

**INTEGRATED CONTROL OF DOWNY MILDEW IN CRISP LETTUCE**

J M LI DAVIES

ADAS Terrington, Terrington St Clement, King's Lynn, Norfolk PE34 4PW

**ABSTRACT**

The effect of fungicides, applied during propagation in the summer months to control lettuce downy mildew in the field, was evaluated in Buckinghamshire (1991) and Norfolk (1993). Control was achieved with fosetyl-aluminium either as a drench in propagation at the 2-3 leaf stage and rinsed with water after application, or as a compost-incorporated treatment. In Norfolk, downy mildew was also controlled by compost-incorporated propamocarb hydrochloride and by foliar sprays of metalaxyl + thiram, zineb and thiram. Fungicides to control downy mildew in the field were evaluated in Lancashire (1991) and in Lincolnshire (1993). Foliar sprays of zineb, metalaxyl + thiram, propamocarb hydrochloride and in addition, in Lincolnshire, thiram and mancozeb gave control. Fosetyl-aluminium drench and rinsed off with water reduced disease only in Lancashire. No downy mildew occurred during propagation. There was no effect of treatment on yield of lettuce. There is scope to apply fungicides during propagation, in addition to in the field, to control downy mildew.

**INTRODUCTION**

Downy mildew caused by *Bremia lactucae* is the most important disease of field grown lettuce. ADAS disease surveys in 1988 and 1989 showed that downy mildew caused estimated losses of £3.8 and £1.2 million, respectively. Disease development is dependent on very high humidities during cool conditions and is mostly a problem in the UK in spring and in the autumn. Although there are genes for resistance to downy mildew bred into modern butterhead cultivars there are no effective resistance genes in current outdoor crisp cultivars. The aim of this work was to investigate any effects of fungicides applied during propagation, or in the field, on the control of downy mildew in the growing crop.

**MATERIALS AND METHODS**Fungicides applied in propagation

There were field experiments at Taplow, Buckinghamshire in 1991 and at Terrington St Clement, Norfolk in 1993. July sown cv. Baltic raised in 4.3 and 3.8 cm<sup>3</sup> peat blocks (Levington Blocking Compost) planted at Buckinghamshire and Norfolk respectively was treated during propagation with fosetyl-aluminium 'Aliette' compost-incorporated at 720 g AI/m<sup>3</sup> prior to blocking and drench treatments of propamocarb hydrochloride 'Filex' at 216 g AI/m<sup>3</sup> compost prior to blocking (apart from in 1991 when 21.6 g AI/m<sup>3</sup> was applied prior to blocking and the equivalent of 194.4 g AI/m<sup>3</sup> applied when the cotyledons unfurled), fosetyl-aluminium at 8 g AI in 2 l/water/m<sup>2</sup> blocks at 2-3 true leaves irrigated with 2 mm water

immediately after application as directed in the Specific Off-label Approval Scheme (SOLA) 91/0556 and propamocarb hydrochloride applied prior to the crop planted out at 3.61 g AI in 2 l water/m<sup>2</sup> and the foliage irrigated with water. Two foliar spray treatments of metalaxyl + thiram 'Favour 600 FW' at 0.5 g + 2.5 g AI and, in 1993 only, zineb 'Unicrop Zineb' at 3.5 g AI, mancozeb 'Unicrop Mancozeb' at 3.6 g AI, thiram 'Unicrop Thianosan' at 8.0 g AI, fluazinam 'ASC 66825', (ISK Biosciences) at 1.25 g AI in 2.5 l water per 70 m<sup>2</sup> blocks at the first true leaf and per 50 m<sup>2</sup> blocks at 2-3 true leaves were applied respectively. Zineb dust 'FS Zineb 15% dust' at 0.48g AI/m<sup>2</sup> blocks was applied at 2-3 and 4-5 true leaves. An untreated control received no fungicides during propagation. At Buckinghamshire the blocks were planted on 19 August and the plants harvested on 15 October. Zineb 'Hortag Zineb Wettable' was applied at 1.4 kg AI in 1000 l water/ha on 13 September and 2 October. In Norfolk the blocks were planted on 18 August and harvested on 22 October. Mancozeb was applied at 1.04 kg AI in 750 l water/ha on 25 August, 9 September and at 2.16 kg AI in 1500 water/ha on 22 September.

Compost incorporation was achieved by spraying each chemical with an MDM Precision Sprayer, using a 04-F110 jet at 100 kPa in 400 ml water, evenly over a thin layer of 10 l compost on a plastic sheet and then gathering the sheet together to facilitate mixing. Fosetyl-aluminium drenches were applied with an MDM Precision Sprayer using a 8008E jet at 100 kPa. Foliar sprays were applied in propagation with an MDM Precision Sprayer with a 01-F110 jet at 100 kPa at first true leaf and with a 02-F110 jet at 100 kPa at 2-3 true leaves and in the field with 004-F80 jets at 200 kPa.

#### Fungicides applied in the field

There were field experiments at Sollam, Lancashire in 1991 and at Holbeach St Marks, Lincolnshire in 1993. During propagation the plants received zineb foliar sprays in 1991 and a fosetyl-aluminium drench in 1993 (SOLA 91/0556). At those sites cvs. Telda and Saladin respectively were planted on 9 August and 18 August and were harvested on 14 October and 1 November. Drench treatments of fosetyl-aluminium at 24 g AI in 20 l/100 m<sup>2</sup> were applied at 5 and 7 days and at 18 and 35 days post-planting respectively at each site with (SOLA 91/0556) and without being rinsed off one hour later with 2 mm water. These were compared with three foliar sprays of propamocarb hydrochloride at 1.083 kg AI in 750 l water/ha applied 3, 18 and 31 days and 7, 35 and 51 days post-planting respectively at each site, metalaxyl + thiram at 0.15 kg + 0.75 kg AI in 750 l water/ha 3 and 7 days post-planting respectively at each site followed by metalaxyl + thiram 0.3 kg + 1.5 kg AI in 1500 l water/ha 18, 31 and 51 and 35, 51 days post-planting, zineb 'Hortag Zineb Wettable' 1.4 kg AI in 1000 l water/ha applied 3, 18 and 31 days post-planting and phosphonic acid (as potassium phosphonate) 1.2 l AI in 500 l water/ha applied 3, 18 and 31 days and 7, 35 and 51 days post-planting respectively at each site. In 1993, phosphonic acid was not included and the zineb treatment was replaced with zineb 'Unicrop Zineb Wettable' at 1.4 kg AI, and in addition mancozeb 1.44 kg AI, and thiram 3.2 kg AI in 1000 l water/ha applied 7 days post-planting followed by zineb at 1.4 kg AI, mancozeb 1.44 kg AI and thiram 3.2 kg AI respectively in 1500 l water/ha 35 and 51 days post-planting. Foliar sprays were applied with an MDM Precision Sprayer with 08-F110 jets at 200 kPa.

In all experiments, plots from 2.4 to 4.5 m long by 1 bed wide with 4 rows of plants were located within a commercial crop of transplanted crisp lettuce apart from the 1993 experiment in Norfolk. Fertilisers and herbicides were applied as normal commercial practice. Downy

mildew assessments (using ADAS Disease Assessment Key 10.1.3. at harvest expressed as a severity index) and weights of trimmed lettuce were recorded for 20 plants per plot. All data were subjected to analysis of variance. Standard errors of differences between means are quoted when probability  $P$  is  $<0.05$ . Significance is indicated as \*  $P<0.05$  \*\*  $P<0.01$  \*\*\*  $P<0.001$  and NS = not significant  $P>0.05$ .

## RESULTS

### Field Experiments

In Buckinghamshire the disease developed soon after planting out. At harvest only the two fosetyl-aluminium treatments gave a reduction in downy mildew. There was no effect of treatment on yield. (Table 1)

TABLE 1. Effect of fungicides (compost-incorporated, drenches and foliar sprays) on lettuce downy mildew and yield Buckinghamshire 1991

Treatment in propagation	% Downy mildew	Mean yield (kg)
Control - no treatment during propagation	24.7	0.41
Fosetyl-aluminium compost-incorporated	16.1	0.48
Propamocarb hydrochloride compost-incorporated	26.3	0.41
Fosetyl-aluminium plant drench	20.0	0.44
Propamocarb hydrochloride plant drench	28.4	0.46
Metalaxyl + thiram foliar sprays	28.9	0.45
Zineb dust	26.7	0.46
Significance	*	NS
SED (18 df) $\pm$	2.0	0.065

In Norfolk low levels of downy mildew were recorded in untreated plots in late September but the disease developed dramatically after mid-October. Plants were not mature when harvested due to the late season. Control in incidence of mildew was achieved only by the fosetyl-aluminium treatments. Control in severity of mildew was achieved by the two fosetyl-aluminium treatments, which also had the lowest disease scores, by foliar sprays of metalaxyl + thiram, zineb and thiram and also by propamocarb hydrochloride compost-incorporated. There was no effect of treatment on yield. (Table 2).

