Australian Government
Australian Pesticides and Veterinary Medicines Authority

Ref: 9311

E-MAILED
Date 12/6 By

12 June 2012

Senator the Hon. Glenn Sterle
Chairman
Senate Rural and Regional Affairs and Transport Legislation Committee
Department of the Senate
PO Box 210
Parliament House
CANBERRA ACT 2600

Dear Senator Sterle

SENATE ESTIMATES HEARINGS 22 MAY 2012 – PERMIT TO USE DIMETHOATE ON TOMATOES FOR EXPORT

I refer to the Estimates Hearings of the Senate Rural and Regional Affairs and Transport Legislation Committee of 22 May 2012. In the Estimates Hearings Senator Nash requested that the APVMA provide a copy of the determination on its reconsideration of the APVMA's decision of 23 December 2011 to refuse an application to use dimethoate on tomatoes that are destined for export.

The determination was made on Friday 8 June 2012. The determination is to affirm the previous decision to refuse the permit application. A copy of the determination is enclosed as requested.

Yours sincerely

RECEIVED
14 JUN 2012
Senate Rural and Regional Affairs and Transport Committee

James Suter
General Counsel

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Australian Government
Australian Pesticides and Veterinary Medicines Authority

Ref: G3000

8 June 2012

Occidental Odyssey Pty Ltd
PO Box 98
Brisbane Markets
ROCKLEA QLD 4106

Attention: Alistair Scott, Managing Director

Dear Mr Scott

RECONSIDERATION – DECISION TO REFUSE
PERMIT APPLICATION #13172

By letter dated 17 January 2012 you requested the APVMA to reconsider its decision of 23 December 2011 to refuse your application for a minor use permit to use the product Nufarm Dimethoate Systemic Insecticide 32962 as a post-harvest treatment of tomatoes.

In reconsidering this matter, I have had regard to the assessments carried out by the Residues Section of APVMA's Pesticides Program and the matters raised in the submissions made on your behalf by your lawyers in letters dated 12 March 2012 and.15 May 2012.

I have decided to affirm the APVMA's decision of 23 December 2011 to refuse permit application 13172. A statement of reasons for my decision is attached.

You have certain rights of review of this decision. A separate notice regarding those rights is enclosed.

Yours sincerely,

Eva Bennet-Jenkins

Dr Eva Bennet-Jenkins

Chief Executive Officer

Enclosure: Notice: Your rights to seek reasons for this decision or to have it reviewed

Cc: Robert Cunningham, Middletons Brisbane

STATEMENT OF REASONS

1. I, Dr Eva Bennet-Jenkins, Chief Executive Officer of the Australian Pesticides and Veterinary Medicines Authority (**APVMA**) set out the reasons for my decision to affirm the APVMA's decision of 23 December 2011 to refuse permit application number 13172 made by Occidental Odyssey Pty Ltd (**Occidental**) for a minor use permit to allow the use of a Nufarm Dimethoate Systemic Insecticide 32962 (**the Product**) a 400 ppm dimethoate product as post-harvest treatment of fresh tomatoes.

THE LEGISLATIVE FRAMEWORK

2. The decision to refuse permit application number 13172 is made under Part 7 of the *Agricultural and Veterinary Chemicals Code* (**Agvet Code**)[1] and in particular sections 112(2) and 112(3). These sections relevantly provide:

112 APVMA may grant or refuse application

(1) The APVMA must consider the application and take into account any recommendations made by a co-ordinator.

(2) The APVMA must grant the application if it is satisfied of the following:

(a) that, having regard to criteria determined by it, the applicant is a suitable person to hold the permit applied for;

(b) that the applicant has complied with subsection 110(2) and any requirement made by a co-ordinator to the APVMA under paragraph 111(1)(b);

(c) that any requirement made under section 157 or 159 has been complied with;

(d) that, if necessary, section 158 has been complied with;

(e) that any requirements prescribed by the regulations in relation to such an application have been complied with;

(f)that, having regard to the matters referred to in subsection 14(4) or (5), as the case requires, the use of, or any other dealing with, the constituent or product as proposed in the application for the permit:

(i)would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and

(g) (ii) would not be likely to have an effect that is harmful to human beings; and

(h) (iii) would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and

(i)(iv) would not unduly prejudice trade or commerce between Australia and places outside Australia;

(j)(g) that, having regard to the matters referred to in subsection 14(6), the use of the product as proposed in the application for the permit would be effective according to criteria that the APVMA has determined for the product;

(k) (h) that any requirements prescribed by the regulations in relation to the issue of such a permit have been complied with;

(i) if an application has not been made for approval of the constituent or registration or listed registration of the product or such an application has not been determined—that there are reasonable grounds for the application not having been made or for issuing the permit pending determination of the application, as the case may be.

