



Australian Government
**Australian Pesticides and
Veterinary Medicines Authority**



Representative Crops and Extrapolation Principles for risk assessment and data waivers

AUGUST 2018

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INTRODUCTION

As part of the Australian Government's commitment to Improved Access to Agricultural and Veterinary Chemicals, the Australian Pesticides and Veterinary Medicines Authority (APVMA) has been working to develop Australian crop groups. Crop grouping schemes, once established, enable formal recognition of data generated and risk assessments conducted in a subset of crops to be extrapolated to other related crops of the same crop group. This mechanism identifies key crops where data generation may occur and where that data may then be used to support registration in other related crops. It assists applicants by clearly understanding what those crops are and maximises the value of that data once generated.

Crop grouping and the principle of data extrapolation also improves access to chemicals for minor crops where registrants may not otherwise consider their inclusion for reasons of insufficient economic return. The assessment and requirements for approving minor crops can therefore leverage off regulatory risk assessments that are conducted and approved in representative crops, which are typically major crops. This is a common practice among international regulators and is used to streamline regulatory assessment and facilitate approvals for minor crops. The APVMA has applied these principles for many years, particularly in assessments for minor crops. This document formalises our approach with the aim to increasing applicant's awareness of its potential use in registration.

PURPOSE OF THIS DOCUMENT

This document represents consultation on the finalisation of the APVMA crop grouping project and outlines the proposed approach for applicants to register label use patterns by adopting crop grouping and extrapolation principles.

The APVMA is seeking comments on:

1. The proposed:
 - i. representative crops/commodities for each crop group, and
 - ii. extrapolations possible from data and/or risk assessments conducted in representative crops/commodities both:
 - a. within a crop group, and
 - b. between crop groups.
2. The format and useability of the document (ie. ease of interpretation)

The APVMA is not seeking comment on the currently published crop group listings. The crop group listings are based on the Codex (CCPR) groups and a comprehensive consultation process was conducted in setting the crops within each group and sub-group, which involved producers and product registrants.

HOW TO MAKE A SUBMISSION

Submissions must be received by the APVMA by close of business on **5 October 2018** and be directed to the contact listed below. All submissions to the APVMA will be acknowledged in writing via email or by post.

When making a submission please include:

- Contact name
- Company or group name (if relevant)
- Email or postal address (if available)
- The date you made the submission.

Written submissions should be addressed in writing to:

Registration Management and Evaluation
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604
Phone: +61 2 6210 4749
Fax: +61 2 6210 4776

Email: enquiries@apvma.gov.au

BACKGROUND

In 2016 (Phase 1 of this project) the APVMA listed and grouped all commodities within each of 23 different crop groups. The complete list of commodities in each group is available on the [crop-groups page](#) on the APVMA website. The groups and commodities within each group were developed based on the *Codex Classification of Foods and Animal Feeds (1993)* and further review of the groupings by the *Codex Committee on Pesticide Residues*. Crops for animal feeds have not been considered or included at this time. Full details of the project can be found on the [crop groupings project](#) on the website..

Phase 2 of this project is now proposing to identify:

- i. representative crops/commodities for each crop group, and
- ii. extrapolations possible from data and/or risk assessments conducted in representative crops/commodities both:
 - a. within a crop group, and
 - b. between related crop groups

The representative crops and extrapolations proposed are being established for the purposes of data and assessment guidance and how they may be applied in the following regulatory risk assessment areas:

- residues,
- environment,
- worker safety (occupational health and safety),
- efficacy, and
- target crop safety.

A trade assessment may be required where a new crop is considered major (as listed in [part 5B Overseas trade of the Data Guidelines](#)) and the use may result in a higher residue potential than has been considered for that crop.

Extrapolation principles contained within this guidance is predicated on the same (or reduced) use pattern (i.e. rate, timing, frequency, method of application, withholding period).

This guidance is presented in two parts:

- PART 1 outlines the representative crops and the data extrapolation and waivers possible WITHIN a crop group, and
- PART 2 outlines the data extrapolation and waivers possible BETWEEN related crop groups.

1 PART 1: REPRESENTATIVE CROPS - DATA EXTRAPOLATION AND WAIVERS WITHIN CROP GROUPS

The representative crops proposed have been selected following scientific review and recognising existing APVMA guidance for the conduct of residue studies and equivalent international approaches. Extrapolation of data from a number of crops to allow registration in other crops is not new and is common practice within Australia and other countries. In preparing this document the APVMA has relied on its extensive experience in conducting assessments for new uses where data extrapolation has been successfully implemented, particularly in the area of assessing minor uses, which have regularly relied on data and associated regulatory risk assessments conducted in typically related major crops. Extrapolation principles between crops typically include considerations of similarities in their botanical classification, morphology, growth habit, portion of the commodity harvested and/or consumed, and cultural practices. Appendix 1 contains further information on the process of crop group development and representative crop selection.

Table 1 below sets out each crop group (Column 1), the proposed representative crops (Column 2) and the risk assessment areas considered in the registration of agricultural chemical products (residues, OHS, environment, efficacy and crop safety).

The table specifies for each crop group and each corresponding risk assessment area where:

- Extrapolation (data waiver) is possible ✓, or
- Extrapolation is not possible C.

If a product is approved or has been assessed for all representative crops (Column 2), expanding the same use to all crops within the crop group (Column 1) a data and assessment waiver is likely to be applied to those risk assessment areas indicated with ✓ *Extrapolation is possible*.