TABLE 2. Effect of fungicides (compost-incorporated, drenches and foliar sprays) on lettuce downy mildew and yield Norfolk 1993

Treatment in propagation	% Downy mildew		Mean yield (kg)
	Incidence	Severity	
Control - no fungicide during propagation	84	4.82	0.19
Fosetyl-aluminium compost-incorporated	15	0.22	0.17
Propamocarb hydrochloride compost-incorporated	48	2.11	0.17
Fosetyl-aluminium plant drench	21	0.71	0.20
Propamocarb hydrochloride plant drench	94	2.78	0.21
Metalaxyl + thiram foliar sprays	49	1.45	0.21
Zineb foliar sprays	60	1.59	0.21
Mancozeb foliar sprays	86	3.79	0.18
Thiram foliar sprays	60	2.22	0.19
Fluazanim foliar sprays	63	2.85	0.20
Significance	**	*	NS
SED (27 df) $\pm$	20.6	1.293	0.024

### Field Experiments

In Lancashire downy mildew was first recorded in early September and was present on all plots. At harvest the best control of downy mildew was given by metalaxyl + thiram and zineb foliar sprays. Propamocarb hydrochloride foliar sprays also reduced disease severity. Phosphonic acid had no effect. There was no effect of treatment on yield. (Table 3).

In Lincolnshire downy mildew developed dramatically in late October. At harvest, disease incidence was reduced by foliar sprays of metalaxyl + thiram, mancozeb, thiram and zineb. Disease severity was reduced by all fungicide treatments apart from fosetyl-aluminium. There was no effect of treatment on yield. (Table 4).

TABLE 3. Effect of fungicides (drenches and foliar sprays) on lettuce downy mildew and yield - Lancashire 1991

Field Treatment	% Downy Mildew	Mean Yield (kg)
Untreated control	18.92	0.35
Fosetyl-aluminium drench + water rinse off	13.02	0.36
Fosetyl-aluminium drench	14.15	0.34
Propamocarb hydrochloride foliar sprays	10.57	0.32
Metalaxyl + thiram foliar sprays	5.50	0.32
Zineb foliar spray	2.95	0.32
Phosphonic acid foliar sprays	13.70	0.36
Significance	***	NS
SED (18 df) $\pm$	2.445	0.05

TABLE 4 Effect of fungicides (drenches and foliar sprays) on lettuce downy mildew and yield, Lincolnshire 1993

Field Treatment	% Downy Mildew		Mean yield (kg)	
	Incidence	Severity		
Untreated control	100	(90.0)#	7.92	0.28
Fosetyl-aluminium drench + water rinse off	100	(90.0)	5.60	0.31
Fosetyl-aluminium drench	100	(90.0)	6.23	0.28
Propamocarb hydro- chloride foliar sprays	96	(81.9)	2.95	0.31
Metalaxyl + thiram foliar sprays	87	(69.2)	1.78	0.31
Zineb foliar sprays	49	(40.6)	0.84	0.34
Mancozeb foliar sprays	33	(34.0)	0.45	0.37
Thiram foliar sprays	68	(59.7)	2.29	0.32
Significance	***	***	NS	
SED (27 df) $\pm$	9.43	1.159	0.03	

# angular transformation

## DISCUSSION

Control of downy mildew in the field following treatment in propagation was achieved by fosetyl-aluminium compost-incorporated and no reductions in yield were recorded at harvest. However in other work (Davies unpublished) severe phytotoxicity occurred following this treatment but this could be explained: as the plants were treated in July and there was a great risk of this treatment being phytotoxic if used in the "high risk" summer months (May-August) as it is not recommended for use at that time. The reason for variability in phytotoxicity cannot be explained. However good control was achieved with fosetyl-aluminium as a drench applied at the 2-3 leaf stage and washed off immediately with water as directed under the Specific Off-label Approval (SOLA 91/0556). Propamocarb hydrochloride compost-incorporated gave control only in Norfolk; lack of control in Buckinghamshire may have been due to incorrect application.

Experiments carried out in 1991 and in 1993 showed that field sprays of propamocarb hydrochloride reduced disease at both sites. Approval for the Off-label use of propamocarb hydrochloride is on protected lettuce only. Fosetyl-aluminium as a field drench followed by irrigation to rinse it off gave control only at Lancashire in 1991; lack of control in Lincolnshire may have been due to the delay in the second application. There were no problems experienced in not rinsing with water after application. This result is in contrast to that obtained in protected lettuce experiments (McPherson 1991). Downy mildew strains resistant to metalaxyl have been found from most lettuce growing areas (Crute *et al.*, 1987). In Norfolk where the strain of downy mildew was sensitive to metalaxyl, foliar sprays of metalaxyl + thiram applied in propagation gave control in the field. Resistance tests were not made in 1991 although the crop in Lancashire was grown in an area where resistant strains had been detected in the past and in Lincolnshire tests showed that a mixture of metalaxyl-resistant and sensitive strains were found; at both these sites field applied metalaxyl + thiram foliar sprays gave control. Disease control was obtained with fosetyl-aluminium in propagation and foliar sprays in the field of metalaxyl + thiram, zineb, mancozeb or thiram. These combined treatments were applied in Lincolnshire with good results and could be a way of using existing fungicides more effectively.

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**Session 7A**  
**Problems of Pesticide**  
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## UK EXPERIENCES WITH THE CO-ORDINATION OF MINOR USE REGISTRATION

C.J.C. WISE

National Farmers' Union, 22 Long Acre, London, WC2E 9LY

## ABSTRACT

A brief summary of the UK pesticide registration process for minor uses of pesticides is provided. The current system of management, facilitated by the minor uses sub-committee of the British Crop Protection Council (BCPC), which seeks to co-ordinate the exchange of information on the registration process, is discussed. An overview of potential changes which may result from new incoming EC legislation is provided and the need for European co-ordination is exposed.

## INTRODUCTION

Growers of the so-called minor crops that provide much of the variety to the European consumers diet, face a significant and accelerating decrease in the range and number of pesticides approved for use on their crops. Judicious use of pesticides is essential still for the economic production and continuity of supply of food acceptable to the public, the processor and the supermarket buyer. The same can be said for producers of ornamental plants, which enhance our gardens and homes. The diversity of crops and the cultivation techniques necessitates a wide range of pesticide uses and without such inputs much of the northern European horticulture would become unviable and imports would rapidly fill the gaps.

Concern about the potential effect of loss of pesticides in the minor crop or minor use area within the UK has led to the remit of BCPC Minor Uses sub-committee to anticipate the withdrawal of necessary pesticides from the market, to determine the implications to the grower with respect to minor uses, to propose alternative uses and stimulate action to prevent unnecessary loss in the range of pesticides available for use. The sub-committee is a multi-disciplinary body which brings together growers' associations, advisory bodies, legislators, research workers, the agrochemical industry and others concerned with horticulture in the United Kingdom. The sub-committee is chaired by the National Farmers Union (NFU) to ensure the resulting consultations with all parties interested in minor crops in the UK are "grower-led".

## THE UK'S 'OFF-LABEL' SYSTEM

The Pesticides Safety Directorate (PSD), who are responsible for implementing regulations on the control of pesticides in the United Kingdom, has a clear remit to a) protect the health of human beings, creatures and plants; b) to safeguard the environment and c) to secure safe, efficient and humane methods of controlling pests. To enable PSD to recommend approval of an individual product for a specific purpose, the applicant/manufacturer must provide data to demonstrate that such a use does not pose an

unacceptable risk to operator, consumer of any treated produce or the wider environment. In addition, evidence must be submitted to demonstrate the effectiveness of a product for its purpose and its safety to the crop.

PSD has always taken a pragmatic attitude towards the registration of minor uses. Often the manufacturer may have little specific data to support a label recommendation for the control of a sporadic pest or disease, or for uses involving crops grown on a small scale and usually it is not economically justifiable to carry out supervised pesticide residue trials on all crops species or cultivars on which their new product may be used. Thus, extrapolation from the residues data that are normally available becomes essential to the estimation of maximum residue levels (MRLs). Extrapolation of residues data is clearly defined by Chapman and Kyle (1993) as the extension or projection of conclusions and estimates made on the evaluated residues data to other crops varieties and cultivars. PSD accept data from a reduced number of residues trials for some minor crops and for certain crops grown under protection (which are not subject to wide variations caused by weather).

Nevertheless, in spite of reducing the data requirements, PSD recognises that growers still have a legitimate need for certain products and have practically resolved the problem by implementing alternative arrangements. Growers may use pesticides legally on crops other than those specified on the label by adopting one of two following options:-

#### Approval by Extrapolation

Approval by extrapolation, colloquially known as the "long term off-label arrangements", permits an extension of use from named crops to other named crops subject to specified conditions. Efficacy data are not considered necessary because use is undertaken at the growers choosing and the commercial risk to the crop is entirely theirs. These extensions of use are permitted because:-

- i) it is possible to extrapolate residue data to these crops;
- ii) the preparation of the crop before consumption is similar, ie. the same part of the crop is eaten with similar processing before consumption;
- iii) similar or lower quantities of food for specified minor crops are consumed;
- iv) the environmental risks are broadly similar.

In general, these 'off-label' arrangements cover three specific areas:-

Non-edible crops and plants: Subject to certain restrictions these may be treated with pesticides which are approved for use on commercial agricultural or horticultural holdings for use on any growing edible crop. Examples of such non-edible crops include hardy ornamental nursery stock, ornamental plants, bulbs, flowers and seed crops where neither the seed nor any part of the plant is to be consumed.

Nursery fruit crops: Pesticides, approved for use on any crop destined for human or animal consumption, may be used on nursery fruit trees, bushes, canes and non-fruiting strawberries, provided any fruit harvested from these crops within a year of treatment is destroyed.

