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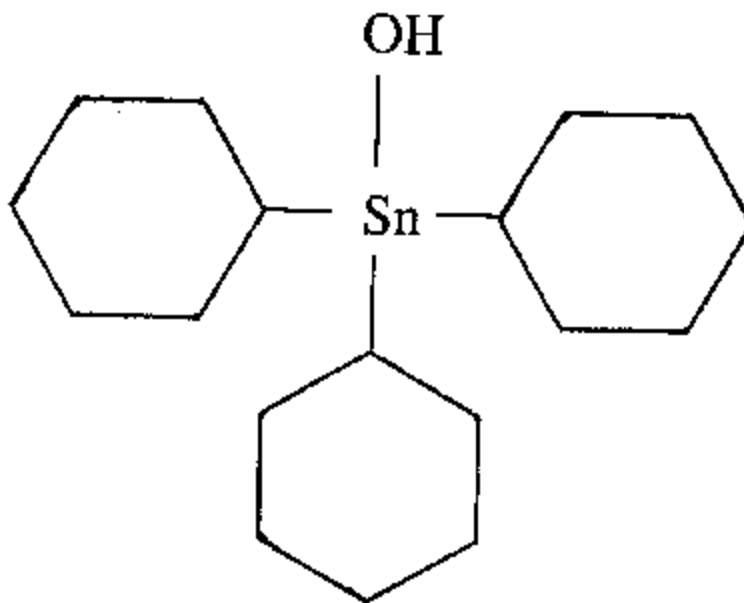
Direction générale,
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Decision Document

E89-01

CYHEXATIN



Miticide

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FOREWORD

CYHEXATIN

As part of the ongoing efforts to provide background information to explain regulatory decisions, a Decision Document has been prepared on cyhexatin. This document reflects input from Agriculture Canada specialists and key interdepartmental advisors. Recognizing that the manufacturer has voluntarily withdrawn cyhexatin from the market and Health and Welfare Canada has revoked the maximum residue limits for the product, Agriculture Canada has cancelled the registration of cyhexatin.

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June 1989

CYHEXATIN (PLICTRAN) DECISION DOCUMENT

1. SUMMARY

The purpose of this document is to summarize information on the risks and benefits of cyhexatin miticide and to announce formal regulatory action.

The benefits of cyhexatin have been assessed by Agriculture Canada while the risks have been characterized by Health and Welfare Canada. The results of these reviews serve as the basis for a recommended action/regulatory position.

Based on this review, and recognizing that the manufacturer has voluntarily withdrawn the product from the market and that Health and Welfare Canada has revoked the maximum residue limits (MRL's) for the product, Agriculture Canada has cancelled the registration of cyhexatin.

2. BACKGROUND

Cyhexatin is the active ingredient in Plictran, a miticide which has been used on fruit crops in Canada since 1971 and worldwide on fruit and nut crops for many years without any reported adverse effects on humans or the environment. MRL's of 0.3 to 4.0 parts per million (ppm) were established under the Food and Drug Regulations to cover residues on almonds, apples, citrus fruit, peaches, pears, plums, strawberries and walnuts. These MRL's were recently revoked by Health and Welfare Canada.

As part of an Environmental Protection Agency (EPA) "Data Call-In" requirement on cyhexatin in the United States, Dow Chemical undertook teratology studies in rats and rabbits. These new oral teratology studies indicated that cyhexatin was teratogenic. Dow Chemical subsequently withdrew cyhexatin from sale in Canada and worldwide in August 1987. In early October 1987, Dow officially requested that Agriculture Canada discontinue the current registration of Plictran 50W Miticide, which contains cyhexatin.

3. HEALTH AND WELFARE ASSESSMENT

3.1 Toxicology

3.1.1 Acute Toxicity

The acute oral Lethal Dose 50% (LD₅₀) studies in the rat demonstrated a moderate order of toxicity with values ranging from 85 to 820 mg/kg body weight (bw) depending upon the strain and vehicle employed. Additional studies with the mouse, rabbit, guinea pig and chicken indicated a slight or low acute oral toxicity (500-1150\mg/kg bw).

