity. In more recent years, the issues of operator safety and environmental contamination have gained in importance. Thus, today the choice of formulation type and active ingredient concentration within it is very much concerned with balancing efficacy, ease of use, operator safety and environmental considerations at an affordable cost of the crop protection treatment to the farmer.

As a consequence, water based formulations have gained at the expense of solvent based ECs reducing the potential operator risk from dermal penetration. Microencapsulation not only results in considerably reduced operator exposure, it also facilitates a gradual release of the active ingredient in the target crop and allows reduction in the frequency of application. The development of new granular formulations has the potential to replace several sprayings with a single targeted treatment. With both formulation types user and environmental contamination are minimised. This is also true for seed application of systemic insecticides, which in addition spare beneficial insects whilst providing protection against sucking insect pests.

Water dispersible granule formulations packed in small sachets suitable for single filling of a knapsack sprayer nearly eliminate user contact with the product. The high bulk density of these formulations also reduces the amount of packaging material necessary and thereby reduces pack disposal problems. Without going into any detail, it should be noted in this context, that the crop protection industry has developed a container management strategy (Anon, undated), the implementation of which should be a major step forward in dealing successfully with the disposal of empty crop protection product containers.

A further step in reducing operator exposure is the development of water soluble bags suitable for packaging both solid and liquid products. These bags are made from polyvinyl alcohol, which is a biodegradable, non-toxic material, and filled with the formulated product are placed unopened into the spray container. They represent a kind of closed system, eliminating operator exposure and, in particular for wettable powder formulations, also exposure of workers in the formulation plants.

Education and training

Education and training are vital ingredients of stewardship activity along the entire chain from invention through to ultimate disposal. For example, successful training will avoid the consequences of bad packaging, loading and transport already referred to above; it can improve the driving skills of the sales force and reduce numbers of motor vehicle accidents, which nowadays are a greater problem than accidents in manufacture.

ZENECA has long been a leader in the field of user education and training. Experience gained around the world has given considerable insight into the varied requirements of different users of crop protection and public health products, as well as expertise in how to satisfy their needs for information and understanding about safe, effective and appropriate product use.

An education and training service is delivered to customers in agriculture and public health through its national companies around the world and in co-operation with distributor organisations, government agencies and others, tailoring its support to suit local situations in which products are used. It aims to encourage and support improvement to the way in which all CPPs are used. It is committed to covering safe distribution, storage, handling and use of agrochemicals and to promoting the best practices of integrated pest and crop management in agriculture and pest control in public health.

The education and training efforts are based on a training cascade using the train-the-trainer principle. This cascade consists of Stewardship staff training Master Instructors. These in turn train a core of local trainers, who in return train farmers at farmer meetings, special field days or by making use of local "lead farmers". All training is highly participative rather than solely lecture and classroom based.

At present, the education and training programme extends to smallholders, commercial growers, plantations and retailers either directly and in co-operation with distributors, government departments local crop protection associations and so on. The programme also addresses the farmers of the future via school programmes.

Integrated crop and pest management

Sustainable crop protection, including the intelligent use of CPPs needs to be supported by the development and implementation of effective education and training programmes.

Such programmes therefore extend to advancing integrated pest management (IPM) techniques, together with integrated crop management (ICM), and training programmes to promote understanding amongst farmers and growers around the world have been developed. The aim is to encourage them to grow healthy crops by combining good crop management with efficient pest control.

The industry is committed to IPM, as defined by the Food and Agriculture Organisation's International Code of Conduct on the Distribution and Use of Pesticides, as an economically viable and socially acceptable approach to crop protection.

The IPM training programmes include the following main elements:

- Techniques for controlling pests through judicious and timely use of CPP's combined with encouraging the natural predator insects which feed on crop pests;
- Selecting crop varieties which have their own high level of resistance to pests;
- Keeping the crop free of pest host plants and destroy crop residues which harbour pests between vegetation periods;
- Pest scouting (using peg boards) and spraying based on the result of such scouting and at the most appropriate stage of pest development (eg at egg or larval rather than fully developed adult stage).

Operator monitoring studies and health surveys

Operator monitoring studies and health surveys in the context of stewardship are concerned with studying the use of crop protection products as it happens in practice, assessing its potential consequences and, where necessary, deriving improved use recommendations and precautionary measures.

Shortly after the introduction on the Dutch market of 'Shirlan' fungicide (active ingredient fluazinam), which is used for the protection of potatoes and lily bulbs against moulds, reports of skin problems were received by ZENECA both from potato growers and a bulb processing company. The nature of the complaints was investigated (Bruynzeel *et al.*, 1995; Ginkel & Sabapathy, 1995) and so was the actual use both by potato growers and the bulb processors. It transpired that fluazinam could cause allergic reactions and that the actual incidences occurred because the farmers did not protect themselves adequately and the bulb processors were exposed as a result of a use not recommended on the label. A special education and training programme was introduced with particular emphasis on supplying the farmers with detailed information about the hazards of the fungicide. On the basis of the programme, the problem has been managed successfully in The Netherlands and other countries, where fluazinam has been introduced subsequently.

Paraquat-containing herbicides are sold globally under widely differing climatic conditions. In temperate or cooler climates spray operators are generally speaking reasonably well protected from exposure by wearing their normal work clothing during spraying and are also used to wearing special protection when handling the formulation concentrate. In hot climates, however, it is not inconceivable that spray operations are carried out with only a limited amount of protective clothing. Under ZENECA's stewardship programme a number of operator monitoring studies were carried out over the years in countries with hot climates and intensive use of paraquat (Howard *et al*, 1981; Chester & Woollen, 1981; Senanayake *et al*, 1993; Chester *et al*, 1993) in order to assess, if the herbicide can be applied long-term without causing any harm to operators, even if the clothing they wear during spraying falls short of label recommendations. All studies conclude, that long-term spraying of paraquat at the recommended spray concentrations does not produce any adverse health effects under practical conditions of use.

A key element in operator monitoring studies is the element of biological monitoring, ie not only is the skin contamination measured, but also the absorption of the active ingredient through the skin. The absorbed dose is the best means of establishing how effective the spray operator is protected by wearing or not wearing certain elements of protective gear. This is readily exemplified by a study involving the herbicide fluazifop-P-butyl (Chester *et al*, 1990). Thirteen mix-loader-applicators were monitored during a one day application by groundboom tractor sprayer. Both direct (surface) monitoring and biological monitoring (complete urine collection for 11 days) were performed. The results of urine monitoring were interpreted using human pharmacokinetic data. Eight workers complied with the label recommendation for use of protection gloves during mixing and loading and five did not. The study results clearly reflected this difference in protection. The workers without gloves had a substantially higher skin contamination and dermal absorption than those who wore gloves. Hand exposure accounted for over 90% of the exposure to workers not wearing gloves and 60% to those who wore gloves. PVC gloves were effective in reducing exposure and absorption of fluazifop-P-butyl.

<u>Raw-water monitoring study</u>

With participation of UK companies a large raw-water monitoring study was carried out in 1985/86 in Germany under the auspices of the German Crop Protection Association, IPS (now IVA) (Anon, 1987). At the time, the implementation of the EU Directive 80/778/EEC concerning the quality of drinking water and, in particular, its single parameter of 0.1 µg/l for all pesticides was discussed - in Germany and elsewhere in Europe - very emotionally. Virtually no reliable data on pesticide contamination in raw-water (the water used for producing drinking water) was available. The German crop protection industry decided that good stewardship for its products required such data to be generated. An extraordinary large programme was designed to clarify - amongst other questions - at what level of contamination crop protection chemicals are to be expected in the raw-water.

Thirty-five crop protection active ingredients were included in the analytical programme. Repeated sampling over a period of up to 2 years of the same 206 wells in 'vulnerable' areas across the entire agriculturally used land of the 'old' (ie pre-unification) Federal Republic of Germany was carried out. The sampling regime generated more than 12000 samples for analysis from a total of more than 1500 samples. It is not within the scope of this paper to list or discuss the results of this monitoring project. Important in the context of this paper is the fact that as a consequence of the crop protection industry taking stewardship seriously, for the first time reliable and meaningful data (ie showing contamination or lack of it over time) of raw-water/drinking water contamination with crop protection chemicals was generated in Europe, if not world-wide. The study, to this date, remains unique in scope and approach for monitoring of water quality, at least as far as published and publicly available monitoring data are concerned.

The conclusion of the study at the end of 1986 did not signal the end of the industry's concern for contamination of water with its products. On the contrary, it gave the impetus for individual companies in Germany and elsewhere in Europe to set up stewardship programmes in conjunction with farmers, their advisers and the drinking water producers geared towards avoiding ground and raw-water contamination with crop protection chemicals and/or reducing and eliminating contamination where this had already occurred. It is important to note that these programmes were not entered into because of imminent danger to health etc, but were purely precautionary in order to comply with an arbitrary, quasi-zero contamination level, for which there is no toxicologically founded basis. Some examples are given in later papers.

## CONCLUSIONS

Good stewardship is not only responsible and ethical behaviour and management of product and process related activities. It also makes good business sense in the way it is operated in crop protection companies. This becomes readily apparent when considering the theoretical concept of stewardship and the examples given to support this concept.

Good stewardship reduces cost and liabilities. It is not difficult to deduce from the examples of industry's stewardship programmes outlined above that stewardship supports the creation of new markets and helps to maintain current markets for crop protection products. It is therefore a vital ingredient and integral part of business for crop protection companies with a longer term interest in the business.