Certain edible crops: Subject to certain restrictions, some minor crops may be treated with pesticides approved for use on a related or similar major edible crop. Some examples

of these uses are given in Table 1; full details were given by Chapman and Kyle (1993). In horticulture, the most particular general restriction for these extensions relates to protected crops. Pesticides cannot be used on protected crops, ie. those grown under glasshouses, polytunnels, cloches or polythene covers, unless the product label specifically allows use on another protected crop. Unless restricted to outdoor crops only, pesticides approved for use on tomatoes, cucumbers, lettuce, chrysanthemum and mushrooms automatically assume use under protection.

TABLE 1. Examples of minor use approvals permitted by extrapolation.

Minor Use	Crops on which use is provisionally or fully approved	Additional special conditions
<u>Arable Crops</u>		
Poppy	Oilseed rape	Products hazardous to bees must not be applied during flowering
Mustard	Oilseed rape	
Evening primrose	Oilseed rape	
Borage (grown for oilseed)	Oilseed rape	
Gold of pleasure	Oilseed rape	
Grass seed crop	Wheat, barley, oats, rye, triticale, grass for grazing or fodder	
<u>Fruit Crops</u>		
Almond	Apple, cherry, plum	For herbicides used on the orchard floor only
Chestnut	Apple	
Hazlenut	Apple	
Walnut	Apple	
<u>Vegetable Crops</u>		
Beetroot	Carrot, radish	
Jerusalem artichoke	Potato, carrot, radish, turnip, swede	
Parsnip	Carrot	
Garlic	Bulb onion, salad onion	
Broccoli	Cauliflower, calabrese	
Edible-podded Peas (mange-tout, sugar snap)	Dwarf French beans, runner beans	
Kohl rabi	Celery, leek, cabbage	

### Specific Off-label Approval (SOLA)

Regrettably 'off-label' approval by extrapolation cannot cover all required uses, therefore, a second option exists known as specific off-label approval (SOLA). In such cases an individual safety assessment of the proposed use is conducted by PSD and safety must be assured before approval can be granted. In assessing such applications PSD access all data available to them rather than relying only on data submitted by the applicant.

In the past, approval for a specific off-label use has often been refused due to lack of relevant residues data but an interim provisional approval has been granted to allow the generation of additional confirmatory data. If these data are not submitted at the prescribed date then the provisional approval is automatically revoked. In some cases residues data generated elsewhere in northern Europe may be acceptable provided the rates and timings are comparable. Recently some SOLAs have been granted following support with German and French data.

When no further data are required full approval for the off-label use is granted for an unlimited period subject to the extant approval of the product.

## MANAGEMENT OF THE SYSTEM

### Identification of Need

With the increasing importance of SOLAs the process of identifying the need has become a wide ranging exercise with liaison between all interested parties. Initially, the identification of need comes from experienced growers who are seeking to treat a particular problem. The field experience of professional advisers and consultants generally gives leads on suitable pesticides where the control of particular problem needs recourse to a product without a relevant labelled use. The product/problem combination or candidate SOLA is then relayed by specific fresh produce associations or grower groups to the NFU, the Horticultural Development Council (HDC) or Horticultural Research International (HRI).

The position of older compounds due for local or European review is also giving cause for concern as the potential return to manufacturer's on investment for re-registering some of these products or their minor recommendations is poor. Hence many horticultural uses are already being lost and growers seek to retain these recommendations or 'transfer' them to other available competing products by means of SOLA's.

### Process of Approval

In order to gain approval for a SOLA, a limited data package has to be submitted to PSD. This consists of detailed specification of the product and formulation, details of use and dose, together with any specific restrictions to use, etc. It is generally apposite to relate the pattern of use to that commonly ascribed to the product in the field of use for which the product already has approval. The key component of this data package is the generation of appropriate residues data, which has to be conducted to both good laboratory practice (GLP) standards and recognised good agricultural practice (GAP). These data are generally required over two seasons and full details are contained in PSD's "Registration Handbook".

There is also a facility for SOLA approvals to be reviewed urgently by PSD under emergency status. Such applications must be supported by a written confirmation of emergency status from the Agricultural Development and Advisory Service (ADAS). Currently these emergency reviews are completed within 90 days.

### Data Generation

The generation of appropriate residues data for vegetable and soft fruit in the UK is conducted principally by HDC. In most instances the commissioned contractor is HRI and these two organisations work in concert with the NFU. Having identified the candidate SOLA, a financial justification must be agreed by the relevant commodity panel within HDC before the contractor commences work. The level of liaison between NFU, HRI, HDC and PSD is very close as deadlines are invariably tight when organising trials on a seasonal crop!

In the UK neither Government nor any other organisation is prepared to pay for the off-label registration costs, therefore, it has fallen to growers to do so using part of their levy funds paid to the HDC. The cost of supporting off-label approval submissions and upgrading from provisional to full has become expensive. In 1992 the HDC had to set aside £500,000 to cover the costs of the residue trials necessary to support the most important upgrades.

### Co-ordination

The overall co-ordination of SOLA's falls to the unique activity of the BCPC minor uses sub-committee. The sub-committee consists of representatives from PSD, manufacturers (British Agrochemicals Association), the Scottish Agricultural Colleges, the Fresh Produce Consortium, ADAS, agrochemical distributors (UK Agricultural Supply Trade Association), HDC, HRI and specific interest groups like the Timber Growers Association. The minutes of these quarterly meetings are consciously structured to provide all interested parties with a regular and comprehensive update on the progress of SOLA's, subject to appropriate commercial confidentiality. These minutes are subsequently widely distributed within the industry, covering interested members from organisations like the British Herb Trades Association, Campden Food and Drink Research Association, the Processors and Growers Research Organisation, Apple and Pear Research Council, Royal Horticultural Society, the Forestry Commission, the National Hops Association, etc.

As well as chairing the sub-committee the NFU is also responsible for maintaining a computer database of all current and past SOLAs and their status, linking the approval number and expiry date to the specified use and crops. This database facilitates the management of SOLAs where approval is only provisional and additional residues data are required for upgrading to fully approved status. In 1994, this database was moved to Campden Food and Drink Research Association's (CFDRA) on-line pesticide database. This has enabled a wider audience to access the database including advisers and consultants, agrochemical manufacturers, food processors, multiple retailers, etc. The database contains the details of more than 300 SOLAs involving 157 products and more than 1500 uses. Examples of specimen reports featuring Hostathion are given in Table 2.

TABLE 2. Specimen reports from the CFDRA/NFU off-label database

SOLAS available per crop		CFDRA pesticides database		3-6-94 page 21
<u>Crops</u>	<u>No.</u>	<u>Product Name</u>	<u>Ingredients</u>	<u>Expiry</u>
Artichokes	0422/92	Turbair Resmethrin Extra	resmethrin	28-2-96
	0592/92	Cyperkill 5	cypermethrin	31-5-96
	0614/92	Lindane 20	gamma HCH	30-6-96
	0692/92	Hostathion	triazophos	30-6-96
Artichokes, Protected	0019/93	Pynosect 30 Fog Soln.	pyrethins + resmethrin	unlimited
	0183/92	Turbair Resmethrin Extra	resmethrin	28-2-96
	0592/92	Cyperkill 5	cypermethrin	31-5-96

Crops approved per SOLA                      CFDRA pesticides database                      3-6-94 page 14  
(Products may also contain approval for protected crop; consult relevant notice)

<u>Product Name</u>	<u>No.</u>	<u>Expiry</u>	<u>Crops</u>
Hostathion	0629/92	30-6-96	Artichokes; Asparagus; Celery; Courgettes; Cucumbers; Fennel; Garlic; Cherkins; Green Beans; Leeks; Mange- tout Peas; Marrows; Navy Beans; Onions, General; Potato Crops; Protected Melons; Protected Pumpkins; Protected Squashes; Rhubarb; Runner Beans; Shallots; Soya Beans; Sugar Beet
Hy-TL	0601/92	Unlimited	Edible Podded Peas
Karamate N	0024/92	31-12-97	Grapes and Vines

SOLA Management report                      CFDRA pesticides database                      3-6-94 page 16

<u>No.</u>	<u>Product</u>	<u>Old. No.</u>	<u>Supplier</u>	<u>MAFF No.</u>	<u>Expiry</u>	<u>Submit</u>	<u>Holder</u>
0627/92	Reglone	0538/89	ICI Agro	04444	30-06-97	30-06-95	NFU
0628/92	Sapcron	0408/89	Ciba Geigy	01861	31-01-97	31-01-95	PHSI
0629/92	Hostathion	0425/89	Hoechst UK	01080	31-06-96	30-06-94	PHSI
0654/92	Apollo 50		Schering	03996	Unlimited		NFU
0655/92	Apollo 50		Schering	03996	30-06-96	30-06-94	NFU

#### Dissemination of Information to Growers

The dissemination of SOLA information is principally through the appropriate horticultural press, bulletins issued by HDC and professional advisory networks eg. ADAS.

Annually, SOLA information is published in the BCPC's 'UK Pesticide Guide'. It is a statutory requirement that growers must be in possession of the relevant 'notice of approval' before commencing treatment as specific information for the products safe use are contained therein. Copies of these notices are available to growers from regional NFU and ADAS offices.

## FUTURE CHALLENGES

The principle of 'minor use' authorisation has been embodied in the EC Directive 91/414. Article 9 makes provision for minor uses, ensuring that individual member states are able to grant extensions to grower groups in the field of application of authorised plant protection products in a similar manner as the current UK SOLA system. While the Directive is being incorporated into UK law, it has been decided that the UK can continue to authorise off-label use by extrapolation, but, once an active ingredient has been placed on Annex 1 of the Directive then specific authorisation for minor uses will have to be sought.