3.1.2 Short-Term Toxicity

A 90-day dietary feeding study in the Wistar rat reported a No Observable Adverse Effect Level (NOAEL) at the lowest dose of 25 ppm, equivalent to approx. 1.5 mg/kg bw. The only effect noted at 25 ppm was a non-significant decreased body weight gain (females) when compared with a biologically significant weight loss at the next dose of 50 ppm (both sexes). Treatment related changes at the higher dose levels of 400 and 800 ppm were associated significant mortality and histopathologically- revealed bile duct inflammation and hypertrophy.

[Further sub-acute studies conducted in the rat under conditions of dietary exposure for up to 15 and 16 weeks duration, respectively, were judged to be unacceptable].

Dietary administration of cyhexatin to mice (ICR) for 90 days revealed a No Observable Effect Level (NOEL) set at the low dose of 25 ppm (equivalent to approximately 3.75 mg/kg bw) based on the observation of decreased body weight gain at the next higher level of 50 ppm.

For the purpose of determining the respective copper levels in tissue (liver), blood and urine - a 90 day dietary feeding study was undertaken in the beagle dog. The NOEL was assigned to the highest dose of 3 mg/kg bw based on the absence of any adverse or treatment-related effects on copper levels or other clinical parameters investigated.

3.1.3 Chronic/Long Term Toxicity

A 2-year chronic feeding study with Long Evans rats revealed a NOAEL of 6 mg/kg bw as a result of a slight non-significant effect on decreased body weights at this level when compared with a significantly decreased weight gain at the next higher level of 12 mg/kg bw. With respect to the evaluation of carcinogenic potential, the present study would serve as a carcinogenesis screen (negative) due primarily to the limited tissue and gross lesion histopathology.

[A second 2-year chronic rat study has apparently been evaluated by EPA. This study, which was not submitted to or evaluated by Food Directorate (FD), Health and Welfare Canada, indicated a NOEL for in-life parameters of <1 mg/kg bw due to an increased incidence of focal bile duct hyperplasia in both sexes at all dose levels. There was no evidence of any treatment-related neoplastic activity up to or at the highest dose level of 6 mg/kg bw. The EPA has stated that this study was not acceptable as a chronic or combined study due to the absence of clinical laboratory assessment, e.g., hematology, blood chemistry].

[FAO/WHO documentation (1981) with reference to the 2-year chronic rat (mentioned above): In an attempt to elucidate the significance of the incidence of focal bile duct hyperplasia noted in the rats, all of the prepared liver slides were re-evaluated microscopically by an independent pathologist Dr. van der Heijden. He has been quoted as stating that focal bile duct hyperplasia is a common finding in livers of aging rats of various strains and is of little pathological significance. However, it appears likely that some environmental factor, e.g., contaminants of food or deficiency, is responsible for the frequently found high incidence. The occurrence of focal bile duct hyperplasia in control and treated rats is considered "spontaneous" and generally not associated with a particular condition of treatment. There is no association between focal bile duct hyperplasia and tumours of liver or bile ducts and no evidence to relate focal bile duct hyperplasia to any preneoplastic condition].

[Results of a 2-year dietary oncogenicity study in the B₆C₃F₁ mouse were reportedly evaluated by EPA (study report not submitted to or evaluated by FD). The NOEL was determined to be 3 mg/kg bw with no evidence of an oncogenic effect at levels of up to 6 mg/kg bw].