It can therefore be safely concluded that, contrary to Knight's view, stewardship is not 'the empty promise' as far as the crop protection industry is concerned. Stewardship is not 'unlikely ever to work', it is already working. It will continue to gain in importance both with regard to the public face of the industry and business success. It does not only help in maintaining the industry's licence to operate, but also in improving its 'bottom line'.

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# GLOBAL PRODUCT STEWARDSHIP - WATER QUALITY PROTECTION

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## ABSTRACT

This paper describes efforts underway within Monsanto Company to further reduce the unintended impacts to the water environment from the use of its crop protection products. Examples of these efforts include monitoring and other surveillance activities, investigation and remediation, new farming practices, training, and prevention.

## INTRODUCTION

The ever increasing demands from the general public for clean water combined with the analytical ability to detect lower levels of contamination are resulting in more focus worldwide for better product stewardship. Manufacturers are being asked, and in some cases forced, to play a much more significant role than in the past.

In the groundwater protection area, efforts are focused on remediation of known contamination, monitoring, and prevention of future contamination via changes in product use practices.

In the surface water protection area, efforts are focused on monitoring and encouraging changes in farming practices.

## GROUNDWATER PROTECTION

### At the well

Reports of crop protection products in groundwater have been numerous in the United States for several decades. The perceived causes of such contamination, at the grower, regulatory, and general public level is that the grower has properly mixed, loaded. and applied the product to the field, the product has than leached or otherwise reached groundwater and contaminated the well water that the grower uses for drinking water.

It has been the experience of the author, after 21 years of investigating such incidents for Monsanto's crop protection products, that this scenario is incorrect in the vast majority of cases. Investigating hundreds of such cases by the author has shown that the cause is improper mixing of the product in close proximity to the well combined with improper construction of the well.

Of the contaminated wells investigated, approximately 25% were hand dug; 50% had either a cracked casing or none at all. In the United States, many of the rural drinking water wells were constructed in the late 1800's and early 1900's when no design standards existed. Most of the wells investigated also either did not have an impervious loading/mixing pad or if they did, it was cracked.

Several of the wells were also found to be contaminated due to failure to utilize a back siphoning or check valve. In these incidents, pump failure at the time of mixing/loading caused the spray tank contents to back siphon into the well.

Thus, it is the opinion of this author that the majority of the contamination observed for Monsanto crop protection chemicals has been improper practice. That practice is the mixing and loading of product next to wells that have been improperly constructed and/or which do not have a proper pad or other impervious surface around the well.

Prevention of future contamination at the end user level is thus centered on education. All product labels either now or in the near future will require that no mixing or loading of product be done within 15 metres of a private drinking water well unless the well meets current design standards and includes an impervious pad. The end user is encouraged to do such mixing and loading in the field. In addition, all pumping must include a check valve to prevent back siphoning.

In an attempt to assist growers in the remediaiton of improperly constructed wells, Monsanto instituted a 'Well Assistance Programme' in 1991. The programme provides financial assistance in the correcting of the contamination. Any private rural drinking well found in the United States to contain any Monsanto crop protection product over the safe drinking water standard is eligible for this programme. Corrective actions most often include removal of the old well and construction of a new one but can also include the installation of carbon filtration equipment. It should be noted that in most cases, these wells are also contaminated with human, animal, fertilizer, petroleum, and other wastes. Whatever was mixed, loaded or spilled around such wells is usually also found in the well water.

It should be mentioned that contamination has also been found in wells at retail locations. Dealers have also been found to have mixed and loaded product in the past from improperly constructed wells. In some cases, levels of contamination have been higher due to the mixing and loading of larger quantities of crop chemicals. However, the majority of contamination at dealer locations has been the lack of adequate mixing/loading pads. With the increased use of bulk repackaging by dealers in the U.S., most such facilities now include secondary containment and impervious pads, thus greatly reducing the potential for future contamination.

In the field

Extensive research by a number of government agencies, as well as Monsanto and other manufacturers, has shown that groundwater in some crop growing areas in the United States is vulnerable. Such areas have three vulnerability criteria in common. These criteria are soil texture, organic matter, and depth to ground water. Although other criteria such as geology and/or man-made drainage do apply in some areas, it is the author's opinion that the majority of contamination found in groundwater, even after proper mixing, loading and application, can be traced to various combinations of soil texture, organic matter, and depth to groundwater.

All current crop protection products in the U.S. containing the active ingredient acetochlor, include a soil restriction that contains these three criteria. This action was taken primarily due to cancellation triggers established by the U.S. Environmental Protection Agency (EPA) as part of this product's conditional registration. The soil restriction states that such products cannot be applied to soil texture/organic matter combinations of sand with less than 3% organic matter, loamy sands with less than 2% organic matter and sandy loams with less than 1% organic matter IF depth to groundwater is less than 9 metres.

As part of the stewardship program implemented to assure compliance with this label restriction, the Acetochlor Registration Partnership (ARP) has been doing extensive mapping to determine the locations of these soil texture/organic matter combinations. The procedure involves four increasing levels of resolution. Using corn intensity data (acetochlor in only registered on corn in the U.S.), state maps are first created for each of the three soil texture/organic matter combinations. In level 2 mapping, each of the three level 1 maps are overlaid; this process identified which counties need higher resolution mapping. In level 3, mapping of the selected counties is done to determine the total area potentially impacted by the restriction. In level 4, copyrighted high resolution technology is used to identify specific locations in the county. Level 4 mapping is estimated to be accurate with a 90% probability.

The level 4 maps are than provided to all personnel selling acetochlor products in that county including the company sales representative and the retailer/dealer. These maps do not include depth to groundwater data due to the variability and lack of such data in many states. If the level 4 maps indicate a particular field may meet the restriction, the farmer must determine the depth to groundwater for the field. Such data can be obtained from his/her drinking water well, local records, and other sources.

The ARP has also made all level 4 maps available via the Internet. Since this effort was started in 1994, over 350 individual county maps have been produced and made available.

Although the effort continues, it is estimated that 3-4% of the corn growing area in the U.S. may meet the soil restriction. The vast majority of these areas are in the Southeastern coastal plains of the U.S. where overall county corn intensity is low.

Last, extensive farmer training continues to be an ongoing effort. Such efforts are coordinated with state agencies. Products that have been found in the groundwater are classified as restricted use products by the EPA. Restricted use products require the applicator to be certified by the state to apply such products. Certification is obtained and maintained via annual training on the proper mixing, loading and application of the product as well as disposal of containers and keeping of use rate records.

## SURFACE WATER PROTECTION

There have also been numerous reports of herbicides being in surface waters of the U.S. The vast majority of these reports indicate corn and soybean pre-emergent chemicals are the most often found. These compounds are predominantly applied in the April through May time period in the Midwestern States. It is important to note that the most often found compounds are also the most often used compounds.

Monsanto is currently monitoring for five such compounds as part of the conditional registration of acetochlor. A total of 175 watersheds in 12 states are being monitored for a 5-year period, 1995-1999.

Most studies now indicate that the main cause of such detections in surface water is run off from treated fields. The amount of such run off is directly related to the proximity of the first rain event to the time of application and the intensity and duration of that rain event. In 1995 and 1996, significant rainfall events in the April-June time frame in the Midwestern States resulted in the majority of corn pre-emergent chemical applications occurring either immediately before or after such rain events.

The watersheds found to be most vulnerable are those that are small and have high corn intensity. Such watersheds usually involve a man-made reservoir that serves as the drinking water supply for the nearest communities. Normally, the reservoirs are lowered in the winter months so that in the spring, they can serve as a means of flood control. However, the collection of run-off in the spring also coincides with most applications of pre-emergent herbicides. Such run-off is then usually held throughout the dry months of the summer, rather than released, to assure the local communities have an adequate supply of water.

It is the opinion of the author that the cause of most herbicide run-off is due to farm practices rather than the chemical itself. Although the environmental properties of a given chemical can impact its fate in surface water, by far the major factor is the farm practices employed by the farmer.

Thus, stewardship efforts concentrate on three farm practices ie. application, the use of conservation tillage, and the use of conservation buffer strips.

In application, extensive training efforts focus on proper rates, equipment setup, minimization of drift and product disposal. More recently, efforts have been increased in the area of precision farming utilizing global positioning and variable rate technology, although the adoption of both is currently slow due to costs and data management and interpretation deficiencies.

In the area of conservation tillage, the vast majority of research indicates that the use of such practices reduces run-off, particularly during the spring when the trash left in the field acts to catch run-off and reduce its velocity. A reduction in run-off velocity also reduces sediment and herbicide run-off. However, the use of conservation buffer strips has been the main factor of the author's surface water stewardship efforts. These efforts concentrate on two general areas, demonstration and incentives.

## DEMONSTRATION

Although the U.S. Government has for many years been researching and demonstrating the concept of conservation buffer strips, an area along rivers, streams, drainage ways and ditches where the land is not cropped but planted with grasses and trees, many farmers have still not adopted the practice. There are many reasons for this but the main one seems to be a general mistrust of the government agencies involved. Because of this, the author has focused on private initiatives. The major initiative has been a programme called 'Operation Greenstripe'.

Operation Greenstripe, first began in 1991, and is a programme whose goal is to educate high school students who will be going into agriculture on the use of conservation buffer strips. The number one association for such students in the U.S. is the 'Future Farmers of America' (FFA). The FFA is made up of several thousand high school student chapters in all 50 states. Operation Greenstripe provides financial grants to chapters who agree to find farmers who will agree to plant a conservation buffer strip. Local retailers cooperate, as part of Operation Greenstripe, by providing free seed for the planting of the buffer. The students participate in the planting and the maintenance of the buffers.

Each year, Operation Greenstripe recognizes the top chapters at the annual FFA conference. Financial awards are given for the best chapters in the country.