Where a particular risk assessment area is indicated with C *Extrapolation is (generally) not possible*. In these instances data and/or other supporting information and further assessments will be required for other members in addition to the representative crops of the crop group for those relevant risk assessment areas. The latter is due to the complex diversity of members within some crop groups, for example, “assorted tropical and sub-tropical fruits - edible peel” and “spices” are very diverse crop groups.

Generating data for representative crops (typically two or more) identified in this paper is not explicit and data need not necessarily be confined to representative crops. The APVMA will consider data/argument from a range of crops within a crop group. That is, the representative crop groups are given as guidance. When planning data generation it is preferable that these crops be used, however the APVMA may consider other crops as representative of the group on the basis of data availability and scientific justification.

1.1 Limitations on using crop grouping and extrapolation to gain data waivers in applications

Extrapolation of a use pattern to a crop group has the following limitations:

- For extrapolations within a crop group (Part 1): the use practices are the same (or reduced), such as the rate, frequency, timing and method of application and target pests/diseases.
- For extrapolations between related crop groups (Part 2), use practices would also need to be the same (or reduced), however alternative target pests/diseases would be considered as part of the residues, efficacy and crop safety assessments.
- Where the latest timing of application for the crop on which the extrapolation is to be based is a growth stage and this is not relevant to the proposed crop to be treated, the latest timing of application **MUST** be conservatively converted into days before harvest i.e. the time between the growth stage and the harvest of the approved crop or another relevant growth stage.
- This guidance is not intended for the following extrapolations:
 - between field and protected crops (e.g. crops grown in glasshouses, poly tunnels or polythene covers). Pesticides approved for field use only cannot be extrapolated to protected crops and similarly pesticides approved only for use in protected situations cannot be extrapolated to field crops
 - post-harvest uses
 - seed treatments
 - livestock feed commodities from post processing of commodity (i.e. crops intended for livestock feed)
 - products other than herbicides, fungicides and insecticides (ie. plant growth regulators), and vertebrate control agents
- In cereal crops, rice may not be relied on to extrapolate for environmental matters, similarly other cereal crops may not be extrapolated to rice (see Appendix 1 for further detail).
- Extrapolation from wheat to oats, rye, triticale and durum wheat will only be considered for treatments applied up to GS32.
- There are no regional specific restrictions for chemical run-off. This applies to environmental matters only (see Appendix 1 for further detail).

In these instances a case-by-case assessment by the APVMA is required. Applicants seeking to rely on the crop groups and representative crops in these instances are advised to submit a [Pre-Application Assistance \(PAA\)](#) request to ensure that all aspects of the submission are considered and establishment of appropriate representative crops for extrapolation.

1.2 Table 1 – Extrapolation and data waiver guidance within crop groups

Crop Group	Representative crops*	Risk Assessment areas								
		Residues	OHS	Environment	Efficacy			Crop safety		
					Herbicide	Fungicide	Insecticide	Herbicide	Fungicide	Insecticide
Citrus fruit	Orange, lemon	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pome fruits	Apple, pear	✓	✓	✓	✓	✓	✓	✓	✓	✓
Stone fruits	Cherry, plum, apricot/peach	✓	✓	✓	✓	✓	✓	✓	✓	✓
Berries and other small fruits	Raspberries, blueberries, grapes, strawberry	✓	✓	✓	✓	✓	✓	✓	✓	✓
Bulb vegetables	Onion - bulb, spring onion	✓	✓	✓	✓	✓	✓	✓	✓	✓
Brassica vegetables (except brassica leafy vegetables)	Cauliflower, cabbage, brussel sprouts	✓	✓	✓	✓	✓	✓	✓	✓	✓
Legumes	Beans, peas	✓	✓	✓	✓	✓	✓	✓	✓	✓
Pulses	Bean, pea	✓	✓	✓	✓	✓	✓	✓	✓	✓
Tree nuts	Almonds, macadamia	✓	✓	✓	✓	✓	✓	✓	C	C
Leafy vegetables: Leafy greens and Brassica leafy vegetables sub groups only	Lettuce - head, leaf, spinach	✓	✓	✓	✓	✓	✓	✓	C	C
Root and tuber vegetables: Root vegetables and tuberous/corm vegetables subgroups only#	Beetroot, carrot, potato	✓	✓	✓	✓	✓	✓	✓	C	C
Cereal grains	Barley, wheat, oats, rice	✓	✓	✓	✓	✓	✓	✓	C	C
Oilseed	Canola, cotton, peanut	✓	✓	✓	✓	✓	✓	✓	C	C
Herbs	Mint, parsley	✓	✓	✓	✓	✓	✓	✓	C	C
Assorted tropical and sub-tropical fruits - inedible peel	Litchi, avocado, banana, mango, pineapple, kiwifruit	✓	✓	✓	✓	✓	✓	✓	C	C
Fruiting vegetables, cucurbits	Cantaloupe, cucumber, summer squash	✓	✓	✓	✓	✓	✓	✓	C	C
Fruiting vegetables, other than cucurbits	Tomato, peppers sweet	✓	✓	✓	✓	✓	✓	✓	C	C
Stalk and stem vegetables	Celery, asparagus, artichoke	✓	✓	✓	✓	✓	✓	✓	C	C
Edible fungi		✓	✓	✓	C	C	C	C	C	C
Grass for sugar production	Sugar cane	✓	✓	✓	C	C	C	C	C	C
Seed for beverages	Coffee	✓	✓	✓	C	C	C	C	C	C
Assorted tropical and sub-tropical fruits - edible peel	These are very diverse crop groups. Applicants should discussed proposed use with the APVMA and likely host crops for determination of appropriate representative crops on a case-by-case bases.									
Spices										

* these are the identified representative crops, however alternatives may be proposed and applicants should discuss any possible alternatives with the APVMA

a separate efficacy data package would be required for aquatic root and tuber vegetable subgroup.

