

Fruit Fly Specific Agrichemical Issues for Horticulture



Plant Health
AUSTRALIA

21
years

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Executive Summary

This study seeks to provide a perspective on the mounting regulatory pressures coming to bear on insecticides currently approved for in-crop fruit fly (Tephritidae) management in Australia. While the focus of the analysis was primarily to highlight current regulatory trends, and their impacts internationally on the authorisations of fruit fly insecticides, it also sought to highlight the potential relevance of these trends from an Australian regulatory context.

It was found that the primary means of in-crop fruit fly management, at the farmer and state quarantine level, are a number of insecticides most at risk from regulatory pressures in the short to medium-term, i.e., the next 3 to 5 years. Listed below are the various insecticides, the likely timeframes in which regulatory activity could be expected, areas of regulatory concern and the Interstate Certification Assurance (ICA) scheme's in which the quarantine entry requirements rely upon the use of these insecticides in Australia.

Insecticide	Timeframes	Primary area of regulatory concern	Relevant ICAs
Dimethoate	Short-term	Pollinator exposure & Public health (dietary exposure)	ICA-1, ICA-2, ICA-18, ICA-19, ICA-21, ICA-26
Malathion	Short to medium term	Environmental contamination, Public health	ICA-19, ICA-20, ICA-21, ICA-26, ICA-28, ICA-34, ICA-56
Methomyl	Medium-term	Public health (dietary exposure)	
Neonicotinoids	Short to medium term	Pollinator exposure	
Acetamiprid	Medium term	Pollinator exposure	
Clothianidin	Short to medium term	Pollinator exposure	ICA-20, ICA-21
Thiacloprid	Short-term	Pollinator exposure, Public health	
Pyrethroids	Medium-term	Pollinators	
Alpha-cypermethrin	Medium-term	Pollinators	
Bifenthrin	Medium-term	Pollinators	
Etofenprox	Medium-term	Pollinators	
Pyrethrins	Medium to long-term	Pollinators	
Spinetoram	Long-term		ICA-34
Tetraniliprole	Long-term		
Trichlorfon	Short-term	Public health, uncertain registrant support	ICA-20, ICA-21, ICA-26, ICA-28, ICA-34
Chlorpyrifos	Short-term	Public health, environmental contamination	ICA-28
Fipronil	Short to medium term	Public health	
Spinosad	Long-term		ICA-19, ICA-20, ICA-34, ICA-56

Short-term: Retaining access/use likely to encounter significant regulatory pressure in next 3 years

Medium-term: Maintaining access/use of potential concern over next 5 years

Long-term: Monitoring required over next 5-10 years

1. Background

The management of fruit flies in Australian horticulture is challenging, not least as a consequence of recent regulatory actions, domestically and internationally, impacting the use of a number of insecticides¹. This report has been prepared to provide insight into key regulatory pressures with the potential to negatively impact the ongoing access to insecticides currently approved for in-field fruit fly management in Australia. This report does not address matters specifically relating to the use of lures or post-harvest treatment of fruit fly susceptible commodities.

Aims/Objectives

Study objectives were to:

1. Provide a summary of the issues associated with gaining and / or maintain regulatory approvals for agvet chemicals along with relevant trends;
2. Identify the factors likely to affect the availability of insecticides in the short, medium and long-term used in fruit fly management in Australia, not only availability of the compounds but their availability for specific commodities;
3. Analyse the impact of insecticide access may have on Australia's international trade in fruit fly susceptible commodities
4. Provide an appraisal of the likely timeframe in which impacts could occur.

The priority for the project was to focus on Objective 1 and to provide an appraisal of key regulatory matters with the potential to impact the various insecticides approved for use in fruit fly management locally. This information would then be available to help inform current and future discussion about appropriate management strategies. It was important for the report to provide an ongoing reference for decision makers, beyond any work on possible responses to current regulatory activities. For this reason specific strategy recommendations were not prepared.

Discussion around study Objectives 2, 3 and 4 was done with reference to the evidence base identified in Objective 1.

¹ APVMA revocation of dimethoate uses (Dimethoate: Regulatory decisions 2017); JMPR Recommendation to delete Codex MRLs for dimethoate (Report 2019 Joint FAO/WHO Meeting on Pesticide Residues) and the non-renewal of approval for dimethoate in the EU (Commission Implementing Regulation (EU)2019/1090)

2. Introduction

The regulatory management of pesticides globally, while generally based on similar risk assessment methodologies, can vary between countries due to differences in the types of risk authorities are willing to accept, i.e. the risk appetite for what is considered sufficiently protective can differ. As a result, while the risk assessments methodologies used by international regulators, to evaluate the potential impacts of pesticides on human health and the environment, are similar the outcomes, i.e., the risk management decisions, can vary. While this is less likely to be an issue for newly developed pesticides it can have a significant impact on assessments for older compounds undergoing re-evaluation.

Adding to the uncertainty over regulatory outcomes for older pesticides has been the development of new and/or more refined risk assessment methodologies in the evaluation of pesticide safety. For older compounds undergoing re-evaluation these new or refined risk assessment methodologies can have a significant impact on the regulatory outcome. With many not meeting contemporary risk assessment standards due to the required data being either unavailable, or if data is available, the outcome of the risk assessment is considered unacceptable. A consequence of either is that their authorisation is either restricted or withdrawn.

While negative regulatory outcomes locally can have a direct impact on Australian growers, similar actions in export markets, while indirect, can have an equivalent effect when disparities in standards between trading partners occur. The lack of an appropriate pesticide maximum residue limit (MRL) in an importing country can, for practical purposes, prohibit the use in the producer country to ensure compliance, as MRL breaches would adversely affect market access.

The effects of the above are to place greater pressure on the availability and use of older pesticides or chemical groups. As a consequence, it is possible that access to, or approval of, a number of locally approved fruit fly insecticides could, in time, be adversely impacted following regulatory actions either in Australia or overseas.

To assist strategic planning, the following information has been prepared to highlight the regulatory threats to currently approved insecticides for the management of fruit fly in Australia.

3. Methods used

The study was delivered through a combination of desk based research and consultation. Profiling of insecticides currently approved in Australia for fruit fly management was completed using team knowledge and literature. Consultation was completed with agricultural and veterinary chemical manufacturers and regulators.

4. Re-evaluation process

In many international jurisdictions the re-evaluation of pesticides occurs on a cyclical basis. At Codex and in the USA re-evaluations are, ostensibly, on a 15 year cycle. In the EU re-evaluation cycle can occur after 7, 10 or 15-years depending upon the outcome of the hazard assessment. Seven years for compounds of concern meeting cut-off hazard criteria², i.e., candidates for substitution, ten years for a standard substance and 15 years for a low-risk substance. Australia does not implement a cyclic re-evaluation process.