"Mutual recognition" a feature of the Directive, however, may soften the blow to growers because GLP studies with an Annex 1-listed active ingredient, conducted in one member state and evaluated in accordance with the Directive, must be accepted in another member state provided the agronomic, plant health and environmental conditions are comparable. Where comparability is confirmed, other member states are obliged to authorise the product concerned on receipt of the data, without undertaking any further evaluation of the data package. This does not mean that all products will automatically become registered throughout the EU; this would depend on the willingness of the manufacturer to request an initial registration in each member state because minor use off-label registrations can only be granted on products registered for other uses in that state.

In the long term as mutual recognition is extended to the evaluation of minor use authorisations, SOLAs could be granted for example, in the United Kingdom without the provision of any UK data. Therefore to obtain the maximum benefit from this facility growers and growers' groups throughout Europe should be liaising and harmonising their approach to data generation to GLP and GAP standards. Clearly, unnecessary and expensive duplication of effort could occur if different producer groups from different member states each applied for the same minor use authorisation for a specific chemical on a given crop.

British growers are understandably concerned that a substantial proportion of their levy funds is paying for residue trials whose data will be ultimately used to set EU MRLs. British growers can envisage the position where they have effectively funded trials which support pan-European use by mutual recognition and have thereby given their overseas competitors access to the same agrochemical product use at their expense. In the long term, the European farmers' unions' organisation Comité des Organisations Professionnelles Agricoles de l'EU (COPA) anticipates that growers in other member states will face a similar situation regarding funding and subsequent commercial sensitivity over mutual recognition by competitors. *Quid pro quo* exchanges are obviously more acceptable to all parties. The formal management, recording and subsequent dissemination of such information currently does not exist in Europe

To avoid such duplication BCPC and the NFU are seeking to establish a mechanism or secretariat to co-ordinate current and future minor use registrations within the EU, possibly hosted by COPA which is based in Brussels. The BCPC's minor uses sub-committee provides a model structure and refined *modus operandi* for such an operation. European Commission officials find the concept appealing but no tangible support has been forthcoming. The extension of the CFDR/NFU off-label database to cover minor uses approved in other member states is a very substantial but not impossible task. The infrastructure is in place, all that is required are resources to input the data. COPA is considering seeking EC financial assistance for such an undertaking.

## CONCLUSION

It is clear that although harmonisation of pesticide registration within Europe may offer benefit to growers it will be a long time before this materialises. Increasing registration costs resulting from demands for additional residue from environmental and efficacy data are causing manufacturers to reduce their label recommendations for minor crops. This will potentially place greater strain on the specific off-label approval system which is under developed in most member states.

It is a general feature of integrated crop management (ICM) that, as more specific crop protection agents are used in preference to broad spectrum and potentially less environmentally favourable products, minor secondary pests may rise to levels requiring treatment. Thus, ironically, although ICM *per se* has achieved reductions in pesticide use, it does require a wide choice of available products for growers. Alternative treatments for some of the withdrawn recommendations are available from more recently introduced products but in some cases the withdrawn uses are important to several minor crop sectors. European growers are therefore facing a conundrum; as they are increasingly successful in adopting ICM and reducing their use of crop protection agents, they face a reduction in the choice of materials available to them at a time when an expanded range is required.

European growers welcome Article 9 of the Authorisations Directive which makes provision for grower groups and other interested parties to apply for registration of minor uses. Under the principle of mutual recognition it is anticipated that regulatory authorities will accept data from other member states whose environmental and growing practices are similar. In time this should enable growers operating in similar environmental and economic conditions to have access to the same range of pesticides, provided manufacturers elect to register the product in each member state. If the manufacturer elects not to register the relevant product, then the convoluted legal issue of importing for personal use products from another member state arises. Legal access to minor off-label uses, however, will require careful orchestration of grower's activities in generating residues data and registering minor uses. Suitably extended BCPC's minor uses sub-committee provides a model for such liaison activities.

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MINOR USES IN PLANT PROTECTION -- SETTLEMENT PROPOSALS FOR PROBLEMS IN THE FEDERAL REPUBLIC OF GERMANY

W. PALLUTT

Federal Biological Research Centre for Agriculture and Forestry  
Department for Plant Protection Products and Application Techniques  
Biology Division  
Stahnsdorfer Damm 81, D-14532 Kleinmachnow, Germany

ABSTRACT

The introduction of authorization of plant protection product uses will aggravate already existing problems in guaranteeing necessary crop protection measures in minor crops (minor uses) in Germany, further weakening the competitiveness of farmers, gardeners and fruit growers within the European Union. The present paper gives an insight into the national activities started to mitigate the problems. We expect, however, only partial solutions. The desire is for internationally concerted action which surpasses, with regard to minor off-label uses, the requirements of EC Council Directive 91/414/EEC for the marketing of plant protection products. For this, the necessary framework has to be agreed.

CURRENT SITUATION

Germany is the only Member State in the European Union which has practiced a legal separation of the marketing and the application of plant protection products since authorization of such products was made statutory in 1968. According to the law, plant protection products can also be applied in fields other than those indicated in the marketing licence, provided the application meets the provisions of the Ordinance on Restrictions of the Use of Plant Protection Products, the Ordinance on Maximum Residue Limits, the principles of Good Agricultural Practice and the conditions tied to the authorization.

This regulation, though not being entirely satisfactory, has allowed German growers to carry out necessary crop protection measures in spite of a dramatic loss in authorized products (Table 1) and a declining number of label recommendations for minor uses.

A comparison of current authorizations in the Member States of the European Union (Table 2) illustrates Germany's difficult situation:

TABLE 1. Number of authorized plant protection products and of active ingredients contained in them in the Federal Republic of Germany.

Year	Products	Active ingredients
1986	1695	308
1987	1542	295
1988	1361	296
1989	958	216
1990	903	200
1991	926	217
1992	914	216
1993	801	218
1994	913	241

TABLE 2. Authorizations of plant protection products in the Member States of the European Union (according to an inquiry by the Standing Committee on Plant Protection, January 1994).

Member State	Products	Active ingredients
Belgium	1596	403
Denmark	1200	250
Germany	860	229
Greece	> 2000	530
Spain 4500	600	
France	7000	650
Ireland	2000	350
Italy 6500	400	
Luxemburg	650	230
Netherlands	1800	300
Portugal	700	200
United Kingdom	3088	332

The main causes of that development lie, above all, in the Plant Protection Act Amendment of 15 September 1986 which calls for extensive, and at the same time expensive, examinations for the protection of the natural balance. This has essentially increased the cost of authorization. Often, authorization was limited to one to three years. The agrochemical industry was no longer interested in products the patent protection of which ran out, or products of little turnover which mostly covered minor uses. Re-authorization or extension of uses was not sought for such products because of the additional testing requirements for environment data. This situation is aggravated by the worsening economic conditions for the chemical industry and dwindling acceptance of chemical plant protection by the public.

Limiting authorization of a plant protection product to the uses for which it is intended according to the label will undoubtedly worsen already existing problems in guaranteeing necessary control measures. In an analysis of the situation of authorizations in March 1993, the Federal Biological Research Centre of Agriculture and Forestry (BBA) found more than 900 off-label uses (Table 3) in Germany, while neighbouring countries had authorized products for most of these.

TABLE 3. Number of off-label uses in the Federal Republic of Germany  
(analysis of March 1993).

	Number of off-label uses	Priority uses	Recommendations to cover priority uses
Arable farming	75	68	172
Vegetable farming, medical and spice plants	527	98	287
Fruit growing	163	57	108
Hop	12	12	18
Viticulture	21	16	40
Ornamentals, nurseries	70	18	68
Forestry	46	46	44
	914	315	737

Off-label uses include pest-host combinations for which -- regardless of the size of the crop and the importance of the pest -- a practicable control method is not available, or which cannot be sufficiently controlled by authorized products' label recommendations. This includes minor uses, which include uses in minor crops and against occasionally occurring pests, authorization of which is not profitable for the agrochemical industry and therefore not sought, but is in the interest of society.

Under the current procedure to authorize products for minor uses, which was installed in Germany in the 1970-ies, 26 out of 91 applications for special product uses were authorized between 1975 and 1991, according to Meinert (1991). These numbers show that the problem of off-label uses cannot be solved shortly, even with strong support in terms of personnel and funds, but is calling for a long-term concept with close international cooperation.

## SETTLEMENT PROPOSALS IN THE FEDERAL REPUBLIC OF GERMANY

Covering off-label uses, and minor uses in particular, requires joint efforts by the legislature, the agrochemical industry, farming associations, the Laender, the Federal Government and its authorities.

Mutual recognition of authorizations within the European Union, as provided for by the Council Directive 91/414/EEC, is expected to greatly ease the problem of off-label uses, though not to fully settle it. Therefore, the Federal Government and the Laender are working on a scheme to secure integrated crop protection with particular regard to covering off-label uses. The following measures and activities are planned:

1. The coming amendment of the Plant Protection Act will stipulate the participation by the Federal Biological Research Centre for Agriculture and Forestry and by the Laender in covering off-label uses to give them a legal basis for more activities in this field.
2. Establishment of a working group under the responsibility of the Federal Ministry of Food, Agriculture and Forestry to shape a procedure to cover off-label uses, including unauthorized minor uses. The working group consists of representatives of the farming and agrochemical industries, the bodies for authorization and consent, and of the relevant departments of the Federal Ministry of Health and of the Federal Ministry of the Environment.
3. Establishment of a working group on minor uses (AK-LÜCK) by the Laender, which is coordinated by the BBA and acts as a liaison and mediation body between growers, the agrochemical industry and the authorities. Members of AK-LÜCK are the heads of the Crop Protection Services of the Laender and representatives of the vine and forest protection services.  
Details are dealt with in six sub-groups:
  - arable farming including tobacco,
  - vegetables, medical and spice plants
  - ornamentals, nurseries
  - fruit cropping, hop
  - viticulture
  - forestry
4. Appointment by the BBA and farming associations of officials in charge of gaps in control measures.