Two-year dietary administration of cyhexatin to beagle dogs failed to indicate a NOEL, the lowest dose of 3 mg/kg bw resulting in a slight tendency toward anemia, decreased urinary copper and grossly observed intestinal discoloration. Furthermore, the acceptability of the study was considered doubtful in light of the significant variability in the ages of the dogs used. A supplementary dietary level of 0.75 mg/kg was introduced with a concomitant control approximately 4 months following the start of the primary study. A NOAEL of 0.75 mg/kg bw or more accurately, the actual intake of 0.69 mg/kg bw was assigned with only one treated male presenting at the 2-year term with intestinal discoloration.

3.1.4 Mutagenicity

No mutagenicity studies have been submitted to or evaluated by FD. [EPA evaluation of the relevant genotoxicity assays has failed to uncover any mutagenic potential for point mutation, chromosome aberrations or DNA repair activity].

3.1.5 Teratogenicity

In a recent study, cyhexatin was found to be teratogenic in the New Zealand White Rabbit resulting in a NOEL of 1.0 mg/kg bw as evidenced by an increased incidence of hydrocephaly at the high dose of 3.0 mg/kg bw. The NOEL for embryo/ fetotoxicity was established to be 0.5 mg/kg bw based on the increased incidence of post implantation loss at the next dose level of 1.0 mg/kg bw. The highest dose revealed a greater frequency of abortions and only a slight effect on maternal body weight gain.

Cyhexatin when administered to Sprague-Dawley rats on days 6 through 15 of gestation failed to reveal any signs of maternal toxicity. An increased number of malformations (i.e., tail malformations, microphthalmia) was observed at the high dose of 5 mg/kg bw. The isolated malformations and/or anomalies observed at the mid-1.0 mg/kg and low dose-0.5 mg/kg bw groups confounded an unequivocal assessment; however, the questionable significance of these observations suggested that a NOAEL of 1.0 mg/kg bw could be acceptable for the rat.

3.1.6 Reproduction

A multi-generation study in Long Evans rats with cyhexatin* indicated a NOEL of 12.5 ppm, equivalent to approximately 0.75 mg/kg bw. The only effect noted at the next higher dietary level of 50 ppm was a slight depression in weaning weight and in the parental weights in several generations. A teratological component revealed no treatment-related abnormalities. (A replacement reproduction study in the Fischer 344 rat was anticipated in 1988).

Treatment with cyhexatin* for reproductive/teratological assessment in the New Zealand White Rabbit failed to elicit any adverse maternal effects at the highest dose of 3 mg/kg bw. The NOAEL, in the absence of any reproductive effects would be set at ≥ 3 mg/kg bw. This study has been superceded by the teratology study discussed above and is mentioned only for the sake of completeness.

3.1.7 Metabolism

Metabolic studies with rats and dogs fed cyhexatin for up to 2 years indicated equilibrium levels of tin (Sn) in the tissues which were comparable between sexes and which were attained only after several months to one year. The highest distribution and accumulation of Sn appeared in the liver and kidney with the lowest concentrations identified in the fat and muscle. Sn levels were slowly eliminated from the tissues upon withdrawal of treated diets with little long-term storage of inorganic Sn.

An experiment with Wistar rats receiving a single oral dose of 25 mg/kg bw suggested limited intestinal absorption with approximately 98% of the dose recovered in the feces and 2% in the urine within 10 days of administration.

* Cyhexatin Risk Characterization Document, Department of Food and Agriculture, State of California, states that the study was conducted with a wettable powder formulation of unknown purity.

3.1.8 Summary of the Toxicity Data

Review of the presently available toxicity data has revealed that the previously assigned acceptable daily intake (ADI) of 0.0069 mg/kg/day (based on the NOEL of 0.69 mg/kg from the 2-year dog study) requires revision. Since cyhexatin (tricyclohexyltin hydroxide) was found to be teratogenic in both the rat and rabbit, a 1000-fold safety factor may be recommended based on a NOEL of 1.0 mg/kg bw (for both rat and rabbit). The resulting ADI of 0.001 mg/kg bw would also provide a 500-fold safety margin with respect to the embryofetotoxicity NOEL of 0.5 mg/kg bw which was based on an increased incidence of post implantation losses at 1.0 mg/kg bw in the rabbit.