Re-evaluations can either be targeted, examining a specific aspect of pesticide use, or general, i.e., a full re-evaluation of all relevant aspects. The risk assessments primarily focus on potential risks to human health (public and occupational) and the environment (wildlife and ecosystem impacts) to satisfy the regulator that approved uses are acceptable from a risk management perspective. Two areas in which the assessment of risk has progressed has resulted in increased regulatory impacts on older pesticides are potential pollinator impacts and dietary exposure. The following provides a brief outline of these two key elements.

² Low acceptable daily intake/acute reference dose, low acceptable operator exposure level or two persistent, bio-accumulative or toxic criteria, or by nature of the critical effects: carcinogen 1A/1B, toxic for reproduction 1A/1B or exhibiting endocrine disruption properties

5. Main areas of potential concern

Outlined below is information detailing three specific areas expected to be of most significance in terms of potential regulatory on insecticides currently approved for use against fruit fly in Australia.

5.1 Environmental - Pollinators

The potential adverse impact of insecticides on pollinators has taken on greater prominence amongst regulators, both in Australia and internationally³.

This increased focus has resulted in additional levels of risk assessment^{4,5} being introduced, and aimed at improving risk characterisation through more accurate estimation of hazard and potential routes and levels of exposure. The aim of which, is to enable the development and implementation of appropriate risk mitigation measures.

At an operational level this is resulting in the use of groups of pesticides, such as the neonicotinoids, being re-evaluated in Australia,⁶ Europe,⁷ New Zealand⁸ and North America.⁹ These reviews have resulted in varying regulatory response from revocation of approval to the introduction of risk mitigation measures limiting the use of these insecticides to reduce potential pollinator exposure. Allied with these re-evaluations is an increased attention placed on potential pollinator impacts for all pesticides seeking to gain regulatory approval.

An outcome of the enhanced levels of risk assessment and associated data requirements is registrants may not support older compounds, i.e., they will be disinclined to invest in new data generation for older generic pesticides. The lack of suitable data can result in the removal or restricting uses in crops in which pollinators are active.

³ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-decision/2021/imidacloprid.html>
<https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/special-registration-decision/2021/clothianidin.html>
<https://www.canada.ca/en/health-canada/services/consumer-product-safety/pesticides-pest-management/public/consultations/proposed-special-review-decision/2021/environmental-risk-related-to-squash-bee/document.html>

⁴ Australian Pesticides and Veterinary Medicines Authority. 2015. Roadmap for insect pollinator risk assessment in Australia.

⁵ <https://www.epa.gov/pollinator-protection/pollinator-risk-assessment-guidance>

⁶ Australian Pesticides and Veterinary Medicines Authority. 2014. Overview Report: Neonicotinoids and the health of honey bees in Australia

⁷ <http://www.efsa.europa.eu/en/press/news/130116>

⁸ <https://www.epa.govt.nz/public-consultations/in-progress/call-for-information-on-the-neonicotinoids-thiacloprid-and-acetamiprid/>

⁹ Joint PMRA/USEPA Re-evaluation update for the pollinator risk assessment of the neonicotinoids insecticides

5.2 Human health - Dietary exposure

Consumer dietary exposure from pesticides are primarily assessed on the basis of long-term (life time) and short-term (single day) scenarios. These involve assessing dietary exposure against health-based guidance values (HBGVs) to ensure the estimated levels of dietary exposure are not of concern, i.e., the predicted dietary exposure is below the relevant health based guidance value. The long-term exposure assessment is done against the acceptable daily intake value (ADI) whereas the short-term risk assessment is done against the acute reference dose (ARfD). These calculations are done using highest large-portion diet intake data (high consumers) with the associated body weight for different population cohorts, e.g., children and the general population.

The current standard practice in Australia and internationally in determining dietary exposure is to apply residue values found from supervised residue trials that reflect the approved use pattern¹⁰. For long-term dietary exposure the standard trial median value for each commodity is used to estimate an aggregate of potential exposures from all approved uses which is compared to the ADI.

For short-term dietary exposure an estimate of exposures over a 24 hour period, or less, on an individual commodity basis is completed. In many jurisdictions the highest residue found in the supervised residue trials is used, though in the EU it is the MRL¹¹. The assessment of short-term dietary exposure is relatively recent having been developed and applied by regulators only in the last 20 years. These calculations are completed both nationally and internationally and can vary due to differences in dietary consumption patterns or the derivation of the HBGVs.

The estimations of dietary exposure are particularly relevant for commodities with edible peel due to the potential for direct ingestion of residues on the raw commodity. Residues resulting from the pre-harvest application of insecticides to edible peel crops can result in the identification of public health concerns, particularly where residues occur in/on the edible portion and the commodity has significant levels of consumption and a low ARfD has been established.

¹⁰ Good Agricultural Practice (GAP)

¹¹ EFSA Journal 2018; 16(1):5147

6. Re-evaluation / Reconsideration of Pesticides

6.1 Australia

Under current Australian legislation re-evaluations of pesticides are initiated following the emergence of new information that suggests the existence of previously unknown risks in terms of human health (dietary and worker exposure), animal or crop safety, or the environment. There is no requirement for pesticides to undergo cyclical re-evaluations. Rather reviews are initiated following consultation with allied agencies, e.g., Departments of Health and/or Environment, and the States.

Currently, the APVMA is in the process of finalising a number of reviews, e.g., chlorpyrifos, malathion, the neonicotinoids¹², procymidone and the bipyridyl herbicides diquat and paraquat. There is also a list of compounds nominated for future re-evaluations, which includes methomyl and trichlorfon¹³.

It is understood the Authority is intending to re-assess the list with regards to its composition and review priorities. Essentially, the APVMA will consider whether other compounds need to be included; whether for the nominated compounds a full re-evaluation, i.e., assessment of aspects relating to public health, worker safety and environmental safety, is necessary; or whether any identified areas of concern could be addressed through specific label amendments. This process is to occur during early 2022.

6.2 Codex Alimentarius

The Codex Alimentarius Commission (CAC) implements the Joint FAO/WHO Food Standards Program. The Codex Alimentarius is a collection of food standards covering foods and feeds moving in international trade. The purpose of which is consumer protection and the facilitation of international trade. The standards established are used global reference points due to the status accorded through the WTO SPS Agreement which identifies Codex standards, guidelines and recommendations established by the various Codex Committees, such as the Codex Committee on Pesticide Residues (CCPR), as the benchmarks against which national measures and regulations can be evaluated. A number of countries currently use Codex MRLs as de facto standards; default to Codex MRLs in the absence of domestic standards, e.g.,

¹² acetamiprid, clothianidin, dinotefuran, imidacloprid, thiacloprid and thiamethoxam

¹³ <http://apvma.gov.au/node/10876>

Malaysia and Singapore; or can utilise Codex MRLs in establishing domestic standards, e.g., Australia¹⁴ and the EU.

