



## **Frequently Asked Questions Concerning the APVMA's Review of Atrazine**

### **Why was atrazine reviewed by the APVMA?**

Atrazine is a herbicide which can be used both pre and post-emergence for the control of grass and broadleaf weeds in crops such as sorghum, maize, sugarcane, lupins, pine and eucalypt plantations, and triazine tolerant (TT) canola. Atrazine belongs to the triazine group of chemicals and was first registered in Australia in the early 1960s.

The APVMA (formerly the National Registration Authority) routinely reviews registered chemicals when new information indicates a possible cause for concern. A very extensive set of data on atrazine was reviewed between 1995 and 1997. The review assessed concerns over possible links to cancer, its potential to contaminate ground and surface water, a lack of Maximum Residue Limits (MRLs) for major commodities, and a reported lack of efficacy for some uses.

In conducting this review the APVMA sought expert advice from the Office of Chemical Safety (OCS) within the Department of Health and Ageing (DoHA) and the Chemical Assessment Section within the Department of the Environment, Water, Heritage and the Arts (DEWHA).

### **What did the review find?**

In November 1997 the APVMA released an extensive atrazine review report, based on a detailed analysis of the information available at that time. This report found that there were no major concerns with atrazine. Specifically the cancer concern was found to be unwarranted. New conditions for the use of atrazine were implemented in order to reduce chemical handling by workers, and to reduce drift and runoff into water bodies. Some of the key changes included:

- No mixing/loading or application within 20 m of any well, sink holes, intermittent or perennial stream.
- No application within 60 m of natural or impounded lakes or dams.
- No use in channels and drains.
- A maximum annual rate of application of 3 kg active ingredient (ai)/ha in all crops except plantation forestry. In plantation forestry, the maximum rates were limited to 4.5 kg ai/ha per year in sandy soils and those defined as 'highly erodible', and 8 kg ai/ha per year in clay loams and heavier textured soils.
- Cancellation of industrial and non-agricultural uses of atrazine (including home-garden uses and all commercial turf uses). Cancellation of sale and supply of these atrazine products took effect from 31 December 1998 with the use of existing stocks allowed to continue until 30 June 1999.
- Inclusion of more extensive safety instructions on product labels to reduce chemical handling by workers, and to reduce spray drift and runoff into water bodies.
- Deletion of maximum residue limits (MRLs) for commodities for which there were no current use patterns (citrus, grapes and pineapples).

The APVMA also found that additional environmental and residue information was required and atrazine manufacturers and product registrants were given up to three years to generate this data. Subsequent assessment of these new data led to the development and publication of a further report.

In April 2002 the APVMA released this report, the *Atrazine Draft Final Review Report* for public comment. At the time of its release, a number of studies were published in the international literature which raised additional concerns that atrazine might cause adverse developmental and reproductive problems in frogs. Because of these new concerns, the APVMA delayed finalisation of the review in order to investigate these new claims and reassess the toxicological and environmental risks of using atrazine.

In December 2004 the APVMA released the *Atrazine Second Draft Final Review Report*. This report considered previous findings, regulatory actions that had been undertaken and published information on developmental and reproductive effects on frogs.

In this report the APVMA found that atrazine was unlikely to have an adverse impact on frogs at existing levels of exposure. However, it concluded that the issue of atrazine and frogs should be revisited if additional data demonstrated that atrazine posed a hazard to frog populations at these levels. The APVMA also found that atrazine did not pose a risk to human health, but that additional risk mitigation measures should be implemented to provide further protection for the environment and human health.

The APVMA was satisfied that by varying product labels to further control how products were used, atrazine products could continue to be used safely.

Accordingly, in the 2004 report the APVMA proposed amending product labels to include:

- additional precautionary statements to further reduce the likelihood that the handling and use of atrazine would result in atrazine entry into waterways.
- A new withholding period of 28 days for grazing on all crops except canola
- Details for reporting incidents of herbicide resistance or breakdowns in efficacy.

Following publication of the 2008 *Atrazine Final Review Report and Regulatory Decision* document (published on 1 May 2008), these amended label instructions have now been implemented.

### **Does atrazine tend to be more persistent in cooler climates?**

Atrazine is considered to be reasonable mobile and persistent in the environment, with microbial degradation under aerobic conditions the main route of dissipation. Temperature, soil moisture and pH affect how rapidly atrazine dissipates from soil.

In the case of temperature, some laboratory tests and field data indicate that colder soil temperatures increase the persistence of atrazine. As described in the APVMA's 1997 environmental risk assessment of atrazine, a laboratory study using loamy soil found that the half life of atrazine was 175 days at 10°C and 56 days at 20°C. In terrestrial field dissipation studies reviewed by the US EPA in its re-registration eligibility decision on atrazine, it was found that atrazine dissipated with half lives of 13, 58, and 261 days in field studies performed in Georgia, California, and

Minnesota, respectively. These differences were attributed to temperature variation because atrazine had longer persistence times in regions that were cooler.