The margins of safety with regard to other effects on intestinal discoloration in the dog (2-year study: NOAEL = 0.69 mg/kg bw) would be almost 700-fold and with respect to the reported focal bile duct hyperplasia in the rat (2-year study: assuming a Lowest Observed Effect Level (LOEL) = 1.0 mg/kg bw) up to 1000-fold.

3.2 Food Exposure

Presently established MRL's result in a theoretical daily intake of 0.004-0.008 mg/kg, well in excess of the revised ADI. If the MRL's for cyhexatin were revoked, the general regulation B.15.002(1) would apply, (i.e., 0.1 ppm limit). At this level the theoretical daily intake would be 0.0003 mg/kg/day which is approximately one-third of the new ADI (0.001 mg/kg bw/day).

3.3 Occupational Exposure

An attempt was made to estimate occupational exposure for the major uses of cyhexatin (Plictran): orchard, ground boom (strawberries) and greenhouse/ ornamentals. Orchard crops and hops are treated intensively and hence the farmers have the potential for high exposure.

3.3.1 Orchard Use (Airblast Equipment)

The registrant submitted two exposure studies in which workers using cyhexatin in orchards were monitored. One of the studies was conducted in Japan and involved an application method that is very different from methods used in Canada; it was therefore not used to estimate exposure to the Canadian worker. The other study, although limited by study design, was used for estimating exposure to mixer/ loader/applicators (M/L/A) as well as to harvesters. The limitations of the study include:

- a) A small number of workers (4 M/L/A's and 2 harvesters) were monitored for a short period of time (about 30-60 min.); this cannot be expected to indicate the range of exposures encountered by typical workers during a normal work day.
- b) The limit of detection for patch samples was very high.
- c) Exposure was not monitored during clean-up or repair.
- d) It does not appear that field recoveries were carried out for all sampling media; the details of the quality-assurance data were not included in the report and have been requested from the registrant.
- e) Hand exposure underneath gloves was not monitored; we therefore have had to assume 100% protection from gloves.

Except for the high limit of detection (b), all other limiting factors would lead to an under-estimate of exposure. Therefore, despite our limited confidence in the precision of the data, this study was used to quantitatively estimate exposure.

Table 1 presents the exposure estimates, based on this study, for a M/L/A (70-kg man or 55-kg\woman) treating 50 acres of a fruit orchard at the maximum Canadian recommended label application rate of 0.67 lb ai/acre (0.75\kg\ai/ha). Exposure estimates are also presented for fruit harvesters assuming they pick for about 7 hours/day on the seventh day after application. This is the preharvest interval recommended on the Canadian label for peaches and nectarines; it is 14 days for apples and pears. The study measured dermal exposure to workers at 18 days and they were all less than the limit of detection (LOD) (although a high exposure is still estimated based on the LOD, i.e., about 2 mg/kg bw/d).

Our estimate of exposure for M/L/A is therefore in the range of 3.5-22.5 mg/kg bw/d for males and 4-29\mg/kg bw/d for females wearing short sleeves and no gloves. If the M/L/A is wearing a rubber suit and gloves (assuming 100% hand protection), the exposure is estimated to range from 7 to 13 and from 9 to 16.5 mg/kg bw/d for males and females respectively. For fruit pickers wearing short sleeves and no gloves and picking on the seventh day post application, exposure is estimated to be 5 mg/kg bw/d for males and 6.5 mg/kg bw/d for females. If the harvesters are wearing long sleeves and gloves (assuming 100% protection), the estimates are 2.5 and 3.5 mg/kg bw/d for males and females respectively.