Since its inception, Operation Greenstripe has worked with over 800 individual student chapters in 16 states. In 1997, the program has been expanded to all 50 states. In 1996, Operation Greenstripe was awarded the National Watershed Award for CF Industries and the Conservation Fund.

## INCENTIVES

The concept of incentives is critical to the future adoption of conservation buffer strips by farmers. In 1997, Monsanto, Cargil, Pioneer, Terra, Farmland, Conagra and Novartis formed the National Conservation Buffer Initiative, a partnership with the U.S. Department of Agriculture whose goal is to plant 2 million miles of conservation buffer strips by the year 2002. The partnership is focused on making sure proper financial incentives are available to farmers to reach this goal.

Via the 'Conservation Reserve Programme', a programme that pays farmers to put highly erodible land in "reserve", payments for land put in buffers are being increased. Sign-up procedures are being streamlined. As important as these changes are in the programme, the partners are focusing on encouraging farmers to sign-up via farm trade associations such as the National Corn Growers Association and the National Association of Farm Cooperatives.

The efforts were announced in May of this year and officially begin on August 1.

## CONCLUSION

Product stewardship aimed at improving and protecting ground and surface water quality is an integral part of Monsanto's agrichemical business. To reach the company's sustainable goals, programs aimed at monitoring, changing and improving current farming practices are essential.

# BEST MANAGEMENT PRACTICES TO REDUCE HEXAZINONE IN GROUNDWATER IN WILD BLUEBERRY FIELDS

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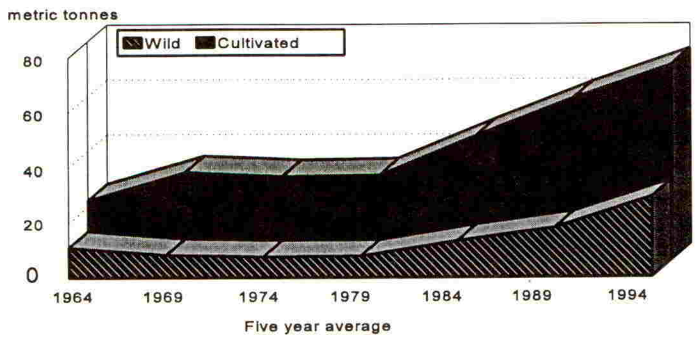
## ABSTRACT

Hexazinone is a pre-emergence herbicide used in wild blueberry fields since 1983, and has been a contributing factor in increasing the wild blueberry production threefold over the past 14 years. This herbicide is also highly soluble and has been detected in the groundwater in Maine. Best management practices have been developed to minimize the leaching of this herbicide into groundwater. Field trials have shown the effectiveness of reducing rates, delaying the timing of application and using a granular formulation in reducing intrusion of hexazinone into the groundwater. An educational program was successful in changing growers practices to mitigate the intrusion of hexazinone in groundwater, which prevented cancellation or restrictions on the use of this herbicide on wild blueberries.

## INTRODUCTION

The use of hexazinone in wild blueberry (*Vaccinium angustifolium*) fields in Maine has increased production (Yarborough & Bhowmik, 1989) by decreasing weed species cover and diversity (Figure 1). With the decrease in weed competition, other inputs, such as fertilizer, bees for pollination and irrigation could be utilized by the blueberry plant and the production increased threefold with only 7% increase in ha. Cultivated blueberry (*V. corymbosum*) production has also increased, but this was accomplished through planting 49% more ha (Moore, 1994). Cultivated blueberries account for 55%, Maine wild blueberries for 22% and Canadian wild blueberries account for 23% of the North American blueberry crop (Holbein, 1995).

Figure 1. Comparison of wild and cultivated blueberry production



Hexazinone has a half-life of 90 days in soil, a solubility of 33,000 mg/liter and a $K_{oc}$ of 54 ml/g (Ahrens, 1994). These are properties which would make this chemical prone to leaching. Because most of the wild blueberry fields are on highly leachable, sandy loam soils, there is concern that it would readily leach from these areas. Hexazinone used on wild blueberry fields is formulated as 'Velpar L', containing 120 g/litre and as a granule, 'Pronone 10G or MG', containing 10% hexazinone (Ahrens, 1994). The liquid may also be applied as a granule by impregnating it on granular fertilizer.

Although most of the hexazinone is decomposed or retained in the upper layers of the soil (Yarborough & Jensen, 1983), detectable levels of hexazinone have been found in the groundwater. In an early survey, Neil *et al.* (1989) found trace amounts of hexazinone in 2 out of 11 test wells sampled between 1985 and 1987, but Gould (1995) found hexazinone at levels of 0.093 to 5.97 ppb in 15 of the 20 sites sampled in 1994. Improvements in the detection technology at the University of Maine has resulted in the minimum detection limit changing from 2.0 to 0.05 ppb, and has increased the ability to detect hexazinone in the environment (Bushway *et al.*, 1996).

In 1994, the public perception of widespread contamination led to a petition to ban the use of hexazinone in the State of Maine. Public pressure was on the Pesticide Board to prohibit or limit the use of hexazinone. However, the low toxicity level (health advisory level 210 ppb) relative to the highest level detected in a test well, 30 ppb, did not justify a ban, but practices would have to be developed that would mitigate the intrusion of hexazinone into the groundwater for its use to be continued. Loss of this herbicide would result in a decline in yield and put the wild blueberry industry at a severe disadvantage relative to the cultivated blueberry.

A proactive approach was taken by the wild blueberry industry in dealing with this challenge. A coalition of wild blueberry growers, university educators and government scientists collaborated to develop a 'Hexazinone Best Management System for Wild Blueberry Fields' (Yarborough, 1995). These practices were then delivered to the wild blueberry growers through a University of Maine Cooperative Extension educational programme consisting of lectures and field demonstrations. Concurrently, research was undertaken to survey well and surface water sites to determine the extent and persistence of hexazinone in groundwater and use these data to test a selected best management practices programme and the effect of formulation on the movement of hexazinone. The Maine Board of Pesticides Control was also under a mandate by the United States Environmental Protection Agency (USEPA) to develop a 'Hexazinone State Management Plan for the Protection of Groundwater'.

## MATERIALS AND METHODS

### Research

Yarborough and Jemison (1994,1995,1996,1997, in press) have surveyed wells to determine if reducing the rate of hexazinone and using a granular formulation reduced the potential intrusion of hexazinone into groundwater. In 1996, wells adjacent to, or in wild blueberry fields were sampled monthly from May through October. Well sites were chosen on the basis of a high probability of finding hexazinone. Fields were grouped by hexazinone treatment: Sites 5, 13, and 23 received the liquid formulation impregnated on diammonium phosphate (DAP) fertilizer; Sites 7, 12, 34, 29, 31, 32, and 33 received the granule fromulation applied in June. Site 9 was not treated. Sites 12, 9 and 11 have been sampled since 1989. Residue analysis of the water was performed at the University of Maine Food Science & Human Nutrition Department with a high pressure liquid chromatograph which has a detection limit of 0.05 ppb.

Education

The 'Hexazinone Best Management System for Wild Blueberry Fields' consists of the following nine major points:

1. Read and follow all directions on the label and labelling.
2. Determine weed species and density, and use the lowest rate of hexazinone needed to suppress weeds and obtain maximum economic yield:

The effect of hexazinone on weeds and blueberries will vary with soil type, texture, and amount and timing of rainfall. Following the blueberry harvest, determine weed species and density, and use weed mapping techniques or log observations on data sheets for future reference. Use guidelines provided by the supplemental label and past experience to determine the lowest rate needed. If, at one to two months after application, you observe blueberry leaf drop throughout the field from the bottom of the stem to the top, your rate is too high. Reduce rates used in future applications. As weeds are controlled, less hexazinone is needed. Weeds not controlled without injury to blueberry plants will need other weed management control strategies.

3. Do not apply hexazinone to frozen or saturated soil.
4. Time application to minimize leaching or run-off:

If possible, hexazinone should not be applied during or just prior to heavy rain because surface run-off or leaching of hexazinone could occur. Apply liquid hexazinone as close to anticipated blueberry emergence as possible, but do not apply liquid after blueberry emergence. Too early an application of hexazinone will result in less weed control and more hexazinone could leach into groundwater. Application of liquid hexazinone after blueberry emergence will cause injury to blueberry plants and is a violation of the supplemental labelling.

It is best to apply liquid hexazinone impregnated on fertilizer or the granular form of hexazinone after blueberry and weed emergence. Do not apply granular formulations if blueberry leaves are wet because of fertilizer burn or uptake of hexazinone by blueberry leaves.

5. Calibrate application equipment.
6. Compare application rate with calibration rate.
7. Use the most accurate placement method of hexazinone available.
8. Modify applications to adjust to site conditions:

Map sensitive areas, such as wetlands, well heads, rock outcroppings, steep slopes, etc. to identify sites that warrant modifications. Maintain 17 m buffer from any wellhead or water reservoir as specified by the supplemental label.

Determine hexazinone usage in the vicinity of a well on a site-specific basis taking into account soil texture, slope depth to bedrock, size of field vegetative cover and type of well.

Do not apply hexazinone over rock outcroppings because they could provide a direct conduit to groundwater.
Use reduced rates on slopes that do not have good blueberry cover.
Use other weed management strategies adjacent to or on portions of a field that slope abruptly toward sensitive areas such as wells, reservoirs or waterways.
When possible, use mowing or light burning to prune blueberries. This promotes organic matter retention and build up, especially on coarse textured soils.

