

AH98001

**Horticultural Industry's Coordinated
Response to the National Registration
Authority's Existing Chemical Review
Program, 1999**

**Dr RH Brown, *et al*
The Expert Foundation Ltd**



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This report is reprinted by the Horticultural Research and Development Corporation for NSW Agriculture to pass on information concerning horticultural research and development undertaken for Australian Horticulture.

The research contained in this report was funded by the Horticultural Research and Development Corporation with the financial support of all levy paying industries.

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Cover price: \$20.00

NSW Agriculture ISBN 1 86423 958 1

Reprinted and distributed by:

Horticultural Research & Development Corporation

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**HORTICULTURAL
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**Partnership in
horticulture**

Horticultural Industry's Coordinated Response to the National Registration Authority's Existing Chemical Review Program

HRDC Project No. ⁴⁴⁹⁸⁰⁰¹~~HC98055~~ (30/6/99)

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AM198001
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Purpose of the Project :

To assist the horticultural industries' coordinate their response to the current NRA reviews of endosulfan, parathion-methyl, and parathion-ethyl within the Existing Chemical Review Program, and to provide a general plan for managing and funding relevant R&D and submissions to the program in the future.

The Expert Foundation Ltd. acknowledges the funding support provided by the Horticultural Research and Development Corporation for this project.

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Table of Contents

	Page
Summary	3
1. Introduction	6
2. Registrants and Products Currently Available	7
2.1 Endosulfan.....	7
2.1.1 Existing Crop Uses.....	8
2.2 Parathion-methyl.....	8
2.2.1 Existing Crop Uses.....	8
2.3 Parathion-ethyl.....	8
2.3.1 Existing Crop Uses.....	8
3. Methods Employed	9
3.1 Identification of Data Gaps.....	9
3.2 Endosulfan.....	9
3.2.1 Occupational Health and Safety.....	9
3.2.2 Residues in Produce.....	10
3.3 Parathion-methyl.....	10
3.3.1 Occupational Health and Safety.....	10
3.3.2 Residues in Produce.....	10
3.4 Parathion-ethyl.....	11
3.4.1 Occupational Health and Safety.....	11
3.4.2 Residues in Produce.....	11
4. Discussions with Stakeholders	12
4.1 Registrants.....	12
4.2 Horticultural Industries.....	12
4.3 Other Stakeholders.....	12
5. Registrants' Policies on Defence of Products	12
5.1 Endosulfan.....	12
5.2 Parathion-methyl.....	13
5.3 Parathion-ethyl.....	13
6. Determination of What Studies are Needed to Fill Data Gaps	13
6.1 Endosulfan.....	13
6.1.1 Occupational Health and Safety.....	13
6.1.2 Residues.....	14

6.2	Parathion-methyl	14
6.2.1	Occupational Health and Safety	14
6.2.2	Residues	15
7.	Preparation of Protocols for the Studies Required.....	15
7.1	Occupational Health and Safety	15
7.2	Residues	15
7.2.1	Endosulfan.....	15
7.2.2	Parathion-methyl.....	16
8.	Selection of Contractors to Undertake the Work.....	16
8.1	Residue Trials.....	16
8.2	Chemical Analyses.....	16
9.	Estimation of Costs, and Cost Sharing Arrangements.....	17
10.	Outcomes.....	18
10.1	Endosulfan.....	18
10.2	Parathion-methyl.....	18
10.3	Parathion-ethyl	18
11.	Problems Encountered with the ECRP.....	18
12.	Proposed Strategy for Handling Future Call-ups in the ECRP	20
13.	Recommendations	22
14.	Acknowledgements.....	22
15.	Relevant Publications	22
16.	Glossary of Abbreviations	23

Summary

The NRA has instituted a program (the Existing Chemical Review Program) to conduct regular reviews of registered agricultural and veterinary chemicals to ensure they meet contemporary standards for safety and efficacy. Some 80 chemicals have been targeted for review, in batches, over the next five years. The first batch of chemicals includes the insecticides endosulfan, parathion-methyl, and parathion-ethyl, all of which have important uses in a wide range of horticultural industries. It is likely that most chemicals under review will require additional data on occupational health and safety to be generated, if they are to retain their status as registered products – this is clearly the case for the three insecticides listed.

Whether or not ongoing use of these insecticides is approved, depends largely on industry's timely response to the NRA's call for submissions, draft determinations, etc. In this case, a few horticultural industries have contributed submissions, and commenced formulating their responses to review outcomes, particularly on endosulfan. The majority of horticultural industries, however, have not responded because they do not have the resources or expertise to do so. As a consequence, HRDC has commissioned this project – to “Coordinate the horticultural industry's response to the NRA's existing chemical review program”.

The registrants and their respective products containing endosulfan, parathion-methyl, and parathion-ethyl were identified, and existing use patterns were determined from current product labels.

Data gaps (both occupational health and safety, and residue) for each of the insecticides were identified from the “Draft Reviews” published by the NRA. Those relating specifically to the horticultural industries, were identified as worker exposure during spray application (broadacre, orchard, greenhouse, and by hand equipment), re-entry into treated crops, and residues in harvested produce.

Registrants' policies on defence (or otherwise) of their products were ascertained from the various chemical companies concerned, in conjunction with their overseas suppliers of active constituents.

Agrevo, the principal registrant of endosulfan seeks to retain most of the existing uses, except for recreational turf (due to environmental risks associated with run-off and contamination of watercourses); and, confined spaces eg. greenhouses/glasshouses (the company has adopted a global policy not to support these uses because of unacceptable health and safety risks). Agrevo will provide some of the funds for worker exposure studies, but will not be generating residue data in horticultural crops.

