Questions on Notice from APVMA Briefing on Fenthion

Date: Thursday, 11 October 2012

1 Australian fresh fruit producers have been using Fenthion for over 40 years. Can you provide any direct evidence of one single case of human harm through consumption of fresh produce?

No.

2 Why is the APVMA proposing to suspend the use of Fenthion, when they can't provide any physical evidence of human harm by fresh produce consumption in over 40 years?

The APVMA does not require physical evidence of harm to the community, chemical users, trade or environment prior to taking regulatory action. The establishment of the acute reference dose (ARfD) for fenthion in 2004 by the Office of Chemical Safety in the Department of Health and Ageing required a re-assessment of existing Maximum Residue Limits (MRLs) and the conduct of dietary exposure assessments to ensure an acceptable level of protection for Australian consumers of fruit and vegetables.

The APVMA makes its decisions according to its governing legislation and undertakes its risk assessments according to international best practice, as set down by the United Nations World Health Organisation and Food and Agriculture Organisation (WHO & FAO). It is proposed that the use of fenthion on certain crops be suspended due to the potential for short-term (acute) dietary exposures of young children (and in some cases all consumers) to be at levels well above the relevant public health standard (the ARfD). As the risk assessment indicates that the ARfD has been exceeded, the existing MRLs are no longer acceptable and the APVMA can no longer be satisfied that these uses of fenthion *would not be an undue hazard to the safety of people using anything containing its residues' and unlikely to be harmful to human beings*. As the legislation requires the APVMA to be satisfied in this respect, it must make changes.

3 The APVMA say they are reviewing Fenthion because it may harm the most vulnerable members of the 2-6 age category, especially children with illness that may be the most susceptible. Children with illnesses are not a new phenomenon over the last 40 years, can the APVMA provide just one case proving any harm to any child, ill or not, in the 2-6 year old range from consumption of fresh produce?

No. Please refer to response under Q.2.

4 What quantity of fresh fruit must a child between the ages of 2 and 6 years old eat each and every day to be considered under threat of harm, according to the levels

specified in the APVMAs report? Does this sound like a reasonable amount of produce for a child 2-6 years old to be able to consume?

This question relates to short-term dietary exposure and long-term dietary exposure and the assessment of risk for each of these. Different health standards are used for each type of exposure assessment. The ARfD is used for the short-term exposure assessment and the Acceptable Daily Intake (ADI) is used for the long-term exposure assessment.

The short-term dietary risk assessment considers exposure during the course of a single day, whereas the long-term dietary risk assessment considers exposure over a lifetime. The data used to determine typical food consumption by people in Australia for short-term exposure and dietary risk that might occur through the whole life of a person are different and are based on surveys that are conducted by FSANZ.

Food consumption figures for each type of assessment are also different and are provided to APVMA by Food Standards Australia New Zealand (FSANZ). The figures are based on Australian survey data. In addition, FSANZ verifies the outcomes of the APVMA's dietary exposure assessments, before APVMA makes a decision on any MRL.

For a use to be approved, or to continue to be approved, all food treated with a pesticide must be safe for consumption, meet the prescribed MRL, and the MRL must be protective of all consumers and the health of the entire population.

The short-term dietary risk assessment is based on the highest likely consumption of individual foods, e.g. peaches over the course of a day (a 24-hour period). The short-term assessment does not consider consumption over more than a single day.

The APVMA report of September 2012 considered residues in fruit at levels corresponding to the maximum label rate. The consumption by a 2-6 year old of greater than the following amounts of fruit may result in exposures over and above the reference health standard (the ARfD). This is on the basis of consumption of a single fruit type during the course of a day not average consumption over a year.

Grapes	27 average sized grapes
Apples	0.4 of an average sized apple
Peaches	0.4 of an average sized peach
Tomatoes	1.1 average sized tomatoes

5 Is the APVMA using the 1995 National Nutrition Survey as data for consumption rated of fruit? If so, why are they using data that has declared variables in the NNS report of +/- 50%? Why are the APVMA using data that may have such major discrepancies? Could data with +/- 50% have any kind of effect on the APVMAs findings?