9. Use multiple weed control measures:

Use of hexazinone alone will not provide an adequate weed management programme.
When using low rates of hexazinone, adopt other weed management strategies to maintain good weed control.
If weed pressure is low, consider not applying hexazinone for a production cycle or using spot applications of hexazinone. However, be prepared to use other weed management techniques to prevent heavy weed pressure in the next treatment cycle.
Consider using an alternative pre-emergent herbicide, for a production cycle.
Use mulch in open areas among blueberry clones to reduce weeds and to encourage blueberry spread.
Hand pull or use a string trimmer to cut weeds taller than blueberries before they go to seed. This will reduce weed pressure in the future.
Cut woody weeds to the ground at the end of June, July and August to suppress growth.
If there are large open areas, consider interplanting blueberries and mulching and additional fertilizer to increase blueberry cover. A full cover of blueberry plants will reduce the need for herbicide applications.
If grasses are the major problem, consider post-emergence applications of selective grass herbicides.
To manage weeds taller than blueberries, use a selective wiper application of a non-selective herbicide. For shorter weeds growing among blueberry clones, use a directed spray of a nonselective herbicide.

A fact sheet was developed (Yarborough, 1995), and multiple educational sessions were held in three of the wild blueberry producing areas in Maine. In addition, field calibration sessions, and in-field experiments were conducted to show growers the results of these practices. Emphasis was put on reducing the rate of hexazinone, since research indicated the rate for optimal yield was less than the rate which gave the best weed control (Figure 2), and on using granular formulations (Figure 3), since the slower release resulted in more retention and consequently less leaching (Yarborough & Hess, 1997).

## Regulation

The Maine Board of Pesticides Control formed a 'Hexazinone State Management Plan Advisory Committee' consisting of Board members and staff, wild blueberry growers, university specialists, a soil scientist and geologist, a chemical industry representative, and members of the public. Their mandate was to develop a specific 'Management Plan for the Protection of Groundwater'. This plan then went to public hearing and comment before being submitted to the USEPA.

Figure 2. Effect of hexazinone on blueberry yield

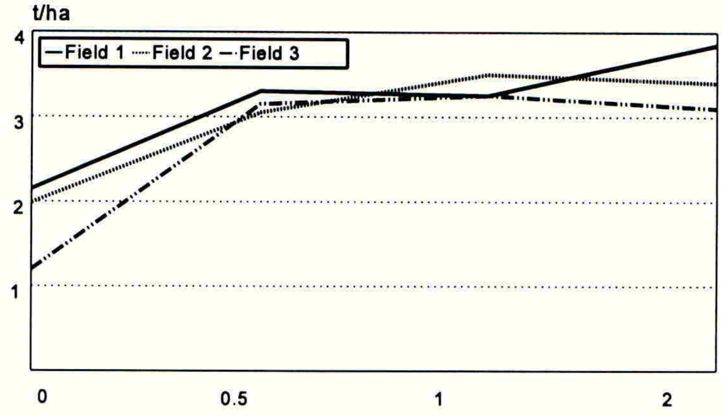
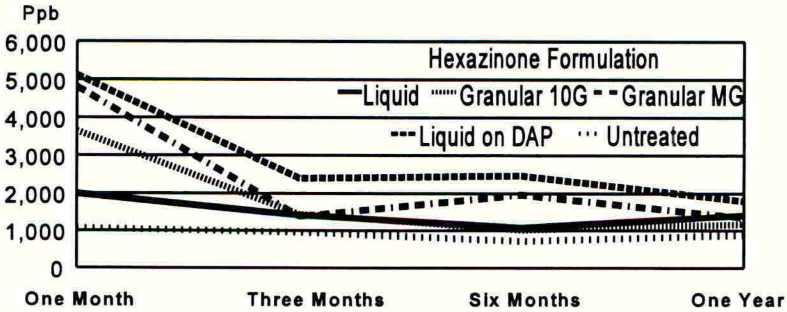



Figure 3. Effect of formulation of hexazinone on retention in the soil at 0-5 cm over time.



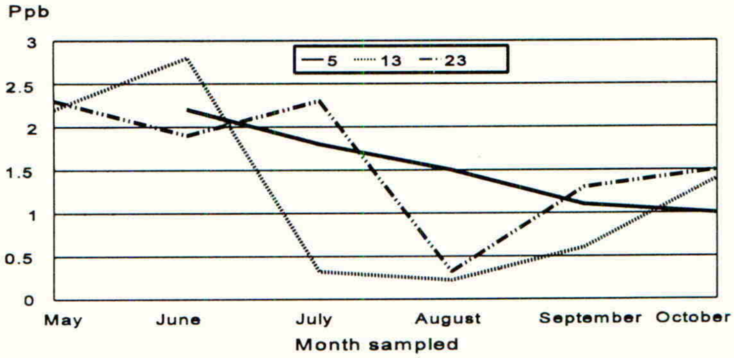

Untreated represents residual hexazinone treatment from the two previous years

## RESULTS AND DISCUSSION

### Research

The wells in fields receiving the liquid formulation impregnated on fertilizer treatement showed a trend of decreasing hexazinone concentration from May through October (Figure 4). On Site 13, the highest level from the drilled well was 8.9 ppb in 1993 after application of 2 kg/ha a.i. of the liquid formulation (Yarborough & Jemison, 1994). The site specific best management practice (BMP) in 1995 was to apply the liquid hexazinone impreganted on fertilizer at 1 kg/ha a.i. with a 17 m well buffer specified by the supplemental label. The hexazinone in the groundwater was 2.1 ppb prior to treatment and 1.8 ppb on the October sample date. Applying hexazinone by the BMP resulted in no increase in the hexazinone groundwater detection.

Figure 4. Hexazinone concentration in well water following application of the liquid formulation impregnated on fertilizer at three sites




Fields treated with the granular formulation showed an increase in hexazinone concentration in wells 7, 12, and 32 and a slight rise in wells 31 and 32 in October (Figure 5). The increases on these sites were the result of two unusual rain events in which the precipitation exceeded 190 mm (Yarborough & Jemison, 1997).

Figure 5. Hexazinone in well water following granular application at seven sites

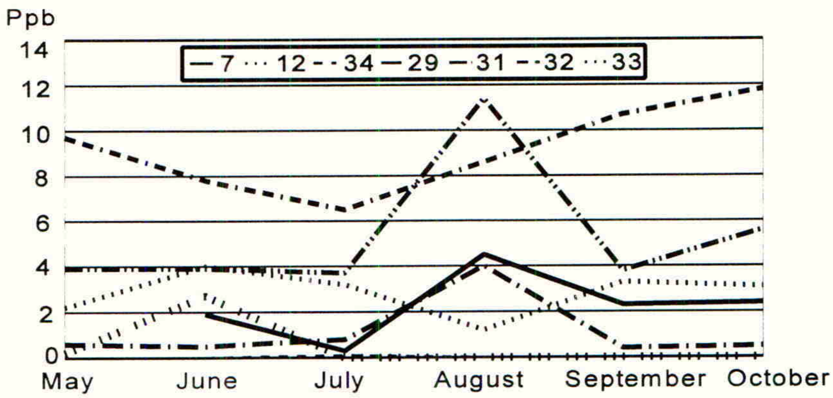
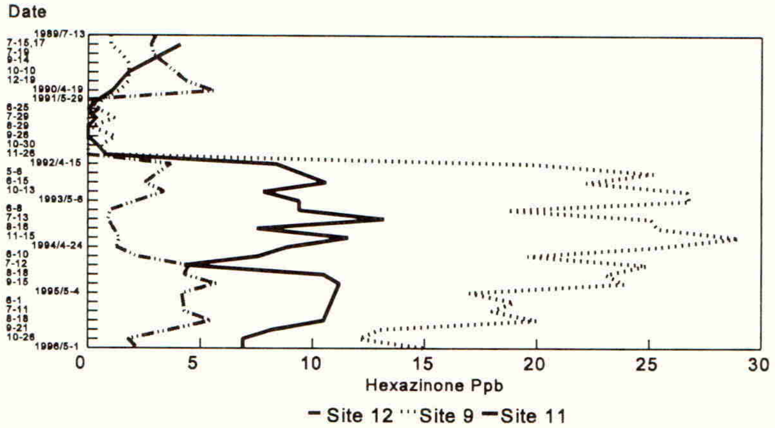



Figure 6 gives a long-term comparison of sites treated with liquid hexazinone (9, and 11). The site with the granular application (12) had lower levels of hexazinone in the groundwater. There will be a need to collect long term data since hexazinone will persist for several years in the groundwater (Figure 6).

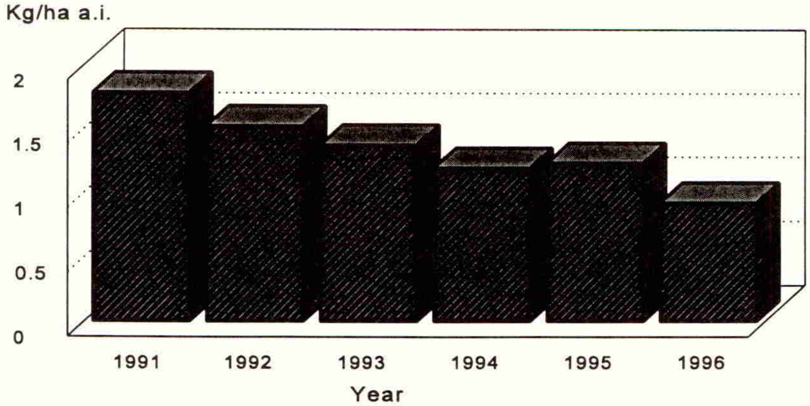
Figure 6. Hexazinone in groundwater from long term test well data 1989-1996 at three sites




## Education

A survey of 8 industry processors representing 46% of the use indicated that the rate of hexazinone decreased by half over five years (Figure 7). A change from liquid to granular applications of hexazinone applied later in the year was also accomplished. The amount of granular hexazinone used went from none in 1993, to 74% of the total a.i. applied in 1996.