### **Why didn't the APVMA act more promptly on its 2004 recommendations?**

The majority of the risk mitigation measures identified through the review process were implemented in 1997. The implementation of the supplementary recommendations arising from the 2004 report was delayed because of continued uncertainty in the scientific and regulatory community about potential harm to frogs and possible implications for human health. Furthermore, some community groups maintained that the 2004 recommendations did not go far enough. Therefore the APVMA delayed taking regulatory action because it is committed to ensuring that its final decisions are consistent with the best available science.

As it turned out (as is often in the case in science), the new research findings continue to be contradictory and controversial, and no clear consensus among scientific experts has yet emerged.

At an APVMA/community forum held on 22 June 2007 all parties agreed that while further studies may be forthcoming, lack of certainty over some issues should not be a reason for the APVMA to delay taking further regulatory action in relation to other issues for which firm conclusions have already been made. The APVMA completed a final review report which was published on 1 May 2008.

### **Atrazine has been banned in Europe so why is it still registered for use in Australia?**

Atrazine has not been 'banned' in Europe. In 2004 the European Commission decided not to list atrazine on its schedule of approved active constituents for plant protection products (its so-called Annex I). It did not do this because of any specific toxicological reasons but because it was concerned that residues in ground water might exceed its nominal limit of 0.1 ppb which it had set for all chemicals for which specific values have not been established.

### **Are Australians at risk from atrazine contamination in groundwater?**

A concern has been raised that some Australians might be at risk from drinking groundwater that has been contaminated with atrazine.

This is not the case. Firstly, most Australians source their drinking water from reservoirs located in highly protected catchment areas. Secondly, relatively small amounts of atrazine are used in Australia. For example, Australia uses much less atrazine in total (about 5-10%) than what is used in the USA where atrazine is the primary herbicide on corn.

Nonetheless, active measures are taken to protect groundwater from all possible chemical contamination. Water supply authorities seek to exclude all sources of chemical contamination from drinking water and also maintain a watching brief on drinking water and possible changes in the way drinking water is sourced. And irrespective of the source of the water, the recommended national drinking water standards should apply.

Systematic water monitoring programs such as that undertaken in Tasmania do occasionally find isolated detections in waterways but these are well below health and environmental levels of concern and are transitory.

The APVMA's current advice from its scientific advisors is that there is no basis to date to conclude that contamination that could be a risk to human health or harmful to the environment is likely to occur when products containing atrazine are used in accordance with label instructions.

**Some have suggested that Australia allows a far higher concentration of atrazine in drinking water than other countries, thereby exposing its citizens to greater potential risk. Is this the case?**

Not at all. The values are actually quite similar.

The current Australian Drinking Water Guidelines (ADWG) were developed by the National Health and Medical Research Council (NHMRC) in collaboration with the Natural Resource Management Ministerial Council (NRMMC). Two values have been set for atrazine, a Guideline Value of 0.1 parts per billion (ppb) and a Health Value of 40 ppb.

The Guideline Value is used to alert water authorities to chemical contamination. If a pesticide is detected at or above the Guideline value, water authorities should identify the source of contamination and take action to prevent further contamination.

The Health Value defines the maximum concentration of a chemical in drinking water that, when considered together with amounts an individual might obtain from other dietary sources, does not exceed a level of concern. This value can be used to guide risk communication and risk management in case of a major incident such as an accidental spillage.

The Australian Guideline level of 0.1 ppb compares favourably with the equivalent United States and European Union values of 3 ppb and 0.1 ppb respectively, while the American health value (called the Drinking Water Level of Comparison) at 68 ppb for the general population is slightly higher than the equivalent Australian Health Value of 40 ppb.

Other authorities have also set drinking water 'guideline' values for atrazine which are not dissimilar to the Australian Health guideline value. For example, Canada has established a 'Chronic Drinking Water Level of Concern' for atrazine of 41.9 ppb and the 1996 EU proposal was for a Maximum Allowable Concentration (MAC) of atrazine in water of 15 ppb.

**If a concentration of 20 ppb causes effects on isolated cells in the test tube, isn't our drinking water Health Value set too high?**

Concerns have been expressed that recent studies from the University of California in San Francisco, showing that a concentration of 20 ppb atrazine affects human placental cells in the test tube mean that Australia's drinking water Health Value of 40 ppm is not safe.

Directly comparing laboratory test tube experiments with the mammalian human body is entirely inappropriate because the body has mechanisms to limit exposure of

its component tissues to toxins. Processes such as metabolism and excretion rapidly deactivate and/or remove chemicals like atrazine if they are ingested.

Even if someone drank a glass of water that contained 40 ppb of atrazine and all of the atrazine was absorbed and distributed without promptly getting metabolised and excreted, the atrazine would be diluted 200-400 times when redistributed into the body's own water component.