Sitting on the sub-groups are crop protection experts from the Laender. If necessary they involve representatives of the farming and agrochemical industries and of the authorities of authorization and consent. The main tasks of the Laender working group and its sub-groups are:

- coordinating works to cover off-label uses on national level
- recording off-label uses and differentiating minor uses
- proposing settlements
- collecting and developing documentation to assist an authorization or approval of minor uses
- passing proposals to extend product uses to authorization holders, or defining necessary research work

A BBA official in charge of minor uses coordinates the work of the sub-groups and the tasks arising for the BBA and the authorities of consent.

First results of the AK-LÜCK working group and its sub-groups include the listing of 315 off-label uses authorization of which has priority. On that basis, authorization holders and research institutes are invited to propose solutions to the problems. The working group also works out its own settlement proposals for such off-label uses. Namely, it has worked out recommendations for 56 products with 287 uses in vegetables and medical and spice plants, and forwarded them to authorization holders with the request to apply for authorization of the recommended uses.

Use data which are necessary to apply for authorizations are collected for a total of more than 700 product uses. The data include description of the product, its active ingredient, the pest to be controlled, the recommended application rate of the product, active ingredient and water, the maximum number of applications, and the intervals between applications and before harvest.

The response is now awaited of authorization holders to the recommendations for applying for label extensions.

Under current law, authorization of a minor use can only be granted on a supplementary application by the manufacturer or distributor of the authorized product, while the process is supported by official services by providing or developing, free of charge, required efficacy data and, where the conditions for Good Laboratory Practice are given, residue data. If requested, the authorization body grants exemption from payment of fees, or reduction of fees. Additional testing of the effects on the natural balance may be required in exceptional cases, for instance if products which have only been authorized for use in glasshouses are now to be used outdoors. The necessary testing is coordinated by the working group on minor uses in agreement with the authorization holders.

In future, if the authorization holder does not submit a supplementary application, the authorization procedure will be as outlined by Article 9 of the Council Directive 91/414/EEC, again being managed or assisted by the working group on minor uses and its sub-groups. Mostly, the greatest problem is the development of residue data. The establishment of maximum residue limits is governed by the same criteria both for major and minor uses, that is sufficient data have to be developed. Extrapolation, under certain conditions, of residue test results from one crop to another, which is scientifically sound and takes account of the conditions in the different countries, may ease the problem and is being discussed at expert level within the European Union, according to Hans (1993).

In the context of extrapolation of residue data, it is also advisable to review and possibly standardize uses with a view to including the greatest possible range of pest organisms. Pragmatic approaches, as proposed by Chapman (1993), should be continued. It would be an illusion to believe that authorizations or approvals can be achieved for all significant host-pest combinations.

## OUTLOOK

An "International Symposium on Minor Uses" hosted by the BBA in May 1993 agreed that minor uses pose a growing problem worldwide. To approach a settlement, efforts are

needed on both national and international level. They should be concentrated on the following aims:

1. A manufacturer applying for authorization of his product should include the broadest possible range of uses to avoid the emergence of off-label uses from the start. This requires a precise description of uses on the basis of groups of pest organisms and groups of crop plants. Within these groups, the pest organisms and crop plants which are representative for the whole group as to efficacy and residue behaviour, and those to which results can be extrapolated, have to be established. Existing cooperation in the European Union in the evaluation of residues and the harmonization of maximum residue limits should be intensified and extended to the field of efficacy evaluation (pest organisms and crops). This should also facilitate the mutual recognition of authorizations.
2. In the field of minor uses, and in particular in the authorization procedure, international exchange of results and close cooperation of the authorization bodies is desirable, and actually inevitable to settle the problem. One could conceive an agreed EU programme which would assign priority tasks to Member States depending on their particular interests. The results would be to the benefit of all Member States. The necessary legal framework and funding would have to be decided shortly. We propose to install an international working group on minor uses to work out proposals for an internationally agreed approach.
3. Not all problems can, nor should they, be dealt with by chemical products or methods. Therefore, resistance breeding and the development of non-chemical control and defence methods are to be boosted in particular in those areas where chemical methods do not provide a solution or where the rightful interests of protecting human and animal health and the environment force growers to look for alternatives.
4. Authorizing off-label uses is vital for the profitable growing of many types of crop and, thus, for broad-range and sustained agriculture. At the same time, a broad range of crops enables a great diversity of the agrarian eco-system, which is required from an ecological point of view.

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AUTHORIZATIONS FOR MINOR USES IN THE NETHERLANDS: PROBLEMS AND PROGRESS

LAETITIA A.M. KUIJPERS, H. DE HEER

Ministry of Agriculture, Nature Management and Fisheries, Plant Health Department, PO Box 20410, 2500 EK The Hague, The Netherlands

ABSTRACT

This paper sets out the difficulties in the Netherlands in placing and keeping authorizations for minor uses on the market. It gives potential solutions to the problems and concludes with a description of the ways in which the solutions are worked out.

INTRODUCTION

'Minor uses' refers to pesticides that are important to growers for reasons of crop protection but are otherwise insignificant or that are applied incidentally or on a limited scale only, as a result of which they are of slight economic interest to authorization holders.

For various reasons it is becoming harder to introduce pesticides for minor uses into the market and keep them there. Both in the Netherlands and abroad this problem becomes more pressing (CAST Task Force, 1992; BBA, 1993). Within the EC member states debate on the predicament of minor uses was prompted by the adoption of Council Directive 91/414/EEC concerning the placing of plant protection products on the market (EEC, 1991) and its Uniform Principles (EEC, 1994).

At a symposium in Braunschweig, Germany, the Netherlands called attention to the problems that have developed regarding minor uses of pesticides in the Netherlands (BBA, 1993). Since then a number of developments have aggravated the situation. This paper will discuss the problems minor uses are faced with in the Netherlands, potential solutions and the manner the Netherlands intends to address these problems.

AGRICULTURE IN THE NETHERLANDS

The Netherlands is characterized by varied and intensive types of agriculture. The largest part of agricultural land is devoted to arable farming. The main arable crops are potatoes, sugar beet, cereals and onions. Economically, arable farming is outstripped by horticulture. The main sectors are floriculture under glass, protected vegetable growing, bulb cultivation, arboriculture, fruit growing and seed production (Ministry of Agriculture, 1994). A total of 600 different crops are grown, which are susceptible to some 5,000 to 6,000 different pests and diseases (Ministry of Agriculture, 1991).

## PESTICIDES

### The Dutch market

Due to the wide variety of crops grown in the Netherlands there is much potential for minor uses. NEFYTO, the Dutch Association of Agrochemical Industries, regards the use of pesticides in potatoes, sugar beet, cereals, forage maize, grassland and hay pastures, stone fruits, fruit vegetables (cucumber, tomato, capsicum), spring-sown onions and ornamental crops (gladiolus, lily and tulip) as major, whereas pesticide use in all other crops is seen as minor (generally speaking, less than 400 to 500 ha). Besides pesticides used for minor crops, 'minor uses' includes pesticides having a very specific effect such as organic products, pheromones and products used as corrective agents in Integrated Pest Management.

Because of the high costs involved in developing new pesticides (about 260 million guilders) new products will initially be screened for crops found throughout the world - cereals, rice, cotton, soya, maize, vines, fruits. Only if the chances of authorization are reasonably fair, minor crop uses will be examined as well. Consequently, pesticides are hardly ever developed especially for the Dutch market. The industry and the growers will have to do with extensions of authorizations for specifically Dutch crops or authorizations developed for other countries. At present some 300 active ingredients and some 2,700 formulated products are registered in the Netherlands.

### The Dutch policy

The high level of productivity and intensive land use in Dutch agriculture result in high pesticide uses compared to the surrounding countries. Between 1985 and 1990 an average volume of 10 kg of active ingredients a year was used per hectare of farmed land. Various problems, both environmental and agricultural, urged the government to draw up a Multi-Year Crop Protection Plan, which states the objective to reduce pesticide use by half in 2000. In 1991 the Plan was adopted by the Second Chamber of Parliament and then implemented. In 1993 pesticide use was reduced by 40% (Ministry of Agriculture, 1994), mainly due to significant reductions in the use of soil disinfectants.

The Multi-Year Crop Protection Plan lays down that the standards for pesticide authorization shall be tightened to reduce the side-effects for the environment in particular. To this end the Pesticides Act, which governs the authorization of products in the Netherlands, was amended. On 1 November 1993 an amendment came into force enabling a specification of criteria for approving or rejecting a pesticide.



#### CAUSES OF THE PROBLEMS REGARDING MINOR USES

As authorizations for pesticides are revoked or no longer applied for, the number of pesticides available to minor uses in the Netherlands will dwindle. Several causes can be pointed out.