Figure 7. Industry survey of hexazinone use




The 'State of Maine Hexazinone State Management Plan for the Protection of Groundwater' (Gould, 1996) adopted the hexazinone BMP's as the preferred practice to apply hexazinone and stressed an educational over a regulatory approach. It also placed some additional requirements on the sales and use of this herbicide. Dealers selling this product were required to have a restricted use license and applicators applying hexazinone were required to have a pesticide license.

## CONCLUSION

Hexazinone is a very soluble herbicide, and if used on sandy loam soils, it has a high potential to leach into groundwater. High levels of precipitation will even result in movement of granular hexazinone. Research and educational efforts are continuing to improve the best management practices which have reduced the intrusion of hexazinone in the groundwater and prevented excess restrictions from being placed on the use of this herbicide.

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# STEWARDING DIURON WITHIN UK AMENITY AREAS

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## ABSTRACT

Stewarding diuron became a critical issue following the revocation of the triazine approvals within the UK amenity use area in the early 1990's. An industry-wide stewardship campaign, with an education programme was launched using the theme of "product placement" and a slogan of "the right product, right place, right time". Bore hole protection schemes and water catchment studies were initiated along with a voluntary revision of all labels for diuron containing products. Levels of diuron in water, as published by the Drinking Water Inspectorate, have fallen during the mid 1990's. Work in managing diuron to ensure the quality of UK water is protected is part of an ongoing programme. Research work has identified the fact that other active ingredients may have an even better fit with use in amenity settings. Chemistry with these characteristics, combined with an appropriate stewardship position, can be used to ensure herbicides can continue in their valuable role in countries around the world.

## INTRODUCTION

Stewardship has been with the UK Agrochemical Industry since its very beginnings. It has always been essential to use each product with due care and attention and this is reflected in the manufacturers instructions. Protection of the environment and operator safety is central to stewardship. Rhône-Poulenc, along with a number of sister multi-nationals has dedicated stewardship professionals within its organisation whose role is that of internal policemen. They direct, influence and audit the performance of the commercial units thereby ensuring the long-term objectives of the company are met. Diuron stewardship offered these professionals and the amenity market a new challenge in the 1990's. The challenge arose with the revocation of the non-crop approvals for triazine containing products.

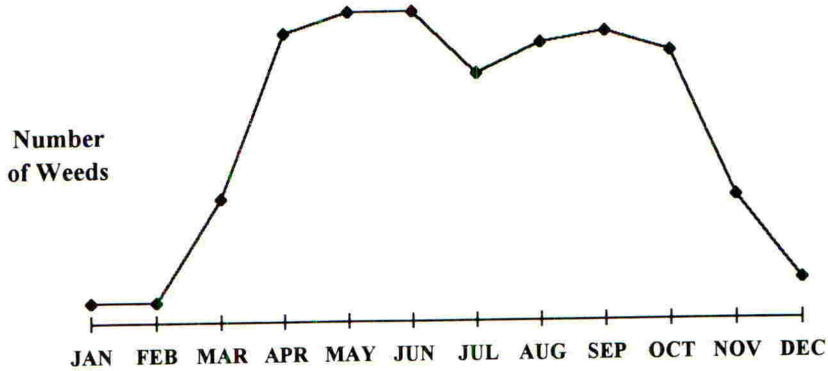
Following its discovery in the late 1950's, diuron had by 1990 found a niche in the UK amenity weed control market as part of a rotation to minimise the build up of herbicide resistance. To meet the EU drinking water directive two triazine active ingredients were removed form the UK amenity market by the UK regulatory body. With their removal diuron became the obvious replacement product. Given the similarities between the triazine group and the urea family in terms of application rates, half lives and KOC it was judged that if the way the products were being used was not changed diuron would, within a matter of months, pose the major herbicide risk to water quality.

## STEWARDSHIP STRATEGY

From the outset of the stewardship campaign it was clear that all companies, the primary manufacturers and also the main amenity marketing companies, had to be involved. Involvement also had to extend to include all of the customers groups that used diuron containing products, from local authorities to railway companies. Water supply companies were central to the approach. Wherever possible all interest groups were involved.

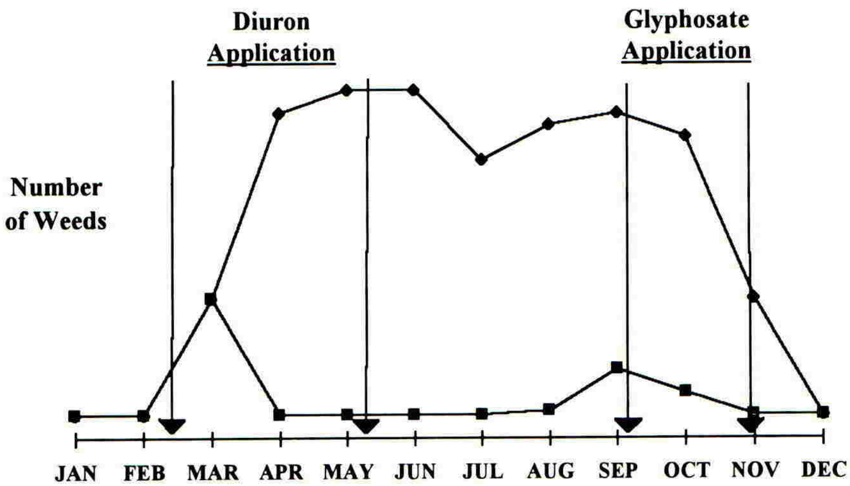
Right at the outset there was a considerable investment in understanding how diuron was being used and how/where this pattern of use posed the largest risk of contaminating water. Davies *et al.* (1993) outlines the main pathway identified by which herbicides used on non-porous surfaces moved to water sources. Point source contamination appeared to constitute a major source of residues. Timing the use of herbicides, to optimise their effect was addressed. Patterns of weed growth and seedling emergence patterns were identified as shown in Figure 1.

Figure 1. Pattern of weed growth in the UK (Davies *et al.*, 1993)




Since weed seeds start to germinate in large numbers from February onwards applying a residual herbicide before emergence constitutes good practice. In the UK a wide range of weed species are found growing in the joints on pavements and beside roadway, from *Poa annua* to *Taraxacum officinale*. In addition, using diuron early in the season coincides with moist cool conditions which are ideal for a substituted urea compound. Programmes for controlling weed growth were devised (Figure 2). Early season applications of low rates (3 kg/ha a.i.) of diuron have been used to reduce the number of emerging weed plants. Any weeds that do survive are then controlled by a late season application of glyphosate.

Figure 2. Sample programme of weed control on pavements in the UK.




The widest possible range of communication media and organisations were involved in ensuring that the "traditional" practice of letting a weed control contract at the start of the local authority financial year, in April, changed. So rather than high rates of residuals being applied to well grown weeds at a time of year when the risk of intense bursts of rainfall were high, lower rates were used before the weeds become established.

With these identified principles established, a simple message was compiled which could be easily understood by both agrochemical industry members, operators and other industry non experts, was compiled. Under the theme of "product placement" uniform messages were communicated by all those companies and organisation who participated. Using "the right product in the right place at the right time" message, avoided the use of diuron where it posed the highest risk to water.

Particular care was taken to ensure that the advice given in the campaign was consistent with other pieces of advisory information such as Department of Environment, 1992. It was key that the advice built on existing good practice. End users find contradictory advice confusing in itself and, in addition, the credibility of the experts involved is eroded.

## FOCUSING THE EFFORT

Having established the highest risk areas, such as drainage points in hard surfaces, and agreed the message the next step was to involve as many of the interested bodies as possible; target audiences were identified. Since resources are always limited, matching the resources to cover the area of greatest risk was central to focusing the effort. The areas of greatest risk where the direct contamination of water was clearly a potential were matched with the most likely causes, and with customer or managers in those areas.

Bore hole protection

In the case of bore holes the single largest potential risk was identified as the control of weeds on railways. As described (Davies, *et al.* 1993), establishing a channel for information between the water supply companies and the spray train contractors (ie. by sharing the location of bore holes and using only non-residual products in their proximity), return on the applied effort was maximised.

Pavements and roadways

In local authority managed non-porous areas such as pavements and roadways, residual products had traditionally been applied by units fitted on the side of kerb sweepers. Product use by these methods meant low levels of control over where the product was applied. Their continuing use as sprayers was actively discouraged. Applications of both hydraulic and controlled droplet formulations of residual products were made over drains and drain covers. Depending on the drainage system some of these drains discharged into open surface waters within a short distance. Backed by voluntary label changes, the use of diuron over open drains and in the channel were removed and an education and training programme put in place to ensure that application practices changed. In addition, local authorities changed their tenders and often modified their tender dates to accommodate the changes.

