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Senate Standing Committees on Rural and Regional Affairs and Transport

Inquiry into the implications of the restriction on the use of Fenthion on Australia's horticultural industry

“There is more likely to be a net benefit if regulation is tailored to the risk posed by a chemical in a particular circumstance (its use), rather than the blunter approach of intervening whenever there is a hazard (Productivity Commission, 2008).”

Introduction

The Productivity Commission's study into the regulation of the chemicals and plastics industry pointed out that the regulation should, wherever possible, be light handed and commensurate with the risk.

This was the position adopted by the Hills Orchard Improvement Group (HOIG) when representatives pointed out to the APMVA that fenthion has been used to control Mediterranean fruit fly for more than 50 years and over that period of time there have been no reported health effects among workers or consumers.

Fenthion is the only product registered and proven by structured in-field testing that will kill the fruit fly larvae or maggot and all other stages of the life cycle. Perth Hills fruit growers produce more than \$40 million a year of stonefruit, apples and pears. HOIG predicted in 2012 a ban on fenthion could lead to the total destruction of the stonefruit crop and the loss of a significant portion of the apple crop in the south west of Western Australia.

While there are 80 growers in the Perth Hills there are about 600 growers in Western Australia who would be affected if fenthion was banned. There remains a generalised view that the APVMA could well destroy great sections of the horticultural industry if it bans fenthion.

The position of the APVMA

The APVMA advised industry groups of the review of fenthion in 1994. The review started in 1997.

After nearly 20 years under review, growers had, perhaps naively, come to the view that if fenthion was damaging to worker and consumer health its review would have been prioritised and the pesticide banned at the earliest possible opportunity.

Prior to September 11, 2012, permits issued by the APVMA for the use of fenthion were for unrestricted usage. The number of applications was not limited or stated. The then permit commented that early in the season it was suggested two applications were sufficient, but there was no strict limit. The permit recommended use later in the season was based on certain intervals between sprays until one week before harvest.

On September 11, 2012, fenthion's use on edible skin produce was suspended. Post-harvest uses on fruiting vegetables such as tomatoes was also banned. Use on all fruit and vegetable crops grown in home gardens was also suspended.

On October 31, 2012, following consultation with industry the suspension was lifted and the APVMA issued a new permit for Western Australia allowing for two applications on stonefruit 10 days apart and with a 7 day withholding period. This permit was to remain in place for twelve months. In other states a new permit was issued that allowed for three sprays with a 21-day withholding period.

On October 16, 2013, the APVMA banned the use of fenthion on peaches and apricots. For other fruits conditions varied. The new permit allowed three applications, 10 days apart, with a 14-day withholding period on nectarines and plums.

On October 29, 2013, following consultation with industry the APVMA lifted the suspension and issued a permit allowing for one application of fenthion on peaches and apricots with a 21-day withholding period.

The APVMA has not justified how fenthion was deemed to pose an unacceptable risk to the public through fruit consumption in September 2012, yet deemed to be safe for public consumption in October 2012. The APVMA in less than two years has twice banned completely the use of fenthion on peaches and apricots because it was said to pose an unacceptable risk to consumers. On both occasions it reversed that decision and fenthion is again allowed to be used on peaches and apricots.

The regulator's decision may be explained by the fact that spraying peaches and apricots with fenthion does not automatically pose a threat to the consumer. The Maximum Residue Limit for fenthion on peaches and apricots is 0.20mg/kg. Fruit recording that level of residue does not represent an actual threat to the consumer, it represents an erosion of the safety margin for daily exposure to the chemical residue. The safety margin in the case of fruit sprayed with fenthion is a factor of 10 times less than the level at which residues may cause observable effects.

Growers are faced with a regulator that on one occasion banned the use of fenthion on all stonefruit, pome fruit, cherries and persimmons but now permits its use. These are not consistent, reliable or justifiable rulings by a regulator.

For this reason alone, HOIG members believe the APVMA needs urgent reform so that its decisions as a regulator can withstand rigorous scrutiny and where those decisions are found to be incorrect it can be held accountable for unnecessary damage caused to industry.

The use of fenthion in other countries

Fenthion is not registered for use on food producing plants in Canada, the European Union, New Zealand or the USA.

The European Commission *Summary Report on Exports and Imports of Chemicals Listed in Annex 1* revealed that in 2011 495 tonnes of fenthion was manufactured in the EU and exported to 19 countries. A breakdown of exported quantities (in tonnes) revealed that 119 tonnes was exported to Africa, 279 tonnes to the Asia-Pacific region (including Australia) 48 tonnes to Central and European States, 39 tonnes to Latin and Caribbean States and 10 tonnes to Western Europe and other states. The production of fenthion outside the EU is difficult to establish but there are a number of manufacturers in China and India. Data on the volume of output is not readily available.