✓	Extrapolation (data waiver) is possible
C	Extrapolation is not possible. Confirmatory data/argument required

1.3 How to use Table 1 – extrapolation and data waivers within a crop group

Where a proposal satisfies the above section on *Limitations* Table 1 may be used for either;

- Registration (new product or label extension) for a crop group where no members of the crop group are currently registered (ie. the product is to be used in the crop group for the first time), OR
- Label extension to a crop group where either all or a subset of the representative crops are currently registered.

Registration for a crop group where no members of the crop group are currently registered (ie. the product is to be used in the crop group for the first time)

Registration of a crop group may be sought through the generation and submission of data from solely those representative crops where *extrapolation is possible* ✓. Applicants may also seek to provide data from non-representative crops in a weight of evidence approach. Applicants who possess and seek to utilise data from a broader range of crops other than the representative crops are encouraged to do so and should seek to discuss the applicability of that data in support of a crop group registration with the APVMA prior to data generation and/or submission through PAA.

For those risk assessment areas where *extrapolation is not possible* C applicants must provide for assessment either additional data and/or scientific justification and further assessments will be required for other members in addition to the representative crops of the crop group for those relevant risk assessment areas.

Label extension to a crop group where either all or a subset of the representative crops are currently registered

Label extension to a whole crop group is most likely to be commonly sought where either;

1. all representative crops are currently registered, or
2. only a subset of the representative crops are currently registered.

Further guidance and examples for each of the above two scenarios is provided below.

Example 1: Extension from all currently registered representative crops to the whole crop group

Where a registration currently exists in ALL representative crops applicants may make submissions to extend to a whole crop group and where *extrapolation is possible* ✓ a data and assessment waiver is applied to those risk assessment areas (ie. either residues, OHS, environment, efficacy and/or crop safety).

For those risk assessment areas where *extrapolation is not possible* C applicants must provide for assessment additional data and/or scientific justification to support other crops within the crop group for those relevant risk assessment areas.

Example 1.1

- An insecticide is currently registered in both apples and pears for the control of thrips.
- Extension is sought to the whole crop group - pome fruit for the control of thrips.
- All other use pattern details and label instructions will be the same.
- The following table depicts the existing (apple & pear) and proposed registration (pome fruit).

Crop	Pest	Rate	WHP	Critical Use Comments
Apple & Pear (existing registration)	Thrips	150mL/100L water	7 Days	Apply a maximum of two sprays per crop with a minimum retreatment interval of 21 days between sprays.
Pome fruit (proposed extension)	Thrips	150mL/100L water	7 Days	Apply a maximum of two sprays per crop with a minimum retreatment interval of 21 days between sprays.

Table 1 states as summarised below:

- the representative crops for pome fruit are apple and pear, and
- all of the risk assessment areas indicate that *extrapolation is possible* ✓ to the crop group.

Crop Group	Representative crops*	Risk Assessment areas				
		Residues	OHS	Environment	Efficacy	Crop safety
					Insecticide	Insecticide
Pome fruit	Apple & pear	✓	✓	✓	✓	✓

In this example a data and assessment waiver would apply to all risk assessment areas and an applicant may lodge an application seeking extension to the whole crop group of pome fruit. Such an application would be suitable under:

- Item 12 where the crop group already had an established crop group MRL or
- Item 14 if consideration was required to establish the crop group MRL. In this instance a level 4 residues module would be applied, without the requirement to submit extra data, to facilitate establishment of the group MRL, noting that trade was considered for the original apple and pear registration.

Example 1.2

- A fungicide is currently registered in tomato and capsicum for the control of powdery mildew.
- Extension is sought to the whole crop group - fruiting vegetables, other than cucurbits for the control of powdery mildew.
- All other use pattern details and label instructions will be the same.
- The following table depicts the existing (tomato & capsicum) and proposed registration (fruiting vegetables, other than cucurbits).

Crop	Pest	Rate	WHP	Critical Use Comments
Tomato & Capsicum (existing registration)	Powdery mildew	50mL/100L water or 500mL/ha	3 Days	Apply prior to or at the first sign of disease. DO NOT exceed three sprays per crop with a minimum retreatment interval of 7 days between sprays.
Fruiting vegetables, other than cucurbits (proposed extension)	Powdery mildew	50mL/100L water or 500mL/ha	3 Days	Apply prior to or at the first sign of disease. DO NOT exceed three sprays per crop with a minimum retreatment interval of 7 days between sprays.

Table 1 states as summarised below:

- the representative crops for fruiting vegetables, other than cucurbits are tomato and sweet peppers (capsicums),
- risk assessment areas of residues, OHS, environment and efficacy indicate that *extrapolation is possible* ✓ to the crop group, and
- the risk assessment area of crop safety indicates that *extrapolation is not possible* C to the crop group.