When establishing Codex MRLs the CCPR utilizes assessments of pesticides completed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR), an expert committee that assess pesticide toxicology and residue data relating to approved uses. The JMPR evaluates new pesticides, new uses or conduct periodic re-evaluations of pesticides sitting within the Codex system.

The scheduling of pesticides for JMPR evaluation is undertaken by the CCPR at the annual meetings. In terms of re-evaluations, compounds that have not been reviewed toxicologically for more than 15 years; or where a concern form has been submitted by a Member State, and accompanying scientific information, upon review, demonstrates a public health concern, are scheduled for JMPR assessment. Where no periodic review has been undertaken for 25 years the compound is to be brought forward for scheduling by CCPR¹⁵.

Under the periodic re-evaluation programme the following compounds have been scheduled for review over the next three years: fipronil (2021), chlorpyrifos, malathion, piperonyl butoxide and permethrin (2023)¹⁶. A further group of compounds have been identified as exceeding 15 years since a previous evaluation but have, as yet, not been scheduled, e.g., deltamethrin, esfenvalerate, methomyl, pyrethrins and spinosad, but have not come under the 25 year rule.

For a number of the compounds the level of support, with respect to the submission of data packages, suitable to meet contemporary risk assessment requirements, is uncertain. In the event of a compound or a Codex MRL being unsupported the Codex MRLs will be deleted, potentially impacting the use of a pesticide applied to commodities that are traded internationally, i.e., the loss of Codex MRLs can negatively impact compliance in many export markets.

6.3 Canada

Canadian legislation¹⁷ requires that the Pest Management Regulatory Agency (PMRA) re-evaluates pesticides on a cyclical basis, or via special reviews when there are changes in the information required to determine that a pesticide meets current health, environment and value standards. Special reviews differ from cyclical re-evaluations in that only specific aspects of a pesticide are examined. One trigger for the

¹⁴ <https://www.foodstandards.gov.au/science/international/codex/Pages/default.aspx>

¹⁵ Codex Alimentarius Commission Procedural Manual 27th Edition 2019 <https://www.fao.org/publications/card/en/c/CA2329EN/>

¹⁶ CX/PR 21/52/19 Establishment of Codex schedules and priority lists of pesticides for evaluation / re-evaluation by JMPR

¹⁷ Pest Control Products Act (the Act)

initiation of a special review is when a member country of the Organisation for Economic Co-operation and Development (OECD) prohibits all uses of an active ingredient for health or environmental reasons. At any point during the special reviews, should evidence become available demonstrating reasonable grounds to believe that one or more of the registered pest control products containing the pesticide endangers human health or the environment, the PMRA may cancel or amend the pesticides registration.

Canada is in the process of finalising cyclic and special re-evaluations (pollinators and impact on aquatic invertebrates) for clothianidin, imidacloprid and thiamethoxam¹⁸. This has resulted in the cancellation of a number of uses, e.g., foliar application in orchards, and reductions in frequency or maximum rates of application.

Other insecticides currently undergoing cyclical re-evaluation in Canada with consultations and regulatory decisions being finalised over the next 2-3 years including: acetamiprid, abamectin, lambda-cyhalothrin, spinetoram and spinosad; with a re-evaluation of thiacloprid schedule to commence in 2023/24.

6.4 Europe

European pesticide regulatory system is 'hazard-based' with regards to pesticide assessment, in which pesticides are assessed on the basis of their intrinsic hazard properties without taking into account the potential for exposure or scope for risk mitigation. The hazard based approach has involved the establishment of "cut-off" criteria for aspects such as carcinogenicity, mutagenicity, being toxic for reproduction, having endocrine disrupting properties, and/or being persistent and bio-accumulative in the environment¹⁹.

The application of the criteria results in whether a pesticide is approved and the nature of the approval. In the EU pesticides can be registered as one of the four types: standard substances (approved for ten years), basic substances (not a substance of concern, no time limit for approval), low-risk substances (low risk to human and animal health and the environment, approved for fifteen years) and candidates for substitution (cut-off criteria imposed and only approved for seven years maximum)²⁰.

¹⁸ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates.html>

¹⁹ Regulation (EC) No 1107/2009 of the European Parliament and of the Council, Concerning the placing of plant protection products on the markets and repealing Council Directives 79/117/EEC and 91/414/EEC

²⁰ Article 24 of Regulation (EC) No 1107/2009

The latter category is significant as it requires Member States to evaluate if the pesticides identified for substitution can be replaced by other adequate more favourable control options. The EU Commission established a list of candidates for substitution²¹. Of the pesticides listed, a number are approved for use in the management of fruit flies in Australia, e.g., alpha-cypermethrin, bifenthrin, dimethoate etofenprox, fipronil, lambda-cyhalothrin, methomyl and thiacloprid. Of these compounds only etofenprox and lambda-cyhalothrin are still approved for use in the EU.

6.5 USA

The US EPA has a regular systematic re-registration programme in which products are assessed at least every 15 years to determine whether they continue to meet the FIFRA²² standard for registration, i.e., to ensure appropriate risk mitigation measures are in place. In addition, the US EPA can initiate Pesticide Special Reviews where concerns have been raised over potentially adverse effects to human health or the environment arising from use of a pesticide.

Under the current registration review schedule of pesticides all pesticides registered as of October 1, 2007 must have their reregistration completed by October 2022. As a result there are a number with anticipated Proposed Interim Decisions and Interim Decisions expected over the next two years for insecticides approved for use in Australia to manage fruit flies. These include the neonicotinoids acetamiprid and clothianidin with Registration Review Interim Decision planned for late-2022²³. Other insecticides currently under review with an October 2022 deadline are the pyrethroids the cypermethrins and etofenprox, and dimethoate, fipronil and malathion²⁴.

²¹ Implementing Regulation (EU) No 2015/408

²² Federal Insecticide, Fungicide and Rodenticide Act

²³ <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides>

²⁴ <https://www.epa.gov/pesticide-reevaluation/explanation-registration-review-schedule>

7. Trade

The regulatory activities involved in pesticide evaluation, re-evaluation and risk management by different jurisdictions can result in the establishment of disparate standards. Where differing standards between trading partners exist trade can be disrupted with authorities in importing states rejecting commodities where residues or quarantine practices do not comply with either local or Codex standards. Such disparities in relation to pesticide residue standards are becoming increasingly problematic, with many countries implementing increased residue monitoring programs coupled with more rigid regulatory frameworks, e.g., Korean and Japanese 'positive lists' with respect to pesticide residues on imported produce²⁵. The outcome of which can see residues of pesticides approved for use in Australia potentially breaching standards in importing countries.

