Plant protection: Regulatory support and co-ordination

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Project Number: AH09003

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This report is published by Horticulture Australia Ltd to pass on information concerning horticultural research and development undertaken for the across industry projects.

The research contained in this report was funded by Horticulture Australia Ltd with the financial support of the across industry projects.

ISBN 0 7341 3336 7

Published and distributed by:
Horticulture Australia Ltd
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179 Elizabeth Street
Sydney NSW 2000
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Fax: (02) 8295 2399

HAL

Horticulture Australia

HAL Project Number: AH09003 (31/5/2014)

Plant protection: Regulatory support and co-ordination

Milestone Report 190 (Final Report)

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31st May 2014

Purpose of the Project:

To provide a coordinated response to farm chemical related regulatory issues at the domestic and international levels such as chemical reviews to ensure continued availability and use of product(s) by the horticultural industries.

This project has been funded by HAL using the across industry levy and matched funds from the Australian Government.

Horticulture Australia

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Media Summary

Global competitiveness and long-term viability have been identified as horticulture industry priorities. From a crop protection perspective to achieve these outcomes horticultural industries will need to not only have access to a broader suite of effective tools but also information on their application to ensure their use does not adversely affect compliance with specific market requirements. From that perspective Project AH09003 has sought to focus on three broad areas; a) Plant protection product access, b) Compliance with international and domestic standards and c) Regulatory engagement.

Dealing with regulation is an ongoing issue for Australian horticulture. From a farm chemicals perspective the outcomes of chemical reviews, increasing data requirements, manufacturer lack of interest, resistance and ensuring compliance in export markets all serve make the task of gaining and or maintaining access to suitable pest management options increasingly problematic. In order to more efficiently deal with the variety of demands posed by these challenges industries have had to become more proactive in identifying emerging issues and seeking to develop appropriate responses.

To help industries deal with the many farm chemical related issues HAL, in partnership with industry have funded Kevin Bodnaruk of AKC Consulting Pty Ltd, to act as a co-ordinator to ensure that a) issues with the potential to impact on chemical access are brought to the attention of horticultural industries, b) that they are given adequate information and c) provided with an opportunity to consider and respond accordingly.

For more information on the chemical review process or the project contact the peak industry body for your industry or Kevin Bodnaruk on 02 94993833.

Technical Summary

The regulatory framework in relation to farm chemicals, domestic and international, within which Australian horticulture operates, is complex and subject to continual change. It has been important, therefore, for horticultural industries to participate, at both levels, to ensure industries have the opportunity to consider and develop responses to issues arising from domestic and international regulators.

In Australia the Australian Pesticides and Veterinary Medicines Authority (APVMA) can reassess currently registered chemicals with regard to residues, occupational health and safety and the environment. Possible outcomes of reviews include confirmation that the chemical is safe and appropriate for registered use, or suspension, cancellation or withdrawal of the chemical from the market. This chemical review process is ongoing with a number of reviews nearing finalisation, such as dimethoate and fenthion. This process, in effect parallels similar programs in other jurisdictions such as the EU, USA, Canada and Japan. The work of the project has been targeted at ensuring industries are informed of any potential impacts arising from these chemical reviews and where required provided with an opportunity to consider any implications and develop a suitable response, e.g., in the event of a data gap possibly funding data generation.

Domestically, regulation of farm chemicals has been undergoing significant change in recent years at both the federal and state level. There has been an ongoing COAG process seeking to achieve a degree of harmonisation between the states in the areas of training, fee-for-service licensing for applicators and control of use. There have been major changes to federal legislation governing the operation of the APVMA in the areas of minor use permits, the application process and chemical review. All changes with the potential to impact on horticultural industries access to farm chemicals. The function of the project has been to keep horticultural industries informed about these changes and facilitate the provision of responses to government where changes could be detrimental with respect to farm chemical access.

At the international level the body responsible for setting standards with regard to chemical residues in food is the Codex Committee on Pesticide Residues (CCPR). The standards established by this body can be particularly important as they act as international benchmarks for commodities that move in trade. These standards can be particularly important for horticultural industries with an export focus as many countries utilise Codex standards in the absence of domestic standards. Engaging in the Codex process has enabled a number of Codex standards to be established based on Australian uses.

Industry responses to World Trade Organisation notifications have been managed and coordinated through the project. Where countries announce MRL changes with the potential to impact on the export of Australian commodities the Department of agriculture is advised and encouraged to make a submission. This input follows consultation with the relevant export industries.

1 INTRODUCTION

1.1 Background

The regulatory framework within which Australian horticulture function's, both domestic and international, is complex and subject to continual change both at the policy and operational level. It has been important, therefore, for horticulture to engage, at both levels, to ensure industries have the opportunity to consider and develop responses to issues arising from domestic and international regulators that potentially impact on chemical access as well as trade.

1.2 Chemical reviews - Domestic

The APVMA is required under legislation to conduct regular reviews of registered agricultural and veterinary chemicals to ensure they meet contemporary regulatory standards for safety and efficacy. As regulatory standards change the Australian Pesticides and Veterinary Medicines Authority (APVMA) reassesses the existing registered chemicals with regard to residues, occupational health and safety and the environment. Registrants, industry and the public are notified of the commencement of reviews and are given opportunities 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, or suspension, cancellation or withdrawal of the chemical from the market.

At the domestic level pesticide reviews by the APVMA are ongoing with a number of reviews in the process of being finalised during the life of the project, e.g., azinphos-methyl, carbendazim, sulphur dioxide and fenthion, while reviews for dimethoate are continuing.

Industry responses to domestic pesticide related issues have been managed and coordinated through the AH09003 project. Since the initiation of AH09003 project residue trials in a range of fruit and vegetable crops have been completed providing data to support continued grower access for a number of pesticides, e.g., dimethoate, trichlorfon and fenthion.

1.3 Chemical reviews - International

At the international level Codex, the United Nations food standards setting body, has a number of committees actively developing standards covering such issues as pesticide MRLs, food hygiene and food contaminants. All of which have the potential to adversely impact on Australian exports. Current horticultural involvement through AH03009 has primarily been with the Committee on Pesticide Residues with a watching brief being maintained over the Committee for Contaminants in Food. To date this participation has enabled Australian horticulture to input in the development of the Australian position with regard to matters arising at these Codex Committees, e.g., the revision of the Codex Classification for Food and Animal Feeds. It has also ensured that Australian horticultural industries have been in a position to consider and develop responses to issues as necessary, such as the proposed revocation of Codex MRLs.

In addition, data from HAL and industry funded residue trials completed for buprofezin, bifenthrin and chlorothalonil have been submitted to the FAO to facilitate either the establishment of or maintenance of international MRLs (Codex), i.e., to provide coverage for commodities moving in international trade.

1.4 Regulatory

The project has been involved in informing industries of issues and facilitating responses to a number of farm chemical related reviews and the current legislative reform agenda of the current and previous governments. These have included the legislative reform process currently being undertaken by the Department of Agriculture, the APVMA review of its cost recovery arrangements, The Department of Agriculture First Principles review of the APVMA cost recovery arrangements, reviews of pesticide legislation by various states such as WA, Vic and NSW, the development of the Product Safety and Integrity Committee (PSIC) discussion paper on control of use, as well as providing input into the development of the APVMA corporate plan.

In addition, through engagement with government the project has ensured that there has been horticultural representation at various farm chemical related government working groups, e.g., APVMA Working groups on Communication, the APVMA Industry and Technical Liaison Committees and the National Industry Reference Group on security sensitive chemicals.

1.5 Trade

Trade related issues are becoming increasingly prominent in the area of farm chemicals. Firstly, with regard to the direct trade differing standards can result in countries rejecting food imports where residues do not comply with either local or Codex standards. The current project has monitored proposed changes occurring at both the Codex and the WTO levels alerting exporting industries to the potential for adverse impacts.

In addition, as part of the chemical approval process the APVMA can choose to publish a Trade Advice Notice (TAN) seeking public comment on a proposed registration from a trade perspective. Information sought can be either direct, i.e., in relation to differences in chemical × commodity standards between Australia and potential export markets, or indirect, with regard to potential impacts on the export of other commodities through livestock feeding of crop by-products. AH09003 has sought to provide relevant input into the TAN process

2. METHODOLOGY

2.1 Outline

Work within the project has been framed primarily by the activities of the various regulatory bodies associated with pesticide regulation in Australia and standard setting at Codex. Within the context of this framework project activities have been undertaken following consultation with the relevant HAL program manager and relevant industry stakeholders. In general the activities undertaken have been in the areas of liaison, communication and data generation and information collation. Liaison activities have been focused on establishing and maintaining contact with regulators at both state and federal levels involved in the areas of policy development and implementation.

Communication activities have centred on ensuring firstly, that horticultural industries are aware of the current status of chemical reviews, WTO notifications and Codex standards and the potential implications of the proposals contained therein. Secondly, that industries are given adequate time in which to develop considered responses to the proposed changes where necessary; thirdly, ensuring that regulatory agencies are provided with the horticultural

industry responses to any issues raised or requiring comment. And lastly, ensuring that chemical manufacturers are contacted and where possible involved in providing support for chemical uses identified as valuable.

2.2 Communication strategy

A communication strategy based upon two elements; direct contact with key stakeholders and an information dissemination strategy has been followed. Direct contact consisted of making contact with stakeholders via face-to-face meetings, telephone contact or participation in meetings and conferences. Information dissemination was based upon the provision of information via detailed updates on current regulatory issues to industry representatives for circulation.

The strategy involved contacting key industry personnel, nominated by HAL, then via electronic and conventional mail providing updates for their consideration and distribution within their associations via industry newsletters or magazines. General articles were also provided to horticulture print media on review progress and outcomes, e.g., Mango Matters and AMGA Journal.

2.3 Communication activities

2.3.1 Reporting/Presentations

I. Regular milestone reports, work plans and activity schedules have been provided, as per the agreed schedule, to HAL. Furthermore, regular updates, both written and verbal, were made to the responsible HAL Program Manager and the industry stakeholders. In addition, presentations on the current status of chemical reviews and the review process were also made to industry meetings, e.g., Mango Growers Conference, HAL Board.

2.3.2 Liaison

I. Liaised with each affected HAL horticultural industry stakeholder, registrants, and allied industries to determine their stance towards chemicals under review.
II. Liaised with horticultural industries, APVMA and registrants to determine and develop the appropriate response from horticultural industries to chemical reviews.

2.3.3 Data generation/submission

I. Liaised with contractors managing R&D effort required to generate data on residues. This involved negotiating data requirements with the APVMA, assisting in the writing of residue trial protocols.

II. Through contact with industry participants facilitated the development and submission of industry responses to Review issues, such as confirming use patterns for pesticides and OH&S related pesticide application practices.

3 RESULTS AND DISCUSSION

3.1 Project Output

3.1.1 Communication activities

I) Ag Chemical Updates Newsletter

AKC Consulting have produced a biannual newsletter which covers a range of chemical regulation issues both domestically and internationally as well as providing readers with contacts and sources of further information. The newsletter was distributed, predominantly, via existing industry based communication networks, such as industry development officers (IDO's) and Peak Industry Body (PIB) periodicals. This has allowed the project to distribute information widely to industry participants, such as growers and advisers. Information was circulated primarily via regular updates (see Attachment I).

II) Liaison

Where matters raised by government, e.g., proposed regulatory reforms or chemical reviews, had the potential to impact on farm chemical access industry representatives were informed and where required the project helped facilitate the development of industry responses. In addition, regular contact was maintained with a range of stakeholders included government authorities, commercial advisers/consultants, manufacturer representatives, Croplife, APVMA, FSANZ, state based bodies such as VFF, WAFF, NSWFA and State Departments, e.g., DAFF Qld and DAFWA. This liaison occurred face-to-face, via telephone, email and in meetings. (See Attachment II)

3.1.2 Facilitation of trial data

I) Input and advice was provided in the development of study plans for residue trial data generation to support the continued access to trichlorfon (SF12011), fenthion (SF12017) and dimethoate (AV12018, CT12015, MT12030 and PI12001). This involved liaising with the APVMA and service providers to ensure data generated would meet regulatory requirements. The resulting data was collated and reports written and submitted to the APVMA at the completion of the projects.

3.1.3 Submissions

I) APVMA

The current chemical review process undertaken by the APVMA follows a cyclic process with three opportunities provided for industry input. The first opportunity comes with the review announcement and the release of the scoping document. The second stage is when the draft Review Report is circulated and finally when the Draft Final Report is circulated for comment. It is understood that under the legislation coming into effect after June 30th that

Chemical review

Formal submissions were made to the APVMA, on behalf of horticultural industries in response to APVMA initial reviews for carbendazim (mushrooms), chlorpyrifos (citrus, diuron (citrus), fenamiphos, fenthion, and dimethoate. Responses to preliminary review findings azinphos methyl, diazinon, diuron, carbaryl, methiocarb etc (see Attachment III).

Permits

Emergency use permit applications were prepared on behalf of industry groups in response to locust plagues, i.e., chlorpyrifos, diazinon, dimethoate, maldison. Permit applications also prepared in response to chemical review outcomes for Queensland fruit fly and Mediterranean fruit fly, e.g., clothianidin, maldison and thiacloprid. (see Attachment IV)

Cost recovery regulatory impact statement.

Submissions were prepared in conjunction with industry groups in response to the APVMA's Cost Recovery Impact Statement in 2009. (See Attachment V)

II) Department of Agriculture

Submission made to the:

- National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals Discussion paper.
- The Better regulation of agricultural & veterinary chemicals legislative reform process.
- First Principles Review of Cost Recovery at the APVMA Consultation Paper
- Senate Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014
- Senate inquiry - Implications of the use of Fenthion on Australia's horticultural industry

(See Attachment VII)

III) Codex

The project help facilitate submissions to the CCPR for MRLs for emamectin, bifenthrin and chlorothalonil. In addition participation in panel meetings and responses provided to help inform Australia's position on a number of Codex related issues. (See Attachment VIII)

IV) Trade

As indicated WTO sanitary and phytosanitary (SPS) notifications are being monitored with input sought from industry and responses provided to government. Outlined below is a list of notifications raised with industry groups for which responses were provided to the Department of Agriculture. (see Attachment IX)

V) Japan

Input has been provided to the APVMA on priority chemical × commodity combinations for MRL support in Japan and Taiwan via project MT12045. These priorities were developed through consultation with industry representatives of the Almond, Citrus Table grape, Macadamia nut, Mango and Pome fruit industries. The project facilitates the provision of data packages, prepared by the APVMA, for submission to the Japanese Ministry of Health, Labour and Welfare, with the aim of gaining permanent MRLs in Japan that reflect Australian standards.

VI) Trade Advice

Responses to APVMA trade advice notices have been prepared and provided for the following; chlorothalonil, clothianidin, etoxazole, flubendiamide, pyraclostrobin, spirotetramat and triclopyr. (See Attachment X)

VII) Security Sensitive Chemicals

Horticultural industry stakeholders have been kept informed of developments in relation to the 29 agvet chemicals identified by the Attorney General's Department as posing a potential security concern. To facilitate the flow of information, a presentation by a representative of the AGD was organised for a HAL Forum, as well as representing horticulture on the National Industry Reference Group. In addition, field site visits, i.e., to farms and reseller establishments, by AGD staff was facilitated (See Attachment XI)

3.1.4 Technical support

AKC Consulting has also provides technical support to horticulture industry participants on matters relevant to pesticide related issues, such as research priorities, data generation requirements, permit applications and MRL compliance in export markets. This has been through involvement in industry working groups such as the previous Vegetable industry chemicals working group, the Summerfruit fruit fly working group and the mushroom industry's risk management project team. This has been done via participation in face-to-face meetings, telephone and email contact.

3.2 PROJECT OUTCOMES

3.2.1 Improved Knowledge and Understanding

Australian horticultural industries continue to be informed about pesticide regulatory changes occurring both nationally and internationally. This has been achieved via project networking, industry liaison, newsletters and participation in industry meetings and conferences.

3.2.2 Pesticide Access

As a consequence of the project access to dimethoate, for the majority of uses sought, have been retained as a consequence of trial data submitted. In addition, access to various chemicals has been gained through the preparation of minor use and emergency use permit applications.

Through linkages with the Minor Use Co-ordinator project, until 2013, AH03009 has been in a position to help inform and provide guidance in the process of seeking chemical access through minor use permits. This has been achieved by highlighting potential opportunities for minor use permit applications due to new Codex chemical × commodity standards, i.e., supporting data exists, or those chemical × commodity combinations whose regulatory future is uncertain, e.g., those where there is no registrant support internationally.

3.2.3 Regulatory reform - Input

An important aspect of the project has been alerting horticulture industry participants of potential impacts of proposed legislative and or policy changes relating to the regulation of pesticides in Australia. This has resulted in horticultural industries being informed of and aided in the preparation and submission of responses to various government consultations on regulatory reform.

3.2.4 Codex Standards

Through maintaining a 'watching brief' horticultural industries have been alerted to proposed changes in MRL standards at the Codex Committee on Pesticide Residues as well as changes to the standard setting process with potential implications to Australian horticulture, e.g., the revision of the Codex Classification of Foods and Animal Feeds and the current working group on minor use.

3.2.5 Improved participation

As a result of project activities in areas related to pesticide regulation Australian horticultural industries have had increased opportunities for involvement and contribution to the agvet chemical policy setting process. As well as being in a better position to provide meaningful and timely feedback to the APVMA on chemical review related queries. Participatory activities have included involvement in Australian panel meetings for the CCPR, involvement with the Australian delegation to CCPR, discussions with representatives of the Agricultural Productivity Division of the Department of Agriculture on issues relating to the development of agvet chemical regulations.

4 FUTURE CONSIDERATIONS:

4.1 Future review chemicals

The ongoing review of existing agvet chemicals will continue. It is envisaged that the APVMA will seek to take steps clear the current backlog of review chemicals over the next 12 to 24 months. It is anticipated the initial APVMA focus will be on chemicals which have had reviews initiated but as yet have not been finalised, i.e., Azinphos-methyl, Chlorpyrifos, Diazinon, Dimethoate, Diquat, Fenamiphos, Fenitrothion, Fenthion, Fipronil, Maldison (Malathion), Methidathion, Methiocarb, Omethoate, Paraquat and Procymidone.

In addition, it is understood that the APVMA intends to revisit the current list of nominated chemicals with a view to re-assessing their priority and the need for a review. Of these a number are of potential importance to horticultural industries, e.g., methomyl, propiconazole, trichlorfon, chlorothalonil, dithiocarbamates (mancozeb), phorate, terbufos, fenbutatin oxide and propargite.

Of particular concern will be how industries engage with the APVMA given the regulatory processes that will come into effect from July 1st 2014. The chemical review procedure will undergo a significant change with regards to regulatory timeframes associated with various review steps. Of particular concern is the 'closed door' approach for data submission and how this may impact on the ability of industry groups to support continued access to chemicals through data generation. Under the reformed procedure from July 1st, the APVMA will have for a specified period following the announcement of a review to accept data submissions, i.e., no data can be accepted outside of the statutory timeframe. This will mean that should an industry wish to support a use the data will need to be available at or close to the time a review is announced. Should data not be available, that industry would need to submit any data following the completion of the review.

From an industry perspective this could have a number of adverse impacts. Firstly, there could be the loss of labelled uses. Should a supported use be removed then industry would need to await the finalisation of the review, submit any data and wait for the completion of that data to be assessed. Resulting in a gap period in which there was no label approval, which could be upto 2 years. Added to this would be the fact that fees would need to be paid to have the data assessed, which added to the cost of data generation could make data submissions problematic from a resource allocation perspective.

Consequently, industries will need to be informed of the potential risks associated with the review process and be in a position to consider any actions well in advance of any review announcements.

4.2 Security Sensitive Chemicals

The Attorney Generals Department (ADG) is in the final stages completing the review of the 96 chemicals that were previously been identified as being of security concern. A risk assessment framework has been developed and the authorities are engaging with industry to develop appropriate levels of risk mitigation via industry based voluntary codes of practice. This will occur through the publishing of a regulatory impact statement (RIS) for public comment. It is expected that the RIS will be published in the second half of 2014.

5 RECOMMENDATIONS:

A. That the project be continued.

B. The ongoing nature and time involved in completing chemical reviews makes the projects critical with regard to horticultural industries being able to respond adequately to the various stages of APVMA reviews.

C. Continue participation in Australian activities at Codex with regards to the Codex Committee on Pesticide Residues and maintain a watching brief over the Codex Committee on Contaminants in Food with respect to standard development with the potential to impact Australian exports.

D. That the project continues to engage with government and industry stakeholders over regulatory reforms relating to pesticide use and access in Australia.

E. That the issue of trade and WTO notices continue to be monitored with information circulated to relevant industry stakeholders for consideration and that government be provided with timely accurate responses where necessary.

6 ATTACHMENT I: AGCHEMICAL UPDATES – INDUSTRY COMMUNICATION

AgChemical Update - 2009
(Project AH04007)

WHATS NEW
Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

Productivity Commission Review
The Productivity Commission has finalised its review of chemicals and plastics regulation in Australia. There are a number of recommendations relevant to horticulture, of particular note are:

that the regulation of Control of Use be consolidated under the authority of the APVMA

that MRLs set by the APVMA should be automatically incorporated into the FSANZ Food Standards Code

COAG have agreed to the proposed recommendations and it is understood that various government departments have been tasked with reviewing current arrangements and develop new approaches for the implementation of the recommendations. The timeframe for completion of this phase set for early 2010.

The full report and recommendations can be found at the link below
http://www.pc.gov.au/projects/study/chemicalsandplastics/docs/finalreport

APVMA Chemical reviews
Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

Priorities: The APVMA priority list of chemicals for review can be found at http://www.apvma.gov.au/chemrev/Nominations.shtml
In all there are 45 chemicals listed with nearly 20 used in horticulture. The Priority 1 list includes acephate, chloropicrin, fipronil, methomyl, propiconazole and trichlorfon.

Fenthion and Dimethoate: The trial program to augment previously submitted data is well underway. The first season's pre-harvest trials have been completed and the second season is underway. Post-harvest residue trials are about to commence. Related trial work on post-harvest treatment rates is also underway.

It is understood that the APVMA is in the process of finalising inert-agency elements of these reviews. It has been indicated that, at this stage, the APVMA intends to finalise the reviews once an assessment of all available data has been completed, including the data from HAL trials once have been completed, submitted and taken into consideration. This is anticipated to be either late 2009 or early 2010. See the link below for more information

http://www.apvma.gov.au/chemrev/dimethoate.shtml
Carbendazim: Bavistin, Spin Flo, Howzat etc) **Thiophanate methyl** (Banrot). As indicated previously the review of these two chemicals was initiated over potential public health and occupational health and safety concerns.
It is understood that the review is well progressed with a draft report becoming available during 2009.

FSANZ
Dieldrin: A request has been made of FSANZ to address the issue of the environmental contaminant dieldrin in the Food Standards Code. Currently few commodities are covered for extraneous

contamination and FSANZ have been asked to amend the Code to include a number of commodities potentially at risk through contact with soil, e.g., cucurbits. In response FSANZ have recently published a notification, (Proposal M1003) indicating that amendments for dieldrin are under consideration. See the link below
http://www.foodstandards.gov.au/_srcfiles/M1003%20MRLs%20(Apr,%20May,%20June,%20Aug%202008)%20AAR%20FINAL.doc

INTERNATIONAL

New Zealand

In NZ Environmental Risk Management Authority has recently revoked approvals for methyl parathion and endosulfan. Whether this decision has any implications for Australian exports to NZ are uncertain. It is believed that under the TTMRA, food meeting FSANZ MRLs for a particular pesticide can be sold in NZ irrespective of the status of the NZ registration for that pesticide or the NZ MRL status.

For example, for endosulfan, despite the registration and use in NZ now being withdrawn, the MRLs are still currently in place, so food from Australia that complies with either, the current NZ MRLs, the FSANZ MRLs or Codex MRLs should be acceptable. Nevertheless, it is understood that clarification of the matter is being pursued through DAFF.

EUROPE

Meanwhile changes to pesticide regulation in Europe continue apace.

Commission Decision 2008/934/EC and the voluntary withdrawal of a number of active substances from regulatory review.

Late last year the EU Commission took a decision not to include 49 compounds in Annex 1 to 91/414/EEC. It is understood that this was, primarily an administrative / bureaucratic solution to allow new data to be submitted while ensuring review timelines were met. This involved giving registrants the option of voluntarily withdrawing their compounds from the review program then resubmitting with any additional supporting data.

The compounds withdrawn are listed below with those registered for use in Australia horticulture underlined: Acetochlor, Acrinathrin, Asulam, Bitertanol, Bupirimate, Carbetamide, Carboxin, Chloropicrin, Clethodim, Cycloxydim, Cyproconazole, Dazomet, Diclofop-methyl, Diethofencarb, Dithianon, Dodine, Ethalfluralin, Etridiazole, Fenazaquin, Fenbuconazole, Fenbutatin oxide, Fenoxycarb, Fluazifop-P, Flufenoxuron, Fluometuron, Fluquinconazole, Flurochloridone, Flutriafol, Guazatine, Hexythiazox, Hymexazol, Isoxaben, Metaldehyde, Metosulam, Myclobutanil, Oryzalin, Oxyfluorfen, Paclobutrazol, Pencycuron, Prochloraz, Propargite, Pyridaben, Quinmerac, Sintofen, Tau-fluvalinate, Tebufenozide, Tefluthrin, Terbuthylazine and Thiobencarb.

See the link below for more detail-
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:333:0011:0014:EN:PDF

Registrants are now able to resubmit these compounds, with the additional data.

Revision of Directive 91/414/EEC
EU Reg 396/2005

On 13 January the European Parliament adopted a Regulation to replace the current legislation on plant protection products. The new legislation is meant to increase the protection of human health and the environment and serve to increase the level of harmonisation within the EU. The new regulation introduces a hazard-based approach to the assessment of pesticides. The final provisions of which were adopted by the European Parliament on 13th of January 2009. It is anticipated that they will be formally adopted by the European Council in March 2009.

Implications

The new rules could result in the removal of a number of chemicals from the EU. The potential impact of this regulation is uncertain due to a lack of detail over the likely hazard criteria and their application.

In addition, it is understood that the new rules will not enter into force until Q3/4 2010 and will only apply to the next regulatory review of chemicals, expected around 2015 for most currently-registered compounds. Contrary to a number of media reports where it was suggested that 22 pesticides were to be banned the new regulation does not contain such a list.
For more information see http://www.apvma.gov.au/new/pesticides_reg.shtml or http://www.europarl.europa.eu/news/expert/background_page/064-45653-012-01-03-911-20090108BKG45652-12-01-2009-2009-false/default_en.htm

Private Standards
The UK Co-operative Supermarket has moved to temporarily prohibit the use of eight insecticides on own-brand fresh produce. These are Acetamiprid, Clothianidin, Dinotefuran, Fipronil, Imidacloprid, Nitenpyram, Thiacloprid and Thiamethoxam. This temporary action is due to a concern over possible impacts on bees.
See the link below for more information
http://www.co-operative.coop/ethicsinaction/takeaction/planbee/what-The-Co-operative-is-doing-for-bees/

Codex Committee on Pesticide Residues
Upcoming MRL decisions
The 2009 meeting of the Codex Committee on Pesticide Residues will be reviewing MRL recommendations made for azoxystrobin (e.g., asparagus, banana, berries, brassica vegetables, bulb vegetables, celery, citrus, cucurbits, grapes, legume vegetables, lettuce, mango, papaya, peanut, pistachio, strawberry and tree nuts), boscalid (banana and kiwi fruit), buprofezin (citrus, mango, cucumber and tomato), chlorantraniliprole (e.g., celery, cucurbits, fruiting vegetables, grapes, leafy vegetables, pome fruit, root and tuber vegetables and stone fruit), cyhalothrin (e.g., asparagus, berries, bulb vegetables, cherries, citrus, cucurbits, fruiting vegetables, flowerhead brassica, legume vegetables, mango, peaches, plums and pome fruit), cypermethrin (e.g., asparagus, berries, brassica vegetables, carambola, cucurbits, durian, grapes, leafy vegetables, legume vegetables, litchi, longan, mango, okra, onion, olives, papaya, sweet peppers, pome fruit, root and tuber vegetables, stone fruit and strawberries), dimethoate (head lettuce and capsicums), imidacloprid (e.g., berries, root and tuber vegetables, strawberry and tree nuts), mandipropamid (e.g., broccoli, cabbage, celery, cucumber, grapes, leafy vegetables, melons, onion bulb, peppers, potatoes and tomato) methomyl (e.g., apples, cucurbits, lettuce, pear and tomato), spinetoram (e.g., lettuce, oranges, pome fruit, tomato and tree nuts), spirotetramat (e.g., cabbage, celery, citrus, cucurbits, fruiting vegetables, grapes, leafy vegetables, pome fruit, stone fruit and tree nuts), and tebuconazole (e.g., brassica vegetables, carrot, garlic, leek, head lettuce, mango, bulb onion, papaya, plums, pome fruit, tomato and watermelon.

More detailed information can be found at http://www.fao.org/ag/AGP/AGPP/Pesticid/JMPR/Download/2008AnnexIFinal.pdf

Further Information
If you have any questions or wish to discuss any points covered in this Update, please contact Kevin Bodnaruk on 02 9499 3833 or email akc_con@zip.com.au.

WHATS NEW

Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

Productivity Commission Review

The progression of the recommendations from the Productivity Commission review has been mixed in that to date no recommendation involving agvet chemicals has been implemented.

MRL harmonisation

It is understood that the recommendation for MRL harmonisation between the APVMA and FSANZ, identified as an 'early harvest' reform has stalled. A rather disappointing outcome given the original anticipated implementation date was March 2009.

Control of use

Activity on the issue of improving the efficiency and effectiveness of the National Registration scheme for agvet chemicals continues. To date a number of consultative meetings have been held nationally resulting in the production of a discussion paper that can be found at http://www.daff.gov.au/__data/assets/pdf_file/0007/1464631/national-scheme.pdf

The discussion paper covers aspects of both the pre-approval process, e.g., assessments, timeframes and costs, and post-approval management of agvet chemicals, i.e., the control-of-use arrangements and the recommendation that responsibility should rest with the APVMA.

In the discussion paper there are 30 questions posed covering a whole range of issues, e.g., whether efficacy data should be a requirement of registration, whether the precautionary principle should be followed, whether there is any value in agvet chemical training etc. Individual industries are encouraged to review the discussion paper and respond accordingly to ensure as many different perspectives are considered in the development of a new framework.

Due date for responses is February 10th.

APVMA Chemical reviews

Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

Fenthion and Dimethoate: The trial program to augment previously submitted data has been completed. Additional post-harvest efficacy work is nearing finalisation. The expectation is that the data will be ready for submission to the APVMA in the near future. Industries are being provided with updates as the data becomes available and preliminary assessments are being completed.

See the link below for more information

http://www.apvma.gov.au/chemrev/dimethoate.shtml

Carbendazim: Bavistin, Spin Flo, Howzat etc) **Thiophanate methyl** (Banrot). It is understood that the reviews of these two compounds is near completion with the publication of review recommendations in the near future.

Quintozene – The APVMA is currently in the process of reviewing the turf fungicide quintozene. It is understood that significant changes are likely to be required.

FSANZ

Dieldrin: The Food Standards Code has recently been updated to include dieldrin EMRLs for Root and tuber vegetables and Cucurbits at 0.1 mg/kg via Amendment No. 113 (FSC 55). See the link below http://www.foodstandards.gov.au/_srcfiles/Gazette%20Notice%20Amendment%20No%20113%20WEB%20VERSION.pdf

Security Sensitive Chemicals

A risk assessment methodology for assessing security risks has been developed and is being refined. The objective is to assess security risks of a range of chemicals, industrial and agricultural, from the perspective of the entire supply chain, i.e., manufacture, storage and transport. It s understood that the initial focus will be on explosive pre-cursors with potentially toxic chemicals, e.g., certain pesticides, to follow.

INTERNATIONAL

EUROPE

Meanwhile changes to pesticide regulation in Europe continue apace.

Commission Decision 2008/934/EC and the voluntary withdrawal of a number of active substances from regulatory review.

In 2008 the EU Commission took a decision not to include a number of compounds in Annex 1 to 91/414/EEC. This involved giving registrants the option of voluntarily withdrawing their compounds from the review program then resubmitting with any additional supporting data.

To date of those compounds voluntarily withdrawn the following have been resubmitted (those registered for use in Australia horticulture are underlined): Acrinathrin, Asulam, Bitertanol, Carbetamide, Carboxin, Chloropicrin, Clethodim, Cycloxydim, Cyproconazole, Dazomet, Diclofop-methyl, Diethofencarb, Dithianon, Dodine, Etridiazole, Fenazaquin, Fenbutatin oxide, Fenoxycarb, Fluazifop-P, Flufenoxuron, Fluometuron, Fluquinconazole, Flurochloridone, Flutriafol, Guazatine, Hexythiazox, Hymexazol, Isoxaben, Metaldehyde, Metosulam, Myclobutanil, Oryzalin, Oxyfluorfen, Paclobutrazol, Pencycuron, Prochloraz, Propargite, Pyridaben, Quinmerac, Sintofen, Tau-fluvalinate, Tebufenozide, Tefluthrin and Terbuthylazine.

Revision of Directive 91/414/EEC

EU Reg 396/2005

The **Regulation**: (EC) 1107/2009 replacing Directive 91/414/EEC, concerning how pesticides are placed on the European market, and the **Directive**: 2009/128/EC establishing requirements on how pesticides are used have been adopted. The Regulation will come into affect around June 2011.

Directive: 2009/128/EC is focused on use with requirements establishing standards for application equipment as well as requiring each Member State develop and adopt a national action plan aimed at reducing environmental and human health risks associated with pesticide use. Linked to this will be a push for Member States to encourage development of IPM in order to reduce dependency on the use of pesticides. European Member States have until December 2012 to communicate these National Action Plans to both the European Commission and to other Member States.

Implications

It is anticipated that the new rules will result in the removal of a number of chemicals from the EU due to the shift towards a hazard-based approach rather than the risk-based approach previously followed, i.e., approvals for certain hazardous pesticides may be revoked irrespective of whether any risk has been minimised. The full potential impact of this regulation is uncertain due to the current lack of detail over the likely hazard criteria and their application.
http://www.apvma.gov.au/new/pesticides_reg.shtml

Codex Committee on Pesticide Residues

Upcoming MRL decisions

The 2010 meeting of the Codex Committee on Pesticide Residues will be reviewing MRL recommendations made for **Benalaxyl** – Grapes, Lettuce, Head, Melons, except watermelon, Onion, Bulb, Potato, Tomato and Watermelon; **Boscalid** - Almond hulls, apple, Banana, Berries and other small fruits (except strawberries and grapes), Brassica (cole or cabbage)

vegetables, Head cabbages, Flowerhead brassicas, Bulb vegetables, Coffee beans, Dried grapes (= currants, Raisins and Sultanas), Fruiting vegetables, Cucurbits, Fruiting vegetables, other than Cucurbits (except fungi, mushroom and sweet corn), Grapes, Kiwifruit, Leafy vegetables, Legume vegetables, Peppers Chili, dried, Pistachio nut, Prunes, Root and tuber vegetables, Stone fruits, Strawberry, Tree nuts (except pistachio); **Buprofezin** - Almond hulls, Almonds, Apple, Cherries, Fruiting vegetables, Cucurbits, Grapes, Dried grapes (= currants, Raisins and Sultanas), Nectarine, Olives, Peach, Pear, Peppers, Peppers chili, dried, Plums (including Prunes) and Strawberry; **Chlorpyrifos-methyl** - Citrus fruits, Egg plant, Grapes, Peppers, Peppers Chili, dried, Pome fruits, Potato, Stone fruits, Strawberry and Tomato; **Cyfluthrin** – Broccoli and Cabbages, Head; **Fenbuconazole** - Almond hulls, Blueberries, Cranberry, Peppers, Peppers Chili, dried, Plums (including Prunes), Pome fruits and Tree nuts; **Fluopicolide** - Brussels sprouts, Cabbages, Head, Celery, Peppers Chili, dried, Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower), Fruiting vegetables, Cucurbits, Fruiting vegetables, other than Cucurbits (except mushrooms and sweet corn), Grapes, Dried grapes (= currants, Raisins and Sultanas), Leafy vegetables, Onion, Bulb, Onion, Welsh; **Haloxyfop** – Banana, Beans (dry), Beans, except broad bean and soya bean, Citrus fruits, Coffee beans, Grapes, Onion, Bulb, Peas (pods and succulent = immature seeds), Peas, shelled (succulent seeds), Pome fruits, Stone fruits; **Hexythiazox** - Citrus fruits, Date, Dried grapes (= currants, Raisins and Sultanas), Egg plant, Fruiting vegetables, Cucurbits (except watermelon), Grapes, Pome fruits, Prunes, Stone fruits, Tomato and Tree nuts; **Indoxacarb** – Cranberry, Fruiting vegetables, Cucurbits, Mints, Prunes and Stone fruits; **Metaflumizone** - Brussels sprouts, Chinese cabbage, (type Pe-tsai), Egg plant, Lettuce, Head, Peppers, Peppers Chili, dried, Potato and Tomato; **Methoxyfenozide** – Avocado, Common bean (pods and/or immature seeds), Beans, shelled, Blueberries, Carrot, Citrus fruits, Cranberry, Papaya, Peas, shelled (succulent seeds), Radish, Radish leaves (including Radish tops), Strawberry, Sugar beet, Sweet potato; **Prochloraz** – Mushrooms; **Spirodiclofen** - Almond hulls, Citrus fruits, Coffee beans, Cucumber, Currants, Black, Red, White, Dried grapes (= Currants, Raisins and Sultanas), Grapes, Gherkin, Hops, dry, Papaya, Peppers, Sweet (including pimento or pimiento), Pome fruits, Stone fruits, Strawberry, Tomato and Tree nuts; **Zoxamide** - Fruiting vegetables, Cucurbits.

More detailed information can be found at
http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

Further Information
If you have any questions or wish to discuss any points covered in this Update, please contact Kevin Bodnaruk on 02 9499 3833 or email akc_con@zip.com.au.

AgCHEMICAL UPDATE – February 2011

(Project AH09003)

WHATS NEW

Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

DAFF Better Regulation Paper

The progression of the review of the agvet chemicals regulatory framework continues. The DAFF discussion paper dealt with potential areas of reform associated with improving operational aspects of the APVMA as well as improving the quality and efficiency of the assessment process. The paper and responses can be found at: http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals

PSIC

The release of the next stage in the development of a proposal for a single, national framework for the regulation of agricultural and veterinary chemicals is anticipated shortly.

It is understood that a detailed implementation plan is to be provided to COAG by June 2011. To achieve this will require a tight schedule. Hopefully, sufficient time for consultation will be incorporated into the process.

APVMA Chemical reviews

Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

It is anticipated that the reviews of **carbaryl, carbendazim** and **chlorpyrifos** will be finalised shortly. It is not anticipated that there will be substantial changes to what has been previously outlined in the Preliminary Review Findings.

Fenthion and Dimethoate: The toxicology report for dimethoate has been published with the acute reference dose (ARfD) and acceptable daily intake (ADI) levels announced. The nest step in the process will be the calculation of dietary intake estimates. It is anticipated that the short-term or acute estimate will be completed first, followed by the long-term or chronic estimate. Upon completion of the assessment process the APVMA will make public their recommendations, which are anticipated before mid-year.

See the link below for more information

http://www.apvma.gov.au/chemrev/dimethoate.shtml

Endosulfan. Registrations of endosulfan based products have been cancelled with a 2 year phase-out period granted. In the interim industries are being canvassed on the need to obtain access to replacement options.

FSANZ

MRL Harmonisation: The new MRL setting process between the APVMA and FSANZ has started. The first MRLs proposed for inclusion were gazetted on March 15th 2011 with inclusion in the Food Code anticipated this month. A 5 month turn around.

From the perspective of keeping track of

MRL proposals, particularly for minor use permits, the process should makes things much quicker and hopefully relatively straightforward.

Security Sensitive Chemicals

The assessment of explosive pre-cursors is continuing. A further 14 chemicals that are stored and/or transported in bulk are to undergo assessment with an anticipated completion date of June 2012. The objective being to assess security risks from the perspective of the supply chain, i.e., manufacture, storage and transport. It is understood that upon completion of these assessments the task of assessing the 29 agricultural chemicals will begin.

New chemicals

A number of applications have been made to the APVMA seeking registration of new chemicals.
Dow is seeking registration of the sap sucking insecticide **sulfoxaflor** under the trade names Expedite® and Transform®.
BASF have recently gained registration for their new fungicide **metrafenone** (Vivando®) for the control of powdery mildew in grapes and cucurbits. The company has also applied for registration of the fungicide **ametoctradin** in a mixture with dimethomorph for the control of downy mildew in grapes to be marketed under the trade name of Zampro®.
Dupont are seeking to have the fungicide **penthiopyrad** (Fontelis®) registered for the control of powdery mildew in a range of crops.

INTERNATIONAL

EUROPE

Meanwhile changes to pesticide regulation in Europe continue apace.

The MRLs for methidathion in the EU are to be set at < 0.02 mg/kg following a recent Commission decision. It is expected that the changes will come into effect within the next 6 months.

Commission Decision 2008/934/EC and the voluntary withdrawal of a number of active substances from regulatory review.

In 2008 the EU Commission took a decision not to include a number of compounds in Annex 1 to 91/414/EEC. This involved giving registrants the option of voluntarily withdrawing their compounds from the review program then resubmitting with any additional supporting data.

To date, of those compounds voluntarily withdrawn, over 60 have been resubmitted. Of these the following have horticultural approvals in Australia:

Asulam, Bifenthrin, Bitertanol, Bupirimate, Clethodim, Cyanamide, Cyproconazole, Dazomet, Dichlobenil, Dicloran, Diphenylamine, Dithianon, Dodine, Etridiazole, Fenbutatin oxide, Fenoxycarb, Fluazifop-P, Fluquinconazole, Guazatine, Hexythiazox, Isoxaben, Metaldehyde, Myclobutanil, Oryzalin, Oxyfluorfen, Paclobutrazol, Pencycuron, Prochloraz, Propargite, Pyridaben, Tau-fluvalinate, Tebufenozide, Terbuthylazine.

At present, of those that have been resubmitted only three have gained inclusion in Annex 1, i.e., dodine, myclobutanil and pyridaben.

Revision of Directive 91/414/EEC
EU Reg 396/2005

The **Regulation**: (EC) 1107/2009 replacing Directive 91/414/EEC, concerning how pesticides are placed on the European market, and the **Directive**: 2009/128/EC establishing requirements on how pesticides are used have been adopted. The Regulation will come into affect around June 2011.

Directive: 2009/128/EC is focused on use with requirements establishing standards for application equipment as well as requiring each Member State develop and adopt a national action plan aimed at reducing environmental and human health risks associated with pesticide use. Linked to this will be a push for Member States to encourage development of IPM in order to reduce dependency on the use of pesticides. European Member States have until December 2012 to communicate

these National Action Plans to both the European Commission and to other Member States.

Implications
It is anticipated that the new rules will result in the removal of a number of chemicals from the EU due to the shift towards a hazard-based approach rather than the risk-based approach previously followed, i.e., approvals for certain hazardous pesticides may be revoked irrespective of whether any risk has been minimised. The full potential impact of this regulation is uncertain due to the current lack of detail over the likely hazard criteria and their application.
http://www.apvma.gov.au/new/pesticides_reg.shtml

USA
Bayer recently reached agreement with the US EPA for a phase out of **aldicarb** (Temik®) based products to the end of 2014. Bayer has also recently applied to voluntarily cancel the registration of their product Nemacur 3 (**fenamiphos**). Once this comes into effect there will no longer be a fenamiphos based product approved for nematode and insect control in fruit and vegetables in the US. Uses in turf are expected to remain with divestment of fenamiphos to Amvac.

Methidathion was also the subject of a request to cancel registrations. The cancelation order came into effect in June with sale and distribution being by registrants manufacturers prohibited from December 2012 and by resellers from December 2014.

The US EPA has also proposed the cancelling the use of **methomyl** on grapes, and the withdraw of all MRLs for **sulfuryl fluoride**.
http://www.epa.gov/pesticides/sulfuryl-fluoride/evaluations.html
A response from the APVMA to the announcement can be found at
http://www.apvma.gov.au/news_media/our_view/2011/2011-01-13_sulfuryl_fluoride_fumigant.php

Codex Committee on Pesticide Residues
Upcoming MRL decisions
The 2011 meeting of the Codex Committee on Pesticide Residues will be meeting in April. At that meeting maximum residue level recommendations made by the 2010 JMPR will be discussed. Of these the following horticultural recommendations were made for:-

Bifenthrin – Banana, Blackberries, Brassica vegetables, Citrus fruits, Cotton seed, Dewberries (including Boysenberry and Loganberry), Egg plant, Hops, Maize, Mango, Mustard greens, Okra, Papaya, Peppers, dried chili peppers, Pulses, Rape seed, Raspberries, Root and tuber vegetables, Strawberry, Tomatoes and Tree nuts;
Boscalid – Citrus fruits, Hops, Stalk and stem vegetables;
Cadusafos - Banana;
Chlorantraniliprole – Berries and other small fruit, Brassica vegetables, Citrus fruits, Grapes, Sweet corn and tree nuts;
Chlorothalonil – Flowerhead brassicas, Brussels sprouts; Celery, Cucumber, Currants, Grapes, Leeks, Papaya, Pulses, Root and tuber vegetables, Spring onion, summer squash and Strawberry;
Clothianidin – Citrus fruit, Pome fruit, Stone fruit, Berries, Grapes, Banana, Papaya, Pineapples, Brassica vegetables, Cucurbits, Fruiting vegetables, Leafy vegetables, Legume vegetables, Celery, Pecan, Coffee beans,;
Cyproconazole – Peas;
Dicamba – Asparagus;
Difenoconazole – Legume vegetables, Papaya, Passion fruit and Tree nuts;
Etoxazole – Citrus fruit, Cucumber, Grapes, Hops, Mint and Tree nuts;
Fenpyroximate – Citrus fruit, Cucumber, Grapes, Fruiting vegetables, Melons, Pome fruit and Tree nuts;
Flubendiamide – Brassica vegetables, Celery, Cucurbits, Grapes, Legume vegetables, Lettuce, Peppers, Pome fruit, Stone fruit, Sweet corn, Tomato and Tree nuts;
Fludioxonil – Citrus fruit, Pomegranate, Sweet potato and Yams;
Fluopyram – Cucumber, Grapes, Dried grapes (= currants, Raisins and Sultanas);
Meptyldinocap – Cucumber, Summer

squash, Grapes, Melons and Strawberry;
Novaluron – Blueberries, beans, Cucurbits, Fruiting vegetables, Stone fruit, Strawberry and Tomatoes;
Thiamethoxam – Banana, Berries, Brassica vegetables, Celery, Citrus fruits, Cucurbits, Fruiting vegetables, Leafy vegetables, Legume vegetables, Papaya, Pineapple, Pome fruit, Root and tuber vegetables, Stone fruits and Sweet corn;

More detailed information can be found at
http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

The following compounds have been nominated for review in 2011 with recommendations for maximum residue levels to be considered by Codex in 2012:
emamectin benzoate – Grapes, potatoes, pome & stone fruits, tomatoes, eggplants, cucurbits (cucumber, melon, watermelon), lettuce, spinach, pepper, beans & peas, brassicas;
Flutriafol – apples, grapes, bananas and coffee;
Propylene-oxide – tree nuts, cacao, spices and dried fruit;
Acetamiprid – citrus, pome fruits, stone fruits, grape, strawberries, small fruits and berries;
Sulfoxaflor – pome fruits, stone fruits, citrus fruits, tree nuts, grapes, dried grapes, strawberries, leafy vegetables, fruiting vegetables, cucurbits, brassica vegetables, and bulb vegetables, legume vegetables, potato, root and tuber vegetables;
Penthiopyrad – Brassica vegetables, bulb vegetables, Cucurbits, fruiting vegetables, leafy vegetables and legume vegetables.

Further Information
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AgCHEMICAL UPDATE – AUGUST 2011

(Project AH09003)

WHATS NEW

Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

DAFF - Better Regulation Reform

The progression of the review of the agvet chemicals regulatory framework continues. The DAFF discussion paper dealt with potential areas of reform associated with improving operational aspects of the APVMA as well as improving the quality and efficiency of the assessment process. The paper and responses can be found at: http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals

PSIC

News on the status of the PSIC reform process is non-existent. Following the consultation meetings in March there have been no further updates on the status of any proposed changes. Given preferred regulatory and funding models and a detailed implementation plan were to be forwarded to COAG in June the lack of communication is a concern, i.e., will stakeholders be given any opportunity to provide further input?

APVMA Chemical reviews

Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

The review of **dichlorvos** has been completed with the use in avocadoes, mushrooms, potatoes and covered crops deleted. The review of **fipronil** is also drawing to a close with label amendments proposed extending the re-entry periods for crops such as bananas, brassica vegetables and turf.

For **azinphos-methyl** use in citrus and kiwi fruit are to be deleted with a shortened withholding period proposed for blueberries. In addition, downwind buffer zones from aquatic areas of 100 to 200 m are to be added to labels.

The environmental assessment for **diuron** has been published, the outcomes of which are likely to have significant impacts on the use of the herbicide in horticulture. The report nominates an upper limit of 0.16 kg ai/ha which is likely to preclude its use in any horticultural crop. The APVMA are seeking input on whether the assumptions upon which the assessment is based are valid, with regards to current usage. The comment period is open till the end of September.

The APVMA recently cancelled the approval for **parathion-methyl** at the request of the approval holder. A two-year phase out period, ending in July 2013 will apply. Despite the cancellation the APVMA intends to publish its final report later this year either in September or October.

It is anticipated that the reviews of **carbaryl** and **chlorpyrifos** will also be finalised shortly. It is not anticipated that there will be substantial changes to what has been previously outlined in the Preliminary Review Findings.

Fenthion, Dimethoate and **omethoate:** The publishing of the preliminary review findings for dimethoate and omethoate is anticipated within the next few months.

The APVMA will be basing its recommendations on current label use patterns. As such there may be an opportunity to seek approval for alternative use patterns to address any concerns that might be identified.

See the link below for more information

http://www.apvma.gov.au/chemrev/dimethoate.shtml

Endosulfan. Registrations of endosulfan based products have been cancelled with a 2 year phase-out period granted, expiring in October 2012. In the interim industries are being canvassed on the need to obtain access to replacement options.

Finally, there are plans for another Cost Recovery review to be undertaken with regards to the fees and charges levied by the APVMA. It is understood that Price Waterhouse Coopers will be conducting an activity based assessment of costs with a draft impact statement anticipated in early 2012.

FSANZ

MRL Harmonisation: The new MRL setting process between the APVMA and FSANZ has started. The first MRLs proposed for inclusion were gazetted on March and April with inclusion in the Food Code anticipated this month. A 5 month turn around, while long is still a significant improvement.

MRLs anticipated to come into the Food Standards Code include mandipropamid in grapes; metrafenone – grapes, cucurbits; boscalid – cucurbits, potato and fruiting vegetables; chlorpyrifos – tree nuts; cyprodinil – bulb onion; ethofumesate – spinach, sugar beet; fenhexamid – lettuce, capsicums, fipronil – tropical fruit, flubendiamide – cucurbits, fruiting vegetables, leafy vegetables; fludioxonil – bulb onion; iprodione – mandarins; kresoxim methyl – cucurbits; milbemectin – stone fruit; propiconazole – leafy vegetables; prohexadione calcium – cherries; pyraclostrobin – tree nuts; tebuconazole – beetroot, silverbeet, chicory, spinach; triadimenol – bulb onion, berry fruit; trifloxystrobin – cucumber.

Security Sensitive Chemicals

The assessment of explosive pre-cursors is continuing. A further 14 chemicals that are stored and/or transported in bulk are to undergo assessment with an anticipated completion date of June 2012. The risk assessment process looks at potential security risks from a supply chain perspective, i.e., manufacture, storage and transport. It is understood that upon completion of these assessments the task of assessing the 29 agricultural chemicals previously identified will begin.

New chemicals

A number of applications have been made to the APVMA seeking registration of new chemicals.
Syngenta has registered the downy mildew fungicide **mandipropamid** for use in grapes under the trade name Revus®. Dow has registered the insecticide **spinetoram** (Success Neo ®) for the control of a broadened range of insect pests and crops. The company has also applied to have the powdery mildew fungicide **proquinazid** (Talendo®) registered for use in cucurbits. Nippon Soda has applied to register their powdery mildew fungicide **cyflufenamid** (Cyflamid®) for use in grapes and cucurbits.
Dupont have sought registration of the herbicide **aminocyclopyrachlor** (Imprelis®) for use in non-crop situations. However, recent issues in the US over the sensitivity of certain landscape trees may impact on availability. Bayer CropScience has applied for registration of their new turf herbicide **foramsulfuron** (Tribute®) for the control of winter grass, ryegrass and crowsfoot grass in couch turf. Sumitomo Chemical is also seeking registration for its herbicide **bispyribac sodium** (Nominee®) for the control of winter grass in turf. Finally Syngenta have applied for registration of the turf herbicide **prodiamine** (Barricade®) for the control of winter grass, summer grass and crowsfoot grass.

INTERNATIONAL

EUROPE

Meanwhile the impacts of changes to pesticide regulation in Europe continue across the board. For example, it has been reported that 13, of the 27 pesticides listed for use in organic farming under the EU's Organic Regulation (Annex II of Reg 889/2008), have not gained inclusion in Annex 1 to 91/414/EEC.
http://www.agronaplo.hu/files/file/Organic%20farming.pdf

Of those, to date not gaining inclusion are **azadirachtin**, **fatty acid potassium salts**, **paraffin oils**, **mineral oils**, **aluminium sulphate**, **pine oil** and **rotenone**. Those approved include **pyrethrins**, **copper**, **sulphur**, **calcium hydroxide** and **ferris phosphate**.

For more information see
http://www.ecpa.eu/news-item/agriculture-today/pesticides-used-organic-farming

The MRLs for methidathion in the EU are to be set at < 0.02 mg/kg following a recent Commission decision. It is expected that the changes will come into effect before the end of the year.

Commission Decision 2008/934/EC and the voluntary withdrawal of a number of active substances from regulatory review.

In 2008 the EU Commission took a decision not to include a number of compounds in Annex 1 to 91/414/EEC. This involved giving registrants the option of voluntarily withdrawing their compounds from the review program then resubmitting with any additional supporting data.

To date, of those compounds voluntarily withdrawn, over 60 have been resubmitted. Of these the following have horticultural approvals in Australia:

Asulam, Bifenthrin, Bitertanol, Bupirimate, Clethodim, Cyanamide, Cyproconazole, Dazomet, Dichlobenil, Dicloran, Diphenylamine, Dithianon, Dodine, Etridiazole, Fenbutatin oxide, Fenoxycarb, Fluazifop-P, Fluquinconazole, Guazatine, Hexythiazox, Isoxaben, Metaldehyde, Myclobutanil, Oryzalin, Oxyfluorfen, Paclobutrazol, Pencycuron, Prochloraz, Propargite, Pyridaben, Tau-fluvalinate, Tebufenozide, Terbuthylazine.

At present, of those that have been resubmitted the number gaining inclusion in Annex 1 is low, e.g., bifenthrin, dodine, myclobutanil and pyridaben. An outcome of this process has been the reduction of MRLs for many of the compounds still undergoing assessment. For example, the new apple and pear MRLs proposed for **diphenylamine** and **trichlorfon** are *0.01 mg/kg, well below the previous 10, 5 and 1 mg/kg previously set.

USA

Carbofuran was the subject of a request to cancel registrations. The cancellation request follows the US Supreme Court denying a petition by FMC for a review of the US EPA decision to revoke all domestic MRLs. This will leave only import tolerances for rice, bananas, coffee and sugar cane.

The US EPA has also announced a voluntary cancellation request for **methyl-parathion** which will take effect from December 31st, 2012.

Hong Kong

In a significant move away from the current approach to MRLs, i.e., adoption of Codex standards, Hong Kong is to implement a positive list MRL system. Recently the Hong Kong authorities published a draft MRL listing for consideration and are undertaking a period of consultation domestically as well as through the WTO process. The authorities anticipate implementation by the end of 2013 or early 2014.

http://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/files/Draft_MRL_for_technical_meeting_28032011.pdf

Codex Committee on Pesticide Residues

Recent MRL decisions

At the Codex Alimentarius Commission meeting in July the MRL recommendations made at the April meeting of the Codex Committee on Pesticide Residues were adopted. Maximum residue levels for the following will now be incorporated into the Codex system:-

Bifenazate - Blackberries, legume vegetables, Raspberries; **Bifenthrin** – Banana, Blackberries, Brassica vegetables, Citrus fruits, Cotton seed, Dewberries (including Boysenberry and Loganberry), Egg plant, Hops, Maize, Mustard greens, Peppers, dried chili peppers, Pulses, Rape seed, Raspberries, Root and tuber vegetables, Strawberry, Tomatoes and Tree nuts;
Boscalid – Citrus fruits, Hops, Leafy vegetables, Stalk and stem vegetables;
Cadusafos - Banana;
Chlorantraniliprole – Berries and other small fruit, Brassica vegetables, Citrus fruits, Sweet corn and tree nuts;
Chlorothalonil – Flowerhead brassicas, Brussels sprouts; Celery, Cucumber, Currants, Grapes, Leeks, Papaya, Pulses, Root and tuber vegetables, Spring onion, summer squash and Strawberry;
Clothianidin – Citrus fruit, Pome fruit, Stone fruit, Berries, Papaya, Pineapple, Brassica vegetables, Cucurbits, Fruiting vegetables, Leafy vegetables, Legume vegetables, Celery, Pecan, Coffee beans;
Cyproconazole – Peas, sugar beet;
Dicamba – Asparagus;
Difenoconazole – Peas, Passion fruit and Tree nuts; **Etoxazole** – Citrus fruit, Cucumber, Grapes, Hops, Mint and Tree nuts; **Fenpyroximate** – Citrus fruit, Cucumber, Grapes, Fruiting vegetables, Melons, Pome fruit and Tree nuts;
Flubendiamide – Brassica vegetables, Celery, Cucurbits, Grapes, Legume vegetables, Lettuce, Peppers, Pome fruit, Stone fruit, Sweet corn, Tomato and Tree nuts;
Fludioxonil – Citrus fruit, Pomegranate, Sweet potato and Yams; **Fluopicolide** – cabbages, celery, leafy vegetables;
Fluopyram – Cucumber, Grapes, Dried grapes (= currants, Raisins and Sultanas);
Haloxyfop – grapes; **Meptyldinocap** – Cucumber, Summer squash, Grapes, Melons and Strawberry; **Novaluron** – Blueberries, beans, Cucurbits, Fruiting vegetables, Stone fruit, Strawberry and Tomatoes; **Thiamethoxam** – Banana, Berries, Brassica vegetables, Celery, Citrus fruits, Cucurbits, Fruiting vegetables, Leafy vegetables, Legume vegetables, Papaya, Pineapple, Pome fruit, Root and tuber vegetables, Stone fruits and Sweet corn;

More detailed information can be found at http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

The following compounds have been nominated for review in 2011 with recommendations for maximum residue levels to be considered by Codex in 2012:
emamectin benzoate – Grapes, potatoes, pome & stone fruits, tomatoes, eggplants, cucurbits (cucumber, melon, watermelon), lettuce, spinach, pepper, beans & peas, brassicas;
Flutriafol – apples, grapes, bananas and coffee;
Propylene-oxide – tree nuts, cacao, spices and dried fruit;
Acetamiprid – citrus, pome fruits, stone fruits, grape, strawberries, small fruits and berries;
Sulfoxaflor – pome fruits, stone fruits, citrus fruits, tree nuts, grapes, dried grapes, strawberries, leafy vegetables, fruiting vegetables, cucurbits, brassica vegetables, and bulb vegetables, legume vegetables, potato, root and tuber vegetables;
Penthiopyrad – Brassica vegetables, bulb vegetables, Cucurbits, fruiting vegetables, leafy vegetables and legume vegetables.

Further Information

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AgCHEMICAL UPDATE – February 2012

(Project AH09003)

WHATS NEW

Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

DAFF - Better Regulation Reform

The progression of the review of the agvet chemicals regulatory framework continues. DAFF released a regulatory Impact Statement, draft legislation and explanatory guides for public comment. Of significant concern were the proposed changes to the application process and their potential impact on minor use permits. Essentially, it is feared that the process of seeking and gaining a minor use permit will become protracted and more costly making it harder for industries to gain access to much needed pest management tools.
The information on the proposed reforms can be found at:
http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals

PSIC

The PSIC run reform process to develop a single, national framework for agvet chemical regulation has been delayed 12 months. Concerns have been expressed that there is a risk disconnect may occur between the proposed DAFF reforms and those that eventuate via PSIC. At this stage it is unclear whether stakeholders be given further opportunities to provide input?

APVMA & Chemical reviews

Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

The review of **quintozene** appears to be drawing to a close. The current suspension will expire on April 13th and a final decision is anticipated soon after.
It is anticipated that the OH&S component of the **dimethoate** review will be completed shortly. The publishing of the preliminary review findings for f**enthion** is anticipated within the next few months. The APVMA will be basing its recommendations on current label use patterns. As such there may be an opportunity to seek approval for alternative use patterns to address any concerns that might be identified.

The APVMA is currently seeking input/feedback from industry on how it undertakes its **consultation process**. Finally, there are plans for another Cost Recovery review to be undertaken with a discussion paper recently released for comment by the APVMA. On a positive note the APVMA has proposed maintaining permit fees at their current levels, though they would be indexed. The discussion paper can be found at:
http://www.apvma.gov.au/consultation/public/2012/interim_cost_recovery.php

FSANZ

MRL Harmonisation: The new MRL setting process between the APVMA and FSANZ is up and running. Over the last 9 months the time lag between establishment of an APVMA MRL and its promulgation into the Food Standards Code of FSANZ is now down to about 10-14 weeks. This is a significant improvement on the previous 9 to 18 months.

Security Sensitive Chemicals

Following completion of its risk assessments the Attorney-General's Dept. (AGD) have released a Regulation Impact Statement (RIS) seeking input from industries. In the RIS four options are outlined to address the identified areas of vulnerability with regard to the management of the 11 identified chemicals with the potential of being used in the manufacture homemade explosives. Of the 11 a number can have horticultural applications, such as potassium nitrate.