Crop Group	Representative crops*	Risk Assessment areas				
		Residues	OHS	Environment	Efficacy	Crop safety
					Fungicide	Fungicide
Fruiting vegetables, other than cucurbits	Tomato and sweet peppers	✓	✓	✓	✓	C

In this example an applicant may lodge an application seeking extension to the whole crop group of fruiting vegetables, other than cucurbits, with a requirement to address crop safety in other members of the group. This may be via additional crop safety data conducted in other crops of the group and/or via scientific argument. For the other risk areas of residues (if MRL establishment was not required), OHS, environment and efficacy a data and

assessment waiver would apply. Such an application would be suitable under Item 14. A level 4 residues module would be applied, without the requirement to submit extra data, to facilitate establishment of the group MRL as required.

Example 2: Extension from a subset of registered representative crops to the whole crop group

Applicants seeking to extend from a subset of registered representative crops to a crop group may do so through the submission of additional data solely in those representative crops not currently registered and where *extrapolation is possible* ✓. As mentioned above applications may contain data from non-representative crops in a weight of evidence approach. Applicants who possess and seek to utilise data from a broader range of crops other than representative crops are encouraged to discuss the applicability of that data in support of registration to a crop group with the APVMA prior to data generation or submission through PAA.

For those assessment areas where *extrapolation is not possible* C applicants must provide for assessment additional data and/or scientific justification to support other crops within the crop group for those relevant risk assessment areas.

Example 2.1

- An insecticide is currently registered in apples for the control of thrips.
- Extension is sought to the whole crop group (pome fruit) for the control of thrips.
- All other use pattern details and label instructions will be the same.
- The following table depicts the existing (apple) and proposed registration (pome fruit).

Crop	Pest	Rate	WHP	Critical Use Comments
Apple (existing registration)	Thrips	150mL/100L water	7 Days	Apply a maximum of two sprays per crop with a minimum retreatment interval of 21 days between sprays.
Pome fruit (proposed extension)	Thrips	150mL/100L water	7 Days	Apply a maximum of two sprays per crop with a minimum retreatment interval of 21 days between sprays.

Table 1 states as summarised below:

- the representative crops for pome fruit are apple and pear, and
- all of the risk assessment areas indicate that extrapolation is possible ✓ to the crop group where all representative crops are registered, that being both apple and pear.

Crop Group	Representative crops*	Risk Assessment areas				
		Residues	OHS	Environment	Efficacy	Crop safety
					Insecticide	Insecticide
Pome fruit	Apple & pear	✓	✓	✓	✓	✓

In this example an applicant would need to prepare an application which addressed all risk areas of residues, OHS, environment, efficacy and crop safety for the additional representative crop - **pear** to support an extension to the whole crop group of pome fruit.

Such an application would be suitable under Item 14.

Example 2.2

A fungicide is currently registered in tomato for the control of powdery mildew.

Extension is sought to the whole crop group - fruiting vegetables, other than cucurbits for the control of powdery mildew.

All other use pattern details and label instructions will be the same.

The following table depicts the existing (tomato) and proposed registration (fruiting vegetables, other than cucurbits).

Crop	Pest	Rate	WHP	Critical Use Comments
Tomato (existing registration)	Powdery mildew	50mL/100L water or 50mL/ha	3 Days	Apply prior to or at the first sign of disease. DO NOT exceed three sprays per crop with a minimum retreatment interval of 7 days between sprays.
Fruiting vegetables, other than cucurbits (proposed extension)	Powdery mildew	50mL/100L water or 50mL/ha	3 Days	Apply prior to or at the first sign of disease. DO NOT exceed three sprays per crop with a minimum retreatment interval of 7 days between sprays.

Table 1 states as summarised below:

- the representative crops for fruiting vegetables, other than cucurbits are tomato and sweet peppers (capsicums),
- the risk assessment areas of residues, OHS, environment indicate that extrapolation is possible ✓ to the crop group where all representative crops are registered, that being both tomato and sweet peppers (capsicum), and

- the risk assessment area of crop safety indicates that extrapolation is not possible **C** to the crop group.

Crop Group	Representative crops*	Risk Assessment areas				
		Residues	OHS	Environment	Efficacy	Crop safety
					Fungicide	Fungicide
Fruiting vegetables, other than cucurbits	Tomato and sweet peppers	✓	✓	✓	✓	C

In this example an applicant would need to prepare an application which addressed all risk areas of residues, OHS, environment, efficacy and crop safety for the additional representative crop - sweet peppers (capsicum) to support an extension to the whole crop group of fruiting vegetables, other than cucurbits.

Such an application would be suitable under Item 14.

2 PART 2: EXTRAPOLATIONS BETWEEN RELATED CROP GROUPS

The individual crop groups discussed above in Part 1 are in this section (Part 2) further allocated into the following related crop groups:

- tree and tropical fruit crops
- bush & vine fruit crops
- vegetable crops
- field (broadacre) crops

Extrapolations from one crop group to another related crop group may be acceptable in some risk assessment areas without need for further assessment where an equivalent (or reduced) exposure is expected.

The same principles discussed above for extrapolation within crop groups would also apply to extrapolations between related crop groups. That being where the proposed use must:

1. satisfy the requirements outlined in the Limitations section above, and
2. be approved in either;
 - a related crop group, or
 - all representative crops of a related crop group.

Table 2 summarises the risk assessment areas where extrapolations between crop groups may be suitable where an equivalent (or reduced) exposure is expected between the related crop groups. Extrapolations outlined in Table 2 ONLY apply between those crop groups contained within each related crop group (ie. only between crop groups contained in table 2A for tree and tropical fruit crops).