In the case of parathion-methyl, Bayer, the principal registrant will defend its use only on cotton, pome and stone fruits (in the Goulburn Valley) and tomatoes in

Queensland. Their rationale is that the users in these industries are more highly trained than are those in other industries and, the areas in which the product is used are geographically restricted. Bayer and their supplier Cheminova will fund both the worker exposure and residue studies needed for these crops, but other industries (viz. citrus, grapes, and vegetables) must fund their own residue studies if they want to retain this use.

The registrants are not defending the use of parathion-ethyl, and the NRA has subsequently withdrawn its registration. The apple and pear industries have independently negotiated a phased withdrawal of the product over the next three years. Stringent conditions will apply to its use during this period.

Following discussions with all relevant stakeholders (registrants, horticultural industries, NRA, NOHSC, and Rural Industry R&D Corporations), the nature of the studies required to fill data gaps was determined. Protocols for worker exposure studies were developed in conjunction with the Agricultural Health Unit (NSW Health Department) in Moree (for endosulfan), and the environmental consultants Woodward Clyde in Sydney (for parathion-methyl), as these contractors had already been commissioned by the cotton industry, and Bayer respectively.

NRA-approved protocols were developed for residue studies with both endosulfan and parathion-methyl. In the case of endosulfan, they were prepared for almonds, apples, avocados, beans (green), beetroot, broccoli, brussels sprouts, cabbage, capsicum, carrots, cauliflower, celery, cucumber, custard apple, eggplant, leek, lemon, lettuce (head and leaf), longan, lychee, macadamia, mandarin, mango, melons, nashi, okra, orange, paw paw, peas, pears, pistachio, potato, silverbeet, strawberry, sweetcorn, taro, tomato, and zucchini. Parathion-methyl protocols were prepared for apricot, beans (green), beetroot, broccoli, brussels sprouts, cabbage, carrots, cauliflower, celery, cherry, cucumber, eggplant, grapes, leek, lemon, lettuce (head and leaf), mandarin, nectarines, orange, peaches, peas, plums, potato, quince, silverbeet, sweetcorn, taro, tomato, and zucchini.

Two agricultural contractors were invited to provide indicative costs for undertaking the residue trials needed, on the following bases :

- endosulfan alone, trials in all crops
- parathion-methyl alone, trials in all crops
- endosulfan and parathion-methyl in conjunction, trials in all crops
- endosulfan and parathion-methyl in conjunction, individual trials per crop, and
- endosulfan, or parathion-methyl alone, individual trials per crop

Three NATA accredited chemical analytical laboratories were also invited to provide indicative quotes to undertake the residue analyses.

The total costs for residue studies are estimated to exceed \$500,000 for endosulfan, and \$450,000 for parathion methyl, if all industries are willing to support the studies needed. Estimated average costs for the field component are \$2,850 per trial and,

together with ca. \$90 per sample for chemical analysis, total about \$3,930 per trial. A major constraint in accurately determining costs, is our inability to define precisely the numbers of trials which will be required as there are many industry sectors which have not yet indicated their willingness to participate in the program. There may be opportunities to save costs by generating Group MRLs, striking "bulk deals" with contractors, evaluating two chemicals concurrently (say endosulfan and parathion-methyl), etc.

The worker exposure studies for endosulfan are estimated to cost ca. \$700,000, and are designed primarily to meet the needs of the cotton industry. By including additional treatments to address horticultural needs, we are able to "piggy back" on their activities thereby significantly saving costs. Horticulture's share is ca. \$225,000, with any shortfall expected to be covered by the principal registrant. In the case of parathion-methyl, the late submission of additional occupational health and safety data by Cheminova to NOHSC (and not yet evaluated by the Health Department), means that the final cost of studies can not be determined. Most of the cost, however, will be borne by the registrant Cheminova Australia Pty. Ltd. These studies, again, are largely for the benefit of the cotton industry, but some horticultural needs will also be addressed at no extra cost. Additional horticultural requirements for the citrus, vegetable, and possibly grape industries will cost between \$265,000 and \$375,000.

A number of problems were encountered during the project, making it difficult to ensure a satisfactory outcome for the various industries affected by the current ECRP call-up. Methods for circumventing these were identified which, if adopted, will be of considerable value in future chemical call-ups. These include : closer and more timely liaison with the NRA; development of a definitive register of industry spokespersons with the authority to act on behalf of their respective industries; closer liaison with registrants; and, seeking opportunities for reducing duplication and costs by cooperating with other stakeholders.

A strategy for successfully addressing future call-ups in the ECRP is proposed. The strategy outlines a series of recommended actions to be taken by the various horticultural industries, in response to the NRA's scheduled timetable of requirements. Adoption of the proposed strategy should ensure that the horticultural industries are better positioned than they are now, to successfully defend and retain the use of other valuable pesticides which are destined for review in the future.

A series of recommendations is made to HRDC to facilitate the ECRP process.

1. Introduction

The National Registration Authority (NRA) – Australia’s national body for regulating the use of pesticides – is required under its supporting legislation, to conduct regular reviews of registered agricultural and veterinary chemicals to ensure that they meet contemporary standards for safety and efficacy. As more scientific data about the possible harmful effects or the longer term impacts of chemicals becomes available, the NRA reassesses older registered chemicals for their possible harmful effects on human health, occupational health and safety, the environment, efficacy and implications for trade. Registrants, industry and the public are notified of reviews such as the Existing Chemical Review Program (ECRP), and are given time to submit information in support of continued, or discontinued, registration of the chemical. Possible outcomes of reviews include confirmation that the chemical is safe and appropriate for registered use; the generation of new data to support the continued use, or suspension, cancellation, or withdrawal of the chemical from the market.