The four options comprise differing levels of possible regulation, i.e., whether measures were voluntary or mandatory, how the measures would be managed, i.e., via industry driven codes of practice or government directed; and linked to the above the ownership of the management scheme, i.e., industry or government. The consultation period closes March 30th. The RIS can be found at the ADG's website

It is understood that the task of assessing the 29 agricultural chemicals, such as methidathion, methomyl, paraquat and terbufos, will begin mid-2012. At which time AGD personnel will be seeking to engage with industry to gain a clearer understanding of how these products move through the supply chain.

New chemicals

A number of applications have been made to the APVMA seeking registration of new chemicals.
Janssen-Cilag are seeking to register a post-harvest fungicide **Philabuster®** (pyrimethanil + imazalil) for the control of blue and green mould in citrus.
Ishihara are seeking to have the insecticide **flonicamid** registered.
Vita (Europe) has applied for a shelf registration for their Varroa mite product **Apistan®** (tau-fluvalinate). In the event of a Varroa mite incursion Apistan would be an important element of any eradication or management strategy.
Syngenta have applied to extend the registration of their Botrytis fungicide **Switch®** (cyprodinil + fludioxonil) into a range of vegetable crops.

INTERNATIONAL

EUROPE

Non-renewal of the approval for cyclanilide (Reg (EU) 1022/2011) Recent authorisations include acrinathrin (Reg (EU) 974/2011) and fluxapyroxad

The MRLs for aldicarb, methidathion, fenthion, methabenzthiazuron and simazine in the EU are now set at or about the limit of quantitation (Reg (EU) 310/2011)

Commission Decision 2008/934/EC and the voluntary withdrawal of a number of active substances from regulatory review.

In 2008 the EU Commission took a decision not to include a number of compounds in Annex 1 to 91/414/EEC. This involved giving registrants the option of voluntarily withdrawing their compounds from the review program then resubmitting with any additional supporting data.

To date, of those compounds voluntarily withdrawn, over 60 have been resubmitted with a number approved for inclusion as of June 1st 2011 following re-submission. See below the status of those with horticultural approvals in Australia:

Asulam (not approved Withdrawal of authorisations by 31/12/2011. Max period of grace: 31/12/2012), Bifenthrin, Bitertanol (approved) Bupirimate (approved), Clethodim (approved), Cyanamide, Cyproconazole (approved), Dazomet (approved), Dichlobenil (not approved), Dicloran (not approved), Diphenylamine, Dithianon (approved), Dodine (approved), Etridiazole (approved), Fenbutatin oxide (approved), Fenoxycarb (approved), Fluazifop-P (approved), Fluquinconazole (approved), Guazatine (not approved), Hexythiazox (approved), Isoxaben (approved), Metaldehyde (approved), Myclobutanil (approved), Oryzalin (approved), Oxyfluorfen (approved), Paclobutrazol (approved), Pencycuron (approved), Prochloraz (approved), Propargite (not

approved authorisation withdrawn Max period of grace: 12/2012), Pyridaben (approved), Tau-fluvalinate (approved), Tebufenozide (approved), Terbuthylazine (approved).

At present, of those that have been resubmitted a few are still under consideration. For example, the initial apple MRL proposed for **diphenylamine** was *0.01 mg/kg, a re-evaluation completed in January 2012 has resulted in a revised MRL proposal of 7 mg/kg to cover its use as a drench in apples.

USA

The US EPA recently completed a cumulative risk assessment for potential exposures from the many current uses of **pyrethrins** and **pyrethroid** insecticides and concluded they do not pose risk concerns for children or adults. As aconsequence the EPA will consider registering additional new uses of these pesticides. **Dicofol** was the subject of a request to cancel registrations. The cancellations of the end use registration will come into effect October 2013.

Hong Kong

The Hong Kong authorities completed a consultation process on the proposed legislation in September 2011. The proposed regulation on pesticide residues in food is anticipated shortly with full implementation by the end of 2013 or early 2014.

http://www.cfs.gov.hk/english/whatsnew/whatsnew_fstr/files/Draft_MRL_for_technical_meeting_28032011.pdf

Codex Committee on Pesticide Residues

Recent MRL recommendations
At the upcoming of the Codex Committee on Pesticide Residues Maximum residue level recommendations to be discussed cover the following:-

Acetamiprid – Beans, cabbages, Berry fruit, celery, citrus fruit, cherries, capsicums, cucurbits, leafy vegetables, eggplant, tomatoes, nectarines, peaches, peas, pome fruit and tree nuts; **Azoxystrobin** – coffee beans; **Cypermethrin** – Asparagus, Citrus fruit and Tree nuts; **Dicamba** – Soya bean; **Emamectin benzoate** – Beans, Lettuce, Grapes, Cucurbits, Nectarine, Peaches, Eggplant, Capsicum, Tomato, and Pome fruit;
Etoxazole – Pome fruit; **Flutriafol** – Bananas, coffee beans, grapes, peanuts, capsicums and pome fruit; **Glyphosate** – Sweet corn; **Hexythiazox** – Strawberries, Tea; **Isopyrazam** – Bananas;
Pyraclostrobin – Globe artichoke, Blueberries, Cherries, Citrus fruit, Cucurbits, garlic, nectarine, peach, plum, raspberries and tree nuts; **Saflufenacil** – Bananas, citrus fruit, grapes, coffee beans, peas, pome fruit, sweet corn, stone fruit and tree nuts; **Spinosad** – Blackberries, blueberries, Dewberries, Bulb onion, passion fruit, raspberries, spring onions and tree nuts; **Spirotetramat** – Legume vegetables, litchi, kiwifruit, mango, bulb onion and papaya; **Tebuconazole** – Apple, apricot, globe artichoke, bananas, broccoli, Brussels sprouts, cabbages, cauliflower, carrot, cherries, coffee beans, cucumber, eggplant, garlic, grapes, mango, nectarine, olives, bulb onion, papaya, peach, Pears, capsicums, plums, squash, tomato and tree nuts;;

More detailed information can be found at http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

The following compounds have been nominated for review in 2012 with recommendations for maximum residue levels to be considered by Codex in 2013:
Ametoctradin Tomato , Pepper , Cucumber , Squash , Melon , Head lettuce , Leaf lettuce , Spinach , Grapes , Potatoes , Bulb onions , Spring Onion, Broccoli, Cabbage, Mustard greens, Celery, Hops , Zucchini, Brassica vegetables;
Chlorfenapyr Potato, Tomato, Red Pepper , Citrus, Melons, Papaya ,

Eggplant, Onion, Garlic, and Tea; **Glufosinate-Ammonium** Citrus Fruits, Tree Nuts, Almonds Hulls, Pome Fruits, Stone Fruits, Berries And Other Small Fruits (Except Currants) , Currants (Black, Red, White) , Banana, Assorted Tropical And Sub-Tropical Fruits - Inedible Peel, Potato, Carrot, Bulb Onion, Corn Salad, Head Lettuce, Common Bean (Pods And/Or Immature Seeds), Asparagus, Broad Bean (Dry) , Common Bean (Dry), Peas (Dry), Olive, Rape Seed ,Crude, Soya Bean (Dry), Sunflower Seed And Crude Sunflower Seed Oil, Cotton, Maize Grain, Maize Fodder, Rice, Sugar Beet, Coffee, Palm Oil, Meat (From Mammals Other Than Marine Mammals), Poultry Meat, Edible Offal (Mammalian), Edible Offal Of Poultry, Eggs, Milks; **Buprofezin** coffee; **Chlorothalonil** Bananas; **mancozeb** mango, okra, papaya mandarin; **Fludioxonill** Mango; **Imidacloprid** artichoke, tropical fruit (avocado , papaya , lychee guava), okra, peas, pomegranate, pistachio (from almond), strawberry, banana , spinach, celery., celery, mango; **Methoxyfenozide** New GAP for on spinach; alfalfa forage; alfalfa fodder; citrus fruits, beans with pods, Cucurbit vegetables: cucumber, Summer squash, melon Cantaloupe , tropical fruit (guava, lychee –, papaya-), beans (snap and dry peas), citrus fruit (request to raise MRL to 10 ppm; orange, grapefruit, lemon), pomegranate (by extrapolation), onion (green), artichoke; **Spinetoram** New GAP for stone fruits; cabbage, head; broccoli; citrus fruits; grapes; dried grapes; onion, bulb; leafy vegetables; broad bean; tree nuts, blueberries; raspberries, red and black; onions, green, **Thiamethoxam** Papaya; **Trifloxystrobin** beans with pods, mango, papaya, passionfruit, strawberry, lettuce head, olive, aubergine, radish, papaya and asparagus.

Further Information

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Ag Chemical Update – August 2012

WHATS NEW

Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

DAFF - Better Regulation Reform

The progression of the review of the agvet chemicals regulatory framework has slowed as DAFF are working on an update of the exposure draft Bill. Once completed it is planned that a second round of consultation will occur prior to its introduction into parliament.

First-principles review of the cost recovery arrangements for the APVMA

DAFF) are seeking public submissions for a first-principles review of the cost recovery arrangements for the APVMA. The first-principles review aims to examine and recommend options to strengthen the financial sustainability, transparency and accountability of the APVMA's cost recovery arrangements.

The review is focused on the structure of the APVMA's cost recovery framework.
For more information on this consultation and to make a submission see the web address below
http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements

PSIC

The PSIC run reform process to develop a single, national framework for agvet chemical regulation has been delayed 12 months. Concerns have been expressed that there is a risk of a disconnect occurring between the proposed DAFF reforms and those that eventuate via PSIC. At this stage it is unclear whether stakeholders will be given further opportunities to provide input to any initiatives proposed by PSIC?

APVMA & Chemical reviews

Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

It is anticipated that the OH&S component of the **dimethoate** review will released for public comment shortly. The APVMA will be basing its recommendations on current label use patterns. As such there may be an opportunity to seek approval for alternative use patterns to address any OH&S concerns that might be identified. The publishing of the preliminary review findings for f**enthion** is also anticipated within the next few weeks.

FSANZ

MRL Harmonisation: The new MRL setting process between the APVMA and FSANZ commenced on March 1st 2011. The time now taken to change MRLs in the Food Standards Code has been reduced from 12 to 18 months to 12 to 14 weeks.

Security Sensitive Chemicals

The Attorney-General's Dept. (AGD) is currently finalising a summary report on 14 chemicals that were identified as transported and/or stored in bulk (primarily acids/gases).

As to the 29 agricultural chemicals under consideration, the ADG are progressing with preparatory work. Part of which involves arranging future site visits to farms and reseller outlets, which are being organised through industry representatives. The aim being to see firsthand how farm chemicals are managed. It is understood that it is planned that these will occur in the latter part of the year.

New chemicals

A number of applications have been made to the APVMA seeking registration of new chemicals.
Agriphar are seeking to register a **triclopyr** based product (Tops Plant Growth Regulator®) for thinning and increasing fruit size in oranges and mandarins and reducing

fruit drop in litchi.
Dupont have are seeking to have the insecticide **cyantraniliprole** (Benevia®) registered.
Syngenta have applied to register a turf insecticide (**chlorantraniliprole + thiamethoxam**) for the control of Argentine stem weevil, scarab beetle larvae and caterpillars.

INTERNATIONAL

Rotterdam Convention

The eighth meeting of the Chemical Review Committee agreed to recommend to the Conference of the Parties that trichlorfon **be listed in Annex III of the Rotterdam Convention**.

The eighth meeting of the Chemical Review Committee also agreed to establish a drafting group to prepare a draft decision guidance document for trichlorfon.

EUROPE

The review of pesticide regulation isn't just confined to Australia with the UK Department for Environment Food and Rural Affairs issuing a draft plan on the future of pesticide use in that country. It is the next stage in the implementation of the EU Directive on the sustainable use of pesticides.

The draft plan focuses on the continuing use of voluntary approaches to meet pesticide targets, i.e., ways to improve best practice without the need to regulate. The intention of the plan is to ensure that pesticides can be used sustainably in the UK and is being developed in consultation with stakeholders including members of the public.

In a recent decision the EU Commission has decided to not include diphenylamine (DPA) in Annex 1 to Directive 91/414/EEC. was **not** included EU (Reg (EU) 578/2012).

Fenpyrazamine, a new pyrazole fungicide from Sumitomo has been approved for use in the EU (Reg (EU) 595/2012). It is targeted against *Botrytis* in grapes, fruiting vegetables and cucurbits.

New MRLs for oxadixyl (parsley, celery & leeks), captan (currants, raspberries and blackberries), cyprodinil (fresh herbs, spinach, lettuce and rocket), fluopicolide (radish,& potatoes) and phosmet (potatoes) were established (Reg (EU) 592/2012).

USA

The US EPA has initiated a reregistration review for dichlorbenil, buprofezin and trifluralin.

The EPA recently registered the fungicide cyflufenamid in cucurbits; pome fruit; small fruit vine climbing, except fuzzy kiwifruit; grape, raisin, and low growing berry except cranberry.

The EPA has declined a recent request seeking an emergency suspension of clothianidin on the basis it is a hazard to bees. The US EPA did not believe there was a substantial likelihood of imminent serious harm from the use of clothianidin.

Nevertheless, the EPA is undertaking an evaluation of all the neonicotinoid pesticides, including clothianidin. The aim being to determine whether any restrictions are necessary to protect people, the environment or pollinators. Also, in September, the EPA will seek an independent scientific peer review on how to better assess the risks of pesticides to pollinators.

Hong Kong

Hong Kong, China Hong Kong have recently circulated a WTO notification indicating that the Pesticide Residues in Food Regulation will enter into force on 1 August, following a two-year grace period.
The key features of the Regulation appear to be that; i) residue monitoring is to be ramped-up, ii) in the absence of a HK MRL non-detect will apply, iii) Codex MRLs will be incorporated into the HK system but will not be the only source of MRLs; and iv) Chinese MRLs will also be incorporated.

Codex Committee on Pesticide Residues

Recent MRL recommendations
The recent Meeting of the Codex Committee on Pesticide Residues agreed to the adoption

of Codex MRLs for the following chemical x commodity combinations:-

Acetamiprid – Beans, cabbages, Berry fruit, celery, citrus fruit, cherries, capsicums, cucurbits, eggplant, tomatoes, nectarines, peaches, peas, pome fruit and tree nuts; **Azoxystrobin** – coffee beans; **Clothianidin** – bananas, grapes, pome fruit, stalk and stem vegetables and sweet corn; **Cypermethrin** – Asparagus, Citrus fruit and Tree nuts; **Emamectin benzoate** – Beans, Lettuce, Grapes, Cucurbits, Nectarine, Peaches, Eggplant, Capsicum, Tomato, and Pome fruit; **Etoxazole** – Pome fruit; **Flutriafol** – Bananas, coffee beans, grapes, peanuts, capsicums and pome fruit; **Glyphosate** – Sweet corn; **Hexythiazox** – Tea; **Isopyrazam** – Bananas; **Pyraclostrobin** – Globe artichoke, Blackberries, Blueberries, Cherries, Citrus fruit, Cucurbits, Citrus fruit, garlic, nectarine, onions, papaya, peach, plum, raspberries, strawberries and tree nuts; **Saflufenacil** – Bananas, citrus fruit, grapes, coffee beans, peas, pome fruit, sweet corn, stone fruit and tree nuts; **Spinosad** – Blackberries, blueberries, Dewberries, Bulb onion, passion fruit, raspberries, spring onions and tree nuts; **Spirotetramat** – Legume vegetables, litchi, kiwifruit, mango, bulb onion and papaya; **Tebuconazole** – Apple, apricot, globe artichoke, bananas, broccoli, Brussels sprouts, cabbages, cauliflower, carrot, cherries, coffee beans, cucumber, eggplant, garlic, grapes, mango, nectarine, olives, bulb onion, papaya, peach, Pears, capsicums, plums, squash, tomato and tree nuts.

More detailed information can be found at http://www.fao.org/agriculture/crops/core-themes/theme/pests/pm/jmpr/jmpr-rep/en/

Further Information

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AgChemical Update - February 2013
(Project AH09003)

WHATS NEW
Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

DAFF - Better Regulation Reform
Various industry groups have raised concerns over aspects of the new legislation, in particular that it will add to the regulatory and cost burden already borne by growers

In early February the 'Better Regs' Bill was the subject of reviews by both Senate and House of Representatives committees. The committees have been looking into aspects of the regulation and have received submissions from a range of stakeholders, including grower industry representatives, environmentalists and the chemical industry. Transcripts of the committee proceedings can be found at Hansard on the parliamentary website.

NASP (PSIC)
Last year a new committee was created to deal with aspects of pesticide regulation, the National Agvet System Policy (NASP) Taskforce. The purpose of this committee is to progress the Council of Australian Governments' (COAG) reforms for a single national framework for agvet chemicals. A task previously managed by PSIC on the crop side.

The reform process, unfortunately, appears to have run into some difficulties over how best to implement harmonized training and licensing requirements covering fee for service providers, i.e., contract applicators. Agreement on harmonized control of use has also appeared to have stalled with finalisation appearing no closer.

APVMA & Chemical reviews
Updated below are those issues and reviews either recently initiated or where progress has occurred or anticipated in the near future.

The publication of the OH&S component of the **dimethoate** review and the environment component for **fenthion** are anticipated next. The APVMA will be basing recommendations on current label use patterns. As indicated previously there may be opportunities to amend use patterns to mitigate any OH&S or environmental concerns that might be identified.

In terms of other reviews the preliminary review findings for **fenamiphos** may be available later this year, while **chlorpyrifos, maldison** (malathion), **methidathion, diquat, paraquat** and **procymidone** are all in assessment.

Security Sensitive Chemicals
Following grower and reseller visits by Attorney General Department (ADG) staff it is understood that the assessment of the 29 agricultural chemicals under consideration, is progressing the aim is for finalisation by June 30.

New chemicals
A number of applications have been made to the APVMA seeking registration or active ingredient approvals for new chemicals.

Dupont have registered the carboxamide fungicide **penthiopyrad** (Fontelis®) for use in pome fruit, stone fruit, tree nuts, strawberries and various vegetable crops for the control of Botrytis, Sclerotinia, Powdery mildew, Alternaria etc.

BASF have registered the fungicide **ametoctradin** (Zampro®) for use in grapes for the control of downy mildew. The ametoctradin is co-formulated with dimethomorph.

Farmoz have made an application to the APVMA for a new nematicide for use in vegetables based on the compound **fluensulfone**.

ISK, have applied to register the fungicide **cyazofamid**. It is registered in the US (Ranman®) for the control of downy mildew and Pythium in vegetables and grapes. The company is also seeking an active constituent approval for the insecticide **flonicamid**. It is registered in the USA (Beleaf®) for the control of aphids and other sucking pests in various vegetables and tree fruit crops.

INTERNATIONAL

New Zealand

The New Zealand Environmental Protection Authority has called for submissions from the public on its reassessment of a group of 29 organophosphate and carbamate insecticides: including: acephate**,** carbaryl**,** carbofuran**,** carbosulfan**,** chlorpyrifos**,** chlorpyrifos-methyl**,** diazinon**,** dichlorvos**,** **d**imethoate**,** fenamiphos**,** fenitrothion**,** malathion**,** methamidophos, methomyl, omethoate, oxamyl, phorate, pirimicarb, prothiophos **and** terbufos**.**

A final decision will be made in June 2013. The potential outcomes of the reassessments, are recommendations either to revoke, phase-out or retain.

EUROPE

The European Commission has responded to a recent report from EFSA in which questions were raised over the impact of neonicotinoid pesticides on bees. The Commission has indicated that action would be taken to "mitigate the threat to pollinators". The Commission indicated that the action would be "proportional" and that a total ban was not justified.

Metaldehyde has recently achieved Annex 1 listing under the European pesticide re-approvals process and is currently moving through national approvals processes in individual member states.

Cyflumetofen, the European Commission proposes to formally approve a new acaricide from Otsuka has been approved for use in the EU. It is targeted for use against mites in tree fruit, nuts and vegetables.

MRLs have been proposed for bifenazate (citrus, cucurbits, pome fruit, grapes & stone fruit), fludioxonil (celery), chlorantraniliprole (carrots, celeriac, parsnips and parsnip root), etoxazole (pome fruit), pyraclostrobin (cherries, peaches & plums) and penthiopyrad (pome fruit, cherries, peaches, plums, strawberries, root and tuber vegetables, bulb vegetables, cucurbits, fruiting vegetables and brassica vegetables) (SANCO 12787/2012, 12703/2012 & 12668/2012).

USA

The US EPA has moved to cancel the registrations for the insecticides halofenozide, aldicarb and allethrin. The action is in response to some voluntarily cancel requests from registrants.
The US EPA has proposed to approve Valent USA's new fungicide, **Fenpyrazamine** (V-10135 4), for use on almonds, small fruit vine climbing, head and leaf lettuce, and low growing berries, bush berries, caneberries, ginseng, pistachio and ornamentals.

Canada

Canadian Pest Management Regulatory Authority (PMRA) has proposed phasing out the sale and use of all **linuron** products following the completion of its re-evaluation of the herbicide. The proposed move is likely to have a significant impact on vegetable producers in that country.

Japan

The Japanese Ministry of Health, Labour and Welfare have indicated that they wish to finalise risk assessments for the remaining provisional MRLs created when the positive list came into effect. MHLW have identified 307 chemicals for which risk assessments need

to be finalised and sought feedback from Australia (via DAFF) on which MRLs industries wish retained are and prepared to support.
It is understood that responses were provided to DAFF by grains, wine, horticulture, meat and dairy industries. The information was collated by DAFF and submitted to Japan. The next stage will be liaison with the APVMA and DAFF to clarify the process to be followed over the preparation and submission of the required data to Japan.

Further Information
If you have any questions or wish to discuss any points covered in this Update, please contact Kevin Bodnaruk on 02 9499 3833 or email kevinakc@bigpond.net.au

AgChemical Update - August 2013
(Project AH09003)

WHATS NEW
Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

AgVet Chemical Reforms
The AgVet Chemical legislation has been passed and will come into effect on July 1st 2014. The Act and the explanatory memorandum are available on the ComLaw website.
http://www.comlaw.gov.au/Details/C2013A00125/Download
The accompanying Regulations have now been registered and can be found at http://www.comlaw.gov.au/Details/F2013L01458. Of note are the regulations associated with the re-approval and re-registration scheme. In particular, the use of European Commission regulatory environmental (aquatic) thresholds for determining renewal dates. A review of the relevant EU Regulation suggests that there will be a very long list of compounds that will need to be reviewed sooner rather than later. The likely outcome is that the APVMA review team and their activities will need to be expanded significantly as the number and frequency of reviews grow.

The Regulations also indicate there is to be a review conducted in *"relation to mechanisms to improve access to chemical products for minor uses".* Which sounds promising except that the terms of reference state the review recommendations will relate only to "*matters within the APVMA's functions and powers*". So the possibility of any significant policy change or minor use initiative in the context of minor crops and market failure would seem to be remote at best.

Control of Use
The Standing Council on Primary Industries (SCoPI), have developed a regulatory model for a single national framework for assessment, registration and control of use of agricultural chemicals and veterinary medicines (agvet chemicals). At the May meeting the Council confirmed that the regulatory model, funding model and the Inter-Governmental Agreement, (which form the single national regulatory framework for agvet chemicals), were finalised.

Ministers representing the Australian, New South Wales, Victorian, Western Australian, South Australian, Tasmanian and Northern Territory governments signed the agreement today. The Queensland and the Australian Capital Territory governments gave in-principle support, to be confirmed once formally agreed to by their respective cabinets.

The national scheme is intended to harmonise minimum licensing and training requirements for businesses and individuals and chemical usage record keeping requirements. The national scheme is also to be supported by a nationally coordinated produce monitoring system that will monitor the level of chemical residue on produce.

The planned National Residue Monitoring system is intended to operate over the next 5 years at a cost of $25.4 million. According to DAFF the results will be published and the purpose, in part, will be "*feeding back to the regulators, to industry and to the individuals what we have found, then trying to investigate why that has occurred and change behaviour around that if need be".* (Matt Koval First Assistant Secretary, Agricultural Productivity Division at Senate Estimates - May 28, 2013.)

APVMA & Chemical reviews
The new APVMA cost recovery arrangements have come into effect. From the perspective of minor use permits the fees have remained at $350 per application/renewal. However, what is changing are the statutory timeframes associated the APVMA undertaking their assessments, with certain types of assessments potentially extending the time available beyond the current six months.

Regarding reviews the preliminary review findings for **fenamiphos** were published in late February. The outcome of which essentially being a recommendation to withdraw current label uses. The critical aspect of the findings was the conclusion that current label uses posed "*potentially unacceptable risks to birds, aquatic organisms and terrestrial organisms*".
The publication of the review findings for **dimethoate** review and the environment component for **fenthion** are anticipated next. The APVMA will be basing recommendations on current label use patterns. As indicated previously there may be opportunities to amend use patterns to mitigate any OH&S or environmental concerns that might be identified.

Security Sensitive Chemicals

The Attorney General Department (ADG) are moving ahead with their assessment of the 29 agricultural chemicals identified as being of potential security concern. The approach being taken is to assess the compounds on a group by group basis across the entire chemical supply chain, e.g., transport, retail and end-users, with risk being assessed at each level on a worse-case basis. Aspects being considered in the risk assessments include availability, concentration, lethality and employability.

Following completion of the risk assessment the Chemical Security Co-ordination Unit will then begin consideration of potential risk management measures. This is anticipated to occur late 2013 or early 2014.

Additional information can be obtained from the Chemical Security website.
http://www.chemicalsecurity.gov.au/Pages/default.aspx

New chemicals

A number of applications have been made to the APVMA seeking registration or active ingredient approvals for new chemicals.

Agriphar S.A, have applied to register Tops Plant Growth Regulator (**triclopyr**) for thinning and increasing fruit size in oranges and mandarins.

Syngenta have applied to register their fungicide Switch® (**fludioxonil + cyprodinil**) for use in green beans. A Trade Advice Notice has been published seeking comment on the potential for the proposed use to prejudice Australian trade in animal commodities, i.e. through the feeding of bean hay or by-products.

Syngenta is also currently developing a new selective herbicide **bicyclopyrone** for use in corn and sugarcane. Bicyclopyrone inhibits belongs to a subclass of the triketone family of chemistry and exhibits selective broad spectrum control of grass and dicot weeds.

Dow are seeking to register a new sucking pest insecticide **sulfoxaflor** (to be marketed as Transform®) in cucurbits, fruiting vegetables, legume vegetables, leafy vegetables, root and tuber vegetables, brassica vegetables, citrus, grapes, pome fruit and stone fruit.

INTERNATIONAL

New Zealand

The New Zealand Environmental Protection Authority has finalised its assessment of 29 organophosphate and carbamate insecticides. The following compounds have had their approvals withdrawn:- benomyl, carbofuran, carbosulfan, dichlofenthion, ethion, famphur, isazofos, omethoate, phoxim and pyrazophos.

Diazinon, fenamiphos, methamidophos, prothiofos, terbufos, fenitrothion and phorate have time limited approvals of between 3 and 15 years, after which their use will no longer be allowed.

Other substances, including acephate, carbaryl, chlorpyrifos, chlorpyrifos-methyl, dichlorvos, dimethoate, malathion, methomyl, oxamyl and pirimicarb continue to be approved but are subject to additional controls.
See http://www.epa.govt.nz/search-databases/HSNO%20Application%20Register%20Documents/APP201045_APP201045_Decision_FI

NAL.pdf for details.

EUROPE

The European Commission has responded to a recent report from EFSA in which questions were raised over the impact of neonictinoid pesticides on bees. The Commission has indicated that action would be taken to "mitigate the threat to pollinators". The Commission indicated that the action would be "proportional" and that a total ban was not justified.
The restrictions, as outlined in SANCO/10262/2013 Rev. 29 April 2013 affect clothianidin, thiamethoxam and imidacloprid only, i.e., not other neonicotinoids such as acetamiprid or thiacloprid.

The restrictions are as follows:

the complete withdrawal of amateur uses , i.e., home garden
the withdrawal of professional uses (Uses as seed treatment, soil treatment or foliar application) of clothianidin, imidacloprid and thiamethoxam on crops considered attractive to bees.
The above restrictions will apply after September 30th, but there is a derogation allowing for Member States to apply for a period of grace allowing uses to continue to November 30th.
Exceptions to the restrictions are:-
When the use is in a greenhouse,
Or if the foliar treatments are after flowering
Or on crops harvested before flowering, such as brassica vegetables and onions.

The European Commission has announced the restrictions for the use of the herbicide glufosinate, which will be effective from Nov 13, 2013.

The European Commission has proposed to approve Bayer CropScience's bionematicide *Bacillus firmus* strain I-1582 and FuturEco's insecticide, *Paecilomyces fumosoroseus* strain Fe 9901.under under the EU Plant protection regulation(1107/2009).

The European Commission has also announced its decision on the non-inclusion of formaldehyde (product type 20 – preservatives for food or feedstocks) under Annexes 1, 1A or 1B of the biocidal products Directive 98/8/EC.

Biocides used as feed preservatives and containing formaldehyde will be banned from 1 July 2015.

Cyflumetofen, the European Commission has proposed formal approve of a new acaricide from Otsuka has been approved for use in the EU. It is targeted for use against mites in tree fruit, nuts and vegetables.

MRLs have also been proposed for bifenazate (citrus, cucurbits, pome fruit, grapes & stone fruit), fludioxonil (celery), chlorantraniliprole (carrots, celeriac, parsnips and parsnip root), etoxazole (pome fruit), pyraclostrobin (cherries, peaches & plums) and penthiopyrad (pome fruit, cherries, peaches, plums, strawberries, root and tuber vegetables, bulb vegetables, cucurbits, fruiting vegetables and brassica vegetables) (SANCO 12787/2012, 12703/2012 & 12668/2012).

USA

The US EPA has proposed to approve the new active ingredient, **cyantraniliprole**. The proposed uses for cyantraniliprole include bushberries, fruit (citrus, pome, stone), nut tree, oilseed, vegetable (brassica leafy, bulb, cucurbit, fruiting, leafy, tuberous and corm). Ornamentals and turf.
Bayer CropScience is applying to register for its new insecticide, **flupyradifurone** (Sivanto) for use on a range of crops covering corn, soybeans, cotton, peanuts, coffee, cereals, fruits, and vegetables.

The US pheromone company Alpha Scents is seeking approval for the pheromone/mating disruptant, (Z,Z)-7,11-Hexadecadienal, for control of Citrus Leafminer (*Phyllocnistis citrella*).
The EPA has granted approval for the Dow insecticide **sulfoxaflor** for use on barley, bulb vegetables, canola, citrus, cotton, cucurbit vegetables, fruiting vegetables, leafy vegetables, low-growing berries, okra,

ornamentals (herbaceous and woody), pistachio, pome fruits, root and tuber vegetables, small vine climbing fruit (except fuzzy kiwifruit), soybean, stone fruit, succulent, edible podded and dry beans, tree nuts, triticale, turfgrass, watercress and wheat.
EPA has proposed to approve Valent USA's new fungicide, **Fenpyrazamine** (Protexio), for use on almonds, small fruit vine climbing, head and leaf lettuce, and low growing berries, bush berries, caneberries, ginseng, pistachio and ornamentals.
US EPA recently received several applications to register pesticide products containing new active ingredients. They are: Syngenta's fungicides, **benzovindiflupyr** in sweet corn, cucurbits, pome fruit, small vine climbing fruit, peas and beans and potatoes; Bayer CropSciences' insecticide/miticide, S*treptomyces microflavus* strain AQ 6121, Gowan's herbicide, **benzobicyclon**; ISK Biosciences' fungicide, **isofetamid** for lettuce, almonds, small vine berry low growing; AgBiTech's insecticide, *Helicoverpa zea Nucleopolyhedrovirus*; Phyllom's insecticide, *bacillus thuringiensis subsp. galleriae* strain SDS–502 at 85.0%.
Finally the US EPA has announced registration reviews for abamectin, captan, fenhexamid, indoxacarb, methoxyfenozide, propaziine, and pymetrozine

Canada

Canadian Pest Management Regulatory Authority (PMRA) has proposed phasing out the sale and use of all **linuron** products following the completion of its re-evaluation of the herbicide. The proposed move is likely to have a significant impact on vegetable producers in that country.

Japan

The Japanese Ministry of Health, Labour and Welfare have indicated that they wish to finalise risk assessments for the remaining provisional MRLs created when the positive list came into effect. MHLW have identified 307 chemicals for which risk assessments need to be finalised and sought feedback from Australia (via DAFF) on which MRLs industries wish retained are and prepared to support.
The first submission to Japan was made in March. Each APVMA submission to Japan will include the following information.
A list of Australian MRLs for currently approved uses;
Copies of Australian product labels detailing approved uses;
Copies of toxicology evaluations; and
Copies of residues evaluations that provide justification for Australian MRLs.

The next data submission is planned for December 2013. The final data submission is planned for mid-2014 The information was collated by DAFF and submitted to Japan.

Further Information

If you have any questions or wish to discuss any points covered in this Update, please contact Kevin Bodnaruk on 02 9499 3833 or email kevinakc@bigpond.net.au

AgChemical Update - March 2014
(Project AH09003)

WHATS NEW
Below is a summary of various regulatory issues and chemical reviews currently underway both locally and internationally.

NATIONAL REGULATORY ISSUES

Cost Recovery
In November last year, the Department of Agriculture released a consultation paper on cost recovery for the APVMA. The consultation paper presented potential cost recovery options and sought stakeholder comment on those options.
Of particular concern to a number of industry groups was the option for full cost recovery of permits. Under under such an approach the estimated minor use permit fee would rise from $350 to $15,000 to $25,000 depending upon thetype of assessment required.
To view background information to the paper and the submissions made in response, visit the website below.
http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements

Reforms to regulation of agricultural chemicals and veterinary medicines

The government is moving to repeal the re-approval and re-registration requirements as previously drafted. The intention is that the Agricultural and Veterinary Chemicals Legislation (Removing Re-approval and Re-registration) Amendment Bill 2013 to pass through Parliament by 30 June 2014.

For additional information see
http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals

Control of Use
The Standing Council on Primary Industries (SCoPI), has been discontinued. The **Council of Australian Governments (COAG) met on Friday 13 December 2013, and decided to streamline its Council system to focus on COAG's priorities. The number of councils were reduced from 22 to 8 with the Standing Council on Primary Industries not included in the list of councils to continue under COAG. The**

Agvet Chemical Regulation Committee
In March 2013, the Agvet Chemical Regulation Committee (ACRC) was established to oversee the implementation of reforms to agricultural chemicals and veterinary medicines (agvet chemicals) control of use regulation and identify areas for future reform. This committee reported to ScoPI,

National Produce Monitoring System
The National Produce Monitoring System is underway. To date there has been little information available on its implementation or operation.

APVMA & Chemical reviews
Regarding reviews the preliminary review findings for **fenamiphos** were published in late February. The outcome of which essentially being a recommendation to withdraw current label uses. The critical aspect of the findings was the conclusion that current label uses posed "*potentially unacceptable risks to birds, aquatic organisms and terrestrial organisms*".
The publication of the review findings for **dimethoate** review and the environment component for **fenthion** are anticipated by mid-year. As outlined previously the APVMA will base its recommendations on existing label use patterns. Upon publishing of the final Review outcomes stakeholders will be provided an opportunity to provide responses.

Security Sensitive Chemicals
The Attorney General Department (ADG) are finalising the assessment of the remaining agricultural chemicals identified as being of

potential security concern. The risk management approach to be taken will be elaborated over the next few months following consultation with industry and regulators with a regulatory impact statement anticipated in the second half of the year.

Additional information can be obtained from the Chemical Security website. http://www.chemicalsecurity.gov.au/Pages/default.aspx

New chemicals

A number of applications have been made to the APVMA seeking registration or active ingredient approvals for new chemicals.

BASF have sought approval for the insecticide metaflumizone. It is registered in the USA as Venom® for the control of sucking and chewing insects in cucurbits, fruiting vegetables, grapes, brassica vegetables, leafy vegetables, potatoes, onions, berries, peach and nectarines.

Bayer have applied for approval for a new fungicide Fenamidone. It is regiasered in the US (Reason®) for the control of Downy mildew, Albugo, Alternaria, in Brassica vegetables, Bulb vegetables, Cucurbit vegetables, leafy vegetables, potatoes,fruiting vegetables and grapes.

INTERNATIONAL

Rotterdam Convention

At the October meeting of the Chemical Review Committee it was recommended that **trichlorfon** be listed in Annex III to the Convention (on the Prior Informed Consent).

The Convention deals with the transboundary movement and trade of hazardous chemicals and their management. Once a chemical is listed signatory countries can decide whether to allow or ban the importation of listed chemicals, and exporting countries are obliged to make sure that producers within their jurisdiction comply with guidance.

Additional information can be obtained from: http://www.pic.int/TheConvention/ChemicalReviewCommittee/ReportsandDecisions/tabid/1058/language/en-US/Default.aspx

EUROPE

The European Commission has withdrawn approval for flusilazole with all authorisations revoked. As a result uses are to be phased-out with storage and use permitted till October 12th 2014.

The European Commission has announced MRLs for pyriofenone, an aryl phenyl ketone fungicide used for the control powdery mildew grape and cereals. ISK Biosciences applied for an active ingredient approval

Cyflumetofen, the European Commission has proposed formal approve of a new acaricide from Otsuka has been approved for use in the EU. It is targeted for use against mites in tree fruit, nuts and vegetables.

MRLs have also been proposed for bifenazate (citrus, cucurbits, pome fruit, grapes & stone fruit), fludioxonil (celery), chlorantraniliprole (carrots, celeriac, parsnips and parsnip root), etoxazole (pome fruit), pyraclostrobin (cherries, peaches & plums) and penthiopyrad (pome fruit, cherries, peaches, plums, strawberries, root and tuber vegetables, bulb vegetables, cucurbits, fruiting vegetables and brassica vegetables) (SANCO 12787/2012, 12703/2012 & 12668/2012).

USA

The US EPA has established MRLs for fenamidone in or on ginseng; bean, succulent, except cowpea; onion, blub, subgroup 3-07A; and onion, green, subgroup 3-07B *Pseudomonas fluorescens* strain D7. *Product type:* Herbicide. *Proposed uses:* For suppression of downy brome, medusahead, Japanese brome and jointed goatgrass on cropland, rangeland, turf and non-crop areas *Active ingredient: Bacillus subtilis* strain IAB/BS03. *Product type:* Fungicide. *Proposed uses:* Greenhouse, field use, and home and garden use on various fruits and vegetables, cotton, hops, tobacco, fruit and nut trees, turf,

and ornamentals.
Beauveria bassiana strain ANT-03. *Product type:* Microbial insecticide. *Proposed uses:* Foliar-applied insecticide to protect turf, horticultural or agricultural plants in the field or greenhouse.
.
US EPA recently received several applications to register pesticide products containing new active ingredients. They are: Syngenta's fungicides, **benzovindiflupyr** in sweet corn, cucurbits, pome fruit, small vine climbing fruit, peas and beans and potatoes; Bayer CropSciences' insecticide/miticide, S*treptomyces microflavus* strain AQ 6121, Gowan's herbicide, **benzobicyclon**; ISK Biosciences' fungicide, **isofetamid** for lettuce, almonds, small vine berry low growing; AgBiTech's insecticide, *Helicoverpa zea Nucleopolyhedrovirus*; Phyllom's insecticide, *bacillus thuringiensis subsp. galleriae* strain SDS–502 at 85.0%.
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Copies of toxicology evaluations; and
Copies of residues evaluations that provide justification for Australian MRLs.

The next data submission is planned for December 2013. The final data submission is planned for mid-2014 The information was collated by DAFF and submitted to Japan.

Further Information
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ATTACHMENT II: STAKEHOLDER LIAISON

Meeting Date	Who	Where	Topic
17.9.10	Syngenta	Nth Ryde	Company liaison
11.10.10	Ospray	Nth Sydney	Company liaison
21.10.10	HAL	Sydney	Spray drift meeting
26.10.10	APVMA	Canberra	Dim/fen discussions
4.11.10	APVMA	Canberra	ILC meeting
16.11.10	Ausveg	Pymble	Teleconference
17.11.10	OCPPO	Pymble	Teleconference
26.11.10	Growcom	Pymble	Teleconference
7.12.10	AMGA	Sydney	Mgt meeting
8.12.10	DAFF	Canberra	Meeting – Agvet chem regulation
8.12.10	OCPPO	Canberra	Dim/fen discussions
8.12.10	CCPR	Canberra	Panel meeting
9.12.10	PHA	Canberra	Dim/fen discussions
10.12.10	Ausveg	Pymble	Teleconference
12.1.11	APVMA	Canberra	Dim/fen discussions
12.1.11	APVMA	Canberra	Carbendazim/endosulfan etc discussions
14.1.11	AIC	Pymble	R De Vos meeting
2.3.11	Codex	Canberra	Panel meeting
3.3.11	APVMA	Canberra	Liaison
16.3.11	PSIC	Sydney	Stakeholder meeting
18.3.11	Sumitomo	Epping	Company liaison
22.3.11	OCPPO	Pymble	Teleconference
24.3.11	Dow	Sydney	Company liaison
29.3.11	Dupont	Sydney	Company liaison
1-9.4.11	Codex Meeting	Beijing	CCPR Committee meeting
14.4.11	Ausveg	Brisbane	Chem WG meeting
15.4.11	Ausveg	Brisbane	National Conference
27.4.11	APVMA	Canberra	Liaison
2.5.11	NSWFA	Sydney	Liaison – Dimethoate/fenthion Update
11.5.11	PHA	Canberra	Liaison – Dimethoate/fenthion Update
11.5.11	APVMA	Canberra	Liaison
18-20.5.11	AMGA	Darwin	Mango national conference
23-24.5.11	NZFSA	Wellington	Liaison
15.6.11	Cheminova/Ospray	Sydney	Liaison
16.6.11	PHA	Canberra	Liaison – Dimethoate/fenthion Update
17.6.11	APVMA	Canberra	Liaison
17.6.11	DAFF	Canberra	Liaison – Better Regulation Reform
26.7.11	Organic crop Prot	Sydney	Liaison
28.7.11	Syngenta	Nth Ryde	Company liaison
2.8.11	NIRG	Canberra	Security Sensitive Chemicals Meeting
3.8.11	APVMA	Canberra	Liaison
	DAFF	Canberra	Liaison
	CropLife	Canberra	Liaison
4.8.11	APVMA	Canberra	ILC Meeting
8.8.11	Sumitomo	Sydney	Liaison
1.9.11	Cheminova/Ospray	Nth Sydney	Company liaison
6.9.11	APVMA	Canberra	Liaison
6.9.11	APVMA	Canberra	Liaison
4.10.11	HAL	Sydney	Dimethoate meeting
13.10.11	APVMA	Canberra	Liaison
25.10.11	SAL	Brisbane	Dimethoate meeting
27.10.11	Syngenta	Sydney	Company liaison
2.11.11	APVMA	Canberra	Dimethoate review discussions
3.11.11	APVMA	Canberra	ILC meeting (see attached)
30.11.11	DAFF	Canberra	Liaison – Better Regulation Reform

Meeting Date	Who	Where	Topic
30.11.11	DAFF - OCPPO	Canberra	Dimethoate review discussions
30.11.11	DAFF	Canberra	CCPR Panel Meeting
1.12.11	PHA	Canberra	Dimethoate review discussion
8.12.11	Cheminova/Ospray	Nth Sydney	Company liaison
9.12.11	Sumitomo	Epping	Company liaison
8.2.12	APVMA	Canberra	Communication Steering group meeting
9.2.12	APVMA	Canberra	Liaison
1.9.11	Cheminova/Ospray	Nth Sydney	Company liaison
6.9.11	APVMA	Canberra	Liaison
6.9.11	APVMA	Canberra	Liaison
4.10.11	HAL	Sydney	Dimethoate meeting
13.10.11	APVMA	Canberra	Liaison
25.10.11	SAL	Brisbane	Dimethoate meeting
27.10.11	Syngenta	Sydney	Company liaison
2.11.11	APVMA	Canberra	Dimethoate review discussions
3.11.11	APVMA	Canberra	ILC meeting (see attached)
30.11.11	DAFF	Canberra	Liaison – Better Regulation Reform
30.11.11	DAFF - OCPPO	Canberra	Dimethoate review discussions
30.11.11	DAFF	Canberra	CCPR Panel Meeting
1.12.11	PHA	Canberra	Dimethoate review discussion
8.12.11	Cheminova/Ospray	Nth Sydney	Company liaison
9.12.11	Sumitomo	Epping	Company liaison
8.2.12	APVMA	Canberra	Communication Steering group meeting
9.2.12	APVMA	Canberra	Liaison
7.3.12	Citrus	Melbourne	Export forum
8.3.12	Bayer	Melbourne	Company liaison
8.3.12	Nufarm	Melbourne	Company liaison
13.3.12	AMGA	Sydney	R&D Mgt Committee meeting
20.3.12	DAFF	Canberra	CCPR Panel Meeting
20.3.12	DAFF	Canberra	Liaison – Better Regulation Reform
27.3.12	Dow	Sydney	Company liaison
29.3.12	SAL	Brisbane	Summer fruit WG meeting
30.3.12	APVMA	Canberra	Communication Steering group meeting
3.4.12	PHA	Canberra	Liaison
5.4.12	Dupont	Sydney	Company liaison
21-28.4.12	Codex Meeting	Shanghai	CCPR Committee meeting
10.5.12	Ausveg	Hobart	Chem WG meeting
11-12.5.12	Ausveg	Hobart	National Conference
5.6.12	DAFF	Canberra	CCPR Panel Meeting
6.6.12	APVMA	Canberra	Liaison – chemical review
12.6.12	PHA	Canberra	Liaison – Dimethoate/fenthion update
26.6.12	Ospray	Sydney	Company liaison
20.7.12	Sumitomo	Sydney	Company liaison
2.8.12	SAL	Melbourne	Summer fruit WG meeting
3.8.12	DAFF	Melbourne	Market access workshop
7.3.12	Citrus	Melbourne	Export forum
8.3.12	Bayer	Melbourne	Company liaison
8.3.12	Nufarm	Melbourne	Company liaison
13.3.12	AMGA	Sydney	R&D Mgt Committee meeting
20.3.12	DAFF	Canberra	CCPR Panel Meeting
20.3.12	DAFF	Canberra	Liaison – Better Regulation Reform
27.3.12	Dow	Sydney	Company liaison
29.3.12	SAL	Brisbane	Summer fruit WG meeting
30.3.12	APVMA	Canberra	Communication Steering group meeting
3.4.12	PHA	Canberra	Liaison
5.4.12	Dupont	Sydney	Company liaison
21-28.4.12	Codex Meeting	Shanghai	CCPR Committee meeting

Meeting Date	Who	Where	Topic
10.5.12	Ausveg	Hobart	Chem WG meeting
11-12.5.12	Ausveg	Hobart	National Conference
5.6.12	DAFF	Canberra	CCPR Panel Meeting
6.6.12	APVMA	Canberra	Liaison – chemical review
12.6.12	PHA	Canberra	Liaison – Dimethoate/fenthion update
26.6.12	Ospray	Sydney	Company liaison
20.7.12	Sumitomo	Sydney	Company liaison
2.8.12	SAL	Melbourne	Summer fruit WG meeting
3.8.12	DAFF	Melbourne	Market access workshop
16.8.12	SARDI	Adelaide	Liaison – G Baker - insecticide research
16.8.12	AWRI	Adelaide	Liaison – M Esseling - MRL compliance
17.8.12	PIRSA	Adelaide	Liaison – COAG Reforms J Kassebaum
21.8.12	Nufarm	Brisbane	Company liaison - A Wells, F Taylor
27.8.12	Bayer	Melbourne	Company liaison - D Gregor
3.9.12	Ospray	Nth Sydney	Company liaison - A McCorquodale
11.9.12	APVMA	Canberra	Liaison - A Norden, J Lutze
2.10.12	APVMA	Canberra	Liaison - A Norden, J Lutze
10.12.12	APVMA	Canberra	Liaison with Taiwanese delegation
24.10.12	Syngenta	Sydney	Company liaison – K McKee
1.11.12	APVMA	Canberra	ILC meeting
2.11.12	APVMA	Canberra	Dimethoate review discussions
20.11.12	HAL	Sydney	Fruit Fly forum
22.11.12	Dow	Sydney	Company liaison – C Sharpe
23.11.12	Sumitomo	Sydney	Company liaison – L Streit
4.12.12	DAFF	Canberra	CCPR Panel Meeting
7.1.13	APVMA	Canberra	Liaison – Chemical review – R Schipp
22.1.13	Syngenta	Sydney	Company liaison – K Patterson
4.2.13	(Senator Ruston)	Adelaide	Agvet chemical reform legislation - A Green
12.2.13	APVMA	Canberra	Liaison – Minor use/Ethephon mangoes - A Norden, J Lutze
12.2.13	(Senator Ruston)	Canberra	Agvet chemical reform legislation - A Green
7.3.13	HAL	Sydney	Fruit fly forum
12.3.13	Bayer	Melbourne	Company liaison
13.3.13	Nufarm	Melbourne	Company liaison
13.3.13	BASF	Melbourne	Company liaison
19.3.13	VFF	Mildura	Trade & MRL compliance
19.3.13	Citrus Aus Ltd	Mildura	Trade & MRL compliance
25.3.13	Dupont	Sydney	Company liaison
26.3.13	HAL	Sydney	Turf pesticides meeting
27.3.13	Dow	Sydney	Company liaison
28.3.13	Sumitomo	Sydney	Company liaison
9.4.13	DAFF	Canberra	CCPR Panel Meeting
10.4.13	APVMA	Canberra	Liaison – Chemical review
6-10.5.13	Codex Meeting	Beijing	CCPR Committee meeting
15-16.5.13	AMIA	Cairns	Mango industry conference
21.5.13	A-G Department	Sydney	Security Sensitive Chemicals
27.5.13	APVMA	Canberra	Liaison
13.6.13	DAFF	Canberra	CCPR Panel Meeting
14.6.13	APVMA	Canberra	Liaison – Chemical review
19.6.13	HAL	Sydney	Project liaison
24.6.13	Ospray/Cheminova	Sydney	Dimethoate liaison
26.6.13	APVMA	Canberra	Liaison – Chemical review
27.6.13	PHA	Canberra	Minor Use liaison
16.7.13	NSWFA	Sydney	Fruit fly control presentation
17.7.13	Sumitomo	Sydney	Company liaison
1.8.13	APVMA	Canberra	Liaison – Chemical review
7.8.13	NSW DPI	Sydney	Teleconference – Fruit fly control project

Meeting Date	Who	Where	Topic
14.8.13	HAL	Sydney	Project liaison
29.8.13	NSW DPI	Sydney	Teleconference – Fruit spotting bug
7.3.13	HAL	Sydney	Fruit fly forum
12.3.13	Bayer	Melbourne	Company liaison
13.3.13	Nufarm	Melbourne	Company liaison
13.3.13	BASF	Melbourne	Company liaison
19.3.13	VFF	Mildura	Trade & MRL compliance
19.3.13	Citrus Aus Ltd	Mildura	Trade & MRL compliance
25.3.13	Dupont	Sydney	Company liaison
26.3.13	HAL	Sydney	Turf pesticides meeting
27.3.13	Dow	Sydney	Company liaison
28.3.13	Sumitomo	Sydney	Company liaison
9.4.13	DAFF	Canberra	CCPR Panel Meeting
10.4.13	APVMA	Canberra	Liaison – Chemical review
6-10.5.13	Codex Meeting	Beijing	CCPR Committee meeting
15-16.5.13	AMIA	Cairns	Mango industry conference
21.5.13	A-G Department	Sydney	Security Sensitive Chemicals
27.5.13	APVMA	Canberra	Liaison
13.6.13	DAFF	Canberra	CCPR Panel Meeting
14.6.13	APVMA	Canberra	Liaison – Chemical review
19.6.13	HAL	Sydney	Project liaison
24.6.13	Ospray/Cheminova	Sydney	Dimethoate liaison
26.6.13	APVMA	Canberra	Liaison – Chemical review
27.6.13	PHA	Canberra	Minor Use liaison
16.7.13	NSWFA	Sydney	Fruit fly control presentation
17.7.13	Sumitomo	Sydney	Company liaison
1.8.13	APVMA	Canberra	Liaison – Chemical review
7.8.13	NSW DPI	Sydney	Teleconference – Fruit fly control project
14.8.13	HAL	Sydney	Project liaison
29.8.13	NSW DPI	Sydney	Teleconference – Fruit spotting bug
3.9.13	Ospray	Nth Sydney	Company liaison - A McCorquodale
11-12.9.13	Citrus	Melbourne	Pest Management meeting
16.9.13	NSW FA	Sydney	Presentation to NSWFA Horticulture meeting
24.10.13	APVMA	Pymble	Teleconference re chemical review
18.11.13	Bayer	Sydney	Teleconference – China MRLs
20.11.13	HAL	Sydney	Olive permit discussion
9.12.13	DAFF	Canberra	CCPR Panel meeting
10.12.13	APVMA	Canberra	Chemical review discussion
22.1.14	Ausveg	Melbourne	Registrant liaison
21.2.14	Dow	Pymble	Company liaison
25.2.14	HAL	Sydney	HAL Board presentation
6.3.14	APVMA	Canberra	Regulatory guidelines workshop
7.3.14	Sumitomo	Sydney	Company liaison
11.3.14	Dupont	Sydney	Company liaison
19.3.14	DAFF	Canberra	CCPR Panel meeting
20.3.14	NSW FA	Sydney	Industry liaison
9.4.14	DAFF	Canberra	CCPR Panel Meeting
29.4.14	APVMA	Canberra	Liaison – Chemical review
1.5.14	AMGA	Sydney	Mushroom Pest & Disease Committee meeting
5-10.5.14	Codex Meeting	Nanjing	CCPR Committee meeting

ATTACHMENT III: APVMA Chemical Review Submissions

Horticulture Industry response to the FIPRONIL Review Scope Document

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INTRODUCTION:

In response to the Review Scope Document input was sought from peak industry body representatives, growers, advisers and researchers associated with those crops in which Fipronil is currently either registered or approved for use, e.g., bananas, brassica vegetables, potatoes and the nursery industry. Information outlined below provides general background information and specific information relating to the use of the product in main industries.

From comments received it is apparent that Fipronil has a significant role in crop production in all crops for the management of a range of pests, e.g., Banana weevil borer, (*Cosmopolites sordidus*), Banana rust thrips (*Chaetanaphothrips signipennis*), Diamond back moth (*Plutella xylostella*), Cabbage white butterfly (*Pieris rapae*), Cabbage cluster caterpillar (*Crocidolomia pavonona*), Mushroom flies, Whitefringed weevil (*Naupactus leucoloma*), wireworm and Western flower thrips (*Frankliniella orientalis*) as per PER4415.

It was indicated that the use of fipronil is an important part of pest management strategies in all crops. In particular, is its use as a rotational option for the management of pests prone to the development of resistance, e.g., Diamond back moth and Western flower thrips. In general Fipronil is used no more than 1-2 applications per crop with uses governed by Avcare resistance management strategies. Commodity specific comments are indicated below.

CROP BACKGROUND INFORMATION:

BRASSICA VEGETABLES
Fipronil is a key chemical for the control of Diamond back moth as it forms part of grower's resistance management strategy. The use of fipronil is limited by the Avcare Diamond back moth resistance strategy to a specific 'window' during the year, i.e., it cannot be applied to all crops. Its use is further limited by a maximum number of four applications per year. It can also be occasionally used for the control of incidental caterpillar infestations, e.g., Cabbage cluster caterpillar and Cabbage white butterfly.

NURSERY INDUSTRY
It is used for the control of Western flower thrips a significant pest of seedlings and ornamental plants. In the nursery industry it is used as part of rotational pest management programs. The application of fipronil is done on as need basis with only one application per crop.

BANANAS
Fipronil can be used for the control of Banana weevil borer and Banana rust thrips in bananas. As with other uses it is applied as part of resistance management programs, i.e., due to its use as a rotational option. Applications are limited by need and would only occur 1-2 times per year.

MUSHROOMS
Fipronil is used to control can be used for the control of Banana weevil borer and Banana rust thrips in bananas. As with other uses it is applied as part of management programs, i.e., due to its use as a rotational option for resistance management. Further information regarding the use of Fipronil in mushrooms is contained in the response from the AMGA[1].

POTATOES
Fipronil is approved to control whitefringed weevil and wireworm in potatoes. Applications, when used, are made prior to crop planting once per season. The use of Fipronil is not great in potatoes.

[1] **Australian Mushroom Growers Association**

CROP OH&S INFORMATION

Background:

Crop group/crop:	Nursery crops	**No. App/crop:**	One
State/region:	National	**No. Crop/year:**	Variable
Product:	Regent (Fipronil)		
Pest group/pest:	Western Flower Thrips		
Field or greenhouse:	Greenhouse & Field		
Crop growth stage:	Seedling/tube stock	**Date:**	March 2004

Use Pattern:

Application	App. Method:	High & low volume
	Equipment type:	Hand gun on retractable hose/knapsack/drenching
	Equipment:	Single Nozzle
	Treatment zone:	Pot/tray
	Water volume:	100 – 500
	Nozzle type:	Even Fan/Flood jets/Cone nozzles
	Nozzle size:	5 - 150 L/min
	Nozzle spacing:	N/A
	Pressure:	1-3 bar
	Tank capacity (L):	15/200

Operator safety	No. of operators:	One mixer/loader/applicator or one mixer/loader + one applicator
	Enclosed cab:	No
	PPE during mix/loading:	Yes
	PPE during application:	Yes
	Treated area/volume (ha or L/day):	Under 500 L/day (250L/ha)
	Work rate (hours/day):	2-3
	No. of operations/day for M/L:	1-2
	Operation duration M/L	5-10 minutes
	Operation duration App.	1-1.5 hours

Re-entry activity	Type of activity:	Stock movement/despatch/weeding/fertilising
	Date (days after App.):	2 days after App
	Duration (hours/day):	30 minutes – 6 hours
	Crop height:	Low 0.10-0.25 m
	Remarks:	PPE in use includes hat, mask/respirator, goggles, gloves, long sleeves, long pants and boots.

Background:

Crop group/crop:	Brassica crops	**No. App/crop:**	1-2[2]
State/region:	National	**No. Crop/year:**	3-4
Product:	Regent (Fipronil)		
Pest group/pest:	Diamond Backed Moth		
Field or greenhouse:	Field		
Crop growth stage:	variable	**Date:**	March 2004

Use Pattern:

Application	App. Method:	High volume
	Equipment type:	Tractor mounted
	Equipment:	Boom spray
	Treatment zone:	Row
	Water volume:	100 – 500
	Nozzle type:	Hollow cone
	Nozzle size:	1 L/min
	Nozzle spacing:	50 cm
	Pressure:	1-3 bar
	Tank capacity (L):	2000

Operator safety	No. of operators:	One mixer/loader/applicator or one mixer/loader + one applicator
	Enclosed cab:	Yes
	PPE during mix/loading:	Yes
	PPE during application:	No
	Treated area (ha/day):	4-5
	Work rate (hours/day):	6
	No. of operations/day for M/L:	1-2

Re-entry activity	Type of activity:	Scouting, harvesting
	Date (days after App.):	Scouting – 2 to 3 days Harvesting – 7 days
	Duration (hours/day):	2-4
	Crop height:	Low 0.5-0.75 m
	Remarks:	

[2] **No more than 4 applications per year.**

Background:

Crop group/crop:	Banana crops	**No. App/crop:**	1-2
State/region:	National	**No. Crop/year:**	1
Product:	Regent (Fipronil)		
Pest group/pest:	Banana rust thrips & Banana weevil borer		
Field or greenhouse:	Field		
Crop growth stage:		**Date:**	March 2004

Use Pattern:

Application	App. Method:	High volume
	Equipment type:	Tractor mounted
	Equipment:	Boom or band spray
	Treatment zone:	Row (plant row & butts)
	Water volume:	40 – 80 L/100m
	Nozzle type:	Hollow cone
	Nozzle size:	1 L/min
	Nozzle spacing:	50 cm
	Pressure:	1-3 bar
	Tank capacity (L):	2000

Operator safety	No. of operators:	One mixer/loader/applicator or one mixer/loader + one applicator
	Enclosed cab:	Yes
	PPE during mix/loading:	Yes
	PPE during application:	No
	Treated area (ha/day):	4-5
	Work rate (hours/day):	6
	No. of operations/day for M/L:	1-2

Re-entry activity	Type of activity:	Scouting, harvesting & deleafing
	Date (days after App.):	Scouting – 7 days at the earliest Harvesting – 1-2 months Deleafing – 7-14 days at the earliest
	Duration (hours/day):	2-4
	Crop height:	High 2.5-3.0 m
	Remarks:	

Dimethoate

The AUSVEG is the peak industry body for the Australian vegetable industry and welcomes the opportunity to provide a response to the recently released report on Dimethoate. Nevertheless, AUSVEG is concerned at the short-time frame allowed to the industry assess the findings and seek, prepare and submit a consolidated industry response. For a number of commodities individual commodity groups have expressed a desire to provide additional support to preserve uses, however in the time allowed this has been impossible as the exact amount of additional data that might be required is unknown and the administrative and governance processes the industry works within precludes the ability to provide definitive answers within the timeframe allowed.
Further for a number of vegetable commodities AUSVEG believes there is sufficient data available to

warrant reconsideration of a number of the recommendations to suspend pre-harvest dimethoate use. For these commodities it is argued that a revised analysis is warranted on the basis one or a combination of the following three factors, i.e., an alternative use pattern, application of the principle of proportionality or a review of the consumption levels applied in the dietary intake calculations. AUSVEG believes that the results of such reconsiderations would yield sufficient justification for the APVMA to withdraw these proposed suspensions as dimethoate use would not result in an exceedance of the acute reference dose (ARfD). Outlined below are the arguments supporting the various uses for commodities in which access to dimethoate is still seen as being important.

BRASSICA VEGETABLES

Brussels sprouts

The vegetable industry wishes to flag two aspects it believes warrants reconsideration of the proposed suspension of dimethoate in Brussels sprouts, i.e., trial numbers and the exceedance of the ARfD.

Trial numbers

In the Report it is indicated that the European data is considered not to support the Australian GAP. As the rate applied in the European trials is higher (1.3×) the Australian rate the industry believes that the APVMA should consider applying the principle of proportionality as outlined by MacLachlan & Hamilton (2011)[3]. In their review it was indicated that a proportional relationship between pesticide application rate and the resulting residues in harvested commodities existed and that guidance on the selection of residue trials be modified to recognise the proportionality principle for application rate. Further in its 2010 Report[4] the JMPR also advocated the use of scaling where residue levels are above the currently accepted ± 25% variation in application rates[5].