Such differences can occur due to differing use patterns resulting in the establishment of non-aligned MRLs; through registrants not seeking the establishment of relevant MRLs in an importing country; or a pesticide re-evaluation resulting in the removal or placing restrictions on use, impacting the corresponding MRLs.

The issue of MRL disparity between trading partners is currently a significant issue internationally. It has been raised and discussed at the Committee on Sanitary and Phytosanitary Measures (SPS) by WTO member states²⁶. The United States International Trade Commission has recently published two reports exploring the global economic impacts of MRL disparities²⁷ and an APEC Guideline on import MRL setting has been published²⁸. The APEC Guideline outlined an assessment approach that member economies could potentially follow in the establishment of import MRLs. In addition, an APEC Compendium of government administrative requirements with regards to MRL setting has also been published²⁹.

What these various activities highlight is that potential issues over MRL disparities are not uncommon. In the absence of generalised mechanisms to address MRL disparities between trading countries, exporting industries can either attempt to amend farming practices to ensure compliance in export markets, or seek to have standards established in the importing country. The difficulty with the latter approach was highlighted in the Compendium to the APEC Guideline where it was identified that some economies have

²⁵ Korean Ministry of Food and Drug Safety: New system for management of pesticide residues in food. (Positive List System) 2016

²⁶ G/SPS/R/85. & G/SPS/W/292/Rev.4.
https://www.wto.org/english/news_e/news17_e/sps_02nov17_e.htm

²⁷ https://www.usitc.gov/press_room/news_release/2021/er030211730.htm

²⁸ <https://www.APEC.org/publications/2016/08/import-MRL-guideline-for-pesticides>.

²⁹ http://fscf-ptin.apec.org/docs/2019/Final_APEC_Compndium_18_February_2019.pdf

no formal framework with which to establish import MRLs; and where such systems exist, data requirements, associated fees and assessment timeframes can vary greatly between economies. The issue of meeting data requirements can be particularly problematic, where access to, and availability of the required data may be uncertain.

For new pesticides, as part of the approval process the APVMA can choose to publish a Trade Advice Notice (TAN) seeking public comment on a proposed registration of a pesticide. 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. Adverse public comment can see the approval of a pesticide use delayed, amended or refused should the APVMA deem the proposed use to have the potential to adversely affect trade. For currently approved pesticides there is no mechanism, other than via a reconsideration, through which trade risks can be assessed.

At the national level the quarantine entry requirements for interstate movement of fruit fly susceptible commodities are managed through a variety of regulatory tools, including 64 Interstate Certification Assurance (ICA) arrangements, and corresponding Tasmanian Import Requirements. These arrangements outline a range of practices to be followed to allow the cross-border movement of various fruit fly susceptible commodities. The procedures approved under the various ICA's are to ensure quarantine entry requirements for interstate traded commodities are met and are fruit fly free. These include the use of insecticides applied as in-crop (cover or bait sprays) or post-harvest treatments, visual inspection, fumigation with methyl bromide, maturity, cold storage, irradiation, vapour heat or hot water and the transportation, storage and handling of commodities post treatment.

In a situation not dissimilar to that of international MRLs, it is understood that not all ICA's are accepted by all states and territories, i.e., some states or territories require additional quarantine certification measures. Further increasing complexity are apparent differences in the updating of ICAs between different jurisdictions, e.g., SA ICA 2 still carries reference to the cancelled insecticide fenthion. Plus potential inconsistencies exist between some ICA insecticide treatment regimes, e.g., NSW ICA-21 indicates use of clothianidin, trichlorfon and/or malathion as a cover sprays while QLD ICA-21 is currently unavailable as it is still being updated following the cancellation of fenthion in 2014. Further there appears to be a potential discrepancy relating to the use of malathion between the product label and NSW ICA-21. The labelled use pattern indicates a maximum of four applications at 101.2 g ai/100L whereas the

NSW ICA-21 indicates a maximum of three applications at 61.6 g ai/100L. It is unclear why the lower rate is proposed as the rate applied should, presumably, be determined by the extent of fruit fly activity.

8. Insecticides of interest

8.1 Dimethoate

Dimethoate is currently approved for use in Australia as a foliar cover spray against fruit flies in avocados, blueberries, citrus, eggplant (PER12506), mangoes, capsicums and tomatoes. It is also approved as an orchard clean-up spray after harvest has been completed (PER13859). It is approved for use in Canada and the USA for the management of the fruit flies the Blueberry maggot (*Rhagoletis mendax*), the Cherry fruit fly (*Rhagoletis indifferens*) and the Pepper maggot (*Zonosemata electa*)³⁰.

Regulatory status

The APVMA finalised a review the APVMA in 2017. A number of uses on edible peel commodities were removed due to dietary exposure concerns, however use in blueberries, capsicums and tomatoes (processing) were retained³¹. Following the recent periodic re-evaluation under the Codex system the JMPR recommended the deletion of all Codex MRLs due to questions over the genotoxicity of metabolites³². Dimethoate is no longer authorised in the EU due to concerns over the toxicological significance of various metabolites³³.

Dimethoate is currently undergoing re-registration in the USA with a completion date of October 2022. In the US EPA Human Health Risk Assessment exceedances of the ARfD were noted³⁴. Consequently, there is the possibility that use patterns could either be deleted or significantly amended, to reduce the estimated levels of consumer dietary exposure. In India the Ministry of Agriculture issued a draft Banning of Insecticides Order in 2020 proposing the removal from use of dimethoate³⁵.

While not currently nominated for re-evaluation by the APVMA it is likely that uses of dimethoate could be impacted as a result of international regulatory activity, i.e., deletion of Codex MRLs. Should this occur it is likely to come under significant regulatory pressure in the short to medium term, i.e., the next 3 to 5 years.

³⁰ USA Cygon 480 EC label

³¹ <https://apvma.gov.au/dimethoate> Dimethoate decision report.

³² FAO and WHO. 2020. Pesticide residues in food 2019 - Report 2019 - Joint FAO/WHO Meeting on Pesticide Residues. Rome

³³ <http://www.efsa.europa.eu/en/efsajournal/pub/4647>

³⁴ <https://www.regulations.gov/document/EPA-HQ-OPP-2009-0059-0027>

³⁵ Notification S.O.1512 (E) dated 14th May 2020 (F.No.13035/15/2019)

8.2 Malathion/maldison

Malathion currently approved for use in Australia as a foliar cover spray against fruit flies in apples, pears, citrus, grapevines, persimmons, Stone fruit, strawberries, blueberries, Rubus, capsicum and tomato and mangoes (PER83998). It is also approved for application as a strip or spot spray in citrus, table grapes, Summerfruit, mangoes, cherries, berries and avocados. It is approved in the USA for the management of fruit flies the Blueberry maggot (*R. mendax*), the Cherry fruit fly (*R. indifferens*), the Mediterranean fruit fly (*Ceratitis capitata*), the Pepper maggot (*Z. electa*) and the Walnut husk fly (*Rhagoletis completa*)³⁶.