(3) If the APVMA is not satisfied as mentioned in subsection (2), it must refuse the application.

[1] which is contained in the schedule to the *Agricultural and Veterinary Chemicals Code Act 1994* (Cth)

3. Section 112(2)(f) requires the APVMA to have regard to, relevantly, the matters in subsection 14(5) of the Agvet Code which provides:

> (5) In satisfying itself for the purposes of subsection (1) whether the use of a chemical product in accordance with the instructions for its use that the APVMA has approved or approves would be an undue hazard as mentioned in subparagraph (3)(e)(i), or would be likely to have an effect that is harmful as mentioned in subparagraph (3)(e)(ii) or (iii), the APVMA may have regard to such matters as it thinks relevant but must have regard to the following:
>
> (a) the toxicity of the product and its residues in relation to relevant organisms and ecosystems, including human beings;
>
> (b) the relevant poison classification of the product under the law in force in this jurisdiction;
>
> (c) how the product is formulated;
>
> (d) the composition and form of the constituents of the product;
>
> (e) the acceptable daily intake of each active constituent contained in the product;
>
> (f)(ea) any dietary exposure assessment prepared under subsection 82(4) of the *Food Standards Australia New Zealand Act 1991* as a result of any proposed variation notified under subsection 82(3) of that Act in relation to the product, and any comments on the assessment given to the APVMA under subsection 82(4) of that Act;
>
> (g) whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves;
>
> (h) the stability of the product;
>
> (i) the specifications for containers for the product;
>
> (j) any other matters prescribed by the regulations.

APVMA'S REGULATION OF DIMEOATHE

4. I note that in January 2010, the Office of Chemical Safety (OCS) *Human Health Risk Assessment of Dimethoate* dated January 2010 revised the Acceptable Daily Intake (ADI) of dimethoate from 0.02 mg/kg/day to 0.001 mg/kg bw/day and established an Acute Reference Dose (ARfD) of 0.02 mg/kg bw. [2] The APVMA published the OCS assessment in January 2011.

5. This OCS assessment informed the APVMA's review of the use of dimethoate on food crops, contained in a report dated August 2011[3] which concluded that concluded that the post-harvest use of dimethoate on tomatoes was unacceptable due to the acute dietary exposure estimates for children.

6. This led the APVMA, in October 2011, to suspend the use of dimethoate on a number of food crops, including all post-harvest uses on tomatoes, due to likely harmful effects in humans due to the consumption of those food crops.

7. APVMA issued Permit 13155, which approved a maximum residues limit (**MRL**) of 0.02mg/kg for the use of dimethoate in tomatoes. That MRL allows use of dimethoate on tomatoes that are grown for processing into things such as canned tomatoes, tomato juice and tomato puree. Permit 13155 allows the Product to be applied no later than 21 days before harvest.

THE ORIGINAL DECISION

8. On 17 October 2011, Occidental made its initial application for granting of a permit to use the Product as a post-harvest fruit fly treatment for tomatoes *"for supply interstate and export to New Zealand and the Pacific Islands"*.

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[2] www.apvma.gov.au/products/review/docs/dimethoate_human_health_tox.pdf

[3] *Dimethoate Residues and Dietary Risk Assessment Report,* August 2011 www.apvma.gov.au/products/review/docs/dimethoate_residues_report.pdf

9. An initial assessment was conducted by the Pesticides Residues Section of APVMA's Pesticides Program in relation to the permit application to use the Product for post-harvest use of dimethoate to control fruit flies on tomatoes, for supply domestically and internationally, with a proposed 7- day withholding period. This assessment, dated 28 November 2011, referred to the residues data obtained in tests conducted and stated:

    - the National Estimated daily Intake (**NEDI**) for dimethoate is equivalent to 127% of the acceptable daily intake (**ADI**) if the proposed post-harvest use on tomatoes is considered alongside the interim dimethoate review MRL recommendations, with the entry for tomatoes alone accounting for 43% of the ADI;
    - therefore, the chronic (long term) exposure estimate for dimethoate exceeds the ADI following inclusion of residues arising from the proposed use;
    - the acute exposure to dimethoate residues in tomatoes is 110% of the acute reference dose (**ARfD**) for children aged 2-6 years; and
    - therefore, the acute dietary exposure estimates for children are unacceptable.