In the Dimethoate Report for a number of the European trials the rate reported was 0.04 kg ai/ha, i.e., 33% above the Australian label rate, marginally outside the ± 25% variation. Through the use of scaling it is argued that these trials can be used in the assessment and would result in a sufficient number of trials.

Dietary intake

In Appendix 1 of the Dimethoate Report it is indicated that the dietary consumption level applied was 7.526 g/kg bw. AUSVEG understand that this level represents the consumption level for Flowerhead brassicas, e.g., cauliflower and broccoli, and believes that use of this consumption level results in a significant over estimation of Brussels sprout consumption and the resultant estimate of dimethoate/omethoate dietary intake. AUSVEG suggests that a more appropriate default consumption level to apply would be that of cabbages, i.e., 4.368 g/kg bw.

Alternative GAP

AUSVEG also believes there is scope for considering an alternative use pattern, i.e., alternative GAP. In the eight Brussels sprout trials reported by the 2003 JMPR[6] residues found at 14 days after the final application were 0.03 (2), 0.04, 0.06, 0.1 (2) and 0.11(2) mg/kg for dimethoate and < 0.01 (2), 0.02, 0.03 (2), 0.04, 0.07 and 0.11 mg/kg for omethoate. Even without the application of proportionality estimates of dietary intake from the resulting residues do not exceed the ARfD.

Conclusion

Through the application of scaling and the use of the cabbage consumption level or an alternative

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[3] MacLachlan, D.J. & Hamilton, D. 2011. A review of the effect of different application rates on pesticide residue levels in supervised residue trials. Pest Management Science Volume 67, Issue 6, pages 609–615, June 2011

[4] **Pesticide Residues in Food – 2010. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper, 200, 2011.**

[5] *Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Levels in Food and Feed.*. FAO plant production and protection paper 197: pp 40. 2nd edition, FAO, Rome, Italy (2009

[6] **Pesticide Residues in Food – 2003. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper, 176, 2004.**

GAP AUSVEG believes the estimate of short-term intake for children between the ages of 2 and 6 years will be below the ARfD. Ausveg therefore considers that there is sufficient data for the APVMA to reconsider the proposed suspension of use in Brussels sprouts with either a 7 or 14 day WHP.

	Observed total HR mg/kg	**Residue for acute dietary exposure assessment mg/kg**	**Acute Exposure (% of ARfD)**		**Use acceptable?**
			2–6 years	**2+ years**	
Brussels sprouts	0.76	2.77	60	35	Yes
	0.77	0.87	32.7		Yes

Cauliflower

Trial numbers

As with Brussels sprouts it was outlined in the Dimethoate Report that the data set for cauliflower was considered inadequate and that the European trials did not comply with the Australian GAP. Ausveg, however, believes that the European data is supportive and should be considered in the dietary intake assessment. The rate applied in the European trials while higher (1.3×) can be considered complying with the Australian GAP through application of the proportionality concept. This would significantly increase the number of trials available.

Alternative GAP

As the current use pattern results in residues that exceed the ARfD the industry wishes to propose an alternative use pattern. In the European trials reported by the APVM[7] residues found at 21 days after the final application were < 0.01 (4), < 0.02 (2), 0.01, 0.03(2) 0.21 mg/kg for dimethoate and < 0.01 (7),< 0.02, 0.02 and 0.05 mg/kg for omethoate. Even without the scaling of residues the estimates of dietary intake from the resulting residues do not exceed the ARfD.

Broccoli

Alternative GAP

AUSVEG also believes there is scope for considering an alternative use pattern for broccoli, i.e., an extended WHP to 21 days. While there is no trial data from longer harvest intervals Ausveg believes that residue trial data submitted in support of cauliflowers is sufficient to allow extrapolation.

Cabbage

Trial numbers

As with Brussels sprouts and cauliflower it is indicated in the Dimethoate Report that the European trials do not comply with the Australian GAP and not considered supportive. Despite the rate applied in the European trials being higher (1.3× the Australian rate) the industry believes that the APVMA should apply the concept of proportionality. This would allow the use of scaling where residue levels are above the currently accepted ± 25% variation in application rates[8].

Alternative GAP

As the current use pattern results in residues that exceed the ARfD the industry wishes to propose an alternative use pattern. Residue levels reported for cabbages reflected varietal differences in plant morphology. Three types of cabbage varieties were used in the European trials, i.e., cv Compacta a Spring cabbage variety grown for its loose-leafed pointed or conical shape head; cv Winchester a Savoy type; and Krypton, Tundra and White cabbage all drum-headed varieties with tightly held leaves. As a consequence the differing crop morphologies it is considered problematic whether all of the European trial data belongs to the same residue population as the Australian data which was completed on drum-head varieties.

[7] **Appendix 7 to the Dimethoate Report**

[8] *Submission and Evaluation of Pesticide Residue Data for the Estimation of Maximum Residue Levels in Food and Feed.*. FAO plant production and protection paper 197: pp 40. 2nd edition, FAO, Rome, Italy (2009

In the European trials reported by the APVMA[9] residues found at 21 days after the final application in drum head varieties were < 0.01, 0.01, 0.02 and 0.06 mg/kg for dimethoate and < 0.01, 0.01 and 0.02 (2) mg/kg for omethoate. As a consequence Ausveg proposes that the APVMA give consideration to restricting the use of dimethoate to drum-head varieties only with an alternative GAP of a 21 day withholding period.
Through the restriction to drum-head varieties and the application of an alternative GAP AUSVEG believes the estimate of short-term intake for children between the ages of 2 and 6 years will be significantly below the ARfD. Ausveg therefore considers that as there is sufficient data available that the APVMA reconsiders the proposed suspension of use in cabbages and allow use in cabbages, drum-head varieties only.

ROOT AND TUBER VEGETABLES

Beetroot

Trial numbers

It is indicated in the Dimethoate Report that the European trials do not address the Australian GAP. However, AUSVEG believes the European trials reported by the APVMA[7] with an application rate of 0.6 kg ai/ha are supportive and should be considered in the dietary intake assessment. The rate applied in the European trials while higher (2×) can be considered complying with the Australian GAP through application of the proportionality concept. Following such an approach would increase the number of trials upon which to base the dietary intake assessment.

Alternative GAP

As the European data does not support a 7 day WHP the industry wishes to propose an alternative use pattern of a 14 day WHP. In the European trials reported by the JMPR residues found at 14 days after the final application were < 0.002 (4) mg/kg for dimethoate and < 0.002 (3) and < 0.01 mg/kg for omethoate.

Using the highest residue levels found in these trials from Day 14 the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 5.6% of the ARfD for children between the ages of 2 and 6 years.

Carrot

Trial numbers

It is indicated in the Dimethoate Report that the European trials do not appropriately address the Australian GAP. Nine trials in carrots were reported by the 1998 JMPR[10] with an application rate of 0.6 kg ai/ha. Ausveg believes that these European trials are supportive and should be considered in the dietary intake assessment. The rate applied in the European trials while higher (2×) can be considered complying with the Australian GAP through application of the proportionality concept. Following such an approach would significantly increase the number of trials upon which to base the dietary intake assessment.

Alternative GAP

As the European data does not support a 7 day WHP and use of potato data results in an exceedance of the ARfD the industry wishes to propose an alternative use pattern by extending the withholding period to 14 days. In the European trials reported by the JMPR residues found at 14 days after the final application were 0.001 (2), 0.006, 0.008, 0.013, 0.019, 0.02 and 0.097 mg/kg for dimethoate and < 0.002 (2), 0.002, 0.003, 0.004 (2), 0.02 and 0.053 mg/kg for omethoate.

Using the highest residue levels found in these trials from Day 14 the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 25.4% of the ARfD for children

[9] Appendix 7 to the Dimethoate Report

[10] Table 49. Pesticide Residues in Food – 1998. Report of the Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Core Assessment Group. FAO Plant Production and Protection Paper, 148, 1999.

between the ages of 2 and 6 years.

Potato

Trial numbers

It is indicated in the Dimethoate Report that the European trials do not appropriately address the Australian GAP. The rate range in the European trials was 0.32 to 0.48 kg ai/ha which, at the lower rates is comparable to the Australian use rate of 0.3 kg ai/ha.

Alternative GAP

As the current use pattern results in residues that exceed the ARfD the industry wishes to propose an alternative use pattern consisting of an extended withholding period of 14 days. In the European trials reported by the APVM[11] residues found at 14 days after the final application were < 0.0012, < 0.01 (6), < 0.02 (5) and 0.01 mg/kg for dimethoate and 0.0049, < 0.01 (7), < 0.02 (4) and 0.02 mg/kg for omethoate.

Using the highest residue levels found in these trials from Day 14 the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 16.2% of the ARfD for children between the ages of 2 and 6 years.

Radish

Alternative GAP

As the current use pattern results in residues exceeding the ARfD the industry wishes to propose a 14 day WHP as the basis for an alternative GAP. In the European trials reported by the APVM[12] residues found radish roots at 14 days after the final application were 0.5, 0.54, 0.8, 1.1, 1.4, 1.9 and 2 mg/kg for dimethoate and < 0.1 (6) and 0.1 mg/kg for omethoate.

Using the highest residue levels found in these trials from Day 14 the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 76.7% of the ARfD for children between the ages of 2 and 6 years.

Turnip

Alternative GAP

As there is no data supporting the current use pattern AUSVEG wishes to propose a 14 day WHP as the basis for an alternative GAP. In the US trials reported by the APVM[13] residues found in turnip roots at 14 days after the final application were < 0.1(7) mg/kg for dimethoate and < 0.1 (7) mg/kg for omethoate.

Using the highest residue levels found in these trials from Day 14 the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 19.5% of the ARfD for children between the ages of 2 and 6 years.

Conclusion

Through the combination of scaling and the application of an alternative GAP (14 day WHP), AUSVEG believes that estimates of short-term dietary intake for the commodity group Root and tuber vegetables years will not exceed the ARfD for children between the ages of 2 and 6. AUSVEG suggests, therefore that on the basis of the European and US trials sufficient data is available for the APVMA to reconsider the proposed suspension of dimethoate uses for the commodity group.

FRUITING VEGETABLES, CUCURBITS

Cucumber

Alternative GAP

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[11] Appendix 7 to the Dimethoate Report
[12] Appendix 7 to the Dimethoate Report
[13] Appendix 7 to the Dimethoate Report

As the current use pattern results in residues exceeding the ARfD the industry wishes to propose a 3 day WHP as the basis for an alternative GAP. Combining the Australian cucumber and zucchini trial data, residues found 3 days after the final application were 0.12 and 0.05 mg/kg for dimethoate and 0.05 and 0.08 mg/kg for omethoate.

Using the highest residue levels found in the two trials, the dietary intake assessment does not result in an exceedance of the ARfD for the raw commodity, i.e., 19.5% of the ARfD for children between the ages of 2 and 6 years.

FRUITING VEGETABLES, OTHER THAN CUCURBITS

Eggplant

Dietary intake

In Appendix 1 of the Dimethoate Report it is indicated that the dietary consumption level applied was 8.842 g/kg bw, i.e., the tomato consumption level. AUSVEG believes that use of this consumption level causes a significant over estimation of eggplant consumption leading to the exceedance in the dimethoate/omethoate dietary intake estimate. AUSVEG suggests that a more appropriate default consumption level is that of capsicums, i.e., 3.158 g/kg bw. AUSVEG proposes this level as it is noted that such an approach has previously been employed by the APVMA in undertaking short-term dietary intake estimations, e.g., endosulfan[14].

Chilli peppers

Dietary intake

In the Dimethoate Report it is indicated that as no data was available to assess dietary intake that the use should be restricted to capsicums, i.e., sweet peppers only. AUSVEG believes that the APVMA should not exclude chilli peppers. Consumption of chilli peppers by children between the ages of 2 and 6 years is highly unlikely to be significant. The current dietary consumption level of chilli peppers for children between the ages of 2 and 6 years is 1.61 g/kg bw. AUSVEG acknowledges that there were insufficient respondents to validate the consumption level but nevertheless suggests that use of the capsicum level would compensate for any differences in resulting residues, i.e., that dietary intake would be below the acute reference dose.

STALK AND STEM VEGETABLES

Celery

Alternative GAP

As the current use pattern results in residues exceeding the ARfD the industry wishes to propose a 21 day WHP as the basis for an alternative GAP. In the Dimethoate Report the European trials are considered to not comply with the Australian GAP and therefore not considered supportive. AUSVEG however, suggests that, as with other commodities, the APVMA should consider scaling the residues from the European trials.

In the European trials reported by the APVM[15] dimethoate residues found at 21 days following two applications at 0.5 kg ai/ha were < 0.01, 0.07, 0.09 and 0.28 mg/kg for dimethoate and < 0.01, 0.02 and 0.04 (2) mg/kg for omethoate. Using the highest residue levels found in the trials, the dietary intake assessment does not result in an exceedance of the ARfD. For example, scaled residues result 22.4% of the ARfD for children between the ages of 2 and 6 years, whereas unscaled results in 37.1%.

Artichoke, globe

Alternative GAP

As current use pattern results in residues exceeding the ARfD the industry wishes to propose a 14 day WHP as the basis for an alternative GAP. On the basis of the European trials reported by the APVM[16] dimethoate residues found at 14 days following two applications at 0.5 kg ai/ha were 0.02 and

[14] **http://www.apvma.gov.au/products/review/docs/endosulfan_final_residues.pdf**
[15] **Appendix 7 to the Dimethoate Report**
[16] **Appendix 7 to the Dimethoate Report**

0.43 mg/kg for dimethoate and < 0.01, and 0.07 mg/kg for omethoate. Using the highest residue levels found in the trials, the dietary intake assessment does not result in an exceedance of the ARfD, i.e., 58.8% of the ARfD for children between the ages of 2 and 6 years.

Citrus Australia Ltd
PO Box 10336
Mildura, Vic 3502

S Pike
Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

Re: Diuron Environmental Report

Dear Sharon,
As per the submission previously made to the Preliminary Review Findings, Citrus Australia believes that potential environmental risks associated with diuron use in citrus orchards are over stated and that nevertheless, any risks while small can be further minimised. In particular, Citrus Australia believes that as a consequence of the way diuron is currently used the application of an addition risk mitigation measure would enable the Citrus Industry to continue using diuron without necessitating a reduction in the maximum application rates. Outlined below is the background to the Citrus Australia perspective.

Firstly, Citrus Australia is concerned that the proposed rate restriction which would unfairly penalise the entire industry, is upon an assessment, which in part is being influenced by issues identified from one growing region, i.e., the Murrumbidgee Irrigation Area (MIA). Citrus is grown throughout Australia with NSW accounting for approximately 36% of total production. Of this the Murrumbidgee Irrigation Area (MIA) accounts for some 70% of the state's production, i.e., 25% of national production[17]. This fact is significant in that this is the only part of the industry that relies upon a managed channel based irrigation system. In other words the detections attributable to the MIA are unique to the MIA. As a result a possible capping of the maximum use rate of diuron would unduly penalise 75% of the industry where to our knowledge no problems exist.

In regards to the diuron detections in the MIA, Citrus Australia believe that such detections stem from the current use of diuron on irrigation channels and drains, rather than from an in-crop use. Citrus Australia understands that the use of diuron in the MIA includes application to dry channels prior to the commencement of irrigation, i.e., as reflected by the monitoring data where it was found that diuron was found at higher levels in the cooler months[18]. Consequently, Citrus Australia believes that the removal of such uses would eliminate the primary source of surface water detections in the MIA.

Secondly, due to issues associated with water security, its cost, availability, salinity (salt moving into the tree root zone) and the negative impacts of waterlogging, the citrus industry has had to develop more efficient irrigation systems which has necessitated a move away from flood irrigation to drip and under-tree irrigation systems, i.e., flood irrigation is now extremely limited. For example, it is estimated that around 2,400 ha of 'open hydroponics' have been adopted in the industry. Such a move further reduces the likelihood of off-site movement from diuron treated areas.

Thirdly, the utilisation of diuron and residual herbicides in general, has become more a targeted use with growers relying more on the application of strategically timed knockdown herbicides for their primary weed control. The application of diuron is more an issue of weed spectrum and concerns over

[17] The Australian Horticulture Statistics Handbook 2004.
[18] Page 31 Diuron – Environment assessment

herbicide resistance, i.e., for hard to control weeds or as a rotational option. The outcome of which is that the estimated frequency of use as well as the rate of application of diuron in citrus has been greatly reduced.

Finally, it is standard practise within the citrus industry for there to be permanent vegetated inter-rows, i.e., areas to which no diuron is applied (see below). These vegetated strips act to slow water movement and as a consequence reduce any off-farm movement of herbicide acting as a buffer zone, i.e., limiting soil particle and surface water movement that might contain diuron residues. As a consequence of these vegetated inter-rows, diuron is only sprayed in bands either side of the tree line. These sprayed bands range in size from about 1 to 2.5 m in width, resulting in the actual amount of diuron applied per hectare of orchard reduced by as much as 65–70% at tree densities of 300 to 500 trees per hectare, i.e., the actual amount applied if sprayed at the current maximum rate would be approximately 1.2 kg ai/ha.

Coupled with the current use of vegetated inter-rows Citrus Australia proposes the inclusion of a requirement that vegetated perimeter buffers be used to further reduce the likelihood of any off-site movement of diuron. Citrus Australia understands that research has shown that such buffers can be very effective in reducing the off-site movement of pesticides[19]. On this basis Citrus Australia believes that the adoption of a 10 m vegetated buffer in relation water courses would further reduce the risk of any off target movement of diuron[20].

Yours sincerely,

Andrew Harty
General Manager – Market Development
Andrew.harty@citrusaustralia.com.au
Tel: 0350236333

[19] Reichenberger, S., Bach, M., Skitschak, A., Frede, H.-G., 2007. Mitigation strategies to reduce pesticide inputs into ground- and surface water and their effectiveness, a review. Science of the Total Environmental 384, 1–35
[20] Liu et al. 2008 Major factors influencing efficacy of vegetated buffers on sediment trapping. 2008. Journal of Environmental Quality • Volume 37

Horticulture Australia Ltd
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30 October 2009

Australian Pesticides and Veterinary Medicines Authority
PO Box 240
KINGSTON ACT 2604

Attn: R Marks

Chlorpyrifos Chemical Review

Horticulture Australia Limited (HAL) welcomes this opportunity to comment on the September 2009 Chlorpyrifos Preliminary Review Findings (PRF). HAL, as the industry body representing the Horticulture sector, has consulted industries potentially affected by the recommendations contained within the Chlorpyrifos PRF. Outlined below are both general and specific comments on individual recommendations contained in the PRF based on industry feedback.

Firstly HAL would also like to take the opportunity to express its appreciation at the level of industry consultation undertaken by the APVMA in the development of the PRF. HAL believes the level of engagement has been beneficial. HAL has also received positive feedback on the way in which the recommendations and proposed MRL amendments have been structured within the PRF with respect to readability, e.g., the use of colour in delineating proposed changes.

Specific comments

Asparagus & Celery
PRF recommendation: The continued use for the control of cutworms and baiting of crickets is supported.
HAL response: HAL agrees with the position taken by the APVMA that soil and or bait applications are not residue issues.

Banana
PRF recommendation: The continued use as a soil and butt treatment for the control of Banana weevil borer is supported.
The continued use of chlorpyrifos as a bell treatment is supported
HAL response: HAL agrees with the position taken by the APVMA to maintain the soil, butt and bell applications.

Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas
PRF recommendation: The use as an at-planting or pre-planting treatment or for the baiting of crickets is supported.
HAL response: HAL agrees with the position taken by the APVMA that soil and or bait applications are not residue issues.

Citrus fruits
PRF recommendation: The continued use for foliar applications, butt and soil treatment for is supported.
HAL response: HAL agrees with the decision taken by the APVMA regarding foliar, butt and soil applications.

Trade: In relation to potential trade concern highlighted in the PRF HAL between the proposed MRL and that of trading partners. HAL believes that the industry has the appropriate mechanisms in place

to address the issue. Citrus Australia Ltd (CAL) currently provides industry participants with information on MRLs in export markets and guidelines on achieving compliance. This approach has been successfully applied for a number of years and HAL believes would be sufficient to mitigate any potential risk.

Grapes

PRF recommendation: The continued use as a pre-harvest foliar treatment for the control of Light brown apple moth and Grapevine moth are supported.

The continued use of chlorpyrifos as a dormant treatment for Grapevine scale is supported

HAL response: HAL agrees with the position taken by the APVMA to support the uses for Light brown apple moth, Grapevine moth and Grapevine scale.

Mango

PRF recommendation: The ongoing use in mangoes according to the current use pattern with an amended MRL is supported.

HAL response: HAL agrees with the decision taken by the APVMA to maintain the current use pattern.

Pineapple

PRF recommendation: The ongoing use in pineapples according to the current use pattern is supported.

HAL response: HAL agrees with the decision taken by the APVMA to maintain the current use pattern.

Pome fruits

PRF recommendation: The ongoing use in pome fruit according to the current use pattern is supported.

HAL response: HAL agrees with the decision taken by the APVMA to maintain the current use pattern.

Trade: As with the citrus industry the Apple and Pears Australia Ltd (APAL) has put in place a mechanism aimed at addressing issues relating to MRL discrepancies. APAL currently provides industry participants with information on MRLs in export markets and guidelines on achieving compliance. This approach has been successfully applied for a number of years and HAL believes would be sufficient to mitigate any potential risk.

Stone fruits

PRF recommendation: The ongoing use in stone fruit according to the current use pattern is supported.

HAL response: HAL acknowledges the lack of residue trial data precludes the APVMA from supporting continued foliar pre-harvest use in peaches. However, HAL proposes that the APVMA consider a label restraint of 'Do not apply after bud break'. HAL believes allowing use early, after the breaking of dormancy use would address the residue issue, i.e., ensure non-detectable residues, while still maintaining access for a much needed San José scale control option. To support such a step HAL suggests the APVMA consider extrapolation from chlorpyrifos-methyl stone fruit residue data, given the two compounds are structurally similar and share an identical degradation pathway, i.e., hydrolysis to 3,5,6-trichloro-2-pyridinol (TCP).

HAL understands that supervised residue trial data for chlorpyrifos-methyl in peaches were submitted to the 2009 JMPR, in which applications of chlorpyrifos-methyl resulted in residues below the LOQ (< 0.01 mg/kg) 40 days after treatment. Given an at bud-break application would precede the development of fruit and be more than 40 days prior to harvest HAL believes such an approach would be practicable.

Currently the only other options available for the control of San Jose scale in stone fruit are azinphos-

methyl, chlorpyrifos, diazinon, methidathion, parathion-methyl and petroleum oil. Of these only chlorpyrifos and petroleum oil are considered compatible with integrated pest management. Therefore maintaining access would be beneficial to the industry.

Trade: The stone fruit industry provides information on MRLs in major export markets to industry participants. Consequently, HAL believes the provision of this information should be sufficient to alert exporters for the necessity to undertake measures to mitigate any potential risk.

Tomato
PRF recommendation: Use in processing tomatoes, only is supported.
HAL response: HAL agrees with the decision taken by the APVMA to maintain access for processing tomatoes.

Vegetables [except asparagus; brassica vegetables; cassava; celery; potato; tomato]
PRF recommendation: The ongoing use of the 'Vegetable' crop group not supported.
HAL response: In the absence of relevant residue trial data HAL agrees with the decision taken by the APVMA to not support foliar in crop use.

Growcom the peak industry body representing horticultural industries in Queensland welcomes the opportunity to provide a response to the recently released report *Dimethoate: Residues and Dietary Exposure Assessment.* In particular, Growcom believes there is sufficient data available to warrant a reconsideration of a number of the recommendations to suspend pre-harvest uses of dimethoate. For these commodities additional data and argument is provided that Growcom believes warrants a revised analysis. Outlined below are the arguments supporting the various uses for commodities in which access to dimethoate is still seen as being important.

TROPICAL FRUIT, INEDIBLE PEEL

Avocado

As with Brussels sprouts it was outlined in the Dimethoate Report that the data set for cauliflower was considered inadequate and that the European trials did not comply with the Australian GAP. Ausveg, however, believes that the European data is supportive and should be considered in the dietary intake assessment. The rate applied in the European trials while higher (1.3×) can be considered complying with the Australian GAP through application of the proportionality concept. This would significantly increase the number of trials available.

Alternative GAP

As the current use pattern results in residues that exceed the ARfD the industry wishes to propose an alternative use pattern. In the European trials reported by the APVM[21] residues found at 21 days after the final application were < 0.01 (4), < 0.02 (2), 0.01, 0.03(2) 0.21 mg/kg for dimethoate and < 0.01 (7),< 0.02, 0.02 and 0.05 mg/kg for omethoate. Even without the scaling of residues the estimates of dietary intake from the resulting residues do not exceed the ARfD.

Other assorted tropical and sub-tropical fruit, inedible peel

Pre harvest application of dimethoate to abiu, avocado, banana, casimiroa (white sapote), durian granadilla, santol, sapodilla, wax jambu, custard apple, mangosteen, papaya (pawpaw), passionfruit and rambutan is no longer supported.

Passionfruit

Growcom wishes to provide the results of a residue trial completed by northern NSW in 2003. Passionfruit plants received four applications of dimethoate at 0.028 kg ai/hL with a spray interval of 21 days. Residues found in the fruit 7 days after the final application were 0.15 mg/kg for dimethoate and 0.14 mg/kg for omethoate (see Table 1 below).

Table 1 Dimethoate and omethoate residues from multiple applications of dimethoate to passionfruit[22]

Application rate	Application No	WHP	Residue Dimethoate	Residue Omethoate
Newrybar, northern NSW 28 g ai/100L	4	0	0.56	0.11
		1	0.33 0.52	0.14 0.17
		2	0.32	0.13
		7	0.15	0.14

Dietary intake

The residue levels reported in Table 1 are for whole fruit. On the basis of residues found 7 days after the final application, an estimate of short-term dietary intake was calculated. The resultant estimate of dimethoate/omethoate dietary intake shows that the ARfD would not be exceeded for children between the ages of 2 and 6 years, i.e., 22%.

Commodity group

Data from litchi, mango and passionfruit

[21] **Appendix 7 to the Dimethoate Report**

[22] **See Attachment I**

Draft
Summerfruit Australia Ltd – Fruit Fly Funding Options

Meeting held at Novotel Hotel Brisbane Airport [October 25th 2011]

Background
The APVMA reviews of dimethoate and fenthion are reconsidering the approvals and registrations of dimethoate and fenthion based products. Dimethoate was assessed on the basis of toxicology, OH&S and residues, whereas the fenthion review will assess toxicology, OH&S, residues and the environment.

To date the APVMA have completed the reviews of toxicology and residues for dimethoate, the outcome of which was published in August 2011 with a number of recommendations relating to continued use in various crops.

Following stakeholder consultation the APVMA have permitted continued use of dimethoate in summer fruit under permit PER13155 as a pre-flowering treatment to aid in the management of thrips. This permit will expire on October 5th 2012. The occupational health and safety report for dimethoate has yet to be finalized and could also have implications for continued access.

The APVMA review of fenthion residue trial data is currently underway with an expected release of the preliminary findings in early 2012. It is also anticipated that the environment assessment will become available at this time.

The Issue
Given the reliance that industry currently has had on dimethoate and fenthion treatments for the management of fruit flies, an assessment was undertaken of potential research options that could be pursued should current uses of either or both of the compounds be restricted or removed.

Options were identified, firstly from the perspective of addressing short-term fruit fly control and market access needs with or without the continued availability of fenthion. Additional options were elaborated that, depending upon the outcomes of the APVMA reviews, could provide potentially medium to long-term solutions.

Scenario A: Fenthion - Approval is granted for the active ingredient to remain on the market.

Preliminary dietary intake assessments, based on residue data generated under project MT06022 and by Bayer CropSciences submitted to the APVMA, indicate that the current 3 day withholding period for summer fruit is unlikely to pass the acute dietary intake assessment.

Should approval for fenthion continue the probable regulatory action from the APVMA will be to suspend the current use. The available residue trial data suggests that an alternative use pattern, based on a longer withholding period, may be a possibility, i.e., 21 or 28 days. If such a longer withholding period is possible there will be a need to access fruit fly treatments to cover the intervening period from the last application till harvest. The industry could still retain the current use pattern for ICA21 for interstate Biosecurity, i.e., fenthion applications made 6, 4, 3, 2 and 1 week before harvest for each variety, with the last three cover sprays, i.e., 3, 2 and 1 week before harvest, replaced by either maldison or trichlorfon.

If the suspension of fenthion from summer fruit is an outcome research Option 1 would address short-term needs while Option 2, if successful, could provide a medium term solution.

Scenario B: Fenthion – Approval is not granted for the active ingredient to remain on the market.

There is a real possibility that the APVMA may decide to seek withdrawal of all fenthion uses. Should this occur there will be an urgent need for alternative options. In the event of a complete suspension of fenthion, research Option 1 could provide a short-term solution and Option 3 a potential medium solution.

Potential Research Options

Option 1: Combination of applications of Fenthion together with Maldison and Trichlorfon

The insecticides maldison and trichlorfon have been identified as potential options for use following fenthion applications, i.e., through till harvest. Fenthion would be used as the initial applications at 21 to 28 days from harvest, followed by either Maldison and /or Trichlorfon. Guidance was sought from the APVMA on the data requirements to gain regulatory approval.

Maldison:

Maldison is currently registered for use in stone fruit at 62 g ai/hL for the control of aphids with a 3 day WHP. Efficacy trial data or scientific argument that satisfies the APVMA of efficacy against fruit fly at this rate will be required.

The APVMA does not have specific data requirements for insecticide efficacy trials. However, as a rule of thumb six to eight valid trials spread over at least two seasons that cover each major production area where the pest is a problem, should be sufficient.

If a higher rate is needed then a full complement of residue trials will also be needed, in addition to any efficacy data. There may be scope to reduce the amount of residue and efficacy trial data required should a manufacturer be prepared to provide overseas trial data in support of the use.

Trichlorfon:

Trichlorfon is registered for use in stone fruit for the control of Queensland fruit fly. In the discussion with the APVMA it was indicated that the APVMA holds little or no data on trichlorfon. As trichlorfon has been nominated for review it was indicated that residue trial data would be needed to ensure ongoing access.

Fenthion:

The trial data submitted to the APVMA contained studies in which longer WHPs were investigated. On the basis of this data it appears that at longer WHPs the use of fenthion may pass the short-term dietary intake test. However, it is anticipated that additional data from residue trials would be needed to satisfy the APVMA.

Option 2: Lower rates of fenthion as a foliar treatment

As indicated above at the current use pattern, i.e., 75 mL/100 L with a 3 day withholding period, fenthion residues in summer fruit fail the acute dietary intake assessment. However, fenthion has shown high levels of efficacy at lower rates in post-harvest trials. Consequently, the possibility of exploring lower application rates to overcome the dietary intake concerns has been identified as a potential research option.

Given the uncertainty over the likelihood of success it is proposed that should research be undertaken it is staggered. Initial ‘sighter’ residue trials would need to be completed to determine whether residue levels from lower rates would pass the acute dietary intake assessment. If this proved successful then evaluate efficacy at the rate which passes the acute dietary intake assessment. Residue levels would need to be at or below 0.24 mg/kg for nectarines and 0.22 mg/kg for peaches.

Option 3: Lower rates of dimethoate as a post-harvest treatment
As indicated by the APVMA post-harvest treatment of summer fruit with dimethoate at 100 mL/100 L did not pass the acute dietary intake assessment. Previous trial work reported by Corcoran and Nobel (1996) indicates that residue levels resulting from dipping 'defuzzed' peaches were 0.82 mg/kg (no omethoate analysis undertaken). At such a level the acute dietary intake assessment would be failed but the exceedance was not great. There is no residue data at a lower rate in peaches, i.e., 50 ppm, for nectarines, or from flood sprays. Consequently, there is a possibility of exploring lower post-harvest application rates to overcome the dietary intake concerns.

Given the uncertainty over the likelihood of success it is proposed that should research be undertaken it is staggered. Initial 'sighter' residue trials would need to be completed to determine whether residue levels from lower rates would pass the acute dietary intake assessment. Total residue levels (dimethoate + omethoate) would need to be below 0.7 mg/kg for nectarines and 0.63 mg/kg for peaches. If this proved successful then the rate which passes the acute dietary intake assessment could be evaluated for efficacy.

Option 4: Spinetoram pre-harvest cover sprays
The insecticide spinetoram could provide an effective additional fruit fly management option for summer fruit. The compound is registered for use in in summer fruit with a 3 day WHP and offers an opportunity to gain access to an insecticide that does not have any potentially adverse regulatory implications. At this stage the manufacturer has indicated a preparedness to co-fund efficacy trial work. Gaining approval for the use of spinetoram for fruit fly control would also provide a useful option for inclusion in any future development of systems approaches.

Option 5: Systems approach
From the long-term perspective Summerfruit Australia will need to explore opportunities to develop and include other technologies such as Attract-and-kill, mass trapping mating disruption etc., as part of the suite of control options available to growers.

As the control of fruit flies is an issue across many horticultural industries closer collaboration between peak bodies is required. Consequently, there may be opportunities to collaborate in multi-industry research projects.

Indicative Costs

Compound	**Trial type**	**Number**	**Indicative costs**
Option 1: Fenthion + maldison & trichlorfon			
Fenthion	Residue	5 trials	$40,000
Maldison	Efficacy	8-10 trials	$48-60,000
	Residues (if required)	10 trials	$80,000
Trichlorfon	Residues	10 trials	$80,000
Option 2: Lower rate fenthion			
Fenthion	Residue	10 trials	$80,000
	Efficacy	8-10 trials	$48-60,000
Option 3: Lower rate dimethoate post-harvest			
Dimethoate	Residue	8 trials	$80,000
	Efficacy	8-10 trials	$48-60,000
Option 4: Spinetoram pre-harvest cover sprays			
Spinetoram	Efficacy	8-10 trials	$48-60,000
Option 5: Systems approach			

Threats
Results from proposed residue trials indicate an exceedance of the acute reference dose for the various

insecticides nominated.

Both trichlorfon and maldison are both nominated for review by the APVMA. As a result regulatory activity can be expected within the next 3-5 years. An outcome of which could be a restriction on their use.

Manager Chemical Review
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

chemicalreview@apvma.gov.au

Dear Sir/Madam,

Summerfruit Australia Limited (SAL) requests that the APVMA reconsider its recommendation as outlined in the Supplementary residues and dietary risk assessment of fenthion for the withdrawal of fenthion use in peaches and apricots. In particular, SAL asks that the APVMA amend PER13841 and PER13840 to allow the continued use of fenthion in peaches and apricots but restricting the use to a single application but with an extended withholding period. Outlined below is the supporting SAL rationale.

In previously provided data, namely trial site 166 from 07-HAL-005(a)GLP Volume 2, after multiple applications of fenthion residues in peaches 21 days after the final application were well below the ARfD, i.e., 0.16 mg/kg. SAL acknowledges that this result is from one trial only but believes that to give APVMA confidence fenthion residues in peaches and apricots would be compliant, i.e., below the ARfD, suggests restricting the use to a single application.

Currently, the number of available options available in peaches and apricots are limited and having access to fenthion, albeit with a longer 21 day WHP would still be of benefit to growers allowing them to apply other products closer to harvest. It would also allow growers who have purchased fenthion prior to the proposed regulatory action to utilise the stock they have available.

SAL therefore asks that the APVMA give urgent consideration to this proposal so as to provide some certainty to the peach and apricot growers, in terms of fruit fly control options, going forward into the 2013 season.

Yours sincerely,

John Moore

ATTACHMENT IV: PERMITS

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Application for a Minor Use Permit (Agriculture)

SECTION 1: THIS SECTION MUST BE COMPLETED FOR ALL PRODUCTS

1. FEE & CATEGORY DETAILS		
Proposed category number: **21** *Refer to Ag MORAG on the APVMA website for a description of Category 21 requirements*		
Fee enclosed: $ 320 ☒ YES ☐ NO ☐ FEE EXEMPT NOTE: Fee exemptions only apply to Australian, State or Territory governments for activities in support of their core business. For further details refer to: http://www.apvma.gov.au/MORAG_ag/vol_2/category_21.html		
2. APPLICANT CONTACT DETAILS		
Full name of applicant (can be a company): Name of contact person: Position/title: ACN / Overseas equivalent number:		
Street address:		
Postal address:		
Email:	Telephone:	Facsimile:
3. APPROVED PERSON DECLARATION **(this may be the Applicant/Contact person nominated above, or may be a consultant acting on behalf of the Applicant)**		
I hereby declare that the information provided with this application is complete and correct.		
Full name of approved person (can be a company): Position/title:		
Postal address:		
Name of contact person in the company:		
Email:	Telephone:	Facsimile:
Correspondence about this application should be addressed to: ☒ Applicant/registrant or ☐ Approved person Signature (MUST be in ink): _____ Date: ***False declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994.*** NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.		

PROPOSED PRODUCT & USE REGIME	
Product trade name	Samurai Systemic Insecticide
Active constituent(s) and amount (g/kg or g/L)	Containing: 500 g ai/L clothianidin as its only active constituent.
Crop or situation	Cherries, Persimmons, Pome fruit and Stone fruit
	Is the crop grown in ☒ field, ☐ undercover (protected) or ☐ both.

Target disease, pest or purpose (include common and scientific names)	Common Name	Fruit flies	
	Scientific name	*Ceratitis* and *Bactrocera* species	
Application rate, spray volume and addition of wetters (or other proposed additives/mixtures)	Application rate (eg. 100mL or 100g product / 100L and/or 1L or 1kg / ha)	Spray volume (eg. 500L/ha)	Addition of wetter (eg. plus 200mL/100L – please specify wetter)
	Foliar: 40 g/100L		MAXX Organosilicone Surfactant ™ at 50 mL/ 100L of water
Timing of application/growth stage (eg. apply at budburst, blossom bloom etc.)	Apply two consecutive sprays 7-10 days apart when monitoring indicates fruit fly activity.		
Maximum number of applications and interval between applications.	Maximum number of applications per crop, season or year (please specify)	Minimum re-treatment interval (days) between consecutive applications	
	2 applications per crop	7 days	
Application method & equipment	Application method (e.g., foliar, drench, in-furrow, aerial)	Application equipment (e.g., knapsack, air-blast sprayer, boom spray)	
	Foliar	Airblast sprayer	
Proposed withholding periods (food and/or livestock feed crops only)	Harvest - number of days or weeks between last application and harvest (or Nil)	Grazing & Cutting for Livestock (or Nil)	
	7	Do Not Graze or cut for Livestock	
Any special precautions / critical use comments (eg. target larvae < 10mm in length; thorough coverage is essential; IPM or resistance management issues etc.)	Effective control of insect pests requires an integrated approach. As the sensitivity of some species and varieties of the crops to be treated under this permit has not been fully evaluated. It is advisable, therefore, to only treat a small number of plants to ascertain their reaction before treating the whole crop.		

NOTE: please complete ALL fields. In situations where instructions are NOT APPLICABLE please include N/A, if not known please state NOT KNOWN.

5. JUSTIFICATION FOR THE PROPOSED MINOR USE

Describe the purpose of the application. Where alternative products are currently registered for the proposed use in Australia those products should be listed and reasons provided against each as to why they are either unsuitable or ineffective.

Queensland fruit fly (*Bactrocera tryoni)* is endemic to the major horticultural production regions in northern Australia while Medfly is present in Western Australia only. Both species are serious pests of a range of horticultural crops in other regions where incursions occur. Recently the numbers of control options available to the nominated industries have been significantly reduced. Historically, control has relied upon the use of the insecticides dimethoate and fenthion. However, the use of these compounds have either been removed or significantly restricted. As a consequence, due to the significance of the pests, additional control options are being sought under an APVMA permit.

Currently, insecticides approved for the control of Qld fruit fly in pome fruit, Summer fruit, cherries and persimmons is limited. In summer fruit only trichlorfon, maldison (PER12907), spinetoram (PER12590 – suppression) are approved and in pome fruit only trichlorfon and spinetoram (PER12590 – suppression) are approved. For persimmons trichlorfon (PER12450) and maldison (PER13815) are approved.

For Medfly insecticides approved for use in stone fruit include trichlorfon (PER12690), maldison (PER12907) and fenthion (PER13940) and for pome fruit fenthion (PER13480) is approved. For persimmons trichlorfon (PER12450), fenthion (PER13480) and maldison (PER13815) are approved.

Consequently, approval is sought for clothianidin (Group 4A Insecticide) to both improve crop production flexibility and to provide an additional control option with a different mode of action. The availability of clothianidin would therefore add substantially to the immediate viability of pome fruit, summer fruit, cherry and persimmon production in Australia.
As a result gaining access to clothianidin would provide a significant benefit to growers.

6. MINOR USE CLASSIFICATION

The crop or situation is a minor use via (*check one box only*): For guidance on Schedules refer to Page 2 *Background details to the Guidelines for Determining Minor Uses*

☒	Schedule 1
☐	a proposed Schedule 2
☐	a proposed Schedule 3

For proposals seeking acceptance as a minor use under either Schedules 2 or 3 please provide supporting reasons:

Pome fruit, Stone fruit and Cherries are, according to the APVMA *Guidelines for Determining Minor Uses*, major crops as they are listed as major commodities under Schedule 1
Persimmons is according to the APVMA *Guidelines for Determining Minor Uses*, a minor crop as it is not listed as a major commodity under Schedule 1.

7. PROPOSED END USERS Persons to be covered by the permit ***(check the most relevant)*:**	
☒ 'Persons generally' (includes everyone – ie. no restrictions)	
☐ A specific group or class of persons (eg licensed pest control operators, licensed aerial operators etc)	Details of end user/s (*if not 'Persons generally' as above*)**:**
☐ One or more nominated individuals	

8. PROPOSED DURATION OF USE, STATES OR REGIONS & AREA/TONNAGE TO BE TREATED									
Proposed duration of use:	First date of proposed use	Upon granting of the permit.							
	Annual timing of use (ie. from Sep – Mar or ongoing throughout year)	The production time for all crops is spring/summer. As a result it is likely that the product could be required from October to March depending upon the crop being harvested.							
	Proposed permit duration (ie. 1, 2, 5, 10 yrs or ongoing)	5 years							
Proposed use is to occur in:	All States ☒	QLD ☐	NSW ☐	SA ☐	TAS ☐	WA ☐	NT ☐	VIC ☐	ACT ☐
	OR								
	The use will be undertaken in a specific location/region only (please specify):								
Extent/area of proposed use per annum:	Specify the estimated area in hectares or tonnage of produce to be treated per annum:								

SECTION 2: THIS SECTION MUST BE COMPLETED ONLY FOR PRODUCTS THAT ARE CURRENTLY REGISTERED IN AUSTRALIA

In considering the application please complete the following questions and sections. Labels of most registered products may be obtained from the APVMA website at: *www.apvma.gov.au*

Rate and method of application

Is the rate and method of application similar to existing rates approved in other commodities/situations already registered for the product?

☒ Yes

If yes, please explain in the area provided below including appropriate examples from the approved label for the product

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to operators/users and the environment. This may include the provision of supporting data and/or risk mitigation strategies.

The rate and method of application are comparable to that currently approved for the use of clothianidin for the control of aphids, mealy bugs, codling moth and oriental fruit moth in pome fruit, peaches and nectarines in Australia.

Target Crop/Situation

Is the product currently registered for the proposed crop/situation OR has the crop been subject to phytotoxicity testing under the proposed use regime?

☒ Yes

If yes, please outline in the area provided below brief details including any supporting data and attach that data with your application.

☒ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to the crop. This may include a discussion on extrapolation of crop tolerance based upon existing registrations in botanically related commodities, or where the use pattern or chemistry is such that adverse effects are unlikely.

The product is registered in pome fruit, peaches and nectarines. As a consequence adverse effects are not anticipated as crop safety has previously been established.

Adverse crop effects are considered unlikely in persimmons, cherries, apricots and plums as clothianidin is approved for use in a range of crops at similar rates and application in other jurisdictions such as the USA, Japan and Korea suggesting there are no unacceptable risks to these crops in Australia.

Target Pest/Disease

Is the product proposed for this use currently registered against the target pest/disease in another crop/situation for which efficacy is being based, including situations where bridging or limited bioequivalence data is being presented?

☐ Yes

If yes, please explain in the area provided below how the existing registration in other commodities is relevant (ie. can be extrapolated) to the proposed use in demonstrating that equivalent efficacy will be achieved, including reference to any bridging or bioequivalence data which is being presented.

☒ No

If no, please provide supporting data or a valid scientific argument in the area provided below which demonstrates that the proposed use will be efficacious. Scientific arguments will be considered on their merits. Examples can include scientific arguments (ie. extrapolation) based upon the chemicals known activity (ie. Mode of Action) and registration status against similar pests/diseases. Additionally relevant data from trials or published literature may be provided.

Specific efficacy data to the use pattern supporting the control of the nominated pests is presented. In addition, the APVMA is asked to take into consideration existing approved use patterns in other crops as providing sufficient evidence to support extrapolation, without the need for additional local crop/insect specific data.

Crop Residues (food-crops only) - MRLs

Is a current Maximum Residue Limit (MRL) established, or has exemption from requiring an MRL been given for the chemical on this commodity?. Note: MRLs can be obtained from the MRL Standard available on the APVMA website at:
http://www.apvma.gov.au/residues/mrl_standard.shtml

☒ Yes

If yes, in the area below please provide details on that MRL or exemption.

☒ No

If no, in order to enable an MRL to be established please indicate if you are providing either (and detail this in the area below):

☐ supporting residue data, or

☐ a valid scientific argument which demonstrates that the proposed use will not result in detectable residues, or

☒ a valid scientific argument based upon extrapolation from registered uses in a similar commodity and its MRL.

Australian MRLs exist for apple and peas @ 0.5 mg/kg and for peaches and nectarines at 2 mg/kg

The 2010 JMPR reported residues resulting from multiple applications of clothianidin to cherries, apricots, plums and persimmons. On the basis of this data it is believed that the proposed uses plums, cherries and apricots would comply with the MRL of 2 mg/kg and that for persimmons would comply with a MRL of 0.5 mg/kg. See the attached Justification for details.

Crop Residues – livestock feeding

Is the raw commodity, or waste or by-products from processing, fed to livestock or sold for use as livestock feed?

OR is the commodity subject, or likely to be subject, to a Commodity Vendor Declaration (CVD) or By-Product Vendor Declaration (BVD)?

☒ Yes ☐ No

If yes, please provide details against each area listed below.

The portion of the commodity that is fed to livestock	Apple Pomace
Species of livestock consuming treated produce	Cattle
Amounts which may be fed and proportion of diet	100%
Details of the CVD or BVD applicable to the commodity	Not applicable as potential livestock exposure would have already been assessed when clothianidin was first approved in pome fruit

Trade (food-crops only)

Is the commodity subject to export trade?

☐ Yes ☒ No

If yes, please provide details against each area listed below.

Quantity of produce exported (incl. $ value)	See the attached
Countries of destination	See attached
Proposed mechanisms for ensuring the treated commodity will meet importing country MRL requirements	For persimmons, apricots and plums potential impacts on trade are considered to be minimal as exports are low Where exports do occur the respective industries .propose seek to inform export oriented growers in production zones dealing with fruit fly infestations of the MRL disparities allowing growers to adopt suitable MRL compliance strategies

Please indicate if any supporting data is attached/provided for;

☒ Residues and trade considerations (food and feed producing crops only)

☒ Occupational Health and Safety

☒ Environmental Safety

☒ Efficacy and Crop/Host Safety

☒ Other data or information

Please return the fully completed application form with Sections 1 & 2 only to:

The Screening Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Application for a Minor Use Permit (Agriculture)

SECTION 1: THIS SECTION MUST BE COMPLETED FOR ALL PRODUCTS

1. FEE & CATEGORY DETAILS		
Proposed category number: **21** *Refer to Ag MORAG on the APVMA website for a description of Category 21 requirements*		
Fee enclosed: $ 350 ☒ YES ☐ NO ☐ FEE EXEMPT NOTE: Fee exemptions only apply to Australian, State or Territory governments for activities in support of their core business. For further details refer to: http://www.apvma.gov.au		
2. APPLICANT CONTACT DETAILS		
Full name of applicant (can be a company): Name of contact person: Position/title: ACN / Overseas equivalent number:	Queensland Fruit and Vegetable Growers Ltd T/a Growcom Janine Clark, Pest Management Officer 090816827	
Street address:	68 Anderson Street Fortitude Valley Qld 4006	
Postal address:	PO Box 202, Fortitude Valley Qld 4006	
Email: jclark@growcom.com.au	Telephone: 07 3620 3878	Facsimile: 07 3620 3880
3. APPROVED PERSON DECLARATION (this may be the Applicant/Contact person nominated above, or may be a consultant acting on behalf of the Applicant)		
Full name of approved person (can be a company): Position/title:	Janine Clark Pest Management Officer	
Postal address:	PO Box 202, Fortitude Valley Qld 4006	
Name of contact person in the company:		
Email: jclark@growcom.com.au	Telephone: 07 3620 3878	Facsimile: 07 3620 3880
Correspondence about this application is to be addressed to: ☒ Applicant/registrant or ☐ Approved person		

Giving false or misleading information is a serious offence. A false or misleading declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994 or the Criminal Code Act 1995.

I declare that:

I am an Australian resident over 18 years of age;

the applicant/registrant is a body incorporated in Australia, or an Australian resident over 18 years of age;

the approved person (if applicable) is a body incorporated in Australia, or an Australian resident over 18 years of age;

the information provided with this application, including formulation information and the content provided on all pages of this application form, is true and correct; and

I understand there are penalties for deliberately providing false or misleading information.

Signature (MUST be in ink): _____ Date: _____

NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.

PROPOSED PRODUCT & USE REGIME	
Product trade name	Various
Active constituent(s) and amount (g/kg or g/L)	Containing: 100 g ai/L alpha-cypermethrin as its only active constituent.

Crop or situation	Stone fruit		
	Is the crop grown in ☒ field, ☐ undercover (protected) or ☐ both.		
Target disease, pest or purpose (include common and scientific names)	Common Name	Queensland fruit fly and Mediterranean fruit fly	
	Scientific name	*Ceratitis* and *Bactrocera* species	
Application rate, spray volume and addition of wetters (or other proposed additives/mixtures)	Application rate (eg. 100mL or 100g product / 100L and/or 1L or 1kg / ha)	Spray volume (eg. 500L/ha)	Addition of wetter (eg. plus 200mL/100L – please specify wetter)
	Foliar 50-100 mL/hL	1000 L/ha Ensure thorough coverage	Not required
Timing of application/growth stage (eg. apply at budburst, blossom bloom etc.)	Apply when monitoring indicates fruit fly activity.		
Maximum number of applications and interval between applications.	Maximum number of applications per crop, season or year (please specify)	Minimum re-treatment interval (days) between consecutive applications	
	6 applications per crop	7 days	
Application method & equipment	Application method (eg. foliar, drench, in-furrow, aerial)	Application equipment (eg. knapsack, air-blast sprayer, boomspray)	
	Foliar	Air blast sprayer	
Proposed withholding periods (food and/or livestock feed crops only)	Harvest - number of days or weeks between last application and harvest (or Nil)	Grazing & Cutting for Livestock (or Nil)	
	14 Days	Do Not Graze any plants that were in the sprayed area at the time of application	
Any special precautions / critical use comments (eg. target larvae < 10mm in length; thorough coverage is essential; IPM or resistance management issues etc.)	Effective control of insect pests requires an integrated approach.		

NOTE: please complete ALL fields. In situations where instructions are NOT APPLICABLE please include N/A, if not known please state NOT KNOWN.

5. JUSTIFICATION FOR THE PROPOSED MINOR USE

Describe the purpose of the application. Where alternative products are currently registered for the proposed use in Australia those products should be listed and reasons provided against each as to why they are either unsuitable or ineffective.

Queensland fruit fly (*Bactrocera tryoni)* is endemic to the major horticultural production regions in northern Australia while Medfly is present in Western Australia only. Both species are serious pests of a range of horticultural crops in other regions where incursions occur. Recently the numbers of control options available to the nominated industries have been significantly reduced. Historically, control has relied upon the use of the insecticides dimethoate and fenthion. However, the use of these compounds have either been removed or significantly restricted. As a consequence, due to the significance of the pests, additional control options are being sought under an APVMA permit.

Currently, insecticides approved for the control of Qld fruit fly in Summer fruit is limited. In summer fruit trichlorfon, maldison (PER12907), spinetoram (PER12590 – suppression) and clothianidin (PER14252) are approved. For Medfly insecticides approved for use in stone fruit include trichlorfon (PER12690), maldison (PER12907) and clothianidin (PER14252) and thiacloprid (PER14562) are approved. The use of clothianidin and thiacloprid are limited by restrictions on the number of applications that can be applied.

Consequently, approval is sought for alpha-cypermethrin (Group 3A Insecticide) to both improve crop production flexibility and to provide an additional control option due to the limitation on numbers of applications associated with the above approved compounds. The availability of alpha-cypermethrin would therefore add substantially to the immediate viability of stonefruit production in fruit fly affected areas of Australia.
As a result gaining access to thiacloprid would provide a significant benefit to growers.

6. MINOR USE CLASSIFICATION

The crop or situation is a minor use via (*check one box only*): For guidance on Schedules refer to Page 2 *Background details to the Guidelines for Determining Minor Uses*

☐	Schedule 1
☒	a proposed Schedule 2
☐	a proposed Schedule 3

For proposals seeking acceptance as a minor use under either Schedules 2 or 3 please provide supporting reasons:

Stone fruits are, according to the APVMA Guidelines for Determining Minor Uses, a major crop as they are listed as major commodities under Schedule 1. However, as the proposed use is limited to WA for Med fly, and those areas where Qld fruit fly were endemic it is believed the proposed use would comply with Schedule 2 of the Guideline, i.e., a minor use in a major crop.

7. PROPOSED END USERS Persons to be covered by the permit ***(check the most relevant)*:**	
☒ 'Persons generally' (includes everyone – ie. no restrictions)	
☐ A specific group or class of persons (eg licensed pest control operators, licensed aerial operators etc)	Details of end user/s (*if not 'Persons generally' as above*)**:**
☐ One or more nominated individuals	

8. PROPOSED DURATION OF USE, STATES OR REGIONS & AREA/TONNAGE TO BE TREATED									
Proposed duration of use:	First date of proposed use	Upon granting of the permit.							
	Annual timing of use (ie. from Sep – Mar or ongoing throughout year)	The production time for all crops is spring/summer. As a result it is likely that the product could be required from October to March depending upon the crop being harvested.							
	Proposed permit duration (ie. 1, 2, 5, 10 yrs or ongoing)	5 years							
Proposed use is to occur in:	All States ☒	QLD ☐	NSW ☐	SA ☐	TAS ☐	WA ☐	NT ☐	VIC ☐	ACT ☐
	OR								
	The use will be undertaken in a specific location/region only (please specify):								
Extent/area of proposed use per annum:	Specify the estimated area in hectares or tonnage of produce to be treated per annum: < 1000 ha								

SECTION 2: THIS SECTION MUST BE COMPLETED ONLY FOR PRODUCTS THAT ARE CURRENTLY REGISTERED IN AUSTRALIA

In considering the application please complete the following questions and sections. Labels of most registered products may be obtained from the APVMA website at: *www.apvma.gov.au*

Rate and method of application

Is the rate and method of application similar to existing rates approved in other commodities/situations already registered for the product?

☒ Yes

If yes, please explain in the area provided below including appropriate examples from the approved label for the product

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to operators/users and the environment. This may include the provision of supporting data and/or risk mitigation strategies.

The rate and method of application is comparable to that currently approved for the use of cypermethrin for the control of fruit flies in stone fruit in the USA. The higher proposed rate was identified as efficacious against Qld fruit fly in research trials undertaken by the NSW DPI.

Efficacy & Crop Safety

Are you aware of any local efficacy or crop safety trials/studies conducted: ☒ Yes ☐ No

If Yes, please provide the following answers.

The person/organisation who conducted the study Dr O Reynolds NSW DPI

Is a report of the study available. : ☒ Yes ☐ No

See the attached

Overseas Registration

Are you aware if this use pattern is registered overseas: ☒ Yes ☐ No

If yes, please name country(ies) and provide a copy of label, if available.

Have you spoken with the local manufacturer/registrant for support of this use and do they have any supporting data.

☐ Yes ☒ No

If yes, please provide their response. The company is supportive and have provided a summary of their efficacy data.

Target Crop/Situation

Is the product currently registered for the proposed crop/situation OR has the crop been subject to phototoxicity testing under the proposed use regime?

☒ Yes

If yes, please outline in the area provided below brief details including any supporting data and attach that data with your application.

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to the crop. This may include a discussion on extrapolation of crop tolerance based upon existing registrations in botanically related commodities, or where the use pattern or chemistry is such that adverse effects are unlikely.

The product is registered in stone fruit as a trunk spray for the control of Apple weevil and Garden weevil. As a consequence adverse effects are not anticipated as crop safety has previously been established.

Target Pest/Disease

Is the product proposed for this use currently registered against the target pest/disease in another crop/situation for which efficacy is being based, including situations where bridging or limited bioequivalence data is being presented?

☐ Yes

If yes, please explain in the area provided below how the existing registration in other commodities is relevant (ie. can be extrapolated) to the proposed use in demonstrating that equivalent efficacy will be achieved, including reference to any bridging or bioequivalence data which is being presented.

☒ No

If no, please provide supporting data or a valid scientific argument in the area provided below which demonstrates that the proposed use will be efficacious. Scientific arguments will be considered on their merits. Examples can include scientific arguments (ie. extrapolation) based upon the chemicals known activity (ie. Mode of Action) and registration status against similar pests/diseases. Additionally relevant data from trials or published literature may be provided.

Specific efficacy data to the use pattern supporting the control of the nominated pests is presented. In addition, the APVMA is asked to take into consideration existing approved use patterns in other jurisdictions against related Tephritid species as providing sufficient evidence to support extrapolation, without the need for additional local crop/insect specific data (see attached US label).

Crop Residues (food-crops only) - MRLs

Is a current Maximum Residue Limit (MRL) established, or has exemption from requiring an MRL been given for the chemical on this commodity?. Note: MRLs can be obtained from the MRL Standard available on the APVMA website at: http://www.apvma.gov.au

☒ Yes

If yes, in the area below please provide details on that MRL or exemption.

☐ No

If no, in order to enable an MRL to be established please indicate if you are providing either (and detail this in the area below):

☐ supporting residue data, or

☐ a valid scientific argument which demonstrates that the proposed use will not result in detectable residues, or

☐ a valid scientific argument based upon extrapolation from registered uses in a similar commodity and its MRL.

The highest residue found in Summerfruit residue trials reported by the 2008 JMPR was 0.27 mg/kg following six applications of alpha-cypermethrin at a rate of 56 g ai/ha (5.6 g ai/hL) with a 14 day PHI. Allowing for the higher rate requested residues from the proposed use pattern would not be expected to exceed the current Australian MRL of 1 mg/kg for Stone fruit (except cherries). As a result the industry believes the trade risk from the proposed use would be low.

MRLs internationally are as follows:

	Codex	Europe	China	Japan	Korea	Taiwan	USA
Stone fruit	2	2	-	-	-	2	1
Apricot	-	-	-	1	2	-	-
Nectarine	-	-	-	2	2	-	-
Peach	-	-	1	2	2	-	-
Plum	-	-	-	0.5	1	-	-

Crop Residues – livestock feeding

Is the raw commodity, or waste or by-products from processing, fed to livestock or sold for use as livestock feed? OR is the commodity subject, or likely to be subject, to a Commodity Vendor Declaration (CVD) or By-Product Vendor Declaration (BVD)?

☐ Yes ☒ No

If yes, please provide details against each area listed below.

The portion of the commodity that is fed to livestock	NA
Species of livestock consuming treated produce	NA
Amounts which may be fed and proportion of diet	NA
Details of the CVD or BVD applicable to the commodity	NA

Trade (food-crops only)

Is the commodity subject to export trade?

☒ Yes ☐ No

If yes, please provide details against each area listed below.

Quantity of produce exported (incl. $ value)			
	Production (tonnes)	Exports (tonnes)	Percentage
Apricots	13,284	281	2.1
Nectarines & peaches	97,233	5,123	5.3
Plums	15,907	2,477	1.6
Countries of destination	Hong Kong, UAE, Singapore, Taiwan and Malaysia		
Proposed mechanisms for ensuring the treated commodity will meet importing country MRL requirements	SAL believes that the potential risks to trade posed by the proposed use are low due to existing MRLs internationally. In addition, exports of apricots and plums are extremely small at only 2.1% and 1.6% of national production. Further as more than a third of the exports originate from Tasmania and South Australia, i.e., fruit fly free regions, use under the proposed permit would be on only a portion of fruit destined for export and would be unlikely to have a major impact on trade. For peaches and nectarines and other stone fruit grown in fruit fly endemic areas SAL believes that any risk can be managed through the provision of information to growers, i.e., that MRL compliance in certain export markets for fruit treated with alpha-cypermethrin could be problematic.		

Please indicate if any supporting data is attached/provided for;

☒ Residues and trade considerations (food and feed producing crops only)

☒ Occupational Health and Safety

☒ Environmental Safety

☒ Efficacy and Crop/Host Safety

☒ Other data or information

Please return the fully completed application form with Sections 1 & 2 only to:

The Screening Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Application for a Minor Use Permit (Agriculture)

SECTION 1: THIS SECTION MUST BE COMPLETED FOR ALL PRODUCTS

1. FEE & CATEGORY DETAILS

Proposed category number: **21**

Refer to Ag MORAG on the APVMA website for a description of Category 21 requirements

Fee enclosed: $ 350 ☒ YES ☐ NO ☐ FEE EXEMPT

NOTE: Fee exemptions only apply to Australian, State or Territory governments for activities in support of their core business. For further details refer to: http://www.apvma.gov.au

2. APPLICANT CONTACT DETAILS

Full name of applicant (can be a company):	Queensland Fruit and Vegetable Growers Ltd T/a Growcom
Name of contact person:	Janine Clark,
Position/title:	Pest Management Officer
ACN / Overseas equivalent number:	090816827
Street address:	68 Anderson Street Fortitude Valley Qld 4006
Postal address:	PO Box 202, Fortitude Valley Qld 4006

Email: jclark@growcom.com.au	Telephone: 07 3620 3878	Facsimile: 07 3620 3880

3. APPROVED PERSON DECLARATION

(this may be the Applicant/Contact person nominated above, or may be a consultant acting on behalf of the Applicant)

Full name of approved person (can be a company):	Janine Clark
Position/title:	Pest Management Officer
Postal address:	PO Box 202, Fortitude Valley Qld 4006
Name of contact person in the company:	

Email: jclark@growcom.com.au	Telephone: 07 3620 3878	Facsimile: 07 3620 3880

Correspondence about this application is to be addressed to: ☒ Applicant/registrant or ☐ Approved person

Giving false or misleading information is a serious offence. A false or misleading declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994 or the Criminal Code Act 1995.