##### Tightened authorization standards

Stricter requirements of environmental protection and efficacy and residue research may result in the disappearance of pesticides for minor uses as:

- \* Tightened environmental standards may result in the withdrawal of products for more major uses, causing manufacturers to withdraw these products for smaller uses for commercial reasons.
- \* The authorizing organization establishes whether a product is efficacious and whether undesired residues will develop on the basis of research results. This is why it issues more and more authorizations for closely defined application areas instead of authorizations for a wide range, due to which fact minor uses may disappear.

##### Uneconomic cost-benefit ratios for authorization holders

Already it is not very profitable for manufacturers to develop pesticides specifically for minor uses and to keep them on the market because minor-use pesticides are often applied to capital-intensive crops and therefore involve high financial risks from the viewpoint of product liability. Moreover, costs will continue to increase because:

- \* As of October 1991 a fee of 1,500 guilders a year per authorization must be paid to renew the authorization of products. Manufacturers will therefore revoke any unprofitable authorizations, which generally are minor-use authorizations.
- \* As of February 1994 the application and assessment costs were increased to cover costs for the independent Pesticide Registration Board. The costs for a new authorization, for example, have been increased from 1,000 guilders to 25,000 guilders.

##### EC regulations

Council Directive 91/414/EEC concerning the placing of plant protection products on the market (EEC, 1991) and Directives 93/57/EEC and 93/58/EEC establishing MRLs for pesticide residues may result in fewer authorizations for minor uses because of increased research requirements.

Council Directive 91/414/EEC was adopted on 25 July 1991. Under Article 3 of this Directive products are authorized only if used in authorized applications that are specified on the labelling. Annex II and III to this Directive provide information to be submitted before a product can be evaluated. These dossier requirements in principle apply to all uses for which an authorization application has been filed. In most cases the

tests have to be carried out according to the Good Laboratory Practice. In July 1994, after lengthy discussions, the Council of the European Union established the so-called Uniform Principles (EEC, 1994). The Uniform Principles - Annex VI to Council Directive 91/414/EEC (EEC, 1991) - state criteria for assessing pesticides for authorization. These criteria concern agricultural, environmental, public health and grower health aspects. Each Member State has been given one year to implement the Uniform Principles in its national legislation. The specification which the Netherlands at present is completing, for the three criteria mentioned in the Multi-Year Crop Protection Plan (persistence, leaching and aquatic toxicity), have been adjusted for the text of the Uniform Principles. The other criteria mentioned in the Uniform Principles will also be worked out to have Annex VI implemented in time. The extent to which these criteria will result in lower numbers of minor-use authorizations remains to be seen. If they require many field tests, costs may increase and authorization for minor uses will not be applied for.

The EC is also working on the harmonization of residue levels (EEC, 1990) by setting Maximum Residue Limits (MRLs) for all pesticide uses (EEC, 1993). In particular regarding minor uses there are no research data available and therefore MRLs cannot be established. This will lead to fewer authorizations for minor food-crop uses.

#### SOLUTIONS

##### Potential solutions

The number of authorizations for minor uses will remain equal or increase only if the government and the industry co-operate in seeking solutions to the problem described before. International co-operation is imperative to exchange views and to avoid overlaps in planned minor-use research. There are several potential solutions:

- \* extrapolation: information obtained from research carried out on behalf of an authorization application for other products could be extrapolated (formulated products, from edible crops to non-edible crops and between similar edible crops) to reduce researches into the extension of authorization to minor uses. To this end extrapolation tables have to be re-evaluated and possibly extended.
- \* staged authorization: a staged decision tree could minimize the funds and the research required for a minor-use authorization application (rate adjustment/differentiation, less strict requirements regarding GLP in residue tests for minor uses). Article 9 of Council Directive 91/414/EEC (EEC, 1991) leaves some scope for bypassing dossier requirements regarding efficacy and phytotoxicity if the Member States think that extension of the field of application of an authorized product is in the public interest.
- \* government authorization research: field research by experimental stations could yield information to assess the efficacy of pesticides provided that the tests are carried out according to the prescribed

guidelines.

- \* sector organization authorization application: instead of manufacturers, sector organizations could apply for authorization. Costs and liability would then be with the sector organizations. Article 9 of Council Directive 91/414/EEC provides for this possibility.
- \* funding: authorization research for minor uses could be funded by agribusiness.
- \* establishment of a fund: agribusiness could set up a fund for the renewal of authorizations, to apply for new authorizations and to finance authorization research.

#### Approach

The Multi-Year Crop Protection Plan states that a wide range of pesticides should remain available in order to achieve the objectives. A wide range of products might diminish illegal pesticide use. In view of the large number of minor uses in the Netherlands this objective should be realized. In early 1994 the Netherlands organized a workshop on the minor-use issue which was attended by representatives of the government, pesticide manufacturers and agribusiness. After the workshop a project plan was developed to explore the possible solutions. The project was launched in August 1994 and consists of 4 sub-projects as follows:

<u>Sub-project</u>	<u>Leader</u>
Pilot projects	Agriculture Board
Bottlenecks in authorization	Plant Protection Service
Funding and execution of research	Agriculture Board
Authorization policy	Ministry of Agriculture

The sub-project 'Pilot projects' aims to make recommendations for the authorization of a few specific minor-use pesticides by carrying out a number of pilot projects. Pilots will be chosen from specific groups of substances (e.g. seed protectants, pheromones and organic products). The possibility of minimizing dossier requirements and to extrapolate information will be examined. The projects will start in August 1994 and end in August 1995.

The sub-project 'Bottlenecks in authorization' aims to analyse the actual bottlenecks in minor-use authorizations and to eliminate them. The initial phase of the project will inventory the lack of residue limits for edible crops. This phase started at the beginning of 1994 and will end in May 1995. The second phase will consist of a stock-taking of extensions of authorizations wished for by edible and ornamental crop producers. This phase will start in May 1995.

The sub-project 'Funding and execution of research' aims to analyse what funding potential is available for reducing the bottlenecks previously mentioned and for carrying out the required research. It started in April 1994.

The sub-project 'Authorization policy' aims to arrive at a staged authorization system regarding dossier requirements and rate structures based on extrapolations of the results of the other sub-projects. It started in August 1994.

#### CONCLUSIONS

Authorizations for minor uses are under strong pressure; this presents a major problem for the Netherlands. The causes have been recognized and analyzed. All the parties involved are willing to address the problem. Potential solutions are being worked out in several projects, which is to result in a differentiated system of authorization. International co-operation is imperative to exchange views and solutions and to avoid overlaps in research.

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## THE CHALLENGE OF MAINTAINING PESTICIDES FOR MINOR CROPS: A U.S. PERSPECTIVE

R.M. HOLLINGWORTH, S. MIYAZAKI

Pesticide Research Center, Michigan State University, East Lansing, MI 48824-1311, USA

## ABSTRACT

Maintaining the availability of pesticides for the production of minor crops is a common challenge in many countries with strong regulatory systems, but each situation has its own peculiarities and solutions. In the U.S., the problem has been evident for many years but has been greatly intensified by the requirement to reregister all pesticides first registered prior to November, 1984. The response to this intensified challenge has involved increased financial support for the IR-4 minor use registration program, new modes for the rapid dissemination of information about minor use pesticides, and the organization of minor crop growers to defend their interests. Whether these responses will prove adequate to the challenge remains to be seen, but they depend absolutely on communication and collaboration between government agencies, minor crop growers, the agrochemical industry and the network of agricultural research and extension specialists in academia. Several actions are suggested that would further alleviate this formidable threat to minor crop agriculture. In particular, it is proposed that residue data and tolerances already on file could be used to derive tolerances for the same active ingredient in minor crops without appreciable risk to the consumer.

## INTRODUCTION

The first problem in discussing the issue of minor crop pesticides arises in determining what constitutes a "minor" crop. This may be defined by a limited acreage of production or by the value of the crop, but in the context of the availability of pesticides, the best functional definition is that a minor crop is one for which there generally is insufficient incentive for the agrochemical industry to support or continue pesticide registrations. On this basis, probably the only "major" crops in the U.S. are maize, cotton, soybeans and wheat. The contrast between the 72 million acres devoted to maize and the 8 million acres involved in all minor crop production defines the problem. However, even these major crops have some associated minor pesticide needs in which low volume pesticide use is necessary to control occasional or local pests. The growing challenge of ensuring pesticide availability for all these situations therefore is better termed a "minor use" problem.

The value of minor crops in the U. S. is extremely high and belies the "minor" epithet. Some examples for 1987 are provided in Table 1. Minor crops constitute the major crop products of several of the largest agricultural states.

TABLE 1. Value of minor crops in several states in the U. S.

State	Value (x \$million)	Percent of Total Crop Receipts
All states	23,807	40
California	7,358	79
Florida	3,261	98
Hawaii	498	100
Michigan	641	50
North Carolina	1,057	74
Washington	1,117	66

Data from USDA (1991).