10. The Pesticides Residues Section advised Occidental on 28 November 2011 that it was not satisfied that the requirements of section 112(2) of the Agvet Code had been met and that they did not support any issuing of the permit by the APVMA's delegate. In a subsequent telephone call, Occidental proposed that the tomatoes would be released into the export supply chain after treatment, and residues would be managed by a 7-day 'do not consume' period. In an email dated 5 December 2011, Occidental proposed that the permit application be amended for use of dimethoate as an export treatment only for tomatoes.

11. On 12 December 2011 the Pesticides Residues Section produced a further assessment report based on these proposals by Occidental. The report states that it remained unsatisfied that the requirements of s112(2) of the Agvet Code had been met and that they did not support any issuing of the permit by the APVMA's delegate. The report referred to the residues data for dimethoate and indicated that:

    - the conclusions in its earlier assessment were unchanged regarding exposures 7 days after treatment;
    - at 9 and 13 days after treatment, NEDIs were still unacceptable, representing 115% and 99% of the ADI, or 113% at 13 days using the FSANZ DIAMOND model which is regarded as giving a more accurate estimate of exposure and is applied when exposure estimates are in the range of 90-100%;
    - the chronic dietary exposure to dimethoate residues remains unacceptable at 13 days following treatment; and
    - the 2008 JMPR[4] calculation of the International Estimated Daily Intake (**IEDI**) for dimethoate accounted for 90% of the JMPR ADI (which is 0.002 mg/kg bw, double the Australian ADI). When the calculation was repeated with the inclusion of a tomato entry based on the proposed use, the IEDI for the GEMS/Food[5] regional diet, which includes New Zealand, was equivalent to 120% of the JMPR ADI.

    The assessment report also referred to the trade considerations as follows:

    > *Codex CXLs have not been established for use of dimethoate on tomatoes.*
    >
    > *Export of treated produce containing finite (measurable) residues of dimethoate may pose a risk to Australian trade in situations where (i) no residue tolerance (import tolerance) is established in the importing country or (ii) where residues in Australian*

[4] Joint FAO/WHO Meeting on Pesticide Residues
[5] World Health Organization's Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme (GEMS/Food)

produce are likely to exceed a residue tolerance (import tolerance) established in the importing country.

Tomatoes are not considered a major trade commodity as defined in Part 5B of MORAG. The applicant has indicated that tomatoes are exported to New Zealand and the Pacific Islands. Treatment with dimethoate is currently required to allow access of Australian tomatoes to the NZ market. The New Zealand MRL for dimethoate in tomatoes is 1 mg/kg. There is no relevant codex MRL.

12. The assessment report concluded:

The Pesticides Residues Section has evaluated residues aspects of Permit No. RP13172. The Pesticides Residues Section has considered available data and argument, including that submitted in support of the permit. The Pesticide Residue Section is not satisfied that the residues requirements of Section 112(2) of the Agricultural and Veterinary Chemicals Codes have been met. Issuance of the Permit RP13172 from a residues perspective is not supported as the APVMA cannot be satisfied that the proposed use would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and cannot be satisfied that the proposed use would not be likely to have an effect that is harmful to human beings as:

1. *the acute dietary exposure estimates for children are unacceptable as the estimate of acute (short term exposure) to dimethoate arising from the proposed use exceeds the established acute reference dose (ARfD) after the originally proposed 'do not consume' period of 7 days and;*

2. *the chronic (long term) exposure estimate for dimethoate exceeds the acceptable daily intake (ADI) following inclusion of residues remaining 13 days after treatment.*

13. On the basis of the above advice, the delegate, the acting Program Manager Pesticides, determined that the APVMA could not be satisfied that the proposed use of the product would not be an undue hazard to people using anything containing its residues, or would not be likely to have an effect that is harmful to human beings. As a consequence, the delegate determined that the application did not meet the criteria of s112(2)(f), and that the application must therefore be refused as required by s112(3). This **"Original Decision"** was advised to the applicant by letter dated 23 December 2011.