The ECRP as currently exists, has targetted some 80 pesticides for progressive review over a timeframe of about five years. It is planned to review these pesticides in batches – the first such group being currently under investigation includes three insecticides of major interest to a range of horticultural industries; they are *endosulfan*, *parathion-methyl*, and *parathion-ethyl*.

In September, 1998, the AusHort Research and Development Committee met to consider the issues surrounding horticulture’s response to the ECRP. The AusHort Research and Development Committee is an HRDC initiative to ensure that the Board of the Corporation is fully advised on multi-industry issues impacting on horticulture. Individual horticultural industries have contributed submissions to the ECRP in respect of the three insecticides concerned (endosulfan, parathion-methyl, and parathion-ethyl), and commenced formulating their responses to the review outcomes on endosulfan. Many of the activities undertaken during these reviews are common to more than one horticultural industry, and include such things as communication with agricultural chemical companies (the registrants), demonstration of reductions in environmental contamination, and the generation of supporting data to fill data gaps (eg. worker exposure, and residue data). The AusHort Research and Development Committee considered that most horticultural industries which rely on the use of these insecticides, did not have the resources or expertise to respond appropriately and that all industries would benefit from coordinated research and development and submissions to the ECRP.

In November, 1998, HRDC called for expressions of interest to undertake a consultancy (this project), with the following Terms of Reference ;

1. Determine the current stance, analyses and activities by each horticultural industry, registrants, and allied industries (e.g. cotton) towards the reviews of endosulfan, parathion-methyl, and parathion-ethyl.

2. Liaise with all stakeholders, horticultural industries, NRA, agrochemical companies, Environment Australia, National Occupational Health and Safety Commission (NOHSC), etc. to determine each industry's response to the ECRP.
3. Coordinate and help manage the most efficient and cost-effective performance of R&D and application of submissions for endosulfan, parathion-methyl, and parathion-ethyl.
4. Develop and implement an action plan with all stakeholders to coordinate, manage and fund processes for on-going responses to ECRP.

Management of the project is vested in the following Steering Committee :

Dr. M. Smith, HRDC Program Manager (Chairman)
Ms. J. Purbrick, representing the Apple and Pear industry
Mr. R. Dalton, representing the Avocado industry
Mr. I. Atkinson, representing the Nursery industry, and
Mr. C. Feutrill, representing the Vegetable industry.

The nominated outcomes for the project were :

1. Coordinated response to the outcomes of the NRA review of endosulfan.
2. Briefs outlining a plan for the response to the NRA review of endosulfan, including the likelihood of success and cost of data generation.
3. Submissions to the NRA on parathion-methyl, and parathion-ethyl reviews.
4. Plan of appropriate R&D to respond to NRA reviews of parathion-methyl, and Parathion-ethyl, and
5. General plan for horticultural industries to manage and fund relevant R&D and submissions to the ongoing ECRP.

2. Registrants and the Products Currently Available

2.1 Endosulfan

Registrants with a current interest in endosulfan, include :

Agrevo Pty Ltd – Thiodan EC
Nufarm Limited – Endosulfan 350EC, and
Farnoz Chemicals Pty Ltd – Endosulfan 350EC

2.1.1 Existing Crop Uses

The following horticultural crop uses appear on the labels of the respective registrants :

Almond, asparagus, avocados, bananas, beans (green), beetroot, berry fruit (currants and related fruit), blueberries, broccoli, Brussels sprouts, cabbage, capsicums, cape gooseberry, carrots, cauliflower, celery, citrus (including grapefruit, mandarins, lemons, and oranges), cucurbits, custard apple, egg plant, faba beans, grapes, guavas, kiwi fruit, leeks, lettuce (head, and leaf), lychees, macadamia nuts, mango, okra, onions, passion fruit, paw paw, peas (field, and green), pecan nuts, persimmons, pome fruits (apples, nashi, and pears), potatoes, silverbeet, stone fruits (cherries, peaches, and plums), strawberries, sweet corn, sweet potato, tomatoes, and taro.

2.2 Parathion-methyl

Bayer Australia Limited – Folidol M500 Insecticide

Colin Campbell (Chemicals) Pty Ltd – Penncap-M Flowable Microencapsulated Insecticide

Cheminova Australia Pty. Ltd. – Parathion Methyl 500 EC Insecticide, and Farnoz Chemicals Pty Ltd – Parathion Methyl 500 Insecticide

2.2.1 Existing Crop Uses

The following horticultural crop uses appear on the labels of the respective registrants :

Apples, beans (including French), brassicas, capsicums, carrots, citrus, crucifers, cucurbits, egg plant, grapes, pears, peas (green), pome fruit, potatoes, stone fruit, tomatoes, and vegetables.

2.3 Parathion-ethyl

Cheminova Australia Pty. Ltd. – Novafos E 500 Insecticide

Farnoz Pty Ltd – Farnoz Parathion E Insecticide, and

Tebing Pty. Ltd.– Tebing Parathion Insecticide

2.3.1 Existing Crop Uses

The following horticultural crop uses appear on the labels of the respective registrants :

Apples, apricots, cherries, citrus, fruit trees, grapes, nectarines, peaches, pears, plums, quinces, and vegetables.