Regulatory status

Malathion is currently under review by the APVMA. From an Australian perspective the most significant issue has been the stability of formulations and the presence of trialkyl phosphorothioate, as they can increase the toxicity of the formulated product³⁷. Consequently, the APVMA will make determinations on formulation specifications relating to limiting the presence of the impurities, i.e., only products in which the impurities are either not present, or below threshold levels, will continue to be available. It is anticipated that the APVMAs review of malathion will be finalised in 2022 with the likely result, a specification on labels indicating a 'Use by date', based on the date of manufacture. Of further note is that, of the malathion based products approved for use in Australian agriculture only one label currently carries the cover spray use recommendation.

In the USA malathion is currently undergoing re-registration with a completion date of October 2022. In the recently published draft Biological Opinion it was concluded that the "*registration of malathion is likely to jeopardize the continued existence of 78 species*"³⁸. In the EU it is currently under review following its restriction to use in permanent greenhouses only, based on high risk to birds³⁹. In India the Ministry of Agriculture issued a draft Banning of Insecticides Order in 2020 proposing the removal from use of malathion⁴⁰. In Canada malathion was last re-evaluated in 2012.

At Codex, malathion has been re-scheduled for periodic re-evaluation by the JMPR from 2022 to 2023 at the request of the sponsor. The Committee is awaiting advice on supported commodities. It is understood the requested rescheduling was due, in part, to await the outcomes of the EU and USA reviews.

³⁶ Fyfanon®

³⁷ <http://apvma.gov.au/node/12586>

³⁸ <https://www.epa.gov/endangered-species/biological-opinions-available-public-comment>

³⁹ Commission Implementing Regulation (EU) 2019/1495

⁴⁰ Notification S.O.1512 (E) dated 14th May 2020 (F.No.13035/15/2019)

Given the environmental concerns highlighted and the compound being classified by the International Agency for Research on Cancer (IARC) as a probable human carcinogen⁴¹ it is likely that uses of malathion will come under significant regulatory pressure in the short to medium term, i.e., the next 3 to 5 years.

8.3 Methomyl

Methomyl is approved in Australia as a foliar cover spray in capsicums and tomatoes (PER13566). Methomyl is approved for use in the USA for the management of the Blueberry maggot (*R. mendax*) and the Spotted winged drosophila (*Drosophila suzukii*)⁴².

Regulatory status

Methomyl has been listed for review by the APVMA in its 2015 prioritised listing, due to concerns over public health, worker and environmental safety. The Canadian PMRA completed a review in 2018, an outcome of which was the removal of the majority uses⁴³ or uses being restricted, e.g., retained vegetable crop uses are restricted to one application per year, no tree crop uses were retained.

In the EU methomyl is no longer authorised with the majority of MRLs set at the LOQ⁴⁴. The compound is currently under review in the US with a recent Biological Evaluation finding that it is “likely to adversely affect” a number of “threatened and endangered species”⁴⁵. This element of the assessment has yet to be finalised. At Codex methomyl was last fully evaluated by the JMPR in 2001. Consequently, it is likely that Codex Member States may push for it to be scheduled for periodic re-evaluation by the JMPR within the next 2-3 years.

In Malaysia residues of methomyl are banned in food. In India the Ministry of Agriculture issued a draft Banning of Insecticides Order in 2020 proposing the removal from use of a number of pesticides including methomyl⁴⁶. The Uruguayan Ministry of Livestock, Agriculture, and Fisheries (MGAP) has also moved to prohibit its use.

⁴¹ IARC Monograph Vol 30, Sup 7, 112 2017

⁴² Lannate® SP

⁴³ Re-evaluation Decision - RVD2018-05

⁴⁴ Reg. (EU) 2016/1822

⁴⁵ <https://www.epa.gov/pesticides/epa-releases-final-biological-evaluations-carbaryl-and-methomylys-impacts-endangered>

⁴⁶ Notification S.O.1512 (E) dated 14th May 2020 (F.No.13035/15/2019)

Given the extent and nature of regulatory actions in other jurisdictions and its nomination for review by the APVMA it is probable that methomyl use in Australia will be significantly impacted in the medium term with re-evaluation by the APVMA likely within the next 5 years.

8.4 Neonicotinoids

The neonicotinoids acetamiprid, clothianidin and thiacloprid are approved for use as foliar cover sprays against fruit flies in a range of crops in Australia.

Regulatory status

Members of the group of chemicals are undergoing re-evaluation in a number of jurisdictions primarily over environmental concerns, i.e., potential impacts on pollinators and invertebrates in aquatic environments⁴⁷. In Australia acetamiprid, clothianidin and thiacloprid are under review by the APVMA on the basis of potential risks to the environment and to ensure safety instructions on products meet contemporary standards⁴⁸. Proposed regulatory decisions are expected in late 2022. In New Zealand the Environmental Protection Authority has indicated a reassessment is to be initiated to investigate environmental risks from use of imidacloprid, clothianidin, thiamethoxam, thiacloprid and acetamiprid⁴⁹. The US EPA recently published proposed regulatory decisions for acetamiprid and clothianidin⁵⁰, see below.

Another potential concern associated with acetamiprid, clothianidin and thiacloprid, is that they share a common metabolite, 6-chloronicotinic acid (6-CNA) with imidacloprid and thiamethoxam. The question over the toxicity of 6-CNA has been flagged, i.e., whether toxicologically significant. If deemed to be of concern, a possible outcome could be a requirement for all compounds, from which 6-CAN is derived, to be assessed in aggregate against any HBGVs that might be established.

8.4.1 Acetamiprid

In Australia acetamiprid, when applied with pyriproxyfen, is approved for the suppression of fruit flies in Avocados, Citrus, Mangoes, Custard apple, Lychee, Papaya, Passion fruit and Persimmons (PER89943).

⁴⁷ http://www.hc-sc.gc.ca/cps-spc/pest/part/consultations/_prvd2016-20/prvd2016-20-eng.php

⁴⁸ APVMA Gazette No. 23 – 19 November 2019

⁴⁹ <https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/current-reassessments/#Active>

⁵⁰ <https://www.epa.gov/pollinator-protection/proposed-interim-registration-review-decision-neonicotinoids>

When applied with novaluron it is approved for the suppression of fruit flies in Summerfruit and Cherries. In the USA acetamiprid is approved for the management of Cherry fruit fly (*R. indifferens*) and the Spotted winged drosophila (*D. suzukii*). In Canada it is approved for the management of the Apple maggot (*Rhagoletis pomonella*) and the Blueberry maggot (*R. mendax*)⁵¹.