I declare that:

I am an Australian resident over 18 years of age;

the applicant/registrant is a body incorporated in Australia, or an Australian resident over 18 years of age;

the approved person (if applicable) is a body incorporated in Australia, or an Australian resident over 18 years of age;

the information provided with this application, including formulation information and the content provided on all pages of this application form, is true and correct; and

I understand there are penalties for deliberately providing false or misleading information.

Signature (MUST be in ink): _____

Date: _____

NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.

PROPOSED PRODUCT & USE REGIME			
Product trade name	Calypso Insecticide		
Active constituent(s) and amount (g/kg or g/L)	Containing: 480 g ai/L thiacloprid as its only active constituent.		
Crop or situation	Pome fruit and Stone fruit		
	Is the crop grown in ☒ field, ☐ undercover (protected) or ☐ both.		
Target disease, pest or purpose (include common and scientific names)	Common Name	Mediterranean Fruit fly (Medfly)	
	Scientific name	*Ceratitis capitata*	
Application rate, spray volume and addition of wetters (or other proposed additives/mixtures)	Application rate (eg. 100mL or 100g product / 100L and/or 1L or 1kg / ha)	Spray volume (eg. 500L/ha)	Addition of wetter (eg. plus 200mL/100L – please specify wetter)
	Foliar 37.5 mL/hL	Ensure thorough coverage	Add a Non-ionic wetting agent at 10 mL/ 100L of water
Timing of application/growth stage (eg. apply at budburst, blossom bloom etc.)	Apply when monitoring indicates fruit fly activity.		
Maximum number of applications and interval between applications.	Maximum number of applications per crop, season or year (please specify)	Minimum re-treatment interval (days) between consecutive applications	
	3 applications per crop	14 days	
Application method & equipment	Application method (eg. foliar, drench, in-furrow, aerial)	Application equipment (eg. knapsack, air-blast sprayer, boomspray)	
	Foliar	Air blast sprayer	
Proposed withholding periods (food and/or livestock feed crops only)	Harvest - number of days or weeks between last application and harvest (or Nil)	Grazing & Cutting for Livestock (or Nil)	
	Stonefruit (excluding peaches): 14 Days Pome fruit and peaches : 21 days	Do Not Graze any plants that were in the sprayed area at the time of application	
Any special precautions / critical use comments (eg. target larvae < 10mm in length; thorough coverage is essential; IPM or resistance management issues etc.)	Effective control of insect pests requires an integrated approach.		

NOTE: please complete ALL fields. In situations where instructions are NOT APPLICABLE please include N/A, if not known please state NOT KNOWN.

5. JUSTIFICATION FOR THE PROPOSED MINOR USE

Describe the purpose of the application. Where alternative products are currently registered for the proposed use in Australia those products should be listed and reasons provided against each as to why they are either unsuitable or ineffective.

Mediterranean fruit fly (*Ceratitis capitata)*) is present in the major horticultural production regions in Western Australia. It is a serious pest of a range of horticultural crops. Recently the numbers of control options available to the nominated industries have been significantly reduced. Historically, control has relied upon the use of the insecticide fenthion. However, the use of this compound has been significantly restricted. As a consequence, due to the significance of the pests, additional control options are being sought under an APVMA permit.

Currently, insecticides approved for the control of Medfly in Stonefruit in WA is limited to trichlorfon (PER12690), maldison (PER12907, fenthion (PER14501 and PER13840) and clothianidin (PER14252). For pome fruit it is limited to fenthion (PER13840) and clothianidin (PER14252).

Consequently, approval is sought for thiacloprid (Group 4A Insecticide) to both improve crop production flexibility and to provide an additional control option due to the limitation on numbers of applications associated with PER14501, PER13840 and PER14252. The availability of thiacloprid would therefore add substantially to the immediate viability of pome fruit and stonefruit production in West Australia. As a result gaining access to thiacloprid would provide a significant benefit to growers.

6. MINOR USE CLASSIFICATION

The crop or situation is a minor use via (*check one box only*): For guidance on Schedules refer to Page 2 *Background details to the Guidelines for Determining Minor Uses*

☐	Schedule 1
☒	a proposed Schedule 2
☐	a proposed Schedule 3

For proposals seeking acceptance as a minor use under either Schedules 2 or 3 please provide supporting reasons:

Pome fruit and Stone fruits are, according to the APVMA Guidelines for Determining Minor Uses, major crops as they are listed as major commodities under Schedule 1. However, as the proposed use is limited to WA only it is believed the proposed use would comply with Schedule 2 of the Guideline, i.e., a minor use in a major crop. Stonefruit production in WA constitutes approximately 5% of national production and Pome fruit approximately 10%. **(ABS - 7121.0 - Agricultural Commodities, Australia, 2010-11)**

7. PROPOSED END USERS Persons to be covered by the permit ***(check the most relevant)*:**	
☒ 'Persons generally' (includes everyone – ie. no restrictions)	
☐ A specific group or class of persons (eg licensed pest control operators, licensed aerial operators etc)	Details of end user/s (*if not 'Persons generally' as above*)**:**
☐ One or more nominated individuals	

8. PROPOSED DURATION OF USE, STATES OR REGIONS & AREA/TONNAGE TO BE TREATED									
Proposed duration of use:	First date of proposed use	Upon granting of the permit.							
	Annual timing of use (ie. from Sep – Mar or ongoing throughout year)	The production time for all crops is spring/summer. As a result it is likely that the product could be required from October to March depending upon the crop being harvested.							
	Proposed permit duration (ie. 1, 2, 5, 10 yrs or ongoing)	5 years							
Proposed use is to occur in:	All States ☐	QLD ☐	NSW ☐	SA ☐	TAS ☐	WA ☒	NT ☐	VIC ☐	ACT ☐
	OR								
	The use will be undertaken in a specific location/region only (please specify):								
Extent/area of proposed use per annum:	Specify the estimated area in hectares or tonnage of produce to be treated per annum: ~2000 ha								

SECTION 2: THIS SECTION MUST BE COMPLETED ONLY FOR PRODUCTS THAT ARE CURRENTLY REGISTERED IN AUSTRALIA

In considering the application please complete the following questions and sections. Labels of most registered products may be obtained from the APVMA website at: *www.apvma.gov.au*

Rate and method of application

Is the rate and method of application similar to existing rates approved in other commodities/situations already registered for the product?

☐ Yes

If yes, please explain in the area provided below including appropriate examples from the approved label for the product

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to operators/users and the environment. This may include the provision of supporting data and/or risk mitigation strategies.

The rate and method of application is comparable to that currently approved for the use of thiacloprid for the control of oriental fruit moth in stone fruit and oriental fruit moth and codling moth in pome fruit in Australia.

Efficacy & Crop Safety

Are you aware of any local efficacy or crop safety trials/studies conducted: ☒ Yes ☐ No

If Yes, please provide the following answers.

The person/organisation who conducted the study Bayer Cropsciences

Is a report of the study available. : ☒ Yes ☐ No

See the attached

Overseas Registration

Are you aware if this use pattern is registered overseas: ☐ Yes ☒ No

If yes, please name country(ies) and provide a copy of label, if available.

Have you spoken with the local manufacturer/registrant for support of this use and do they have any supporting data. ☒ Yes ☐ No

If yes, please provide their response. The company is supportive and have provided a summary of their efficacy data.

Target Crop/Situation

Is the product currently registered for the proposed crop/situation OR has the crop been subject to phototoxicity testing under the proposed use regime?

☒ Yes

If yes, please outline in the area provided below brief details including any supporting data and attach that data with your application.

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to the crop. This may include a discussion on extrapolation of crop tolerance based upon existing registrations in botanically related commodities, or where the use pattern or chemistry is such that adverse effects are unlikely.

The product is registered in pome and stone fruit. As a consequence adverse effects are not anticipated as crop safety has previously been established.

Target Pest/Disease

Is the product proposed for this use currently registered against the target pest/disease in another crop/situation for which efficacy is being based, including situations where bridging or limited bioequivalence data is being presented?

☐ Yes

If yes, please explain in the area provided below how the existing registration in other commodities is relevant (ie. can be extrapolated) to the proposed use in demonstrating that equivalent efficacy will be achieved, including reference to any bridging or bioequivalence data which is being presented.

☐ No

If no, please provide supporting data or a valid scientific argument in the area provided below which demonstrates that the proposed use will be efficacious. Scientific arguments will be considered on their merits. Examples can include scientific arguments (ie. extrapolation) based upon the chemicals known activity (ie. Mode of Action) and registration status against similar pests/diseases. Additionally relevant data from trials or published literature may be provided.

Specific efficacy data to the use pattern supporting the control of the nominated pests is presented. In addition, the APVMA is asked to take into consideration existing approved use patterns in other crops against related species as providing sufficient evidence to support extrapolation, without the need for additional local crop/insect specific data (see attached US label).

Crop Residues (food-crops only) - MRLs

Is a current Maximum Residue Limit (MRL) established, or has exemption from requiring an MRL been given for the chemical on this commodity?. Note: MRLs can be obtained from the MRL Standard available on the APVMA website at: http://www.apvma.gov.au

☒ Yes

If yes, in the area below please provide details on that MRL or exemption.

☐ No

If no, in order to enable an MRL to be established please indicate if you are providing either (and detail this in the area below):

☐ supporting residue data, or

☐ a valid scientific argument which demonstrates that the proposed use will not result in detectable residues, or

☐ a valid scientific argument based upon extrapolation from registered uses in a similar commodity and its MRL.

Australian MRL exists for Stone fruit @ 2 mg/kg and for Pome fruit @ 1 mg/kg

Crop Residues – livestock feeding Is the raw commodity, or waste or by-products from processing, fed to livestock or sold for use as livestock feed? OR is the commodity subject, or likely to be subject, to a Commodity Vendor Declaration (CVD) or By-Product Vendor Declaration (BVD)? ☐ Yes ☒ No If yes, please provide details against each area listed below.	
The portion of the commodity that is fed to livestock	Apple pomace
Species of livestock consuming treated produce	cattle
Amounts which may be fed and proportion of diet	10%
Details of the CVD or BVD applicable to the commodity	NA

Trade (food-crops only) Is the commodity subject to export trade? ☒ Yes ☐ No If yes, please provide details against each area listed below.	
Quantity of produce exported (incl. $ value)	Stone fruit 479 tonnes - $1.75 mio Pome fruit 46 tonnes
Countries of destination	Hong Kong, UAE, Singapore
Proposed mechanisms for ensuring the treated commodity will meet importing country MRL requirements	For WA potential impacts on trade are considered to be minimal as exports are low, i.e., total WA exports comprise less than 5% of the national total. Where exports do occur the respective industries propose informing export oriented growers, dealing with Medfly infestations, of the MRL disparities allowing growers to adopt suitable MRL compliance strategies

Please indicate if any supporting data is attached/provided for;
☒ Residues and trade considerations (food and feed producing crops only)
☒ Occupational Health and Safety
☒ Environmental Safety
☒ Efficacy and Crop/Host Safety
☒ Other data or information

Please return the fully completed application form with Sections 1 & 2 only to:
The Screening Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Australian Government
Australian Pesticides and Veterinary Medicines Authority

Application for a Minor Use Permit (Agriculture)

SECTION 1: THIS SECTION MUST BE COMPLETED FOR ALL PRODUCTS

1. FEE & CATEGORY DETAILS		
Proposed category number: **21** *Refer to Ag MORAG on the APVMA website for a description of Category 21 requirements*		
Fee enclosed: $ ☐ YES ☐ NO ☐ FEE EXEMPT NOTE: Fee exemptions only apply to Australian, State or Territory governments for activities in support of their core business. For further details refer to: http://www.apvma.gov.au		
2. APPLICANT CONTACT DETAILS		
Full name of applicant (can be a company): Name of contact person: Position/title: ACN / Overseas equivalent number:		
Street address:		
Postal address:		
Email:	Telephone:	Facsimile:
3. APPROVED PERSON DECLARATION **(this may be the Applicant/Contact person nominated above, or may be a consultant acting on behalf of the Applicant)**		
Note: Only an Australian resident or a body incorporated in Australia can be appointed an approved person for this application.		
Full name of approved person (can be a company): Position/title:	Peter Dal Santo Project Scientist	
Postal address:	21 Rosella Avenue Strathfieldsaye VIC 3551	
Name of contact person in the company:	Peter Dal Santo	
Email: pds@agaware.com.au	Telephone: 03 5439 5916	Facsimile: 03 5439 3391
Correspondence about this application is to be addressed to: ☒ Applicant/registrant or ☐ Approved person		
I declare that the information provided with this application is complete and correct. Signature (MUST be in ink): _____ Date: ***False declaration may lead to prosecution under the Agricultural and Veterinary Chemicals Code Act 1994.***NOTE: When an applicant elects to appoint a different approved person, a letter of authority is required. Refer to MORAG Volume 1 'Procedures for making an application' for additional information on approved persons.		

PROPOSED PRODUCT & USE REGIME	
Product trade name	Various

<table>
<tr><td>Active constituent(s) and amount (g/kg or g/L)</td><td colspan="3">Containing maldison as its only active ingredient (440 g/L, 500 g/L, 1000 g/L and 1150 g/L)</td></tr>
<tr><td>Crop or situation</td><td colspan="3">Capsicums and cucurbits</td></tr>
<tr><td></td><td colspan="3">Is the crop grown in ☐ field, ☐ undercover (protected) or ☒ both.</td></tr>
<tr><td rowspan="2">Target disease, pest or purpose (include common and scientific names)</td><td>Common Name</td><td colspan="2">Cucumber fly, Queensland fruit fly and Mediterranean fruit fly</td></tr>
<tr><td>Scientific name</td><td colspan="2">Bactrocera cucumis, B. tryoni & Ceratitis capitata</td></tr>
<tr><td rowspan="2">Application rate, spray volume and addition of wetters (or other proposed additives/mixtures)</td><td>Application rate (eg. 100mL or 100g product / 100L and/or 1L or 1kg / ha)</td><td>Spray volume (eg. 500L/ha)</td><td>Addition of wetter (eg. plus 200mL/100L – please specify wetter)</td></tr>
<tr><td>130 g ai/hL
(295 mL/hL - 440 g/L
260 mL/hL – 500 g/L
130 mL/hL – 1000 g/L
115 mL/hL – 1150 g/L)</td><td></td><td></td></tr>
<tr><td>Timing of application/growth stage (eg. apply at budburst, blossom bloom etc.)</td><td colspan="3">Apply at first sign of pest as determined by regular orchard scouting and fruit fly trapping.</td></tr>
<tr><td rowspan="2">Maximum number of applications and interval between applications.</td><td>Maximum number of applications per crop, season or year (please specify)</td><td colspan="2">Minimum re-treatment interval (days) between consecutive applications</td></tr>
<tr><td>Four</td><td colspan="2">Allow a minimum of 7 days between applications.</td></tr>
<tr><td rowspan="2">Application method & equipment</td><td>Application method (eg. foliar, drench, in-furrow, aerial)</td><td colspan="2">Application equipment (eg. knapsack, air-blast sprayer, boomspray)</td></tr>
<tr><td>foliar</td><td colspan="2">Boom or air blast sprayer</td></tr>
<tr><td rowspan="2">Proposed withholding periods
(food and/or livestock feed crops only)</td><td>Harvest - number of days or weeks between last application and harvest
(or Nil)</td><td colspan="2">Grazing & Cutting for Livestock
(or Nil)</td></tr>
<tr><td>3 Days</td><td colspan="2">NA</td></tr>
<tr><td>Any special precautions / critical use comments (eg. target larvae < 10mm in length; thorough coverage is essential; IPM or resistance management issues etc.)</td><td colspan="3">Do not spray on any plants in flower while bees are foraging.
Ensure adequate coverage.</td></tr>
</table>

NOTE: please complete ALL fields. In situations where instructions are NOT APPLICABLE please include N/A, if not known please state NOT KNOWN.

5. JUSTIFICATION FOR THE PROPOSED MINOR USE

Describe the purpose of the application. Where alternative products are currently registered for the proposed use in Australia those products should be listed and reasons provided against each as to why they are either unsuitable or ineffective.

Dimethoate, fenthion and trichlorfon foliar sprays are registered for control of fruit flies in vegetable crops. With dimethoate and fenthion current industry standards due to the level of control provided. However, as these two pesticides are under APVMA review concerns exist that the approval for pre-harvest control of fruit flies may be amended or suspended. It is anticipated that the impact on the industry could be significant should such regulatory action be taken as this would leave only one pesticide, trichlorfon, available for use. Trichlorfon which is non-systemic, while effective against fruit flies, only has a half-life of 1-2 days in plants[1], i.e., potentially reliant on multiple repeated applications in the event of sustained fruit fly pressure.

As a consequence the vegetable industry is seeking to gain access to additional treatment options that would allow the use of trichlorfon but in a more strategic manner. To this end the industry is seeking access to maldison to broaden control options thereby ensuring production is not impaired aiding in the continuation of supply.

There are international registrations for the control of a range of fruit flies and control of other species of flies as follows:

USA

Berry fruit	Mediterranean fruit fly	1-8 pts/A (1.12 – 9 kg ai/ha)
Citrus fruit	Mediterranean fruit fly	1-8 pts/A (1.12 – 9 kg ai/ha)
Figs	Vinegar flies	2.5 pts/A (2.8 kg ai/ha)
Grapes	Drosophila	2-2.5 pts/A (2.24-2.8 kg ai/ha)
Guava	Fruit flies	0.75 pts/A (0.85 kg ai/ha)
Mango	Fruit flies	0.75 pts/A (0.85 kg ai/ha)
Passion fruit	Fruit flies	0.75 pts/A (0.85 kg ai/ha)
Walnuts	Walnut husk fly	4-12.5 pts/A (4.5-14 kg ai/ha)
Cherries	Cherry fruit fly	1-1.5 pts/A (0.7-1 kg ai/ha)

(see attached labels)

Malathion is also approved for the control of flies around buildings housing animals, homes and yards.

[1] Pesticide Residues in Food: Report of the 1971 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, FAO Agricultural Studies, 1972, No. 88.

6. MINOR USE CLASSIFICATION

The crop or situation is a minor use via (*check one box only*): For guidance on Schedules refer to Page 2 *Background details to the Guidelines for Determining Minor Uses*

☐	Schedule 1
☒	a proposed Schedule 2
☐	a proposed Schedule 3

For proposals seeking acceptance as a minor use under either Schedules 2 or 3 please provide supporting reasons:

7. PROPOSED END USERS Persons to be covered by the permit ***(check the most relevant*)**:	
☒ 'Persons generally' (includes everyone – ie. no restrictions)	
☐ A specific group or class of persons (eg licensed pest control operators, licensed aerial operators etc)	Details of end user/s (*if not 'Persons generally' as above*)**:**
☐ One or more nominated individuals	

8. PROPOSED DURATION OF USE, STATES OR REGIONS & AREA/TONNAGE TO BE TREATED									
Proposed duration of use:	First date of proposed use	From issue of permit							
	Annual timing of use (ie. from Sep – Mar or ongoing throughout year)	Ongoing throughout the year.							
	Proposed permit duration (ie. 1, 2, 5, 10 yrs or ongoing)	5 years							
Proposed use is to occur in:	All States ☐	QLD ☒	NSW ☒	SA ☐	TAS ☐	WA ☒	NT ☒	VIC ☐	ACT ☐
	OR								
	The use will be undertaken in a specific location/region only (please specify): Cucumber fly, Queensland fruit fly and Mediterranean fruit fly endemic areas of Australia where capsicums and cucurbits are grown, i.e., West Australia, Northern Territory, Queensland and NSW.								
Extent/area of proposed use per annum:									

SECTION 2: THIS SECTION MUST BE COMPLETED ONLY FOR PRODUCTS THAT ARE CURRENTLY REGISTERED IN AUSTRALIA

In considering the application please complete the following questions and sections. Labels of most registered products may be obtained from the APVMA website at: *www.apvma.gov.au*

Rate and method of application

Is the rate and method of application similar to existing rates approved in other commodities/situations already registered for the product?

☒ Yes

If yes, please explain in the area provided below including appropriate examples from the approved label for the product

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to operators/users and the environment. This may include the provision of supporting data and/or risk mitigation strategies.

Maldison is currently registered in Australia for use on Vegetables at 60-100 g ai/hL for the control of a range of insect pests. It is also currently approved for use as a bait spray for fruit fly control in fruit trees at a rate of 308 g ai/hL.

The proposed rate of 130 g ai/hL is comparable to currently registered rates in that it exceeds current maximum rates by approximately 30%.

Efficacy & Crop Safety

Are you aware of any local efficacy or crop safety trials/studies conducted: ☐ Yes ☒ No

If Yes, please provide the following answers.

The person/organisation who conducted the study

Is a report of the study available. : ☐ Yes ☒ No

A crop safety study is believed unnecessary as maldison has been approved for use in cucurbits and capsicums for a number of years, at comparable rates with nop adverse experiences reported.

Efficacy is based on extrapolation from approvals in the USA. While the US rates are variable they reflect the relative application volumes required in the various crops. The US label indicates water volumes for tree and vine crops of 100-800 gallons/A, i.e., approx 900-7000 L/ha. When a conversion is done on the basis of rates and water volumes these translate to 95-128 g ai/hL.

Overseas Registration

Are you aware if this use pattern is registered overseas: ☒ Yes ☐ No

If yes, please name country(ies) and provide a copy of label, if available.

Maldison is registered for the control of Medfly, fruit flies, vinegar flies and Drosophila flies in a range of crops in the USA. The registered rates are generally in alignment with the registered rates on the Australian label for fruit and vegetables.

Have you spoken with the local manufacturer/registrant for support of this use and do they have any supporting data. ☒ Yes ☐ No

If yes, please provide their response.

Ospray Australia are supportive of the permit application seeking approval to use maldison for the control of Cucumber fly, Queensland fruit fly and Medfly in capsicums and cucurbits.

Target Crop/Situation

Is the product currently registered for the proposed crop/situation OR has the crop been subject to phototoxicity testing under the proposed use regime?

☒ Yes

If yes, please outline in the area provided below brief details including any supporting data and attach that data with your application.

☐ No

If no, please explain in the area provided below how the proposed use will not pose unacceptable risks to the crop. This may include a discussion on extrapolation of crop tolerance based upon existing registrations in botanically related commodities, or where the use pattern or chemistry is such that adverse effects are unlikely.

Maldison is currently registered for use in vegetables with no current restraints on use. Consequently, no adverse crop effects are anticipated in capsicums.

Target Pest/Disease

Is the product proposed for this use currently registered against the target pest/disease in another crop/situation for which efficacy is being based, including situations where bridging or limited bioequivalence data is being presented?

☒ Yes

If yes, please explain in the area provided below how the existing registration in other commodities is relevant (ie. can be extrapolated) to the proposed use in demonstrating that equivalent efficacy will be achieved, including reference to any bridging or bioequivalence data which is being presented.

☐ No

If no, please provide supporting data or a valid scientific argument in the area provided below which demonstrates that the proposed use will be efficacious. Scientific arguments will be considered on their merits. Examples can include scientific arguments (ie. extrapolation) based upon the chemicals known activity (ie. Mode of Action) and registration status against similar pests/diseases. Additionally relevant data from trials or published literature may be provided.

The Australian registered use pattern for the use of maldison in the control of fruit flies is as a bait spray, i.e., contact activity has been previously established. Further the registrations for the control of a range of Dipteran crop pests in the USA adds further support to the argument that maldison would be effective in controlling fruit flies.

Crop Residues (food-crops only) - MRLs

Is a current Maximum Residue Limit (MRL) established, or has exemption from requiring an MRL been given for the chemical on this commodity? Note: MRLs can be obtained from the MRL Standard available on the APVMA website at: http://www.apvma.gov.au

☒ Yes

If yes, in the area below please provide details on that MRL or exemption.

☐ No

If no, in order to enable an MRL to be established please indicate if you are providing either (and detail this in the area below):

☐ supporting residue data, or

☐ a valid scientific argument which demonstrates that the proposed use will not result in detectable residues, or

☐ a valid scientific argument based upon extrapolation from registered uses in a similar commodity and its MRL.

The proposed use pattern is based, in part, on GAP from other countries, e.g., GAP for tomato in Italy a rate of 0.16 kg ai/hL, and use approved use patterns for the control of Medfly, e.g., stonefruit 0.135 kg ai/hL.

MRLs have been established at Codex for use in peppers and cucumbers (see below). The Codex MRL in cucumbers is based on a GAP of 3 x 2.1 kg ai/ha, that for peppers 5 applications at 1.8 kg ai/ha[2]. Rates above that which proposed for the Australian uses.

	Australia	Codex
Cucumber	2 mg/kg	0.2 mg/kg
Peppers, Sweet	0.5 mg/kg;	0.1 mg/kg
Tomatoes	3	0.5
Vegetables	2 mg/kg	-

[2] Pesticide Residues in Food: Report of the 1999 Joint Meeting of the FAO Working Party of Experts on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, FAO Agricultural Studies, 2000, No. 157.

Crop Residues – livestock feeding

Is the raw commodity, or waste or by-products from processing, fed to livestock or sold for use as livestock feed?
OR is the commodity subject, or likely to be subject, to a Commodity Vendor Declaration (CVD) or By-Product Vendor Declaration (BVD)?

☐ Yes ☒ No

If yes, please provide details against each area listed below.

The portion of the commodity that is fed to livestock	N/A
Species of livestock consuming treated produce	N/A
Amounts which may be fed and proportion of diet	N/A
Details of the CVD or BVD applicable to the commodity	

Trade (food-crops only)

Is the commodity subject to export trade?

☒ Yes ☐ No

If yes, please provide details against each area listed below.

Quantity of produce exported (incl. $ value)	**Cucumbers**: The primary export market is New Zealand with approximately 70% of exports. For other export destination s it is believed the Codex MRLs would be sufficient to accommodate the use. **Capsicums**: As with cucumbers New Zealand is the primary export destination accounting for 78% of exports.
Countries of destination	Treated produce mostly for domestic markets Exports Include: Singapore, Hong Kong
Proposed mechanisms for ensuring the treated commodity will meet importing country MRL requirements	Compliance with Food Standards Australia New Zealand MRL would ensure acceptance in New Zealand due to the TTMRA. Existing Codex MRLs should ensure compliance in other markets.

Please indicate if any supporting data is attached/provided for;

☒ Residues and trade considerations (food and feed producing crops only)

☒ Occupational Health and Safety

☒ Environmental Safety
☒ Efficacy and Crop/Host Safety
☐ Other data or information

Please return the fully completed application form with Sections 1 & 2 only to:

The Screening Officer
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

ATTACHMENT V WTO NOTIFICATIONS

Year	WTO Notifications
2009/10	Liaised with potentially affected industries and provided input to DAFF over MRL changes in export markets, e.g., WTO notifications China 313; EEC – 389; Japan – 262 and Taiwan – 187, 191, 200, 203, 210, 211, 214 and 219; Korea – 358.
2010/11	Liaised with potentially affected industries and provided input to DAFF over MRL changes in export markets, e.g., WTO notifications: EEC – 393, 394 & 395; Japan – 274, 278, 281 and Taiwan – 222, 226, 230, 232, 233, 234 and 237; Korea – 383 & 387.
2011/12	Liaised with potentially affected industries and provided input to DAFF over MRL changes in export markets, e.g., WTO notifications: China – 511, 522 and 600; Japan – 283, 284, 285, 289, 293 307 and 310; Taiwan – 242 & 247, 267 & 273; Hong Kong – 36; Korea – 403,433 & 435; USA 2265, 2266, 22367 & 2504
2012/13	Liaised with potentially affected industries and provided input to DAFF over MRL changes in export markets, e.g., WTO notifications: EU 42, Japan – 298 and 319; Taiwan – 258, 280 & 287; Korea – 433 & 447; USA 2530, 2543, 2544 & 2568, Canada 664, 681, 695 & 703
2013/14	Liaised with potentially affected industries and provided input to DAFF over MRL changes in export markets, e.g., WTO notifications: China – 600; Japan – 307 and 310; Taiwan – 267 & 273; Hong Kong – 36; Korea – 433 & 435; USA 2504

ATTACHMENT VI – APVMA CRIS Industry Responses

February XXX, 2009

Review of Cost Recovery Arrangements 2008 – Draft CRIS
APVMA
PO Box 6182
KINGSTON ACT 2604

Re: Review of Cost Recovery Arrangements

Horticulture Australia Ltd (HAL) appreciates the opportunity to contribute to the further development of the APVMA's cost recovery arrangements.

In general terms HAL is supportive of the APVMA's current approach, i.e., using the levy as a balancing factor and not pursuing 100% cost-recovery through fees. HAL agrees that such an approach would act as a significant disincentive for new products and innovation. However, HAL strongly disagrees with the proposed changes to fees associated with minor use permits; HAL objections are outlined in detail below.

The APVMA's Operational Plan[23] indicates that new guidelines and policies for minor use are to be developed to 'enable timely access to safe and effective chemicals'. The introduction of a $700 fee would not only seem to contradict this objective, it would also serve to penalise growers seeking access.

The draft CRIS indicates that minor use permits are required because manufacturers find the registration of certain pesticide uses is not commercially justifiable. This infers there is only a small market for the minor use. Anecdotal/market information tells us that this situation continues to prevail, and that manufacturer interest in minor crops has not increased, in fact it may even be decreasing. For this reason, a minor use fee increase would seem to be counter-productive.

The draft CRIS describes the current $320 fee as nominal, HAL understands this level was primarily chosen to discourage impractical permit requests, and to a lesser extent in recognition of the industry's limited capacity to pay. A combination of the sustained drought, increased costs, and market conditions have further eroded minor crop growers' ability to pay.

The APVMA acknowledges in the draft CRIS that growers and grower organisations already pay both the costs of generating required data and the permit fee, yet the APVMA proposes to more than double the minor use permit fee indicating that this constitutes 100% recovery of its administration costs.

[23] **Operational Plan 2008-2009**

A $700 administration fee suggests that a considerable amount of time needs to be devoted to processing 3-4 page permit applications. Is this the case in reality or has the amount been derived via extrapolation from other application related activities, i.e., handling full registration dossiers for new products? Unfortunately, no information is provided as to the basis of the $700 fee.

This lack of clarity suggests that the stated APVMA position on minor use lacks sincerity, i.e., income generation rather than the development of new guidelines to enable 'access to safe and effective chemicals' is the primary motivation. This view is reinforced with the proposed fee to cover both new applications and renewals. In the case of renewals, where no additional data is provided, it is difficult to see how $700 administration costs could be incurred. In addition, the proposal that fees be indexed would, over time, increase costs to growers and further inhibit minor industries' access to chemicals. Strengthening the impression the APVMA see minor use as an income stream to be exploited.

The Federal governments guidelines on Cost Recovery[24] indicate that agencies should – "assess whether adopting cost recovery would undermine the objective of the activity" and "ensure that cost-recovery is not undertaken simply to earn revenue". Given the APVMA position on minor use the introduction of a $700 fee would seem contradict both these objectives.

In summary, HAL believes the outcome of these proposals will be to penalise and constrain small and minor industries by restricting their ability to access needed chemicals. If costs are too prohibitive, this could have the unfortunate and undesired effect of encouraging illegal use. This result would be in no-one's interests

HAL therefore strongly rejects the proposal to increase minor use fees to levels that cannot be sustained by growers. HAL believes that a fairer and more equitable two tiered fee structure, as follows, should be considered:

- No fee charged for a minor use permit application that arises from an industry strategic review of pest management needs
- A nominal fee ($320) payable for ad hoc requests, i.e., those not origination from an industry review.

This would reward those industries that have given due consideration to issues such as IPM and trade, and still provide a revenue stream for the APVMA. HAL would welcome an opportunity to discuss, in more detail, the above proposal.

While acknowledging the need for the APVMA to adequately fund it's activities HAL does not believe lifting fees for minor use is a cost-effective mechanism of achieving this outcome.

Yours sincerely,

[24] Australian Government Cost Recovery Guidelines July 2005 Financial Management Guidance No.4

Program Manager, Corporate Services

APVMA

PO Box 6182
Kingston ACT 2604

Re: APVMA Cost Recovery Discussion Paper

Access to agvet chemicals is a significant issue for the custard apple industry, due to the diverse cropping systems, geographical locations and its relatively small size access to pest management options can be problematic. As a consequence the industry has relied heavily on the minor use permit scheme of the APVMA for the provision of much needed pest, disease and weed management tools.

The ACAGA therefore, welcomes the APVMA's proposed retention of the 2005 fee approach in which the balance of costs associated with minor use permits are recovered through the levy on wholesale sales. ACAGA sees this as particularly important as minor use permits are sought on behalf of mango growers to fulfil pest management needs due to a lack of interest from registrants/manufacturers, i.e., pursuit of regulatory approvals are seen as not being commercially justified. Consequently, the industry supports a proposed approach in which the balance of costs continues to be recovered via the levy, particularly as user groups are unable to recoup costs associated with seeking and gaining minor use approvals.

To further, lessen the financial burden on user groups ACAGA recommends that the APVMA consider reducing the fee for minor use permit renewals, in situations where no technical assessment is required. Where processing of the permit renewal is essentially administrative AMIA believes that either a nil or substantially reduced fee should apply.

In summary, ACAGA welcomes the proposed retention of the current minor use fee approach and suggests that the APVMA take the opportunity to extend the current cost recovery model to reduce renewal fees as a way of further lessening the financial burdens on growers of minor crops.

Yours sincerely,

Program Manager, Corporate Services

APVMA

PO Box 6182
Kingston ACT 2604

Re: APVMA Cost Recovery Discussion Paper

The Australian Mushroom Growers Association (AMGA) represents the interests of Australian mushroom industry which is primarily focused on supplying the domestic market. Access to agvet chemicals is a significant issue for the mushroom industry, in part due to the unique nature of the crop and production system but also due to the fact agvet chemical use is not great. As a consequence the industry has relied heavily on the minor use permit scheme of the APVMA to provide much needed pest and diseases management tools.

The AMGA therefore, welcomes the proposed retention of the 2005 fee approach with respect to minor use permits in which the balance of costs are recovered through the levy on wholesale sales. The AMGA sees this as particularly important as minor use permits are sought on behalf of producers where registrants/manufacturers have deemed seeking registration uneconomical, i.e., the need for a minor use permit arises due to market failure. Consequently, the AMGA supports an proposed approach whereby the balance of costs continues to be recovered via the levy.

Further, the AMGA suggests a refinement to the current fee associated with minor use permit renewals, where no technical assessment is required, should be considered. In such cases where processing of the permit renewal is essentially administrative the industry believes that either a nil or substantially reduced fee should apply. This would help further reduce the financial burden on minor agricultural industries.

To further enhance its activities in the area of minor use the AMGA suggests that the APVMA should also apply the current approach to minor use permit fees to user industry initiated Category 25 registration applications. In its 2009-10 Annual Report the APVMA, under “Pathways for the Registration of Minor Uses” indicated that it had piloted a new mechanism that of user industry initiated Category 25 applications.

The mushroom industry considers the progression of minor use permits to registered labels as being more desirable than relying upon permits, *per se*, long-term. As a result the industry see's this initiative as a promising step forward and wishes to explore potential opportunities for its utilisation.

To date the mushroom industry has had to support minor use permit applications through the funding of local efficacy and residue data generation. If the APVMA were to apply an equivalent fee for user industry initiated Category 25 applications, the opportunity would exist for the mushroom industry to pursue more permanent regulatory solutions to its pest management needs, i.e., registrations via label extensions. However, the current modular fee structures associated with a Category 25 application creates a significant hurdle, making such an approach potentially prohibitively expensive, i.e., modular fees coupled with the cost of data generation

As indicated the AMGA welcomes the proposed approach with respect to minor use permit fees. Nevertheless, the industry believes that the APVMA could considerably enhance its current approach through the refinements indicated above.

Yours sincerely,

Program Manager, Corporate Services

APVMA

PO Box 6182
Kingston ACT 2604

Re: APVMA Cost Recovery Discussion Paper

Access to agvet chemicals is a significant issue for the mango industry, due to the diverse cropping systems, geographical locations and relatively small size access to needed pest management options can be problematic. As a consequence the industry has relied heavily on the minor use permit scheme of the APVMA for the provision of much needed pest, disease and weed management tools.

The AMIA therefore, welcomes the APVMA's proposed retention of the 2005 fee approach in which the balance of costs associated with minor use permits are recovered through the levy on wholesale sales. AMGA sees this as particularly important as minor use permits are sought on behalf of mango growers to fulfil pest management needs due to a lack of interest from registrants/manufacturers, i.e., pursuit of regulatory approvals are seen as not being commercially justified. Consequently, the industry supports a proposed approach in which the balance of costs continues to be recovered via the levy, particularly as user groups are unable to recoup costs associated with seeking and gaining minor use approvals.

To further, lessen the financial burden on user groups AMIA recommends that the APVMA consider reducing the fee for minor use permit renewals, in situations where no technical assessment is required. Where processing of the permit renewal is essentially administrative AMIA believes that either a nil or substantially reduced fee should apply.

AMIA has recently become aware of an initiative in which user industries can seek to have labels amended, via Category 25 applications. The mango industry sees this as a potentially important advance that will help facilitate industry led innovation. However, despite the attractiveness of the concept the fees that would be incurred, in pursuing such a label amendment, are expensive from the perspective of a relatively small industry group such as AMIA and would preclude its consideration. Consequently, AMIA would ask that the APVMA consider developing a more economical fee structure for such applications mirroring

that of minor use permits, which the industry believes would see the initiative supported by industry groups as a more permanent solution to minor use pesticide needs.

In summary, AMIA welcomes the proposed retention of the current minor use fee approach and suggests that the APVMA take the opportunity to extend the current cost recovery model to include fees associated with Category 25 applications as a way of further developing effective pathways through which regulatory approvals can be gained for minor crops. above.

Yours sincerely,

Program Manager, Corporate Services

APVMA

PO Box 6182
Kingston ACT 2604

Re: APVMA Cost Recovery Discussion Paper

Access to agvet chemicals is a significant issue for the vegetable industry. Due to the wide variety of commodities, diverse cropping systems, geographical locations and their relatively small size vegetable growers have had to rely on off-label minor use permits to meet their pest management needs. Minor use permits are sought on behalf of growers to address pest management gaps arising, most often, from registrants/manufacturers not pursuing regulatory approvals for chemical × commodity uses as they are deemed to be uneconomical.

Ausveg therefore, welcomes and supports the proposed retention of the 2005 fee approach with respect to minor use permits in which the balance of costs are recovered through the levy on wholesale sales of pesticides. Ausveg sees this as particularly important from the perspective lessening the cost burden on the industry. Currently, there are over 240 off-label minor use permits in place addressing vegetable grower pest management needs. Any increase in costs would severely impact on the industry's ability to meet growers' needs, particularly when the cost of data generation is also taken into consideration.

To further enhance the current minor use scheme Ausveg believes that the APVMA should consider a fee reduction for permit renewals in cases where no technical assessment is warranted. It is the belief of Ausveg that as such renewals are essentially administrative in nature either a nil or substantially reduced fee should apply. Such a move would help further reduce the financial burden on the minor vegetable industries.

As indicated Ausveg welcomes the proposed cost recovery approach outlined for minor use permit fees and believes that the APVMA should consider revising the fees associated with permit renewals.

Yours sincerely,

SUBMISSION to APVMA CRIS REVIEW
By
Australian Mushroom Growers Association

About The AMGA

The AMGA is the peak industry body for the mushroom industry in Australia and has been representing the industry on a wide range of issues since it was formed in 1961. Its members encompass the mushroom supply chain and include all but two of the industry's 85 growers.

AMGA works hard to ensure safe and effective use of pesticides in the mushroom industry. Our objective is safe food, safe work places, and sustainable businesses. An important part of this work is an industry funded and managed pest and disease R&D and communication program. The key research facility is the Marsh Lawson Mushroom Research Unit located at Sydney University. Its major focus is the conduct of experiments to assist growers in maintaining access to pesticides.

AMGA has invested over $0.5 million to produce and submit residue and efficacy data to AVPMA in support of label extensions and permits for mushrooms over many years. AMGA holds several APVMA minor use pesticide permits on behalf of all mushroom growers.

AMGA supports the Horticulture Australia submission to APVMA on the CRIS but also wishes to reinforce a couple of the key issues with specific reference to the situation in the mushroom industry.

The Mushroom Industry Submission

1) AMGA is concerned about increasing the minor use permit fee from $320 to $700. The industry already spends significant funds to collect data to maintain legal access to pesticides. We don't need another cost increase that is difficult to justify.

   AMGA repeats HAL's observation that the APVMA's strategic plan indicates that new guidelines for minor use will be developed to 'enable access to safe and effective chemicals'; and the Federal government's guidelines on Cost Recovery indicate that agencies should – "assess whether adopting cost recovery would undermine the objective of the activity" and "ensure that cost-recovery is not undertaken simply to earn revenue".

   AMGA is adamant the introduction of a $700 minor use permit fee is not consistent with government's guidelines or APVMA's strategic objective because it penalises growers seeking minor use access.

2) AMGA is concerned that the mushroom industry's reliance on minor use permits are going to increase. The mushroom industry is extremely small on global scale, let alone the Australian market. Currently, there is no commercial incentive for chemical companies to even consider registering pesticides for use on mushrooms. This situation appears to be worsening so industry minor use access costs are likely to increase even without the proposed fee hike.

3) CRIS indicates that minor use permits are required because manufacturers claim that registration of certain pesticide uses is not commercially justified. This infers there is only a small market for the minor use. Anecdotal/market information tells us that this situation continues to prevail, and that manufacturer interest in minor crops has not increased, in fact it may even be decreasing. For this reason, a minor use fee increase would seem to be counter-productive.

4) CRIS describes the current $320 fee as nominal, at a level set to discourage impractical permit requests, and in recognition of the industry's limited capacity to pay. A combination of the sustained drought, increased costs, and market conditions have further eroded small growers' ability to pay, yet the APVMA proposes to seek 100% recovery of its administration costs – more than doubling the minor use permit fees - at the expense of the growers.

5) Since the APVMA acknowledges that the growers and the grower organizations pay both the costs of generating required data and the permit fee, why does the organization now propose 100% recovery of administration costs? And on what basis was a fee of $700 determined?

6) The APVMA also needs to disclose why it proposes to set a $700 fee for a simple permit renewal. In such cases where no additional data is provided, it is difficult to see where increased administration costs are incurred.

7) The lack of clarity over the basis and need for the $700 fee suggests that the stated APVMA position on minor use lacks sincerity, i.e., income generation rather than the development of new guidelines to 'enable access to safe and effective chemicals' is the primary motivation.

8) The proposal that fees be indexed would, over time, increase costs to growers and further inhibit minor industries' access to chemicals. Strengthening the impression the APVMA see minor use as an income stream to be exploited.

9) In summary, the outcome of these proposals will be to penalise and constrain small and minor industries by restricting their ability to access needed chemicals. If costs are too prohibitive, this could have the unfortunate and undesired effect of encouraging illegal use. This result would be in no-one's interests

10) The industry strongly rejects the proposal to increase fees to levels that cannot be sustained by growers. A fairer and more equitable approach would be a two tiered fee structure, as follows:
    - No fee charged for a minor use permit application that arises from an industry strategic review of pest management needs
    - A nominal fee ($320) payable for ad hoc requests, i.e., those not origination from an industry review.

    This would reward those industries that have given due consideration to issues such as IPM and trade, and still provide a revenue stream for the APVMA.

Nursery & Garden Industry Australia

NGIA Response to the APVMA Cost Recovery Impact Statement

February 2009

Industry Profile 2009

The Nursery & Garden Industry Australia (NGIA) is the national peak industry body representing producers, retailers and allied trades involved in the production of greenlife across Australia. NGIA works in close association with the state and territory peak industry bodies providing a nationally united position on issues of commonality and importance.

The combined 'supply chain' of the Australian nursery industry has an annual value exceeding $5.5 billion, includes more than 20 000 small to medium sized businesses and employs approximately 45 000 FTE. The industry is located in every state and territory across Australia, and in most communities and environments, providing greenlife to a diverse customer base. The production sector is broad based producing in excess of 10 000 plant species with many and varying target markets that have an estimated annual value to the Australian economy exceeding $10 billion including:

Production Nursery	Horticultural markets
Container stock	Ornamental/urban horticulture
Foliage plants	Interior-scapes
Seedling stock	Vegetable growers
Forestry stock	Plantation timber
Fruit and nut tree stock	Orchardists (citrus, mango, etc)
Landscape stock	Domestic & commercial projects
Plug and tube stock	Cut flower, ornamental, etc
Revegetation stock	Farmers, government, landcare
Mine revegetation	Mine site rehabilitation

The Australian nursery industry is a small user (by volume) of pesticides however due to the more than 10 000 crop lines produced the industry requires a large range of products to combat the various pests, diseases and weeds that threaten the many different production systems in operation across the country. Due to the low volume of pesticides utilised throughout nursery production the pesticide manufacturers see the industry as a minor player within the market and as such tend to focus on the broader horticultural and agricultural markets to maximise the returns on their investment. This has resulted, over recent years, in a low number of label registered pesticides being available to nursery production in most states and territories. As such the industry is reliant on the Minor Use provisions provided for by the APVMA to gain access to modern pesticides to efficiently combat the various pests, diseases and weeds impacting on their businesses.

Current APVMA Process

NGIA understands the need to ensure that Minor Use Permits are valued by applicants and that realistic costs are recovered allowing the service to continue. The costs imposed on industry must be a reflection of the true cost and not an arbitratory figure selected to address internal budgetary concerns.

Industry supports the current APVMA mix of cost recovery methods including the application fee combined with the APVMA levy returns associated with product sales. This distribution of the APVMA income stream assists in keeping up-front fees to a

minium and also ensures that all beneficiaries of the permit contribute to the overall cost of its approval and use.

Response to draft Cost Recovery Impact Statement (CRIS)

Of significant concern to the nursery industry is the recommendation from the CRIS to increase the cost of Minor Use Permits (MUP) by more than 100% from $320 to $700 to ensure full cost recovery of adminstraton fees. NGIA has a number of concerns with this conclusion and has itemised them below:

1. NGIA questions the methodology that has arrived at a cost increase of more than 100% as outlined in the CRIS. In 2008 the Productivity Commission review of chemical regulation recommended that the APVMA ensure the cost of assessments are commensurate with the risk. NGIA believes that this recommendation has not been applied to the assessment of the costs of delivering MUP's to the nursery industry.

2. The industry will find it difficult to cover the increased costs of MUP's as they are struggling with the current costs imposed by the APVMA over recent years. With community and government pressures on growers increasing (product & environmental safety) access to quality pesticides is essential. The industry considers increased fee's a barrier to improving pest management on-farm due to a reduced access to new or effective chemistry(s).

3. The expertise once provided by state governments to industry MUP applications is no longer available except under an emergency response scenario. Therefore industry must now pay for this assistance which has added a significant cost to the preparation of MUP applications.

4. The cost of MUP's has gone from an approximate $60 to more than $2500 for industry over the past 4 - 5 years, higher for food based industries, putting enormous pressure on already stretched R&D budgets. This higher cost is due to the APVMA initial increasing of the cost of a MUP ($320) plus the increased documentation (application) costs due to the specialist input required plus efficacy, worker exposure and food safety data. NGIA believes that industry is adequately contributing its share under the current APVMA cost recovery system through a) Grower application fees b) Data generation costs and c) APVMA product sales levy.

5. With Minor Use Permits sought for products already registered within Agriculture/Horticulture in Australia NGIA considers the assessment of an application by the APVMA to be a straight forward process. NGIA has estimated that the new fee recommended in the CRIS reflects a minium of 20 hours required to assess a 4 page MUP application. Furthermore the same fee is proposed for the granting of a MUP Renewal which in many cases requires no additional effort or administration by the APVMA. NGIA questions both of these assumptions and believes the APVMA needs to produce conclusive costings to satisfy the concerns of industry.

6. The nursery industry anticipates manufacturers will continue to ignore industry needs and therefore MUP's will be considered the norm as opposed to the exception. Manufacturers have cited low revenue returns as a reason for not progressing label registrations for low volume users. Increasing MUP costs will place an added financial burden on industry which is facing various pressures through drought, water restrictions, the slowing economy and climate change (increased pest pressures).

7. Higher MUP costs will limit the ability of industry to access new chemistry that may have greater efficacy against the target pest(s), a reduced environmental impact, lower toxicity to humans or minimal off-target impacts (fish, etc). Currently the industry has a reliance on older chemistries including organophosphates, many of which are under review, that are considered to have a broad spectrum of activity, are environmentally persistent and toxic to humans. The fee increase will not improve access to better pesticides for industry instead it will limit their timely introduction into many cropping systems.

8. The CRIS considers the producer, or industry, to be the sole beneficiary of the registration process and therefore must cover the entire cost. This is a flawed concept as the community and environment also benefit from the correct pesticide being used at the correct rate and therefore the costs should be distributed appropriately across all stakeholders. Therefore it should be recognised that the costs associated with MUP's need to be proportionally covered by industry and by government who represents both the community and the environment.

Conclusion

The Australian nursery industry has a proven track record as a progressive, innovative and adaptive industry embracing concepts such as Environmental Management Systems and Integrated Pest Management. An important aspect of both the above concepts is the application of pest management tools that fit to the strategies employed by growers to meet their obligations of reduced and specific pesticide use, safe places of work and environmental stewardship. Potentially limiting access to new and advanced chemistries through increased cost burdens will reduce the progress made by industry over recent years. Misspelt

ATTACHMENT VII Department of Agriculture submissions

February XXX, 2010

Product Safety and Integrity Committee Secretariat
Innovation, Productivity and Food Security Branch
Department of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601

(Or emailed to psic@daff.gov.au)

Re: Review of National Registration Scheme

Horticulture Australia Ltd (HAL) appreciates the opportunity to contribute to the discussion of the National Registration Scheme. HAL is a not-for-profit, industry-owned company working in partnership with Australia's horticulture industries to invest in research, development and marketing programs for the benefit of industry and the wider community.

From this perspective HAL would like to comment on aspects of the current review potentially impacting on various activities partnered between HAL and individual horticultural industries, i.e., pest management, minor use and industry stewardship programs.

In terms of pest management many horticultural industries are seeking to reduce their reliance on the use of conventional pesticides through the development of integrated pest management programs. An element of this process is the identification of alternative pest management technologies. To date this process has been hampered by the difficulty associated with gaining access, i.e., regulatory approval. HAL understands that currently, all substances/products seeking approval are required to meet the same high regulatory standards, a requirement which is potentially inhibiting the market development of alternative low-risk products. HAL considers that there would be substantial benefit to horticultural industries, and the wider community, were greater flexibility the regulatory requirements to be revised so as to reflect the level of risk, i.e., level of assessment commensurate with the level of risk.

Fundamental to the issue of pest management has been that of access to suitable pesticides. Horticultural producers often need to gain access to pesticides. This need can arise for a number of reasons such as exotic pest/disease incursions, resistance development, the growing of new crops, the development of IPM or from a lack of approvals. The latter need arising due to the relative small size of many industries, resulting in manufacturers considering product development not commercially justifiable. As a consequence many industries have invested significant resources towards data generation and submission in order to gain and maintain necessary regulatory approvals to fill those gaps.

Integral to this process has been the minor use permit system of the APVMA. HAL

understands that many industries would have difficulty in continuing to participate in this process should higher costs be an outcome of the review, i.e., increases in fees and/or the cost of pesticides. Such an eventuality could adversely affect the long-term viability of these industries by limiting their capacity to foster innovation or further refine current pest management practices, i.e., significant increases in the costs of newer pesticides could have the effect of narrowing the agvet chemical tool kit forcing users to rely too heavily on a few products resulting in resistance and or the development of secondary pest problems, which could, potentially, have an adverse impact on the long-term sustainability of horticulture.

From an industry stewardship perspective many horticultural industries are seeking to address issues such as productivity, natural resource management and climate change through the development of best management practice programs (BMPs). For example, the vegetable and the nursery industries have developed and begun implementing environmental management plans. Allied to these plans are matters relating to chemical management, e.g., that pesticides are used appropriately and in accordance with label or permit instructions. A potential limiting factor in the development and implementation of these plans is the variation in control of use arrangements between states. These differences can add a layer of complexity and increased cost to industry and can constrain the capacity of HAL to offer the level of support required for the successful development and implementation of an industry's national BMP, e.g., training requirements. Consequently, HAL would support the concept of a consistent national approach to control-of-use where due consideration is given to ensuring the system is both effective and efficient.

Yours sincerely,

Permissible uses
It is understood that the issue of crop groups has been under discussion between the States, the APVMA and the chemical industry now for a number of years.

Control of Use
As the consultation paper indicates there is a lot of similarity between the various control of use regimes operated by the various states and territories.

Tiered approach

- The consultation paper outlines an approach whereby
- It's unclear how the three tiered approach would in fact work, why wouldn't users just utilise the freedom provided by the permissible use Tier, i.e., why would they bother with Tiers 1 or 2.
- What incentive would there be for a manufacturer to pursue a broadened label given the freedom provided by Tier 3, i.e., why go to the expense of extending a label if uses and sales already occur.
- From a practical perspective Tier 2 would in effect be redundant. Permissible uses would in effect be exempt from the application of any control of use regulations

Managing residues

- How will uses in crops be managed where residue profiles are unknown, i.e., if residues must be at non-detect levels, i.e., below the LOQ.
- No definitive evidence has been provided showing the outcome of specific off-label uses in Victoria, i.e., the residue results from specific chemical × commodity off-label uses.
- In reviewing Victorian monitoring data (see the summary table below) across all commodities the violation rate has averaged about 7.23%. For comparison purposes residue monitoring data from NSW[25] (1995 to 2005) indicates an average violation rate of 4.5%.
    - While this provides an overarching view when the VPMP data is looked at in detail, areas of concern emerge. For example, the 08/09 data[26] indicates that for carrots 50% of samples were violative, parsnips 66% and for squash and cucumber 33% were violative.
    - While these violations were unlikely to raise any health concerns they go to the heart to the issue of maintaining consumer confidence.

- In the 08/09 VPMP Report it was indicated that 64% of samples contained no detectable residues. Therefore, 36% of samples had detectable residues and presumably the majority complied with the relevant MRLs.
- In the most recent FSANZ Notifications M1006 & M1007 60%[27] of new MRLs proposed for inclusion in the Food Code arose from permits.
- Therefore, if detectable residues are anticipated, how will standards be established into the future under a permissible uses approach?

[25] **http://www.dpi.nsw.gov.au/agriculture/horticulture/vegetables/soil/monitoring**
[26] **http://new.dpi.vic.gov.au/agriculture/about-agriculture/publications-resources/produce-monitoring-report-200809**
[27] **Excluding import tolerances**

Commodity	YEAR % compliance								
	08-09	07-08	2006	2005	2004	2003	2002	99-00	TOTAL
All samples	5%	8.54%	11.42 %	8.44%	4.43%	5.18%	3.34%	11.5%	7.23%
All Fruit	2.5%	9.1%	7.2%	1.2%	Nil	Nil	3.5%	20%	5.44%
All Vegetables	6.25%	7.5%	11.8%	10.7%	5.2%	6.3%	4%	8%	7.5%
All Herbs	25%	Not tested	24%	42%	15%	16%	Not tested	Not tested	24.4%
Grains	Not tested	Not tested	Not tested	Not tested	6%	Not tested	Nil	Nil	2%

Managing the ADI

- The APVMA in assessing dietary intake doesn't necessarily take the position that no residues reported as non-detect mean that no residues are present.
- Depending upon the compound, a residue value (at or below the LOQ) may in fact be applied when doing a long-term dietary intake assessment.
- For compounds with a low ADI the potential for an exceedance would exist if all potential uses had to be included in the assessment.
- In other words residues results reported as below the LOQ, i.e., non-detectable, are unlikely to be treated as zero residues.
- The implication being that for compounds with a low ADI, an outcome of a permissible use scheme would potentially be to 'tip' them over the ADI threshold triggering a review.

Managing information to support off-label uses?

- Who is going to generate the data/information needed to support off-label uses, particularly if generic products are involved? Will responsibility fall back on the PIBs?
- Has any thought been given to how the information is to be communicated, or will it be strictly up to the user?
- If information is to be provided on permissible uses:
    - and the responsibility for risk assessment and risk management of pesticide use, under a permissible use regime falls entirely onto the user, what level of culpability will be shared by data providers in the event an adverse experience occurs?
    - Also does that mean a user has no recourse, should they have an adverse experience from an off-label/permissible use recommended by a 3rd party?

Finally, is a permissible use scheme more about trying to legalise off-label use rather than actually trying to solve the problem?

PSIC Secretariat, Agricultural Productivity Division
Dept of Agriculture, Fisheries and Forestry
GPO Box 858
CANBERRA ACT 2601
Or emailed to PSIC@daff.gov.au.

To whom it may concern,

The Australian Mushroom Growers Association (AMGA) welcomes the opportunity to provide input into the development of a single national framework for agricultural and veterinary chemical regulation. Before providing more specific responses to elements of the consultation regulation impact statement (RIS) the AMGA would like to make some preliminary remarks.

The AMGA does not believe that a command and control style approach to regulation of agvet chemicals is either practical or appropriate. Consequently the association is supportive of reform aimed at reducing the regulatory burden and to improve the efficiency and effectiveness of agvet chemical regulation in Australia. However, the association wishes to flag its deep concern over two aspects of the current reform process.

Firstly, the AMGA is critical of the way in which the consultative process is being managed. The allowance of little more than one month to consider and respond to the RIS is totally inadequate. Of further concern is the apparent lack of any future opportunity for consultation prior to the June submission of a framework proposal to COAG. As a consequence the association believes the current process has not been in keeping with COAG Principles[28].

Secondly, the RIS provides little indication of potential costs associated with the various options presented. From a stakeholder perspective being asked to identify favoured options, in the absence of indicative costings is unsatisfactory. The AMGA is therefore concerned that a number of options are presented with no linkage between potential benefits and an assessment of costs. Without such analysis it is unreasonable to expect stakeholders to provide considered responses or nominate preferences.

Nevertheless, the AMGA has attempted to address some of the issues raised despite this lack of information.

Governance model

Regarding the governance model the AMGA is supportive of any move towards harmonising regulatory requirements related to control of use, training and accreditation. On that basis the AMGA preferred approach would be Option 2. However, due to the lack of detail provided it is unclear how this or the other options might operate in practice, i.e., in Option 1 what level of government would be given the task of determining the appropriate level of regulatory effort in relation to compliance and enforcement, the States, the Federal agency or both?

[28] COAG Principles of Best Practice Regulation. Principle 7 - consulting effectively with affected stakeholders at all stages of the regulatory cycle.

Assessment and registration – Efficacy data

The AMGA supports limiting data requirements associated with efficacy. The association believes that the fundamental purpose of agvet chemical assessment is to ensure they can be used safely thereby maintaining community confidence. As the assessment of efficacy data is not central to this function it should not be an essential element for registration.

Facilitating access to minor uses

The mushroom industry in general suffers from a lack of pest management options and as a consequence the AMGA welcomes proposals aimed at facilitating improved access for minor crops. In particular, the association believes that improvement in data protection arrangements, and the utilisation of other mechanisms such as expedited assessments, fee waivers, and transferrable credits would be pa positive step. As a result the association would support the exploration of such refinements under Option 1.

Permissible uses

While the AMGA is sympathetic to less burdensome approaches in the management of off-label use, it has misgivings over the wider implications of adopting a more liberal approach to unassessed risk. The AMGA believes that maintaining community confidence in the regulation of agvet chemicals is critical and as a result has significant reservations over any scheme that could undermine that confidence.

The RIS indicates that there "*would be negative productivity effects consequent to loss of access*" which "*could lead to substantial losses*"[29]. However, no evidence is provided as to which sectors utilise off-label use and the extent such access is relied upon. As a result there is no way to gauge whether such an approach is likely to provide the necessary balance between risks, costs and benefits?

The association is therefore of the opinion that regulatory oversight should remain an essential part of risk assessment and as a consequence offers in principle support for an approach based on either Options 1 or 2, incorporating elements of the recently adopted West Australian control of use regulations[30].

[29] **Consultation Regulation Impact Statement - A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals: Page 39**

[30] Regulation 87 Use in accordance with label (Health (Pesticides) Regulations 2011) allowing
- Use of a pesticide for an unspecified pest on a registered crop,
- Use of a pesticide at a lower frequency than that shown on the label,
- Use of a pesticide at a lower rate of application than that shown on the label, and
- Use of a pesticide for a crop/pest combination registered in another jurisdiction

http://www.austlii.edu.au/au/legis/wa/consol_reg/hr2011277/

Control of Use

As previously indicated the AMGA does not agree with a command and control style approach to the regulation of agvet chemicals and therefore agrees that punitive legal action should not be the primary regulatory device. The association is therefore supportive of approaches to explore how regulatory requirements and those associated with QA, stewardship and other industry schemes could be integrated to provide less restrictive incentive-based controls.

The association however considers that relying solely on compliance activities, e.g., monitoring, traceback and response, as the main mechanism to achieve more effective risk management is unlikely to achieve its aim. In its simplest form monitoring will provide a measure of performance, i.e., whether standards are complied with, as well as an indication of whether current risk mitigation measures are adequate. While monitoring is important, to provide a basis for ongoing improvement the association believes such activity must be linked with research programs, e.g., chemical × commodity data generation, in order to facilitate future enhancements in both the delivery of additional pest management options as well as ensuring ongoing improvement in both risk management and monitoring strategies.

Regards,

G Seymour
General Manager

Proposed Tiered approach and permissible uses - Critique

It's unclear how the three tiered approach would address the issue of moving minor uses onto labels. Firstly, where no current approvals exist, what would motivate individual users to pursue permits, given the freedom provided by the permissible use Tier, i.e., why would they bother with Tiers 1 or 2 (see Figure 1)? Going forward there would be no incentive for users to pursue permits because gaining an approval would restrict their control options, i.e., gaining a permit would preclude the use of otherwise permissible products. Secondly, from a registrant's perspective, given registrations of minor uses are currently deemed unprofitable, why would they pursue label extensions, if use of their product was already permissible, i.e., sales were already occurring. Finally, under a permissible use scheme who will have responsibility for the provision of data to ensure safe and efficacious uses of pesticides?

