Dissenting report – Australian Greens

- 1.1 The Australian Pesticides and Veterinary Medicines Authority (APVMA) has only just gained the legislative triggers it needs to systematically review and quickly remove highly hazardous and unmanageable pesticides from the market if they fail to meet today's scientific and regulatory standards, making way for safer, greener pesticides.
- 1.2 It is extremely disappointing that these important and long overdue amendments due to come into effect in July are being unwound. The re-approval and re-registration scheme would ensure Australia finally undertook a systematic review of its ag-vet chemical inventory, many of which have never been subject to contemporary risk assessment and are not considered safe by any modern measure, yet persist in our community.
- 1.3 Legislated risk-based re-registration schemes operate in the USA, Canada and the European Union. The key focus of re-registration in these jurisdictions is to ensure older pesticides on the market are subjected to the same standards applied to pesticides registered today.
- 1.4 Australia has a problem and the re-registration scheme is designed to fix it. Australia has hundreds of pesticides that were 'grandfathered' into the National Registration Scheme that have never been risk assessed. These products are sold and used today and the risks they pose to the community, the environment and trade have never been quantified and the risk management strategies needed to control their negative impacts have not been specified.
- 1.5 Without re-registration, the APVMA will continue to operate in much the same way it always has with respect to chemical reviews and the fundamental problem of inadequately assessed pesticides remaining on the market will not be systematically addressed.
- 1.6 The APVMA has a poor track record with its chemical review program with many high risk pesticides under review for 10-15 years without adequate action being taken to mitigate risks, or indeed remove pesticides from use that are clearly just too dangerous.
- 1.7 Without a re-registration scheme, the APVMA has only an ad hoc approach to chemical review. There is no rationale in what ends up on the chemical review list and no guarantee that regulatory effort will be focused in on the pesticides of greatest risk.
- 1.8 According to the submission to the Senate Rural and Regional Affairs and Transport Legislation Committee Inquiry by the Queensland Government (the control of use regulator):

The general concept of re-registration and re-approval has merit and is utilised by many overseas regulators as a way of ensuring that agvet chemicals have been approved by modern risk assessment principles. In Australia, there are a large number of uses if agvet chemical products that

were approved by the registration system of the States and Territories, prior to the formation of the APVMA that have not been reassessed by modern risk assessment principles.

One of the great promises of national registration was that the 'grandfathered' products would be re-assessed. There has been limited progress in re-assessing the uses of these products under the APVMA Chemical Review program."

- 1.9 The re-approval and re-registration scheme does not undermine a risk-based regulatory scheme it enhances it. The current situation saw hundreds of products permitted to be on the market without ever having been risk-assessed to contemporary standards, and they're not likely to be under the Governments proposed ad hoc approach, this isn't a rigorous science-based risk assessment scheme; it's hit and miss regulation.
- 1.10 The re-registration scheme is based on scientific information and designed to make sure full chemical risk assessment reviews are done on the most high-risk products. In the first instance, the re-registration scheme sorts chemicals based on high, medium or low risk with hazard criteria helping to inform this sorting process. For instance, if a pesticide causes cancer and bioaccumulates in our bodies and the environment, then it should go to the top of the list as a high priority.
- 1.11 Once sorted, the regulator determines whether they are satisfied based on the science before it for that the product can continue to be used safely, or whether it needs to conduct a full risk-assessment to ensure the product can continue or not. If there are no concerns and current risk management statements are adequate, then the pesticide doesn't undergo full risk-assessment.
- 1.12 There's been a lot of discussion about hazard versus risk during this inquiry and these are terms that need to be understood in the context of chemical regulation. A risk assessment is a 'science-based tool' while 'a hazard-based approach takes away the scientific rigour of risk assessments.' The Australian Greens support the retention of the risk based framework, however we do not agree with the assertions that last year's reforms undermined this framework.
- 1.13 Re-regulation is still a risk-based process, even though it is initially informed by hazard assessment. Nor are the initial hazard assessments fundamentally different to risk assessments in this context. They are still based on the same toxicological and epidemiological research as risk assessment (obviously, since risk assessment is the next step after hazard assessment).
- 1.14 Risk assessment uses an extra set of data (exposure scenarios) but whether or not that makes it 'more science-based' must surely depend on the quality of the science behind the extra data. An extra volume of data does not necessarily improve the management of risk from a chemical; risk can still be underestimated because an absence of data or because the impact of an exposure to that chemical is simply too complex to model.
- 1.15 This is why in some circumstances a line needs to be drawn in the sand, even within a risk-based system. There are some pesticides that simply cannot be risk-

managed and this must be acknowledged. The global direction is to move away from highly hazardous pesticides towards safer ones and Australia shouldn't be left behind.