Extrapolation between related crop groups is most suitable for the risk assessment areas of OHS and environment. Extrapolation to other risk areas, such as residues, efficacy and crop safety will typically require the provision of supporting data specific to representative (or other) crops within the new crop group.

Limited extrapolation between crop groups to some crops of a related crop group may be possible for residues in instances such as:

- situations where residues are expected to be lower than the limit of quantification (e.g. pre-emergence herbicide uses, some pre-flowering treatments),
- seed treatments, if all data from treatment of several different 'representative' seed types report no detectable residues in the commodities from crops grown from the treated seed,
- post-harvest treatments for non-systemic pesticides to commodities of similar size, weight and morphology on the basis of the same treatment regimes, and
- soil treatments with granulated product formulations.

2.1 Table 2 – Extrapolation between related crop groups

Crop group	Related Crop Group	Risk assessment area				
		Residues	Efficacy	Crop Safety	OHS	Environment
TABLE 2A: TREE & TROPICAL FRUIT CROPS						
Citrus	All tree & tropical fruit crops	R	C	C	✓	✓
Pome fruits		R	C	C	✓	✓
Stone fruits		R	C	C	✓	✓
Tree nuts		R	C	C	✓	✓
Assorted tropical and sub-tropical fruits, edible peel		R	C	C	✓	C
Assorted tropical and sub-tropical fruits, inedible peel		R	C	C	✓	C
TABLE 2B: BUSH & VINE FRUIT CROPS						
Berries and other small fruit	All bush & vine crops	R	C	C	✓	C
Assorted tropical and sub-tropical fruits, edible peel		R	C	C	✓	C
TABLE 2C: VEGETABLE CROPS						
Bulb	All vegetables	R	C	C	✓	✓
Brassica		R	C	C	✓	✓
Cucurbits		R	C	C	✓	✓
Fruiting vegetables		R	C	C	✓	✓
Leafy vegetables		R	C	C	✓	✓
Legume vegetables		R	C	C	✓	✓
Root and tuber		R	C	C	✓	✓
Stalk and stem		R	C	C	✓	✓
Herbs		R	C	C	✓	✓
TABLE 2D: FIELD CROPS						
Pulses	All field crops	R	C	C	✓	✓
Cereal	All field crops, excluding sorghum grain and millet, maize cereal subgroups	R	C	C	✓	✓
Oilseeds	All field crops, excluding cotton seed sub group	R	C	C	✓	✓

* for similar use patterns

✓	Extrapolation is possible
R	Extrapolation not possible. Residue data required from members of the new crop group.
C	Extrapolation not possible. Confirmatory data/argument required

2.2 How to use Table 2 – extrapolation between related crop groups

Where a proposal satisfies the above section on *Limitations* Table 2 may be used for registration into a new crop group where;

- an existing related crop group is currently registered, OR
- all representative crops of an existing related crop group are currently registered.

The extrapolations possible and not possible as contained in Table 2 are summarised as follows:

Risk assessment areas where *Extrapolation is possible* as indicated by ✓ in Table 2 includes:

- i. all instances for OHS, and
- ii. all instances for environment excluding *assorted tropical and sub-tropical fruits and berries and other small fruit*.

In these instances further data or risk assessment is not necessary.

Risk assessment areas where *Extrapolation is not possible* as indicated by R OR C in Table 2 includes:

- i. all instances for residues, efficacy and crop safety, and
- ii. for environment the *assorted tropical and sub-tropical fruits and berries and other small fruit* (as noted above).

In these instances applicants must provide additional data and/or scientific justification for assessment to support the new crop group for those relevant risk assessment areas.

Example 1

An insecticide is currently registered in pome fruit for the control of thrips.

Extension is sought to the whole crop group – stone fruit for the control of aphids.

The proposed new use pattern in stone fruit will be no greater than that already approved in pome fruit (ie. rate, frequency and number of applications).

The following table depicts the existing (pome fruit) and proposed registration (stone fruit).

Crop	Pest	Rate	WHP	Critical Use Comments
Pome fruit (existing registration)	Thrips	150mL/100L water	7 Days	Apply a maximum of three sprays per crop with a minimum retreatment interval of 14 days between sprays.

Crop	Pest	Rate	WHP	Critical Use Comments
Stone fruit (proposed extension)	Aphids	150mL/100L water	7 days	Apply a maximum of two sprays per crop with a minimum retreatment interval of 21 days between sprays.

Table 2 states as summarised below:

- Pome fruit and stone fruit are within the same related crop group of all tree & tropical fruit crops,
- risk assessment areas of OHS and environment indicate that *extrapolation is possible* ✓ to the crop group, and
- the risk assessment areas of residues, efficacy and crop safety indicate that *extrapolation is not possible* **R OR C** to the crop group.

Crop Group	Related Crop Group	Risk Assessment areas				
		Residues	Efficacy	Crop Safety	OHS	Environment
Pome fruit	All tree & tropical fruit crops	R	C	C	✓	✓
Stone fruit	All tree & tropical fruit crops	R	C	C	✓	✓

In this example an applicant may lodge an application seeking extension to the whole crop group of stone fruit with a requirement to address residues, efficacy and crop safety in stone fruit. For the risk areas of OHS and environment a data and assessment waiver would apply. Such an application would be suitable under Item 14.