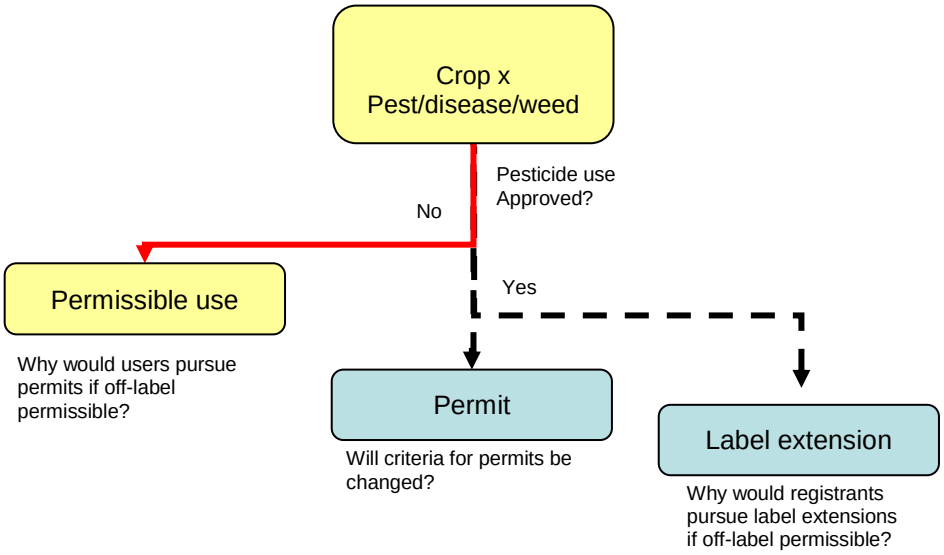

Figure 1 Permissible use hierarchy

Case study
In order to explore the possible mechanics of how a permissible scheme might operate the recent registration of the fungicide mandipropamid (Revus®) for the control of downy mildew in grapes was taken as a case study.

To gain an appreciation of the extent of the minor use issue, all currently approved horticultural uses for downy mildew control were collated (see Table 1). From the table it can be seen that there are a substantial number of permits in place, with many crops relying solely on permit approvals, i.e., 56% of all approved uses × commodities. Under the proposed Tiered approach, mandipropamid could not be used in any of the 104 commodities (other than grapes) as approvals currently exist for a downy mildew fungicide.

However, what is unclear is what will happen as permits expire? In those 59 commodities relying on permits alone why would a permit holder pursue a permit renewal? Once the existing permits expire they would be free to use mandipropamid or any other downy mildew fungicide, rather than be restricted to what is approved. If that were to occur who establishes the appropriate use pattern and how would MRLs for mandipropamid be established?

Under the proposed scheme, it is understood that an approved use would disallow a permissible use. In effect the current situation in the majority of Australian jurisdictions, i.e.,

off-label use would be illegal. From a quick scan of the list of commodities (see Annex 1) it can be seen that grapes (table and wine) are the primary target markets for registrants; followed by cucurbits, lettuce and onions. Given registrants currently rarely pursue label extensions for minor crops, due to the lack of profitability; it is difficult to see why this situation would change, i.e., why would they pursue registrations for crops such as basil, mint or snake gourd under a permissible use scheme.

Also, under a permissible use scheme mandipropamid would be available for use in the various crops lacking approvals; as a result sales would already be occurring. In which case there would be little incentive for the registrant to commit resources to legitimise uses with no expectation of additional financial gain.

Table 1 Downy mildew approvals

Types of approvals	**Numbers**
Commodities – registrations alone	25
commodities – registrations + permits	21
Commodities – permit alone	59
Total	105

Data protection incentives

Class A

While indicated in legislation it is unclear whether any criteria or system has been applied, whereby the addition of non-major uses gained a registrant an extension in data protection. Nevertheless, an approach that provided incentives for registrants to pursue label extensions is worth considering. However, a potential failing of the current concept of extended data protection for minor crop/use label additions for Class A data was identified by registrants.

The added length of data protection would need to be significant. It is not uncommon for the length of patent protection to exceed the period of data protection in Australia. Therefore, for this approach to be attractive the period of data protection on offer would need to exceed the patent period by a significant margin. Using mandipropamid as an example, it is understood that the patent expires in 2021, which is two years longer than the time period provided under current regulatory arrangements. It is therefore difficult to see why a registrant would pursue 15 minor use label extensions to gain one additional year?

Class B

Class B data protection arrangements were described by registrants as a form of 'Clayton's' data protection. In that, while data protection may exist, in practical terms a registrant would be hard pressed to gain any financial advantage where generic competitor products existed. The difficulties stemmed from:

an inability to seek a premium as this would be commercially disadvantageous in other crops;

the likelihood that users were more likely to purchase the cheapest rather than the approved; and

the fact that there was no effective way of enforcing compliance, i.e., once a use was approved there was no effective mechanism whereby users could be compelled to purchase the approved product.

At the time State government regulators acknowledged that it was highly unlikely a user of a non-approved product, where an approved use existed, would be pursued, as the key regulatory elements were in place, i.e., GAP[31] and MRL. Quality assurance programs have been raised as potential options, however, the uptake of QA schemes in agriculture is not universal and placing the responsibility for ensuring compliance onto private QA schemes

[31] **Good Agricultural Practice**

and their auditors would seem somewhat problematic.

Crop Groupings
The concept of crop groupings is not new to either, industry, manufacturers or the APVMA. At issue has always been the matter of providing sufficient data to satisfy the APVMA and the manufacturers that the application of a crop grouping is unlikely to jeopardise either efficacy or crop safety. Under a Tiered approach I doubt that is likely to change. Registrants are unlikely to pursue crop groupings where any uncertainty exists. In order to remove any potential uncertainty trial data will be required. It is unclear under the proposed permissible use scheme who will have the responsibility of generating the data.

Residues
Managing residues
In a permissible use scheme it is unclear how the issue of residue compliance will be managed. What use patterns will be followed where residue profiles are unknown, i.e., what will constitute good agricultural practice to achieve compliance, whether at non-detect levels (below the LOQ) or below a default MRL. Who will have the responsibility of generating the required data?

Establishment of MRLs
Concerns have been expressed that the current Victorian system is underpinned, in part, by other States requiring APVMA approval, i.e., risk assessments are completed and appropriate standards established.
Highlighting this fact in the most recent FSANZ Notifications M1006 & M1007 60%[32] of new MRLs proposed for inclusion in the Food Code arose from permits.
If the need for permits decline, due to permissible uses, through what mechanism will standards be established going into the future, particularly if detectable residues are anticipated

Residue violations
In reviewing Victorian monitoring data (see the Table 2 below) across all commodities the violation rate has averaged about 7.23%. For comparison purposes residue monitoring data from NSW[33] (1995 to 2005) indicates an average violation rate of 4.5%.
While this provides an overarching view, when the VPMP data is looked at in detail areas of concern emerge. For example, the 08/09 data[34] indicates that for carrots 50% of samples were violative, parsnips 66% and for squash and cucumber 33% were violative.
While these violations were unlikely to raise any health concerns they go to the heart to the issue of maintaining consumer confidence and the rigour of the regulatory system.

In the 08/09 VPMP Report it was indicated that 64% of samples contained no detectable residues. Therefore, 36% of samples had detectable residues and presumably the majority complied with the relevant MRLs.

Table 2 Summary of VPMP residue monitoring data reported for1999 to 2009.

Commodity	YEAR % compliance								
	08-09	07-08	2006	2005	2004	2003	2002	99-00	TOTAL
All samples	5%	8.54%	11.42 %	8.44%	4.43%	5.18%	3.34%	11.5%	7.23%
All Fruit	2.5%	9.1%	7.2%	1.2%	Nil	Nil	3.5%	20%	5.44%

[32] **Excluding import tolerances**
[33] **http://www.dpi.nsw.gov.au/agriculture/horticulture/vegetables/soil/monitoring**
[34] **http://new.dpi.vic.gov.au/agriculture/about-agriculture/publications-resources/produce-monitoring-report-200809**

All Vegetables	6.25%	7.5%	11.8%	10.7%	5.2%	6.3%	4%	8%	7.5%
All Herbs	**25%**	**Not tested**	24%	42%	15%	16%	Not tested	Not tested	24.4%
Grains	**Not tested**	**Not tested**	**Not tested**	**Not tested**	6%	Not tested	Nil	Nil	2%

Residue compliance and assessment
It is understood that the concept of a default MRL has been raised as a means of managing incidental low level residues in food where no MRL exists.

The implications of such an approach would be:-
The current APVMA and FSANZ approach when assessing dietary intake of pesticides, i.e., only considering exposure from approved uses, would need to be reviewed.
Under a default MRL scenario all pesticide × commodity combinations would need to be assessed to determine whether any public health concerns would arise from consumption at the default level. Presumably this would involve both short-term and long-term intake assessments.
Consideration as to how residues, reported as non-detectable, would be assessed from a dietary intake perspective would also be needed.

If the APVMA and FSANZ, in assessing long-term dietary intake, were to apply a default level of 0.1 mg/kg, for a number of pesticides, there is a risk of triggering an exceedance of the ADI level. The implication being that for compounds with a low ADI, an outcome of a permissible use scheme, coupled with default MRLs could potentially 'tip' them over the ADI threshold triggering a review.

Based on a preliminary assessment such a situation is unlikely to have an adverse impact on many recently approved compounds but would be likely to impact primarily on older generic pesticides, e.g., abamectin, fipronil, haloxyfop and propineb.

Further, in assessing dietary intake residues reported as non-detect may not necessarily be considered as being zero, from a dietary intake perspective. A residue value (at or below the LOQ) may in fact be applied when doing a long-term dietary intake assessment. In other words residues results reported as below the LOQ, i.e., non-detectable, are unlikely to be treated as zero residues.

Annex 1 Currently approved uses for the control of Downy mildew in horticultural crops.

Commodity	Currently approved pesticides for Downy mildew control	Approved pesticides excluding permits
Balm (Lemon balm) (leaves)	chlorothalonil (PER11526)	
Basil	chlorothalonil (PER11526)	
Beetroot	Copper, mancozeb,	Copper, mancozeb
Bilberries	chlorothalonil (PER11950)	
Bitter melons (gourds)	mancozeb (PER10679)	
Blackberries	chlorothalonil (PER11950)	
Blueberries	chlorothalonil (PER11950)	
Boysenberries	chlorothalonil (PER11950)	
Brassica (Cole) vegetables	Copper, mancozeb,	Copper, mancozeb
Brassica leafy vegetables	mancozeb + metalaxyl (PER10674), phosphorous acid (PER12052), Zineb (PER10845)	
Broccoli	Copper, mancozeb, mancozeb + metalaxyl (PER10674), metiram, phosphorous acid (PER11951)	Copper, mancozeb, metiram
Brussels Sprouts	Copper, mancozeb, mancozeb + metalaxyl (PER10674), metiram, phosphorous acid (PER11951)	Copper, mancozeb, metiram
Burnet (Salad Burnet)	chlorothalonil (PER11526)	
Cabbages	Copper, mancozeb, zineb	Copper, mancozeb, zineb
Cauliflower	Copper, mancozeb, mancozeb + metalaxyl (PER10674), metiram, phosphorous acid (PER11951), zineb	Copper, mancozeb, metiram, zineb
Chervil	chlorothalonil (PER11526)	
Chicory (Leaves)	copper (PER12385), mancozeb + metalaxyl (PER11849), phosphorous acid (PER11951)	
Chillis	mancozeb (PER10679)	
Chinese Broccoli (Gai lan)	dimethomorph + mancozeb (PER10907) Expired	
Chinese Cabbage - Wombok/Pe-tsai/Haksukai	dimethomorph + mancozeb (PER10907) Expired	
Chinese Cabbages (various)	copper,	copper
Chinese Flat Cabbage - Tatsoi	dimethomorph + mancozeb (PER10907) Expired	
Chinese Flowering Cabbage (Choisum)	dimethomorph + mancozeb (PER10907) Expired	
Chinese White Cabbage (Pak-choi)	dimethomorph + mancozeb (PER10907) Expired	
Chinese White Cabbage - Bok choy	dimethomorph + mancozeb (PER10907) Expired	
Chives	chlorothalonil (PER11526)	
Collards	copper	copper

Commodity	Currently approved pesticides for Downy mildew control	Approved pesticides excluding permits
Coriander	chlorothalonil (PER11526)	
Cranberries	chlorothalonil (PER11950)	
Crucifers	zineb	zineb
Cucumbers	chlorothalonil, copper, mancozeb, metalaxyl, metiram, propineb	chlorothalonil, copper, mancozeb, metalaxyl, metiram, propineb
Cucurbits	azoxystrobin, chlorothalonil, copper, dimethomorph, mancozeb, metalaxyl, metiram, phosphorous acid, propineb, oxadyxil, zineb	azoxystrobin, chlorothalonil, copper, dimethomorph, mancozeb, metalaxyl, metiram, phosphorous acid, propineb, oxadyxil, zineb
Curled Mustard - Taishona	dimethomorph + mancozeb (PER10907) Expired	
Currants	chlorothalonil (PER11950)	
Dill	chlorothalonil (PER11526)	
Egg plant	mancozeb (PER10679)	
Egg plants - Asian/Thai varieties	mancozeb (PER10679)	
Endive	copper (PER12385), phosphorous acid (PER11951)	
Fennel (Bulb)	chlorothalonil (PER9043), phosphorous acid (PER7905)	
Fennel (Herb)	chlorothalonil (PER11526)	
Garlic	chlorothalonil (PER10384), copper (PER10484), mancozeb, metalaxyl (PER10379), phosphorous acid (PER7905)	mancozeb
Goa (Winged) beans (immature seeds/pods)	mancozeb (PER10679)	
Gooseberries	chlorothalonil (PER11950)	
Gourds - Bottle (Calabash)	mancozeb (PER10679)	
Gourds - Wax (Winter melons)	mancozeb (PER10679)	
Grapes	*Ametoctradin*, azoxystrobin, captan, copper, dimethomorph, mancozeb, *mandipropamid*, metalaxyl, metiram, phosphorous acid, propineb, oxadyxil, pyraclostrobin, trifloxystrobin, zineb	*Ametoctradin*, azoxystrobin, captan, copper, dimethomorph, mancozeb, *mandipropamid*, metalaxyl, metiram, phosphorous acid, propineb, oxadyxil, pyraclostrobin, trifloxystrobin, zineb
Grapes - Table	chlorothalonil, copper	chlorothalonil, copper
Grapes - Wine	chlorothalonil, copper	chlorothalonil, copper
Honeydew Melons	chlorothalonil	chlorothalonil
Horseradish	azoxystrobin (PER10816) Expired	
Indian Mustard - Gai choy/Am soi	dimethomorph + mancozeb (PER10907) Expired	
Indian Mustard Cabbage - Kai choi	dimethomorph + mancozeb (PER10907) Expired	
Kale	copper, dimethomorph + mancozeb (PER10907) Expired	copper
Kohlrabi	copper	copper

Commodity	Currently approved pesticides for Downy mildew control	Approved pesticides excluding permits
Komatsuma (Spinach mustard)	dimethomorph + mancozeb (PER10907) Expired	
Leeks	azoxystrobin (PER10914), copper, metalaxyl, dimethomorph (PER10902), mancozeb (PER10088), phosphorous acid (PER7905)	copper, metalaxyl
Lettuce - Head	copper, dimethomorph, mancozeb, metalaxyl, phosphorous acid (PER7905), propineb, oxadixyl	copper, dimethomorph, mancozeb, metalaxyl, propineb, oxadixyl
Lettuce - Head/Leaf	copper, dimethomorph, mancozeb, metalaxyl, phosphorous acid (PER7905), propineb, oxadixyl	copper, dimethomorph, mancozeb, metalaxyl, propineb, oxadixyl
Loganberries	chlorothalonil (PER11950)	
Long Beans (Snakebeans)	mancozeb (PER10679)	
Marjoram (Oregano)	chlorothalonil (PER11526)	
Melons	copper, mancozeb	copper, mancozeb
Mibuna	dimethomorph + mancozeb (PER10907) Expired	
Mint	chlorothalonil (PER11526)	
Mizuna (greens)	dimethomorph + mancozeb (PER10907) Expired	
Muskmelon	chlorothalonil	chlorothalonil
Mustard greens	dimethomorph + mancozeb (PER10907) Expired	copper
Mustard/s - Leafy	copper, dimethomorph + mancozeb (PER10907) Expired	copper
Nasturtium leaves	chlorothalonil (PER11526)	
Onions	chlorothalonil, copper, dimethomorph, mancozeb, metalaxyl, phosphorous acid (PER7905), oxadixyl, propineb, zineb	chlorothalonil, copper, dimethomorph, mancozeb, metalaxyl, oxadixyl, propineb, zineb
Paprika	mancozeb + metalaxyl (PER10760) Expired	
Parsley	chlorothalonil (PER11526)	
Peas	chlorothalonil, mancozeb, zineb	chlorothalonil, mancozeb, zineb
Peas - Processing	chlorothalonil	chlorothalonil
Peas - Snow	copper (PER12385), dimethomorph + mancozeb (PER13497), zineb	zineb
Peas - Sugar/Snap (young pods)	copper (PER12385), dimethomorph + mancozeb (PER9485), zineb	zineb
Pumpkins	chlorothalonil, copper, mancozeb	chlorothalonil, copper, mancozeb
Pumpkins - Butternut	copper	copper
Pumpkins - Kabocha	mancozeb (PER10679)	
Radicchio (Italian chicory)	phosphorous acid (PER11951)	
Radishes	copper, metalaxyl	copper, metalaxyl

Commodity	Currently approved pesticides for Downy mildew control	Approved pesticides excluding permits
Rape	copper	copper
Raspberries	chlorothalonil (PER11950), copper	copper
Rhubarb	copper, mancozeb, metalaxyl, phosphorous acid (PER13586)	copper, mancozeb, metalaxyl
Rockmelons (Cantaloupes)	chlorothalonil, copper, mancozeb, propineb	chlorothalonil, copper, mancozeb, propineb
Rucola (Rocket)	mancozeb + metalaxyl (PER10674)	
Rutabaga Greens	dimethomorph + mancozeb (PER10907)	
Sage	chlorothalonil (PER11526)	
Shallots	copper, metalaxyl, dimethomorph + mancozeb (PER11937), mancozeb (PER10088), phosphorous acid (PER7905)	copper, metalaxyl
Silvanberries	chlorothalonil (PER11950)	
Silverbeet (Chard)	chlorothalonil (PER11572), copper, dimethomorph (PER13089), mancozeb, metalaxyl, (PER10727), phosphorous acid (PER11951)	copper
Snake gourds	mancozeb (PER10679)	
Sorrel	chlorothalonil (PER11526)	
Soybeans (immature seeds/pods)	mancozeb (PER10679)	
Spinach	chlorothalonil (PER11572), copper, dimethomorph (PER10906), mancozeb, metalaxyl, (PER10727), phosphorous acid (PER11951)	copper, mancozeb
Spring Onions	chlorothalonil (PER11950), copper, dimethomorph + mancozeb (PER11937), metalaxyl, phosphorous acid (PER7905)	copper, metalaxyl
Squash - various	chlorothalonil, copper, mancozeb	chlorothalonil, copper, mancozeb
Swedes	copper, metalaxyl	copper, metalaxyl
Tobacco	mancozeb, metalaxyl, metiram, propineb, zineb	mancozeb, metalaxyl, metiram, propineb, zineb
Tree Onions	phosphorous acid (PER7905)	
Turnip greens	mancozeb (PER10679)	
Turnips (garden)	copper	copper
Vegetables - Bulb	phosphorous acid (PER7905)	
Vegetables - Leafy - Brassica	copper, metalaxyl, dimethomorph + mancozeb (PER10907) Expired, mancozeb + metalaxyl (PER10674), zineb (PER10845)	copper, metalaxyl
Watermelons	chlorothalonil, copper	chlorothalonil, copper
Youngberries	chlorothalonil (PER11950)	

Commodity	Currently approved pesticides for Downy mildew control	Approved pesticides excluding permits
Zucchinis	chlorothalonil, copper, mancozeb	chlorothalonil, copper, mancozeb

Compounds approved for Downy mildew control

Compound			Registered crops	Crop use Under permit
Copper	M1	Inorganic	Grape vines	Garlic
			Brassica vegetables	Spring onions
			Lettuce	Shallots
			Onions	
			Red beet	
			Rhubarb	
			Spinach, silverbeet	
			Ornamentals	
Furalaxyl	4	Phenylamide	Ornamentals	
Metalaxyl, benalaxyl, oxadixyl	4	Phenylamide	Grapes	Garlic
			Cucurbits	Brassica vegetables
			Lettuce	Brassica leafy veg
			Onions	Silver beet & spinach
			Poppies	
Mancozeb, Metiram, Propineb, Thiram, ziram	M3	Dithiocarbamates	Poppies	Brassica leafy veg
			Cole crops	
			Cucurbits	
			Lettuce	
			Onion & garlic	
			Rhubarb	
			Spinach, silverbeet & beetroot	
			Grapes	
			Peas	
captan	M4	Phthalimide	Grapes	
chlorothalonil	M5	Chloronitriles	Cucurbits	Garlic
			Grapes	Herbs
			Onions	
Dithianon	M9	Anthraquinone	Grapes	
azoxystrobin	11	Quinone outside Inhibitors	Grapes	ornamentals
			Poppies	
			Cucurbits	
trifloxystrobin	11		Grapes	
pyraclostrobin	11		Grapes	
dimethomorph	40	Carboxylic acid amide	Cucurbits	
			Grapes	

Compound			Registered crops	Crop use Under permit
			Lettuce	
			Onions	
			Poppies	
mandipropamid	Group 40	Mandelic acid amide	Grapes	
Phosphorous acid	Group 33	phosphonates	Grapes	
			Cucurbits	
			Poppies	
ametoctradin	Group 45	triazolo-pyrimidylamine	Grapes	

Meeting to discuss the Consultation Regulation Impact Statement for A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals

March 16th, 2011 Meeting Report

A consultation meeting was recently held in Sydney to discuss the Consultation Regulation Impact Statement (CRIS) for A National Scheme for Assessment, Registration and Control of Use of Agricultural and Veterinary Chemicals. Outlined below are a number of the issues raised during the meeting and subsequent discussions.

General

A number of people raised concerns over the lack of any detail on the possible funding model(s) that would underpin the framework.

The point was made that the PSIC website states "process of developing the new framework also considered how the costs of regulatory activities under the new framework will be funded and mechanisms for recovering those costs", however, in the Consultation RIS there was no indication of potential costs associated with different options which potentially would have a significant impact on the selection of preferred options.

Further concerns were raised over the consultative process. Namely the short time provided at this stage and it is uncertain what opportunities will be available into the future.

Concerns were also raised that many of the options presented for consideration in the CRIS were very superficial in nature.

Regulation and assessment

A concern was raised that the various options were being considered in isolation from funding.

Questions raised over the chemical review process w.r.t.: What standard should a product meet, and what impact would the review process have on competition.

Resourcing was raised as an issue as to whether the current model was effective.

That the lack of an overarching policy on chemical usage made the process of identifying possible risk hierarchies or governance models difficult.

Training and licensing

At issue appears to be whether AQF Levels are appropriate levels of training and if so, is Level 3 sufficient to be the base national level for competencies.

That the risks associated with different sectors might require differing levels of competencies, e.g., higher for urban pest controllers.

Whether professional development programs, rather than mandatory recertification, could be utilised in different sectors, depending upon the level of risk.

The issue of competency of training providers was raised.

Control of Use

Regulatory burden

A more liberal approach to management of off-label use was consistent with COAG agreed reforms aimed at "reducing the burden on business from the complex regulation of chemicals".

That the Dairy industry, functions successfully in Victoria, which has the most liberal approach to permitting off-label use. This is success is underpinned through licensing, use of Vendor declarations, the Australian Milk residue survey and audited food safety programs approved by State Dairy Food Authorities.

Standard establishment

Concerns were raised over what impact a more liberal approach would have on the establishment of standards. It was pointed out that in the recent FSANZ notifications more than half of the proposed MRLs arose from permits. If a more liberal approach was adopted what would be the driver for standard establishment and who would provide the data required.

Trade
What are the trade risks of a more liberal control of use scheme?
How would residue compliance be managed? Will this become an industry responsibility?

OH&S
It was pointed out that the RIS was silent on issues to do with worker safety
that under a more liberal scheme current label directions would be insufficient, e.g., re-entry periods, PPE etc may not be appropriate for all potential uses.

Minor use
That there was a need to identify those sectors with the greatest need for increased access. This might allow the development of tailored approaches on permissible uses to address those sectors with greatest needs.
Currently, there is a heavy reliance on permits, which places the cost burden onto users. It was proposed that a government funded program should be initiated to take on that responsibility.

Product Safety & Integrity Committee (PSIC)
Stakeholder Workshop Report

Background
Meeting held in Canberra on the 30th of June, co-ordinated by DAFF. The meeting was attended by over 50 people representing various industry bodies and government agencies (both State and Federal).

It was indicated that a policy framework had been developed that contained agreed policy principles and desired outcomes. This framework has been submitted to the Council of Australian Governments (COAG) for consideration and possible endorsement.

It was also outlined that the guiding principle for the framework is that it must safeguard human health and hold risks to the environment, animal welfare and trade to acceptable limits.

On this basis PSIC are now focussing its activity on developing some policy detail around this framework. The stakeholder workshop was one such activity with participants given an opportunity to outline what features they deemed necessary/desirable in a future a regulatory framework (see the attachment for additional background to the policy framework).

Meeting highlights

As can be expected a broad range of issues were canvassed and discussed during the workshop. These are listed below.

National consistency – The current inconsistencies between state requirements was seen to create impediments to efficient operation. The point was made that any 'boundaries' associated with chemical use should be based on agronomic or climatic criteria rather than state boundaries.

Training, licensing & label advice – As per above the lack of national consistency impacted on requirements with respect to certification, monitoring and enforcement.

Risk appetite – Differing risk appetite was highlighted as reason for different levels of regulation. Further the point was made that the current system lacked a resolution mechanism in the event of divergent advice. This was seen as a concern, particularly by chemical manufacturers, as it impacted on the predictability of the regulatory process. The concept of 'subversive gate-keeping' was also raised in the context of no one agency having primacy with respect to divergent risk assessments.

Minor Use – Current pathways to registration was raised as an issue, in that the current system, i.e., the current one-size-fits-all approach was not designed to meet current needs. The point was made by a number of people that any new system should provide alternative mechanisms that allow 'easier/simpler' pathways to gain regulatory approvals.

Quality Assurance – The possibility of quality assurance schemes being linked with the regulatory framework and user access to chemicals was also raised. Given the purpose of the regulatory framework is to manage risk, whether there was a potential role for QA schemes, codes of practice and best management practice schemes etc to have a role in compliance and enforcement was raised.

Food safety – The perception that pesticide use and MRLs were food safety issues was discussed. Availability of monitoring data and the level of monitoring of imported food was also raised.

New products/technologies – Any system cannot be expected to cover all possible future innovations therefore it needs to be flexible. One means by which this might be achieved was through the development of a tiered approach with regard to risk which are linked to different levels of restriction, i.e., as risks are better understood restriction on use can be either relaxed or tightened.

Regulatory efficiency – Issues raised were both operational and policy related in nature. From an operational perspective the IT system and fee structures were identified as impediments. From a policy perspective the concept of conditional registrations was raised, i.e., conditional registration where minor data gaps identified, greater utilisation of OECD Global Joint Reviews, development of internal assessment guidelines and training to ensure consistency in risk characterisation and decision making of APVMA staff.

Funding – The possible funding mechanisms for the new regulatory system was also touched upon, i.e., part government contributions + fees & chargers vs total user pays. The issue of 'industry capture' being a perception should funding be totally from chemical industry and users was raised, i.e., perception that the regulator would do industry bidding. From a minor use perspective the issue of public funding of minor use was also discussed. The need for a 'public benefit vs private benefit' test was flagged as being needed to justify public funding.

Timeframe & Process

A staged approach is being taken. The first stage has been the development of the overarching national policy framework for the assessment, registration and control of use of agvet chemicals.

Assuming endorsement by COAG a consultation Regulatory Impact Statement (RIS) is planned for circulation and input from stakeholders by the end of September 2010.

Policy Framework – Background

The policy framework sets out agreed policy principles and outcomes. These will provide a firm basis for developing and analysing options and determining a preferred regulatory model.

The focus of PSIC's work for the next 12 months will be on the following
developing the details of the policy instruments needed to implement the new national scheme
examining options for achieving an effective and efficient integrated regulatory scheme such as transfer of powers or national harmonisation of control of use through, for example, the adoption of model legislation
finalising the scope of the framework and determining the roles and responsibilities of the various jurisdictional agencies
developing options for funding the national scheme such as government funding and/or funding by industry (chemical manufacturer and users).

The following *four working groups* of government and non-government stakeholders have been established to assist PSIC in developing a proposal for a new national regulatory framework
Corporate Governance and Policy Development
Assessment and Registration
Training and Licensing
Control of Use.

The *terms of reference* for the working groups are as follows
Consider issues/problems relevant to the particular work area using those raised in the discussion paper as a starting point.
Develop and/or investigate options to address these issues/problems.
Analyse the impact of the options on the efficiency and effectiveness of agvet chemical regulation - that is, benefits and costs.
Report to PSIC on all options and, where possible, recommend a preferred option for PSIC consideration and decision.

The feedback provided by stakeholders in submissions provided in response to the Discussion Paper will be an important input into working group deliberations. Working group discussions will be in-confidence (for government use only) as will any documentation provided to, or produced by, the working groups. The notes and deliberations of working groups may be circulated to PSIC members for constructive comment and input to ensure issues have been adequately considered.

The policy framework includes a number of elements that will need to be considered:
The Operating Environment
Assessment and Registration
Assessment and Use Information (standard/label)
Permissible Uses
Management of the Chemical Portfolio
Continuous Improvement (feedback)

- Compliance – including product quality.

ATTACHMENT A

TIMETABLE FOR DEVELOPING THE IMPLEMENTATION DETAILS OF THE NATIONAL AGVET CHEMICAL REGULATORY FRAMEWORK

TASK	2010							2011					
	J	J	A	S	O	N	D	J	F	M	A	M	J
COAG endorsement of national policy framework													
Stakeholder information sharing/consultation													
Develop implementation details													
Prepare COAG consultation RIS													
Prepare PSIC/AWPIT agenda papers which seek endorsement to release the COAG consultation RIS													
PSIC/AWPIT endorsement													
Stakeholder comments on COAG consultation RIS													
Finalise COAG decision RIS													
Prepare PISC PIMC agenda papers which seek endorsement of the new regulatory model													
PSIC/AWPIT endorsement													
PISC meeting (10/11 March)													
PIMC meeting (14/15 April)													
BRCWG meeting (date to be advised)													
COAG meeting													

Better Regulations – Agvet chemical reform

The XXXX Association is the representative body of the domestic Australian XXX industry. We have reviewed the proposed Better Regulatory reforms on behalf of XXXXX growers and offer our comments as follows.

As we understand it, the purpose of the proposed reforms is to improve the regulatory process, in particular to address issues relating to larger manufacturer registrants who may be exploiting the system by making substandard applications and in so doing waste APVMA time and resources.

While we support the overall objective, the industry is concerned that minor agricultural industries, who do not have the same resources at their disposal, will be unfairly caught in the same regulatory net. Minor crop industries are forced to seek access to essential agchemicals, because major manufacturers see no commercial imperative in seeking registration for them. These industries have to bear the cost of seeking permits, and these costs cannot be recouped.

Thus far, the smaller industries have been heavily reliant on the minor use permit scheme of the APVMA to provide vital pest and disease management tools.

The proposed regulatory reforms appear to focus on a wholesale solution to misdemeanours perpetrated by the larger manufacturers seeking permits. The reforms do not address the unique predicament faced by minor crop industries. A no doubt unintended consequence is that by treating minor use permit applications with the same constraints, this will severely impact XXXX members' ability to access off-label minor use permits, with the potential to adversely affect their businesses.

The proposed regulations would make preparing and applying for minor use permits significantly more difficult and expensive for minor use industries. The draft regulations appear to preclude any consultation or negotiation by the APVMA with an industry once their application has been lodged and clearly curtail the APVMA's flexibility in dealing with minor use permit applications.

We are aware that there is option of pre-submission consultations. However, it appears that such consultations would result in an additional cost, and this is far less feasible for the XXXX industry as a minor participant. Again, it seems the minor growers are being caught in the large chemical manufacturers' net.

Also, the former Subsection 11 (3) allowed for minor industries to consult the APVMA regarding aspects of a minor use permit application.

However, the draft new regulations imply that the APVMA will refuse an application if any errors, omissions, or even queries are found during the preliminary assessment. This will give virtually no scope to amend an application. Minor use permit applications are often characterised by uncertainty, so this proposal foreshadows a likely significant increase in rejected applications, followed by re-submitted applications which will attract a new application fee, and further expense for smaller growers.

We also believe that amendments to Subsection 11A (3) will mean that once a flaw in the application is identified, the application will be refused irrespective of the nature of the deficiency. Often errors are easily rectified, e.g. missing ABN number or changed address, but the revised clause not only removes the APVMA's ability to judiciously exercise its discretion, it also puts small growers in the same basket as larger manufacturers who have significantly greater resources with which to ensure correct applications.

Finally, where a minor use application has passed the preliminary assessment but additional information is sought by the APVMA, a key amendment is of great concern. It is proposed that in Subsection 159 (3) the word **mus**t will be used instead of **may.** Although there is the proviso of 'reasonable excuse', the industry fears that an inability to supply further information, perhaps based on a lack of understanding on the part of the grower, will result in refusal without consultation. Allowing for no flexibility and judgment on the part of the APVMA would be disastrous for the minor industries..

Summary

The industry believes that minor use needs will not be served by including that sector's permit applications in the proposed regulatory framework. It will directly contradict the APVMA and government's policy objectives of allowing appropriately regulated access to safe and effective chemicals for minor use industries. We would strongly argue that DAFF needs to exempt minor use permits from these proposed arrangements.

Agvet Chemicals (Better Regulation Reforms)
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry
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The Australian Mushroom Growers Association (AMGA) welcomes the opportunity to provide additional input into the AgVet chemical regulatory reform process. As indicated in the December 2010 submission the AMGA welcomes proposals aimed at facilitating improved administrative processes, timeframes, use of overseas data and assessments, and communication with agvet chemical stakeholders. Of particular interest to the AMGA are initiatives that may help address matters related to minor crops and pesticide access.

With this in mind the AMGA notes that within the draft legislation is proposed an alternative pathway to that of the current Category 25 applications[35], whereby third parties can apply to vary a product label with the consent of a registrant. As indicated in 2010 the relatively small usage of agvet chemicals by the mushroom industry has meant there is little interest from registrants to pursue uses in mushrooms.

As a consequence the AMGA has been actively exploring options to improve access via minor use permits and possible Category 25 applications. However, as previously indicated, while third party label amendments, such as Category 25 applications, are potentially attractive the fees they incur were a significant disincentive. The AMGA therefore reiterates its previous position that a mechanism through which fees could be mitigated fir minor industries should be explored via the implementing regulations.

With regards to permit applications, as indicated the AMGA participates in the APVMA's minor use permit system. From that perspective the AMGA believes that the applications could be more efficiently managed through the development and implementation of electronic application lodgement rather than via legislating preliminary assessment processes[36]. AMGA understood the purpose of the legislation was to "improve the efficiency and effectiveness of the current regulatory arrangements". However, the AMGA struggles to see how laying down specific processes via legislation will achieve this outcome when the application of currently available technology would achieve the outcome more efficiently.

Also of concern to the AMGA is the 10 year exclusion period from applying for permits in the event of being ordered to pay a pecuniary penalty for the contravention of an agvet penalty provision[37]. While the AMGA is confident that such provisions are unlikely to ever affect the Association, there is a concern over how they might impact an individual permit holder or applicant. The AMGA questions the basis for the 10 year period of exclusion. The period cited appears to be an application, in reverse, of the time associated with spent convictions. The AMGA fails to understand the basis for a wholesale application of 10 years with no provisions for, or recognition of, potential minor breaches. AMGA believes such an approach is inconsistent with legislation on spent convictions[38], where minor

[35] **Part 2 Division 3 Section 27 Applications (2) (a).**
[36] **Part 7 Section 110A Preliminary assessment (1)**
[37] **Part 7 Section 112 (3A) (b) (i)**
[38] **Spent Convictions Bill 2009 - South Australia**

offences may be disregarded. Essentially, the AMGA considers the approach, as outlined, to be disproportionate and suggests it should be reconsidered.

Finally, in the legislation it is being proposed that a trigger for the APVMA to consider the need for a review is when 2 or more of 7 nominated overseas regulatory authorities have prohibited use. AMGA is concerned that as these agencies cover both the crop and veterinary sectors, problems may emerge for compounds used in both areas, e.g., deltamethrin, cyromazine or abamectin. The AMGA is concerned that the APVMA could be forced to consider a large number of such compounds upon the implementation of the EU hazard based regulatory scheme, i.e., where use of a compound with dual applications may be prohibited on the basis of policy rather than risk, nevertheless triggering APVMA action.

Yours sincerely,

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Dear

AUSVEG welcomes the opportunity to submit comment on the Government's reform process for the Australian Pesticides and Veterinary Medicines Authority (APVMA), as proposed by the Hon. Joe Ludwig in the Policy Discussion Paper issued in November.

AUSVEG acknowledges that the protection of human health and the environment needs to form the foundation of the agvet chemical regulation. However, AUSVEG wishes to emphasis that this can be best served by ensuring users have access to the necessary tools protection consumer and environmental protection This is just the beginning of the consultation phase, and to this point, AUSVEG believes many of the proposals have merit and is supportive of a risk assessment framework based on sound science, the foundation of which being a weight of evidence approach.

From a user industry perspective, AUSVEG acknowledges there is merit in much of what is proposed but believes these proposals fail to fully address the current situation where access to agchemicals for minor crops can be problematic.

In terms of the objectives as outlined in the discussion paper the industry position on what is considered to be the key elements. The first being issues associated with the APVMA processes involved approving an agvet chemical or its use: e.g., assessment of data, costs and timeframes; and secondly the level of flexibility with regard to compliance with label conditions, e.g., activities falling under State and Territory jurisdictions controlling the use regimes.

1. Implementing complete risk frameworks for agvet chemicals assessment and review

The industry is supportive of an approach where the anticipated outcome is a better alignment in the level of assessment with the level of risk. However, what is unclear from the information provided is how risk, per se, will be determined, particularly on an inter agency basis. The concern from an industry perspective is that a process be developed to avoid situations where differences in the 'risk appetite' between the APVMA and its co-regulators impacts chemical regulation.

Also, what mechanisms for review would be available to ensure the approaches adopted by the respective agencies continue to reflect best practise? Further will the approach to risk be consistent across the respective agencies or will the outcome see the status quo maintained, albeit with better documentation.

Is there likely to be opportunities for stakeholder input into any discussion related to risk and risk management? Particularly as the development of an overarching risk framework is likely to have multi-level impacts on vegetable producers, in terms of pesticide access, use and training.

2. Improve the quality and efficiency of agvet chemical assessment and registration processes

AUSVEG believes that streamlining processes to enable more timely assessments, registrations and reviews is vital. AUSVEG also agrees that the level of assessment required for low-risk products should be reviewed. However, AUSVEG is concerned at the lack of detail provided in the discussion paper. To ensure consistency in decision making what criteria will be used to identify 'low-risk' and how will they be applied? This is particularly important in relation to efficacy data where an independent assessment by the APVMA provides a form of chemical user protection, i.e., that the product is fit for purpose.

Perhaps an approach modelled on that of the US might be appropriate, where for those applications meeting the specified criteria, the submission of efficacy and crop safety data would not be required but should be available in the event confirmation of a claim is required.

Amending the regulated timeframes and developing a process in which extensions to this timeline would need to be mutually agreed upon are viewed as a positive change. However, the offer of an accelerated assessment process for those who are prepared to pay for full-fee cost recovery is not welcomed by AUSVEG. The authority should be providing this service as part of its current government funding.

One aspect that is not explicit in the discussion paper is that of providing regulatory reform that can facilitate registrations of agvet chemicals for minor or speciality crops. AUSVEG believes that a more efficient assessment and registration process, while desirable, is unlikely to substantially alter the current minor use situation, i.e., process changes as outlined are unlikely to alter the current market failure where economic return does not justify the pursuit of registration.

Therefore, AUSVEG would be supportive of reforms where enhanced chemical access for minor uses was a stated outcome. To this end AUSVEG believes that consideration should be given to exploring initiatives in the areas of process efficiency, data protection and fees, which would improve chemical access by facilitating minor uses onto label registrations.

From a process efficiency perspective AUSVEG suggests that a simplified approach whereby agchemical minor uses could be dealt with as an administrative procedure would be desirable. The development of a system modelled on that previously operational in the UK, called the Long Term Arrangements for Extension of Use (LTAEU), would improve access while addressing issues of risk. The UK system allowed Agvet chemicals to be used for minor uses which complied with a range of specified conditions/restrictions, e.g., commodities were not traded, fed to livestock or were significant in the diet. The approach was based on a system of allowed extrapolations, in which crops (with approvals) were listed from which extrapolations could be made to minor crops, e.g., oilseed rape to mustard and linseed or carrot to horseradish, parsnip, salsify and parsley root. Where a proposed commodity × chemical combination complied with the criteria any approval sought could then be dealt with at a purely administrative level, i.e., not require substantive risk assessments to be undertaken. Such an approach would significantly reduce pressure on the APVMAs resources as well as provide clear guidance to ensure compliance from a control-of use perspective.

AUSVEG also urges a change be considered to current data protection arrangements to ensure that options provide incentives for applicants to more actively seek minor use registrations and/or data generation. The changes could include extending the period of data protection through the inclusion of minor crops on labels and protecting data provided in support of minor use permit applications. Coupled with this could be a re-definition of "minor" crops and meaningful crop groupings.

Finally, it is the belief of AUSVEG that the current structure of fees in relation to minor uses needs to be re-assessed. Currently, user groups have two regulatory avenues available to pursue for minor use approvals, minor use permits or Category 25 applications. The Category

25 approach is attractive in that it achieves the outcome of placing uses directly onto product labels. Unfortunately, an anomalous situation exists whereby a minor use permit fee is $350 and the fee for a Category 25 could range from $2,200 to as much as $4,500, for in effect the same assessments. This difference in fees is a significant disincentive. For example, there are currently more 200 minor use permits approved for a range of vegetable crops. In terms of fees, the cost of permits would be of the order of $75,000 whereas for Category 25 applications costs would be a minimum of $450,000 to as much as $850,000.

From an industry perspective, where gaining label claims is the desired outcome, the cost differential is prohibitive and in effect forces industry to pursue minor use permits. As a result AUSVEG believes that consideration should be given to either waiving or substantially reducing the fees associated with Category 25 applications. Such a move would succeed in moving uses onto labels and remove much of the difficulty currently associated with minor use permits.

3 Enhancing the agvet chemical review arrangements

AUSVEG sees as positive the proposal to have a tiered or targeted and structured approach whereby technical reviews will not be required for all registrations. However, there are concerns over the implications of certain elements of the proposal such as the requirements that all agvet chemical approvals and registrations be periodically checked, the concept of 'sunset approvals' and set timeframes for the submission of data.

While AUSVEG acknowledges the importance of ensuring agvet chemicals meet contemporary standards the frequency of these period checks is unclear, what timeframes are likely to be involved in 'sunset approvals', will there be scope to negotiate appropriate timeframes should significant data gaps be identified and lastly, what are the resource implications for this activity, i.e., will it add considerably to the APVMA workload? The provision of further detail on how it is envisaged these elements would function would be helpful.

At present concerns exist that these initiatives may increase regulatory pressure on generic agvet chemicals resulting in a reduction in pest management options, particularly where there is little or incentive for a manufacturer to provide support. This situation can be particularly acute for minor crops. AUSVEG believes that amending the current Class C data protection arrangements, where data protection commences from date of decision rather than date of submission would be a significant improvement.

4. Using overseas assessments to their full extent.

By recognising, in legislation, the ability for overseas research to be considered as applicable in Australia by the APVMA and its co-regulators, AUSVEG believes will allow for a more efficient and informed approval process.

5. Establishing an independent science panel

AUSVEG considers the proposal to establish an independent science panel as positive on the assumption the purpose of the panel is to ensure that decision making is based on sound science and reflects best practise. AUSVEG assumes that the panel would cover not only the APVMA but also its co-regulators.

7. Improving legal interaction with the APVMA

AUSVG believes that improved communication with agvet chemical stakeholders would be a welcome change.

8. Improving the APVMA's compliance enforcement capacity

While not questioning the need for a modern compliance regime AUSVEG queries how such a scheme is to be funded? It is assumed this initiative would involve considerably greater compliance activity on the part of the APVMA which will need to be resourced. Given the governments policy on cost recovery, i.e., from fees and or charges, the ultimate cost of running an increased program will in all likelihood fall to the users.

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Dear

The Australian Mushroom Growers Association (AMGA) welcomes the opportunity to provide a response to Policy Discussion Paper on Australian Pesticides and Veterinary Medicines Authority (APVMA) reform recently released by the Hon. Joe Ludwig.

In representing the interests of the Australian mushroom industry the AMGA takes a broad view of who are its stakeholders, i.e., AMGA attempts to act for the benefit of the whole supply chain not just mushroom producers. The activities undertaken can cover a range of issues but are evident in the gaining and maintaining access to agvet chemicals. Where AMGA is seeking to not just address producer needs but also to ensure wholesalers, retailers and consumers can have confidence that mushrooms are of the highest quality.

The nature of the crop and production system has meant that agvet chemicals, suitable for use in mushrooms, are not only rare but also difficult to access. The latter being an outcome of the relatively limited use of agvet chemicals, i.e., economic returns to manufacturers are not seen as justifying the research, development and registration costs. As a consequence, the AMGA has been in regular contact with the APVMA, the majority of time related to the minor use permit scheme.

From this perspective the AMGA welcomes proposals aimed at facilitating improved administrative processes, timeframes, use of overseas data and assessments, and communication with agvet chemical stakeholders. However, the AMGA believes greater effort is needed to address the issues associated with minor use.

As indicated the mushroom industry suffers from a lack of pest management options. To fill these gaps AMGA has sought minor use permits. To have these permits granted data on residues and or efficacy has had to be submitted to enable the APVMA to undertake its risk assessments. The industry has been prepared to accept the responsibility of carrying the load as it was seen as its obligation to the supply chain. Currently, the AMGA holds three minor use permits and is in the process of preparing applications for an additional two agvet chemicals.

While gaining minor use permits has assisted the industry, the preference is to have such uses moved directly onto labels. As having uses on labels overcomes a number of potential pitfalls,

when seen from a whole supply chain perspective, e.g., issues of confidence in the use, liability and permit renewal.

As indicated previously the mushroom industry is unique in its requirements, e.g., access to fungicides that do not adversely affect mushroom mycelium. As a consequence the industry has had in operation a Pest and Disease Management Committee. This committee has been tasked with undertaking strategic reviews and identifying potential solutions to fill any pest management gaps.

Given the relatively small usage of agvet chemicals by the mushroom industry there has been little interest form manufacturers to add mushrooms to their product labels. As a consequence the AMGA has been considering exploring opportunities to pursue Category 25 applications to gain label approvals. Unfortunately, the fees associated with Category 25 applications are seen as a significant impediment.

The AMGA acknowledges that a complete abolition of Category 25 fees may be seen as too extreme a step. It is therefore suggested that a fee waiver could be linked to evidence that an industry has undertaken a strategic review, prioritised its pest management needs and is seeking to gain a label approval on that basis. Such an approach would be in line with current practice in the US and Canada. For example, in the US the IR-4 program hold a series of regional and national workshops from which industry needs are agreed and prioritised and for these projects the US EPA waives the submission fees.

Such an approach would not only be of benefit to users, bet manufacturers and the APVMA as well, it would ensure genuine pest management needs are addressed, appropriate risk assessments are undertaken, uses are placed onto labels and the APVMA would not have the prospect of having to assess a renewal application, i.e., better utilisation of resources.

AMGA therefore, commends the idea to DAFF and suggests that such an approach could help address a number of the shortcomings currently associated with the minor use permit scheme.

Regards,

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This submission is a joint response from the undersigned horticultural industry bodies. These industry groups seek to represent the interests of horticultural chemical users nationally. From this perspective welcomes the opportunity to provide a response to the Agricultural and Veterinary Chemicals Legislation Amendments. Outlined below are specific responses to various questions posed in the consultation paper.

(a) What are your views about these proposed changes to legislation?

While recognizing it is essential for agvet chemicals to meet contemporary standards the industries were concerned that the approach towards chemical re-registration in the legislation signified a potential shift in regulatory approach away from risk-based assessment, given the criteria to be utilised in triggering re-registration cycles. Consequently, the industries support the proposed amendments repealing re-registration requirements.

(b) What are your views about requiring electronic lodgement of application information and fees?

Horticultural industries favour the concept of electronic lodgement of application forms as operationally such an approach should provide efficiencies. However, a number of concerns have been raised over how such an approach will impact upon minor use and emergency use permit applicants. Firstly, it is uncertain what information will need to accompany an application. Section 8B (1) of the Act indicates that "*the APVMA may, by legislative instrument, specify the information that must be contained in, or accompany, the application*". As this is currently unknown, concerns exist that potential permit applicants will be unable to lodge their applications as they will not be able to comply with, or complete the requirements as stipulated on an electronic form. As a result the industries believe for Category 20, 21 and

22 applications there needs to be a mechanism where permit applicants, unable to successfully lodge an application electronically, are directed towards an alternative lodgement pathway.

Secondly, the Act, in Section 110A(3) (c)[39], requires that any defects in an application be rectified within 1 month and that the APVMA must refuse the application if defects are not rectified within the month or if the "*APVMA is not satisfied that defects in the application can reasonably be rectified*"[40]. The difficulty from a minor use or emergency use perspective is that permit applicants can often have little data to provide in support of an application.

Unfortunately, as the Regulations[41] currently stand such minor use or emergency use permit applicants will have their applications refused if they are unable to provide certain information within the specified timeframe. Currently, many minor use permit applications are based on extrapolation and scientific argument. In such cases the APVMA may issue a permit with a requirement for future submission of confirmatory data. This allows access to the chemical while the required data is generated. Under the proposed framework this would not be possible and have the effect of delaying access.

Consequently, horticultural industries believe that for permits, applicants must be given the ability to negotiate directly with the APVMA before an application is refused. Such a move would improve the efficiency of the process as it would provide an opportunity for the applicant and the APVMA to agree on how identified data gaps could be addressed without incurring unnecessary application refusals and loss of fees.

To this end the industries propose that the Regulations be further amended as follows (proposed text for inclusion in red):

[39] Agricultural and Veterinary Chemicals Legislation Amendment Bill 2013
[40] Section 110A(4) (a) and (b)
[41] Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 1) Regulation 2013 [Select Legislative Instrument No. 108, 2013]

Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013

8AP Matters for notice for technical assessment

(i) For applications other than those made under s110, that if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code;

For applications made under s110, if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code; or the applicant may agree with the APVMA to a longer timeframe

8AQ Matters for notice in relation to extension of permit

(i) For applications other than those made under s110, that if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code;

For applications made under s110, if the APVMA does not determine the application within the assessment period for the application and any extension to the assessment period, the applicant may notify the APVMA that it wishes to treat the application as having been refused, and may seek review of the refusal in accordance with subsection 165(3) of the Code; or the applicant may agree with the APVMA to a longer timeframe

In sections 65A and 76A of the Regulation there is no text relating to minor use permits allowing an extension to the time periods to provide additional information or for the

APVMA to assess that information. It is suggested that that the following text be inserted.

65A Period for giving additional information, report or sample

(6) For an application for a minor use permit, the maximum period is the period agreed to by the APVMA and the applicant.

76A Extended assessment periods

(2)(a) The extended assessment period for an application for a minor use permit is the period agreed to by the APVMA and the applicant.

Permit Renewals

Under Regulation 57B (h) it is indicated that "reasonable grounds" must be shown as to why an application to register has not been made during the life of the permit. It appears that given *section 27 Applications (2) (a)* of the Act now allows applicants, other than registrants, to apply to amend labels, a permit holder must provide "reasonable grounds" as to why they have not done so. As holders of many minor use permits the horticultural industries are concerned what will be considered 'reasonable grounds' and how this may affect future permit renewals. Could the application of a 'reasonable grounds' test result in applications for permit renewal being refused despite the original circumstances under which a permit was issued remaining, e.g., lack of approved options?

To seek an industry initiated label extension into a minor crop, the fee from July 1st will be $7,775. For many horticultural industries, the cost of fees, and associated data generation, to progress permits to label extensions would be prohibitive. The industries therefore believe to avoid any ambiguity that 57B (h) should also be repealed.

57B Duration of permit—extension for further period

~~(h) if an application has not been made by any person for variation of a relevant particular or condition of approval or registration for the active constituent or chemical product in respect to which the permit is issued – that there are reasonable grounds for the application not having been made.~~

Fit person Test

The Regulations now contain a "Fit Person Test' Under 112 (3A) (b) (i) to (xi) regarding the issuing of permits. It is indicated that the APVMA must refuse an application if the applicant or any other person who makes, or participates in making decisions that affect the whole, or a substantial part, of the applicant's affairs has within the 10 years immediately before the application been convicted or incurred a pecuniary penalty under a variety of Commonwealth, State or Territory laws, as outline in the regulation.

The purpose of this provision in relation to minor use or emergency use permit applicants is unclear and seems unnecessarily punitive. An individual captured under the above criteria can still purchase an agvet product; use it as per any approved uses but is not able to apply for any minor use permit for a period of 10 years. Conceivably, a grower could buy a product for use on an approved crop, but be prohibited from applying for a minor use permit to allow on the same farm for 10 years. In addition, the provisions appear to lack relevance in certain States and Territories, given differing State control of use legislation. For example, the Victorian control of use arrangements or Regulation 87 in WA, allow certain off-label uses irrespective of a 'fit person test'. Also as States can issue permits themselves, e.g., South Australia's horticultural exemption scheme, the 'fit person test' for minor use applicants would appear to be redundant and effectively place growers in certain jurisdictions at a potential competitive disadvantage where they would be prohibited from applying to gain access to an agvet chemical despite this not being the case elsewhere.

It is therefore is difficult to understand what outcome is being sought in relation to minor use or emergency use permits under the "fit person test' regulation. If the intent is to address potential issues associated with the possession and supply of products that are either unregistered or not fit for purpose, i.e., as per s109, then the industry groups would suggest that a more reasonable approach would be to exempt minor and emergency use permit applicants from the 'fit person test' as in reality it serves little practical purpose.

The horticultural industries acknowledges the efforts of the Department to improve efficiencies in the registration process but are concerned that in doing there will be a serious loss of flexibility in pursuing, assessing and managing minor use and emergency use permit applications. As a consequence the industries would ask that the above proposed amendments be given careful consideration within the context of achieving balanced regulatory reform.

Yours sincerely,

Committee Secretary
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Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014

This submission is a joint response from the following horticultural industries bodies. This is a joint submission from the following horticultural industries: Almond Board of Australia, Apple and Pear Australia Ltd, Australian Banana Growers Council Inc, Australian Macadamia Society Ltd, Australian Mango Industry Association Ltd, Australian Melon Association Inc, Australian Mushroom Growers' Association, Australian Nut Industry Council, Australian Onion Industry Association Inc, Australian Table Grape Association Inc, AUSVEG, Avocados Australia Limited, Canned Fruits Industry Council of Australia, Cherry Growers Australia Inc, Chestnuts Australia Inc, Citrus Australia, Custard Apples Australia, Inc Dried Fruits Australia Inc, Growcom, Hazelnut Growers of Australia Inc, Nursery and Garden Industry Australia, Passionfruit Australia Inc, Pistachio Growers Association Inc, Strawberries Australia Inc and Summerfruit Australia Ltd, Turf Australia. Collectively, representing more than 10,500 horticulture farming enterprises nationally.

The above industry groups seek to represent the interests of their grower members on issues that impact on farm productivity and sustainability. It is from this viewpoint the industries welcome the opportunity to provide a submission to the Senate's Rural and Regional Affairs and Transport Legislation Committee inquiry into the proposed Agricultural and Veterinary Chemicals Legislation Amendments.

Agvet chemicals, irrespective of whether they are synthetic or natural in origin, are needed to effectively manage the many weeds, diseases and pests encountered in commercial crop production. Unfortunately, horticultural industries are finding it increasingly difficult to gain

and maintain access to these vital products. It is from this perspective that industries had significant reservations over aspects of the proposed re-approval scheme fearing they would impact negatively on the long-term availability of many agvet chemicals, to the detriment of growers.

Horticultural industries recognize that an important element of the regulatory framework is the re-assessment of older chemicals against contemporary standards. Nevertheless, industries were extremely concerned that the approach taken in the legislation signified a more prescriptive regulatory approach which appeared to be moving away from current risk-based assessments.

From an industry perspective the area of primary concern related to the criteria covering the re-registration timeframes under Section 17A and 17B subsection 8. In particular, the fact that the Regulation adopted the EU classifications with respect to aquatic hazard (Acute I or Chronic I)[42] as one criteria in determining the priority and re-assessment period for agvet chemicals, i.e., compounds categorised under the EU Acute I or Chronic I classification would be subjected to shorter re-registration timeframes of 10 years.

The impact of such an approach would have been significant from both an APVMA and user perspective as the number of compounds meeting the EU criteria is substantial. An analysis of the EU Regulation found over 120 agvet chemicals, old and new, currently approved for use in Australia that fell within the EU classification. These included relatively new chemicals, e.g., azoxystrobin, and etoxazole, many older compounds, e.g., maldison and ziram, disinfectants, e.g., quaternary ammonium compounds and sodium hypochlorite, and compounds used in organic crop production such as copper sulphate and pyrethrins.

Industry groups struggle to understand the rationale behind the adoption of an essentially EU approach to aquatic hazards and cut-off criteria. Environmental toxicity of chemicals can be affected by several factors, such as the magnitude, duration and frequency of exposure. From that perspective the relevance of an EU hazard classification to risk assessment, under Australian conditions, is unclear.

[42] **REGULATION (EC) No 1272/2008**

The required earlier re-assessment of such a large number of 'priority' compounds would have had significant resourcing and workload implications for the APVMA and allied agencies. Under Section 81 of Schedule 1 "**End dates and last renewal dates for existing approvals and registrations"**[43] it is indicated under subregulation 3 that

a) the end date for the approval of the active constituent mentioned in subregulation (4) is 30 June 2015;
b) the last renewal date for the registration of the chemical product containing an active constituent mentioned in subregulation (4) is 30 June 2015.

Subregulation 4 (o) (ii) indicates the end date of June 30th 2015 applies to any compound classified as Aquatic Chronic 1 in Table 3.1 of Annex VI of the European Community Regulation Number 1272/2008 as in force on the registration date. This would potentially require the APVMA to schedule over 120 agvet chemicals for re-assessment within 10 years of June 30, 2015, irrespective of whether any evidence existed of environmental or human health concerns, i.e., purely due to their presence on the EU aquatic hazard list. Such an overly-prescriptive approach would likely have led to a disproportionately expensive regime, for the APVMA, the registrants and the users.

Coupled with this would have been the requirement for supporting data to be provided for those compounds to be reviewed. Given the primary driver for registrants is financial return it is likely that many agvet chemicals would not be supported due to a need to for registrants to prioritise their resources on a return on investment basis. Further the costs incurred in re-registering agvet chemicals would add significantly to the costs passed on to users, i.e., the growers, placing them at further competitive disadvantage. The allocation of resources would also have been the scenario facing horticultural industries wishing to support continued access to agvet chemicals under re-assessment, i.e., industry funding to support all nominated compounds could not be provided in the requisite timeframes. The unforseen outcome of which would have been the loss of access to many needed agvet chemicals, irrespective of any identified concerns.

Finally, the legislation contained a trigger for the APVMA to consider the need for a review when 2 or more of 7 'prescribed' foreign regulatory authorities have prohibited use[44]. Industry concern over such a provision stems from the fact that countries can seek to prohibit uses

[43] Agricultural and Veterinary Chemicals Legislation Amendment (2013 Measures No. 2) Regulation 2013 Select Legislative Instrument No. 179, 2013

[44] **Regulation 22D**

based on factors other than science. The outcome of which would be such agvet chemicals would automatically have to be considered for re-assessment by the APVMA, again irrespective of any identified concerns locally.

The industries understand that repealing the legislation will not remove the requirement for re-assessment but will help ensure a more balanced approach to the review process that will help ensure regulatory action is proportionate to risk. Consequently, the undersigned industries support the proposed amendments to repeal re-registration requirements.

Yours sincerely,

The implications of the restriction on the use of Fenthion on Australia's horticultural industry.

Ausveg welcomes this opportunity to contribute to the Senate Rural and Regional Affairs and Transport References Committee inquiry into the implications of the use of fenthion. Ausveg is the national peak industry body for the vegetable sector, one of the largest agricultural industries in Australia, with a retail value in excess of $1.8 billion annually. In this capacity Ausveg works towards meeting both the current and strategic needs of individual vegetable industries across a number of issues including biosecurity and chemical access. As the review of fenthion is affecting the fruit fly susceptible, fruiting vegetable commodities of capsicums, eggplants and cucurbits Ausveg has had firsthand experience of the impacts the fenthion review is having on growers.

From a general perspective Ausveg wishes to make two broad points. Firstly, to express the disappointment growers have with the level and nature of support provided from both federal and state government agencies with regards fruit fly management. Secondly, Ausveg acknowledges that agricultural chemicals used in Australia, both new and old, should meet contemporary standards for safety and that the risk assessment process should be science based and decisions made on a weight of evidence basis. Nevertheless, Ausveg has concerns over aspects of the process associated with the management of any identified risk.

It is from these standpoints that Ausveg would like to provide comments in relation to the specific questions raised by the Committee.

a) *the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;*

Broadly speaking, Ausveg believes that in relation to the regulation of pesticides and veterinary chemicals in Australia there has been a significant disconnect both between and within the various levels of government. This disconnect can be seen at both the policy and operational levels.