We compared our exposure estimates to surrogate data on wettable powder formulations applied with airblast orchard equipment. The surrogate data generated slightly lower estimates for workers in short sleeves and no gloves but there was a definite overlap in the range of exposures. The surrogate estimates for workers wearing long sleeves and gloves was lower than that estimated from the Dow study, but the Dow workers (long sleeves and

gloves) were all in an open cab. It should also be noted that it is extremely difficult to compare studies in which clothing scenarios and methods of data collection and analysis are all different.

3.3.2 Field Use (Ground Boom Equipment)

The registrant did not submit any studies that could be utilized to estimate exposure to workers using ground boom equipment, (e.g., for strawberries). We therefore considered surrogate data. Unfortunately, no appropriate studies were available in which workers were monitored during the M/L/A of WP formulations with ground boom equipment. For the M/L component, therefore, three studies were considered in which airblast or aerial applications with very similar tanks to those used for ground boom application were used. The obvious shortcoming is that we are using surrogate data from different scenarios on only one aspect of the use, without including spraying, cleanup and repair. Nevertheless, the exposure for workers mixing sufficient Plictran to treat 50 acres/day at the maximum application rate of 1.1 lb ai/acre and wearing short sleeves and no gloves is estimated to be 0.2-7.8 and 0.2-9.9 mg/kg bw/d for males and females respectively (Table 1). If short sleeves and gloves (100% hand protection assumed) were worn, the estimates would be 0.3-1.6 and 0.04-2.0 mg/kg bw/d for males and females respectively.

3.3.3 Greenhouse Use

The registrant did not submit any exposure information for the greenhouse scenario. A published study conducted in Florida several pesticides and several types of application equipment was reviewed and considered but the large number of assumptions necessary to estimate exposure for the Canadian worker made the extrapolation very tenuous. For that reason a quantitative estimate of exposure for the greenhouse scenario has not been presented. Little exposure information exists on the greenhouse setting but it is assumed that the potential for exposure is high. Because the NOEL for teratology with cyhexatin is very low and because a proportion of greenhouse workers are women, exposure data on the greenhouse scenario is essential for an assessment of safety.

Since no estimate of dermal absorption is available, it was necessary to assume 100% absorption for estimates used in this report.

Table 2 presents margin of safety (MOS) calculations for the toxicological endpoints, fetotoxicity and teratology.

TABLE 1 EXPOSURE TO CYHEXATIN FOR CANADIAN WORKERS

Use Scenario	Clothing	Exposure mg/kg bw/d			
		Males		Females	
		Open Cab	Closed Cab	Open Cab	Closed Cab
<u>Orchard (Airblast Equipment)</u>					
M/L/A ¹	Short Sleeves	8.4 - 22.6	3.5 - 4.3	10.7 - 28.8	4.5 - 5.5
	No Gloves				
	Rubber Suit, Gloves ²	7.2 - 13.0	---	9.1 - 16.5	---
Picking (7 d) ³	Short Sleeves, No Gloves	5.0		6.3	
	Long Sleeves, Gloves ²	2.6		3.3	
<u>Field (Ground Boom)</u>					
M/L ⁴	Short Sleeves, No Gloves	0.2 - 7.8		0.2 - 0.9	
	Short Sleeves, Gloves ²	0.03 - 1.6		0.04 - 2.0	
<u>Greenhouse</u>	INSUFFICIENT DATA TO QUANTITATE				

- 1 Based on a worker (70-kg male or 55-kg female, treating 50 acres in one day at the maximum application rate of 0.67/lb ai/acre.
- 2 Assuming gloves provide 100% hand protection, a known overestimate.
- 3 Based on a worker (70-kg male or 55-kg female) picking fruit for 7 hours /day.
- 4 Based on a worker (70-kg male or 55-kg female) treating 50 acres in one day at maximum application rate for strawberries of 1.1 lb ai/acre.