Regulatory status

Acetamiprid is authorised for use in the EU, with an expiry date of February 2033. In Canada a cyclic/general re-evaluation consultation has been indicated to occur in 2023⁵². In 2020 the US EPA published proposed regulatory decisions for acetamiprid⁵³. In which mitigation measures were proposed to address risks identified to occupational handlers (updated personnel protective equipment (PPE) standards), to birds and invertebrates (spray drift mitigation and buffer zones to limit off-target the movement). At Codex it was last evaluated by the JMPR in 2011 and will not be scheduled for periodic re-evaluation before 2026.

As a result is unlikely that acetamiprid use in Australia will be significantly impacted in the medium to long-term, i.e., 5+ years.

8.4.2 Clothianidin

Clothianidin is approved for the management of fruit flies in Australia in Fruiting vegetables (PER80100), Mangoes (PER83944), Grapes, Pome fruit, Summerfruit, Cherries and Cucurbit vegetables (PER80101). In the USA it is approved for use against the Apple maggot (*R. pomonella*). There are no relevant approvals in Canada.

Regulatory status

Clothianidin is no longer authorised for use in the EU over the potential for adverse impacts on pollinators⁵⁴. In Canada clothianidin has undergone special reviews on impacts on pollinators⁵⁵, aquatic

⁵¹ USA ArVida® 70 WP label

⁵² <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-note/2021/special-review-work-plan-2021-2026.html>

⁵³ <https://www.epa.gov/pollinator-protection/proposed-interim-registration-review-decision-neonicotinoids>

⁵⁴ Commission Implementing Regulation (EU) 2018/784

⁵⁵ Review Decisions RVD2019-05

invertebrates⁵⁶ and on a non-honey bee pollinator the Squash bee⁵⁷. It is also the subject of cyclical re-evaluations with consultations indicated for 2023⁵⁸.

In 2020 the US EPA published proposed regulatory decisions for clothianidin⁵⁹. These included the proposed cancellation of some uses, a 15-20% reduction in seasonal application rates, crop stage restrictions, such as prohibiting use until after flowering, updated PPE, spray drift mitigation and buffer zones to limit off-target movement. At Codex it was last evaluated by the JMPR in 2010 and is unlikely to be scheduled for periodic re-evaluation before 2025.

As clothianidin is the subject of a number reviews driven by concerns over possible adverse impacts on pollinators it is probable that use in crops frequented by pollinators will face increasing regulatory pressures. The outcome of which is likely to be increased restrictions on use in the short to medium-term, i.e., 3-5 years.

8.4.3 Thiacloprid

Thiacloprid is approved for use in Australia against the Mediterranean fruit fly (*C. capitata*) in pome fruit and stone fruit. It is approved for use in Canada for the control of the Apple maggot (*R. pomonella*).

Regulatory status

Thiacloprid is currently under review by the APVMA on the basis of potential risks to the environment and to ensure safety instructions on products meet contemporary standards. The proposed regulatory decisions are expected in the latter part of 2022, or early 2023. It is no longer approved for use in the EU or the USA. The compound was not re-authorised in the EU as it was classified as toxic for reproduction (Category 1B⁶⁰); carcinogenic (Category 2) with metabolites predicted to leach into groundwater⁶¹. In the USA it was voluntarily withdrawn by the registrant⁶². From the perspective of Codex it was last reviewed in 2006 in which case it could be scheduled for re-evaluation in the near future. In Canada it is only approved for use in pome fruit.

Given pollinator and human health concerns it is probable that crop uses will face significant restrictions in the short to medium-term, i.e., 3-5 years.

⁵⁶ Special Review Decisions SRD2021-03

⁵⁷ Proposed Special Review Decisions PSRD2021-02

⁵⁸ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-note/2021/special-review-work-plan-2021-2026.html>

⁵⁹ <https://www.epa.gov/pollinator-protection/proposed-interim-registration-review-decision-neonicotinoids>

⁶⁰ GHS Classification of Hazardous chemicals

⁶¹ Commission Implementing Regulation (EU) 2020/23

⁶² <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoid-pesticides>

8.5 Pyrethroids and pyrethrins

The US EPA is currently reviewing the pyrethroid group as part of an ecological and human exposure risk assessment. The agency recently published its draft cumulative risk assessment for the group, in which it was concluded that there were no cumulative estimated dietary risks of concern for the currently registered uses. The Agency is still determining whether additional pollinator data is needed for the pyrethroids, as the group are considered highly toxic to bees⁶³.

8.5.1 Alpha-cypermethrin

Alpha-cypermethrin is approved for the control of fruit flies in Australia in Blueberries (PER90027), Cucurbit vegetables (PER80138), Fruiting vegetables (PER80099), Persimmons (PER85550) and Summerfruit (PER91059). Cypermethrin is registered in Canada for the control of the Apple maggot (*R. pomonella*) and the Spotted winged drosophila (*D. suzukii*)⁶⁴. It is registered in the US for the management of the Pepper maggot (*Z. electa*) and the Walnut husk fly (*R. completa*)⁶⁵.

Regulatory status

Alpha-cypermethrin is part of the US EPA review of the pyrethroid group⁶⁶ which is expected to be completed in 2022. The authorisation in EU has been withdrawn as the compound was no longer supported by the registrant⁶⁷. A period of grace has been established for use of existing stocks of alpha-cypermethrin containing products, which is to expire on the 7th of December 2022. At Codex the cypermethrins were last evaluated by the JMPR for toxicology in 2006. Consequently, the scheduling for a re-evaluation within the next 3 to 5 years is possible.

Given pollinator concerns it is probable that crop uses will face regulatory pressure in the medium-term, i.e., 5+ years.

⁶³ Ecological risk management rationale for pyrethroids in registration review. <https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0384-0048>

⁶⁴ Ripcord™ 400EC

⁶⁵ Fastac® CS Insecticide

⁶⁶ <https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids>

⁶⁷ Commission Implementing Regulation (EU) 2021/795

8.5.2 Bifenthrin

Bifenthrin is approved for use as foliar cover sprays against fruit flies in capsicums (peppers) and tomatoes in Australia. It is approved for use in the USA against Blueberry maggot (*R. mendax*) and the Spotted winged drosophila (*D. suzukii*)⁶⁸.

Regulatory status

In the EU it has been identified as a candidate for substitution due to meeting bioaccumulation and environmental hazard criteria⁶⁹. It is no longer authorised for use in Canada and has also been included in the US EPA ecological and human exposure risk assessment of the pyrethroid group⁷⁰. The compound was last evaluated by the JMPR in 2009 and would be due for periodic evaluation in 2024.

Given pollinator concerns and actions in the EU and Canada it is probable that crop uses will face regulatory pressure in the medium-term, i.e., within the next 5 years.