3. Methods Employed

3.1 Identification of Data Gaps

Data gaps were identified by examining the Draft Reviews for the three insecticides concerned, and published by the NRA [Anon. (1998a), (1998b), and (1998c)]. These listed the gaps for which new data needed to be generated if the products containing these active constituents were to continue to be legally available for use. The data gaps identified fall into two categories, “occupational health and safety”, and “residues” in harvested produce. The gaps were :

3.1.1 *Endosulfan*

3.1.2 *Occupational Health and Safety*

Worker exposure data for a number of agriculture uses are required to verify that current work practices are adequately safe, or to determine how to modify those practices to ensure safety. The work practices concerned include :

- Mixer/loaders in ground and aerial applications
- Orchard ground spray applicators
- Broadacre ground spray applicators
- Manual flaggers for aerial applications
- Workers applying endosulfan in greenhouses
- Workers using hand directed spray applicators
- Determination of a safe re-entry period for greenhouses
- Determination of safe re-entry periods for field crops, both high (over waist height) and low (under waist height), and
- Determination of a safe re-entry period for orchards.

The NRA has stated that it “does not want a worker exposure study for each crop type”. The smallest number of studies which will support the preceding work practices and situations will be sufficient. For example, different crops with common work practices and application equipment can be covered by one good quality study. It is recommended that relevant industries , commodity groups and grower organisations co-ordinate their efforts with State agricultural authorities to achieve the desired results with the least amount of expense and duplication”.

It is evident that from the above list of study requirements, all except that relating to “manual flaggers for aerial applications” (which applies specifically to the cotton industry) is relevant to the horticultural industries.

3.1.3 *Residues in Produce*

The following is a list of horticultural commodities for which Temporary Maximum Residue Levels (MRLs), measured in parts per million (ppm) is now approved. To retain the registration of the product in that crop, full MRL approvals must be obtained. This requires the generation of local residue data :

Crop/Commodity Group	MRL (ppm)
Assorted tropical and sub-tropical fruits – edible peel	T2
Assorted tropical and sub – tropical fruits – inedible peel	T2
Berries and other small fruits	T2
Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T2
Citrus fruits	T2
Cucurbits	T2
Fruiting vegetables, other than cucurbits	T2
Leafy vegetables (including brassica leafy vegetables)	T2
Legume vegetables	T2
Onion, bulb	T0.2
Pome fruits	T2
Root and tuber vegetables	T2
Shallots	T2
Stalk and stem vegetables	T2
Stone fruits	T2
Tree nuts	T2

3.2.1 *Parathion-methyl*

3.2.2 *Occupational Health and Safety*

Worker exposure data for a number of agricultural uses are required to verify that current work practices are adequately safe, or to determine how to modify those practices to ensure safety. The work practices concerned include :

- Broadacre ground spray applicators in the following crops –
Vegetables, pome and stone fruit, citrus, and grapes
- Worker re-entry, for the same group of crops

3.2.3 *Residues in Produce*

The following is a list of horticultural commodities for which Maximum Residue Levels (MRLs) are required :

Crop/Commodity Group

Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T0.1
Carrots	T0.5
Celery	T3
Citrus fruits	T1
Cucurbits	T1
Fruiting vegetables, cucurbits	T1
Fruiting vegetables other than cucurbits (except sweetcorn)	T0.2
Grapes	T0.5
Legume vegetables	T0.5
Pome fruits	T0.5
Stone fruits	T0.2

3.3.1 *Parathion-ethyl*

3.3.2 *Occupational Health and Safety*

Worker exposure data for the application of parathion-ethyl in crops such as pome and stone fruits, citrus, and grapes is required, and for worker re-entry into treated crops.

The NRA has recommended a series of actions to be taken by users of parathion-ethyl during the period of data generation. In addition to specific requirements which will appear on the label, the following will apply ;

- During the period of data generation, parathion-ethyl will be available for use only by persons trained in the use of chemicals.
- Registrants will carry the primary responsibility for ensuring that users are aware of, and complying with the restrictions.
- The amounts of chemical handled by the users would be minimised by reducing rates and frequency of use, and rationalising the number of uses, and
- Product labels will be strengthened to include appropriate environmental warnings, including intervals between applications to reduce potential environmental exposure.

3.3.3 *Residues in Produce*

Temporary MRLs are required for the following crops : apples, apricots, cherries, citrus, grapes, nectarines, peaches, pears, plums, quinces, fruit pomace, and all vegetable crops.

4. Discussions with Stakeholders

4.1 Registrants

Discussions were held with Agrevo, Farnoz and Nufarm (on endosulfan); Bayer, Campbell, Cheminova, and Farnoz (on parathion-methyl); and, Bayer, Farnoz, and Tebing (on parathion-ethyl), to ascertain their policies on supporting product retention (ie. whether they would support the generation of the data needed and, if so, fund it themselves, expect others to do it; or not support the continued use of the product, etc. by the generation, or provision of the required data).

4.2 Horticultural Industries

Representatives of most of the industries which use endosulfan, parathion-methyl, and parathion-ethyl (as nominated by HRDC), were consulted about their need to retain the use of these products. Attempts were also made to determine their willingness, or otherwise, to fund the generation of the data demanded by the NRA, to support continued use of the products.

4.3 Other Stakeholders

Several industries and organisations other than those involved in horticulture, also have an interest in the use of these insecticides. In the case of endosulfan, the cotton industry is the greatest single user and, it is imperative that there be consultation and discussions with this industry and its associated groups if there is to be a coordinated approach to generating the data required. Discussions were therefore held with Cotton Australia, and the Cotton Research and Development Corporation (CRDC).

In the case of endosulfan, the cotton industry had already commenced negotiations with the Agricultural Health Unit at Moree (a unit of the NSW Health Department) to commission the occupational health and safety studies needed, before this project was initiated. It was therefore important that discussions also be held with this group.