Example 2

- A herbicide is currently registered in cereals for the control of capeweed.
- Extension is sought to the whole crop group – oilseeds for the control of saffron thistle.
- The proposed new use pattern in oilseeds will be no greater than that already approved in cereals (ie. rate, frequency and number of applications).
- The following table depicts the existing (cereals) and proposed registration (oilseeds).

Crop	Pest	Rate	Critical Use Comments
Cereals (existing registration)	Capeweed	750mL/ha	Weeds should be young and actively growing and be up to 10cm in diameter (4-8 leaf).
Oilseeds	Saffron thistle	750mL/ha	Weeds should be young and actively growing and be up to 10cm in diameter (4-8 leaf).

Crop	Pest	Rate	Critical Use Comments
(proposed extension)			

Table 2 states as summarised below:

- cereals and oilseeds are within the same related crop group of field crops,
- the risk assessment areas of OHS and environment indicate that extrapolation is possible ✓ to the crop group, and
- the risk assessment areas of residues, efficacy and crop safety indicate that extrapolation is not possible **R OR C** to the crop group.

Crop Group	Related Crop Group	Risk Assessment areas				
		Residues	Efficacy	Crop Safety	OHS	Environment
Cereals	Field crops	R	C	C	✓	✓
Oilseeds	Field crops	R	C	C	✓	✓

In this example an applicant may lodge an application seeking extension to the whole crop group of oilseeds with a requirement to address residues, efficacy and crop safety in oilseeds. For the risk areas of OHS and environment a data and assessment waiver would apply. Such an application would be suitable under Item 14.

Example 3

- A fungicide is currently registered in tree nuts for the control of anthracnose.
- Extension is sought to the whole crop group – assorted tropical and sub-tropical fruits, edible peel for the control of leaf spot.
- The proposed new use pattern in assorted tropical and sub-tropical fruits, edible peel will be no greater than that already approved in tree nuts (ie. rate, frequency and number of applications).
- The following table depicts the existing (tree nut) and proposed registration (assorted tropical and sub-tropical fruits, edible peel).

Crop	Pest	Rate	Critical Use Comments
Tree nuts (existing registration)	Anthraco nose	600mL/100L	Apply a maximum of two consecutive applications at 14 day intervals.
Assorted tropical and sub-tropical fruits, edible peel	Leaf spot	400mL/100L	Apply a maximum of two consecutive applications at 21 day intervals.

Crop	Pest	Rate	Critical Use Comments
(proposed extension)			

Table 2 states as summarised below:

- tree nuts and assorted tropical and sub-tropical fruits – edible peel are within the same related crop group of tree & tropical fruit crops,
- the risk assessment area of OHS indicate that extrapolation is possible ✓ to the crop group, and
- the risk assessment areas of residues, efficacy, crop safety and environment, indicate that extrapolation is not possible **R OR C** to the crop group.

Crop Group	Related Crop Group	Risk Assessment areas				
		Residues	Efficacy	Crop Safety	OHS	Environment
Tree nuts	Tree & Tropical Fruit Crops	R	C	C	✓	✓
Assorted tropical and sub-tropical fruits, edible peel	Tree & Tropical Fruit Crops	R	C	C	✓	C

In this example an applicant may lodge an application seeking extension to the whole crop group of assorted tropical and sub-tropical fruits, edible peel with a requirement to address residues, efficacy, crop safety and environment, in assorted tropical and sub-tropical fruits, edible peel. For the risk area of OHS a data and assessment waiver would apply. Such an application would be suitable under Item 14.

Example 4

- A fungicide is currently registered in pome fruit for the control of black spot.
- Extension is sought to the whole crop group – leafy vegetables for the control of downy mildew.
- **The proposal does NOT qualify for extrapolation** as pome fruit and leafy vegetables are not within the same related crop group. Where pome fruit is a member of the tree & tropical fruit crops (Table 2A) and leafy vegetables is a member of the vegetables (Table 2C).

3 MAKING APPLICATIONS TO THE APVMA USING THIS DOCUMENT

The APVMA is proposing to initially operate this guidance document as a pilot for a period of 12 months.

During the pilot applicants seeking to rely on this guidance document will be required to submit proposals initially to the APVMA via Pre-Application Assistance (PAA). The APVMA would accept proposals under either:

- Tier 1 PAA with relevant fees and a 1 month assessment timeframe for those proposals where all risk assessment areas in this document indicate that extrapolation is possible ✓ (ie. all of residues, OHS, environment, efficacy and crop safety), or
- Tier 2 PAA with relevant fees and a 2 month assessment timeframe for those proposals where any risk assessment area in this document is indicated with extrapolation is not possible **R OR C** (ie. any of either residues, OHS, environment, efficacy and/or crop safety)

Tier 3 PAA would apply to any applications that also sought assessment of a trial protocol.

Subsequent applications for registration (typically to be lodged as either Item 12 or Item 14) would be applicable for the relevant Pre-Application Assistance rebate where the product application fee will be reduced by an amount prescribed in the Agvet Code Regulations.

Applications for PAA should ensure that they contain:

- A brief summary of the proposed application (ie. extrapolate from which representative crop(s) to a full crop group or sub-group),
- A copy of the proposed draft label clearly identifying (highlighting) the areas of change,
- A description of how the proposed change aligns with the guidance document presented in a similar format to the examples provided in this document, and
- Where necessary a description of the data or argument to be provided in an application to satisfy the APVMA in any risk assessment areas where extrapolation is not possible **R OR C** for the proposed use.