Identifying the gaps

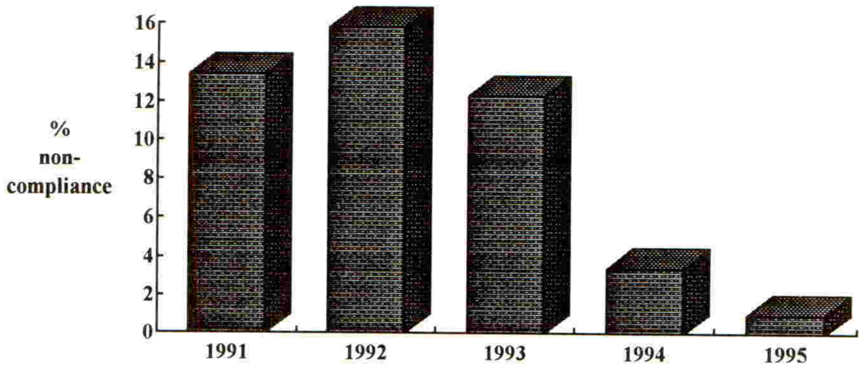
In any communication or stewardship campaign there is a need to take stock, identify the gaps and the successful tools. A survey with end users (Davies, *et al.* 1995) helped with this task. As a result of understanding how people responded to the campaign, additional workshops were held with the local authorities aimed at the actual spray operator rather than the contract specifier.

In the case of the bore hole scheme no gaps were identified. For surface water, it was recognised by all of those involved that there was a need for research into the pathways and transport mechanisms behind the use of all amenity chemicals on "hard" non-porous surfaces.

Monitoring progress

Central to any system is the monitoring function. In the case of UK drinking water quality the Drinking Water Inspectorate (DWI) produce annual reports on the quality of UK drinking water (DWI, 1992 - 96). Not only did the annual reports provide an objective assessment of progress (Figure 3) but it also assisted in identifying which water service company areas were having the greatest difficulty. Armed with this information great efforts were directed at these catchment areas.

Figure 3. Diuron % non-compliance (number of water samples where diuron exceeded the 0.1ppb standard as a percentage of the total number of samples analysed) for England and Wales.




It is clear that the considerable investment in filtration equipment has impacted on the levels of herbicides as has the recent dry weather, White & Pinkstone (1993), however, effective stewardship has had a major influence on the recent decline in the diuron levels and frequency of occurrence. During this period it is worth noting that the level of use had risen as recorded by the Department of Environment reports (1989, 1996). Approximately three times as much diuron was applied in 1996 as compared to 1989 and yet the non-compliance with the EC Drinking Water Directive has been reduced to less than 1 % of water tested.

Throughout the stewardship initiative contacts have been maintained with the Pesticides Safety Directorate and with key end users. By 1995 it was thought that there was a risk that those involved may become complacent. Added to this there was a need to ensure that the effort that all those local authority managers and spray contractors that had made in changing their practices in response to the diuron campaign was acknowledged. With this in mind a leaflet was produced (Hill 1996) which recorded the progress that had been made in reducing diuron levels. It formally thanked those involved for all their hard work. Finally, it re-stated the need for using "the right product in the right place at the right time".

To avoid all of the earlier progress being undermined by complacency the leaflet was mailed to all of the key industry and customer contacts. In addition a series of nationwide seminars were held during which the issue for the need of continuing care, when using diuron containing products, was highlighted. Local authority and railway managers continue to respond positively and support the objectives of the campaign. The role for continuous feedback is essential for the ongoing success of the project and future projects will be carried out to maintain high levels of awareness.

## ROLE OF R&D

Understanding the role of herbicide use on all amenity settings, including hard surfaces, in contaminating water is central to developing an effective stewardship campaign. One factor which needs further study is the effect of herbicide parameters controlling movement on hard surfaces such as KOC and solubility. As part of the previously described co-operative research effort, Rhône-Poulenc has undertaken wash-off studies which show that these parameters can have a major effect. Both simulated and natural rainfall has been used to study how much active is moved off a range of hard surfaces. KOC and water solubility even in these worst case scenarios has a major impact on the potential contamination of water sources by herbicides. So the choice of active can influence the amount of pesticides that move off hard surfaces

As might be expected the type of surface also has a dramatic influence on the amounts of active that are removed from the point where they were applied. Gravel/ballast surface retain far higher levels that smooth concrete areas.

Rainfall intensity (Parsons personal communication) also had a major impact on active movement off hard surfaces. Active levels in runoff water has been measured above the solubility level of material under study indicating that particularly on smooth surfaces the mass flow of pesticides occurs.

Understanding how the chemical characteristics of each active interacts with the application surface and the proximity of the nearest water source will be central to future planning of diuron and other herbicide use. In addition, selection of the next generation of actives must take account of these factors.

## CONCLUSION

It is clear that planned and supported stewardship initiatives, based on sound science, and focused on the areas of maximum impact can influence the way pesticides are used. This UK model has potential application in other markets around the world. In this case reducing the maximum dose applied, ensuring the product was used at the time of year when it has the greatest effect and avoiding its direct introduction to surface water has had a major effect in helping improve water quality. Given this experience new chemistry with even more favourable characteristics can be introduced to the UK amenity market.

It is understood that other countries are taking a different approach to the self regulation which has been successful in the UK. In France, where it has not yet been possible to initiate a stewardship campaign, the regulatory authorities have imposed a reduction of the maximum rates allowed for diuron (Zangiacomi personal communication). This has been seen as the first step in the enforced withdrawal of diuron from French amenity uses. Since a wider range of actives are approved for total weed control use on hard surfaces rather than change working practices the option of moving on to previously unused chemistry seems to be the path that is being followed.

Over the years, all those involved in managing amenity herbicide use in the UK have consistently agreed that, the preferred option was to highlight the key pathways to water contamination and then change the working practices so that the herbicide did not reach these pathways.

To date in the UK this approval has paid off so that all of those involved in managing herbicides in the amenity setting can consider introducing new chemistry to the use areas. With the results from the research and development area combining with the experience gained from the stewardship campaign, actives with more favourable characteristics can be introduced to the market. These materials are not viewed as replacements but as additional tools that can facilitate the evolution of rotational strategies for weed control including the use of diuron.

ACKNOWLEDGMENTS

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# A STEWARDSHIP PROGRAMME FOR ISOPROTURON AND WATER QUALITY - A TALE OF TWO INDUSTRIES

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## ABSTRACT

Isoproturon (IPU) is the most widely used cereal herbicide in the UK. The movement of IPU into water has led to many water sources exceeding the 0.1ug/litre standard for drinking water required by European and UK legislation. In 1995 the IPU Task Force began a Stewardship Programme to protect water quality which has produced practical guidance to advisers, farmers and spray operatives in order to reduce the amounts of IPU reaching water sources. By involving experts from a range of fields the Task Force has drawn on unpublished information and new research to identify circumstances leading to water contamination and to recommend solutions that go beyond the minimum legal requirements. Communicating the problems and solutions has been tackled through advisory booklets aimed at spray-operatives, farm managers and distributors. Gauging the success of the Stewardship Programme is complicated by variable weather patterns and the difficulties of surveying changes in behaviour. However, the available data shows an increased awareness of the risks to water and measurable reductions in the amounts of IPU entering water courses. The lessons learnt provide a model for other stewardship programmes.

## INTRODUCTION

The Water Supply (Water Quality) Regulations 1989 (Anon. 1989) formalised the arrangements for monitoring and reporting the quality of drinking water in England and Wales. The Regulations incorporated the standards required by the European Drinking Water Directive 80/778/EEC and included the standards for individual and total pesticides of 0.1ug/litre and 0.5ug/litre respectively. The results for 1990 were summarised by the Drinking Water Inspectorate in July 1991 (DWI, 1991) and provided the first national picture of water quality across England and Wales. A key feature of the data was that pesticides accounted for more than half of all the failures to meet national and European standards (Table 1).

Table 1. Contraventions of quality standards in water supply zones in England and Wales 1990

| Parameter | Number of contraventions | Percentage of total contraventions |
|---|---|---|
| Pesticides | 13209 | 51 |
| Coliforms | 3835 | 15 |
| Iron | 2226 | 9 |
| Nitrite | 1743 | 7 |
| Lead | 1598 | 6 |
| Nitrate | 1117 | 4 |
| Others | 2204 | 8 |
| Total | 25932 | |

Where water companies had identified failures of the pesticide standard they were obliged to give legally binding undertakings to install additional treatment plant. Typically this involved treatments such as ozone and granular activated carbon to break down and adsorb the pesticides. The size and complexity of these capital schemes, often costing £10 million or more for a single treatment works, meant that they would take several years to complete. In the meantime the pesticide concentrations would be solely determined by the concentrations in the raw water and would periodically exceed the legal standard.

In explaining its position to customers and the media, the water industry stressed that users of pesticides and the agrochemical companies had a part to play in reducing the amounts of pesticides reaching water sources. For its part the agrochemical industry argued that the standards for pesticides in drinking water were unscientific and unnecessarily stringent to protect health. It was also suggested that controlling these substances at source would require radical changes in agricultural practice with adverse effects on production and efficiency. Caught in the middle of this debate were the users of pesticides, eg farmers, British Rail and local authorities, and their representatives. They contended that they were using pesticides in an approved manner and that there was little they could do by themselves.

Recognising the need for a more constructive dialogue the associations representing the water and agrochemical industries in the UK met in November 1991 to exchange information and to explore ways of working together. The water industry was represented by the Water Services Association and the Water Companies Association, the agrochemicals industry by the British Agrochemical Association.

Although the perspective of the pesticide standard was different, both industries came to understand each others position and to learn more about the technical issues and legal constraints which they both faced. Through a series of further meetings and joint seminars it was agreed that the pesticide standard was a legal obligation on water companies and that treatment alone was insufficient to ensure compliance. This provided common ground for the two industries to support each other on several initiatives to minimise the impact on water quality (White & Pinkstone 1993, Davies *et al.*, 1993, Court *et al.*, 1995).