From a policy perspective this disconnect has been highlighted through the relatively poor track record of the States and Territories in reaching agreement on various agvet chemical related COAG reforms. Added to this has been the lack of regard shown by the Department of Agriculture to industry concerns raised over elements of the recently enacted reforms to Agvet chemical legislation, such as the re-registration scheme, reinforcing a view that government has had little interest in working with stakeholder to achieve sound outcomes.

The lack of commitment from government can also be seen from the perspective of fruit fly management. Ausveg understand that the implementation of the National Fruit Fly Strategy is currently in limbo. Seven years after its conception, the formation of an implementation committee in 2009 and release of plan in 2010, a functioning strategy is no nearer to fruition.

Regarding chemical reviews, and fenthion in particular, Ausveg believes the level of engagement from government agencies, both state and federal, has also been weak. Ausveg understands that the APVMA is limited in what information can be shared with outside parties, such as users, and cannot pre-judge or pre-empt potential review outcomes. However, other state and federal agencies should be in a position to provide advice and or support with regards to potential review consequences over the life of a review. To date, such activity has been sporadic and reactive.

While there has been some co-ordination regarding domestic quarantine and market access requirements, usually after the fact, there has been a general lack of government involvement in helping to identify and drive the research needed into alternative options and technologies. Industries have essentially been left to seek advice and determine how best to deal with the review and identify and fill the resulting pest management gaps themselves. Those industries with the resources have been in a position to initiate funded research. Those without the

requisite capacity, unfortunately have not.

From a risk management perspective Ausveg understands that the APVMA is constrained by its enabling legislation in what can be considered relevant when undertaking risk assessments of agvet chemicals. Nevertheless, Ausveg believes that there is a case to consider economic impact when developing risk management options. Particularly, when there is a lack of suitable alternatives. Recognizing that safety should not be compromised Ausveg believes that the APVMA, being the risk assessor, would be in the best position to identify 'satisfactory' use patterns.

Currently, where significant safety concerns are identified immediate suspensions/withdrawal of uses occurs. In such cases the APVMA could engage with user groups to develop potential alternative use arrangements and strategies to mitigate the identified risk. Currently, this is being done on an ad hoc, back and forth basis, with industry groups having to develop and propose potential multiple use patterns, following the announced withdrawal, for the APVMA to review and determine what is acceptable. A more efficient approach would be for the APVMA, following discussions with industry, to identify potentially acceptable use arrangements to discuss with users. Such an approach would have the added benefit of creating an approach more focused on achieving reasoned and informed outcomes, both from perspective of the authority and the users.

b) the short- and long-term impact of the decision on stakeholders;

In the short-term the impact on capsicum, eggplant and cucurbit growers has been significant, particularly following on from restrictions placed on dimethoate, further impairing the ability of growers to effectively manage fruit flies. In the interim permits have been sought allowing the use of alternative pesticides to try and fill the gap, often at considerably greater cost.

In addition, a number of the alternatives insecticides sought have also been earmarked for review, casting doubt on their viability as long-term fruit fly control options. In order to address these gaps industry groups, with the capacity, have been obliged to fund research into identifying alternatives.

For other, newer insecticides, with potential to play a role in fruit fly management the research required will, by necessity need to be comprehensive. Firstly, rate screening to determine efficacy, would then be followed by residue analysis to enable the establishment of maximum residue limits. For industries that export there would be the added burden of seeking to have international MRLs established in order to facilitate trade.

Ausveg currently seeks to work collaboratively with registrants to facilitate this process. However, for smaller industries this will be problematic as their small acreage are likely to provide insufficient economic incentive for registrants to pursue approval. Leaving those commodities potentially exposed through a lack of control options.

From a long-term perspective growers also face uncertainty over their ability to maintain market access, both domestic and international. The use of fenthion, and dimethoate, has underpinned many of the practices required under existing market access protocols. The loss of access to fenthion has meant industry groups having to fund the research to develop alternative quarantine procedures.

c) *the effectiveness and sustainability of chemicals other than Fenthion to manage fruit fly;*

As indicated above a number of the currently approved alternatives fruit fly insecticides are earmarked for APVMA review. Given the age of these compounds Ausveg anticipates that data, sufficient to meet contemporary regulatory standards, will be lacking. As a result it is probable that users of these compounds will face also restrictions. Given the limited resources of industry groups the ability to fund research to fill data gaps will be limited. As a result Ausveg considers the reliance on many of these compounds to be unsustainable.

There are a number of newer insecticides and technologies that may have the potential to aid in fruit fly management. The difficulty for many horticultural industries is that efficacy is uncertain and considerable time and resources will be needed to assemble the necessary data with which to first satisfy the APVMA to gain regulatory approval for use, then secondly to gain acceptance of their use as quarantine treatments for market access. As a result it is likely that if effective these options will, at best, only be available in the medium to long-term.

Summerfruit

DAFF – Better Regulation Reforms

As we understand it, the purpose of the proposed reforms is to improve the regulatory process, in particular to address issues relating to chemical manufacturer who may be exploiting the system by making substandard applications and in so doing waste APVMA time and resources.

While we support the overall objective, Summerfruit is concerned that minor agricultural industries, who do not have the same resources at their disposal, will be unfairly caught in the same regulatory net. Many horticultural industries are forced to seek access to essential agchemicals via permits, because the manufacturers see no commercial benefit in pursuing registration. These industries have to bear the cost of seeking permits, and these costs cannot be recouped.

The proposed regulatory reforms appear to focus on a wholesale solution to misdemeanours perpetrated by manufacturers. The reforms do not address the unique predicament faced by many horticultural industries. A no doubt unintended consequence is that by treating minor use permit applications with the same constraints, this will severely impact growers ability to access off-label minor use permits, with the potential to adversely affect their businesses.

The concern is that the proposed regulations will make preparing and applying for minor use permits significantly more difficult and expensive. The draft regulations appear to preclude any consultation or negotiation by the APVMA with an industry once their application has been lodged and clearly curtail the APVMA's flexibility in dealing with minor use permit applications.

The draft new regulations imply that the APVMA will refuse an application if any errors, omissions, are found or even if queries arise during the preliminary assessment. This will give virtually no scope to amend an application. Minor use permit applications are often characterised by uncertainty, so this proposal foreshadows a likely significant increase in rejected applications, followed by re-

submitted applications which will attract a new application fee, and further expense for growers.

Finally, where a minor use application has passed the preliminary assessment but additional information is sought by the APVMA, a key amendment of great concern relates to timeframes It is proposed that in Subsection 159 (3) the word **mus**t will be used instead of **may.** Although there is the proviso of 'reasonable excuse', the industry fears that an inability to supply further information within the timeframe, perhaps based on a lack of understanding on the part of the grower, will result in refusal without consultation. Allowing for no flexibility and judgment on the part of the APVMA would be disastrous for horticultural industries..

Summary

Summerfruit believes that industry needs will not be served by including that sector's permit applications in the proposed regulatory framework. It will directly contradict the APVMA and government's policy objectives of allowing appropriately regulated access to safe and effective chemicals for minor use industries. We would strongly argue that DAFF needs to exempt minor use permits from these proposed arrangements.

First Principles Review of Cost Recovery at the APVMA Consultation Paper

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First Principles Review of Cost Recovery at the APVMA Consultation Paper

This is a joint submission from the following horticultural industries: the Australian Mushroom Growers Association, Avocadoes Australia, The Macadamia Society, Nursery and Garden Industry Association, Growcom, Apples and Pears Australia Ltd. Collectively, representing more than 1500 horticulture farming enterprises nationally, all of which share the common problem of gaining and maintaining access to needed agvet chemicals.

As a result it is appreciated that an opportunity has been provided to make a submission to the Department of Agriculture's First Principles Review of Cost Recovery at the APVMA[45]. The issue of chemical access is a critical one in horticulture as it impacts on the ability of growers to effectively manage pests, weeds and diseases. Due to the diversity of crops grown (thousands of species), their geographical locations and seasonal conditions under which cropping occurs, pest problems encountered are varied with growers needing a range of solutions to deal with pest management challenges they face.

Given the quantum of fees proposed under a fully cost recovered funding model any increase in fees would be damaging to horticultural productivity and impact negatively on the sustainability of Australian horticulture. It is therefore argued that a consistent set fee, at the currently charged level, should be maintained.

Horticultural industries are alarmed over certain assumptions regarding agvet chemical permits that appear to underpin elements of the Consultation Paper. Firstly, the Paper seems to suggest that minor use permits constitute a form of private good, i.e., that those that rely upon a permit are a narrow and identifiable group. The industries would contend that once

[45] **First Principles Review of Cost Recovery at the APVMA Consultation Paper November 2013.**

granted permits are available to all persons. In fact, other than for prescribed chemicals, it is virtually impossible to exclude or restrict individuals from relying upon a permit.

The Commonwealth Cost Recovery Guidelines indicate that "*Cost recovery through a fee could be appropriate if the applicant were to receive an 'exclusive capturable commercial benefit"*. In the case of agvet chemical permits this is not possible. As an APVMA permit is effectively available to all persons generally, there is no exclusive capturable commercial benefit to be gained by the applicant, i.e., the applicant cannot recoup their costs from those that can use a product under permit.

The second concern relates to a somewhat misguided view around the drivers for minor use and permits. The following statements "*ongoing subsidisation of application fees for permits may discourage applicants from registering"* and "*How could potential registrants be incentivised to apply for registration…. rather than relying on users to apply for permits"* suggests some form of market distortion may exist with registrant's decision making influenced by grower's seeking minor use permits. The Paper appears to overlook the fact that registrants seek to register agvet chemicals in those crops they believe will provide sufficient economic return to justify the investment. This is highlighted by an analysis of commodities for which minor use permits were sought for downy mildew control. In 2012, crops with numerous registered fungicides were grapes, lettuce, bulb onions and cucumbers, i.e., major crops from which registrants believed an economical return could be gained. At the same time there were over 50 commodities, e.g., covering various herbs, berries and vegetable crops, for which there were no registered fungicides, where growers only had minor use permits to allow access to approved fungicides.

This situation is further highlighted when new chemical registrations are compared between Australia and other international jurisdictions, see the Table below. While the number of new agvet chemicals being registered in Australia is comparable with other markets, the actual number of crops being placed on those labels is not. This is a direct consequence of the relatively small size of the Australian market, not the availability of minor use permits inhibiting registrations.

Comparison of Recent Agricultural Chemical Registrations in Australia, Canada and the USA (2008 – 2012)

Chemical Type	Australia		United States		Canada	
	No. of New Chemicals	Av No of Crops per label	No. of New Chemicals	Av No of Crops per label	No. of New Chemicals	Av No of Crops per label
Fungicides	10	7	9	32	7	21

Herbicides	8	2	7	11	5	11
Insecticides	7	9	6	25	4	30
Plant Growth Regulators	1	1	0	0	0	0
Total	**26**	**19**	**25**	**68**	**17**	**62**

Compounding this problem is that as growers seek to diversify into new crops, different pest management problems arise for which there are few, if any, registered uses. The outcome of which is the pursuit of minor use permits. For example, in 2012 there were 18 minor use permits allowing the use of various farm chemicals in the production of Asian (Brassica) leafy vegetables, a small emerging vegetable market segment. In addition, there is the permit gained for such new crops as date palm, industrial hemp and tea tree[46]. In such cases the decision to not register is primarily a consequence of market size and the likelihood of not achieving sufficient economic return to justify the investment. It is from these types of crops that a significant portion of permit needs arise as successful pest management is an integral part of improving industry productivity to meet consumer demands.

Outlined below are comments to those questions for which responses were specifically sought.

6.1.4 Extension of permits

Would the subsidisation of application fees for extensions of permit act as a disincentive in moving from the permit environment to on-label use?

Firstly, as indicated it must be remembered that prior to seeking regulatory approval, registrants determine those crops from which they can capture sufficient economic return to warrant investment. The disincentive to register is in fact the current high cost of regulatory compliance mandated upon the registrants not the existence of the minor use permit program. Secondly, that pest management gaps act as the driver for growers to pursue minor use permits. Given an insufficient return on investment was the basis for registrants not pursuing registration, it is difficult to see how this situation would have altered following the issuance of a minor use permit, i.e., the current subsidisation of fees for permit extensions will have little impact on registrant decision making.

From an end user perspective an option exists for individuals, other than registrants, to seek label amendments. However, this option is not seen as particularly practicable, from the perspective of horticultural industries. This lack of application is a consequence of the associated costs, i.e., fees and charges associated with application preparation. It also highlights the deterrent aspect a fully cost recovered approach would have on the transferral of permitted uses to labels. To emphasize this point illustrative examples, from two divergent industries, are provided below.

Case 1: Blackberry and raspberry growers currently rely upon 12 minor use permits to access needed farm chemicals. In the last six months permit extensions were sought and gained for

[46] **PER13793**

six. From July 1st 2014 to seek label extensions under the current funding model the fees would be $9,360 per application, i.e., $56,160 in APVMA fees alone. Added to this would be the cost of data generation and application preparation, all for an industry with estimated annual R&D Levy income for 2013/14 of $135,000. Should full cost recovery be implemented the fees to progress these uses to label would be $24,773 per application[47], i.e., $148,638, compared to $3,667[48] per permit renewal ($22,002). Well beyond the means of this developing industry and would have the effect of stifling any future growth and development.

Case 2: In 2012, 87 permits were issued for various vegetable crops. Of these 19 required additional data generation and submission for future renewal. The cost of this data generation was $631,630. Under a fully cost recovered approach the APVMA renewal fees would be $169,727. When compared to the current fees of $6,650, this would constitute a 25-fold increase. Were the industry to seek label extensions under a 100% cost recovered scheme the fees would be between $470,000 and $615,000[49], an amount which would impact severely on the industries resources and impair its capacity to fund effective research.

Under a fully cost recovered approach the permit renewal fees would place a considerable strain on industry resources and in fact be beyond the capacity of individuals and smaller developing industries to sustain. The substantially higher fees associated with label extensions are prohibitive and would act as a significant disincentive. In turn this would negate any potential benefit that could be gained from recent legislative reforms.

Would an increase in the application fee of up to 100% of the cost of assessment for extensions of permits deter users from renewing a permit?

Under a fully cost recovered approach the lowest fee for a permit renewal would be $3,667, i.e., where no additional data is required, effectively a 10-fold increase when compared to the current $350 fee. Should additional data be required the renewal fee would be $8,933[50] per application. The financial burden this would place on existing permit holders would be significant and for many individuals and smaller industries effectively put an end to any possibility of them seeking renewal. Essentially, full cost recovery for permit extensions would be detrimental as it would severely limit the capacity of all growers, not just those of minor crops, to gain and maintain access to agvet chemicals.

Charging for such approvals would also penalise the individual/industry that seeks the approval because they would bear the full costs associated with seeking regulatory approval yet there is no scope for them to recoup costs. Registrants recoup their costs through sales of their products to end users (growers) whereas permit applicants cannot as the permit is purely to gain and maintain legal use, i.e., in effect a form of public good.

Should charging for renewing all permits be a consistent fee or should cost recovery arrangements instead align with the charging arrangements for the original permit?

Given the quantum of fees proposed under a fully cost recovered funding model any increase in fees would be damaging to horticultural productivity and impact negatively on the sustainability of Australian horticulture. It is therefore argued that a consistent set fee, at the currently charged level, should be maintained.

[47] **Modules 1, 5.4, 8.2 and 11.4**
[48] **Modules 1 and 11.4**
[49] **Modules 1, 5.2 or 5.4, 8.2 and 11.4**
[50] **Modules 1, 5.5 and 11.3**

6.1.5 Minor use permits

What additional cost recovery mechanism would incentivise users to apply for minor use permits?

The decision to seek a minor use permit is driven by the need to manage a pest, weed or disease problem for which there is an identified gap in registered control options. Fortunately, for many minor use permits, information that satisfies the APVMA requirements can be sourced in the public domain. In such cases the costs to growers are not great, consisting of the APVMA application fee and any additional charges incurred should a regulatory professional be engaged to provide assistance. However, where the required information is unavailable and data generation is required the cost can be significant, as shown with the vegetable industry's commitment of $631,630 to generate data to support the renewal of 19 minor use permits.

From the perspective of cost recovery mechanisms, a desirable incentive would be to have a clearer framework to facilitate the progression of minor use permits to label extensions. Following the issuance and use under a minor use permit, after a pre-determined timeframe, the use could be progressed to a label extension where assessment fees were reduced to a substantially lower base. The availability of such a pathway would encourage the submission of permit applications with the intention to progress to on-label registration approval.

Are decisions about seeking a minor use permit largely driven by the cost of data generation for the application? At what point would an APVMA permit fee become a major factor inhibiting applications?

As indicated above the decision to seek minor use permits is driven by the need to manage a pest, weed or disease problem. Data generation, while an issue for many industries, is often a secondary concern. The primary aim is to obtain access to necessary pest management control options to ensure productivity and sustainability. Industry groups in horticulture have embarked on a program of strategic agrichemical review in which potential gaps or shortfalls in relation to key pests, diseases and weeds are pinpointed and through broader consultation potential management options are identified and prioritised and regulatory approval where possible is pursued.

The current $350 fee is generally not seen as a major inhibiting factor, *per se*, however, the funding for minor use permits, particularly for small developing industries, can be problematic given their limited resources, i.e., the $350 fee coupled with preparation costs and if required data generation costs. Nevertheless, irrespective of size all horticultural industries grapple with the issue of funding to gain and maintain access to farm chemicals given the range of issues requiring research. Consequently any increase in APVMA fees would act as a brake on those groups and individuals seeking to fill priority pest management gaps or maintain the longevity of current pesticides through resistance management strategies, i.e., rotation of chemistries.

If industry cross-subsidisation were used, should this continue to come from the sales levy or from a flat annual fee on all registrants?

In either scenario users will pay. Whether via a sales levy or a flat annual fee registrants will pass on any additional costs to users. As a consequence horticultural industries favour the retention of the sales levy approach as it is seen as a more equitable approach.

Is it appropriate for government to fund some or all of this activity?

It would be appropriate for government to play a greater role in relation to minor use and farm chemical access. Whether this could be done via funding or through the combination of funding and developing minor use oriented policy initiatives would need to be explored further. As a result the industries do not necessarily see government funding as the sole solution to minor use. What is required is the development of a sustainable framework which provides incentives to registrants to reconsider minor crops while reducing regulatory hurdles to chemical access that do not jeopardise safety or trade.

6.1.6 Emergency use permits

How much of a benefit are emergency use permits to the broader industry, in addition to the individual applicants?

The benefits from emergency use permits are generally broadly distributed. In the main they are sought on behalf of an industry or on a cross-industry basis. For example in 2012 the APVMA issued emergency use permits for baits to aid in the containment of mouse plague across large areas of south eastern Australia and in 2010 emergency use permits were issued for the management of myrtle rust in NSW by government and industry. The relevance of such permits are not necessarily restricted to an industry or industry sector, many are issued to government agencies, with benefits being extended to the broader community as well. For example, there are currently 13 permits to allow the use of a range of chemicals for the control of Red Imported Fire Ant in a range of situations including domestic and public service areas.

If a small application fee were introduced to discourage applicants from submitting poor quality applications or for chemicals that are unlikely to meet safety, efficacy and trade criteria applications, at what point would this fee become a major disincentive for these permits?

It should be made clear to what extent the APVMA has received poor quality applications for emergency use permits in the past, i.e., how significant a problem has this been that the imposition of a fee is deemed necessary? The purpose of submitting an emergency use application is for the APVMA to consider the proposed use, identify potential risks, and assess whether the risks can be effectively managed. An applicant is unlikely to know the acceptability, or otherwise, of a proposed use and charging a fee in an emergency situation is unlikely to alter that fact. Consequently, unless there is strong evidence to suggest that poor emergency use applications have constituted a significant problem, it is argued that no fee should apply.

If application fees were to apply, should government agencies pay as well?

No, due to their nature, emergency use permits are often required to enable more than just the deployment of an agvet chemical based control option. In the event of an incursion or a regional outbreak of an endemic pest, a government agency can take the 'lead' to implement an effective management campaign. This is particularly important where the agency is seeking a permit as a means to also inform industry participants and the broader public of what is allowable and what they are required to do, e.g., specific quarantine measures relating to the movement of goods, livestock or machinery into or out of a declared area, or providing guidance on treatment and conditions of use for specific agvet chemicals.

Under such circumstance adopting a fully cost recovered approach in relation to government activities would be counter to the principle elaborated in the Commonwealth's Cost Recovery Guidelines that cost recovery may not be appropriate if it undermined the objective of the activity, i.e., the effective management of an exotic pest incursion or an outbreak of plague locusts.

Additionally, stakeholders are invited to provide input on the preferred cost recovery model from those analysed above, the reasoning as to why it is preferred and any further potentially viable cost recovery models.

The lack of financial resources has been identified as a significant factor limiting Australian agvet innovation[51]. The industries would suggest that a lack of resources would also limit the capacity of industries to achieve improvements in productivity. The implementation of a fully cost recovered approach for agvet chemical permits would only serve to further diminish the financial resources available to industries to pursue such gains.

As a consequence the industries believe that until there is real reform in the area of minor use the only equitable option available to fund permit assessments through cross subsidisation via a levy on agvet chemical sales. Particularly, as it is the users of these agvet chemicals who ultimately bear that cost when purchasing the product.

In conclusion, we the undersigned believe that for Australia's farming sector to remain globally competitive access to and use of safe and effective agvet chemicals is an imperative. It is therefore vital that the regulatory framework does not impede this access through the imposition of burdensome fees that individual growers and horticultural industries can ill afford. Government should, in fact, be seeking to reduce the cost of doing business not increasing it. It is therefore recommend to the Department of Agriculture that the full cost recovery options for permits, as outlined in the Consultation Paper, be discounted.

Yours Sincerely,

[51] BioBridge (2012) Benchmarking the Competitiveness of the Australian Animal Health Industry. Global Benchmarking Survey 2011 – Australia. A Report for IFAH and AHA

AUSVEG

Ausveg welcomes this opportunity to provide a response to the Department of Agriculture's consultation paper on cost recovery arrangements at the APVMA[52]. Ausveg is the national peak industry body for the vegetable sector, one of the largest agricultural industries in Australia, with a retail value in excess of $1.8 billion annually. In this capacity Ausveg works towards meeting both the current and strategic needs of individual vegetable industries across a number of issues such as chemical access.

The vegetable industry is one of the most diverse in agriculture with a wide range of crops and crop types grown to meet the needs of the Australian community. However, with that diversity arises a plethora of problems, the most significant of which is ensuring growers are armed with the necessary tools that allow them to maintain productivity as capably and cost-effectively as possible.

Agvet chemicals are one such tool, where achieving grower access can unfortunately often be problematic. Ausveg is concerned that the adoption of fully cost-recovered options with respect to permits, as outlined in the Consultation Paper, would negatively impact on the ability of vegetable growers to gain and maintain access to those needed Agvet chemicals.

General comments

The vegetable industry has a strong concern that the Consultation paper appears to have taken an overly simplistic, sweeping view of permits. For instance, it is indicated that the Cost Recovery Guidelines "*state that costs should be recovered from users of services or those who create the need for regulation, where they are a narrow and identifiable group*".

However, in reality, there is rarely a narrow or identifiable group. The gaining of a minor use permit is effectively a form of pre-market approval, and as outlined in the Cost Recovery Guidelines, can result in individuals free-riding on approvals gained by others. Charging for such approvals would penalise the individual/firm that seeks the approval because they would bear the costs associated with seeking regulatory approval yet there is no scope for them to recoup costs.

As the Guidelines indicate, a fee-for-service approach is not appropriate where others are able to free ride on the approval of the original applicant. Instead Ausveg suggest that an approach where the balance of costs are met via a levy on sales is a more appropriate and equitable way to recover costs.

The Guidelines also indicate that "*Cost recovery through a fee could be appropriate if the applicant were to receive an 'exclusive capturable commercial benefit"*. However, there is no exclusive capturable commercial benefit to be gained by the applicant for a minor use or emergency use permit, since an APVMA approval is available to all potential users, not just the applicant.

In fact the case of minor use permits is analogous to the cost-recovery arrangements applied by FSANZ in the approval of new food standards. In the FSANZ Act the definition of exclusive capturable commercial benefit is triggered by whether the applicant may derive a financial benefit and that other persons would require the applicant's agreement to benefit from the approval. As indicated above APVMA approvals are available to all and do not require the applicant's approval.

Under FSANZ, an exclusive capturable commercial benefit applies if intellectual property

[52] **First Principles Review of Cost Recovery at the APVMA Consultation Paper November 2013.**

rights are claimed by the applicant (or a related entity) on the standard for which they are seeking approval. Given that no data protection can be claimed for information supporting a minor use or emergency use permit application, such applications would fail the FSANZ test and therefore be exempt from the application of a fee.

The uses for which permits are sought highlight the inappropriateness of a 100% cost-recovered fee for permits. In the APVMA's 2011-12 Annual Report it is indicated that 19% of minor use permits issued were for environmental weeds, vermin (e.g., mice, foxes and feral cats) and invertebrate pests (e.g., Fire ants)[53]. Further it is indicated that nearly 10% of permits issued were for emergency uses. It would not be possible for an applicant to gain an exclusive capturable commercial benefit from the use of an approved product in these circumstances.

The Guidelines also state that it should be ensured that "*cost recovery is not undertaken simply to earn revenue*". Based on the amounts quoted, full cost recovery of all permits, minor, emergency and research would add approximately $950K to the APVMA's budget of $30.4 million - approximately 3%. Any benefit to the APVMA would be vastly outweighed by the adverse impact that such an approach would have on the capacity of rural industries to gain and maintain access to new agvet chemicals.

Therefore, from the perspective of permits and permit renewals, Ausveg believes the Commonwealth's Cost Recovery Guidelines provide sufficient justifications to endorse the retention of the current funding approach.

[53] **http://www.apvma.gov.au/about/corporate/annual_reports/index.php**

Specific points
The Paper invites comment on the advantages and disadvantages of the options detailed.

Firstly, there is insufficient detail in the background information on the costs incurred by the APVMA in assessing Category 20, 21 and 22 permit applications.

The Consultation paper indicates that "less than 20% of the cost of the assessment is recovered through the application fee" of $350. It then outlines that in 2011-12, 287 Category 20 (renewal) applications were evaluated by the APVMA at a cost of $775,474. For the same period the APVMA is said to have issued 154 Category 21 (minor use) permits with an assessment cost of $411,026 and 57 Category 22 (emergency use) permits with an assessment cost of $154,014. On an individual permit basis this amounts to $2702 per permit for a renewal, $2702 per permit for an emergency use and $2668 per new permit assessment.

Ausveg questions how these costs have been derived, i.e., how can the average cost of an emergency use permit equal that of a permit renewal? The close alignment of the these costs suggests their derivation is not the result of any real attempt to identify relative costs. Rather they appear to be the result of simple arithmetic. Given that the majority of permit renewals would involve primarily administrative tasks with no data assessment, it is difficult to understand how the assessment cost of renewals could exceed or equal that of a new application, whether for a minor or emergency use. Particularly, when the APVMA's 2009 CRIS cited $700 as a 100% cost-recovered administration fee for a permit. More detailed information on how permit assessment costs were calculated is required.

Secondly, there is no information available in the Paper on why 2011-12 costs are used as the basis for the cost-recovery consultation. Is 2011-12 an appropriate benchmark, what is the contribution of veterinary versus pesticide permits to the costs, and how do these costs compare to historical trends. The APVMA Annual Report for 2011-12 indicated that "*Of the permits finalised, approximately 75 per cent were for minor use permits, 13 per cent were for research purposes, 10 per cent were for emergency uses, and 2 per cent were for export*"[54]. From the apparent simplistic assessment costs provided it is impossible determine to what extent these and other permit types contributed to the assessment cost of the APVMA that year?

Having such information would enable a more considered response regarding the desirability, or otherwise, of the outlined cost recovery options. Information should also be provided on the main drivers of assessment costs to the APVMA, across the range of permit types. For example, the consultation paper indicates that a potential disadvantage of a Sales levy based approach may result in poor quality applications which "*could mean that the APVMA's resources are not best utilised*"[55]. Yet we are given no indication of how significant an issue this is for emergency or minor use permits and, if so, an estimate of what that cost may have been. Basically, the Paper fails to demonstrate that current APVMA practices are effective and efficient, and that the indicated cost of assessments are fair and reasonable.

Emergency Use
In relation to emergency use permits the Paper fails to grasp the basis for emergency use and why government agencies would apply for such permits. Due to their nature, these permits are needed to enable more than just the deployment of chemical control options against a pest or disease. In the event of an incursion a government agency can take the 'lead' to effectively manage the campaign. This is particularly important where the agency is seeking a permit as a means of informing industry participants and the broader public of what is allowable and what

[54] **http://www.apvma.gov.au/about/corporate/annual_reports/2011-12/2-performance-against.html**
[55] **Page 56 Consultation paper**

they are required to do, e.g., specific quarantine measures relating to the movement of goods, livestock or machinery into or out of a declared area, or providing guidance on conditions of use and treatment requirements.

When a pest outbreak flares to plague proportions, agencies can seek to manage control measures by ensuring consistency in control options across a broad range of crops and geographically distinct regions, e.g., locusts. In relation to locusts the Australian Plague Locust Commission is tasked with managing locust populations in inland Australia, i.e., predominantly non-farming areas, which have the potential to inflict damage in more than one member state. In such situations it is difficult to see how Cost Recovery principles of exclusive capturable commercial benefit or that costs should be recovered from users of services or where they are a narrow and identifiable group can be applied.

Minor Use permits, and permit renewals

Ausveg is greatly concerned at the impact a fully cost recovered funding approach would have on chemical access via minor use permits.

Costs

Based on the fees indicated in Appendix 6 of the Paper, the lowest amount, under a 100% cost recovered scheme would be for minor use permit application in a minor crop where no residue assessment was required, i.e., $5,381[56]. Should a residue assessment be required the fee would be $25,880[57]. From the vegetable industries perspective such an increase in fees would make the pursuit of agvet chemical access prohibitive.

For example, in 2011-12 there were 87 permits issued for vegetable commodities. Application fees for these permits were $30,450. Information presented to the Vegetable industry's Technical Advisory Group in 2012, indicated that in 201175% of all new permit applications for minor crops required a residue assessment. Based on that ratio, under a full cost recovery approach, application fees would have been $1,682,200.

In addition, for 19 of the permits the industry has commissioned confirmatory trials to generate data to support future renewal applications[58]. The cost of this data generation is $631,630. The application fees under a fully cost recovered approach to renew these permits would be $8,933 per permit, i.e., $169,727[59] compared to fees of $6,650 under the current approach. For the remaining permits, where no additional data is required, where renewal is sought the fee would be $3,667/permit, i.e., $249,356[60], compared to $350 per permit or $23,800 under the current funding model.

For the vegetable industry such a fee structure would severely restrict the industries capacity to pursue such uses on behalf of growers. This situation would be even more acute for the majority of other horticultural industries given their comparatively small size, i.e., they would lack the resources to fund both data generation and APVMA fees. Effectively making permits or label extensions untenable, thereby severely limiting an industry's ability to develop. For this reason, 100% cost recovery would be inappropriate, particularly given the Cost Recovery Guideline principle that cost recovery may not be warranted where "*it would unduly stifle competition and industry innovation*".

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[56] [Modules 1 (screening - $1,775), 8.3 (efficacy - $1,448) and 11.3 (finalisation - $2,158)]

[57] [Modules 1 (screening - $1,775), 5.3 (residues - $20,499), 8.3 (efficacy - $1,448) and 11.3 (finalisation - $2,158)]

[58] PER13147, PER13089, PER13291, PER11994, PER13579, PER13031, PER13032, PER13111, PER12442, PER13090, PER12947, PER11848, PER13323, PER13860, PER12017, PER11853, PER13466, PER11850 and PER13349

[59] [Modules 1 (screening - $1,775), 5.5 (residues - $5,000) and 11.4 (finalisation - $1,892)]

[60] [Modules 1 (screening - $1,775) and 11.4 (finalisation - $1,892)]

Policy
On page 55 it is stated that "*to reduce barriers to access minor use permits could interfere with policy efforts to encourage registration of new products or uses*" with reference made to section 27 of the Act[61], which is permits applicants, other than registrants, to seek to amend labels. It appears to have been overlooked that such applications are already subject to modular fees, i.e., full cost recovery. The consultation paper appears to argue that charging such applicants full cost recovery will somehow contribute to innovation and facilitate new uses being added to labels rather than impair innovation and development. The paper appears to ignore previous submissions to government from industry groups that the costs of the modular fees were significant barriers in the pursuit of label extensions, e.g., the Australian Mushroom Growers Association[62].

Based on the figures provided in Annex 6[63] of the Paper, an application to vary a label to add a minor crop would fall under Category 14 and be subject to modular fees at a cost of $26,741 or $33,390[64]. If there was a need for a higher rate, then an OH&S assessment and possibly an environmental assessment would be required. In which case the costs would include the OH&S module 6.3 ($9,945) and possibly an environmental assessment module 7.2 ($18,285) would be required. For such an application the fee would be $53,980.

The potential impact of full cost recovery can be highlighted with regards to permit renewals versus label extensions. Should the vegetable industry wish to ultimately progress the 19 uses under permit for which data is being generated onto labels the fee differentials are enormous, virtually equivalent to the cost of data generation (see below). Application fees under a fully cost recovered scheme will reduce the capacity of industry to seek access to agvet chemicals to such an extent as to make the approach unsustainable.

	Data generation	Current arrangements		100% cost recovered	
		Permit renewal	Label extension	Permit renewal	Label extension
19 permits	$631,630	$6,650	$177,840	$169,727	$508,079 – 634,410

Agvet' chemicals are essential for effective and sustainable farming operations. Majority of our members are end-users of 'agvet' chemicals, and do not directly participate in the APVMA 'agvet' chemical registration, approval and labelling processes. However, the APVMA fee structures and cost recovery approach will impact these end-users through higher costs and delaying the availability, or non-availability of chemicals.

Ausveg is concerned that equity issues will arise if a fully cost recovered structure makes more costly for smaller companies and smaller industry groups to participate in APVMA's processes and support R&D activities. Therefore, it would be in the best interest of both the industry and other stakeholders that the goal of any proposed funding reforms should be to ensure the chemical regulatory framework is consistent, streamlined, continually improved,

[61] section 27 Applications (2) (a) of the Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012
[62] http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCsQFjAA&url=http%3A%2F%2Fwww.daff.gov.au%2F__data%2Fassets%2Fpdf_file%2F0006%2F2220855%2FAustralian_Mushroom_Growers_Association.pdf&ei=4Z3YUrDCIoG1lQXOhoC4CQ&usg=AFQjCNEd2RL6qbUfCJN7KHHwd5Z9JKbZiw&bvm=bv.59568121,d.dGI
[63] Pages 122 -123 Appendix 6 of the Consultation paper
[64] Modules 1 (screening - $1,775), 5.2 or 5.4 (residues - $26,309 or 18,667), 8.2 (efficacy - $2,439) and 11.2 (finalisation - $3,860)

flexible, clear and unambiguous, equitable, effective and efficient in order to achieve the desired outcomes at the lowest possible cost. And that there are provisions made for reviews to assess the effectiveness of the resulting structures and outcomes.

Regards,

Response: Cost Recovery – First Principle Consultation paper

General comments

It is indicated that the Cost Recovery Guidelines *"state that costs should be recovered from users of services or those who create the need for regulation, where they are a narrow and identifiable group*". However, the Consultation paper appears to have taken an overly simplistic, sweeping view of permits, i.e., that the group in fact may not always be narrow or identifiable. The gaining of a minor use permit is in effect a form of pre-market approval, and as outlined in the Cost Recovery Guidelines, can result in individuals free-riding on the approval of others. Charging for such approvals would therefore penalise the individual/firm that seeks the approval as the costs associated with seeking regulatory approval are borne by the applicant, i.e., there is no scope to recoup costs. As the Guidelines indicate a fee-for-service approach is not appropriate where others are able to free ride on the approval of the original applicant, in these circumstance cost recovery through a levy approach is more appropriate.

The Guidelines do indicate that "*Cost recovery through a fee could be appropriate if the applicant were to receive an 'exclusive capturable commercial benefit"*. In the case of minor use permits this is not possible as an APVMA approval is available to all potential users, i.e., there is no exclusive capturable commercial benefit to be gained by the applicant as there are more users of a permit than just the applicant. The case of minor use permits is analogous to the cost-recovery arrangements applied by FSANZ in the approval of new food standards. In the FSANZ Act the definition of ECCB is triggered by whether the applicant may derive a financial benefit and that other persons would require the applicant's agreement to benefit from the approval. As indicated above APVMA approvals are available to all and do not require the applicants approval.

FSANZ's approach is that an exclusive capturable commercial benefit will be considered to be conferred if intellectual property rights are claimed by the applicant or a related entity in relation to the standard that is sought to be approved. Given that no data protection can be claimed for information supporting a minor use permit application, such applications would fail the FSANZ test and therefore be exempt from the application of a fee.

The inappropriateness of a 100% cost-recovered fee for permits is further highlighted when the uses for which permits are sought are examined. In the APVMA's 2011-12 Annual Report it is indicated that 19% of minor use permits issued were for environmental weeds, vermin (e.g., foxes and feral cats) and invertebrate pests (e.g., Fire ants)[65]. How would an applicant seek to gain an exclusive capturable commercial benefit from the use of an approved product?

The Guidelines also state that it should be ensured that "*cost recovery is not undertaken simply to earn revenue*". Based on the amounts quoted full cost recovery of all permits, minor, emergency and research is expected to add approximately $950K to the APVMA's budget of $30.4 million, i.e., ~3%. Given the adverse impact that such an approach would have on the capacity of rural industries to gain access to new agvet chemicals any benefit to the APVMA would be vastly outweighed by the damage done.

The Specific comments: - 6.1.4 Extensions of permits and 6.1.5 Minor use permits

The Paper invites comment on the advantages and the disadvantages of the options detailed. Firstly, there is a lack of detail in the background information relating to the costs incurred by the APVMA in assessing Category 20 and 21 permit applications. The Consultation paper indicates that "less than 20% of the cost of the assessment is recovered through the

[65] **http://www.apvma.gov.au/about/corporate/annual_reports/index.php**

application fee". It then outlines in 2011-12, 287 Category 20 applications were evaluated by the APVMA at a cost of $775,474. For the same period the APVMA is said to have issued 154 minor use permits with an assessment cost of $411,026.

On an individual permit basis this amounts to $2702 per permit renewal and $2668 per new permit assessment. Given that the majority of permit renewals would involve primarily administrative tasks, i.e., no data assessment; it is difficult to understand how the assessment cost of renewals could exceed that of new applications. Particularly, as the APVMA's 2009 CRIS cited a figure of $700 as a 100% cost recovered administration fee for a permit. As application fees for Category 23 research permits are modular a clearer explanation as to how the cost attributed to the assessment of permits was calculated is required.

Secondly, the APVMA Annual Report for 2011-12 indicated that "Of the permits finalised, approximately 75 per cent were for minor use permits, 13 per cent were for research purposes, 10 per cent were for emergency uses, and 2 per cent were for export"[66]. Seventeen of these permits were for the use of zinc phosphide in the control of mouse plagues. To what extent did these permits and other permit types contribute to the assessment cost to the APVMA that year? Having this information available would help provide a clearer indication of the main driver of assessment costs to the APVMA, i.e., is 2011-12 an appropriate benchmark, how do these costs compare to historical trends. Having such information would enable a more considered response regarding the desirability, or otherwise, of the outlined options.

There is also the question over the user versus the applicant. The Consultation paper highlights the principle that costs should be sought to be recovered from those who create the need for regulation, "*where they are a narrow and identifiable group*". In relation to Option 4A under disadvantages an assumption appears to have been made that such is the case, given statements such as "*the user of the renewed permit is the applicant*". However, as indicated previously that is not necessarily the case given the broad scope of potential users.

On page 55 it is stated that "*to reduce barriers to access minor use permits could interfere with policy efforts to encourage registration of new products or uses*" with reference made to section 27 Applications (2) (a) of the Better Regs Bill, which is to permit other applicants to amend labels. What appears to have been overlooked is that such applications would be subject to modular fees (Category 14 applications), i.e., full cost recovery. The consultation paper appears to argue that charging such applicants full cost recovery will somehow contribute to innovation and facilitate new uses being added to labels rather than impair innovation and product development. The paper appears to ignore previous submissions from industry groups that the costs of the modular fees were significant barriers in the pursuit of label extensions, e.g., the Australian Mushroom Growers Association[67] and Pulse Aust.

Emergency use permits
The current approach is for the cost of emergency use permits to be recovered through the annual sales levy. Four options are outlined in the paper

The consultation paper indicates that 57 emergency use permits were issued at a cost of $154,014 in 2011-12.

Currently, a variation to a label seeking to include a new minor crop which includes the submission of residues trial data would require the following Modules 1 (screening - $535),

[66] **http://www.apvma.gov.au/about/corporate/annual_reports/2011-12/2-performance-against.html**
[67] **http://www.google.com.au/url?sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=0CCsQFjAA&url=http%3A%2F%2Fwww.daff.gov.au%2F__data%2Fassets%2Fpdf_file%2F0006%2F2220855%2FAustralian_Mushroom_Growers_Association.pdf&ei=4Z3YUrDCIoG1lQXOhoC4CQ&usg=AFQjCNEd2RL6qbUfCJN7KHHwd5Z9JKbZiw&bvm=bv.59568121,d.dGI**

5.3 (residues - $20,499), 8.3 (efficacy - $1,448) and 11.3 (finalisation - $2,158) at a cost of $24,640[68]. If there was also a need for either an OH&S assessment, e.g., a higher rate, or an environmental assessment, e.g., aerial application, then the fees would increase under modules 6.3 by $9,945 for OH&S or under module 7.3 by $4,306 for the environmental assessment with the finalisation fee increasing to $10,134. For such an application the fee would become $42,561 with the addition of an OH&S assessment or $36,922 with an environmental assessment.

Such costs would be prohibitive to industry groups. For example, in 2011-12 the APVMA issued 11 minor use permits for Rubus sp., e.g., Raspberries and blackberries. The permits were to cover a range of pests and diseases as well provide options for resistance management. Using the above costs, where just efficacy and residues assessment was required, under a 100% cost recovered approach, the industry could not have funded have had to paid $88,660 in fees. Given the size of the industry such a fee structure would preclude the industry from pursuing such uses. As the majority of horticultural industries are of a comparatively small size, they would lack the resources to fund data generation and APVMA fees, in effect making permits or label extensions untenable, severely limiting the industry's ability to develop. Reinforcing the view that 100% cost recovery would be inappropriate, particularly given the principle that cost recovery may not be warranted where "*it would unduly stifle competition and industry innovation*".

Under **Options 4A** and **5A** it is indicated that the "*ongoing subsidisation of application fees for permits may discourage applicants from registering",* i.e., suggesting that there would be little incentive to apply for registration while use can occur under a permit. The primary driver for minor use permits arises because the small market size provides insufficient economic incentive for registrants to pursue regulatory approvals, i.e., the cost outweighs the potential benefit. Given that the fee structure for a registrant would either remain the same, or increase, should 100% upfront fee registrations be implemented, it is difficult to see how inhibiting access to permits will improve the economic incentive for registrants. Added to this is the fact that a significant portion of minor use permit applications seek older generic chemistry[69], i.e., multiple registrants further reducing the attractiveness of pursuing label extensions.

Regarding **Option 4B** it is likely that the cost of assessing a renewal application for a minor use permit will be lower than that incurred for the original permit assessment. The renewal of the majority of minor use permits is often administrative in nature. Therefore, as indicated under Option 4B a new set of application fees would need to be introduced for permit extensions. As flagged in the Paper this would add to administrative complexity. Given limited resources it is highly likely that increased permit renewal fees would act as a significant deterrent to potential permit applicants. When looked at in the context of funding data generation, potential fee increases for new applications and the prospect of significant ongoing renewal fees, seeking and maintaining access to agvet chemicals via permits would be beyond the capacity of many industry groups.

Further disadvantages of **Option 4A** relate to a potential disconnect between the fee structures for permits and those for renewals. It is suggested that should one change then there would create unnecessary complexity. However, if there are no changes, i.e., both remain unchanged there would be no disadvantages.

Under **Option 5A** the Paper reiterates that costs should be recovered from users of services or

[68] Appendix 6 Cost Recovery Consultation paper – 100% cost recovered application fee.

[69] Submission on Reforms to Deliver Sustainable Minor Use Crop Protection Solutions for Australia's Agricultural Industries. Dr Stephen Goodwin, Biocontrol Solutions (March 2011).

those who create the need for regulation. However, as indicated previously the Guidelines also indicate that "*Cost recovery through a fee could be appropriate if the applicant were to receive an 'exclusive capturable commercial benefit"*. As previously explained there is little to no scope for an applicant to gain any exclusive capturable commercial benefit, particularly where the permit is for the control of noxious, declared or environmental pest or weed. As a result this should not be considered a disadvantage under Option 5A.

Another disadvantage nominated for **Option 5A** is that "*the level of annual product sales is likely to fall below thresholds set for collection of a sales levy*" and as a result the APVMA would "*probably not be able to recover any costs*". This appears to reflect some confusion between the concept of minor use and that of agvet chemicals where sales fall below leviable thresholds. Minor use, from a cropping context, refers to approvals sought for the use of pesticides on niche or specialty crops, i.e., not specifically for pesticides with limited sales. Minor use permits are predominantly sought for mainstream products, i.e., leviable sales of a product for use under a minor use permit will be captured under the current arrangements. Regarding the reference to unregistered products the Paper lacks detail regarding the extent to which the use of unregistered products have relied upon access via permits, other than for research purposes, which attract modular (full cost recovered) fees, i.e., is this disadvantage real?

Under **Option 5B** it is indicated that "*assessing data for a minor use permit is generally similar to the cost of assessing an application for registration*", and that "*removing the subsidisation of the permit application fee, some parties may instead seek to register the use of a product*". As indicated previously the need for minor use permits is driven by the anticipated low financial return to be gained by a registrant. This is exemplified through a comparison of new agvet chemical registrations between Australia and the USA over the period of 2008 to 1012. During that period 10 new fungicides were approved for use in Australia as compared to nine in the USA. In Australia there was an average of 7 crops per new label, whereas in the USA the number was 32 crops per new label. As these are for new proprietary compounds the difference reflects the commercial attractiveness of those crops. Implementing increased permit fees will not change this situation.

It is argued that an advantage of **Option 5B** is that any user may be permitted to access an agvet chemical under a permit and that subsequent applicants seeking identical minor use permits are able to leverage on the previously completed technical assessment. However, this would apply to all options, not just Option 5B.

Regarding the cost of data generation, currently, where data is required to support an application costs can vary from $10,000 to $35,000 depending upon the number of residue and/or efficacy trials required. As a result seeking permits are for uses considered priorities by industry advisory committees. The cost of the application preparation and fee, while a consideration, is secondary to that of the capacity to fund data generation. In the event that full cost recovery were introduced the cost of fees would become a significant factor. For example, based on current modules a permit for a new minor crop would require the following Modules 1 (screening - $535), 5.4 (residues - $5,600), 8.2 (efficacy - $750) and 11.2 (finalisation - $1,175) at a cost of $8,060[70]. If there was a need for OH&S, e.g., a higher rate, and an environmental assessment, e.g., aerial application, then assessments under modules 6.3 (OH&S) and 7.2 (environment) would be required. For such an application the fee would be $16,530.

Such costs would be prohibitive to industry groups. For example, in 2011-12 the APVMA issued 11 minor use permits for Rubus sp., e.g., Raspberries and blackberries. The permits

[70] **http://www.apvma.gov.au/morag_ag/vol_2/variation/category_14.php**

covered a range of pests and diseases as well providing differing options for resistance management. Using the above scenario where just efficacy and residues assessment was re

quired, under a 100% cost recovered approach, the industry would have had to pay $88,660 in fees. Given the size of the industry such a fee structure would preclude the industry from pursuing such uses. As the majority of horticultural industries are of a comparatively small size, they would lack the resources to fund data generation and APVMA fees, making permits or label extensions untenable, limiting the industry's ability to develop. Reinforcing the view that 100% cost recovery would be inappropriate, particularly given the principle that cost recovery may not be warranted where "*it would unduly stifle competition and industry innovation*".

ATTACHMENT VIII – Codex Meeting Reports

REPORT of 44th SESSION CODEX COMMITTEE ON PESTICIDE RESIDUES

23-28 April 2012, Shanghai, China

Introduction

The Codex Committee on Pesticide Residues (CCPR) held its 44th Session in Shanghai, China, from 23 to 28 April 2012, with two pre-meeting workshops on minor use and risk analysis held on the 21st and 22nd of April. The Meeting was attended by 253 delegates representing 68 Member Countries, one Member Organization and Observers from six international organizations. The full agenda papers and report of the meeting are available at: ftp://ftp.fao.org/codex/meetings/CCPR/CCPR44/

The Australian delegation was led by Mr Ian Reichstein, DAFF, and comprised of seven members representing government (APVMA, DAFF & Qld Health) and industry sectors (horticulture and grains).

The Committee advanced 251 MRLs for adoption as Codex CXLs, i.e., to Step 8 or Step 5/8 (see Appendix I). Of these MRLs, 231 were fast-tracked to Step 5/8. In these cases, Codex CXLs will be established less than a year after evaluation by the Joint Meeting on Pesticide Residues (JMPR

A number of proposals were discussed with regards to new initiatives aimed at improving efficiencies in MRL assessments and promulgations. These included the use of the Proportionality approach, pilot project on MRL estimation prior to registrations, amendments to the Codex classification of foods and feeds; extrapolation, MRLs for minor crops, development of risk analysis principles and agreeing forward priorities for JMPR assessments.

Proportionality

In assessing residue trial data the previous JMPR policy was to only accept a ± 25% variance between trial application rates and the approved application rate. Consequently, for some commodities there was deemed to be insufficient data upon which to base and MRL estimate. A recent study of residue data has identified the possibility of using the concept proportionality. This involves scaling the residues on the basis of the application rate in situations in which the rate applied differed by more than ± 25%.

Adopting such an approach enables the JMPR to recommend more MRLs, particularly for minor crops where the number of trials can be limited. Unfortunately, despite strong argument from a number of counties, including Australia, that were supportive the Delegation of the EU opposed the advancement of all draft MRLs recommended on the basis of proportionality and argued that clear guidance was required before the concept was applied by the JMPR. Australia is chairing an electronic Working Group (eWG) to develop principles and guidance for use of the concept of proportionality to estimate maximum residue levels.

Pilot Project: Codex MRLs before national registrations

At CCPR 43 a pilot project was approved in which residue trial data was assessed by the JMPR prior to a national registration. The 2011 JMPR evaluated **Sulfoxaflor**, an insecticide from DOW and proposed a number of levels that could be used as MRLs. It was agreed by the Meeting to not consider the proposed MRLs until such time as national registrations have occurred and an evaluation of the pilot project is completed, i.e., how closely do the JMPR proposals match those of national approvals.

Codex Classification

The revision of the Codex Classification of Food and Animal Feed is progressing with the draft revision of the Classification for the fruit commodity groups: Citrus fruits, Pome fruits, Stone fruits, Berries and small fruits, and Assorted tropical and subtropical fruits, edible and inedible peel to the Commission for adoption. The next phase of the work is the revision of vegetable commodity classifications.

Principles and guidance for selection of representative commodities for extrapolation

This initiative is to provide guidance on identifying commodities suitable for use as representative commodities to establish crop group MRLs. The basis of the principles is that the selection of representative commodities should take into account similar residue behaviour and that the ALARA (as low as reasonably achievable) Principle should be considered when estimating group MRLs, particularly when considering the potential impact of derived values on dietary risk assessments. The revised draft, together with a table providing examples of the selection of representative fruit commodities, was advanced to Step 8.

MRLs for minor crops and specialty commodities

An eWG chaired by France will continue work towards a new approach to determine the minimum number of field trials required to establish MRLs for minor/specialty commodities. The eWG is using global consumption data as a basis for determining trial number requirements and to develop a table showing the number of trials required for particular commodities.

Risk analysis principles

Little progress was made on revision of the Risk Analysis Principles as Applied by the CCPR. The basis for this work are concerns from some Member countries of the loss of MRLs for older generic pesticides through lack of manufacturer support. Consequently, they are hoping to develop risk analysis principles that would allow the retention of MRLs if no toxicological concerns are identified irrespective of manufacturer support.

As a result the toxicological data requirement, for a JMPR re-evaluation in cases where a pesticide is not supported by the manufacturer, is currently a major point of contention within the Committee. The 2012 JMPR will consider the requirements for data submission in such cases and report back to the 45th CCPR, however the WHO JMPR Joint Secretary indicated

that toxicological data should fulfill the same criteria irrespective of who submitted it.

Priorities

Australia chaired the eWG on Priorities and relevant discussion at plenary. The Committee agreed to the proposed schedule for JMPR evaluations in 2013 (see Appendix II).

The next Session of the CCPR was tentatively scheduled to be held in China in 2013, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

Appendix I MRLs agreed for adoption at CCPR 44.

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
Acephate (095) ADI: 0–0.03 mg/kg bw ARfD: 0.1 mg/kg bw	Rice, husked Rice straw and fodder, dry	1 0.3	
Acetamiprid (246)* ADI: 0–0.07 mg/kg bw ARfD: 0.1 mg/kg bw	Beans, except broad bean and soya bean Beans, shelled Berries and other small fruit (except grapes and strawberries) Cabbages, Head Celery Cherries Citrus fruits Cotton seed Peppers Chili, dried Prunes Edible offal (Mammalian) Eggs Flowerhead brassicas (includes Broccoli: Broccoli, Chinese and Cauliflower) Fruiting vegetables, Cucurbits Fruiting vegetables, other than Cucurbits (except sweet corn & mushrooms) Garlic Grapes Mammalian fats (except milk fats) Meat (from mammals other than marine mammals) Milks Nectarine Onion, Bulb Peach Peas, shelled (succulent seeds) Plums (including Prunes) Pome fruits Poultry meat Poultry, Edible offal of Spinach Spring onions Strawberry Tree nuts	0.4 0.3 2 0.7 1.5 1.5 0.8 0.7 2 0.6 0.05 0.01 * 0.4 0.2 0.2 0.02 0.5 0.02 0.02 0.02 0.7 0.02 0.7 0.3 0.2 0.8 0.01 * 0.05 * 5 e 5 0.5 0.06	
Azoxystrobin (229) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	Coffee beans Ginseng Ginseng, dried including red ginseng	0.02 0.1 0.5	
Clothianidin (238) ADI: 0–0.1 mg/kg bw	Grape juice	0.2	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
ARfD: 0.6 mg/kg bw	Banana	0.02	
	Dried grapes (= currants, raisins and sultanas)	1	
	Edible offal (mammalian)	0.02 (*)	
	Eggs	0.01 (*)	
	Grapes	0.7	
	Mammalian fats (except milk fats)	0.02 (*)	
	Meat (from mammals other than marine mammals)	0.02 (*)	
	Milks	0.02	
	Pome fruits	0.4	
	Poultry fats	0.01 (*)	
	Poultry meat	0.01 (*)	
	Rice	0.5	
	Sorghum	0.01 (*)	
	Sorghum straw and fodder, dry	0.01 (*)	
	Stalk and stem vegetables	0.04	
	Sugar cane	0.4	
	Sweet corn (corn-on-the-cob)	0.01 (*)	
Cypermethrins (including alpha- and zeta- cypermethrin) (118)	Asparagus	0.4	0.01*
ADI: 0–0.02 mg/kg bw	Citrus fruits (except shaddocks or pomelos)	0.3	2
ARfD: 0.04 mg/kg bw	Eggs	0.01*	0.01*
	Poultry, Edible offal of	0.05*	0.05*
	Poultry meat	0.1 (fat)	0.1 (fat)
	Poultry fats	0.1	
	Shaddocks or pomelos	0.5	
	Tea, Green, Black (black, fermented and dried)	15	20
	Tree nuts	0.05*	
Emamectin benzoate (247)*			
ADI: 0–0.0005 mg/kg bw	Beans, except broad bean and soya bean	0.015	
ARfD: 0.03 mg/kg bw	Cos lettuce	1	
	Cotton seed	0.002*	
	Edible offal (Mammalian)	0.08	
	Grapes	0.03	
	Fruiting vegetables, Cucurbits	0.007	
	Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms)	0.02	
	Lettuce, Head	1	
	Lettuce, Leaf	1	
	Mammalian fats (except milk fats)	0.02	
	Meat (from mammals other than marine	0.004	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	mammals)		
	Milks	0.002	
	Mustard greens	0.2	
	Nectarine	0.03	
	Peach	0.03	
	Peppers, Chili (dried)	0.2	
	Pome fruits	0.02	
Etofenprox (184)** ADI: 0–0.03 mg/kg bw ARfD: 1 mg/kg bw	Apple	0.6	
	Beans (dry)	0.05	
	Dried grapes (= currants, Raisins and Sultanas)	8	
	Edible offal (Mammalian)	0.05	
	Eggs	0.01 *	
	Maize	0.05 *	
	Meat (from mammals other than marine mammals)	0.5 (fat)	
	Milks	0.02	
	Nectarine	0.6	
	Pear	0.6	
	Peach	0.6	
	Pome fruits	W	1
	Potato	W	0.01 *
	Poultry meat	0.01 *	
	Poultry, Edible offal of	0.01 *	
	Rape seed	0.01 *	
	Rice	0.01 *	
	Rice straw and fodder, dry	0.05	
Etoxazole (241) ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	Pome fruits	0.07	
Flutriafol (248) * ADI: 0–0.01 mg/kg bw ARfD: 0.05 mg/kg bw	Banana	0.3	
	Coffee beans	0.15	
	Dried grapes (= currants, Raisins and Sultanas)	2	
	Grapes	0.8	
	Peanut	0.15	
	Peanut fodder	20	
	Peppers, Sweet (including pimento or pimiento)	1	
	Peppers Chili, dried	10	
	Pome fruits	0.3	
	Soya bean (dry)	0.4	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Wheat	0.15	
	Wheat bran, unprocessed	0.3	
	Wheat straw and fodder, dry	8	
Glyphosate (158) ADI: 0–mg/kg bw ARfD: Unnecessary	Lentils (dry)	5	
	Sugar beet	15	
	Sweet corn (corn-on-the-cob)	3	
Hexythiazox (176) ADI: 0–0.03 mg/kg bw ARfD: Unnecessary	Hops, dry	3	2 h
	Tea, Green, Black (black, fermented and dried)	15	
Isopyrazam (249)* ADI: 0–0.06 mg/kg bw ARfD: 0.3 mg/kg bw	Banana	0.06	
	Barley	0.07	
	Barley straw and fodder, dry	3	
	Edible offal (Mammalian)	0.02	
	Mammalian fats (except milk fats)	0.01*	
	Meat (from mammals other than marine mammals)	0.01*	
	Milks	0.01*	
	Milk fats	0.02	
	Poultry fats	0.01*	
	Poultry meat	0.01*	
	Poultry, Edible offal of	0.01*	
	Eggs	0.01*	
	Rye	0.03	
	Rye straw and fodder, dry	3	
	Triticale	0.03	
	Triticale straw and fodder, dry	3	
	Wheat	0.03	
	Wheat straw and fodder, dry	3	
	Wheat bran, unprocessed	0.15	
Methamidophos (100) ADI:0-0.004 mg/kg bw ARfD: 0.1 mg/kg bw	Rice, husked	0.6 h	-
	Rice straw and fodder, dry	0.1 h	
			-
Profenofos (171) ADI: 0–0.03 mg/kg bw ARfD: 1.0 mg/kg bw	Peppers, Chili	3	5 l
	Peppers Chili, dried	20	50 l
Pyraclostrobin (210)	Alfalfa fodder	30	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
ADI: 0–0.03 mg/kg bw	Almond	W n	0.02*
ARfD: 0.05 mg/kg bw	Almond hulls	W o	2
	Artichoke, globe	2	
	Barley	1	0.5
	Blackberries	3	
	Blueberries	4	1
	Cherries	3	
	Citrus fruits	2	1
	Cucumber	W p	0.5
	Fruiting vegetables, Cucurbits	0.5	
	Garlic	0.15	0.05*
	Melons, except Watermelon	W p	
	Nectarine	0.3	
	Oats	1	0.5
	Oil seed except peanut	0.4	
	Onion, bulb	1.5	0.2
	Spring onion	1.5	
	Papaya	0.15	0.05*
	Peach	0.3	
	Pecan	W n	0.02*
	Plums (including Prunes)	0.8	
	Raspberries, Red, Black	3	2
	Rye	0.2	
	Sorghum	0.5	
	Squash, Summer	W p	0.3
	Stone fruits	W	1
	Strawberry	1.5	0.5
	Sunflower seed	W q	0.3
	Tree nuts	0.02*	
	Triticale	0.2	
	Orange oil	10	
Saflufenacil (2251)*	Banana	0.01	
ADI: 0–0.05 mg/kg bw	Barley straw and fodder, dry	0.05	
ARfD: Unnecessary	Beans (dry)	0.3	
	Cereal grains	0.01	
	Citrus fruits	0.01	
	Coffee beans	0.01	
	Cotton seed	0.2	
	Grapes	0.01	
	Edible offal (Mammalian)	0.3	
	Maize fodder	0.05	
	Mammalian fats (except milk fats)	0.01	
	Meat (from mammals other than marine mammals)	0.01	
	Milks	0.01	
	Peas (pods and succulent = immature seeds)	0.01	
	Peas, shelled (succulent seeds)	0.01	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Peas, dry	0.05	
	Pome fruits	0.01	
	Rape seed	0.6	
	Sorghum straw and fodder dry	0.05	
	Soya bean (immature seeds)	0.01	
	Soya bean (dry)	0.07	
	Stone fruits	0.01	
	Sunflower seed	0.7	
	Sweet corn	0.01	
	Tree nuts	0.01	
	Wheat straw and fodder, dry	0.05	
Spinosad (203) ADI: 0–0.02 mg/kg bw ARfD: Unnecessary	Blackberries	1	
	Blueberries	0.4	
	Cranberry	0.02	
	Dewberries (including Boysenberry and Loganberry)	1	
	Onion, Bulb	0.1	
	Passion fruit	0.7	
	Raspberries, Red, Black	1	
	Spring onion	4	
	Tree nuts	0.07	
Spirotetramat (234) ADI: 0–0.5 mg/kg bw ARfD: 1.0 mg/kg bw	Cotton seed	0.4	
	Cotton seed meal	1	
	Edible offal (Mammalian)	1	0.03
	Eggs	0.01	
	Legume animal feeds	30	
	Legume vegetables	1.5	
	Litchi	15	
	Kiwifruit	0.02 *	
	Mango	0.3	
	Meat (from mammals other than marine mammals)	0.05	0.01*
	Milks	0.01	0.005*
	Onion, Bulb	0.4	
	Papaya	0.4	
	Poultry meat	0.01*	
	Poultry, Edible offal of	0.01	
	Pulses [except soya bean (dry)]	2	
	Soya bean (dry)	4	
Tebuconazole (189)** ADI: 0–0.03 mg/kg bw ARfD: 0.3 mg/kg bw	Apple	1	
	Apricot	2	
	Artichoke, globe	0.6	0.5
	Banana	0.05	0.05
	Barley	2	0.2 u

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Barley straw and fodder, dry	40	10 (30 u)
	Beans (dry)	0.3	
	Broccoli	0.2	
	Brussels sprout	0.3	
	Cabbages, Head	1	
	Cauliflower	0.05*	
	Carrot	0.4	0.5 u
	Cattle, edible offal of	W	0.05*
	Cherries	4	5
	Cotton seed	2	
	Coffee beans	0.1	0.1
	Coffee beans, roasted	W	0.5
	Cucumber	0.15	0.2
	Dried grapes (=currants, Raisins and Sultanas)	7	3
	Edible offal (Mammalian)	0.2	0.5
	Egg plant	0.1	
	Eggs	0.05*	0.05*
	Elderberries	1.5	2
	Garlic	0.1	0.1 u
	Grapes	6	2
	Hops, dry	40	30
	Leek	0.7	1 u
	Maize	W	0.1 u
	Maize fodder	6	
	Mango	0.05	0.1 u
	Meat (from mammals other than marine mammals)	0.05*	0.05*
	Melons, except Watermelon	0.15	0.2
	Milks	0.01*	0.01*
	Nectarine	2	
	Oats	2	0.05*
	Olives	0.05*	
	Onion, bulb	0.1	0.1
	Papaya	2	2 u
	Passion fruit	0.1	
	Peach	2	1
	Peanut	0.15	0.1 u
	Peanut fodder	40	30
	Pear	1	
	Peppers Chili, dried	10	5
	Peppers, Sweet (including pimento or pimiento)	1	0.5
	Plums (including Prunes) [except prunes]	1	0.2 u
	Plum preserve		
	Prunes	3	0.5 u
	Poultry meat	0.05*	0.05*
	Poultry, Edible offal of	0.05*	0.05*
	Rape seed	0.3	0.5
	Rice	1.5	2
	Rye	0.15	0.05*
	Rye straw and fodder, Dry	40	5

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Soya bean (dry)	0.15	0.1
	Soya bean oil, refined		
	Squash, Summer	0.2	0.02
	Sweet corn (corn-on-the-cob)	0.6	0.1 u
	Tomato	0.7	0.2 (0.5 u)
	Triticale	0.15	
	Tree nuts	0.05*	
	Watermelon	W	0.1 u
	Wheat	0.15	0.05
	Wheat straw and fodder, dry	40	10

Appendix II Priority list of pesticides to be evaluated in 2013 for MRL promulgation in 2014.