Because their high value is distributed over many crops, the barriers to pursuing pesticide registrations for any but the most valuable of these crops are considerable and growing. These barriers are primarily economic and include such factors as the cost of performing the requisite studies to obtain minor use clearances and the fees associated with establishing and maintaining each registration. The considerable financial liability inherent in marketing pesticides for use on low volume but high value crops can be a further disincentive. In addition there are logistical problems for registrants in organizing, conducting and reporting the very large number of studies mandated by the 1997 reregistration deadline and minor crop registrations necessarily receive low priority. Regulatory barriers arise because adding a large number of minor uses for a widely-used pesticide may cause the acceptable daily intake (ADI; RfD as used by USEPA) to be exceeded. Societal pressures to reduce the use of pesticides on fruit and vegetable crops have an indirect but powerful and growing influence on minor crop registrations. Concern over residues, particularly in the diets of infants and children, is leading to new, more complex approaches to setting tolerances (Maximum Residue Levels; MRLs) and the calculation of dietary risk on the part of USEPA. State and federal funding for research on pesticides has declined, research groups have been disbanded, and fewer scientists work in this area despite the evident need and the general lack of effective alternatives to pesticides (CAST, 1992; Gianessi, 1993).

#### IMPACT OF FIFRA 88 REREGISTRATION REQUIREMENTS

The requirement to reregister all pesticides first registered before Nov. 1984 was established by a 1988 amendment (FIFRA 88) to the Federal Insecticide, Fungicide and Rodenticide Act that vests pesticide regulatory authority in the United States Environmental Protection Agency (USEPA). A recent report from the agency (USEPA, 1994) chronicles the continuing impact of this requirement on pesticide registration in the U.S.

At the start of reregistration in 1988, 1138 active ingredients (AIs) representing about 45,000 formulated products were eligible for reregistration. Of these, 548 AIs representing about 22,000 products were not supported by their registrant. Fortunately,

many of these were compounds with little or no recent production and the impact for growers was not proportional to the prodigious loss of AIs and products. Most of the remaining supported AIs still are awaiting data submission and review, but by early 1994, Registration Eligibility Decisions (REDs) had been issued for approximately 13% of these cases.

The status of the first 38 REDs issued by January, 1994 involving 57 AIs and 2271 products is reviewed in Table 2.

TABLE 2. The impact of FIFRA 88 registration requirements on pesticide registration in the U.S. as indicated by the results of the first 38 Registration Eligibility Decisions issued by USEPA.

	Number of Products	Percent of Total
Reregistered	302	13.3
Amended registration	11	0.6
Suspended	474	20.9
Canceled	706	31.1
Status undecided	678	34.2

Data from USEPA (1994).

Only 14% of these REDs have so far resulted in product reregistration and over 50% of the products have been suspended (generally due to failure to provide adequate data) or canceled. It is not easy to identify the impact on minor crops from these statistics, which include data for substances such as germicides that are not traditionally considered pesticides. However, it is clear that after this first round of reregistration is completed, very many conventional pesticide products will have disappeared and the impact on minor crop growers will be considerable and disproportionately high. It has been estimated by the IR-4 program (described below) that ultimately as many as 1000 of the approximately 4000 minor crop registrations active in 1988 will be lost during reregistration, but the real number is, as yet, unknowable and could be higher.

## RESPONSES TO THE MINOR USE CHALLENGE

### Recognition and analysis of the problem

The potentially negative impact of reregistration on minor crop agriculture has been widely recognized in the U.S. e.g. a draft report was produced as a result of a White House Conference (Evans, 1992), the Council on Agricultural Science and Technology published a report on this topic (CAST, 1992), and further analysis of the problem and its likely consequences has been made by Gianessi and Puffer (1992). In 1993, the National Association of State Departments of Agriculture released policy statements regarding the

need for continued availability of pesticides for minor crops and supporting proposed amendments to FIFRA to provide relief and incentives for minor crop registrations.

The critical need for broad communication of the status of this rapidly changing field was soon recognized. The growers potentially affected by reregistration decisions are far-flung and the time frame for developing an organized response to the loss of critical pesticides is short. The establishment of a Reregistration Notification Network by the USDA provides regular updates on reregistration actions to a broad constituency and acts as an early warning device for proposed actions that may impact minor crop producers. Additionally, the National Agricultural Chemical Association formed a Minor Use Committee to assist in informing interested parties about decisions made on voluntary cancellations by their members. Within the federal government, several inter- and intra-agency groups have been formed such as the Interagency Reregistration Task Force and the USDA Minor Crop Working Group which enhance communication and coordinate activities.

A further key response has been the organization of minor crop growers to ensure that their interests are fully represented and to aid in finding appropriate solutions to the unanticipated impact of FIFRA 88. These growers have established a national organization, the Minor Crop Farmer's Alliance. The Alliance has drafted legislation intended to facilitate the retention of current minor use registrations and to encourage the development of new ones through data waivers, conditional registrations, resurrection of canceled registrations, and extension of time frames for the development of minor use data. These concepts have received support from the USEPA and have appeared in several bills to revise FIFRA which are now under consideration by the U.S. Congress. However, with the long-continuing gridlock over pesticide regulatory reform, it is unclear when such modifications to FIFRA may be enacted. Unfortunately, although recognition of, and concern over, the minor use problem is widespread, it has not yet resulted in effective policy development at the legislative level.

The USEPA has repeatedly emphasized its concern over the probable loss of minor use registrations and works closely with USDA and the IR-4 program to develop solutions. They have furnished a degree of regulatory relief for minor crops by providing data and fee waivers, shown flexibility in enforcing time lines for data submission, and have provided other inducements to encourage minor crop registrations. The USEPA has also encouraged expanded crop groupings as a means to encourage registrants to add new minor uses. In this case, residue data obtained from a representative group of crops can be automatically extended to provide tolerances for biologically similar crops.

Because of concern regarding impacts on their agriculture and economies, some states dependent on minor crops have also addressed minor crop pesticide issues. For example, Michigan State University has developed an in-depth analysis of minor crop pest management challenges in the state in order to focus its resources on areas of critical need for Michigan growers (Vergot, 1994).



### The IR-4 program

This program (IR-4 stands for Interregional Research Project No. 4) was organized in 1963 specifically to address the problem of minor use registrations on food and feed crops. In 1977, the project was expanded to include pesticide clearances for nursery and ornamental crops, forest seedlings and turfgrass. A further expansion of objectives in 1982 added the registration of biological pesticides (such as pheromones and microbial agents) to IR-4's mission. The operations of IR-4 have been reviewed in detail by Guest (1993).

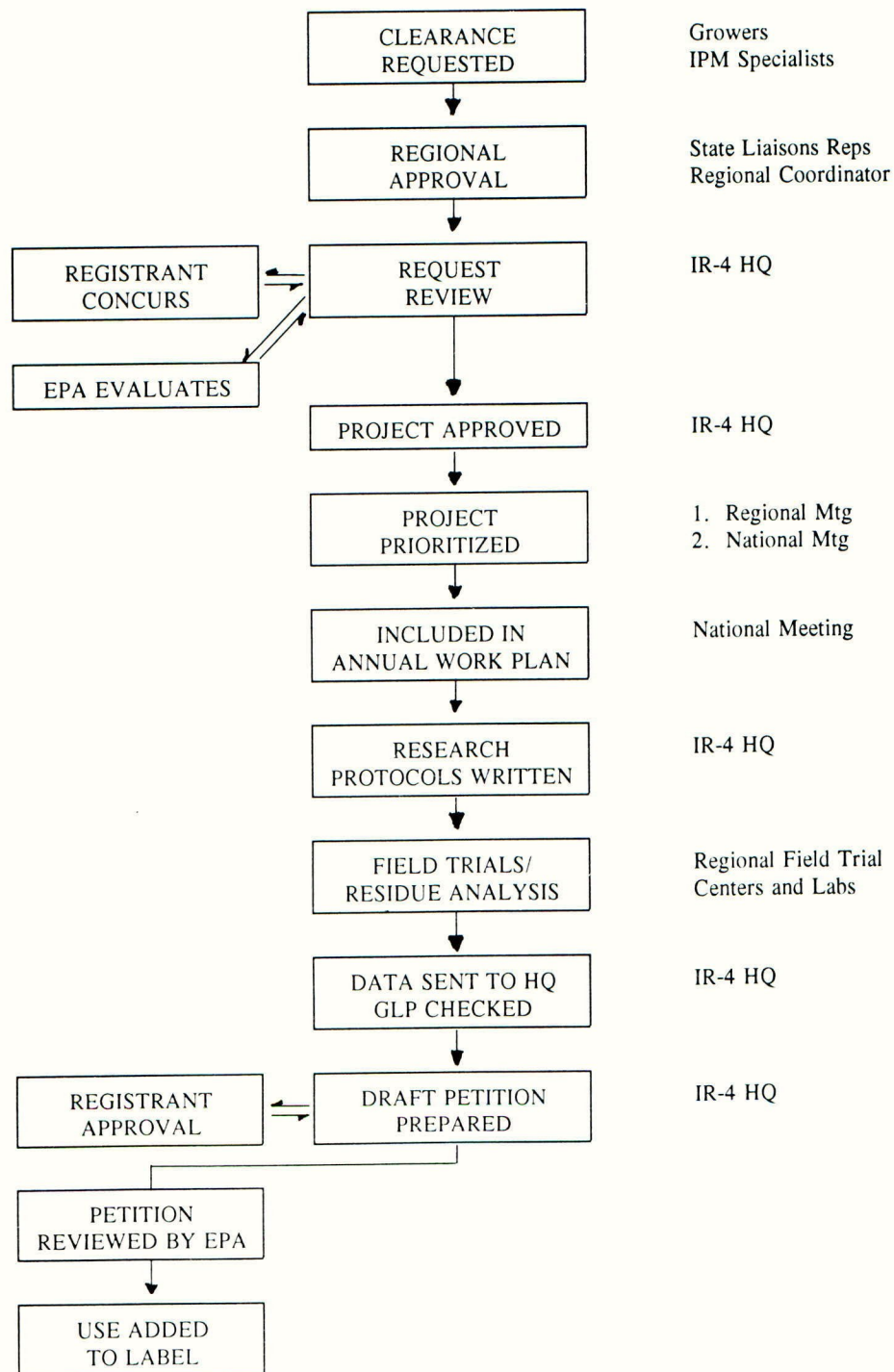
Throughout its lifetime, IR-4 has been funded by the United States Department of Agriculture (USDA). In 1994 the project received a total of about \$9 million for its programs from USDA with additional support from growers' groups bringing the total close to \$10 million. The program consists of three major elements: The IR-4 Headquarters at Rutgers University, several regional centers located at universities and USDA facilities, and IR-4 liaison representatives from land grant universities in each state.