8.5.3 Etofenprox

Etofenprox is approved for use as a foliar spray for fruit flies in Summerfruit in Australia. It is registered in the EU for the control of the Cherry fruit fly (*R. cerasi*) and the Mediterranean fruit fly (*C. capitata*)⁷¹.

Regulatory status

In the EU etofenprox has been identified as a candidate for substitution due to it meeting EU bioaccumulation and environmental hazard criteria⁷². It is currently under review with the EU authorisation set to expire in December 2022. The compound was last evaluated by the JMPR in 2011 with Codex MRLs established for pome fruit, nectarine, peach and grapes. These Codex MRLs were based on European data and use patterns. Should the EU authorisation for etofenprox not be renewed, the legitimacy of the Codex MRLs may be questioned. Otherwise it is unlikely to be scheduled for periodic re-evaluation until some point after 2026. It has no approvals in Canada and the only plant protection approval in the USA is in rice.

⁶⁸ USA Bifenture 10DF label

⁶⁹ Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009: Final report

⁷⁰ <https://www.epa.gov/ingredients-used-pesticide-products/pyrethrins-and-pyrethroids>

⁷¹ Trebon® UP

⁷² Ad-hoc study to support the initial establishment of the list of candidates for substitution as required in Article 80(7) of Regulation (EC) No 1107/2009: Final report

Aside from uncertainty over the status of the EU authorisation, and the basis for Codex MRLs, regulatory action in the short to medium-term in Australia or elsewhere appears unlikely.

8.5.4 Pyrethrins

Pyrethrins are currently approved as a fruit fly 'clean-up' spray to be applied immediately prior to harvest in berries, citrus fruit, summer fruit, cherries, avocado and mango. In the USA they are approved for use in fruit crops against generic 'fruit fly'⁷³. There do not appear to be any relevant approvals in Canada or the EU.

Regulatory status

Pyrethrins are currently being reviewed as part of the EU re-authorisation process. Issues have been flagged with the consumer risk assessment due to uncertainties over the toxicity profiles of certain metabolites. Finalisation of the Canadian review of the pyrethrins is indicated for October 2022. It has been recently reviewed in Canada with a decision that continued registration of pyrethrins was acceptable with additional risk mitigation measures⁷⁴. These include increased worker PPE, crop stage restrictions to reduce potential pollinator exposure, buffer zones and the cancellation of a number of crop uses due to a lack of data, e.g., apples, cranberries, cucumbers, eggplants, squash and peppers, and the removal of generic fruit tree and vegetable claims from labels. It has not been scheduled at CCPR for JMPR re-evaluation. Registrant support is uncertain as no manufacturer has been identified at this time.

Pyrethrins are not currently listed as a priority for re-evaluation by the APVMA and as a result their use is unlikely to come under regulatory pressure in the medium to long-term. However, the experience in Canada highlights that a lack of data availability can impact ongoing access in the event of a re-evaluation occurring in the future.

⁷³ USA EverGreen® Crop Protection EC 60-6 label

⁷⁴ PRVD2020-08

8.6 Spinetoram

Spinetoram is currently approved in Australia for the management of fruit fly adults in pome fruit and stone fruit (PER12590) and Rubus and blueberries (PER87408). It is approved for use in the USA against apple maggot (*Rhagoletis pomonella*) Blueberry maggot (*R. mendax*), Cherry fruit fly (*R. indifferens*), Currant fruit fly (*Epochra canadensis*) and the Spotted winged drosophila (*D. suzukii*). In Canada it is approved for use against the apple maggot, Walnut husk fly (*R. completa*), Cherry fruit fly and the Spotted winged drosophila.

Regulatory status

A general review of spinetoram is planned to commence in Canada within the next 2 to 3 years. The authorisation in the EU is set to expire in September 2024 with data supporting re-authorisation to be submitted no later than 3 years before the expiry.

8.7 Tetraniliprole

A relatively new diamide (Group 28) insecticide recently registered for use in Australia against Medfly in stone fruit crops. It is registered in Canada for the suppression of the Apple maggot (*R. pomonella*)⁷⁵.

Regulatory status

It is approved for use in crops in Canada, New Zealand and the USA (seed treatment). MRLs have been established in Japan and Korea and the compound is scheduled for JMPR evaluation for the estimation of Codex MRLs in 2022. At present no approvals or standards have been established in China, the EU, Hong Kong, Indonesia, Malaysia, Singapore, Taiwan or the United Kingdom.

Adverse regulatory action in the medium to long-term is considered unlikely.

⁷⁵ USA Vayego 200 SC label

8.8 Trichlorfon

Trichlorfon is approved in Australia for the control of fruit flies in Pome fruit, capsicums, cherries (PER80542), guava (PER14683), Stone fruit (PER14683), table grapes (PER12439), tomatoes and tropical fruit (PER12450).

Regulatory status

Trichlorfon has been listed for review by the APVMA due to public health concerns⁷⁶. This pesticide has been deleted from the Codex system and has no approvals for use in crop protection in Canada, the EU, New Zealand, or the USA and has recently been phased-out in India and in Malaysia it is approved as an animal treatment only. MRLs, and presumably approvals, exist in China, Hong Kong, Korea, Japan, Singapore and Taiwan. No MRLs were found in Thailand.

Currently, there are six registered products in Australia. However, it is uncertain whether there is likely to be registrant support should the APVMA initiate the proposed review, i.e., the legacy registrant, Bayer, no longer supports the compound. Further it is understood that data suitable for submission to the APVMA is limited.

Given the stated public health concerns, and questions over data availability it is probable that crop uses will face significant regulatory pressure in the short-term, i.e., within the next 3 years. As a result it is considered a real possibility that the withdrawal of trichlorfon from the Australian market could occur.

⁷⁶ <http://apvma.gov.au/node/10876>

9. Secondary insecticides

9.1 Abamectin

Abamectin is approved for use in avocados, citrus, table grapes, Summerfruit, mangoes, cherries and berries as a spot or strip spray when applied in conjunction with lures/baits. It is registered in the USA, co-formulated with cyantraniliprole⁷⁷, for the Apple maggot (*R. pomonella*), Cherry fruit fly (*R. indifferens*) and Spotted winged drosophila (*D. suzukii*).

Regulatory status

In Canada abamectin is under cyclic re-evaluation with public consultation indicated for 2022⁷⁸. In the EU abamectin use has been restricted to permanent greenhouses⁷⁹. At Codex it was last evaluated by the JMPR in 2015, in which case it is unlikely to be scheduled for periodic re-evaluation before to 2030 unless a significant public health concern is identified. It is under review in Canada with public consultation indicated for February 2022.

It is therefore, unlikely to encounter regulatory pressures in the medium to long-term, i.e., 5-10 years.

9.2 Chlorpyrifos

Chlorpyrifos is approved for use in avocado, citrus, pome fruit, passion fruit and stone fruit for fruit fly control as a spot or strip spray applied in conjunction with lures. While contact with fruit is to be avoided, its use could, nevertheless, be problematic given the risk of inadvertent fruit contamination.