TABLE 2 MOS CALCULATIONS FOR DIFFERENT USE SCENARIOS¹

Use Scenario	Margins of Safety	
	Fetotoxicity (NOEL - 0.5 mg/kg bw/d)	Teratology (NOEL = 1.0mg/kg bw/d)
<u>Orchard (Airblast)</u>		
a) M/L/A		
Short Sleeves, No Gloves	No MOS	No MOS
Rubber Suit, Gloves ²	No MOS	No MOS
b) Picking (7 days post-application)		
Short Sleeves, No Gloves	No MOS	No MOS
Long Sleeves, Gloves ²	No MOS	No MOS
Field (Ground Boom)		
M/L ³		
Short Sleeves, No Gloves	0-2.5	0-5
Short Sleeves, Gloves ²	0-12.5	0-25
<u>Greenhouse</u>	INSUFFICIENT DATA TO QUANTITATE	
<u>Hops</u>	INSUFFICIENT DATA TO QUANTITATE	
1	These MOS calculations are based on fetotoxicity and teratology. As pointed out in the toxicology section, there are many data gaps and there may well be other toxicologic endpoints that affect both sexes. Exposure during only M/L/A was considered. Exposure during cleanup and repair could not be assessed.	
2	Assuming gloves provide 100% hand protection, a known overestimate.	
3	Only M/L component considered; exposure during spraying, cleanup and repair could not be assessed.	

4. RESIDUE MONITORING IN 1987

In August 1987, Agriculture Canada initiated a national sampling and analysis program to assess cyhexatin levels remaining at harvest on apples and pears. Samples of apple juice and apple sauce were analyzed by Health and Welfare Canada.

Seventy-one per cent (71%) of pears and 85% of apples had levels less than the reporting level of 0.2 ppm or 10x less than the then current maximum residue level of 2 ppm. Only trace levels of cyhexatin and its metabolites were found (≤ 0.05 ppm) in apple sauce or apple juice. These results indicate exposures to cyhexatin from food residues were minimal and covered by a newly revised ADI established by Health and Welfare Canada.

Continued exposure through imported food products are not expected since Dow has discontinued worldwide production of this compound. Analysis of imported products in 1987 did not find levels of cyhexatin which would raise concern.

5. THE ECONOMIC BENEFITS OF PLICTRAN IN CANADA

5.1 Agronomics of Cyhexatin (Plictran)

Plictran is an organotin miticide which was used for the control of plant-feeding mites such as European red mite, two-spotted spider mite, apple rust mite, pear rust mite, and McDaniel spider mite. Its effectiveness in terms of speed of action, tolerable effects on predator mites and low toxicity to bees made Plictran a valuable chemical in the production of apples, pears, peaches, strawberries and hops.

5.2 Damage

In 1986, the farm value of the above-mentioned crops in Canada was estimated at approximately \$230 million, that is, \$122 million for apples, \$13 million for pears, \$21 million for peaches, \$47 million for strawberries and \$27 million for raspberries. While pears and peaches are grown mostly in Ontario and British Columbia and hops are produced only in specific areas of British Columbia, apples, raspberries and strawberries are grown widely across the country. For the latter three commodities, Ontario and British Columbia remain, however, the main production centers.

The control of mites is particularly important to fruit growers because of the adverse effects they have on yield and product quality. The extent of the damage mites can cause varies widely between areas and crops. While the yield drop can average 10% to 35% for apples, it can vary from 20% to 100% for raspberries and strawberries, and as much as 25% for hops. The decrease in quality is even more significant, ranging from 10% to 50% for apples and from 50% to 100% for raspberries, strawberries and hops. The latter estimates reflect an extreme case of infestation where the fragile crops would become completely unmarketable.