The APVMA will provide written responses to all PAAs outlining the relevant assessment Item and/or modules, fees and timeframes that would apply to the proposed application.

APPENDIX 1 – INDIVIDUAL RISK AREA ASSESSMENT PERSPECTIVES

The following provides details on the APVMA consideration for selecting representative crops in the crop groups, and sub-groups, across all risk assessment areas.

Efficacy and crop safety

The two most important aspects of efficacy evaluation are the demonstration of direct efficacy against the target pest, and demonstration of safety to the crop. For major uses, efficacy data are mainly obtained in trials set up according to the principles of good experimental practice. For extrapolation of existing uses to a crop group, the following information may be used, to establish efficacy and crop safety for the minor crops within the crop group:

- Comparison and extrapolation from the original registered uses
- Use of data from a limited number of efficacy trials for the minor uses;
- Use of data from other sources.

For a new registration, data on the representative crops provides the basis for the comparison and extrapolation, and may require supplementary data for the minor uses in some cases. In identifying the representative crops, the APVMA has utilised the European and Mediterranean Plant Protection Organisation (EPPO) standard as the basis for accepted extrapolations, with supplementary data required in some instances. This Standard deals specifically with comparison and extrapolation from original registered uses, and the same principles can be applied to new registrations when data on the representative crops are provided.

Extrapolation is the means by which efficacy data supporting the registration of a product against a target pest on a crop are used to justify efficacy against either the same target pest on a different crop or a different target pest on the same or different crop.

Taxonomic links between target pests alone are generally not sufficient evidence of similarity for extrapolation and information on the biology of crop/pest interactions should be provided. Extrapolation requires knowledge and understanding of the target pest, weed or disease and mode of action of the product as well as the relationship with the target from which extrapolation is intended. For extrapolation between crops, it requires an understanding of the relationship and similarity of the crops and the interaction both with the product and the target pest.

Substantive information is already available internationally on extrapolation. The EPPO guidance "EPPO PP1/257 Efficacy and crop safety extrapolations for minor uses" provides a comprehensive insight into the principles of extrapolation. Associated with this document are a series of crop specific tables which identify extrapolations between crops or between targets that will form a basis for satisfaction of the efficacy and crop safety criteria. <http://www.eppo.fr/PPPRODUCTS/extrapolation/tables.htm>.

The EPPO document is continuous development with new tables being developed and new extrapolations being added. They are also predominately focussed on targets across the EPPO region (and as such Europe) but many of the target pests and crops are relevant to Australia in the majority of cases, and the principles of extrapolation can be applied to any target or crop. As indicated in EPPO PP1/257, it is important that extrapolations are considered and verified by national experts to take account of local conditions, such as different agronomic

practices or resistance to Plant Protection Product's. The APVMA relied on this document in developing the Australian crop groups and will continue to do so for all extrapolation decisions.

Certain groups of pests or crops are considered to be more or less equivalent in relation to the efficacy of plant protection products. However, differences may exist between different regions both within Australia and also internationally. This has been considered for the extrapolations which are included in the extrapolation tables for effectiveness/crop safety of plant protection products.

The extrapolations are based on an examination of biological and chemical evidence that justifies assumptions of efficacy without a specific set of supportive data (for the particular commodity or pest/disease). The extrapolation tables are not exhaustive. When an extrapolation is not listed, it does not mean that it may not be acceptable. The effects of climate on pest/crop interrelationships need be taken into account. However, climate is only one factor that may affect the effectiveness and crop safety of a product in addition to other factors (agronomic, edaphic, target-related) is as important in efficacy of the product.

Extrapolations will only be considered for the extension of use of a given plant protection product used at the same dose, applied under similar conditions (e.g. timings, growth stages, application methods, soil conditions) as that currently on an APVMA approved label, or proposed by way of data/ use pattern for the representative crops submitted for new registrations.

The extrapolation tables are based on the principle that certain crops can be considered equivalent in relation to effectiveness or crop safety and can be grouped together in crop groups. A crop group contains all crops for which an extrapolation may be performed from a representative crop(s) (for a particular plant protection product), regarding either:

- Effectiveness against a particular pest;
- Safety for a particular crop.

Representative crops are those crops which can be considered representative of effectiveness or crop safety for their crop group and for which a set of data is or will be available.

Within a crop group there might be some crops for which certain pests are considered to be more difficult to control and therefore collecting some additional evidence is recommended while extrapolating from an indicator (representative) crop. It should be noted that it is preferable to have data on several of the crops within the crop group, but data on the representative crops should always be available. If effectiveness of a plant protection product has been adequately demonstrated against a major pest or a range of related pests for a particular crop group, it may be possible to extrapolate to other related pests in other crop groups.

Phytotoxicity is particularly relevant with certain products, such as herbicides, some types of application, such as soil or seed/plant treatments, and for specific crops such as ornamentals. Phytotoxicity can vary considerably between different crop species, cultivars of the same crop and between different plant protection products. Extrapolation from representative crops to a whole crop group for herbicides is possible in some situations but generally will not be supported without a data base or sound justification for crop safety for all members of the crop group.

Extrapolation to complete crop groups may not be possible where use of the product has resulted in crop damage on some crops or cultivars, where crops concerned are significantly different, or when a crop is known to be particularly sensitive.

Application of extrapolation principles to a registration submission.