A typical flow chart for an IR-4 project is shown in Fig. 1. The need for a minor use project is identified locally by farmers, growers' organizations, or pest management experts and is transmitted through state liaison representatives to the regional offices. After initial verification of need, these requests are forwarded to Headquarters for entry on the master list. Before the project becomes active it is cleared through the manufacturer, who must express a willingness to include the new use on the label, and through EPA to assure that there are no foreseeable impediments to the registration. The collected requests are prioritized annually by pest management specialists and growers' groups, first regionally and then at a national meeting. A final national meeting is held to coordinate and distribute the highest priority projects among the regional field trial sites and residue laboratories. After conduct of the project, the data are checked for completeness and compliance with Good Laboratory Practice (GLP) at the regional centers and then transmitted to headquarters for further assessment and petition preparation. After review and approval by the pesticide manufacturer, the data are submitted to EPA for approval of the proposed registration. The project is successfully terminated when the new use is added to the label by the manufacturer.

Over the 30 years of its existence, IR-4 has developed data to support 4222 food use clearances and 3150 registrations for uses on ornamentals. This represents 50% of all minor crop pesticide clearances for food uses and 80% of all clearances for ornamentals. Effort on biological pesticides has been more limited, but 15 of these projects have been funded. Clearances have been obtained for pesticides on a total of about 230 different food crops. In 1994, research has been planned on 316 food use projects, many involving field trials at multiple sites across the U. S. Ornamental projects will number 380.

It would be fair to say that without this program, minor crop agriculture would be very different and much less successful in the U.S. IR-4 remains the primary means of addressing pesticide clearances for minor uses. Its success ultimately depends on the cooperation and common vision of a broad range of organizations. Manufacturers must agree to accept the proposed minor use and often provide assistance with field trials and residue analysis. Growers provide input regarding their needs, financial assistance, and can help to make the need for minor crop pesticide registrations clear to their political

Fig. 1. Progress of a minor use clearance through the IR-4 system



representatives. EPA is supportive in many ways from the initial review of the feasibility of proposed projects to waivers of fees for IR-4 projects. To facilitate this close relationship, an EPA chemist is permanently located at IR-4 Headquarters and a scientist within EPA is assigned to act as a liaison with IR-4. Within USDA, internal cooperation between different agencies has been notable. Finally, hundreds of scientists around the U.S. act as IR-4 cooperators in identifying and prioritizing needs and in conducting field trials. The IR-4 program absolutely depends on the existing network of agricultural scientists at state and federal experiment stations and in the Cooperative Extension Service. It is estimated that by accessing this network, IR-4 receives three dollars of added support for every dollar it invests.

In 1990, IR-4 developed a detailed strategy to respond to the minor crop challenge and in 1991 and 1994 the IR-4 budget was increased considerably in recognition of the increased severity and demands of this challenge. As a result of the expanded funding, IR-4 has established a chain of field research centers to centralize field trials under GLP, and has expanded its analytical laboratory capabilities. A Commodity Liaison Committee has been developed to encourage closer linkages to and support from minor crop producers. In the belief that biological pesticides have a bright future in pest management, IR-4 has also committed to set aside a significant portion of this increased funding to further develop its biopesticide registration program and has recently appointed a coordinator for this segment of its activities.

Biopesticides provide a novel situation for minor crop registrations. They tend to have a narrow spectrum of action that, in combination with minor crop applications, often provides insufficient incentive for commercial development by major agrochemical companies. In contrast to chemical pesticides, there will frequently be no primary data package already developed to support major uses upon which an organization such as IR-4 can depend in adding minor uses. Thus, although the total costs of registration of a biopesticide may be quite modest compared to those of a typical chemical pesticide, the entire cost of providing safety data must be born by the minor crop registrant. For this reason, the strategy of IR-4 here is different from that used for conventional pesticides. In order to develop clearances it is necessary for the project to fund studies at an earlier stage of development. Consequently IR-4 has funded late stage efficacy field trials for promising projects, and studies to provide safety data at least through Tier I testing. This can entail much higher costs than for a typical minor use pesticide clearance. On the other hand the recent registration of a pseudomonad to control bacterial blotch in mushroom production was obtained at minimal cost by drawing on existing literature to support the petition.

## FUTURE CHALLENGES

Though the efforts reviewed above have been effective in providing substantial aid to minor crop growers, severe challenges remain. IR-4 has never had the resources to meet all the legitimate needs of minor crop growers and a backlog of nearly 1500 researchable projects exists within the system. New requests are added at the rate of about 200 food use projects per year, but with current resources, 150 or fewer clearance requests can be developed annually for submission to EPA. After recent increases, funding for the IR-4 program has been decreased by 10% in the 1995 federal budget and now represents only

one third of the \$24 million per year that IR-4 estimates will be necessary to meet the identified needs of minor crop food production.

The need for added funding is a reflection of the increasing expense of conducting food use studies. A recent evaluation by IR-4 concluded that the costs of GLP compliance now constitute about 48% of the expense of conducting a field trial and 29% of the residue analytical phase of the project. There has been a tendency for USEPA to request increasing numbers of field trials per project which increases costs. Revised guidelines defining the location and number of field trials for studies leading to national registrations on a given crop have recently been issued. While this will increase flexibility in deciding where trials may be conducted within a given region in the U.S., the average number of field trials per project will increase by 50-100%.

A further uncertainty is the final impact of reregistration on minor uses. Unfavorable results of the new safety studies being conducted with many of the older active ingredients may mean their loss in part or in whole for minor crop protection. Also, it is probable that further suspensions and cancellations of minor uses will occur due to difficulties in meeting the firm 1997 deadline for the submission of reregistration studies. Because it necessarily takes several years to complete a food use project, it may be impossible for the IR-4 program to effectively address any crises arising from losses occurring at this deadline.

It is clear that henceforth reregistration is likely to be an ongoing, cyclical process. Renewed stress will be placed on existing minor uses at each turn of the cycle, and long range solutions to the problem are essential. Changes in pesticide regulation being considered by USEPA also include a new requirement to develop multiple MRLs that define legal residues in produce at different stages between the farm and the table. If instituted, this too may increase the cost of obtaining minor crop registrations.

## SOME SOLUTIONS

There is no simple panacea that will permanently solve the minor use conundrum. However, a few relatively simple actions would largely defuse the problem. These include:

- \* Passage of legislative relief to favor minor crop registrations.
- \* Increased and stable funding for the IR-4 program.
- \* Development by USDA of an enhanced focus on minor crops within an overall comprehensive pesticide strategy. This must stress realistic expectations and an orderly transition in reducing pesticide use.
- \* Development and adequate funding of a program to discover and register safer alternatives to current pesticides and to integrate these alternatives into minor crop pest management programs so that reliance on higher risk pesticides is reduced.

A final thought relates to the current data requirements for truly minor crop registrations. The requirement for full scale supervised field trials and residue determinations for crops which constitute a very minor part of the human diet should be

reconsidered. For example, about 55% of the minor food crops individually compose less than 0.01% of the diet of either the general population or non-nursing infants. Considerable uncertainties and approximations already attend each stage of the development of an MRL including the estimation of anticipated residue levels from field trials, the magnitude of dietary intakes of pesticides, and the definition of the ADI's and/or cancer potencies representing possible health effects. The very low dietary intake of many minor crops means that from the viewpoint of consumer protection, high accuracy in the setting of tolerances is unnecessary. Even rather inaccurate estimates of residues from supervised field trials in these cases should not lead to significantly altered total dietary risk estimates for the AI. This is recognized implicitly in the new USEPA guidance document on the number and location of field trials in which some reduction of the number of trials is accepted for crops representing less than 0.02% of the human diet. But this does not go far enough. The logical extension of this concept suggests that it is not necessary to conduct field trials at all in some cases. As discussed in detail by Bates (1990), because of extensive existing data on residue levels and dissipation rates derived from previous supervised field trials, the extrapolation of residue data between crops should be possible in many cases. This "extrapolated residue" approach for crops having very low dietary intakes should be an option available to registrants if existing residue data from other crops are available. This further, relatively minor, approximation in tolerance setting would eliminate the need for many of the field trials and residue studies currently required of IR-4 and would allow the program to focus its limited resources on developing data for crops with the highest dietary intakes.

Whether it involves these, or other remedies, action to safeguard and maintain minor crop production in the U.S. is vital. We should note carefully the conclusion of the White House draft report on minor use pesticides (Evans, 1992): "Unless it becomes public policy to assure the availability of safe minor-use pesticides there will be unnecessary hardship for U.S. producers and consumers. Failure to adopt reasonable policies will be devastating for individual growers and adversely impact national and regional economies."

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