Food consumption figures are provided to APVMA by FSANZ for use in the dietary exposure assessments for regulatory purposes. While, the data for adults is based on the 1995 National Nutrition Survey, the data for children aged 2-6 years is based on the 2007 Australian National Children's Nutrition and Physical Activity Survey.

6 Furthermore is there any chance whatsoever eating habits and consumption rates have changed in the 17 years since this survey?

Please refer to response under Q.5.

7 Is the APVMA testing residue levels according to standard orchard practice? Why are the APVMA testing residue levels for 5 applications of Fenthion, when standard orchard practice is 1 application with a second follow up application only applied under conditions of attack by Fruit Fly? Could this be responsible for inaccurately high residues levels?

The APVMA does not test for residues. Current label instructions for fenthion allow up to 5 sprays of fenthion on stone fruit. The APVMA used data submitted by the chemical manufacturer and other interested parties, such as Horticulture Australia Limited (HAL) to assess the residues arising out of the maximum use pattern allowed by the currently approved label. Information regarding two applications was not provided.

8 Why does the APVMA have no data for applications that relate to standard orchard practice?

Please refer to response under Q.7.

9 Does the APVMA admit that the reduction from 5 applications, which they erroneously used to collate their data, and the actual Standard Orchard Practice usage pattern of 1-2 applications could minimize risk and remove the threat of harm from the 2-6 year old age range? Do they have any data at all to disprove this? If no, don't the APVMA as a scientific body, think this very data should be attained before a decision that will cripple an industry is made?

The data provided to the APVMA and the corresponding risk assessment reflects the uses on the current label and the APVMA must assess the maximum label use pattern to establish appropriate MRLs. At the time of publication of the *Fenthion Residues and Dietary Risk Assessment Report (September 2012)* the APVMA invited submissions containing information, such as alternate use patterns or modifications of use, for consideration by the APVMA. Emails inviting submissions were sent to 258 stakeholders as well as being publicised together with the report: http://www.apvma.gov.au/products/review/current/fenthion_faq.php

10 The APVMA admit that according to their testing the amount of Fenthion being consumed in Australian diets is only 17% of maximum ADI (Average Dietary Intake). Fresh fruit and veg contribute 4.7%. Is the 4.7% figure overly inflated due to the APVMA testing at a maximum use scenario, rather than standard orchard practice?

The exposure assessment referred to in this question is the long-term exposure to fenthion residues in the diet. No actions are currently proposed on the basis of long-term exposure to fenthion residues. It should be noted that the APVMA does not undertake residue testing.

11 Milk, at 5.1%, and beef protein, at 4.9%, both provide higher contributions to the ADI than fresh fruit and vegetables. Why is the APVMA targeting suspension of fenthion for the fruit and vegetable industry when there are higher residues levels in the cattle industry?

Please refer to responses under Q.4 and Q.9.

The proposed suspension action is on the basis of unacceptable short-term dietary risks. It should be noted that there is only one veterinary product (for use on cattle) and it is also under review. The APVMA is close to finalising the residues assessment for this product.

12 Were the APVMA aware that fruit producers do not spray according to maximum recommendations on the tin and only use Fenthion in as minimal capacity as possible, & have done so consistently for the last 40 years?

The APVMA acknowledges regional differences in the use of fenthion as allowed under state control of use legislation. However, for the purposes of establishing MRLs that accommodate all variations of use, the APVMA risk assessment must reflect the current label use pattern and its acceptability or otherwise. The APVMA invited interested parties, including industry groups to nominate alternate uses, or modifications of existing label uses and a number of submissions from users groups are currently being assessed against the statutory criteria to determine if some uses may be retained in a modified fashion.