THE RECONSIDERATION REQUEST

14. Occidental's Managing Director, Alastair Scott wrote to APVMA on 16 January 2012 requesting a reconsideration of the Original Decision. That letter specified that the permit is "only for the purpose of treating tomatoes, specifically for export to New Zealand". This raises the question as to whether the APVMA has a valid reconsideration request before it, as Occidental is seeking reconsideration of something different to that contained in the original application for the permit. However, Occidental is nevertheless still seeking to use the Product in a way that, without a permit, would otherwise be an offence against an eligible law, namely s.13A of the *Chemical Usage (Agricultural and Veterinary) Control Act 1988 (Qld).*

15. I do not consider the change to Occidental's application, to limit use of the Product as a post-harvest fruit fly treatment of tomatoes for export only to New Zealand, to be material. The substance of the permit application is to use the Product in a way such that a permit is required

under Part 7 of the Agvet Code in order for that use to be lawful. I therefore consider the reconsideration request to be valid.

16. Occidental was invited by email, 18 January 2012 to submit any new information or argument for consideration as part of the reconsideration. Occidental, through their solicitors Middletons, provided further argument in a letter dated 12 March 2012 which was received on 15 March 2012.

MY RECONSIDERATION

Residues assessments

17. I note that in determining whether the use of the Product under the permit would not be an undue hazard to the safety of people using anything containing its residues, and would not be likely to have an effect that is harmful to human beings, I am obliged by s14(5)(f) to have regard to:

> whether any trials or laboratory experiments have been carried out to determine the residues of the product and, if so, the results of those trials or experiments and whether those results show that the residues of the product will not be greater than limits that the APVMA has approved or approves

18. In making my reconsideration of the original decision, I reviewed the residues assessments conducted by the Pesticides Residues Section of 28 November 2011 and 12 December 2011 mentioned above. I paid particular attention to the fact that dietary exposure estimates have used the revised dimethoate ADI determined by OCS (0.001 mg/kg bw/day) and have used the ARfD determined by OCS (0.02 mg/kg bw). The OCS recommendations are based on their evaluation of short- and long-term toxicological studies with standard safety factors incorporated to account for uncertainty.

19. Under Permit 13155, the MRL that the APVMA has approved for the use of dimethoate in tomatoes is 0.02mg/kg. That MRL allows use of dimethoate on tomatoes that are grown for processing into things such as canned tomatoes, tomato juice and tomato puree. In the case of the Product it can be applied no later than 21 days before harvest. Use of the Product in accordance with Permit 13155 ensures that the residues of dimethoate are below the limit that the APVMA has approved and when used in this way, dimethoate is not likely to have an effect that is harmful to human beings.

20. However, in the case of the use of the Product proposed by Occidental in permit application 13172, the residues of dimethoate on tomatoes would be greater than the limit that the APVMA has approved. Residue data provided by Occidental shows that the residue amount of dimethoate at 7 days after treatment will be 0.36mg/kg and 0.20 mg/kg 13 days after treatment. The presence of that amount of dimethoate residue is likely to have an effect that is harmful to human beings both in terms of chronic and acute exposure.

21. The number of tomatoes that would need to be consumed to amount to an acute exposure is extremely low. The 97.5th percentile consumption data (high consumer, over 24 hours) for tomatoes is 168g for 2-6 year olds and 351g for the general population. Based on Australian survey data the 'average' tomato (non-cherry/grape) weighs 130g. This equates to consumption of 1.3 tomatoes for a 2-6 year old or 2.7 tomatoes for a member of the general population over 6 years old in a 24 hour period.

Effect of dimethoate

22. I have also had regard to the following regarding Dimethoate, which is drawn from advice provided to me by the Principal Scientist, Pesticides.

23. Dimethoate is an organophosphorous (**OP**) insecticide. OP insecticides are regulated on the basis of their ability to inhibit enzymes which break down acetylcholine, a neurotransmitter chemical in both the central and peripheral nervous systems.