2013 JMPR NEW COMPOUND EVALUATIONS				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
bixafen [Bayer CropScience] Germany	Bixafen	Registered MRLs > LOQ	Cereal grains, rape seed, rape seed oil; meat from mammals and poultry, milk and eggs	Cereals (48), oilseed rape (22)
cyantraniliprole [DuPont] – USA	cyantraniliprole	Not registered (expected in 2013)	pome fruit, stone fruit, brassica vegetables, cucurbit vegetables, fruiting vegetables, leafy vegetables, bulb vegetables, green/long beans, grape, potato, sweet potato, rice, cotton, canola, citrus, tree nuts	pome fruit (59+), stone fruit (51+), brassica vegetables (50+), cucurbit vegetables (146+), fruiting vegetables (192+), leafy vegetables (80+), bulb vegetables (85), green/long beans (18), grape (33), potato (46), rice (9), cotton (22+), canola (29), citrus (52), tree nuts (12)
fluensulfone	fluensulfone	Not registered	Further advice required	
imazapic BASF	Imazapic	Registered MRLs mostly at LOQ	Corn, peanut, rapeseed, rice, soybean, sugarcane, wheat, animal feedstuffs	Corn (6), grass (15), peanut (18), peanut hay (10), rapeseed (4), rice (8), soybean (15), sugarcane (8), wheat (6), wheat feedstuffs(14)
imazapyr BASF Brazil priority 1 – moved from 2012	Imazapyr	Registered MRLs mostly at LOQ	Corn, lentils, cereals (wheat, corn, rice), oilseeds (rapeseed, soybean, sunflower), rice, sugarcane	Corn (27), lentils (5), rapeseed (23), rice (4), Soybean (22), sugarcane (2), sunflower (33), wheat (8)
isoxaflutole [Bayer CropScience] Germany	Isoxaflutole	Registered MRLs mostly at LOQ	Maize, maize fodder and forage, soybean (dry), soybean oil, sugarcane, meat from mammals and poultry, milk and eggs	Maize (61), Soybean (31), sugarcane (25)
tolfenpyrad [Nihon Nohyaku] Japan	Tolfenpyrad	Registered in Japan, the Dominican Republic, Thailand, Taiwan, UAE, Indonesia, Saudi Arabia, China, Malaysia and Jordan	Almonds, pecans, grape (table), raisin, juice (if MRL not included under table grape), plum, peach, cherry, pear, lemon, grapefruits, oranges, cantaloupe, cucumbers, summer squash, peppers, tomatoes, cauliflower, potatoes, cotton seed, tea and corresponding animal commodity MRLs.	almond (5), pecan (5), grape (12), cherries (6), peach (9), plum (6), prune (2), pear (6), orange (12), grapefruit (6), lemon(5), cucumber (6), cantaloupe (6), squash (5), tomato (12), pepper (bell+chili) (6+3), cauliflower (6), potato (16), cottonseed (12), tea (4)
triflumizole	Triflumizole	Registered	Pome fruits, stone	Pome fruits (38, P5),

2013 JMPR NEW COMPOUND EVALUATIONS				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
[Nippon Soda] USA		MRLs > LOQ	fruits, grape, star apple, American persimmon, mangoes, papaya, pineapple, strawberries, cucurbits, squash, melons, leafy brassica, head and stem brassica, kohlrabi, lettuce, cress, land cress, spinach, purslane, beet leaves, chervil parsley, hazelnuts, hops and animal commodities	stone fruits, grape (25, P14), papaya (4), pineapple (3), strawberries (8), cucumber (5), squash (5), melons (6), cabbage (9), mustard green (10), swiss chard (3), lettuce (17), broccoli (10), hops (3) and animal commodities (feeding goat, poultry) P = processing data
trinexapac – [Syngenta] - USA	Trinexapac	Registered MRLs > LOQ	Wheat, Barley, Oats, Sugarcane	Wheat (20), Barley (12), grasses grown for seed (12), Sugarcane (8)
Benzovindiflupyr (formally known as SYN545192) [Syngenta] - Switzerland	Benzovindiflupyr	Not registered Registration expected in 2012	Wheat, barley, soybean, corn, coffee, pome fruit, grape, sugarcane	Wheat (44-46), barley (44-46), soybean (28), corn (28), coffee (12), pome fruit (16), grape (16) and sugarcane (12).

2013 JMPR FOLLOW-UP EVALUATIONS		
RESIDUE	**Commodities**	**Residue trials provided**
azoxystrobin [Syngenta] USA (229)	Potato (USA), coffee, chickpea, lentil and dry pea	Potato (5), coffee (7), Dry Pea (2), Dry Bean (5)
cyproconazole [Syngenta] (239)	Coffee (Brazil)	Coffee (10)
cyprodinil (207)	Apple, Pear, Pistachio, Almond, Pecan	Apple and Pear (18), Pistachio (3), Almond and Pecan (10)
[Syngenta] USA	Spinach (+ lettuce to raise MRL?), Carrot, Radish, Chives, Parsley,	Spinach (11) (+ lettuce to raise MRL?, 14 trials), Carrot (10) +
(moved from 2012)	*Brassica* leafy greens, Beans (Snap, Lima and Dry), Pepper (+ Fruiting Veg. Crop Group), Melons, Lemon, Lime, Basil, Avocado, Guava, Lychee, Pomegranate, Watercress, Caneberry, Strawberry, Blueberry, Kiwifruit	Radish (6), chives (3), parsley (4), Brassica leafy greens (7 brassica + 7 broc + 6 cab + 9 mg), Beans (Snap(8), Lima (8) and Dry(9)), Pepper (14+5GH) (+ Fruiting Veg. Crop Group), melons (Company data?), lemon (5) + lime, caneberry (5), blueberry (8), strawberry (8), basil (3), avocado (6), guava (5), lychee (3), pomegranate (4), watercress (2), kiwifruit (3)
difenoconazole (224) [Syngenta] USA,	Grape, raisin, citrus, *Brassica* (broccoli, Brussels sprouts, cabbage, etc.), bulb vegetables, fruiting vegetables (pepper), cucurbits, potato]	Cantaloupe, Cucumber and Summer Squash as Representative Commodities of Vegetable, Cucurbit, Group 9 (17), Tomato and Pepper as Representative Commodities of Vegetable, Fruiting, Group 8 (20), Onions, Green and Dry Bulb, as Representative Commodities of

2013 JMPR FOLLOW-UP EVALUATIONS		
RESIDUE	**Commodities**	**Residue trials provided**
		Vegetable, Bulb, Group 3 (11), Broccoli, Cabbage, and Mustard Greens, as Representative Commodities of Brassica (Cole) Leafy Vegetables, Subgroups 5A and 5B (17), Fruit, Citrus, Group 10 (23), Grapes (12), Potato (5)
fenbuconazole (197) [Dow AgroSciences]	blueberries; new GAP for citrus fruits	Blueberries (8); citrus fruits (30
fenpyroximate (193) [Nihon Nohyaku] - USA	Avocado, bean (snap), cucumber, potato, stone fruit (cherry, peach, plum), tea strawberry watermelon	Avocado (5), Bean, snap (8), Cucumber (9), Potato (16), Cherry (8), Peach (10), Plum (6), Strawberry (8) watermelon (bridge from residue data for cantaloupe[8])
fludioxonil (211) [Syngenta] - USA	Ginseng, Spinach (+ lettuce to raise MRL?), Carrot, Radish, Chives, Parsley, *Brassica* leafy greens, Beans (Snap, Lima and Dry), Pepper (+ Fruiting Veg. Crop Group), Melons, Lemon, Lime, Basil, Avocado, Guava, Lychee, Pomegranate, Watercress, Caneberry, Strawberry, Blueberry, Kiwifruit Tomato, Potato, Pineapple Chickpea, Lentil	Ginseng (4), Spinach (11) (+ lettuce to raise MRL?, 14 trials), Carrot (10) + Radish (6), chives (3), parsley (4), Brassica leafy greens (7 brassica + 7 broc + 6 cab + 9 mg), Beans (Snap(8), Lima (8) and Dry(9)), Pepper (14+5GH) (+ Fruiting Veg. Crop Group), melons (Company data?), lemon (5) + lime, caneberry (5), blueberry (8), strawberry (8), basil (3), avocado (6), guava (5), lychee (3), pomegranate (4), watercress (2), kiwifruit (3) Tomato (6, Potato (5), Pineapple (4) Chickpea (9), Lentils (5),
flutolanil (205) [Nihon Nohyaku]	leafy brassica, root vegetables, ginseng	Broccoli (11), cabbage(9), mustard greens(10), Carrot (9), radish (5), ginseng(4)
chlorantraniliprole (230) [DuPont] - USA	Artichoke, globe Berries and other Small Fruits: Citrus: Coffee Fruiting vegetables (other than cucurbits, except mushrooms and sweet corn), Hops, Legume vegetables , Oilseeds, sweet rocket, tallowwood, tea oil plant, vernonia, Rice, Root and tuber	Artichokes (4), Blueberry (11), Carrots (18), coffee (8), Cranberry (6), Canola (6) and Sunflowers (6), succulent peas - Shelled (6); ediblepodded (7), snap beans (9), green peas, processing peas, sugar snap peas, snow peas and beans (7), radishes (6), rice (27), dried soybean (16), Strawberries (8+8 [different GAP]), hops (4), Green onion (5), Welsh onion (2), Scallion (1)
malathion (49) [Cheminova] - USA	Cherry	6 trials with sweet cherries (3 57% EC and 3 ULV) and 6 trials with tart cherries (3 57% EC and 3 ULV
mandipropamid (231) [Syngenta] - USA	hops	Hops (11)
Picoxystrobin – [Dupont] USA	Fruiting vegetables, cucurbits, stone fruit, pome fruit, grapes, legume vegetables, bulb vegetables, strawberry, brassica vegetables, leafy vegetables, root and tuber vegetables, sunflower, tree nut,	Brassica (Broccoli, cauliflower, cabbage, mustard greens), 30; Bulb Vegetables (Green Onion, Dry Bulb Onion), 15; Coffee, 4; Cotton, 13; Cucurbits, 30 (Cucumbers; 12;

2013 JMPR FOLLOW-UP EVALUATIONS		
RESIDUE	**Commodities**	**Residue trials provided**
	peanut, rice, cotton and tomato.	muskmelons: 9; summer squash 9; Fruiting Vegetables, 44 (tomatoes: 24; bell peppers: 13; 7 non-bell peppers); Grape, 13; Leafy Vegetables, 44 trials (Leaf lettuce 10, Head lettuce: 11; Celery: 10; Spinach 9); Peanut, 13; Pome (apple, pear), 26 (Apple 17, Pear 9); Rice, 11; Root and Tuber Vegetables, 56 Trials (Potatoes: 21; sugarbeets: 13; radishes: 6; carrots: 10; turnips: 6); Stone Fruit (Cherries, peaches, plums), 30; Strawberry, 9; Succulent/edible podded legumes, 40 (8 edible podded bean, 4 edible podded pea,' 17 succulent bean, and 11 succulent pea); Sugarcane, 4; Sunflower, 9; Tree Nuts, 12 (6 Almond; 6 Pecan)
propiconazole (160) [Syngenta] - USA	Oranges, grapefruit, lemon, peaches, nectarines, plum, tomato, cherry, strawberry, tree nuts not supported Dry Bean, Lima bean, Snap bean, Mustard greens, Carrot, Radish, Mint, Pineapple, Watercress	Cherry (all stone fruits to get group tolerance) (6), Strawberry (8), Cherry (postharvest) (3), Tomato (postharvest) (6), Citrus (postharvest) (12), Stone fruit (postharvest) (9) Dry Bean (12), Snap bean (7), Lima Bean (6), mustard greens (9), carrot (Co. Data?) + radish (7), turnip (6), mint (5), pineapple (3), watercress (3)
Pyrimethanil (226) (priority 1) Janssen PMP - USA	Re-evaluation of CXLs for peaches, cherries, apricots, plums, apple, pear blueberry	Stone fruit (3), Pome fruit (5), blueberry (5)
spirotetramate(234) [Bayer CropScience] – USA	Cranberry Artichoke, Banana, Blueberry, Coffee, Onion, Pomegranate, pineapple, watercress	Cranberry (6) Artichoke (5), Banana (7), Blueberry (11), Coffee (5), Onion (12), Pomegranate (4), pineapple (5), watercress (4)

REPORT of 45th SESSION CODEX COMMITTEE ON PESTICIDE RESIDUES
21-28 April 2012, Shanghai, China

Introduction

The Codex Committee on Pesticide Residues (CCPR) held its Forty-fifth Session in Beijing, China, from the 6th to the 11th of May 2013, with a pre-meeting workshop on the safety assessment of pesticide residues held on the 5th of May. The Meeting was attended by 257 delegates representing 62 Member Countries, one Member Organization and Observers from eight international organizations. The full agenda papers and report of the meeting are available at: http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=012013

The Australian delegation was led by Mr Ian Reichstein, DAFF, and comprised of five members representing government (APVMA and DAFF) and industry sectors (horticulture and grains).

A large number of maximum residue level recommendations were discussed by the Committee. In addition, a number of proposals were discussed regarding new initiatives aimed at improving efficiencies in MRL assessments and promulgations. These included the use of the Proportionality approach; Pilot project on MRL estimation prior to registrations; amendments to the Codex classification of foods and feeds; extrapolation; MRLs for minor crops; development of risk analysis principles and agreeing forward priorities for JMPR assessments.

Maximum Residue Limits

The Committee advanced 328 MRLs for adoption as Codex CXLs, i.e., to Step 8 or Step 5/8 (see Appendix I). Of these MRLs, 302 were fast-tracked to Step 5/8. In these cases, Codex CXLs will be established less than a year after evaluation by the Joint Meeting on Pesticide Residues (JMPR). The recent Codex Commission meeting adopted all draft and proposed draft MRLs for the various pesticide/commodity combinations as proposed by the CCPR[71] (See Appendix I).

Proportionality

Australia (Dr Bhula) chaired the electronic working group and led the in-session meeting. Following discussions the Committee agreed that proportionality was applicable to insecticides, fungicides, herbicides and plant growth regulators, with desiccants to be excluded. It was clarified that 100% scaled data could be used for large data sets and that "at least 50% of trials at GAP may be requested on a case-by-case basis depending for example on the range of scaling factors", and that some trials at GAP might be useful as confirmatory data.

[71] **Report of the 36th Session of the Codex Alimentarius Commission**
http://www.codexalimentarius.org/meetings-reports/en/?sortingDate=012013

Pilot Project: Codex MRLs before national registrations

At CCPR 43 a pilot project was approved in which residue trial data was assessed by the JMPR prior to a national registration. The 2011 JMPR evaluated **Sulfoxaflor**, an insecticide from DOW and proposed a number of levels that could be used as MRLs. The JMPR recommendations from the pilot project were discussed. It was decided that a detailed evaluation of the pilot project was needed before progressing. Consensus could not be reached, with the majority of delegations expressing opinion that the label must be approved and provided to JMPR for review before recommendation of MRLs. The MRLs proposed by the USA for sulfoxaflor were discussed at length. The Committee agreed to advance some of the MRLs recommended by JMPR, with the others held back at Step 4 awaiting data that matched labels.

Codex Classification

The next phase of the work, the revision of vegetable commodity classifications has begun with a draft revision of the Classification for the Root and tuber vegetable commodity group which was moved to Step 5 in the Codex procedure. The Commodity groups for Brassica (cole or cabbage vegetables, head and flowerhead heads; Leafy vegetables (including brassica leafy vegetables); and Stalk and stem vegetables are at Step 7 pending finalization of the *Classification of Food and Feed* in relation to the remaining vegetable commodity groups.

Principles and guidance for selection of representative commodities for extrapolation

The aim of this initiative is to provide guidance on identifying commodities suitable for use as representative commodities to aid in the establishment of crop group MRLs. The working group has continued developing the principle of selecting of representative commodities should take into account similar residue behaviour and that the ALARA (as low as reasonably achievable) Principle should be considered when estimating group MRLs, particularly when considering the potential impact of derived values on dietary risk assessments. The revised draft, together with a table providing examples of the selection of representative fruit commodities, was advanced to Step 8. The Committee agreed to continue working on the revision of the *Classification of Food and Feed* through the identification of other vegetable commodity groups.

MRLs for minor crops and specialty commodities

An eWG chaired by France will continue working towards an approach to determine the minimum number of field trials required to establish MRLs for minor/specialty commodities. The WG recommended a 0.5% threshold as the cut-off diet criteria, i.e., below 0.5% consumption a crop is potentially minor. The calculation was done using the formula below.

$$\%_i = \left(\frac{\sum^c \frac{\text{consumption}_{i,c} \text{ x } \text{population}_c}{\text{population}_w}}{\sum^c \frac{\text{total consumption}_c \text{ x } \text{population}_c}{\text{population}_w}} \right) \text{x } 100$$

Concerns were raised as the calculation method relies upon the FAO STAT 2 and GEMS/FOOD databases, which may not capture or have sufficient data to allow accurate calculations. It was agreed that the eWG should continue with the tasks of finalizing the crop groups and seeking additional consumption data from member states.

Risk analysis principles

Progress was made on the development of the Risk Analysis Principles regarding the periodic re-evaluation of compound. Appendix 2A and 2B of the Priorities was included to deal with those compounds that fall under the 15 years rule. The three cases previously identified for prioritizing were scaled down to two, being supported compounds (case A) or unsupported compounds (case B).

Priorities

Australia chaired the eWG on Priorities and relevant discussion at plenary. The Committee agreed to the proposed schedule for JMPR evaluations in 2014 (see Appendix II).

The next Session of the CCPR was tentatively scheduled to be held in China in 2014, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

Appendix I MRLs agreed for adoption at CCPR 45.

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
Ametoctradin (253) ADI: Unnecessary ARfD: Unnecessary	Grapes Dried grapes (=currants, raisins and sultanas) Garlic Onion, Bulb Shallot Spring Onion Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Fruiting vegetables, Cucurbits, except cucumber Cucumber Fruiting vegetables, other than cucurbits, except sweet corn and except mushroom Hops, dry Peppers Chili, dried Leafy vegetables Potato Celery Poultry meat Poultry fats Poultry, Edible offal of Eggs	6 20 1.5 1.5 1.5 20 9 3 0.4 1.5 30 15 50 0.05 20 0.03* 0.03* 0.03* 0.03*	
Azoxystrobin (229) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	Carambola Ginseng, dried including red ginseng Ginseng, extracts Ginseng processed products(dried, red, ethanol and water extracts)	0.1 0.3 0.5 W	 0.5
Buprofezin (173) ADI: 0-0.009 mg/kg bw ARfD: 0.5 mg/kg bw	Banana Tea, Green	0.3 30	
Carbofuran (096) ADI: 0-0.001 mg/kg bw ARfD: 0.001 mg/kg bw	Banana	0.01*	0.02*
Chlorothalonil (081) ADI: 0-0.02 mg/kg bw ARfD: 0.6 mg/kg bw	Bananas Chard [a] Based on bagged bananas	15 50	0.01* [a]
Chlorpyrifos-methyl (090) ADI: 0-0.01 mg/kg bw	Maize	W	3 Po

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
ARfD: 0.1 mg/kg bw			
Cycloxydim (179)	Beans, dry	20	2
ADI:0-0.07 mg/kg bw	Beans except broad bean & soya bean (green pods & immature seeds)	15	
ARfD: 2 mg/kg bw for Women of childbearing Age. Not necessary for the general population.	Beetroot	0.2	
	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	9	2
	Carrot	5	0.5
	Celeriac	1	
	Edible offal (Mammalian)	0.5	
	Eggs	0.15	
	Grapes	0.3	0.5
	Kale, curly	3	
	Leek	4	
	Lettuce, Head	1.5	0.2
	Lettuce, Leaf	1.5	0.2
	Linseed	7	
	Mammalian fats (except milk fats)	0.1	
	Maize	0.2	
	Maize fodder (dry)	2	
	Meat (from mammals other than marine mammals)	0.05	
	Milks	0.02	
	Onion, Bulb	3	
	Peas (pods and succulent=immature seeds)	W	1
	Peas (dry)	20	
	Peas, Shelled (succulent seeds)	15	2
	Peppers	9	
	Peppers Chilli, dried	90	
	Pome fruits	0.09*	
	Potato	3	2
	Poultry meat	0.03*	
	Poultry fats	0.03*	
	Poultry, Edible offal of	0.02	
	Rape seed	7	2
	Rice	0.09*	
	Rice straw or fodder Dry	0.09	
	Soya bean (dry)	80	2
	Stone fruits	0.09*	
	Strawberry	3	0.5
	Sugar beet	0.2	0.2
	Sunflower seed	6	
	Swede	0.2	
	Tomato	1.5	
Cyfluthrin/beta-cyfluthrin (157)	Cabbages, Head	0.08	4
ADI: 0-0.04 mg/kg bw	Edible offal (mammalian)	0.02	
ARfD: 0.04 mg/kg bw	Kidney of cattle, goats, pigs and sheep	W	0.05
	Liver of cattle, goats, pigs and sheep	W	0.05
	Meat (from mammals other than marine mammals)	0.2 fat	1.0

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Milks	0.01	0.04
	Soya bean (dry)	0.03	
	Soya bean fodder	4	
Cyromazine (169)	Chick-pea (dry)	3	
ADI: 0-0.06 mg/kg bw	Lentil (dry)	3	
ARfD: 0.1 mg/kg bw	Lupin (dry)	3	
Dichlorvos (025)	Cereal grains	W	5
ADI: 0–0.004 mg/kg bw	Edible offal (mammalian)	0.01 *	
ARfD: 0.1 mg/kg bw	Eggs	0.01 *	
	Mammalian fats (except milk fats)	0.01 *	
	Meat (from mammals other than marine mammals)	0.01 *	
	Milks	0.01 *	
	Poultry fat	0.01 *	
	Poultry meat	0.01 *	
	Poultry, Edible offal of	0.01 *	
	Rice	7	
	Rice bran, Unprocessed	15 PoP	
	Rice, Husked	1.5 PoP	
	Rice, Polished	0.15 PoP	
	Wheat	7 Po	
	Wheat bran, Unprocessed	15 PoP	10
	Wheat flour	0.7PoP	1
	Wheat germ	W	10
	Wheat wholemeal	3 PoP	2
Dicofol (026)	Beans (dry)	W	0.1
ADI: 0–0.002 mg/kg bw	Cattle meat	W	3(fat)
ARfD: 0. 2 mg/kg bw	Cattle, Edible offal of	W	1
	Cherries	W	5
	Citrus fruits	W	5
	Common bean (pods and/or immature seeds)	W	2
	Cotton seed	W	0.1
	Cotton seed oil, Crude	W	0.5
	Cotton seed oil, Edible	W	0.5
	Cucumber	W	0.5
	Eggs	W	0.05
	Grapes	W	5
	Hops, Dry	W	50
	Melons, except watermelon	W	0.2
	Milks	W	0.1
	Peach	W	5
	Pecan	W	0.01*
	Peppers	W	1
	Peppers Chili, dried	W	10

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Plums (including prunes)	W	1
	Poultry meat	W	0.1(fat)
	Poultry, Edible offal of	W	0.05*
	Prunes	W	3
	Squash, summer	W	1
	Tea, Green, Black (black, fermented and dried)	40	50
	Walnuts	W	0.01*
Dinotefuran (255) ADI: 0-0.2 mg/kg bw ARfD: 1 mg/kg bw	Brassica (Cole or Cabbage) Vegetables, Head Cabbage, Flowerhead Brassicas	2	
	Celery	0.6	
	Cotton seed	0.2	
	Cranberry	0.15	
	Dried grapes (= currants, Raisins and Sultanas)	3	
	Edible offal (Mammalian),	0.1	
	Eggs	0.02*	
	Fruiting vegetables, Cucurbits	0.5	
	Fruiting vegetables other than Cucurbits (except sweet corn and mushrooms)	0.5	
	Grapes	0.9	
	Leafy vegetables	6	
	Meat (from mammals other than marine mammals	0.1	
	Milks	0.1	
	Nectarine	0.8	
	Onion, Bulb	0.1	
	Peach	0.8	
	Peppers, Chili, dried	5	
	Poultry, Edible offal of	0.02*	
	Poultry meat	0.02*	
	Rice	8	
	Rice, Polished	0.3	
	Rice straw and fodder, Dry	6	
	Spring Onion	4	
	Watercress	7	
Fenvalerate (119) ADI: 0-0.02 mg/kg bw ARfD: 0.2 mg/kg bw	Alfalfa fodder	W	20
	Beans, Shelled	W	0.1
	Beans, except broad beans and soya beans	W	1
	Berries and other small fruits	W	1
	Broccoli	W	2
	Broccoli, Chinese	3	
	Brussels sprouts	W	2
	Cabbages, Head	W	3
	Cauliflower	W	2
	Celery	W	2
	Cereal grains	W	2 (Po)
	Cherries	W	2
	Chinese cabbage (type pack-choi)	W	1
	Citrus fruits	W	2
	Cotton seed	W	0.2
	Cotton seed oil, Crude	W	0.1

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Cotton seed oil, Edible	W	0.1
	Cucumber	W	0.02
	Edible offal (mammalian)	W	0.02
	Kale (including among others: Collards, Curly kale, Scotch kale, thousand-headed kale; not including Marrow-stem kale)	W	10
	Kiwifruit	W	5
	Lettuce, Head	W	2
	Mango	1.5	-
	Meat (from mammals other than marine mammals)	W	1 (fat)
	Melons, except watermelons	W	0.2
	Milks	W	0.1F
	Peach	W	5
	Peanut, whole	W	0.1
	Peas, Shelled (succulent seeds)	W	0.1
	Peppers, Sweet (including pimento or pimiento)	W	0.5
	Pome fruits	W	2
	Root and tuber vegetables	W	0.05
	Soya bean (dry)	W	0.1
	Squash, summer	W	0.5
	Sunflower seed	W	0.1
	Sweet corn (corn-on-the-cob)	W	0.1
	Tomato	W	1
	Tree nuts	W	0.2
	Watermelon	W	0.5
	Wheat bran, Unprocessed	W	5 (Po)
	Wheat flour	W	0.2 (Po)
	Wheat wholemeal	W	2 (Po)
	Winter squash	W	2
Fludioxonil (211) ADI: 0-0.4 mg/kg bw ARfD: Unnecessary	Mango	2	
Fluopyram (243) ADI: 0-0.01 mg/kg bw ARfD: 0.5 mg/kg bw	Banana	0.8	
	Beans (dry)	0.07	
	Carrot	0.4	
	Cherries	0.7	
	Chick-pea (dry)	0.07	
	Edible offal (mammalian)	W	0.7
	Eggs	0.3	
	Kidney of cattle, goats, pigs and sheep	0.5	
	Lentil (dry)	0.07	
	Liver of cattle, goats, pigs and sheep	3	
	Lupin (dry)	0.07	
	Meat (from mammals other than marine mammals)	0.5	0.1
	Milks	0.3	0.07
	Peach	0.4	
	Peanut	0.03	
	Peppers	0.5	
	Peppers Chili, dried	5	
	Pome fruits	0.5	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Potato	0.03	
	Poultry meat	0.2	
	Poultry, Edible offal of	0.7	
	Strawberry	0.4	
	Sugar beet	0.04	
	Tomato	0.4	
	Tree nuts	0.04	
Fluxapyroxad (256) ADI: 0-0.02 mg/kg bw ARfD: 0.3 mg/kg bw	Barley	2	
	Barley bran	4	
	Barley straw and fodder, Dry	30	
	Beans (dry)	0.3	
	Beans, except broad bean and soya bean	2	
	Beans, shelled	0.09	
	Chick-pea (dry)	0.4	
	Cotton seed	0.01*	
	Edible offal (mammalian)	0.1	
	Eggs	0.02	
	Fruiting vegetables other than cucurbits (except sweet corn and mushrooms)	0.6	
	Lentil (dry)	0.4	
	Maize	0.01*	
	Maize fodder (dry)	15	
	Meat (from mammals other than marine mammals) (fat)	0.2 (fat)	
	Milks	0.02	
	Milk fats	0.5	
	Oats	2	
	Oat straw and fodder, Dry	30	
	Oilseed (except peanut and cotton)	1.5	
	Pea hay or Pea fodder (dry) (dry weight)	40	
	Peas (pods and succulent = immature seeds)	2	
	Peas, Shelled (succulent seeds)	0.09	
	Peanut	0.01	
	Peas (dry)	0.4	
	Pome fruits	0.9	
	Potato	0.03	
	Poultry meat	0.02	
	Poultry fats	0.05	
	Poultry, Edible offal of	0.02	
	Prunes	5	
	Rye	0.3	
	Rye straw and fodder, Dry	30	
	Soya bean (dry)	0.15	
	Soya bean hulls	0.3	
	Soya bean (immature seeds)	0.5	
	Soya bean fodder (dry weight)	30	
	Soya bean (young pod)	1.5	
	Stone fruits	2	
	Sugar beet	0.15	
	Sweet corn (corn-on-the-cob)	0.15	
	Triticale	0.3	

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
	Triticale straw and fodder, Dry	30	
	Wheat	0.3	
	Wheat bran	1	
	Wheat straw and fodder, Dry	30	
	Wheat germ		
Glufosinate ammonium (175)	Almond hulls	W	0.5
ADI: 0-0.01 mg/kg bw	Asparagus	0.4	0.05 *
ARfD: 0.01 mg/kg bw	Assorted tropical and sub- tropical fruits - inedible peel (except banana)	W	0.05 *
	Assorted tropical and sub- tropical fruits - inedible peel (except banana and kiwifruit)	0.1	
	Assorted tropical and sub- tropical fruits - edible peel	0.1	
	Bean fodder	1	
	Berries and other small fruits (except currants)	W	0.1
	Blueberries	0.1	
	Broad bean (dry)	W	2
	Carrot	0.05	0.05 *
	Citrus fruits	0.05	0.1
	Common bean (dry)	0.05	2
	Coffee beans	0.1	
	Common bean (pods and/or immature seeds)	0.05 *	0.05 *
	Corn salad	0.05	0.05 *
	Cotton seed	5	
	Currants, Black, Red, White	1	0.5
	Eggs	0.05 *	0.05 *
	Gooseberry	0.1	
	Grapes	0.15	
	Lettuce, Head	0.4	
	Maize	0.1	0.1
	Maize fodder (dry)	8	10
	Maize forage	W	5
	Meat (from mammals other than marine mammals)	0.05	0.05 *
	Milks	0.02 *	0.02 *
	Onion, Bulb	0.05	0.05
	Peas (dry)	W	3
	Pome fruits	0.1	0.05 *
	Potato	0.1	0.5
	Poultry meat	0.05 *	0.05 *
	Poultry, Edible offal of	0.1 *	0.1 *
	Prunes	0.3	
	Rape seed	1.5	5
	Rape seed oil, Crude	0.05 *	0.05 *
	Raspberries, Red, Black	0.1	
	Rice	0.9	
	Rice straw and fodder, dry	2	
	Stone fruits	0.15	0.05 *
	Strawberry	0.3	
	Sugar beet	1.5	0.05 *
	Sugar beet molasses	8	
	Sunflower seed	3	5
	Sunflower seed oil, crude	0.05 *	0.05 *
	Tree nuts	0.1	0.1

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
Imidacloprid (206) ADI: 0-0.06 mg/kg bw ARfD: 0.4 mg/kg bw	Celery Peas (dry) Pulses (except soya beans)	6 W 2	 2
Indoxacarb (216) ADI: 0-0.01 mg/kg bw ARfD: 0.1 mg/kg bw	Lettuce, Leaf	3	15
MCPA (257) ADI: 0-0.1 mg/kg bw ARfD: 0.6 mg/kg bw	Barley Barley straw and fodder, Dry Eggs Flax-seed Hay or fodder (dry) of grasses Edible offal (mammalian) Maize Maize straw and fodder, Dry Mammalian fats Meat from mammals other than marine mammals Milks Oat Oat straw and fodder, Dry Peas, dry Poultry meat Poultry fats Poultry, Edible offal of Rye Rye straw and fodder, Dry Triticale Triticale straw and fodder, Dry Wheat Wheat straw and fodder, Dry	0.2 50 0.05* 0.01* 500 3 0.01* 0.3 0.2 0.1 0.04 0.2 50 0.01* 0.05* 0.05* 0.05* 0.2 50 0.2 50 0.2 50	
Methoxyfenozide (209) ADI: 0-0.1 mg/kg bw ARfD: 0.9 mg/kg bw	Citrus fruits Fruiting vegetable, cucurbits, except watermelon Spring Onion Common bean (pods and/or immature seeds) Peas (pods and succulent=immature seeds) Peas (dry) Mammalian fats (except milk fats) Edible offal (mammalian) Meat (from mammals other than marine mammals)	2 0.3 6 2 5 0.3 0.2 0.3 (fat)	0.7 2 0.2 0.1 0.2 (fat)
Phorate (112) ADI: 0-0.0007 mg/kg bw ARfD: 0.003 mg/kg bw	Potato	0.3	0.5

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
Pyraclostrobin (210) ADI: 0–0.03 mg/kg bw ARfD: 0.05 mg/kg bw	Citrus oil, edible Orange oil, edible	10 W	 10
Saflufenacil (251) ADI: 0–0.05 mg/kg bw ARfD: Unnecessary	Beans (dry) Peas (dry) Pulses Soya bean (dry)	W W 0.3 W	0.3 0.05 0.07
Sedaxane (259) ADI: 0-0.1 mg/kg bw ARfD: 0.3 mg/kg bw	Barley Barley straw and fodder, Dry Edible offal (Mammalian) Mammalian fats (except milk fat) Meat (from mammals other than marine mammals) Milks Milk fats Oat Oat straw and fodder, Dry Poultry fats Poultry meat Poultry, Edible offal of Eggs Rape seed Rye Rye straw and fodder, Dry Triticale Triticale straw and fodder, Dry Wheat Wheat straw and fodder, Dry	0.01* 0.1 0.01* 0.01* 0.01* (fat) 0.01* 0.01* 0.01* 0.1 0.01* 0.01* 0.01* 0.01* 0.01* 0.01* 0.1 0.01* 0.1 0.01* 0.1	
Spinetoram (233) ADI: 0-0.05 mg/kg bw ARfD: Unnecessary	Beans, except broad bean and soya bean (green pods and immature seeds) Blueberries Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas Celery Eggs Grapes Nectarine Onion, Bulb Onion, Welsh Peach Poultry fats Poultry meat	0.05 0.2 0.3 6 0.01 * 0.3 0.3 0.01 * 0.8 0.3 0.01 * 0.01 *	
Spirotetramat (234) ADI: 0-0.05 mg/kg bw	Milks	0.005	0.01

Pesticide (Codex reference number)	Commodity	Recommended MRL mg/kg	
		New	Previous
ARfD: 1.0 mg/kg bw			
Sulfoxaflor (252) ADI: 0–0.05 mg/kg bw ARfD: 0.3 mg/kg bw	Barley Barley straw and fodder, dry Broccoli Cabbages, Head Cauliflower Celery Cotton seed Dried grapes (= Currants, Raisins, and Sultanas) Edible offal (Mammalian) Eggs Fruiting vegetables, Cucurbits Fruiting vegetables, other than Cucurbits (except sweet corn and mushrooms) Garlic Grapes Leafy vegetables Meat (from mammals other than marine mammals) Milks Onion, bulb Spring onion Peppers, Chili (dried) Poultry meat Meat (from mammals other than marine mammals) Milks Onion, bulb Spring onion Peppers, Chili (dried) Poultry meat Poultry, Edible offal of Rape seed Root and tuber vegetables Soya bean fodder Soya bean (immature seeds) Strawberry Triticale Watercress Wheat Wheat straw and fodder, dry	0.6 3 3 0.4 0.04 1.5 0.4 6 0.6 0.1 0.5 1.5 0.01 * 2 6 0.3 0.2 0.01* 0.7 15 0.1 0.3 0.2 0.01* 0.7 15 0.1 0.3 0.15 0.03 3 0.3 0.5 0.2 6 0.2 3	
Trifloxystrobin (213) ADI: 0-0.04 mg/kg bw ARfD: Unnecessary	Asparagus Eggplant Lettuce, head Olives Olive oil, crude Olive oil, refined Papaya Radish leaves Radish Strawberry	0.05* 0.7 15 0.3 0.9 1.2 0.6 15 0.08 1	 0.2

Appendix II Priority list of pesticides to be evaluated in 2014 for consideration and potential MRL promulgation in 2015.

2014 JMPR - NEW COMPOUND EVALUATIONS – SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
Aminocyclopyrachlor [DuPont] - USA	Aminocyclopyrachlor	Registered MRLs > LOQ	Meat; milk and edible offal	22 (cattle) - magnitude of residue studies in pasture and rangeland grasses - 20 MOR test sites and 2 decline test sites (to determine residues in hay and forage)
Benzovindiflupyr [Syngenta] – Switzerland Tox Evaluation 2013	Benzovindiflupyr	Registered	soybean; corn; sugarcane; cotton; dry beans	Soybean (12); corn (11); sugarcane (12); cotton (11); dry beans (11)
Cyflumetofen [BASF] USA	Cyflumetofen	Not registered MRLs > LOQ	Apple; pear; citrus; orange; grapefruit; lemon; strawberry; almond; pecan; grapes; tomato; melon; tea	Apple (17: 1 EU, 12 USA, 4 Japan); pear (7: 5 USA, 2 Japan); citrus (4 Japan); orange (18: 12 USA, 6 Brazil); grapefruit (6 USA); lemon (5 USA); strawberry (8 USA); almond (5 USA); pecan (5 USA); grapes (12 USA); tomato (16 USA); melon (2 Japan); tea (2 Japan); processed commodities: apple (2 USA); orange (2 USA); grapes (4); tomato (2)
Dichlobenil – [Chemtura] USA	Dichlobenil	Registered MRLs > LOQ	Cranberry; blackberry; blueberry; raspberry; grapes; cherry; pome fruit; hazelnut; and rhubarb rhubarb (IR-4 Study)	Apple (5); blueberry (2); blackberry (3); cherry (12); cranberry (4); filberts (3); grapes (12); peach (4); plum (3) Rhubarb (3 IR-4 trials)

2014 JMPR - NEW COMPOUND EVALUATIONS – SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
Fenamidone [Bayer CropScience] Germany Tox evaluation in 2013	Fenamidone	Registered MRLs > LOQ	Broccoli; brussels sprouts; carrots; Chinese cabbage; cauliflower; courgettes (summer squash); cucumber; eggplant; gherkin; grapes (table and wine); head cabbage; kale; leek; lettuce (head and leafy); melon; onion; pepper (bell and sweet); potato; pumpkin (winter squash); spinach; strawberries; sunflower seeds; tomato; watermelon IR-4 Add-On: carrots; sunflower; ginseng; snap bean; lima bean	Fruiting vegetables (75); leafy vegetables (30); bulb vegetables (12); brassica vegetables (20); potato and tuberous vegetables (34); root vegetables (13); berries and small fruit (34); oilseeds (23) Additional IR-4 data: carrots (13); sunflower (9); ginseng (5); snap bean (8); lima bean (9)
Fluensulfone Makhteshim Tox evaluation in 2013	Fluensulfone	To be registered in October 2013	Tomatoes; peppers (bell and non-bell); cucumbers; courgette (zucchini); squash; cantaloupe (rockmelon)	Tomatoes (31); peppers (bell and non-bell) (19); cucumbers (15); courgette (zucchini) (3); squash (10); cantaloupe (rockmelon) (16)
Imazamox [BASF] Argentina	Imazamox	Registered	Legume group: peas and beans (fresh); beans and beans (pulses); lentils; soybean; peanuts; cereal group (rice; wheat, maize); oilseed group (sunflower, oilseed rape); alfalfa	29 OSR; 19 sunflower; 35 wheat; 26 maize; 5 rice; 18 beans; 23 peas; 5 lentils; 36 soybeans; 4 alfalfa; 7 peanuts; 19 alfalfa Additional IR-4 data: bean (snap) (6); pea (EP & SS) (9); bean (lima) (7); bean (dry) (10); pea (dry) (6); sunflower (6)

2014 JMPR - NEW COMPOUND EVALUATIONS – SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
Mesotrione – [Syngenta] – USA moved from 2013 P1	Mesotrione	Registered MRLs some at LOQ	Asparagus; berries; corn (grain, pop, sweet); cranberry; millet; lingonberry; oat (grain); rhubarb; sorghum (grain); soybean; sugarcane; okra	Asparagus (8); berries (10); sweet corn (12); field corn (20); cranberry (5); millet (5); oats (16); okra (5) rhubarb (4); grain sorghum (12); soybean (20); sugarcane (8) IR-4 data: cranberry (5)
Pymetrozine [Syngenta] – USA moved from 2013 P1	Pymetrozine	Registered MRLs > LOQ	Citrus, Pome Fruit, Peach, Strawberries, Rice, Pecans, Oilseed rape, Cotton, Hops, Brassica vegetables, Fruiting vegetables cucurbits, Fruiting veg other than cucurbits, Lettuce, Asparagus, Potatoes, Animal commodities	Citrus (26), Apple/Pear (8), Peach (10), Strawberry (12), Brassica (24), Rice (8), Pecans (5), OSR (12), Cotton (4), Hops (12), Cucurbits /edible (20), Cucurbits/inedible (16), Pepper (16), Tomato (16), Lettuce (26), Asparagus (4), Potatoes (10)
Fufenoxuron BASF Brazil priority 1 – moved from 2012 - RESERVE	Flufenoxuron	Registered MRLs > LOQ	Soybean; pome fruit (apple, pear); orange; melon; tomato; grape; tea	Soybean (8); pome fruit (8); citrus (12); melon (7); tomato (12); grape (12); tea (8)

2014 JMPR - NEW COMPOUND EVALUATIONS – SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation Criteria**	**Commodities**	**Residue trials provided**
Metrafenone [BASF] USA RESERVE	Metrafenone	Registered MRLs > LOQ	Grape (table, wine, raisin); pome fruits (apple, pears); cherries; fruiting vegetables (tomatoes, peppers, eggplant); cucurbits (cucumber, squash, melon); cereals (wheat, barley, oats, rye, triticale); hops IR-4 Add-On: peach	Grapes (table and wine) (24 USA) (14 EU); raisins (dried grapes); (1 USA); pome fruits (apples, pears) (18); cherries (16); fruiting vegetables (tomatoes, peppers, eggplant) (28); cucurbits (cucumber, squash, cantaloupe) (32); cereals (wheat, barley, oats rye, triticale) (67); hops (6 EU) (5 USA) IR-4 data: tomato (19); cantaloupe (12); squash (14); cherry (16); peach (16); hops (5)

2014 JMPR - NEW USES AND OTHER EVALUATIONS – SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
	2,4-D (020) [Dow AgroSciences]	New GAP for soya bean moved from 2012 on request from manufacturer	Soya bean (24)
JMPR 2013	Buprofezin (173)	Coffee	
	Chlorantraniliprole (230) [DuPont] - USA	Green bulb vegetables; peanuts; pulses (mung beans, chick peas, soy beans); cereal grains	Green bulb vegetables (8); peanuts (6); pulses (mung beans (3); chick peas (3); soy beans (4); cereal grains (barley 3; sorghum 3; wheat (5)
JMPR 2013	Chlorpyrifos-methyl (90) [Dow AgroScience]	New GAP / label – wheat and barley	

2014 JMPR - NEW USES AND OTHER EVALUATIONS – SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
Chlorfenapyr (254) [BASF] Review tox data on metabolites JMPR 2013			
JMPR 2013	Clothianidin [Bayer] (238)	Root tuber vegetables (EU)	
JMPR 2013	Dicamba (240) [BASF]	Soybean	Soybean (12) additional trials at 1x rate
Diflubenzuron [Chemtura] (130) EU – request to review toxicological data		IR-4 Add-On: carrot; mustard greens; wheat; barley; peach; plum; peanut	Additional IR-4 data: carrot (10); mustard greens (8); wheat & barley (12); peach & plum (12); peanut (15)
	Dimethomorph [BASF] (225)	Bulb onions (including shallots, garlic, silverskin onions); green onions; leek; head cabbage; flowerhead brassica (broccoli); whole group leafy vegetables (excluding brassica); celery; globe artichokes; oranges; strawberry; grapes; ginseng IR-4 Add-On: fruiting veg. pepper (+ tomato?) to raise MRL; mustard greens; lima beans; taro	Bulb onions (including shallots, garlic, silverskin onions), 10 (USA); green onions, 6 (USA); leek, 20 (EU); head cabbage, 10 (USA); flowerhead brassica (broccoli), 10 (USA) Whole group leafy vegetables (excluding brassica), 25 (head and leaf lettuce; spinach) (USA); celery, 9 (USA); globe artichokes, 10 (EU); oranges, 8 (EU); strawberry, 8 (EU); grapes, 13 (USA); ginseng, 4 (USA; IR-4) Additional IR-4 data (or IR-4 data to be submitted): ginseng (4); taro (3); onion (DB) (8); onion (Gr) (4); lettuce head (6); lettuce leaf (9); mustard greens (8); lima bean (6); pepper (B+NB) (12)
	Dithiocarbamates - mancozeb (105) [Dow AgroSciences]	Mandarin, Ginseng (RoK) Okra; chili pepper (Thailand) Seed spices [HS 190]; fruit and berry spices [HS 191] (India)	<u>Await further advice</u> Ginseng (3) USA Ginseng (5) RoK
	Emamectin benzoate (247) [Syngenta]	Canola (Australia) Tree nuts, including pistachios	Tree nuts (4 almond; 4 pecan)

2014 JMPR - NEW USES AND OTHER EVALUATIONS – SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
	Fluopyram (243) [Bayer CropScience	Leek; onions; asparagus; lettuce heads; herbs; cabbage; bush berries; rape seed; sunflower and hops	Leek (24); onions (37); asparagus (12); lettuce heads (50); herbs (6); cabbage head (16); Chinese cabbage (16); bush berries (8); rape seed (16); sunflower (18) and hops (8)
Glufosinate [Bayer CropScience] (175) JMPR 2013	Glufosinate [Bayer CropScience] (175)	Toxicological equivalence factors (banana, kiwifruit, soya bean, edible offal [mammalian], lettuce leaf, sunflower)	
JMPR 2013	Penthiopyrad (253)	Livestock commodity MRLs	
	Phosmet [Gowan] (103) - USA	Cranberry; tart cherry	Cranberry (5); tart cherry (15) - tart cherry - 5 pre-GLP trials (2 USA; 3 Canada), 6 GLP (Italy), 4 GLP (France)
	Propamocarb (148); Bayer CropScience	Broccoli; cauliflower; Brussels sprouts; head cabbage; kale; onions; leeks IR-4 Add-On: lima bean	Broccoli (10); cauliflower (10); Brussels sprouts (8); cabbages, head (12); kale (9); onion, bulb (21); leek (12) Additional IR-4 data: bean (lima) (6)
Propylene oxide [Balchem] (250) JMPR 2013	Propylene oxide [Balchem] (250)	Tree nuts	
	Prothioconazole [Bayer CropScience] (232)	Cranberry; blueberry; cucurbits, soya bean, maize, potato, peanut, oilseed rape	Cranberry (6), Blueberry (11), Cucurbits (24), Soya bean (20), Maize (62), Potato (20), peanut (8), oilseed rape (34)
	Pyraclostrobin [BASF] (210)	Apricot	Apricot - trials?
	Sedaxane [Syngenta] (259)	Potatoes; corn; pulses and sorghum	Potato – 29 trials total – 13 in Canada + 16 in USA Corn – 29 trials total – 3 in Canada (sweet corn only) + 26 in USA (field and sweet Corn) Sorghum – 12 trials total 12 in USA Pulses (dry peas and beans) – 23 trials total 13 trials in Canada (5 dry bean + 8 dry pea trials) + 10 trials in USA (5 dry bean + 5 dry pea trials)

2014 JMPR - NEW USES AND OTHER EVALUATIONS – SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
	Spirodiclofen (237) Bayer CropScience	Avocados; blueberry	Avocados (5), Blueberry (12)
	Sulfoxaflor (252)	Review of residue data sets	
	Thiamethoxam (245) [Syngenta]	persimmon (RoK) IR-4 Add-On: legume veg. (beans, peas, lentils, pulses, chick pea, etc.); avocado; hops; mint	persimmon (6) Additional IR-4 data: bean (succulent) (13); pea (EP + SS) (10); bean (dry) (9); pea (dry) (5); avocado (3); hops (4); mint (5)
	Triadimenol (168) Bayer CropScience	Grapes	Grapes (16)

REPORT of 46th SESSION CODEX COMMITTEE ON PESTICIDE RESIDUES
5-10 May 2014, Nanjing, China

Introduction

The Codex Committee on Pesticide Residues (CCPR) held its Forty-sixth Session in Nanjing, China, from the 5th to the 10th of May 2014. The Meeting was attended by 263 delegates representing 59 Member Countries, one Member Organization and Observers from 10 international organizations. The full agenda papers and report of the meeting are available at: ftp://ftp.fao.org/codex/meetings/CCPR/CCPR46/

The Australian delegation was led by Mr Ian Reichstein, DAFF, and comprised four members representing government (APVMA and DAFF) and industry sectors (horticulture and grains).

A large number of maximum residue level recommendations were discussed with 344 MRLs recommended for adoption by the Committee. In addition, a number of proposals were discussed regarding new initiatives aimed at improving efficiencies in MRL assessments and promulgations. These included the possibility of holding a second JMPR meeting in 2015.

Maximum Residue Limits

The Committee advanced 344 MRLs for adoption as Codex CXLs, i.e., to Step 8 or Step 5/8 (see Appendix I). Of these MRLs, 343 were fast-tracked. In these cases, Codex CXLs will be established less than a year after evaluation by the Joint Meeting on Pesticide Residues (JMPR). One hundred and four MRLs were recommended for deletion.

Cumulative risk assessment

JMPR Secretariat informed the Committee about ongoing discussions on the development of cumulative risk assessment methodology, i.e., assessing the aggregated risk from chemicals with similar modes of or sites of action.

Residue trial data from different geographical locations

The FAO JMPR Secretariat noted the variable nature of residue trial data but indicated that geographical location shouldn't be a barrier to the establishment of Codex MRLs. The EU indicated that if combining data from different regions the overall measurement uncertainty shouldn't be increased. It was proposed to ask further explanation and clarification from the JMPR through practical examples in the next JMPR report.

Codex Classifications of vegetables

The next phase of the work, the revision of vegetable commodity classifications has finalised the revision of the Classification for the Root and tuber vegetable commodity and agreed to hold the group at Step 7 with Brassica (cole or cabbage vegetables, head and flowerhead heads; Leafy vegetables (including brassica leafy vegetables); and Stalk and stem vegetables pending finalization of the *Classification of Food and Feed* in relation to the remaining vegetable commodity groups.

The Committee also discussed the proposed revised classifications for Cucurbit vegetables and legume vegetables. Of particular interest were the proposals to divide Cucurbit vegetables into three sub groups (Fruiting vegetables, Cucurbits – Cucumber and Summer Squashes, Fruiting vegetables, Cucurbits – Melons and Fruiting vegetables, Cucurbits – Winter squashes) and whether to divide legume vegetables into two (i.e. legume vegetables with or without pods) or four subgroups (i.e. beans with pods; peas with pods; succulent beans without pods; and succulent peas without pods). Discussions on the proposed

MRLs for minor crops and specialty commodities

The Committee agreed to seek feedback from the 2014 JMPR on the criteria, methodology and minor and major crop lists and whether the proposed approach could be used as a starting point in determining the number of trials considered necessary in the setting of MRLs for minor crops.

Priorities

Australia chaired the eWG on Priorities and relevant discussion at plenary. The Committee agreed to the proposed schedule for JMPR evaluations in 2015 (see Appendix II).

The next Session of the CCPR was tentatively scheduled to be held in China in 20-25th of April 2015, the final arrangements being subject to confirmation by the Host Country and the Codex Secretariat.

Appendix I MRLs agreed for adoption at CCPR 46.