13 Is the APVMA aware of the presence of Fenthion in insect controls that can be applied to the household pet? A liquid containing Fenthion can be applied directly to the back of a pets neck, a child is able to then pat the pet, then bring their hands to their mouth. Is this more of a threat to the said child, as it can be absorbed directly before it has had time to break down, when compared to the consumption of produce that has the recommended WHPs in place and is under the application systems of fruit producers, who have training in applying chemicals safely and correctly?

There are currently no registered fenthion products for use of companion animals. These have been progressively withdrawn from the market The last product was withdrawn in 2010.

14 Is Trichlorfon a more dangerous chemical than Fenthion in terms of its mutagenic and carcinogenic capabilities?

The WHO has classified active ingredients of pesticides according to their acute toxicity. The latest report (from 2009; available at: www.who.int/ipcs/publications/pesticides_hazard/en/) classifies both fenthion and trichlorfon as moderately hazardous.

In the 2008 toxicology report prepared by the Office of Chemical Safety (OCS) for the dichlorvos review some aspects of trichlorfon toxicity were considered; see www.apvma.gov.au/products/review/completed/dichlorvos.php . The OCS concluded that there was no evidence that trichlorfon was carcinogenic and that it was unlikely to pose a genotoxic risk to humans.

15 On the APVMA's own website Trichlorfon is listed as a mutagen and a likely carcinogen and Fenthion is listed as neither. Why is the APVMA removing Fenthion from use when, in over 40 years, it has proven to do no harm to humans and why are they recommending the more dangerous Trichlorfon as an alternative?

Please refer to responses under Q.2 and Q.14.

16 A With Holding Period is defined as the number of days between spray application and harvest. It allows time for a chemical to break down in produce. Why was the WHP reduced from 7 days to 3 days during the time the APVMA was reviewing Fenthion?

The WHP for fenthion use on stone fruit was reduced from 7 days to 3 days in June 1997 following assessment of a request by the product registrant. The fenthion MRL for stone fruit was subsequently increased from 2 mg/kg to 5 mg/kg. At that time there was no acute reference dose (ARfD) for fenthion, and hence only long term dietary exposure was required to be considered.

17 Why did the APVMA not flag this change if they considered Fenthion as hazardous?

Please refer to response under Q.16

18 Does the reduction of the WHP not indicate that Fenthion is safer, rather than more harmful?

No.

19 The APVMA say Fenthion is banned world wide. Is the APVMA aware of the use of Fenthion in Washington since 2010 to control Suzuki Fly, a pest that is attacking apples and other fruits? Is the APVMA aware of the use of Fenthion in Germany and Switzerland on cherries, as well as in South Africa on peaches?

The APVMA stated that there are no crop protection uses remaining in the EU, Canada, USA and New Zealand. It did not say that it is banned world-wide.

The use of fenthion in other counties is not of relevance to the proposed actions in Australia based on approved labels and uses in Australia and decisions made against statutory criteria in the Agvet Code Act. Regulatory partners in Germany have confirmed that a 2003 decision of the Commission to not include fenthion in Annex I of Directive 91/414 means that all products have been phased out of the EU and no uses remain in Germany. [Fenthion is not approved under EC 1107/2009; removed from Annex 1 in 2004 (2004/140/EC)].

In the US, there are no fenthion MRLs for plant products, only veterinary product MRLs remain, with expiry dates (Table in Attachment 1). We are not aware of any emergency exemptions in the US for fenthion on any insect pests. [USEPA yet to confirm status].

20 Is the APVMA aware that foreign Governments used Fruit Fly eradication schemes, including the release of sterile flies to lower Fruit Fly population pressures to an almost undetectable level, to assist the food producers before removing Fenthion? Is the APVMA aware that our governments over time, Australia wide, have done no such thing leaving producers with impossibly high Fruit Fly population volumes to control via the methods the APVMA suggest?