- 1.16 As new evidence emerges about the possibility of low-dose effects, cumulative toxicity of mixtures, endocrine disruption and so forth all new developments unanticipated by risk assessment practices in the past, the Regulator needs a process in place to respond to the information.
- 1.17 If re-registration were to be repealed, we would return to the status quo whereby the Regulator would be reliant on an ad hoc chemical review program to address the problem of the hundreds of pesticides 'grandfathered' onto the National Registration Scheme that have not been adequately risk-assessed.
- 1.18 While comparable jurisdictions like the USA and Canada move ahead with legislated re-registration programs to ensure the ongoing safety of their pesticide inventories, Australia will continue to lag behind, putting its farmers, consumers, environment and trade at risk.
- 1.19 The science of toxicology is undergoing a revolution with the recognition of unintended impacts of pesticide exposure on our health and the environment. The role that environmental pesticide exposures might play in the development of certain cancers, Parkinson's disease and metabolic disorders for instance is currently subject to a great deal of scientific scrutiny.
- 1.20 Leaving the APVMA without a systematic mechanism to bring products back before it for assessment is asking them to regulate with one hand tied behind their backs. Science is always changing and throwing up new concerns, community expectations are changing and farmers need the safest tools to use.
- 1.21 The Australian Greens support the retention of the re-registration program. However, if re-registration is removed from the Act, then including criteria that will ensure high priority pesticides are identified quickly and —re-assessed is vital. The Greens recommend that the triggers outlined in the letter from then Minister for Agriculture Senator Ludwig, tabled as part of the debate on the APVMA Amendments last year and included as an appendix to these comments, be incorporated into the APVMA Act itself rather than left in regulation.

1.22 These included:

- 1. On toxicity to humans and wildlife:
 - chemicals in Schedule 7 of the Poisons Standard, that is, dangerous poisons with a high potential for causing harm at low exposure and which require special precautions during manufacture, handling or use;
- 2. On bioaccumulation, about chemicals that accumulate in fatty tissues:
 - chemicals with a recognised bioconcentration factor of greater than 500, or with an octanol/water partition coefficient of greater than 4;
- 3. On degradation and persistence, chemicals that remain intact for exceptionally long periods of time:

- chemicals that do not rapidly degrade (assessed using OECD test guidelines 301 or 306) or chemicals with a half-life in water greater than two months or in soil or sediment greater than six months;
- the absence of rapid degradation in the environment can mean that the substance in water can exert toxicity over a wide temporal and spatial scale;
- 4. On long range transport, potential for wide distribution throughout the environment:
 - chemicals that don't rapidly degrade and which may be used in circumstances that can lead to transport beyond the target use site, chemicals measured at levels of concern in locations distant from release.
- 1.23 These criteria can be satisfied by prescribing all substances that are classified as chronic Category 1 under the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) and that are included in Schedule 7 of the Poisons Standard maintained by the Department of Health and Ageing. The letter notes that DAFF's initial assessment was that there are around 42 substances that would meet these criteria.
- 1.24 Furthermore, one or more comparable jurisdictions having banned or severely restricted a pesticide should also be incorporated as triggering a review by the APVMA, if re-registration is repealed.
- 1.25 In conclusion, The Australian Greens believe that unwinding the reregistration scheme will re-introduce the assumption that a pesticide is 'innocent' of any negative impacts until it's proven 'guilty', beyond a doubt that damage is occurring from it. This benefits chemical corporations, not the people or the environment. It is well overdue for Australia to develop a systematic approach to removing previously untested chemicals from the market. The re-registration scheme remains the most rigorous, cost-effective and efficient approach to achieving that outcome.
- 1.26 For these reasons, the Australian Greens recommend that this Bill not be passed.

Senator Rachel Siewert Australian Greens Senator for Western Australia