Alternatives to fenthion

The APVMA and state regulators claim there are registered alternatives to fenthion for fruit fly control or suppression. The APVMA claimed in September 2013 that it had issued a new permit for the use of clothianidin to control fruit fly in pomefruit, stonefruit and persimmons with a withholding period of seven days and this could successfully replace fenthion.

The Department of Agriculture and Food in Western Australia (DAFWA) claims that Mediterranean fruit fly can be controlled by Area Wide Management. This approach encompasses a combination of baiting, biological controls, cover sprays, using other pesticides, oils or kaolin, improved orchard hygiene techniques, the release of sterile male fly and netting and the use of barriers. HOIG notes that these approaches are useful, some are expensive, and some are inferior to others but they are all part of the armoury to control Mediterranean fruit fly in Western Australia.

Surprisingly, both the APVMA and DAFWA overlook the fact that there is no product that will kill the larvae or maggots of Mediterranean fruit fly except fenthion.

The point has to be made, the market for marked (i.e. fruit fly-stung) or infested fruit is non-existent in Australia and therefore the future viability of the industry will be in question if fenthion is removed without a comparable and equally effective alternative.

Some growers advocate the use of organic pesticides such as a rotenone-pyrethrin mixture. When the use of these organic pesticides is compared with Imidan, a "soft" synthetic pesticide, it has been established up to seven applications of a rotenone-pyrethrin mixture must be used to obtain the level of protection provided by two applications of Imidan. It seems unlikely that seven applications of rotenone and pyrethrin are better for the environment than two applications of Imidan, especially when it is known that rotenone is extremely toxic to fish and other aquatic life.

The APVMA's relationship with industry

It is worth considering the experiences of the Western Australian agricultural chemical company Imtrade in dealing with the APVMA. In 2008 the APVMA enlisted the Australian Federal Police to raid Imtrade's Perth premises and threatened criminal charges. Two weeks later the APVMA imposed a compulsory recall of the affected products, some 47 in total, and notified Imtrade that the products were no longer registered. In mid-2008 Imtrade admitted it had given a fictitious name and address in China of the manufacturer of certain active constituents to protect its confidential business information. This was contrary to the rules but a minor offence.

Imtrade appealed to the Administrative Appeals Tribunal, which promptly ordered the recall stayed. The APVMA took it to the Federal Court, which found the APVMA had acted unlawfully and ordered the reinstatement of the registrations. The APVMA ended up paying Imtrade's costs and was probably saved from massive damages because the products were only off the market for two weeks. This case had similarities to the Pan Pharmaceuticals case that led to the payment of \$55 million in damages. Like the Pan case Imtrade involved regulatory overreach.

Since 2000 there have been a number of reports and reviews looking at the performance of the APVMA. Governments of the day have made legislative amendments to try and improve the performance of the Authority.

There are many industry leaders who believe the APVMA has failed innovative companies and farmers by adding millions of dollars of additional costs to farm chemicals and veterinary products. It has been suggested to Parliamentary inquiries that the focus of the APVMA appears to be enhancing its standing among peers in Europe and other regulatory jurisdictions. The Australian regulatory process is expensive, excessive time-consuming and at the whim of the bureaucracy. There is little accountability and no recourse for farmers or registrants. Since its inception, no Federal Minister for Agriculture has succeeded in improving the efficiency and cost-effectiveness of the system.

Efforts to work co-operatively with the APVMA

The APVMA has been widely criticised by industry in a number of reviews for the uncertainty, cost and lack of timeliness in the discharge of its duties.

Briefly, it is worth reflecting on HOIG's contact with the APVMA. During the 2013 review of fenthion, residue of fenthion testing conducted by Horticulture Australia Limited (HAL) indicated levels above the accepted MRL. On examination of the results orchardists considered the results were too high and an analysis of the figures by our consultants was instigated. It was found that the methodology to determine the residue of total fenthion was scientifically questionable, if not flawed. The most contentious element of the methodology was the treatment of residues that were reported as <0.05 or below the Limit of Detection (LOD). These results were reported consistently through the draft report as a residue level of 0.05mg/kg.

HAL advised that the APVMA requested that the approach adopted be to record a residue figure of 0.05mg/kg, even though the test result of <0.05 was below the LOD.

Because of the "methodology" that converts <0.05 into 0.05 we then see the phenomenon where the 'untreated' or control sample fruit returned a residue level of 0.3mg/kg. That is, fruit that was not sprayed returned a residue level above the allowable limit of either 0.20 or 0.25mg/kg.

HOIG members were concerned that the methodology used and the consequential results had the effect of undermining the reputation of the Australian pome and stone fruit industry and raised the questionable methodology with the APVMA.

The results in question were not included in the final report.