Similarly, Bayer Australia and Cheminova Australia Pty. Ltd. had already commissioned Woodward Clyde, an environmental consultant, to undertake the occupational health and safety studies required for parathion-methyl, and it was important that discussions also be held with them.

5. Registrants' Policies on Defence of Products

5.1 Endosulfan

The principal registrant, Agrevo, is willing to retain the product for most of the existing uses, but with the exception of :

- Recreational turf (due to environmental risks associated with run-off and contamination of watercourses)

- Confined spaces eg. greenhouses, glasshouses, etc. (the company has adopted an international policy of no longer supporting these uses because the occupational health and safety risks are unacceptable).

Agrevo will contribute funds towards the generation of occupational health and safety data, but will not fund the generation of residue data in horticultural crops. It will, however, assist in other ways wherever possible. (this could be interpreted as the company not having an interest in horticultural uses, and being prepared to let registrations lapse).

5.2 Parathion-methyl

Bayer, the principal registrant has advised the NRA that it will be defending the use of parathion-methyl **only** on cotton, pome and stone fruits (in the Goulburn Valley of Victoria), and tomatoes in Queensland. Their rationale is that users in these industries are more highly trained than those in other industries and, the areas in which the product is used are geographically restricted. Bayer and Cheminova will fund the occupational health and safety, and residue studies required for these crops but, for other crops, other parties (the industries concerned – i.e. citrus, grapes, and vegetables) will need to fund their own residue studies if they wish to retain and continue using the product.

5.3 Parathion-ethyl

The registrants are not defending the use of parathion, and the NRA has subsequently withdrawn its registration, effective for wholesale sales on December 31, 1999 and retail sales effective on June 30, 2000..

6. Determination of What Studies are Needed to Fill Data Gaps

Following discussion with the registrants, the horticultural industries concerned, and other stakeholders including the NRA and NOHSC, the nature of the studies (both occupational health and safety, and residues) required to fill data gaps, were formulated.

6.1 Endosulfan

6.1.1 Occupational Health and Safety

Studies are required to determine the risks of worker exposure during application of endosulfan in both vegetable crops, and tree crops. Studies being commissioned by the cotton industry on worker exposure during application by broadacre ground equipment, are deemed by the NRA to also apply to the vegetable industries. These will be undertaken with both enclosed and open-cab tractors (supplementary funding will be required for the open-cab component of the study, because it is not a cotton industry practice).

In the case of hand held application equipment for use in nurseries/open production areas, additional studies are required, unless NOHSC consider that adequate extrapolation from vegetables can be made.

Worker exposure during endosulfan application to tree crops requires a separate study. This should include low volume, high concentration application in a high tree crop such as avocado, using open and enclosed-cab tractors on a regular schedule basis, and a fallback position using higher volume low concentration application equipment applied with an open-cab tractor.

In the case of worker re-entry into treated crops, studies being commissioned by the cotton industry are deemed by the NRA to also apply to the vegetable and tree crop industries.

6.1.2 Residues

Residue studies are required for all the crops (and commodity crop groupings) listed on page 8, and funded by the individual horticultural industries concerned.

6.2 Parathion-methyl

6.2.1 Occupational Health and Safety

Cheminova Australia Pty. Ltd. will be funding a boomspray/ground spray (with both open and enclosed-cab tractors) worker exposure study in cotton. NRA have deemed that this will also be relevant to application in the vegetable industries.

It will not, however, cover knapsack applications in vegetable crops, and a separate study will be needed for this, funded by the vegetable industry.

Similarly, worker exposure studies in pome and stone fruits, using airblast sprayers and open and enclosed-cab tractors, will be undertaken and funded by Cheminova. Citrus and grapes may require additional studies because of the different application techniques and volumes of spray applied. We believe that grapes should be covered by the pome and stone fruit study, if it can be shown that the application methods used are no worse, from an exposure point of view, than airblast sprayers.

Citrus, because of oscillating booms, higher water volumes and rates of application will almost certainly require a separate study, which will need to be funded by the citrus industry.

Worker re-entry studies in cotton, and pome and stone fruit crops, will be undertaken by Cheminova to cover the activities of "scouting" and "fruit thinning" respectively. These are considered to be "worst case" scenarios from an exposure point of view, and should also cover re-entry requirements for pome and stone fruits and vegetables, but not citrus. It is likely that a separate study will be needed for citrus, because of the reasons already given.

Any of the additional studies required, can be incorporated into the overall program which is being commissioned through Woodward Clyde.

6.2.2 Residues

Residue studies are required for all of the crops listed on page 8, and funded by the horticultural industries concerned. Cheminova will fund those applying to pome and stone fruits, and tomatoes in Queensland.

7. Preparation of Protocols for the Studies Required

7.1 Occupational Health and Safety

The protocols required for field studies with both endosulfan, and parathion-methyl are being prepared by the Agricultural Health Unit at Moree, and by Woodward Clyde respectively, with input by team members from this consultancy. There has also been close consultation with the NRA, and NOHSC and the final protocols, when completed, will have their endorsement.

7.2 Residues

Representatives of most horticultural industries, which use endosulfan and/or parathion-methyl, were contacted to determine their willingness to support the products by contributing funds for the research necessary to generate the residue data required. Some industries were fully supportive, and prepared to contribute funds, while others wanted the products retained but were not able to/or committed to providing the funds needed. On the assumption that all industries might eventually provide funding, residue trial protocols were prepared as follows :

7.2.1 Endosulfan

Almonds, apples, avocados, beans (green), beetroot, broccoli, brussels sprouts, cabbage, capsicum, carrots, cauliflower, celery, cucumber, custard apple, eggplant, leeks, lemon, lettuce (head, and leaf), longan, lychee, macadamia, mandarin, mango, melons, nashi, okra, orange, paw paw, peas, pears, pistachio, potato, silverbeet, strawberry, sweetcorn, taro, tomato, and zucchini.