## USE AND PROPERTIES OF ISOPROTURON

Isoproturon is a widely used broad-spectrum herbicide with residual activity and has been applied in the UK for over twenty years. Because of its effectiveness against strains of *Alopecurus myosuroides* (black-grass) that are resistant to certain other herbicides, it has become a vital and cost-effective tool in growing cereals, especially on heavy clay soils where *A.myosuroides* can seriously reduce crop yields. In tonnage terms IPU is the second most used pesticide in the UK, second only to the desiccant sulphuric acid, with approximately 2500 tonnes per annum applied across Great Britain (Garthwaite *et al.*, 1995).

Although IPU has residual activity in soil, it is normally retained in the upper 15-30 cm where it is eventually broken down by soil microbes. Soil column tests have also shown that IPU has a low leaching potential and this is borne out by the experience of water companies in that groundwater sources are rarely affected by IPU even when used close to the source.

Although the intrinsic properties of IPU would suggest that it should not reach surface water in significant quantities the analytical data clearly indicates that it does. Recent research has identified "macropore" or "by-pass" flow as providing a mechanism by which IPU and other pesticides can find their way into water courses. In essence macropore flow involves cracks in soil which allows water, dissolved pesticides and even pesticides adsorbed onto soil particles to move readily from the soil surface into field drains and on to surface waters or underlying aquifers (Harris *et al.,* 1994).

## ISOPROTURON AND WATER SUPPLIES

One of the benefits of the liaison between the agrochemical and water industries was the sharing of information on pesticide concentrations in drinking water and water sources. Much of this information was not readily available by other means.

The number of failures of the pesticide standard due to IPU varied widely across the country (Table 2) and could be related to the type of water source and land use. Exceedances of the 0.1ug/l standard for IPU were most common in the South-East of England where lowland rivers are the major source of supply. Very few failures were recorded from upland catchments supplying the North and the West of the country. In addition to the contraventions of the standard for individual pesticides, IPU also made a significant contribution to the number of samples exceeding the standard for total pesticides.

Information on individual water supplies indicates how concentrations of IPU varied throughout the year (Figures 1&2), broadly following seasonal patterns of use and rainfall. These data also demonstrated that the nature of the abstraction was also important. Where a works abstracted directly from a river (Figure 1) the presence of IPU was transient but could reach high concentrations. Where water was stored in reservoirs prior to treatment (Figure 2) the concentrations were generally less variable but could exceed 0.1ug/l for long periods. The different patterns had implications for the design and operation of the new treatment processes that were being installed.

Figure 1. Isoproturon at a treatment works abstracting directly from a river

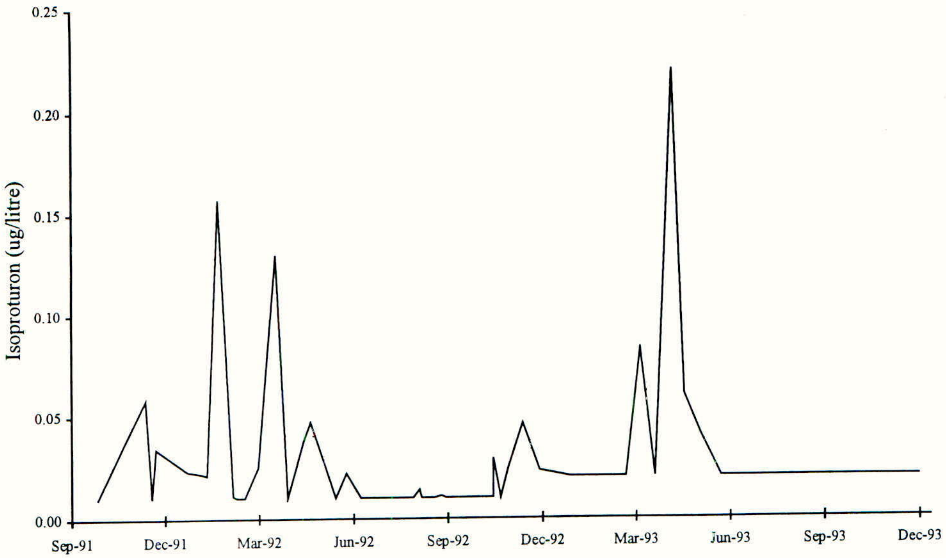


Figure 2. Isoproturon at a treatment works abstracting water from a river via large storage reservoirs

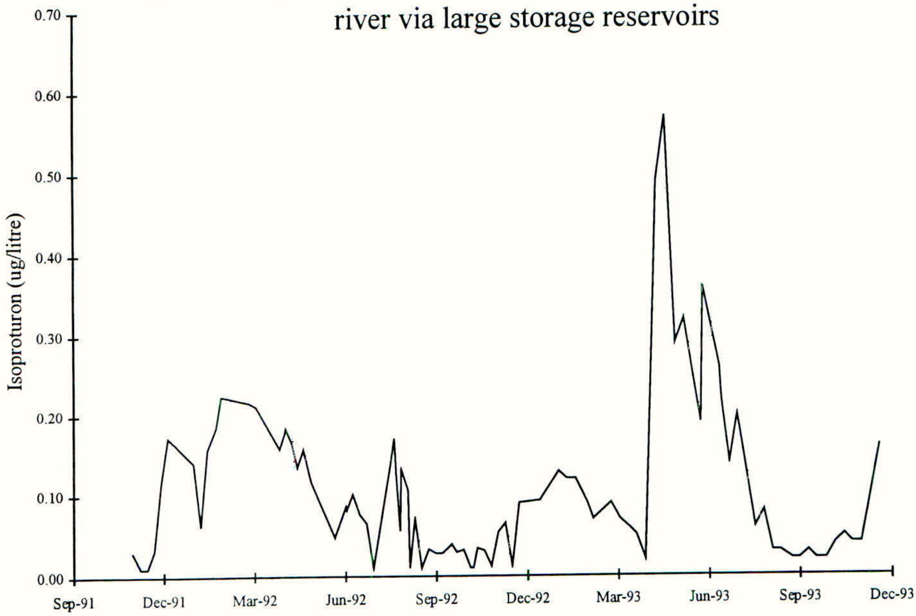

Table 2: Number (and percentage) of drinking water samples >0.1ug/litre for isoproturon reported by five water companies 1991-1993

| Water Company | 1991 | 1992 | 1993 |
|---|---|---|---|
| Anglian | 116 (2.4%) | 464 (15%) | 33 (1.2%) |
| North West | 0 | 0 | 1 (<0.1%) |
| Severn-Trent | 9 (0.2%) | 8 (0.2%) | 12 (0.3%) |
| South-West | 0 | 0 | 0 |
| Thames | 2483 (24%) | 2244 (15%) | 2860 (21%) |

## GROWING PRESSURE ON ISOPROTURON

Although the concentrations of IPU found in water supplies were well below limits derived using standard toxicological approaches - the World Health Organisation has derived a guideline value for IPU in drinking water of 9ug/litre (WHO 1993) - IPU was becoming an increasing problem, at least in relative terms. Figures from the Chief Inspector's report (DWI 1993-1996) showed that despite the installation of new treatment plant and marked reductions in the number of exceedances for largely non-agricultural pesticides, such as atrazine and diuron, the number of exceedances for IPU were largely unchanged (Table 3).

Table 3: Total number of drinking water samples contravening the 0.1ug/litre standard for four pesticides in England and Wales, 1992-1995

| Pesticide | 1992 | 1993 | 1994 | 1995 |
|---|---|---|---|---|
| Isoproturon | 4301 | 4496 | 6200 | 4098 |
| Atrazine | 12729 | 7090 | 1730 | 567 |
| Simazine | 6818 | 4701 | 1722 | 1218 |
| Diuron | 4647 | 3906 | 1302 | 311 |

It is likely that different weather patterns from year to year were a factor in influencing the amounts of IPU reaching water. For example, the autumn/winter of 1993/4 was extremely wet across much of the UK and waterlogged soils made it difficult to get onto the land to apply herbicides. In March 1994 a break in the weather allowed soils to dry out sufficiently to allow spraying to take place. Unfortunately this was followed by more torrential rain during April. Across the country water companies identified large peaks of IPU in raw and treated waters. This was most marked on the Isle of Wight where rainfall had been so heavy that soils had been washed into rivers taking with it large amounts of IPU. Fortunately the works that normally abstracts from the river was closed for other reasons (Barnden, 1995).

Further pressure on IPU came in the guise of a review by the Advisory Committee on Pesticides (ACP). Although this review covered all aspects of IPU use the ACP took the unusual step of asking for data on concentrations in raw and treated water with a view to assessing the impact of IPU use on water abstraction and supply.

STEWARDSHIP PROGRAMME TO PROTECT WATER QUALITY

In 1995 the IPU UK Task Force, comprising the principal manufacturers of IPU in the UK (AgrEvo, Ciba, now Novartis, and Rhône-Poulenc) decided to take a more pro-active approach to address the problems that were drawing attention to the use of IPU and the possible environmental consequences. The Task Force was also aware of imminent changes to the conditions for approval but for practical reasons these statutory requirements would not take effect until the following year. In order to not to miss a season the Task Force sought to produce some guidance that could produce benefits as soon as possible. The stated aim of the booklet was;

"To maintain the use of IPU for the control of black-grass and other weeds in cereals whilst minimising its movement to water which may be utilised for drinking water supplies".

The initial objective was to produce a booklet that provided practical advice to farmers and advisers and to explain that unless concentrations in water could be reduced by means of improved practices there was a real danger that further compulsory restrictions would be introduced. Recognising that it did not have all the answers the Task Force sought input from various experts from research groups, NFU, ADAS and the water companies to help it formulate some key points that farmers and advisers should consider.

The booklet was "launched" in September 1995 at a meeting chaired by the Pesticide Safety Directorate of MAFF to which all interested parties were invited, including all the other manufacturers and suppliers of IPU into the UK market.