Pest control strategies are a matter for industry and state and territory governments.

21 Is the APVMA aware that all chemical alternatives suggested by them only kill the adult, but they give no actual control on the maggots that cause the devastating destruction fruit flies are renowned for?

The APVMA does not recommend chemical alternatives to fenthion or any pesticide. Industry groups, users and chemical manufacturers may make requests for approval of alternative controls where data to support such proposals are available. The APVMA then considers such proposals according to its legislation.

22 The APVMA and fresh food producers both admit that Area Wide Management may be one part of the solution to Fruit Fly control. The APVMA describe AWM on their own website in these terms, "Area-wide management, including systems development, wider community involvement and education is likely to be a long, slow process"
Is there any guarantee that AWM will work? Why are the APVMA removing Fenthion immediately, when they admit AWM is a 'long, slow process', leaving the producers exposed?

Please refer to response under Q.2. Also note that the APVMA advised stonefruit growers as early as May 2006 of the possible outcomes of the dimethoate and fenthion reviews and the need for an urgent industry response.

23 Does the APVMA feel that if their review report and pending recommendations were to be challenged in the Australian Administrative Tribunal, they would be 100% confident of successfully defending their position?

Yes. The conduct of the review by the APVMA has been according to its governing legislation and international best practice in risk assessment of residues and dietary exposure.

24 Do the APVMA think that, considering they are putting crops at risk one month before harvest in the Perth Hills area without a viable or effective alternative, the fruit producers would have grounds for a class action seeking compensation for losses?

The conduct of the review by the APVMA has been according to its governing legislation and international best practice in risk assessment of residues and dietary exposure. Further, the APVMA notes that the statutory criteria determining acceptability of a use do not allow consideration of the economic impact of removing a use.

25 Is the APVMA aware that all chemical alternatives suggested by them only kill the adult, but they give no actual control on the maggots that cause the devastating destruction fruit flies are renowned for?

Please refer to response under Q.21.

26 When will the new MRL for Fenthion be finalised and which agency has responsibility for this process?

The APVMA will vary the APVMA MRL Standard in the weeks following implementation of the proposed suspension. The APVMA will then request that FSANZ vary Standard 1.4.2 of the Australia New Zealand Food Standards Code.

27 Will the APVMA release the HAL report into Fenthion residues under a variety of use patterns? Please provide a link to the website if it is currently available.

No. The data submitted to the APVMA by HAL is summarised in the *Fenthion Residues and Dietary Risk Assessment Report (September 2012)* as published on the APVMA website http://www.apvma.gov.au/products/review/current/fenthion.php .

28 Could a Minor Use Permit be applied for to allow use of Fenthion this season?

Yes. In addition, proposals for modified uses of fenthion that are requested by industry and that meet the APVMA's statutory assessment criteria can be included under new use instructions that will be issued for fenthion products during the proposed suspension period.

ATTACHMENT 1

ELECTRONIC CODE OF FEDERAL REGULATIONS
e-CFR Data is current as of October 11, 2012

Title 40: Protection of Environment

PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD

Subpart C—Specific Tolerances

---

§ 180.214 Fenthion; tolerances for residues.

(a) *General.* Tolerances are established for residues of the insecticide fenthion (*O,O*-dimethyl *O*- [4-(methylthio)- *m*-tolyl] phosphorothioate) and its cholinesterase-inhibiting metabolites in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cattle, fat	0.1	4/1/06
Cattle, meat	0.1	4/1/06
Cattle, meat byproducts	0.1	4/1/06
Hog, fat	0.1	4/1/03
Hog, meat	0.1	4/1/03
Hog, meat byproducts	0.1	4/1/03
Milk	0.01	4/1/03

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[45 FR 86492, Dec. 31, 1980, as amended at 63 FR 57074, Oct. 26, 1998; 66 FR 50833, Oct. 5, 2001; 67 FR 49616, July 31, 2002]