24. OPs can inhibit the activity of acetylcholinesterase (**AChE**), an enzyme specific for the hydrolysis (breakdown) of acetylcholine, as well as the activity of a non-specific esterase

enzyme (sometimes called butylcholinesterase) which in most species is the most common esterase enzyme in blood plasma. This non-specific esterase enzyme (**ChE**) can break down a number of esters of choline, including acetylcholine.

25. While the inhibition of non-specific ChE (or '**plasma ChE**') by OPs does not appear to have any significant adverse physiological consequences in animals or humans, it has been the policy in Australia for many years to use the inhibition of this enzyme in blood plasma to set the ADI. This is because plasma ChE is generally more sensitive to inhibition by OPs than AChE is, meaning that the risk assessment using the ADI is likely to err on the conservative side. The ADI is the regulatory health endpoint against which ongoing regular exposure (ie. chronic exposure) to OP insecticides is assessed.

26. For acute dietary exposures to residues of OPs in food (one meal, or short-term intake over one day), regulators use the Acute Reference Dose (**ARfD**) as the regulatory health endpoint. In this case, inhibition of specific AChE in red blood cells or the brain is used to establish the ARfD.

27. Exposure to OP pesticides can result in both acute and chronic health effects.

28. Acute effects occur rapidly after exposure to toxic doses. The symptoms are well documented. Depending on the dose received, they may include blurred vision, lachrymation, salivation, bronchorrhea, pulmonary oedema, nausea, vomiting, diarrhoea, urination, perspiration, incontinence, bradycardia, arrhythmias, heart block, cramps, headache, dizziness, malaise, apprehension, confusion, hallucinations, manic or bizarre behaviour, convulsions, loss of consciousness, respiratory depression, and possibly death.

29. Chronic health effects from OP poisoning can arise following:

    - an acute poisoning episode;
    - repeated exposures over a short time-period ; or
    - low-level, long-term exposure without any acute poisoning episode(s).

30. Chronic health effects are often hard to diagnose because they occur gradually and may be confused with other conditions causing tiredness, headaches and other flu-like symptoms.

31. Chronic health effects after acute (generally high-dose) OP exposure can include 'intermediate syndrome' (paralysis of cranial motor nerves and respiratory muscles, and muscle weakness, occurring 1-4 days after apparent recovery from the above acute symptoms) or, for a limited number of OPs (no longer marketed), OP-induced delayed polyneuropathy (OPIDP).

32. Other more subtle symptoms including abnormal vibrotactile thresholds (perception of vibration through touch) have been reported as common in a group of farmers previously acutely poisoned.

33. The most thorough studies on chronic health effects following long-term, low-level exposure without acute poisoning have been conducted in UK farmers who dipped sheep in OPs for many years. The term "dipper's flu" was coined to describe their reported flu-like symptoms. There was little evidence to suggest these effects were permanent, unlike the neurological health effects in those who had been poisoned following an acute high-dose exposure.

34. The syndrome chronic OP-induced neuropsychiatric disorder (**COPIND**) which can occur after long-term exposure to subclinical doses of OPs and after acute intoxication has been described in the literature. COPIND includes ten symptoms, which are: incapacitating episodes of "dipper's flu"; personality change with mood destabilisation; impulsive suicidal thinking; memory and attention impairment; language disorder; alcohol intolerance; heightened olfactory acuity; extreme sensitivity to OPs; handwriting deterioration and impaired ability to sustain muscular activity. The prevalence of COPIND in UK sheep farmers exposed to OPs was reported to be around 10%.

35. There appears to be a link between an acute poisoning episode and the subsequent development of chronic neurological health effects. Acute OP intoxication can cause a persistent decrease in neuropsychological performance; poisoned subjects perform significantly worse than controls in a battery of neuropsychological tests including those which assess verbal and visual attention, visual memory, visuomotor speed, sequencing and problem solving, and motor steadiness and dexterity.