Because crops can be grouped by “commodity groupings”, it is possible to reduce the number of trials required, by generating “Group MRLs”. The NRA requires trials on only three major crops within a commodity group, to achieve this (eg. in the category “Assorted tropical and sub-tropical fruits – inedible peel”, relevant crops are avocado, banana, custard apple, longan, lychee, mango, and paw paw. Selection of the major three crops – say, avocado, mango, and paw paw, would eliminate the need for trials on banana, custard apple, longan, and lychee). Similar groupings are possible with other crops.

7.2.2 Parathion-methyl

Apricot, beans (green), beetroot, broccoli, brussels sprouts, cabbage, carrots, cauliflower, celery, cherry, cucumber, eggplant, grapes, leeks, lemon, lettuce (head, and leaf), mandarin, nectarines, orange, peaches, peas, plums, potato, quince, silverbeet, sweetcorn, taro, tomato, and zucchini.

NB. Trials with apples, nashi, pears, and tomatoes in Queensland are being undertaken by Cheminova.

As is the case with endosulfan, it is possible to reduce the number of trials required by generating Group MRLs for some crop groupings.

8. Selection of Contractors to Undertake the Work

8.1 Residue Trials

Three agricultural consulting firms with the capacity to undertake crop residue studies nationally (ie. in all States and Territories), were invited to provide indicative quotes for undertaking the residue trials, on the following basis :

- Endosulfan alone, trials in all crops
- Parathion-methyl alone, trials in all crops
- Endosulfan and parathion-methyl in conjunction, trials in all crops*
- Endosulfan and parathion-methyl in conjunction, individual trials per crop*
- Endosulfan, or parathion-methyl alone, individual trials per crop

*The NRA will permit endosulfan and parathion-methyl residues to be determined concurrently in the same field trial. Although this is technically possible, there needs to be considerable forward planning to allow this to take place. Clearly there are considerable cost savings to be gained if this can occur.

The three consulting firms approached are :

- Agrisearch Pty. Ltd., Orange, NSW
- Serv-Ag Pty. Ltd., Devonport, Tasmania, and
- ICAN Pty. Ltd., Sydney, NSW

8.2 Chemical Analyses

Two NATA accredited analytical laboratories were invited to provide indicative quotes for undertaking the residue analyses required. Quotes were sought on two bases : for either endosulfan, or parathion-methyl alone, and for both insecticides concurrently in the same sample.

The analytical laboratories are :

- Agriculture Victoria, State Chemistry Laboratories, Melbourne, Victoria, and
- Amdel Limited (Analchem), Sydney, NSW

9. Estimation of Costs, and Cost Sharing Arrangements

In attempting to put together a realistic budget for covering the costs of the research required to generate the necessary residue data, a major constraint has been our inability to determine precisely which industries will provide support. The total cost for these studies, depending on the number of industries willing to be involved could easily exceed \$500,000 for endosulfan, and \$450,000 for parathion-methyl (some additional costs for apples, nashi, pears, and tomatoes in Queensland only will be met by Cheminova).

There are greater opportunities for saving costs on residue trials, than on occupational health and safety trials, based on the overall numbers to be undertaken. In the case of endosulfan, for example, more than 150 field trials will be needed if all industries wish to defend its use. Each residue trial will cost approximately \$2,850 for the field component, plus \$90/ sample for chemical analyses (a total of up to \$3,930 depending on the number of samples to be analysed). If precise numbers are known, there may be opportunities for striking “bulk deals” with the contractors who undertake the trials, and the laboratories which undertake the residue analyses. The potential for generating Group MRLs also provides an opportunity to reduce costs, as does the evaluation of two pesticides concurrently (say endosulfan, and parathion-methyl – if there is sufficient lead time to prepare for this).

The occupational health and safety studies required for endosulfan are estimated to cost ca. \$700,000. The trials are geared largely to addressing the needs of the cotton industry, which is the greatest single user of the product. However, by including additional treatments relevant to horticultural crops, we are able to “piggy back” on the cotton industry’s efforts thereby obtaining significant cost savings. Horticulture’s share of the costs is ca. \$225,000 and, the cotton industry is contributing a similar amount. The shortfall is expected to be covered by the principal registrant, but this has not yet been agreed by the company.

The late submission of additional occupational health and safety data (which has yet to be evaluated by the Department of Health) by Cheminova to NOHSC, in the case of parathion-methyl, has made it difficult to determine the final cost of the studies to be undertaken. As with endosulfan, the cotton industry has a major interest in the chemical, and in this case, most of the cost will be borne by Cheminova Australia Pty. Ltd. Some horticultural needs will be met by these studies, at no extra cost, but the additional requirements will cost between \$265,000 and \$375,000.

10. Outcomes

10.1 Endosulfan

Protocols for undertaking occupational health and safety studies, are being developed by the Agricultural Health Unit at Moree (commissioned by the cotton industry) with horticultural input by the project team of consultants. These have yet to be finally approved by the NRA, NOHSC and other bodies.

NRA-approved protocols for undertaking the **residue studies** have also been developed for each of the crops listed as requiring them. Contractors have been identified, who are able to undertake the residue field studies, as have suitable laboratories for undertaking chemical residue analyses. Indicative costings obtained for these services have been provided to HRDC for final competitive tendering.