5.3 Pesticide Usage

Plictran usage varied substantially by crop as follows: apples - 60%, strawberries - 30%, pears - 4%, peaches - 3%, hops - 3%, raspberries - 22%. In the four main use areas, Ontario (44%), Quebec (29%), British Columbia (20%) and the Maritimes (6%), a similar pattern emerged with the exception of Quebec and Atlantic Canada where the use on strawberries was greater than on apples. Based on estimates provided by regional industry experts, nearly all areas in apple, pear and peach production in Ontario were treated with Plictran whereas the chemical was sprayed on less than 5% of the strawberry fields in that province. In British Columbia, the situation was reversed as only 10% of the total orchards were treated compared to 95% for strawberries.

Finally, all of the 329 hectares in hop production in British Columbia were treated with this chemical.

5.4 Efficacy

Plictran offered a high degree of protection against mite damage. Depending on the timing, frequency and rate of application, it could reduce by as much as 95% the detrimental effects mites have on fruit size, color, quality (due largely to russetting) and crop vitality (defoliation). This was particularly true for apples, pears and strawberries. Species of mites, crop varieties, regional growing conditions as well as the complexity of the disease and insect control programs in a region also impacted on the efficacy of Plictran. For example, a survey conducted in 1984, of 45 commercial sites in Ontario where mite control failures were reported, showed that 27% of orchards exhibited evidence of Plictran resistance. This could have resulted from the fact that by 1982, the majority of growers in the area relied mostly upon the use of that chemical for mite control. Under normal circumstances, the development of mite resistance to Plictran was not a problem when other chemicals were used alternately with Plictran in an integrated pest management program.

5.5 Alternatives

Agriculture Canada has recently granted registration for clofentezine (Apollo) for mite control on apples. In addition, products such as dicofol (Kelthane), fenbutatin-oxide (Vendex, Torque), propargite (Omite), formetanate hydrochloride (Carzol), chinomethionat (Morestan) and dormant oils are registered for mite control. Omite, Dicofol and Superior Oil are the most often used of the registered alternatives in Canada, particularly on apple.

The Pesticides Directorate, Agriculture Canada, in conjunction with advisors in Health and Welfare Canada, Environment Canada, and Fisheries and Oceans Canada are currently

reviewing data to support registration of another new miticide. While these new products may be considered as replacement compounds for cyhexatin, all miticides have to be carefully used and managed to avoid possible resistance development.

5.6 Economic Benefits

The data used in the assessment of Plictran were very limited and allowed measurement of only part of its economic impact. The lack of information on mite damage on pears and peaches in Ontario, Nova Scotia and British Columbia, as well as on strawberries and raspberries in all growing areas except Columbia, restricted the analysis to the evaluation of the benefits and cost of using Plictran in the apple sector across Canada and in the strawberry, raspberry and hop industries in British Columbia only.

Although the validity of extrapolating the results presented below in terms of dollar value is debatable, it is possible to use them as an indicator of the magnitude of returns fruit growers were able to from using Plictran. At present, there are insufficient data to evaluate the net benefits of alternative chemicals. However, none of the three most popular pesticides, Omite, Dicofol and Superior Oil, appears to be quite as effective as Plictran the overall control of mite damage. As a result, in this case, the values of the benefits of Plictran could not be discounted by the full amount of returns expected from the use of substitute chemicals since they were not simply substitutes but, to a extent, complemented the use of Plictran. The findings of this study should, therefore, be interpreted with caution, in the context of this analysis only.

Plictran usage was estimated to decrease apple yield losses by 38 Kilo-tonnes (kt) in Ontario, 11 kt in Quebec, 3 kt in Nova Scotia and a little over 1 kt New Brunswick and British Columbia. Based on the 1986 crop market conditions, the total value of these yield losses amounted to \$18.2 million. The yield losses that strawberry, raspberry and hop growers would have incurred without the use of this miticide were valued at \$3.5 million, \$0.1 million and \$0.6 million, respectively. For apple growers, Plictran did not generate as much revenue from reducing quality losses as it did from reducing yield losses, because the total gains in quality amounted to only \$4.7 million. The reverse was true for strawberry and hop producers because they were able to reduce their quality losses by \$5.1 million and \$2.2 million, respectively.