Submissions made by Occidental

36. I have considered the submission made by Occidental's lawyers, Middletons, by letter dated 12 March 2012. This submission argued that:

- the MRL for dimethoate in tomatoes in New Zealand is 1 mg/kg [the current Australian MRL is 0.02 mg/kg]
- references in the Agvet Code to the safety of human beings, animals and the environment can only refer to human beings, animals and the environment in Australia
- the preamble to the Agvet Code requires the APVMA to apply the Code in a way that furthers trade and commerce between Australia and places outside Australia
- test results are well under the New Zealand MRL, except for one result which fell under the New Zealand MRL shortly after treatment
- use of dimethoate as proposed is not an undue hazard to the people of Australia during handling, or from residues as the tomatoes will not be eaten in Australia
- there is no international Codex MRL for dimethoate, and the APVMA's estimate of the chronic dietary exposure that would be done to set a Codex MRL for international trade is irrelevant.

37. I have considered each of these arguments in the following manner:

The MRL for dimethoate in tomatoes in New Zealand is 1 mg/kg [the current Australian MRL is 0.02 mg/kg]

38. The difference between the Australian and New Zealand MRLs for dimethoate is acknowledged. The APVMA's original decision was based on the safety of residues by comparison with ADIs and ARfDs, and was independent of the Australian and New Zealand MRLs for dimethoate.

References in the Agvet Code to the safety of human beings, animals and the environment can only refer to human beings, animals and the environment in Australia

39. I have formed the view that there is nothing in the Agvet Code that limits the meaning of "people" or "human beings" to those in Australia, and that the legislation would specifically state this if its intent was that the safety standards set down in the Agvet Code were only intended to protect people in Australia.

40. The basis for Middleton's proposition is said to be the presumption that legislation is not to have extraterritorial effect. That presumption derives from section 21(1)(b) of the *Acts Interpretation Act 1901 (Cth)*, which provides that, in the absence of a contrary intention, references to localities, jurisdictions and other matters and things shall be construed as references to such localities, jurisdictions and other matters and things in and of the Commonwealth.

41. However, the mere assertion that there is a general presumption against the extraterritorial operation of legislation does not mean that the presumption necessarily applies in this circumstance or, for that matter, that the presumption cannot be rebutted. Section 112(2)(f) requires APVMA to consider whether the proposed use or any other dealing with the product (i) would not be an undue hazard to the safety of people exposed to it

during its handling or people using anything containing its residues or (ii) would not be likely to have an effect that is harmful to "human beings".

42. I consider that the plain meaning of this provision, consistent with the underlying purpose of the Agvet Code as set out in the preamble, is that the reference to human beings is not limited to human beings who reside in Australia. If that was intended, it would be expected that words such as "the Australian community" would appear, instead of the all-encompassing reference to "human beings".

43. The permit sought by Occidental is for the use, in Australia, of dimethoate. This is regulated in Australia by the APVMA under the Agvet Code. In my view, the references in the preamble at (a) and (d), and in s.112(2)(f) to the importance of the safety of human beings, and international trade and commerce, indicate that APVMA's considerations are not confined to matters pertaining to Australia, and in particular, that APVMA may have regard to the safety of human beings beyond Australia's boundaries where relevant.

The preamble to the Agvet Code requires the APVMA to apply the Code in a way that furthers trade and commerce between Australia and places outside Australia

44. The preamble contains a number of general statements setting out the justification for "a system for regulating such products that is cost effective, efficient, predictable, adaptive and responsive". One of those statements is that the Agvet Code provides for trade and commerce between Australia and places outside Australia and that good government practice suggests that the APVMA should not unnecessarily hinder trade. However, it also gives prominence to the importance of protecting the health and safety of human beings.

45. Further, I note that the specific provisions of s.112 must still be satisfied before a permit can be granted. The contents of the preamble cannot override these considerations in s.112.

Test results are well under the New Zealand MRL, except for one result which fell under the New Zealand MRL shortly after treatment

46. This is accepted. The Original decision was based on the safety of residues by comparison with ADIs and ARfDs and was not made by reference to the Australian and New Zealand MRLs for dimethoate. I consider the fact that estimates of dietary exposure to dimethoate exceed the ADI and the ARfD supports the conclusion that the APVMA should not be satisfied that the proposed use would not be an undue hazard to the safety of people using anything containing its residues, or have an effect that is harmful to human beings.

Use of dimethoate as proposed is not an undue hazard to the people of Australia during handling, or from residues as the tomatoes will not be eaten in Australia

47. This is accepted, but this is not the relevant statutory test. As stated above, I have considered the potential for adverse impacts on human beings both within and outside Australia.