10.2 Parathion-methyl

Protocols for undertaking **occupational health and safety studies** are being developed by Woodward Clyde (commissioned by Cheminova), and will be completed by the end of October, 1999. Final protocols will be available mid-November, which will include approval by the NRA or NOHSC pending a review of recently received additional data from Cheminova. Horticultural input has been provided by the project team of consultants. Data generation is not expected to commence until 4Q, 2000.

NRA-approved protocols for undertaking the **residue studies** have been developed for each of the crops requiring them (except for pome and stone fruits, and tomatoes in Queensland, which are being managed by the registrants). As with endosulfan, suitable contractors and analytical laboratories have been identified, indicative costs obtained and the details provided to HRDC.

10.3 Parathion-ethyl

As indicated earlier, the registrants are not defending the use of parathion. The apple and pear industries have, independently, successfully negotiated a three-year phase out of the use of this product with the NRA. Continued use of the chemical during the phase-out period is, however, contingent upon the acceptance of a range of conditions imposed by the NRA.

11. Problems Encountered With the ECRP

During the course of this project, a number of problems were encountered which made it extremely difficult to ensure a satisfactory outcome for the various horticultural industries affected by the current ECRP call-ups. Their identification, and that of potential ways to address or circumvent them, may not be of immediate

direct benefit, but will be of immeasurable value for future reviews when better planning and response processes have been adopted and implemented.

The ECRP is a relatively new program, there is no existing recipe on how to address the issues concerned, and both the NRA and industry are literally “learning on the job” as the first batch of chemicals is being reviewed.

The horticultural industries affected by the current call-up of endosulfan, parathion-methyl, and parathion-ethyl have, with few exceptions, been caught completely unprepared and with limited opportunity to respond effectively within the timeframe set by the NRA. Some industries have been better prepared, and able to make individual and informed submissions to the review, but the fragmented nature of the horticultural industries has meant that most have not responded to calls for feedback on what is proposed.

Stakeholders can not influence the listing and order of priority of the approximately 80 agricultural chemicals, which have already been designated for review by the NRA under this program. Wherever possible, however, the NRA should be lobbied to not review in the same batch, several chemicals which might be crucial to the successful production of a particular crop or industry (eg. if 6 to 8 chemicals were being reviewed concurrently, and half of them were heavily used by say the tomato industry, this would be a particularly heavy burden for the industry to address at the one time).

With the plethora of horticultural industries, many of them small and lacking the resources to fund R&D programs, it has been difficult to identify a “spokesperson” with the necessary authority to speak for the industry on ECRP matters, and to commit funds towards the research which may be required. In the current situation, it has not been possible to go through the normal consultative process with industry because the original deadlines for responding to draft determinations by the NRA have already lapsed. However, if such a definitive register of spokespersons could be developed, it would facilitate timely responses by affected industries in future reviews.

Where several industries (and registrants) have an interest in a chemical under review, it is important that these interests be identified as early as possible in the review process so that there is good coordination in developing the plans for addressing the research which may be required to fill data gaps. Early cooperation can lead to reduced duplication of effort, agreement on sharing workloads and costs, and a united front in discussions with the NRA, NOHSC and other relevant bodies. Despite agreement to cooperate, there can still be problems surrounding ownership and exploitation of data generated, commercial confidentiality, etc. particularly if more than one registrant is involved.

There is a history of difficulty in dealing with a central contact in regulatory agencies such as the NRA. There are examples of what appears to be conflicting advice being presented by different officers of the agency, despite the evident goodwill of

individuals. It is important that, wherever possible, ECRP liaison with the NRA be through a single, senior and responsible officer. Similarly, the horticultural industries should coordinate their activities and channel these through a single contact who liaises with the NRA.

Registrants of the chemicals currently under review have not, in our view, made sufficient and timely contact with the horticultural industries affected, to acquaint them of their plans for defending (or not defending) their products. Timely advice to industry will assist immeasurably in the development of informed responses to the NRA (for example, in the case of endosulfan, the interest of Nufarm Limited, has become known virtually at the end of this project).

There is also a need to identify, and consult with other interested parties such as Rural Industry Research and Development Corporations; agricultural, environmental and occupational health and safety consultants who might be commissioned to undertake field research, and the laboratories capable of undertaking chemical residue analyses. All of these parties have a role to play in the overall program.