Applicants should provide reasoning as to why an extrapolation is acceptable. It may be citing the extrapolation tables, and why it is relevant for the product in question in the Australian context. For extrapolations not listed in the extrapolation tables, a more comprehensive scientific justification will be required. That justification should provide a full explanation of why the extrapolation is considered appropriate, considering the biology of the targets as well as the crops in question, and the interactions with the product, the active substance and its mode of action.

Further guidance on preparing submission is available at in the [pesticides efficacy and crop safety general guideline \(Part 8\)](#).

Additional resources are EPPO Efficacy evaluation of plant protection products Standard available at <http://pp1.eppo.int/list.php> - including PP 1/214 Principles of acceptable efficacy; PP 1/224 Principles of efficacy evaluation for minor Uses; PP 1/269 Comparable climates on a global level; PP 1/257 (2) Efficacy and crop safety extrapolations for minor uses; PP 1/278(1) Principles of zonal data production and evaluation

Confirmatory data may be required to provide confidence in the performance or crop safety of the product as indicated in the tables. The amount of additional data required will be dependent on the level of uncertainty associated with the extrapolation, and the quality of the data.

It may be possible to assess crop safety while obtaining data for residues or effectiveness for a particular plant protection product.

Residues Perspective

Crop groupings allow maximum residue limits (MRLs) to be established for multiple related crops based on data from a representative set of crops. Targeted data sets and data extrapolation are used to provide sufficient data for exposure assessment or for setting MRLs for both individual major and minor crop commodities, and crop commodity groups. Data extrapolation provides the mechanism for extending field trial data from several (typically two or three) representative crop commodities to related crop commodities in the same crop group or subgroup.

Subgroups are primarily indicative of form and growth habit, and generally at least one commodity would be required from each subgroup to set a group MRL. It will be possible to set subgroup MRLs as may be required for some extensions of use.

The representative crop commodity(s) within the crop group are selected on the following basis:

1. major in terms of production and consumption; and
2. most likely to contain highest residue.

Individual crops are allocated to a crop group based on morphological (residue potential) criteria as well as on cultivation practices (Good Agricultural Practice).

Impediments to utilising the crop grouping extrapolation principles include:- commodities that are used for Feed items for livestock and/or poultry (including Importance of Feedstuffs and Percent of Livestock Diet). How the raw agricultural commodity (RAC) is processed (such as oil or flour) and/or Fresh Market as Whole Fruit/Vegetable. These factors mean certain extrapolations will require specific supporting information or data.

Trade Perspective

Establishment of crop group MRLs is generally considered trade enabling, however there may be some cases where a group MRL established in Australia for a minor specialty commodity may not have a corresponding MRL in importing countries MRL standards. This situation may create a barrier to trade for individual commodities.

Maximum residue limits (MRLs) of chemicals in food commodities are established by countries where the chemicals are approved and used in accordance with their approved uses. MRLs (which are also known as 'tolerances' in some countries) can therefore vary from country to country due to different use patterns and other factors. Consequently, legitimate use of a chemical in Australia, including adherence to the registered or approved use pattern, can give rise to residues that exceed the standards of importing countries while complying with Australia's standards.

The APVMA considers potential trade issues as part of the registration process for agvet chemical products. From a crop grouping perspective either the potential trade issues from use of a product would have been undertaken for the initial approved label use or will be considered during evaluation of the residues data submitted for the representative crops.

There may be some cases where the extrapolation from an existing use for select members of a crop group to a whole crop group may need to be considered to address specific potential trade concerns for other members of the crop group

Environmental Perspective

In general, the matters which allow groupings under the Codex Classification of Foods and Animal Feeds (1993 (as updated)) for residues, is also suitable to groupings for environment consideration and assessment. That is, where crop residues allow extrapolation from a representative crop to the rest of the group, there is no reason the same extrapolation can't be made for environmental risk assessment purposes. There are exceptions that need to be highlighted:-

- Cereals - Rice has a very different environmental exposure pattern to any other crop in the cereal grain grouping. Run-off and spray drift are generally not significant issues for rice, but release (scheduled and unscheduled) is a significant route of environmental exposure. Therefore from an environmental perspective rice cannot be extrapolated to any other grain crop and vice versa.
- Region specific run-off, application methods and possibly timing of application for the protection of pollinators. If a crop in the grouping is grown outside of these regions, then extrapolation may not be possible without some assessment.

- Occasionally due to run-off concerns, there will be restrictions of use to specific regions. In general, due to their similarity in plant morphology, it is expected that many crops within a group will be grown in the same regions.

Noting the above, it is still possible to undertake an evaluation of the complete crop group if all representative commodities are considered.

WHS - worker exposure

From a worker exposure risk perspective, representative crop(s) and associated chemical product treatment are taken to pose the greatest exposure risk to workers, allowing the assessment of WHS to be extrapolated to the whole crop group.

The factors affecting the worker exposure from the use of an agricultural product include:

- toxicity of the active constituent in the formulation
- hazard of the product formulation
- formulation type
- product application rate (kg/ha)
- area treated (ha/d)
- application method (aerial, ground, hand)

Most of these factors remain constant when extrapolating a use to a whole crop group. While treated area may differ, the representative crops generally represents the largest treated area and the largest exposure.

In considering worker exposure the APVMA determines, as needed, re-entry periods for post-application activities. Any re-entry period for the representative crop will be applied to all crops within the group.