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
Azoxystrobin (229)	GC 0640	Barley	1.5	0.5
	SB 0716	Coffee beans	0.03	0.02
ADI: 0–0.2 mg/kg bw	SM 0716	Coffee beans, roasted		
ARfD: Unnecessary	GC 0647	Oats	1.5	0.5
	AL 0072	Pea hay or fodder (dry) a	20 a	
	AL 0528	Pea vines (green)		
	VR 0589	Potato	7 Po	
	VD 0070	Pulses, dry, except soya beans	0.07	
	VR 0075	Root and tuber vegetables	W	1
	VR 0075	Root and tuber vegetables, except potato	1	
	GC 0651	Sorghum	10	
	AS 0651	Sorghum straw and fodder, dry	30 a	
	AS 0081	Straw and fodder of cereal grains, except maize	W	15
	AS 0081	Straw and fodder of cereal grains, except maize and sorghum	15 a	
Bentazone (172)**	AL 1020	Alfalfa fodder	0.5	
	GC 0640	Barley	W	0.1
ADI: 0–0.09 mg/kg bw	AS 0640	Barley straw and fodder, dry	0.3	
ARfD: Unnecessary	VD 0071	Beans (dry)	0.04	0.05*
	VP 0061	Beans, except broad bean and soya beans (green pods and immature seeds)	0.01*	
	VP 0062	Beans, shelled (succulent=immature seeds)	0.01*	
	GC 0080	Cereal grains	0.01*	
	VP 0526	Common bean (pods and/or immature seeds)	W	0.2
	PE 0112	Eggs	0.01*	0.05*
	VD 0561	Field pea (dry)	W	1
	VP 0528	Garden pea (young pods)(=succulent, immature seeds)	W	0.2
	AS 0162	Hay of fodder (dry) of grass	2	
	HH 0092	Herbs	0.1	
	VP 0534	Lima bean (young pods and /or immature beans)	W	0.05
	SO 0693	Linseed	0.02*	0.1
	GC 0645	Maize	W	0.2
	AS 0645	Maize fodder	0.4	0.2
	MM 0095	Meat (from mammals other than marine mammals)	W	0.05*
	ML 0106	Milks	0.01*	0.05*
	AS 0646	Millet fodder, dry	0.3	
	GC 0647	Oats	W	0.1
	AF 0647	Oat straw and fodder, dry	0.3	0.1
	VA 0385	Onion, Bulb	0.04	0.1
	SO 0697	Peanut	0.05*	0.05
	VP 0063	Peas (pods and succulent = immature seeds)	1.5	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	VR 0589	Potato	0.1	0.1
	PM 0110	Poultry meat (fat)	0.03	
	PO 0111	Poultry, Edible offal of	0.07	
	GC 0649	Rice	W	0.1
	GC 0650	Rye	W	0.1
	AF 0650	Rye straw and fodder, dry	0.3	
	GC 0651	Sorghum	W	0.1
	VD 0541	Soya bean (dry)	0.01*	0.1
	VA 0389	Spring onion	0.08	
	VO 0447	Sweet corn (corn-on-the-cob)	0.01*	
	AS 0653	Triticale straw and fodder, dry	0.3	
	GC 0654	Wheat	W	0.1
	AF 0654	Wheat straw and fodder, dry	0.3	
Chlorantraniliprole (230)	VS 0620	Artichoke, Globe	2	
ADI: 0–2 mg/kg bw	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.8	
ARfD: Unnecessary	VR 0577	Carrot	0.08	
	GC 0080	Cereal grains	W	0.02
	GC 0080	Cereal grains, except rice	0.02	
	SB 0716	Coffee beans	0.05	
	PE 0112	Eggs	0.2	0.1
	DH 1100	Hops, dry	40	
	VL 0053	Leafy vegetables	W	20
	VL 0053	Leafy vegetables, except radish leaves	20	
	VP 0063	Peas (pods and succulent = immature seeds)	2	
	VP 0064	Peas, shelled (succulent seeds)	0.05	
	FI 0355	Pomegranate	0.4	
	PM 0110	Poultry meat	0.01 *	0.01*
	PO 0111	Poultry, Edible offal of	0.01 *	0.01*
	VR 0494	Radish	0.5	
	VL 0494	Radish leaves, including radish tops	40	
	SO 0495	Rape seed	2	
	GC 0649	Rice	0.4	
		Rice, polished	0.04	
	VR 0075	Root and tuber vegetables	W	0.02
	VR 0075	Root and tuber vegetables, except carrot and radish	0.02	
	SO 0702	Sunflower seed	2	
Clothianidin (238)	VR 0075	Root and tuber vegetables	0.2	
Cyantraniliprole (263)*				
ADI: 0–0.03 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2	
ARfD: Unnecessary	FB 2006	Bush berries	4	
	VX 0624	Celery	15	
	FS 0013	Cherries	6	
	SB 0716	Coffee beans	0.03	
	MO 0105	Edible offal (Mammalian)	0.05	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	PE 0112	Eggs	0.015	
	AM 1051	Fodder beet	0.02	
	VC 0045	Fruiting vegetables, Cucurbits	0.3	
	VO 0050	Fruiting vegetables, other than Cucurbits (except mushrooms & sweet corn)	0.5	
	VA 0381	Garlic	0.05	
	VL 0053	Leafy vegetables (except Lettuce, Head)	20	
	AL 0157	Legume animal feeds	0.8 c	
	VL 0482	Lettuce, Head	5	
	ML 0106	Milks	0.02	
	VA 0385	Onion, Bulb	0.05	
	VA 0387	Onion, Welsh	8	
	FS 0247	Peach	1.5	
	HS 0444	Peppers Chili, dried	5	
	FS 0014	Plums (including prunes)	0.5	
	FP 0009	Pome fruits	0.8	
	VR 0589	Potato	0.05	
	PF 0111	Poultry fat	0.01	
	PM 0110	Poultry meat	0.01	
	PO 0111	Poultry, Edible offal of	0.01	
	DF 0014	Prunes	0.8	
	VR 0075	Root and tuber vegetables except potato	0.05	
	VA 0388	Shallot	0.05	
	VA 0389	Spring onion	8	
	AS 0161	Straw, fodder (dry) & hay of cereal grains and other grass like plants	0.2 c	
	AM 0506	Turnip fodder	0.02	
Cyproconazole (239) ADI: 0–0.02 mg/kg bw ARfD: 0.06 mg/kg bw	SB 0761	Coffee beans	0.07	
	SM 0716	Coffee beans roasted	0.1	
Cyprodinil (207) ADI:0–0.03 mg/kg bw ARfD: Unnecessary	FP 0226	Apple	W	0.05
	FI 0326	Avocado	1	
	VD 0071	Beans (dry)	0.2	
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.7	0.5
	VP 0062	Beans, shelled	0.06	
	FB 0018	Berries and other small fruits, except grapes	10	
	VL 0054	Brassica leafy vegetables	15	
	VB 0041	Cabbages, Head	0.7	
	VR 0577	Carrot	0.7	
	VC 0424	Cucumber	W	0.2
	DH 0170	Dried herbs, except hops, dry	300	
	MO 0105	Edible offal (Mammalian)	0.01	0.01*
	VO 0440	Egg plant	W	0.2
	VB 0042	Flowerhead Brassicas (includes Broccoli: Broccoli , Chinese and Cauliflower)	2	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	VC 0045	Fruiting vegetables, Cucurbits	0.5	
	VO 0050	Fruiting vegetables, other than Cucurbits, except sweet corn and mushroom	2	
	HH 0092	Herbs	40	
	VL 0053	Leafy vegetables, except brassica leafy vegetables	50	
	VL 0482	Lettuce, Head	W	10
	VL 0483	Lettuce, Leaf	W	10
	VR 0588	Parsnip	0.7	
	FP 0230	Pear	W	1
	HS 0444	Peppers Chili, dried	9	
	VO 0445	Peppers, Sweet (including Pimento or pimiento)	W	0.5
	FP 0009	Pome fruits	2	
	VR 0494	Radish	0.3	
	FB 0272	Raspberries, Red, Black	W	0.5
	VC 0431	Squash, Summer	W	0.2
	FB 0275	Strawberry	W	2
	VO 0448	Tomato	W	0.5
Dicamba (240) ADI: 0–0.3 mg/kg bw ARfD: 0.5 mg/kg bw	VD 0541	Soya bean (dry)	10	5
Difenoconazole (224) ADI: 0–0.01 mg/kg bw ARfD: 0.3 mg/kg bw	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	2	
	VB 0400	Broccoli	W	0.5
	VB 0402	Brussels sprouts	W	0.2
	VB 0041	Cabbages, Head	W	0.2
	VB 0404	Cauliflowers	W	0.2
	FC 0001	Citrus fruits	0.6	
	VC 0424	Cucumber	0.2	
	DF 0269	Dried grapes (=currants, Raisins and Sultanas)	6	
	MO 0105	Edible offal (Mammalian)	1.5	0.2
	PE 0112	Eggs	0.03	0.01*
	VO 0050	Fruiting vegetables , other than Cucurbits, except sweet corn and mushroom	0.6	
	VO 0448	Tomato	W	0.5
	VC 0425	Gherkin	0.2	
	VR 0604	Ginseng	0.08	0.5
	DV 0604	Ginseng, dried including red ginseng	0.2	
	DM 0604	Ginseng, extracts	0.6	
	FB 0269	Grapes	3	0.1
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	0.05 (fat)
	VC 0046	Melons, except Watermelon	0.7	
	ML 0106	Milks	0.02	0.005*
	VA 0385	Onion, Bulb	0.1	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	HS 0444	Peppers, Chili, dried	5	
	FP 0009	Pome fruits	0.8	0.5
	VR 0589	Potato	4 Po	0.02
	VA 0389	Spring Onion	9	
	VC 0431	Squash, Summer	0.2	
Diquat (031)**	AL 1020	Alfalfa fodder	W	100
ADI: 0–0.006 mg/kg bw	FI 0327	Banana	0.02*	
ARfD: 0.8 mg/kg bw	GC 0640	Barley	W	5
	FT 2352	Cajou (pseudofruit)	0.02 *	
	FT 0292	Cashew apple	0.02 *	
	TN 0292	Cashew nut	0.02 *	
	FC 0001	Citrus fruits	0.02 *	
	SB 0716	Coffee beans	0.02 *	
	VO 0050	Fruiting vegetables, other than cucurbits (except sweetcorn, fungi and mushrooms)	0.01*	
	VD 0533	Lentil (dry)	W	0.2
	GC 0645	Maize	W	0.05
	GC 0647	Oats	W	2
	VD 0072	Peas (dry)	0.3	0.2
	AL 0072	Pea fodder	50	
	FP 0009	Pome fruits	0.02 *	
	VR 0589	Potato	0.1	0.05
	SO 0495	Rape seed	1.5	2
	GC 0649	Rice	W	10
	CM 0649	Rice, husked	W	1
	CM 1205	Rice, polished	W	0.2
	GC 0651	Sorghum	W	2
	VD 0541	Soya bean (dry)	0.3	0.2
	FS 0012	Stone fruits	0.02 *	
	FB 0275	Strawberry	0.05 *	
	SO 0702	Sunflower seed	0.9	1
	OC 0172	Vegetable oils, Crude	W	0.05
		Vegetables (except as otherwise listed)	W	0.05
	GC 0654	Wheat	W	2
	CM 0654	Wheat bran, unprocessed	W	2
	CF 1211	Wheat flour	W	0.5
	CF 1212	Wheat wholemeal	W	2
	TN 0660	Almonds	0.05*	
Dithianon (180)**	FS 0013	Cherries	W	5a
ADI: 0–0.01 mg/kg bw	FB 0021	Currants, Black, Red, White	2	
ARfD: 0.1 mg/kg bw	DF 0269	Dried grapes (= currants, Raisins and Sultanas)	3.5	
	MO 0105	Edible offal (Mammalian)	0.01*	
	PE 0112	Eggs	0.01*	
	FB 0269	Grapes	W	3 b
	DH 1100	Hops, dry	300	100
	FC 0206	Mandarin	W	3
	MM 0095	Meat (from mammals other than marine mammals)	0.01*	
	ML 0106	Milks	0.01*	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	FP 0009	Pome fruits	1	5
	PM 0110	Poultry meat	0.01*	
	PO 0110	Poultry, Edible offal of	0.01*	
	FC 0005	Shaddocks or pomelos (including Shaddock-like hybrids, among others than grapefruit)	W	3
	FS 0012	Stone fruits	2	
	FB 1235	Table-grapes	2	
	FB 1236	Wine-grapes	5	
Fenbuconazole (197)	FC 0001	Citrus fruit (except Lemons and Limes)	0.5	-
ADI: 0–0.03 mg/kg bw	OR 0001	Citrus oil, edible (except Lemons and Limes)	30	-
ARfD: 0.2 mg/kg bw	AB 0001	Citrus pulp, dry	4	-
	FC 0002	Lemons and Limes (including Citron)	1	-
Fenpyroximate (193)	FI 0326	Avocado	0.2	-
ADI: 0–0.01 mg/kg bw	MO 1280	Cattle kidney	W	0.01*
ARfD: 0.02 mg/kg bw	MO 1281	Cattle liver	W	0.01*
	MM 0812	Cattle meat	W	0.02 (fat)
	ML 0812	Cattle milk	W	0.005* F
	FS 0013	Cherries	2	-
	VP 0526	Common bean (pods and/or immature seeds)	0.4	-
	VC 0424	Cucumber	0.3	0.03
	MO 0105	Edible offal (Mammalian)	0.02	
	MM 0095	Meat (from mammals other than marine mammals)	0.2 (fat)	
	ML 0106	Milks	0.01*	
	VR 0589	Potato	0.05	-
	DF 0014	Prunes	0.7	-
	FS 0012	Stone fruits (except cherries)	0.4	-
	FB 0275	Strawberry	0.8	-
Fludioxonil (211)	FI 0326	Avocado	0.4	
ADI: 0–0.4 mg/kg bw	HH 0772	Basil, sweet	W	10
ARfD: Unnecessary	DH 0772	Basil, dry	W	50
	VP 0061	Beans, except broad bean and soya bean (green pods and immature seeds)	0.6	0.3
	VP 0062	Beans (shelled)	0.4	
	VD 0071	Beans (dry)	0.5	0.07
	VC 4199	Melons	W	0.03
	HH 0727	Chives	W	10
	DH 0727	Chives, dry	W	50
	HS 0444	Peppers Chili, dried	4	
	DH 0092	Dried herbs	60	
	PE 0112	Eggs	0.01*	0.05*
	VC 0045	Fruiting vegetables, Cucurbits	0.5	
	VR 0604	Ginseng	4	
	HH 0092	Herbs	9	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	VL 0483	Lettuce, leaf	40	
	VO 0051	Peppers	1	
	VO 0445	Peppers, sweet (including pimento or pimiento)	W	1
	VR 0589	Potato	5 Po	0.02
	PM 0110	Poultry meat	0.01*	0.01*
	PO 0111	Poultry, Edible offal of	0.05*	0.05*
	VR 0494	Radish	0.3	
	VL 0494	Radish leaves (including Radish tops)	20	
	VP 4453	Snap beans (young pods)	0.6	
	VL 0502	Spinach	30	
	VC 0431	Squash, Summer	W	0.3
	VO 0448	Tomato	2	0.5
Flutolanil (205) ADI: 0–0.09 mg/kg bw ARfD: Unnecessary	VL 0054	Brassica leafy vegetables	0.07	
	VB 0040	Brassica (cole or cabbage) vegetables, Head cabbages, Flowerhead brassicas	0.05*	
	MO 0105	Edible offal	0.5	
	MO 0098	Kidney of cattle, goats, pigs and sheep	W	0.1
	MO 0099	Liver of cattle, goats, pigs and sheep	W	0.2
Glyphosate (158) ADI: 0–1 mg/kg bw ARfD: Unnecessary	SO 0495	Rape seed	30	20
Imazapic (266)* ADI: 0–0.7 mg/kg bw ARfD: Unnecessary	MO 0105	Edible offal (Mammalian)	1	
	PE 0112	Eggs	0.01*	
	AS 0162	Hay or fodder (dry) of grasses	3	
	GC 0645	Maize	0.01*	
	MF 0100	Mammalian fats (except milk fats)	0.1	
	MM 0095	Meat (from mammals other than marine mammals)	0.1	
	ML 0106	Milks	0.1	
	SO 0697	Peanut	0.05*	
	PF 0111	Poultry fats	0.01*	
	PM 0110	Poultry meat	0.01*	
	PO 0111	Poultry, edible offal of	0.01*	
	SO 0495	Rape seed	0.05*	
	GC 0649	Rice	0.05*	
	GC 0654	Wheat	0.05*	
	GS 0659	Sugar cane	0.01*	
	AS 0654	Wheat straw and fodder, dry	0.05*	
Imazapyr (267)* ADI: 0–3 mg/kg bw ARfD: Unnecessary	MO 0105	Edible offal (Mammalian)	0.05*	
	PE 0112	Eggs	0.01*	
	VD 0533	Lentil (dry)	0.3	
	GC 0645	Maize	0.05*	
	MF 0100	Mammalian fats (except milk fats)	0.05*	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	MM 0095	Meat (from mammals other than marine mammals)	0.05*	
	ML 0106	Milks	0.01*	
	PO 0111	Poultry, Edible offal of	0.01*	
	PF 0111	Poultry fats	0.01*	
	PM 0110	Poultry meat	0.01*	
	SO 0495	Rape seed	0.05*	
	SO 0702	Sunflower seed	0.08	
	GC 0654	Wheat	0.05*	
	AS 0654	Wheat straw and fodder, dry	0.05*	
Indoxacarb (216) ADI: 0–0.01 mg/kg bw ARfD: 0.1 mg/kg bw	DT1114	Tea, green, black (black, fermented and dried)	5	
Isoxaflutole (268)* ADI: 0–0.02 mg/kg bw ARfD: Unnecessary	VD 0524	Chick-pea (dry)	0.01*	
	AL 0524	Chick-pea fodder	0.01*	
	MO 0105	Edible offal (Mammalian)	0.1	
	PE 0112	Eggs	0.01*	
	GC 0645	Maize	0.02*	
	AS 0645	Maize fodder	0.02*	
	MF 0100	Mammalian fats (except milk fats)	0.01*	
	MM 0095	Meat (from mammals other than marine mammals)	0.01*	
	ML 0106	Milks	0.01*	
	SO 0698	Poppy seed	0.02*	
	PM 0110	Poultry meat	0.01*	
	PF 0111	Poultry fats	0.01*	
	PO 0111	Poultry, Edible offal of	0.2	
	GS 0659	Sugar cane	0.01*	
	AV 0659	Sugar cane fodder	0.01*	
	VO 0447	Sweet corn (corn-on-the-cob)	0.02*	
Malathion (049) ADI: 0–0.3 mg/kg bw ARfD: 2 mg/kg bw	FS0013	Cherries	3	
Mandipropamid (231) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	DH 1100	Hops, dry	90	
	-	Beer		
Penthiopyrad (253) ADI: 0–0.1 mg/kg bw ARfD: 1 mg/kg bw	GC 0640	Barley	0.2	0.15
	MO 0105	Edible offal (Mammalian)	0.08	
	MF 0100	Mammalian fats (except milk fats)	0.05	
	MM 0095	Meat (from mammals other than marine mammals)	0.04	
	ML 0106	Milks	0.04	
	GC 0647	Oats	0.2	0.15
	GC 0650	Rye	0.1	0.04
	GC 0653	Triticale	0.1	0.04
	GC 0654	Wheat	0.1	0.04
	CM 0654	Wheat, bran	0.2	0.1

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
	CF 1210	Wheat, germ	0.2	0.1
Propiconazole (160) ADI: 0–0.07 mg/kg bw ARfD: 0.3 mg/kg bw	FS 0247 FS 0014 FC 0004 VO 0448	Peach Plums (including prunes) Oranges, Sweet, Sour (including Orange-like hybrids): several cultivars Tomato	5 Po 0.6 Po 9 Po 3	
Pyrimethanil (226) ADI: 0–0.2 mg/kg bw ARfD: Unnecessary	FP 0009 DV 0604 FB 2009 FB 0275	Pome Fruits Ginseng, dried including red ginseng Low growing berries Strawberry	15 Po 1.5 3 W	7 3
Spirotetramat (234) ADI: 0–0.05 mg/kg bw ARfD: 1.0 mg/kg bw	VS 0620 FB 2006 FB 0265	Artichoke, Globe Bush berries Cranberry	1 1.5 0.2	
Sulfoxaflor (252) ADI: 0–0.05 mg/kg bw ARfD: 0.3 mg/kg bw	VD 0071 VR 0577	Beans (dry) Carrots	0.3 0.05	
Tolfenpyrad (269)* ADI: 0–0.006 mg/kg bw ARfD: 0.01 mg/kg bw		Tea, green	30	
Triazophos (143) ADI: 0–0.001 mg/kg bw ARfD: 0.001 mg/kg bw	CM 0649 CM 1205	Rice, husked Rice, polished	2 0.6	
Triflumizole (270)* ADI: 0–0.04 mg/kg bw ARfD: 0.3 mg/kg bw	FS 0013 VC 0424 MO 0105 FB 0269 DH 1100 MF 0100 ML 0106 MM 0095 FI 0350	Cherries Cucumber Edible Offal (Mammalian) Grapes Hops, dry Mammalian fats (except milk fat) Milks Meat (from mammals other than marine mammals) Papaya	4 0.5 0.2 4 30 0.02 0.02 * 0.05 (fat) 2	
Trinexapac-ethyl (271)* ADI: 0–0.3 mg/kg bw	GC 0640	Barley Barley bran	3 6	

Pesticide (Codex reference number)	CCN	Commodity	Recommended Maximum residue level (mg/kg)	
			New	Previous
ARfD: Unnecessary	AS 0640	Barley straw and fodder, dry	0.9	
	MO 0105	Edible offal (Mammalian)	0.1	
	PE 0112	Eggs	0.01*	
	MF 0100	Mammalian fats (except milk fats)	0.01 *	
	MM 0095	Meat (from mammals other than marine mammals)	0.01 *	
	ML 0106	Milks	0.005 *	
	GC 0647	Oats	3	
	AS 0647	Oat straw and fodder, dry	0.9	
	PF 0111	Poultry fats	0.01 *	
	PM 0110	Poultry meat	0.01 *	
	PO 0111	Poultry, Edible offal of	0.05	
	SO 0495	Rape seed	1.5	
	GS 0659	Sugar cane	0.5	
	GC 0653	Triticale	3	
	AS 0653	Triticale straw and fodder, dry	0.9	
	GC 0654	Wheat	3	
	CM 0654	Wheat bran	8	
	AS 0654	Wheat straw and fodder, dry	0.9	

Appendix II Priority list of pesticides to be evaluated in 2015 for consideration and potential MRL promulgation in 2016.

2015 JMPR - NEW COMPOUND EVALUATIONS – PROPOSED SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation criteria**	**Commodities**	**Residue trials provided**
Acetochlor (999) (herbicide) USA [Monsanto]	Acetochlor	Registered MRLs > LOQ	Corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernels plus cob with husks removed; corn, sweet, stover; cotton, gin by-products; cotton, undelinted seed; sorghum, grain forage; sorghum, grain, grain; sorghum, grain, stover; soybean, meal; soybean, seed; beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops; peanut; peanut, hay; peanut, meal For crops planted in rotation which are included in a crop group tolerance or which have a stand-alone tolerance in the USA: Rice, grain; rice, straw; wheat, forage; wheat, hay; wheat, straw; wheat, grain; alfalfa, forage; alfalfa, hay; clover; potatoes; sunflower seed	Corn, field, forage; corn, field, grain; corn, field, stover; corn, pop, grain; corn, pop, stover; corn, sweet, forage; corn, sweet, kernels plus cob with husks removed; corn, sweet, stover (21 total); cotton, gin by-products; cotton, undelinted seed (13 total); sorghum, grain forage; sorghum, grain, grain; sorghum, grain, stover (13 total); soybean, meal; soybean, seed (21 total); beet, sugar, dried pulp; beet, sugar, molasses; beet, sugar, roots; beet, sugar, tops (15 total); peanut; peanut, hay; peanut, meal (13 total) For crops planted in rotation which are included in a crop group tolerance or which have a stand-alone tolerance in the USA: rice, grain; rice, straw; wheat, forage; wheat, hay; wheat, straw; wheat, grain; alfalfa, forage; alfalfa, hay (11); clover (10); potatoes (10); sunflower seed (8); dried beans (9)
Cyazofamid (999) (fungicide) [Ishihara Sangyo Kaisha] USA	Cyazofamid	Registered MRLs > LOQ	Hops; potato; tomato; grape; cucurbits; carrots; brassica vegetables; okra; spinach; other fruiting vegetables; leafy vegetables US add on: Basil; succulent bean*; succulent shelled bean*; chives**; lettuce; spinach US registration date: 02/07/13 – pending registration	USA/Canada: potato (27); tomato (35); cucurbits (11); cucumber (11); muskmelon (9); summer squash; grape (3-USA) (1-Argentina); (10-EU) (1-Mexico); pepper (9-bell and non-bell); carrot (14); broccoli (6); cabbage (9); mustard greens (9); spinach (10); hops (3) Basil (6); succulent bean (8); succulent shelled bean (8); chives (9); lettuce (21); spinach (10)
Fenazaquin (999) (insecticide) [Gowan company] USA	Fenazaquin	Registered MRLs > LOQ	Alfalfa; apples; apricots; berries; citrus; cotton; cucurbits (cucumbers, melons, zucchini, squash, pumpkin); eggplant;	Cucurbits (cucumbers – 6; cantaloupe – 6; zucchini squash – 5); stone fruit (sweet cherries – 3; sour

2015 JMPR - NEW COMPOUND EVALUATIONS – PROPOSED SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation criteria**	**Commodities**	**Residue trials provided**
			grapes; hops; nectarines; peaches; pears; peppers; pineapples; plums; prunes; strawberries; tea; tomatoes; tree nuts; zucchini	cherries – 3; peach – 9; plum – 6); fruiting vegetable (tomato – 12; bell peppers – 6; chili peppers – 3); strawberries – 8; tree nuts (pecan – 5; almond – 5); berries (blueberry – 6; raspberry – 5); Hops – 3; mint (spearmint – 1; peppermint – 4); alfalfa – 4; corn (field, sweet) – 24; cotton – 12; bean (edible podded legumes – 9; succulent shelled pea & bean – 11; dried shelled pea & bean – 14); grape – 12; avocado – 5; citrus (orange – 12; lemon – 5; grapefruit – 6)
Flonicamid (999) (insecticide) [Ishihara Sangyo Kaisha] USA	Flonicamid	Registered MRLs > LOQ	Cucurbit, vegetables; fruiting vegetables; leafy vegetables; pome fruit; potato; stone fruit; head/stem brassica; mustard greens; brassica leafy greens; root vegetables; radish tops; tuberous/corm vegetables; hops; okra; cottonseed; hops US add on: Bean, dry and succulent**; canola; mint*; strawberry US registration date: 02/14– pending registration	USA/Canada: peach (9); cherry (6); plum (6); apple (12); pear (6); cucumber (6); cantaloupe (6); summer squash (5); tomato (21); bell pepper (6); non-bell pepper (3); broccoli (6); cabbage with wrapper leaves (6); cabbage without wrapper leaves (6); mustard greens (5); head lettuce with wrapper leaves (6); head lettuce without wrapper leaves (6); leaf lettuce (6); celery (6); spinach (6); potato tubers (17); carrot roots (8); carrot roots (2); radish roots (5); radish tops (5); dried hop cones (3) Bean, dry (12); canola (8); mint (5); strawberry (8)
Fluazifop-p-butyl (herbicide) [Syngenta] (999) Switzerland moved from 2014	Fluazifop-p-butyl	Registered MRsL>LOQ	Oil seed rape; soybean; dry beans; cotton; potato; sweet potato; sugar beets; citrus fruits; pome fruit; stone fruit; grapes; tree nuts; onion (could include bulb veg); cabbage; carrots; vegetables; bananas; coffee bean; (palm oil) US Add-ons: Lettuce**; rhubarb**; caneberry**; blueberry** Pending registration Brasil - sugarcane; sunflower; cotton seeds; potato; broccoli; onion; soya; tomato	Soybean (20); dry bean (12); oil seed rape (12); cotton (6); potato (16); sweet potato (6); carrots (12); onion (12); sugar beet (16); sugar cane (4); citrus fruit (16); pome fruits (16); stone fruit (16); grape (16); cabbage/brassica (12); lettuce (6); coffee (6); tree nutspecan (12); palm oil (4); tomato (16); asparagus (6); banana (10); cucumber/cucurbit (12) Lettuce (26); rhubarb

2015 JMPR - NEW COMPOUND EVALUATIONS – PROPOSED SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation criteria**	**Commodities**	**Residue trials provided**
			Animal feeding study data to support MRLs in animal commodities given use of cotton seed, rape seed and soybeans or their by-products as animal feeds	(2); caneberry (6); blueberry (9); coffee (2) Animal feeding study data to support MRLs in animal commodities Brasil - sugarcane; sunflower; cotton seeds; potato; broccoli; onion; soya; tomato
Flupyradifurone (insecticide) (999) [Bayer CropScience] Germany	Flupyradifurone	Registered; MRLs > LOQ	Citrus fruit; table and wine grapes and small berries (including blueberry); pome fruit; tree nuts; hops; fruiting and brassica vegetables; lettuce; potatoes; sugar beets; onions; cereals; coffee; soya and cotton US Add-ons:prickly pear cactus	Citrus fruit (54); table & wine grapes & small berries (78); pome fruit (39); tree nuts (10); hops (11); fruiting vegetable, cucurbits (89); fruiting vegetables other than cucurbits (96); brassica vegetables (56); leafy vegetables including brassica leafy vegetables (76); legume vegetables (52); root and tuber vegetables (43); onions (18); cereals (107); coffee (18); soya and cotton (44) Prickly pear cactus (8); blueberry (26)
Flumioxazin USA (herbicide) [Sumitomo] (999)	Flumioxazin	Registered MRLs >LOQ	Alfalfa; artichoke; asparagus; bushberry subgroup; cabbage and Chinese cabbage; cactus; corn; cotton; fish, freshwater; fruit, pome; fruit, stone; garlic; grape; hop; leaf petiole subgroup 4B; nut, tree; okra; olive; onion, bulb; pea and bean; dried shelled, except soybean; peanut; peppermint; pistachio; pomegranate; rapeseed subgroup 20A; shallot bulb; soybean; spearmint; strawberry; sugarcane; sunflower (subgroup 20B); vegetable; cucurbit; group 9; vegetable, fruiting; group 8; vegetable, tuberous and corm subgroup 1C (potato); wheat US add ons: broccoli**; caneberry**; prickly pear cactus Pending registration	Alfalfa: 13; artichoke: 3; asparagus: 8; bushberry subgroup: 5 (blueberry); cabbage and Chinese cabbage: 8; cactus: 2; corn: 21; cotton: 13; freshwater fish: 1 (catfish); 1 (bluegill sunfish); fruit, pome 12 (apple), 6 (pear); fruit, stone 9 (peach), 6 (plum), 6 (cherry); garlic: 9 (dry bulb onion); grape: 13; hop: 3; leaf petiole subgroup 4B; 8 (celery); nut, tree: 5 (pecan), 5 (almond); Okra: included in vegetable, fruiting, group 8; olive: 5; onion, bulb: 9; pea and bean, dried shelled, except soybean: 6 (dry pea), 12 (dry bean); peanut: 16; peppermint: 6; pistachio: 5 (almond); pomegranate: 3; rapeseed subgroup (canola): 8; shallot bulb: 9 (dry bulb onion); soybean: 42; spearmint: 6; strawberry: 8; sugarcane: 9; sunflower (subgroup 20B): 8; vegetable, cucurbit, group 9: 8 (cantaloupe),

2015 JMPR - NEW COMPOUND EVALUATIONS – PROPOSED SCHEDULE				
TOXICOLOGY	**RESIDUE**	**Prioritisation criteria**	**Commodities**	**Residue trials provided**
				8 (squash), 8 (cucumber); vegetable, fruiting, group 8: 12 (tomato), 9 (bell and non-bell pepper); vegetable, tuberous and corm subgroup 1C (potato): 14; wheat: 3 (pre-emergent), 20 (foliar) Broccoli (10); caneberry (8); prickly pear cactus (3)
Lufenuron (999) (insecticide) Brasil [Syngenta] **RESERVE**	Lufenuron	Registered MRLs >LOQ	Soybean; citrus; pome fruit; stone fruit; grapes; fruiting vegetables; melon; cucumber/squash; flowering brassica; head brassica; leafy vegetables; cotton; potato; sunflower; sugarcane; corn; wheat; rice; coffee	Soybean (8); citrus (18); pome fruit (16); stone fruit (16); fruiting vegetables (tomato, pepper) (21); melon (8); cucumber/squash (9); flowering brassica (16); head brassica (8); leafy vegetables (lettuce) (16); cotton (4); potato (4); sunflower (4); sugarcane (4); corn (4); wheat (4); coffee (4); rice (4); tea (4)
Phosphorous acid (fungicide) [Nufarm] Australia (999) **RESERVE**	Phosphorous acid fosetyl-aluminium [Bayer CropScience]	Registered MRLs >LOQ	Grapes US add on: Citrus Post harvest	To be advised Citrus (8)
Quinclorac (999) (herbicide) USA [BASF]	Quinclorac	Registered MRLs > LOQ	Barley; canola; cranberry; rhubarb; rice; sorghum; wheat; and animal feed items	Barley (5); canola (23); cranberry (5); rhubarb (4); rice (40); sorghum (24); wheat (67); and animal feed items (13)

2015 JMPR - NEW USES AND OTHER EVALUATIONS – PROPOSED SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
	2,4-D (020) [Dow AgroSciences] moved from 2012 on request	New GAP for soya bean	Soya bean (24)
	Acetamiprid (246) [Nippon Soda]	Fruiting vegetables other than cucurbits, China (tomatoes and cucumbers); seed spices [HS 190]; fruit and berry spices [HS 191] (India); pistachio (Iran); US Add-ons: Mustard greens; sweet corn; aspargus	Mustard greens (8); sweet corn (8); aspargus (8)
	Bifenthrin [FMC] (178)	strawberry; mango – authorised GAP US Add-ons: Chives; head lettuce; spinach; celery; snap bean; pea; lima bean; blueberry; grape; basil; artichoke	strawberry; mango – (authorised GAP) Chives (3); head lettuce(6); spinach (5); celery (12); snap bean (6); pea (6) lima bean (7); blueberry (9); grape (7); basil (2);

2015 JMPR - NEW USES AND OTHER EVALUATIONS – PROPOSED SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
			artichoke (2)
Moved from 2014 to allow JMPR to conduct one evaluation for all commodity requests.	Chlorothalonil [Syngenta] (81) (4 year rule)	Carrot; cherry; cranberry; bulb onion; peach; sweet and chilli pepper; tomato; common beans; asparagus Blueberry USA; apple and pear (KOREA) US Add-ons: radish (root veg)**; ginseng; horseradish; rhubarb; mustard greens**; pepper (bell); pepper (NB); orange**; lemon**; grapefruit (citrus fruit)**; almond; pistachio; mushroom; guava**; lychee**; mango; papaya; persimmon - **not submitted Brasil - coffee; mango; citrus; watermelon; soya; potato	Cherry (12); peach (12); bulb onion (8); sweet pepper (8); tomato (24); asparagus (8); cranberry (6); blueberry (8); radish (7); ginseng (5); horseradish (3); rhubarb (4); mustard greens (9); pepper (bell) (9); pepper (NB) (8); orange (12); lemon (5); grapefruit (6); almond (5); pistachio (3); mushroom (3); guava (5); lychee (4); mango (4); papaya (4); persimmon (2) Apple, 6 (KOREA); pear 6 (KOREA), Brasil - coffee; mango; citrus; watermelon; soya; potato
	Cyantraniliprole (263) [DuPont] USA	Cucumber; carrot; radish; legumes (succulent and dried); green beans; peas; maize; strawberries; artichokes; tobacco; peanuts; soybeans Potato; coffee; citrus; oil seeds; grapes; olives; sunflower; pomegranate; green beans; rice and tree nuts	Carrots (42 trials); brussels sprouts (10 trials); beans without pods (16 trials); peas without pods (16 trials); cucumber (greenhouse – 5 trials); cherries (14 trials); strawberries (28 trials); peanuts (13 trials); soybeans (21 trials); maize (23 trials); artichokes (6 trials)
	Cyprodinil (207) [Syngenta]	Rapeseed / Canola - MRL > LOQ Brasil - cotton; potato; citrus; sunflower; apple; soya	Rapeseed / Canola (16); Brasil - cotton; potato; citrus; sunflower; apple; soya
	Lambda-cyhalothrin (146) [Syngenta]	Basil (Thailand); Brasil - pineapple; coffee	Brasil - pineapple; coffee
	Carbofuran (145) FMC	Seed spices [HS 190]; fruit and berry spices [HS 191] (India)	
	Dicamba USA [Monsanto] (240)	Cotton – undelinted seed; cotton – gin by-products	Cotton (13)
	Difenoconazole (224) [Syngenta] USA	Papaya (Kenya); Canada – rapeseed / canola US Add-ons: Almond; soybean 13-07G. Low growing berry subgroup - Bearberry; bilberry; blueberry; lowbush; cloudberry; cranberry; lingonberry; muntries; partridgeberry; strawberry; cultivars, varieties, and/or hybrids of these Brasil - avocado; cotton seeds; peanut; rice; coffee; watermelon	Rapeseed / canola (13) Almond (5); soybean (20); strawberry (9) Brasil - avocado; cotton seeds; peanut; rice; coffee; watermelon
	Fluopyram [Bayer CropScience] (243)	Grapes; berries and small fruits; artichoke; tuber vegetables; leek; plum; tomato/aubergine; onion; peppers; cucumber; melon; chicory; beans); peas; maize; wheat & barley; soya bean; cotton; Peanut	Grapes; berries and small fruits (36 trials); artichoke (4); tuber vegetables (16); leek (20); plum (21); tomato/aubergine (12); onion (16); peppers (9); cucumber (8); melon (9); chicory (8); beans (9); peas (12); maize (16); wheat & barley (44); soya bean (21); cotton (11); Peanut (12)
	Flutriafol USA [Cheminova] (248)	Pears; peach/nectarine; plum; cherry; sugar beet; rice; strawberry; almond; pecan; tomato; cucumber; muskmelon; summer squash	Pears (6); peach/nectarine (12); plum (8); cherry (16); sugar beet (12); rice (8); strawberry (10); almond (5); pecan (5); tomato (19); cucumber (9); muskmelon (8); summer squash (8)
	Fluxapyroxad	Tree nuts; berries and small fruit;	Tree nuts (almond (5), pecan (5));

2015 JMPR - NEW USES AND OTHER EVALUATIONS – PROPOSED SCHEDULE			
TOXICOLOGY	**RESIDUE**	**Commodities**	**Residue trials provided**
	USA [BASF] (256)	grape; strawberry; bulb vegetables; brassica, leafy and head and stem, cucurbits; leafy vegetables (lettuce, spinach, celery); root and tuber vegetables (radish, carrot); cereal grains; grasses for sugar production (sugar cane); sorghum	berries and small fruit (blueberry (6), blackberry (1), raspberry (2)); grape (12); strawberry (8); bulb vegetables (green onion (3); dry bulb onion (6)); brassica (broccoli (6); cabbage (6); mustard greens (5)); cucurbits (cucumber (6); cantaloupe (6); summer squash (5)); leafy vegetables (head lettuce (6), leafy lettuce (6), spinach (6), celery (6)); root and tuber vegetables (radish (5), carrot (7)); cereal grains (rice (16)); sorghum (9); grasses for sugar production (sugar cane (8))
	Imazapic (266), imazapyr (267) [BASF] Australia	Soya bean	
Moved from 2014	Imidacloprid (206) [Bayer CropScience]	Stone fruit; olive; tea; Chinese cabbage; kale; pistachio (Iran); seed spices [HS 190]; fruit and berry spices [HS 191] (India), Goji (China), Basil (Thailand)	Stone fruits (40); olive (28); tea (8); Chinese cabbage and kale (4)
	Methoxyfenozide [Dow AgroScience] (209)	Fruiting vegetables / cucurbits, spring onion	
	Pyrimethanil [Bayer CropScience] (226)	Blueberry; blackberry; raspberry; cucumber	Blueberry (8); blackberry (3); raspberry (2); cucumber
	Spirotetramat [Bayer CropScience] (234) USA	Avocado; guava; sweet corn US Add ons: Artichoke; blueberry; coffee; cranberry; onion, green onion; pineapple; pomegranate; watercress	Avocado (5); guava (4); sweet corn (7) Artichoke (5); blueberry (11); coffee (5); cranberry (6); onion (12); green onion (5); pineapple (5); pomegranate (4); watercress (3)
	Tebuconazole (189) [Bayer CropScience] USA	China (banana and cucumber); lettuce head – Ginseng (KOREA); US Add-ons:sunflower; aspargus; onion, bulb; onion, green; garlic	Ginseng (6); sunflower (7); aspargus (8); onion, bulb (8); onion, green (3); garlic (9)
	Trifloxystrobin [Bayer CropScience] (213)	lentils; chick pea; beans; peas; soya beans	Beans (9); peas (9); soya beans (24);
Spices [India]	Spices [India]	Cardamon – cypermethrin (118); lambda-cyhalothrin (146); profenofos (171); triazophos (143) Black Pepper – profenofos (171); ethion (34); triazophos (143) Cumin – phorate (112); profenofos (171); dithiocarbamates (50 and 105); Curry leaves – profenofos (171); chorpyrifos (17); cypermethrin (118); methyl parathion (59); triazophos (143); ethion (34); bifenthrin (178)	Monitoring data

ATTACHMENT IX: Trade Advice Notice responses

Annelies McGaw
Pesticides Division
APVMA
PO Box 6182
KINGSTON ACT 2604

Pyraclostrobin Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the fungicide pyraclostrobin (*Nufarm Aero Fungicide*) recently released by the APVMA for public comment.

Horticulture Australia agrees with the APVMA assessment that the risk to trade of the proposed use of pyraclostrobin in tomatoes, eggplant, capsicums and mangoes is low. Nevertheless, HAL believes that for mangoes there would be value in the manufacturer publicizing a recommendation of an alternate 'Export' harvest interval that ensures either non-detectable residues or residues that will comply with the current Codex MRL.

Currently, many of the major export destinations for Australian mangoes (see below) reference Codex, in the absence of domestic MRLs, and as the Codex MRL (*0.05 mg/kg) is lower than the proposed Australian MRL (0.1 mg/kg) HAL believes it would be beneficial if the manufacturer could advise a suitable harvest interval to ensure compliance.

Value of mango exports (millions of AUD$) 2007-2008[72]

Country	July-07-Aug-08
Singapore	1.49
UAE	0.69
Malaysia	0.55
Japan	2.1
Hong Kong	3.73
New Zealand	0.86
Qatar	0.31

HAL acknowledges the presence of the generic label statement alerting growers to seek additional information where export is intended. However, HAL believes that a specific recommendation should be provided, either to the industry association or via promotional material, rather than relying on grower requests. This would confirm that such information exists and allow growers to plan their disease control programs with confidence.

Regards,

[72] **Source: Australian Bureau of Statistics**

Pat Robinson
Pesticides Division
APVMA
PO Box 6182
KINGSTON ACT 2604

Flubendiamide Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the insecticide flubendiamide (Belt 480 SC) recently released by the APVMA for public comment.

Horticulture Australia essentially agrees with the APVMA conclusion that the overall risk of flubendiamide use in tomatoes, capsicums and lettuce to export trade is small. Nevertheless, HAL believes that for lettuce there would be value in the manufacturer recommending an alternate harvest interval that ensures non-detectable residues.

Currently, the major export destination for Australian tomatoes and capsicums is New Zealand and as such would be covered by the provisions of the TTMRA. However, the lack of international MRLs for lettuce could be of concern. It is acknowledged that lettuce exports are very minor, e.g., in 2006 total exports were approximately 1500 tonnes which constituted less than 1% of total production. As the main export markets reference Codex, in the absence of domestic MRLs, and as there is no Codex MRL it would be beneficial if the manufacturer could provide advice as to a suitable harvest interval to ensure compliance, until such time as a Codex MRL is established.

Lettuce exports by volume 2006-2008[73]

Country	kg Jan-Dec 2006	kg Jan-Dec 2007	kg Jan-Dec 2008
Singapore	171,637	306,164	409,800
Indonesia	113,251	165,116	278,819
Malaysia	89,871	140,294	161,661
New Caledonia	20,789	27,389	118,869
Hong Kong	202,911	149,925	109,820

HAL acknowledges the presence of the proposed generic label statement alerting growers to seek additional information where export is intended. However, HAL believes that a specific recommendation should be provided, either to the industry association or via promotional material, rather than relying upon grower requests. This would confirm that such information exists and allow growers to plan their pest management programs accordingly.

Regards,

[73] **Source: Australian Bureau of Statistics**

Pat Robinson
Pesticides Division
APVMA
PO Box 6182
KINGSTON ACT 2604

Chlorothalonil Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the fungicide chlorothalonil in the product CropCare Barrack 720 recently released by the APVMA for public comment.

In terms of the two issues upon which comment is sought Horticulture Australia Limited considers that both the 60 day ESI and the proposed restraint statement for lactating dairy animals would be adequate in mitigating any risks to trade. Outlined below is the reasoning supporting this opinion.

Firstly, the residue data reported from processing pea forage and fodder was based on a use pattern of four applications at 7 day intervals at the maximum label rate. HAL believes the resultant data represents an exaggerated worse case scenario, i.e., industry practice would not involve four consecutive applications at maximum rates made immediately prior to harvest. Chlorothalonil, a protectant fungicide, is used prophylactically in conjunction with mancozeb, i.e., applied when weather conditions favour infection, to inhibit disease development. Consequently, it is unlikely that chlorothalonil would be applied in such a manner and HAL believes the residue levels found in the forage are higher than would be found in practice.

Secondly, Barrack 720 is currently approved for use in peas with the label carrying the restraint 'DO NOT GRAZE LIVESTOCK ON TREATED CROPS'. Adding the proposed statement against feeding treated pea forage and fodder to lactating dairy animals would, in effect, serve to significantly strengthen this existing DO NOT GRAZE restraint. Given that the combination of the existing restraint and measures already implemented by livestock industries, e.g., Animal Feed Vendor Declarations, have, to date, successfully managed chlorothalonil residues, HAL sees no reason to suggest why the addition of the proposed restraint would not be practical.

Regards,

Pat Robinson
Pesticides Division
APVMA
PO Box 6182
KINGSTON ACT 2604

Chlorothalonil Trade Advice Notice

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Regards,

Annelies McGaw
Pesticides Division
APVMA
PO Box 6182
KINGSTON ACT 2604

Spirotetramat Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the insecticide spirotetramat (Movento 240 SC) recently released by the APVMA for public comment.

HAL acknowledges the importance of the proposed generic label statement alerting growers to seek additional information where export is intended. However, HAL believes that specific recommendations should be provided, either to the industry association or via promotional material, rather than relying upon grower requests. This would confirm that such information exists and allow growers to plan their pest management programs accordingly.

To this end Horticulture Australia has attempted to consult with the manufacturer and industry associations regarding the provision of such advice and any additional concerns they may hold.

In relation to citrus, HAL and Citrus Australia and believes the risk to trade is manageable as the manufacturer has indicated a preparedness to provide a specific recommendation for inclusion into the industry export advisory guidelines.

In terms of onions HAL understands that the manufacturer is not in a position to make a recommendation that would enable compliance with current MRLs in export markets. However, the company has indicated that an EU MRL is to be sought with the intention of accommodating the proposed Australian MRL.

For mangoes, HAL is still seeking industry input to clarify the most likely timing in the use of spirotetramat, i.e., early applications targeted at crawler emergence or late season clean-up. Should early season use be favoured then residue discrepancies are unlikely to pose a major problem. However, if later treatments are likely to be favoured then the lack of MRLs in Codex and export destinations would be problematic.

Regards,

January 19th, 2012

Contact Officer, Pesticides
Pesticides Program
Australian Pesticides and Veterinary Medicines Authority
PO Box 6182
Kingston ACT 2604

Etoxazole Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the miticide etoxazole in the product Paramite Selective Miticide recently released by the APVMA for public comment. In terms of the issue upon which comment is sought Apples and Pears Australia Limited (APAL) does not consider that the proposed shortened withholding period is likely to prejudice Australian trade.

As indicated in the TAN the manufacturer has previously provided advice on a suitable export harvest interval to ensure compliance in export markets lacking MRLs. Further APAL understand that the 2011 JMPR have recommended the establishment of a Codex MRL for Pome fruit at 0.07 mg/kg. While lower than the current Australian MRL APAL believes that once promulgated, the Codex MRL will serve to further mitigate any potential risks to trade, i.e., in markets where Codex MRLs are accepted such as Malaysia, Singapore and Hong Kong.

Yours sincerely,

Kevin Bodnaruk

Andrew Harty
General Manager Market Development
Citrus Australia Ltd
115 Lime Avenue, Mildura, VIC, 3500

20th May, 2013

Pesticide Contact Officer
Pesticides Program
APVMA
PO Box 6182
SYMONSTON ACT 2609

Tops Plant Growth Regulator (triclopyr) Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the plant growth regulator triclopyr in the product Tops Plant Growth Regulator recently released by the APVMA for public comment.

In terms of the potential for the proposed fruit sizing/thinning use to unduly prejudice Australian exports of oranges and mandarins, Citrus Australia Limited considers that additional information is required to allow the industry to properly assess the potential trade risk. Outlined below is the reasoning supporting this opinion.

Firstly, the data reported in part 2.4 of the TAN is an aggregate of triclopyr residues found in oranges and mandarins. Citrus Australia believes to properly assess the risk to trade having the data reported by individual commodity would be more helpful, i.e., were finite residues found in both commodities?

Secondly, Citrus Australia assumes that the residue data reported in the TAN was for the critical GAP of 2 g ai/hL at the later fruit sizing timing. Were residue data also submitted for the fruit thinning timing and/or at the lower rate of 1 g ai/hL? If so, did the fruit thinning treatment or lower rate result in finite residues in the two commodities? Having this information available would allow users to better understand the residue profile and assess how trade risks can be effectively managed.

Citrus Australia, estimates that as the highest residue (0.083 mg/kg) is lower than established MRLs in export markets the ostensible risk to trade is low. Nevertheless, the industry believes that the provision of additional information on residues by commodity and the nature of residue decline would enable the industry to more fully assess any risks to trade.

Regards,

Andrew Harty

John Moore
CEO
Summerfruit Australia Ltd
8/452 Swift Street,
Albury, NSW 2640

12th June, 2013

Permit Applications Coordinator
Pesticides Program
APVMA
PO Box 6182
SYMONSTON ACT 2609

Samurai Systemic Insecticide (clothianidin) Trade Advice Notice

Regarding the Trade Advice Notice (TAN) for the insecticide clothianidin in the product Sumitomo Samurai Systemic Insecticide recently released by the APVMA for public comment.

Summerfruit Australia Limited does not anticipate that the proposed use would be likely to unduly prejudice Australian exports. Outlined below is information supporting this conclusion.

Exports of apricots are extremely small, in 2011/12 282 tonnes, with a value of AUD$1.32 million, were exported, constituting 2.1% of total production[74]. The major export destinations for Australian apricots in 2011/12 were the UAE (42%), Hong Kong (33.5%), Saudi Arabia (5.7%), Russia (3.2%) and Singapore (2.9%).

In the 2010 JMPR Evaluation of clothianidin, four residue trials in apricots were reported from Japan. Clothianidin was applied three times as a foliar spray at a rate of 8 g ai/hL with the total amount applied ranging from 560 to 640 g ai/ha, i.e., equivalent to application volumes of 2800–3200 L/ha based on the current Australian label rate of 20 g ai/hL, with harvest occurred 3 to 28 days after the final application. In two trials residues reported at the proposed WHP of 21 days were 0.32 and 0.56 mg/kg (see the Table 1 below).

[74] **ABS Stats Agricultural Commodities, Australia, 2010-11**

Table 1 Residues of clothianidin in Japanese apricot (pitted fruit) after foliar spray treatment in the field

Trial, Location Country, year (Variety)	Form	No	Interval (d)	g ai/ha	g ai/hL	method, timing	DAT	parent, mg/kg [a]	
Iizaka-machi, Fukushima, Japan, 2001 (Shiro-kaga)	160 SP	3	7–8 7–8	3× 560	3× 8.0	Foliar spray, 5 June; 29 May; 22 May, 22 May [c]	7 14 21 28	0.95 0.26 0.32 0.05	0.97 0.26 0.30 0.09
Arita-gun, Wakayama, Japan, 2001 (Nanko)	160 SP	3	4–10 4–10	400–640; 400–640; 640	3× 8.0	Foliar spray, 7 June; 29 May; 25 May; 15 May, [d]	7 14 21 28	1.0 1.1 0.56 0.60	1.1 0.87 0.56 0.50

[a] Results are from two replicate field samples

It is anticipated that residues, resulting from the proposed use in apricots, would be lower than the residues levels reported by the JMPR. Summerfruit believes that this would be the case as firstly, fewer applications are proposed under permit 13527; and secondly, that a lower rate of active ingredient would be applied on a per hectare basis, i.e., 400 g ai/ha. The current label carries the restraint that should water volumes exceed 2000 L/ha only a single application can be made. As a result the industry believes that residues in apricots from the proposed use are likely to be significantly lower than those reported by the JMPR, i.e., well below the temporary MRL of 2 mg/kg proposed by the APVMA.

Further, a major element of Oriental fruit moth control in stone fruit and other tree crops is the use of pheromone based mating disruption. As a result it is anticipated that the use of clothianidin would be used in conjunction with such techniques, i.e., that it would form part of an integrated program, further reducing the likely use and resultant residue levels. The industry, therefore, considers that the risk to trade from approval would be minimal, i.e., additional mitigation measures would be unnecessary.

Therefore, based on the likelihood that the proposed use is likely to result in relatively low residues, coupled with a number of jurisdictions either having MRLs in place or referencing Codex MRLs, e.g., Hong Kong, UAE and Saudi Arabia, the industry considers that the risk to trade from approval would be minimal.

Regards,

John Moore

Pesticide Residues
APVMA
PO Box 6182,
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RE: Trade Advice Notice for the proposed use of clothianidin on stone fruit.

Summerfruit Australia Limited (SAL) is the national peak body representing growers of nectarines, peaches, apricots and plums. SAL welcomes the opportunity to provide a response to the TAN and the two questions for which the APVMA specifically sought comment. Namely:-

1. Can the risks to export trade in pome and stone fruit associated with the proposed use be effectively managed?

2. What processes does the industry have, or will have, in place to ensure that risks to trade associated with the proposed use are effectively communicated and managed?

Regarding Question 1, firstly SAL believes that the APVMA residue assessment and proposed temporary MRLs to be overly conservative. SAL questions the need for a temporary MRL of 5 mg/kg. As indicated in the permit application the total amount of clothianidin applied in the Japanese apricot trials was 400–640 g ai/ha comparable to the Australian label rate of 20 g ai/hL with water volumes of 2000–3000 L/ha. SAL believes that scaling the residues from these trials has resulted in an overestimate of residues likely to result from the proposed use. It appears that the APVMA is assuming that between 1.0 and 1.6 kg ai/ha of clothianidin will be applied equivalent to application volumes of 5000 to 8000 L/ha at current Australian label rates.

As a consequence, SAL questions the size of proposed temporary MRL and suggests that the current MRLs established for peaches and nectarines of 2 mg/kg would be more appropriate for the crop group. While acknowledging that MRL disparities currently exist for nectarines and peaches the fact that they have been successfully exported with MRLs of 2 mg/kg SAL believes that achieving compliance will be possible going into the future.

In any event, regarding the second question, SAL believes that the potential risks to trade posed by the proposed use can still be effectively managed. Exports of apricots and plums, as indicated in the permit application, are extremely small at only 2.1% and 1.6% of national production. As more than a third of the exports originate from Tasmania and South Australia, i.e., fruit fly free regions, use under the proposed permit would be on only a portion of fruit destined for export and would be unlikely to have a major impact on trade. For peaches and nectarines and other stone fruit grown in fruit fly endemic areas SAL believes that any risk can be managed through the provision of information to growers, i.e., that MRL compliance in certain export markets for fruit treated with clothianidin could be problematic.

SAL proposes, following consultation with the registrant and exporters, to inform growers of the potential residue compliance risks associated with the use of clothianidin. This information would be disseminated, in conjunction with the registrant, via current industry communication channels such as the Australian Stonefruit Grower, the official publication for Summerfruit Australia Ltd and Low Chill Australia Inc., email and the SAL website.

The importance of having fruit fly management to the Summerfruit industry cannot be understated and gaining access to clothianidin would provide one additional, much needed management tool. Nevertheless, SAL appreciates that risks exist with regards to achieving MRL compliance in export markets but believes that such risks are manageable through close consultation and communication with the registrant, growers and exporters.

Yours sincerely,

ATTACHMENT X: Security Sensitive Chemicals

Chemicals of security concern published

The Council of Australian Governments (COAG) has recently identified 96 chemicals, some of which are approved for use in horticulture, as being of security concern, which have the potential to be used for unlawful purposes by those wishing to do harm .

COAG, in consultation with industry groups, are working together to minimise the risks associated with unlawful use of these chemicals to ensure public safety and national security.

As a large and diverse number of industrial, agricultural and veterinary chemicals are legitimately used by individuals and organisations every day, COAG is encouraging people involved in the manufacture, importation, transportation, sale and use of chemicals to report any unusual behaviour regarding the sale and/or use of chemicals to the National Security Hotline on 1800 123 400.

In addition, input is currently being sought into aspects of how some of these chemicals should be are managed into the future. From a horticultural perspective an online survey is currently open seeking comment on 11 of the chemicals, two of which are fertilizers, i.e., sodium nitrate and potassium nitrate. The survey will be open till 21 September 2011 at **www.pwc.com.au/surveys/chemical-security**

There is a need for increased security surrounding chemicals in Australia as the threat of terrorism is expected to continue into the foreseeable future. While the risk of misuse of chemicals by terrorists cannot be completely removed, Australian governments and industry are working closely together to mitigate this risk.

Common chemicals have been used by terrorist organisations to create powerful improvised explosive devices (IEDs) or toxic weapons in different parts of the world. Overseas attacks have resulted in many fatalities, injuries, and damage on a massive scale.

To access the full list of chemicals that have been assessed as a potential security concern, visit www.chemicalsecurity.gov.au.

INDUSTRY CAPABILITY STOCKTAKE

The first National Industry Reference Group of Chemical Security (NIRG) meeting in March 2009 agreed to a stocktake of resources available to the Australian chemicals sector to improve chemical security.

On behalf of the NIRG, the Chemical Security Coordination Unit (CSCU) is seeking information on resources such as codes of practice, guidelines, standards, training materials and information sharing protocols that your association has developed, is aware of, or is considering developing; to assist its members improve chemical security.

Whilst completing this questionnaire is voluntary, and we fully appreciate the time and effort required, it will assist in tailoring future engagement activities and strengthening and streamlining chemical security arrangements.

The information provided in this questionnaire is in addition to any information you have provided previously to the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). If your answer to any of the questions has already been provided to another Australian Government agency, such as NICNAS, to save your time, do not provide the information again. Rather, provide the contact details of the relevant government agency and the date it was provided.

Please note that information gathered will be treated in confidence and will only be shared amongst National Government Advisory Group (NGAG) and NIRG members unless permission is given to do otherwise.

Following the return of the surveys, the CSCU will collate the data and present the findings to the next NGAG and NIRG meetings.

Questions about the survey can be directed to Tim.Killesteyn@ag.gov.au or

(02) 6141 2990

Thank you for taking the time to complete this questionnaire.

Contact Details

Association:	Horticulture Australia
Contact name:	
Position:	
Phone:	
Email:	
Address:	

Question 1a

Please select the types of chemicals that are of interest to your association.

- Industrial chemicals
- Agricultural and veterinary chemicals
- Explosives

Question 1b

Please select which elements of the supply chain apply across your association.

- Transport

- Disposal
- Import / export
- Retail
- Storage
- Manufacture
- Wholesale
- Use

Question 1c

Of the 96 chemicals listed in the *COAG Report on the Control of Chemicals of Security Concern*, please circle / tick the chemicals that are relevant to your association. (Please note that the chemicals of potential security concern contained in the list are indicative only)

A	**CAS #**	**E**	**CAS #**	**O**	**CAS #**
Aldicarb	116-06-3	Endosulfan	115-29-7	Omethoate	1113-02-6
Ammonia (anhydrous)	7664-41-7	Ethion	563-12-2	Osmium tetroxide	7446-13-1
Ammonium nitrate*	6484-52-2	Ethyl mercury chloride	107-27-7	Oxamyl	23135-22-0
Ammonium perchlorate^	7790-98-9	Ethyldiethanolamine	139-87-7		
Arsenic pentoxide	1303-28-2			**P**	
Arsenic trioxide	1327-53-3	**F**		Paraquat	2074-50-2
Arsine	7784-42-1	Fenamiphos	22224-92-6	Parathion methyl	63653-66-7
Azinphos methyl	86-50-0	Fluorine gas	7782-41-4	Perchloric acid^	7601-90-3
		Fluoroacetic acid	144-49-0	Phorate	298-02-2
B		Fluoroethyl alcohol	000371-62-0	Phosgene	75-44-5
Bendiocarb	22781-23-3	Fluoroethyl fluoroacetate	459-99-4	Phosphide Al	8005-48-9
Beryllium sulphate	13510-49-1			Phosphide Mg	12057-74-8
Bromine	7726-95-6	**H**		Phosphide Zn	12037-79-5
		Hydrochloric acid	7647-01-0	Phosphine	7803-51-2
C		Hydrogen chloride	7647-01-0	Phosphorus	7723-14-0
Cadusafos	95465-99-9	Hydrogen cyanide	74-90-8	Phosphorus oxychloride	39380-77-3
Carbofuran	1563-66-2	Hydrogen peroxide^	8007-30-5	Phosphorus pentachloride	10026-13-8
Carbon disulphide	75-15-0	Hydrogen sulfide	7783-06-4	Phosphorus trichloride	37231-52-0
Carbon monoxide	630-08-0			Potassium chlorate^	7790-93-4
Chloropicrin	76-06-2	**M**		Potassium nitrate^	96193-83-8
Chlorfenvinphos	470-90-6	Mercuric chloride	7487-94-7	Potassium perchlorate^	7778-74-7
Chlorine gas	7782-50-5	Mercuric nitrate	8046-70-6	Propoxur	114-26-1
Cyanide calcium	592-01-8	Mercuric oxide	8028-34-0		
Cyanide mercury	592-04-1	Mercurous nitrate	7782-86-7	**S**	
Cyanide potassium	151-50-8	Methamidophos	115182-35-9	Sodium azide^	26628-22-8
Cyanide sodium	143-33-9	Methidathion	950-37-8	Sodium chlorate^	7775-09-9
Cyanide zinc	557-21-1	Methiocarb	716-16-5	Sodium fluoroacetate	62-74-8
Cyanogen bromide	506-68-3	Methomyl	16752-77-5	Sodium perchlorate^	7601-89-0
Cyanogen chloride	506-77-4	Methyl fluoroacetate	453-18-9	Sodium nitrate^	7631-99-4
		Methyldiethanolamine	105-59-9	Strychnine	6899-11-2
		Mevinphos	7786-34-7	Sulfur dichloride	39461-36-4

D		**N**		Sulfur monochloride	12771-08-3
Diazinon	333-41-5	Nitric acid^		Sulphuric acid	7664-93-9
Dichlorvos	62-73-7	Nitric oxide	78989-43-2		
Diethyl phosphite	762-04-9	Nitromethane^	90880-94-7	**T**	
Dimethyl phosphite	868-85-9		75-52-5	Terbufos	13071-79-9
Dimethyl mercury	593-74-8			Thallium sulfate	87993-82-6
Dimethyl sulphate	77-78-1			Thionyl chloride	7719-09-7
Disulfoton	298-04-4			Thiophosphoryl chloride	3982-91-0
				Triethanolamine	7376-31-0
				Triethyl phosphite	122-52-1
				Trimethyl phosphite	121-45-9

^ explosive precursor
* security-sensitive ammonium nitrate (SSAN) [ammonium nitrate, ammonium nitrate emulsions and ammonium nitrate mixtures containing greater than 45 per cent ammonium nitrate, excluding solutions]
Note: CAS means the Chemical Abstracts Service, a division of the American Chemical Society

Or

Γ Tick here if all, or potentially all, of the above listed chemicals are relevant to your association.

Do members of your association transport any of the above chemicals and / or products containing the above chemicals in bulk? **Yes / No**

If yes, please list the main chemicals: _____

_____

Do members of your association handle other dangerous goods? **Yes / No**

Question 2

Of the 96 chemicals listed in the *COAG Report on the Control of Chemicals of Security Concern*, there are 12 that are precursor chemicals for explosives. Please indicate which products containing these chemicals are relevant to your association.
Note: If your association/members have already provided this information in the NICNAS voluntary call for information on chemicals, dated 7 April, 2009, please just indicate this rather than repeating what has already been provided.

Precursor chemical	**List products manufactured, transported, sold, used etc which contain this chemical**	**How is your industry involved with this chemical? ie transport, retail, manufacture etc**	**Concentration (if known)**	**Quantities (if known)**
Ammonium perchlorate				
Hydrogen peroxide	Hydrogen Peroxide	Use, irrigation system hygiene	50%	Unknown
Nitric acid	Nitric Acid	Use, irrigation system hygiene	60%	Unknown
Nitromethane				
Perchloric acid				
Potassium chlorate				

Potassium nitrate	Use as fertiliser.	Usually applied via irrigation, but can be foliar.	13.6 % N 37.4% K, Usually granular in 25kg bags	Unknown. Large farms might purchase by the pallet
Potassium perchlorate				
Sodium Azide				
Sodium chlorate				
Sodium perchlorate				
Sodium nitrate				

Question 3

Does your association produce / distribute materials or resources, in relation to chemicals of potential security concern.

These resources could include, for example, codes of practice, guidelines, training programs, industry standards, occupational health and safety standards, security standards, education material, and ongoing education programs.

Please list any relevant codes / guidelines / programs that could potentially be used for future controls or engagement strategies involving chemical security.

Element of Supply Chain	List of relevant codes, guidelines etc
Across whole supply chain	
Import	
Transport	
Manufacture	
Retail	Agsafe
Wholesale	
Use	Individual industries can have Codes of practice, e.g., Olive growers are encouraged to become accredited to OliveCare quality control program. In addition, individual operations will have HACCP, SQF, ISO9002 or GlobalGAP accreditation. Further, individual industries can provide OHS, educational material and training programs in relation to chemicals and their use.
Disposal	

Question 4

Based on other security risks, are there any materials and/or arrangements which you currently do **not** have in place but which you believe could be usefully developed to increase chemical security?

_____

_____

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Question 5

Please name any other associations that currently are **not** a part of the National Industry Reference Group or National Government Advisory Group that you believe have produced materials of value. Please also list these materials if known.

_____

_____

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Question 6a

Please indicate which type of organisations your association represents and liaises directly with:

☒ Directly with industry businesses

☒ Members only organisations (businesses across Australia)

☒ State / territory counterparts

☐ Directly to all businesses within Australia

☐ Australian industry employer groups

☐ Australian industry unions

☐ State / territory industry employer groups

☐ State / territory industry unions

☐ Other e.g. international

_____

_____

Question 6b

How do you communicate with those members/ organisations? Please indicate how often (e.g. weekly, monthly, on an as needs basis, annually):

☒ Group email – Usually on an as needs basis

☒ Newsletters – Can be via monthly or quarterly publications

☒ Forums - Can be on an annual basis

☒ Conferences – As per forums can be on an annual basis, however biennial conferences can also occur for some industries

☐ Briefings_____

☒ Internet - HAL and individual commodity associations have web sites

☒ Training sessions / educational courses - Usually on an as need basis, i.e., where a specific issue is to be addressed

☐ Open days _____

☒ Other - Farm field days, which are usually organised on a regional basis

Question 6c

Of the mechanisms that you indicated that you use, please indicate any methods that could be used to disseminate information regarding chemical security. Please number them in priority order of which you think is the most effective (with 1 being the most effective):

☒ Group email - 1

☒ Newsletters - 2

☒ Forums - 4

☒ Conferences - 4

☐ Briefings_____

☒ Internet – 5

☒ Training sessions / educational courses – 3

☐ Open days _____

☒ Other – 4

If you do not directly liaise with businesses, do you rely on your state / territory counter part to distribute information? **Yes/ No**

Which organisations / sections in your industry do you **not** have contact with?
HAL and the individual national industry associations can and do liaise directly with business but can also utilise State based grower organisations where these exist, e.g., Fruit Growers Victoria or West Australian Fruit Growers Assoc.

Please list any other relevant information and / or comments.

Thank you for your time.

Dr Angelo Valois
Director
Chemical Security Risk Assessment Unit
Australian Government Attorney-General's Department
Robert Garran Offices
National Circuit
Barton ACT 2600

Dear Dr Valois,

Horticulture Australia Limited (HAL) is holding an industry forum with the chairs and CEOs of the peak industry bodies for Australia's horticulture industries in Sydney on 18 November 2009.

We would like to invite yourself, or a representative from your unit, to attend and make a short presentation on the status of security sensitive chemical risk assessments. HAL believes that your participation in the forum would provide an invaluable opportunity to inform a wide range of industry participants.

In terms of the content HAL believes a broad overview would be sufficient, providing some background on what has occurred, the current status of the risk assessment process and outlining how the Attorney General's Department envisages the process will be taken forward.

HAL holds these industry forums twice a year and they provide an opportunity for the leaders of Australia's horticulture industries to hear on important issues and to share their experiences with one another.

Sincerely,