48. I do not consider it appropriate to approve use of the Product for export which would result in tomato produce that did not comply with Australian safety standards.

49. Further, the proposed use may constitute an undue hazard to the safety of people in New Zealand using treated tomatoes containing dimethoate residues, or have an effect that is harmful to human beings in New Zealand. New Zealand uses the JMPR ADI of 0.002 mg/kg for dimethoate, and the calculation that the IEDI for the New Zealand diet was equivalent to 120% of the New Zealand ADI indicates that the use may constitute a hazard for consumers in New Zealand.

There is no international Codex MRL for dimethoate, and the APVMA's estimate of the chronic dietary exposure that would be done to set a Codex MRL for international trade is irrelevant.

50. Contrary to Occidental's assertion, there are Codex MRLs (CXLs) for dimethoate, but not for dimethoate in tomatoes. Codex made a deliberate decision to revoke the CXL for dimethoate in tomatoes, as a consequence of a 2006 recommendation of the Codex Committee on Pesticide Residues based on concerns about dietary exposure risks. This decision indicates that Codex recommends that dimethoate not be used on tomatoes. This reinforces the conclusion that the application does not meet the criteria specified in s112(2)(f)(iv).

51. Furthermore, I consider it is relevant to note APVMA's estimate of Codex MRL for international trade that would be set, noting Australia is required to meet international trading conventions through its international treaty obligations such as the WTO Agreement on Agriculture and the Sanitary and Phytosanitary (SPS) Agreement.

Trade Aspects: s112(2)(f)(iv)

52. I am mindful that New Zealand requires that tomatoes exported from Australia be treated with dimethoate for fruit fly, and that residues data submitted with the permit application show that residues are generally under the New Zealand MRL of 1 mg/kg.

53. On 16 December 2011, APVMA was provided an email dated 16 December 2011 from Mr Andrew Pearson, a Senior Advisor (Toxicology) from the New Zealand Ministry of Agriculture and Forestry (Science and Risk assessment Directorate, Standards Branch) which stated:

> *The requirement in New Zealand, in respect of residues of agricultural compounds, for the food to be sold on the New Zealand market is that it complies with the Maximum Residue Limit.*
>
> *In the case of dimethoate these MRLs are specified in the New Zealand (Maximum Residue Limits of Agricultural compounds) Food Standards 2011 as being 1mg/kg for tomatoes and 2 mg/kg for fruit and vegetables (except tomatoes).*
>
> *Provided produce for sale complies with [the MRL of 1mg/kg for tomatoes] there are no other restrictions put in place by New Zealand in relation to residues of dimethoate in food.*

54. I considered it relevant seek the attitude of the New Zealand food regulator, the New Zealand Ministry for Primary Industries (**MPI**) as to whether that agency was willing to accept fresh tomatoes from Australia that have been treated with dimethoate as a post-harvest treatment and that are intended for human consumption. The purpose of that enquiry was to assist me in determining whether the use of the Product on tomatoes destined for export to New Zealand might unduly prejudice trade between Australia and places outside Australia in terms of s112(2)(f)(iv).

55. On 2 May 2012 the APVMA wrote to Occidental inviting them to obtain the above information from the NZ MPI. At the same time APVMA contacted the Agricultural Compounds and Veterinary Medicines Group of the MPI and provided them with a copy of the APVMA Residues Report dated 12 December 2011, as background to assist in the MPI's response to Occidental Odyssey.

56. Occidental responded to the above invitation, through their lawyers, Middletons by emailed letter dated 4 May 2012. They declined to seek further confirmation from MPI, asserting that the *New Zealand (Maximum Residue Limits of Agricultural compounds) Food Standards 2011*

allows the sale of imported food containing residues not exceeding the MRL. Middletons also referred to the email advice from Mr Pearson dated 16 December 2011.