HOIG also participated in a residue trial developed by the APVMA to establish whether standard orchard practice used in the Hills orchards would allow the continued use of fenthion on pome and stone fruit crops. What HOIG was unaware of was that without reference to them the required results as stipulated by the APVMA was altered from a 4-component residue to a 6-component residue. The testing laboratory was not advised that analyses for fenthion oxon sulphone and fenthion oxon sulphoxide were required by the APVMA. The APVMA subsequently did not accept HOIG's trial results. The APVMA fails to acknowledge changing the residue methodology or failing to communicate this alteration to HOIG.

The results showed that the percentage of samples with no detectable residues for fenthion was 64% and that all residue limits were below accepted levels. It has to be pointed out that all the analysed pome and stone fruit were absolutely safe for consumers according to FAO/WHO (1998) MRLs.

The APVMA committed to advising HOIG of the results of the supplementary residues and dietary exposure assessment (2013) and any revised permit conditions. Contrary to this undertaking, HOIG was advised with an hour's notice that the report would be released and a new permit issued.

The Committee would be aware that HOIG's efforts to protect the stonefruit industry from collapse through the banning of fenthion have unfortunately been undermined by some growers, some representative organisations and by DAFWA.

Options for the future

In November 2013, HOIG approached the APVMA about initiating a three-year phase out period for the use of fenthion. It was HOIG's opinion that such a period of time would allow the industry time to find an alternative to fenthion. Area Wide Management could be used in conjunction with the reduced usage of fenthion but in Western Australia DAFWA has not put in place the necessary protocols, regulations, finances or legislation to ensure that Area Wide Management will be as successful as they predict. Experiences in Western Australia in recent years have seen mixed results. Unfortunately growers only get a crop once a year so it's essential that all the elements to Area Wide Management and alternative cover sprays are in place well before the protection of fenthion is removed.

HOIG adopted a phase-out option after reflecting on the international evidence about the usage of fenthion and the reaction of regulators in comparable jurisdictions. We were

hopeful the APVMA would join us in a collaborative phase-out approach. But they provided us with little comfort, claiming they did not have a statutory basis for negotiating a phase out. This advice contradicts the APVMA's actions in allowing a two-year phase out for the herbicide 2.4_D.

The APVMA said it was compelled to wait until the health and safety and environmental assessments had been completed because they might indicate the need for the immediate removal of fenthion from registration. HOIG, having acquainted itself with the international scientific evaluations of fenthion over the past 15 years, considers that highly unlikely. If new evidence established the requirement to ban fenthion immediately was presented then HOIG would support that decision. The APVMA advised HOIG that a phase-out period was not something contemplated by other jurisdictions. Our research clearly indicates that this occurred in the EU with fenthion and occurs in New Zealand for the very reasons advanced by HOIG. Fenthion was banned in the USA from use in mass aerial spraying in mosquito control programs because it was killing federally protected bird species in Florida when sprayed from airplanes. The Canadian Pest Management Regulatory Agency allowed a two year phase-out period for the sale and use of any remaining fenthion product.

Conclusion

The APVMA acknowledges that the food supply in Australia, including fruit sprayed with fenthion, has caused no injury or sickness. HOIG has attempted to engage with the APVMA in a co-operative fashion but it is proven very difficult.

Fenthion is the only product registered and proven by structured in-field testing that will kill the fruit fly larvae or maggot and all other stages of the life cycle. Perth Hills fruit growers produce more than \$40 million a year of stonefruit, apples and pears. HOIG predicted in 2012 a ban on fenthion could lead to the total destruction of the stonefruit crop and the loss of a significant portion of the apple crop in the south west of Western Australia.

While there are 80 growers in the Perth Hills there are about 600 growers in Western Australia who would be affected if fenthion was banned. There remains a well-considered view that the APVMA could well destroy great sections of the horticultural industry if it bans fenthion.

As an indicator of the crop losses that growers could experience without access to fenthion, in the 2012-13 season adverse weather conditions saw fruit fly numbers rise exponentially. Growers were permitted two applications of fenthion. Crop losses were across the board estimated at 50 per cent. In one orchard the crop loss was 100 per cent.

Industry peak bodies have given evidence to recent Senate and House of Representatives inquiries that the APVMA's regulatory approach has denied Australian producers access to the latest, most effective and least toxic Agvet chemicals, harming their competitiveness. The potential economic cost of APVMA decisions which provide no demonstrable protection to health or the environment is clearly not well understood by government or, we believe, it would act to reform the agency.

On its current path, the APVMA is making regulatory decisions that could profoundly damage agriculture in Australia. Growers faced with the loss of effective chemical tools and subsequent income loss will not invest or create new jobs, reducing production and profits.

In the short to medium term, Hills orchardists, located so close to residential areas where fruit fly is not controlled, will be forced out of business.