The recommendations covered four areas;

Good housekeeping; to prevent leakage, spills and spray drift and to dispose of containers and excess product correctly.

Rates and timings; only apply post-emergence to wheat and barley, only apply to moist soils, doses should not 2,500g of a.i. to any crop and where possible use lower rates.

Manage clay soils; avoid mole draining in the season prior to a cereal crop, remove cracks in soil by ploughing and create a fine consolidated seedbed.

Prevent run-off from sloping fields; use buffer strips, drill across slopes, avoid tramlines down slope, avoid applications prior to heavy rain.

The Task Force produced 50,000 copies of the booklet of which 30,000 were distributed in "Crops" magazine. The other 20,000 were distributed through pesticide suppliers, water companies and the Environment Agency.

At the end of the 1995/6 growing year the Task Force consulted widely to assess the practicality of the advice and whether the impact on water had been reduced. In general the feedback was supportive but some argued that it was impossible to carry out all the recommendations and that some of the recommendations were not soundly based. The Task

Force's response was that they appreciated it may not be possible for all the recommendations to be followed every time, but farmers should do as many as practicable. With regard to the research it was acknowledged that some of the research on which the booklet was based was still ongoing but action was needed as soon as possible. To wait for definitive proof could mean delaying until IPU had been subject to even more stringent restrictions on use, making the research academic.

The water quality data for 1995/6 was supplied by Water Companies and the Environment Agency. The findings were, at best, equivocal, with no obvious decrease in concentrations or incidence. Indeed in some cases concentrations appeared to have increased but this may have been an artifact of an increased sampling frequency (Figure 3). It was conjectured that the Task Force's booklet may have gone out too late to influence farmers plans. It was also considered that the long hot summer of 1995 would have generated considerable cracking in soil structures making it extremely difficult to successfully implement the recommendations. However, a key observation was that the initial peaks of IPU were being found in rivers months before field drains had started to flow.

Although definitive evidence was lacking it lead the Task Force to consider whether small amounts of IPU that might be lost during the filling of spray tanks or cleaning of equipment could account for a significant proportion of the observed concentrations. Such point source contamination had previously been suggested as the cause of high concentrations in the Swavesey catchment study (Harris *et al.*, 1991) but there had been consideration of the cumulative effects of multiple and coincident spillages etc within larger catchments.

In the summer of 1996 the Task Force produced a second booklet which took account of the comments and information received. The main changes were greater emphasis on avoiding contamination from point sources and re-organising the information so that those involved in advising, planning and using IPU could find the relevant information in a specific section. The aim of the Stewardship Programme was also modified to reflect the concerns about retaining the approval for use, the new restrictions for use of winter cereals and the importance of point sources. The new objective was;

> "To maintain approval for the use of IPU in sustainable programmes for the control of black-grass and other weeds in winter cereals whilst minimising both direct contamination and movement from the field to water."

The distribution of the second booklet was similar to the first and was supported by presentations by the Task Force to agrochemical distributors of IPU. A number of farmer meetings were also held. Extensive press coverage also helped get the message across. To illustrate the potential effects of small spillages and other inadvertent losses the booklet included some examples of how a little pesticide can contaminate a large amount of water to the level of the pesticide standard (Figure 4). Although the precise quantities would vary, these illustrations apply to all pesticides. They pose some interesting questions for the pesticide approval process. They also pose a challenge for the agrochemical industry, packaging companies and equipment manufacturers to find practical ways of reducing even very small losses of pesticides into water courses. Further work is needed to understand the importance of these sources compared with losses from fields. However, even very small percentages, $<0.5\%$ of the total applied, could be important at the local scale, especially if they occur over short periods following application.

Figure 3. Isoproturon in the river Thames at Walton

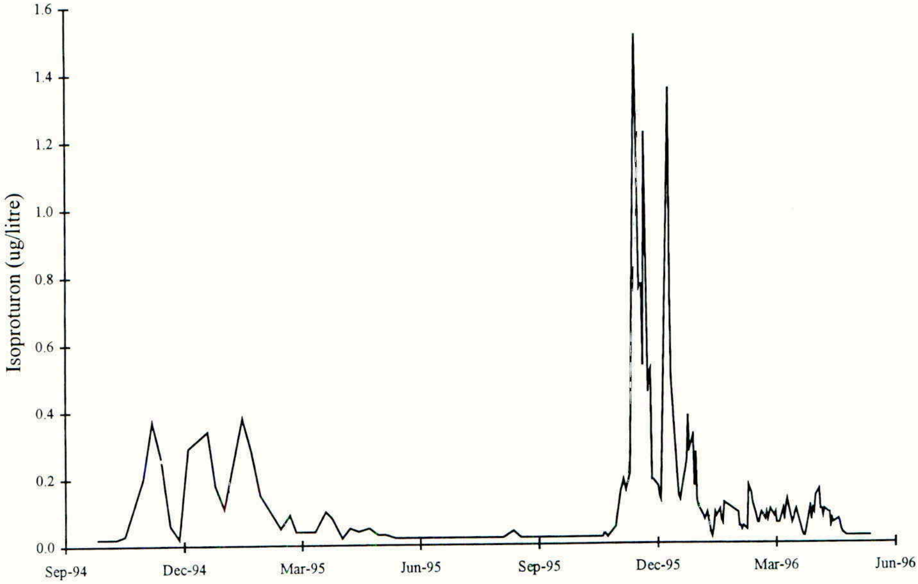


Figure 4. The potential impact of point source contamination on downstream water quality - illustrations from the IPU UK Task Force's second booklet

**The 0.1ug/litre pesticide standard could be exceeded in the following stretches of water from your farm by the following activities;**

| | |
|---|---|
| Washings from gloves after a day's spraying | - a ditch 100m long x 1m wide x 1m deep |
| Washing down the outside of a sprayer after treating 20 hectares | - a stream 250m long x 5m wide and 2m deep |
| Allowing a single nozzle with standard IPU mixture to spray for 1 second over a watercourse | - a stream 250m long x 5m wide and 2m deep |
| Discharge of 50 litres of spray tank washings to a watercourse | - a river 3km long x 10m wide x 5m deep |
| A 100ml spill of IPU concentrate washed into a watercourse | - a river 10km long x 10m wide x 5m deep |
| 50 litre of spray residue of standard field dilution spilt into a watercourse | - a river 125km long x 10m wide x 5m deep |

## MEASURING SUCCESS

It is always difficult to measure the success of any stewardship campaign, especially ones that are aimed at modifying behaviour and attitudes. A survey of farmers and advisers has shown a high level of awareness of the ACP's review of IPU and a quarter said they planned to use or advise the use of lower rates. However, the best measure of how successful the Stewardship Programme has been is the concentration of IPU found in water sources. Unfortunately the weather plays a major influence upon the use and fate of IPU and drawing firm conclusions from one or two year's data would be unwise.

A subjective assessment of IPU data gathered by water companies during 1996/7 suggests that concentrations of IPU in rivers were slightly lower than in previous years but this might be because the winter and spring were relatively dry. In the South of England there was little flow from field drains. Although IPU concentrations may have reduced it is possible that amounts of other herbicides have increased as a result of farmers following the Task Force's advice to reduce IPU application rates. For some water companies mecoprop is already of concern, not least because it is relatively difficult to treat. In recent years several companies have reported increased concentrations of mecoprop in raw waters despite the move towards the herbicidally active isomer, mecoprop-p. It is too early to say whether the increase in mecoprop concentrations represents substitution for IPU or autumn weather conditions that were unsuitable for herbicide applications. It does illustrate however, the need to take a broad view when judging the success of any stewardship campaign.

## LOOKING AHEAD

As water companies complete the installation of new treatment plant to remove pesticides the number of drinking water samples with >0.1ug/litre have reduced dramatically, in 1996 there were only 1026 contraventions compared with more than 4000 in the years 1992-1995. The significant improvement should continue in 1997. While these changes have reduced public and media attention on pesticides in drinking water the water industry are still anxious to achieve further reductions in IPU concentrations. Treatment to remove pesticides is expensive and unless the peak concentrations in raw waters can be reduced by better controls at source there is risk that the removal capacity of the new treatment processes will be overwhelmed and failures of the drinking water standard will occur.

For 1997/8 the Task Force is planning a poster for spray operatives to put into spray sheds. The objective is to raise awareness of how even small spillages and the residues from washing spraying equipment and protective clothing can contribute to water contamination. These posters will be distributed through agrochemical manufacturers.

The European Commission's ongoing review of the drinking water directive offered the opportunity to introduce toxicologically based standards for pesticides. However, both the water and agrochemical industries have conceded that changes to the pesticides standards are unlikely. As a result the pressure for further controls on pesticides at source will continue. Indeed a new drinking water standard for bromate, a byproduct of ozonation will make the pressure even stronger. Ozone has been widely used by the water industry to treat pesticides and is very effective against IPU. If the use of ozone is restricted the water industry will be calling for the lowest possible levels of IPU in water sources.

## CONCLUSION

It would be premature to judge the success of the IPU Stewardship Programme or to speculate how much further concentrations in water sources can be reduced by voluntary action. However, the Stewardship Programme has already illustrated that collaboration between industries can be highly productive, lead to an improved understanding of the issues and produce innovative ways of working towards a solution. The problems posed by IPU in the UK are not unique and many of the messages promoted by the Task Force are relevant to all pesticides. As the 0.1ug/litre standard for drinking water looks set to remain for the foreseeable future a combination of source control and water treatment would appear to be the only viable option. This will require that the agrochemical and water industries will need to maintain their dialogue.


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