57. On 7 May 2012, APVMA received a response to its enquiry of MPI from Ms Debbie Morris, Director, Systems, Support and ACVM in the Standards Branch at MPI. She advised that:

> *We have checked the dietary intake calculation and based on the data specified in the APVMA report we have calculated that the use on tomatoes from Australia would be*
>
> - *% of NZ ADI = 67.3% (where as the % of Australian ADI would equate to 134.7%)*
>
> *Please note:*
>
> - *The residue data for the 7 days after treatment was used in the calculation.*
> - *The NZ ADI (0.002 mg/kg bw/d) is different from the Australian ADI which is 0.001 mg/kg bw/d.*
> - *The NZ ADI is the same as the JMPR one*
> - *The NZ EPA is reviewing this chemical and we expect that this will happen before the end of the year*
> - *The NZ MRL for tomatoes is still valid and the product is still registered for certain uses in NZ - however it is not used on NZ produced tomatoes*
> - *We would note that while dimethoate is required as a post harvest treatment for the control of fruit fly in imported tomatoes, the other in field measures as required by the import health standard must be applied.*
>
> *Given this we have no objections to the permit. If you have any queries please let me know.*

58. On the basis of the above I am satisfied that the use of the Product on tomatoes destined for export to New Zealand would not unduly prejudice trade between Australia and places outside Australia in terms of s112(2)(f)(iv).

Requirements of the Food Standards Code

59. Finally I note that in order to grant the permit the APVMA would need to establish an MRL of 2mg/kg based on the residue data that Occidental has provided. If such an MRL were not established the Product could not be used on the tomatoes. In this regard I note that Clause 1.1 of Standard 1.1.1 of the Food Standards Code relevantly provides:

> **1 Application of this Code**
>
> (1) Unless expressly provided elsewhere in this Code, the provisions of this Code apply to food products –
>
> (a) sold or prepared for sale in Australia or New Zealand; and
>
> (b) imported into Australia or New Zealand.

60. The establishment of the MRL of 2mg/kg by the APVMA is therefore required in order to grant the permit. The granting of the permit would therefore result in a higher MRL in Australia for tomatoes to be consumed in Australia than the current MRL of 0.02mg/kg.

61. **Conclusion**

62. For the above reasons, I consider that whilst use of the Product on tomatoes destined for export to New Zealand would not unduly prejudice trade between Australia and places outside

Australia, the APVMA cannot be satisfied that the proposed use would not be an undue hazard to the safety of people using anything containing its residues, and should not be satisfied that the proposed use would not be likely to have an effect that is harmful to human beings (s112(2)(f)(i)&(ii) of the Agvet Code). I affirm the Original Decision to refuse permit application 13172.

Signed

Eva Bennet-Jenkins

Dr Eva Bennet-Jenkins
Chief Executive Officer

8 June 2012

Australian Government
Australian Pesticides and
Veterinary Medicines Authority

NOTICE

YOUR RIGHTS TO SEEK REASONS FOR THIS DECISION OR TO HAVE IT REVIEWED

FORMAL STATEMENT OF REASONS

You may apply for a formal written 'statement of reasons' from the APVMA setting out the findings, referring to the materials on which those findings were based, and giving the reasons for this decision. Your application must be in writing and should be lodged within 28 days of receiving this notice. Please direct your application to:

General Counsel, Legal Program
Australian Pesticides & Veterinary Medicines Authority
PO Box 6182
KINGSTON ACT 2604

ADMINISTRATIVE APPEALS TRIBUNAL (AAT) REVIEW OF DECISION

The AAT is an independent body that can review certain APVMA decisions on their merits and, where the AAT decides it is appropriate, substitute its own decision. Under section 167 of the Agvet Codes, many of the decisions of the APVMA made under the Agvet Codes are reviewable by the AAT, subject to the *Administrative Appeals Act 1975*. Section 167 of the Agvet Codes sets out the sorts of decisions which are reviewable. They include a decision to refuse an application for registration or variation of registration of a chemical product, to suspend or cancel a registration/approval and to vary the conditions of a label approval. If you are not satisfied with this decision, you are entitled to apply to the AAT to review it. An application for review must be in writing and should be lodged within 28 days of receiving this decision. If you have good reason for not meeting this timeframe, you can write to the AAT and ask for an extension of time, giving details of your reasons. An application fee of $777 is normally payable. If you believe you cannot afford to pay the full fee you can apply to the AAT to pay the reduced fee of $100. You will find further information about making an application to the AAT on it's website at www.aat.gov.au. Your application for review should be forwarded to:

Administrative Appeals Tribunal
GPO Box 9955
in any capital city.