For apple growers alone, the gross benefits of Plictran could, therefore, be as high as million. Considering that, in most provinces, two applications of Plictran on orchards could produce a desirable level of mite control, using this chemical cost \$2.7 million, which meant that the net benefits amounted to \$20.2 million. As for the other fruit crops, the benefits of Plictran were valued anywhere from \$3.5 to \$5.1 million in the case of British Columbia strawberries and from \$0.6 million to \$2.2 million in the case of hops. Treating these crops with Plictran was relatively less expensive than spraying it on orchards (\$0.2

million and \$0.3\million, respectively). This meant that the benefits of Plictran relative to the value of the crops for British Columbia producers were extremely high, that is, from 46% to 64% for strawberries and from 27% to 100% for hops. This reflects the level of vulnerability of these crops to mite damage and the market sensitivity to their quality.

In the absence of Plictran, the efficacy of each the alternatives may be reduced considerably given that a viable mite control program requires proper alternation of chemicals in order to minimize the possibility of pesticide resistance development.

5.7 Conclusions of Economic Benefit Study

Judging by the partial results of this analysis, Plictran was an effective miticide which generate high returns to fruit producers. For example, for each dollar spent on Plictran, apple growers could expect benefits worth \$8.50. Because of the fragility of strawberries and hops and the threat of mites, producers in British Columbia could gain even more from each dollar invested in that chemical (\$17 to \$25 for strawberries and \$20 to \$74 for hops).

In addition to providing a direct protection against mite damage to yield and fruit quality, Plictran offered the indirect advantage of maintaining the efficacy of other chemicals used in mite control. The availability of a sufficient number of effective miticides is crucial to preventing pest resistance development.

The results of this study indicate that Ontario fruit growers benefited the most from the use of Plictran. Based on the use pattern and the economic value of apple, strawberry and raspberry production, Quebec was likely the next largest beneficiary, followed by British Columbia and the Maritimes.

The economic benefits of Plictran were higher in relation to the crop value of small fruit (raspberries and strawberries) and hop crops. However, in real dollar terms, the returns of Plictran in orchards were much higher.

It is difficult to anticipate the long-term consequences of removing Plictran from the market. In the short term, it is evident that the use of other chemicals such as Apollo, Omite, Dicofol and Superior Oil will increase. However, in the long run, alternating these chemicals might not be sufficient to prevent pest resistance. In this case, unless other pesticides are introduced onto the market, some industries like raspberry, strawberry and hop production would likely become too vulnerable to mite damage to remain viable.

6. CANCELLATION CONDITIONS

In the summer of 1987, Dow announced voluntary withdrawal of the product from the market, supported by a stock return and refund program coordinated through local dealers.

By means of a CAPCO Note in August 1987 and based on concerns expressed by Health and Welfare Canada, Agriculture Canada cautioned women who are or may be pregnant against working in treated orchards or fields.

In the interim, Dow has taken a corporate decision to abandon further interest in Plictran and has asked that the original registration be cancelled. Agriculture Canada is taking this action in response to Dow's request and in recognition of Health and Welfare Canada's review, to formally remove this registration from the record.

Agriculture Canada also puts growers on notice that Health and Welfare Canada has revoked residue tolerances, effective January 29, 1989.

7. FUTURE DIRECTIONS IN MITE CONTROL

Much effort in mite control research in horticultural crops has been directed toward developing Integrated Pest Management (IPM) programs which allow for conservation of mite predators. Without these programs, frequency of miticide applications would dramatically increase.

Significant research is also being directed toward understanding the mechanisms underlying resistance so that compounds of different chemistry can be rotated against diseases and insect pests, thus slowing development of resistance to key compounds and maintaining stability in IPM programs.

Much more data are required to critically examine the economic impact of mite species on yield and quality of affected crops. These data would allow economic treatment levels to be established so that miticides are only applied when needed.