Regulatory status

At Codex it is understood that chlorpyrifos is no longer supported by the legacy registrant Corteva. Adama have indicated the company will lead a submission, but is yet to advise which commodities will be supported. In Australia, it is anticipated that the APVMA regulatory proposals will be published by mid-2022, with significant amendments to use patterns likely to occur for any retained uses. It is no longer authorised for use in the EU⁸⁰. In the USA the EPA has proposed withdrawal of all uses on food crops⁸¹. The PMRA in Canada has also decided to cancel all uses with a phase-out period ending in December

⁷⁷ USA Minecto® Pro Label

⁷⁸ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-note/2021/special-review-work-plan-2021-2026.html>

⁷⁹ https://members.wto.org/crnattachments/2021/TBT/EEC/21_1889_00_e.pdf

⁸⁰ Commission Regulation (EU) 2020/1085 set all MRLs at 0.01 mg/kg as of November 13, 2020

⁸¹ <https://www.epa.gov/newsreleases/epa-takes-action-address-risk-chlorpyrifos-and-protect-childrens-health>

2023⁸². In India the Ministry of Agriculture issued a draft Banning of Insecticides Order in 2020 proposing the removal from use of a number of pesticides including chlorpyrifos. The Thai Ministry of Public Health recently published a Notification on Food Containing Pesticide Residues in the Royal Gazette banning chlorpyrifos residues on imported food.

Given the extent of regulatory actions it is probable that authorisations of chlorpyrifos are likely to continue to decrease in the short-term, with probable removal from many jurisdictions.

9.3 Fipronil

Fipronil is approved in Australia for use in a gel bait. It is also approved for a similar use in the USA⁸³.

Regulatory status

Fipronil is not authorised for use in the Canada or the EU. In the EU the approval expired in September 2017⁸⁴. This occurred following the non-provision of supplementary data required to support its renewal⁸⁵. The required information related to potential impacts on bees and other pollinators. The compound is currently under registration review by the US EPA, with interim decisions indicated for publication in 2021. The compound has limited in-crop uses in the USA, i.e., soil application prior to planting potatoes and use in fruit fly lures. Its primary uses being in animal treatment and termite control. It is currently under review by the APVMA over environmental concerns, e.g., persistence in the environment and toxicity to non-target organisms. A recently periodic re-evaluation by the JMPR identified potential public health concern from long-term dietary exposure to residues of fipronil.

9.4 Spinosad

Spinosad is approved for use in bait sprays, lures and residential treatment of fruits and vegetables for fruit fly control in Australia. It is approved for use in bait sprays for the Mediterranean fruit fly (*C. capitata*) and the Natal fruit fly (*C. rosa*) in South Africa. It is also approved for use in the USA against apple maggot (*R. pomonella*), Cherry fruit fly (*R. indifferens*) and the Spotted winged drosophila (*D. suzuki*). There are

⁸² REV2021-02 Update on the Re-evaluation of Chlorpyrifos <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-note/2021/n-methyl-carbamate/chlorpyrifos.html>

⁸³ USA Amulet C-L Fruit Fly Stations

⁸⁴ Commission Implementing Regulation (EU) 2016/2035

⁸⁵ SANCO/11309/2013 rev. 0

MRLs established for a range of horticultural commodities in Australia, Canada, China, Codex, the EU, Indonesia, Japan, Korea, Malaysia, New Zealand, Singapore, the United Kingdom and the USA.

Regulatory status

The compound is currently under review in the EU with short-term consumer dietary exposure concerns indicated for a number of commodities⁸⁶. However, it is believed alternative GAPs resulting in lower residues are available to support continued approvals. Spinosad and spinetoram are scheduled for review in Canada with the start delayed due to resource constraints. The proposed date to commence the re-evaluations is to be announced in early 2022⁸⁷. It was last reviewed by the JMPR in 2001 for toxicology, it is therefore anticipated that the compound will eventually be 'captured' under the 25 year rule for re-evaluation.

Therefore, unless significant public health or environmental concerns are identified in the interim, spinosad is unlikely to encounter regulatory pressures in the medium to long-term, i.e., 5-10 years.

⁸⁶ Focussed assessment of certain existing MRLs of concern for Spinosad 2021. EFSA Journal Vol 19, (2)

⁸⁷ <https://www.canada.ca/en/health-canada/services/consumer-product-safety/reports-publications/pesticides-pest-management/decisions-updates/reevaluation-note/2021/special-review-work-plan-2021-2026.html>

10. Summary

Based on the preceding analysis an indicative summary is provided below. The timeframes indicated relate to potential impacts on access to the respective insecticides. These impacts could be direct, i.e., loss of authorisation in Australia, or indirect through the loss of authorisation and relevant trade facilitating standards in key export markets. Of note is the apparent reliance upon the use of potentially problematic insecticides as either cover or bait sprays to assure fruit fly free status under Interstate Certification Assurance schemes in Australia.

Table 1 Summation of likely regulatory action in relation to insecticides approved for fruit fly management in Australia.

Insecticide	Timeframes	Primary area of regulatory concern	ICAs based on use of the insecticide
Dimethoate	Short-term	Pollinator exposure & Public health (dietary exposure)	ICA-1, ICA-2, ICA-18, ICA-19, ICA-21, ICA-26
Malathion	Short to medium term	Environmental contamination, Public health	ICA-19, ICA-20, ICA-21, ICA-26, ICA-28, ICA-34, ICA-56
Methomyl	Medium-term	Public health (dietary exposure)	
Neonicotinoids	Short to medium term	Pollinator exposure	
Acetamiprid	Medium term	Pollinator exposure	
Clothianidin	Short to medium term	Pollinator exposure	ICA-20, ICA-21
Thiacloprid	Short-term	Pollinator exposure, Public health	
Pyrethroids	Medium-term	Pollinators	
Alpha-cypermethrin	Medium-term	Pollinators	
Bifenthrin	Medium-term	Pollinators	
Etofenprox	Medium-term	Pollinators	
Pyrethrins	Medium to long-term	Pollinators	
Spinetoram	Long-term		ICA-34
Tetraniliprole	Long-term		
Trichlorfon	Short-term	Public health, uncertain registrant support	ICA-20, ICA-21, ICA-26, ICA-28, ICA-34
Chlorpyrifos	Short-term	Public health, environmental contamination	ICA-28
Fipronil	Short to medium term	Public health	
Spinosad	Long-term		ICA-19, ICA-20, ICA-34, ICA-56

Short-term: Retaining access/use likely to encounter significant regulatory pressure in next 3 years

Medium-term: Maintaining access/use of potential concern over next

5 years Long-term: Monitoring required over next 5-10 years