The 40 ppb Health value was established using wide safety margins over no-effect levels of atrazine when tested in a large number of studies, most of which were conducted in living animals.

**Some recent published studies have proposed that atrazine is a risk factor in human reproductive cancers and in endocrine disruption in wildlife. Why does this information not change the APVMA's findings?**

In the case of atrazine a number of studies have been published suggesting a relationship between low concentrations of the chemical and endocrine disruption in frogs. Scientific panels and regulators have been assessing these studies, as well as other contradictory research. Currently there is ongoing debate as to the relevance of this research to likely exposures in field (frogs and other animals) and more particularly, its relevance to humans.

It is the nature of science to seek to explain how the world works and to propose hypotheses explaining cause and effect. A number of articles are published each year suggesting possible effects of pesticides on human health or the environment. That they are published does not mean that the conclusions they make are necessarily significant or that a clear causal path is determined. Frequently, a hypothesis is offered based on initial correlations that later are found not to be completely correct because all factors had not yet been considered or even discovered. Such initial tentative hypotheses often need significant further work and confirmation by other research groups before they are accepted as firm scientific knowledge. It is the role of the scientific and regulatory community to assess all reports and consider whether the weight-of-evidence lends support for a causal linkage between a chemical and the reported effect(s).

On this basis the APVMA has finalised the review. However, the APVMA is prepared to consider another review if the weight of evidence raises environmental or human health concerns, or there is significant new overseas regulatory action based on a sound scientific assessment.

**What about the on-going research?**

Consistent with its commitment to regulatory decision-making based on the best available science, the APVMA takes a keen interest in the directions in which ongoing research into atrazine is heading. It particularly notes recent research into the possible biochemical modes of action of atrazine in frogs and in cultured animal and human cells. The APVMA is seeking further detailed advice from the Department of Health and Ageing on the implications of this research in the broader context of what we now know about the triazine group of herbicides (eg. atrazine and simazine). If the conclusions suggest new areas of concern, the APVMA will reconsider appropriate regulatory measures.

### **Shouldn't the ongoing research prompt a re-opening of the atrazine review?**

Following publication of a study in May 2008 by the University of California, San Francisco, which suggested that atrazine may have effects on genes related to fetal growth retardation and fertility, the APVMA was asked to consider re-opening the atrazine review. The study in question showed a range of *in vitro* (ie. in cells incubated in the test tube) biochemical findings. Based on the observations of effects of direct exposure on isolated cells incubated in the laboratory, the authors hypothesised certain effects on whole organisms (including humans).

The APVMA considers that the results of the test tube studies need to be interpreted with caution, particularly when viewed in the context of the large body of negative findings from studies conducted in living animals. During the Australian atrazine review, several hundred studies were reviewed by the Department of Health and Ageing to establish safe levels of exposure for atrazine. Most of these studies were conducted in whole animals rather than cells in a test tube, looking at effects on general wellbeing, on the possible development of cancers after a lifetime of exposure, as well as on reproduction and development. This work included studies which tested atrazine alone and in combination with other agricultural chemicals which can occur in the environment.

The APVMA will consider the need to re-open the review of atrazine following receipt of a full scientific assessment of recent published studies which is being conducted by the Department of Health and Ageing. A report on this project is likely to be available in late 2008 or early 2009.

### **How does the APVMA communicate review outcomes to stakeholders?**

Two levels of consultation take place when the APVMA undertakes a review: that initiated by the APVMA in developing and communicating its review outcomes; and that undertaken by State/Territory government authorities in giving effect to the outcomes of APVMA's reviews.

In undertaking a review the APVMA consults extensively with the chemical industry, State/Territory and Commonwealth government agencies.

For rural stakeholders, engagement begins early in the review process when the APVMA seeks to establish the major users of the chemical under review. In the lead up to a review and once it commences, significant contact is made with commodity groups. Engagement may take place through farm visits, attendance at meetings and participation in agricultural/horticultural/veterinary fora and conferences. The APVMA also engages the media during the review process and provides information on its website including releasing a preliminary review findings report to allow public comment on proposed review outcomes.

Once a report is concluded, the APVMA puts in place an extensive communication strategy to advise stakeholders, especially chemical users, of the review outcome. This effort includes:

- Letters/phone calls/meetings with key groups with identified concerns that surfaced during the review period.
- A media statement specifically targeting rural and regional Australia.
- Publication of the review report, media statement, frequently asked questions and stakeholder impact statements on the APVMA website. The website also

contains a highly detailed Chemical Review section which provides a regulatory history of reviewed chemicals and all associated documents.

- Provision of advice of the review outcome to over 1200 subscribers to the APVMA email-based 'Regulatory Update'.

The other formal consultation phase is conducted by State/Territory Governments once the APVMA has made its final determination. State/territory officials are responsible for managing or enforcing any new arrangements and undertake their own consultation with chemical users to ensure awareness of any new conditions.