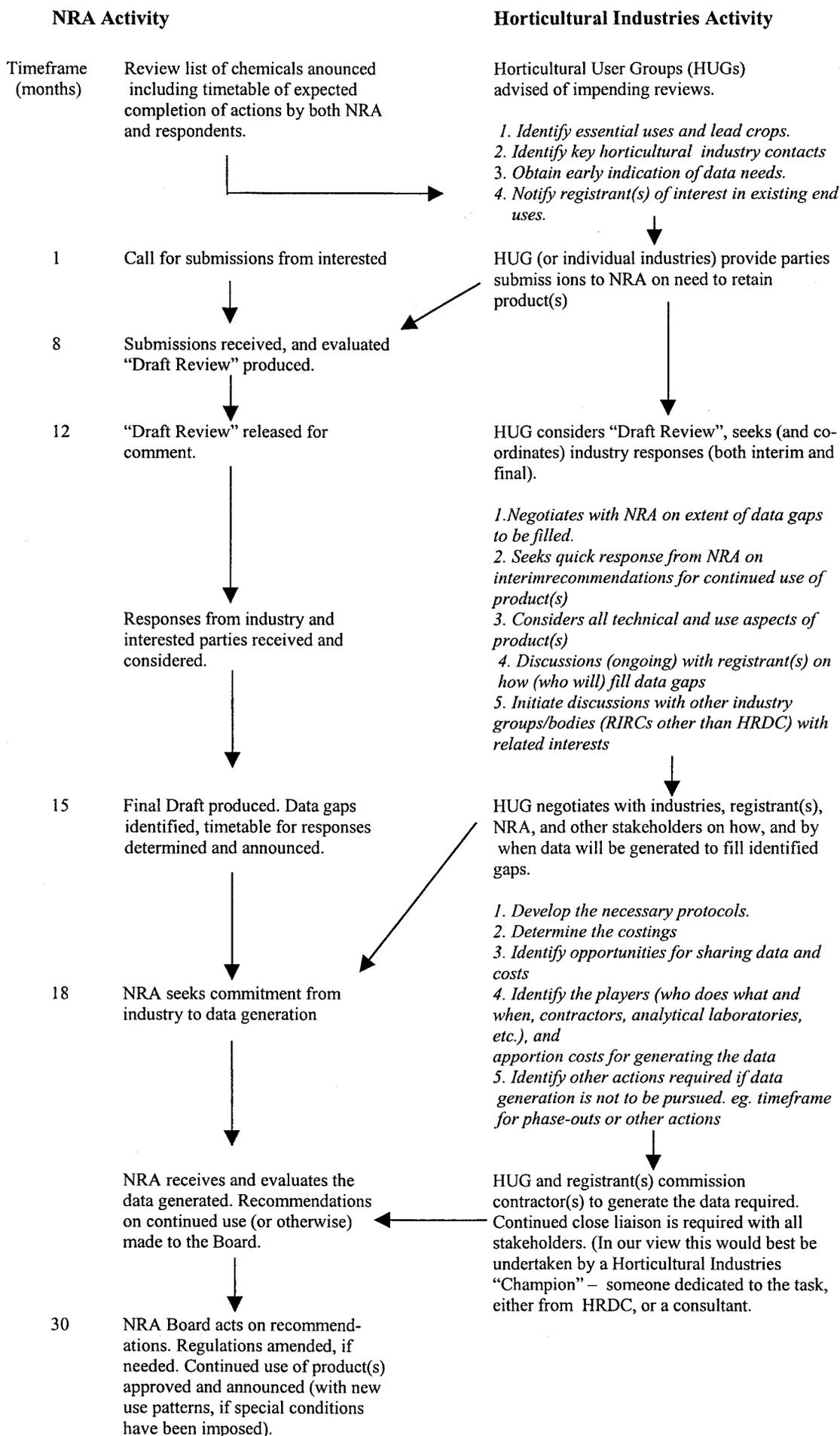
12. Proposed Strategy for Handling Future Call-ups in the ECRP

The following plan illustrates the chronological sequence of events in the Existing Chemical Review Program, with suggested actions that need to be taken by the horticultural industries in response to the specific requirements of the NRA. It should be noted that the timeframe listed is **our** estimate, and not that of the NRA. We believe it to be realistic. The success, or otherwise, of the horticultural industries in this exercise is predicated on the establishment of a peak representative body which we have called the Horticultural Users Group (HUG). We envisage that this group will be responsible for coordinating the various activities involved.

Adoption of a plan such as this should ensure that the horticultural industries are better placed than they have been hitherto, to respond to future chemical call-ups within the ECRP program.

The Starting Point

Use patterns on an existing pesticide to be reviewed by the NRA.



The Finishing Point

Continued availability and use of product(s) by the horticultural industries.

13. Recommendations

- *That HRDC consider establishing a "Horticultural Users Group" (HUG) to coordinate the horticultural industries activities in the ECRP process, and to be the key point of contact in liaison with the NRA, NOHSC, and related bodies.*
- *That a definitive list of **responsible spokespersons with the authority to represent their respective industries** be developed, so that timely decisions can be made on whether or not to support and fund initiatives.*
- *That the opportunity be taken in future chemical call-ups, to save costs in the generation of residue data, by seeking Group MRL's rather than specific crop data.*
- *That wherever possible, if the use of more than one chemical is being reviewed in a crop or commodity group, attempts be made to reduce costs by undertaking concurrent studies in the same field trials.*

14. Acknowledgements

We gratefully acknowledge the assistance and guidance provided by members of the Steering Committee; various members of the National Registration Authority, the National Occupational Health and Safety Commission; key representatives of the horticultural industries concerned; Dr. Lyn Fragar of the Agricultural health Unit, Moree; Woodward Clyde, Sydney; Cotton Australia; Mr. Bruce Pyke of the Cotton Research and Development Corporation; and representatives of the registrants and related companies – Agrevo Pty. Ltd., Bayer Australia Limited, Cheminova Australia Pty. Ltd., Colin Campbell (Chemicals) Pty. Ltd., Farnoz Chemicals Pty. Ltd., Nufarm Limited, and Tebing Pty. Ltd.

15. Relevant Publications

- Anon. (1998a). The NRA review of endosulfan. Volumes 1 and 2, August 1998. The National Registration Authority for Agricultural and Veterinary Chemicals, Canberra.
- Anon. (1998b). The NRA review of parathion-methyl. Volume 1, May 1998. The National Registration Authority for Agricultural and Veterinary Chemicals, Canberra
- Anon. (1998c). The NRA draft review of parathion. Volumes 1, 2 and 3, September 1998. The National Registration Authority for Agricultural and Veterinary Chemicals, Canberra.

16. Glossary of Abbreviations

CRDC	Cotton Research and Development Corporation
ECRP	Existing Chemical Review Program
HRDC	Horticultural Research and Development Corporation
HUG	Horticultural Users Group
MRLs	Maximum Residue Levels
NATA	National Association of Testing Authorities
NOHSC	National Occupational Health and Safety Commission
NRA	National Registration Authority
R&D	Research and Development