

Australian Greens' Minority Report

1.1 The Australian Greens welcome improvements in the regulation of agricultural and veterinary chemicals however the inquiry identified some areas that require amendments in order to improve the effectiveness of this regulation. We therefore cannot agree that the bill should proceed without amendments.

1.2 There is no doubt that some agricultural and veterinary chemicals have damaged human and environmental health and continue to pose risks to both. Risk management should be at the core of any registration program and those chemicals that pose unacceptable and unmanageable risks should not be permitted in Australia.

1.3 We want the approach to risk taken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to reflect contemporary science in toxicology and regulatory approaches in other countries and we are concerned this is currently not the case.

1.4 There is still too much discretion being given to the APVMA to determine “undue hazard” to the safety of people and the environment without a suitable framework under which to determine that risk. These additional comments outline our concerns and provide recommendations to improve how the APVMA carries out its work.

Conflict of interest

1.5 As a fully cost recovered agency, the APVMA can be placed in a position that gives rise to conflict of interest and is sometimes perceived to be unduly influenced by the agrochemical industry in its decisions.

1.6 The APVMA should come under the responsibilities of either the health or environment ministers, or a combination of the two so that any potential for industry’s influence over the APVMA is minimized.

Manageable and Unmanageable risks

1.7 The majority report recognises that many chemistries were ‘grandfathered’ into the present national scheme and that it is time to conduct a full health and environmental risk assessment. Re-registration is a crucial part of that assessment and the Australian Greens strongly support this work. However the Australian Greens are concerned that this assessment will be compromised by a lack of definition around risk.

1.8 While the objectives recognise that the use of chemical products that pose unmanageable risks to the health and safety of human beings, animals and the environment is not appropriate in Australia, there is no definition of ‘unmanageable risks’ in the Bill or regulations.

1.9 Other organisations focused on manageable risk, essentially approaching the definition problem from the opposite perspective, and the weight of evidence raising concerns about the lack of definition around risk is significant.

1.10 The Australian Greens share WWF’s concerns that as the Bill is currently drafted, unmanageable chemicals could still potentially get a 7-year re-approval/re-

registration after a 4.5-year review, which effectively means they could be on the market for another 11.5 years, or possibly longer. In particular the Australian Greens agree with WWF's assessment that:

In its current form, Schedule 2 is unlikely to quickly remove the backlog of unmanageable chemistries from the market that no longer meet the health and safety standards of today because the Bill fails to define 'unmanageable risks' and it doesn't provide clauses for the implementation of this objective, and the proposed timeframes for review and removal of unmanageable products from the market are far too long.¹

1.11 This is absolutely unacceptable. It should be a matter of urgency to identify the chemicals that pose unmanageable risk and fast track this work within the first 12 months.

Definition of unmanageable risk

1.12 WWF provide an example of an internationally accepted definition for a highly hazardous pesticide that could be adopted in Australia, while still taking account of unique use and exposure scenarios in Australia:

Highly hazardous [or unmanageable] pesticides are pesticides that are acknowledged to present particularly high levels of acute or chronic hazards to health or environment according to internationally accepted classification systems such as WHO or GHS or their listing in the annexes of relevant binding international agreements or conventions. In addition, pesticides that cause severe or irreversible harm to health or the environment under conditions of use in a country.²

Definition of 'meets the safety criteria'

1.13 The Bill should also give greater clarity as to how a definition of unmanageable risk might trigger action by the APVMA.

1.14 As well as providing a definition for unmanageable risk, WWF suggested including an addition clause at 5A(1)(d) which explicitly references unmanageable risk to ensure that the APVMA can act to address unmanageable risk and would improve the efficiency of the system by ensuring time and resources are not wasted assessing unmanageable risks.³

Recommendation 1

1.15 That the Bill includes a definition of unmanageable risk in the objects and the assessment triggers of the Bill.

Toxicity of degradation products and metabolites

1.16 In some instances the degradation products and metabolites of an active constituent, may be more toxic or persistent than the parent compound. If the APVMA

1 WWF Australia and National Toxic Network, *Submission 25*, p. 2.

2 WWF Australia and National Toxic Network, *Submission 25*, p. 3.

3 WWF Australia and National Toxic Network, *Submission 25*, p. 6.

are genuinely conducting a risk assessment to determine “undue hazard” to people, animals and the environment, this must be taken into consideration. For the purposes of being satisfied as to whether an active constituent meets the safety criteria, the APVMA must also assess the toxicity of the degradation products and metabolites, of the active constituents. WWF suggested the Bill could be strengthened by including a reference to the toxicity of a chemical’s degradation products and metabolites in the safety criteria at 5A(2)(a)(i).⁴

Recommendation 2

1.17 Include a reference to the degradation products and metabolites as part of any reference to toxicity within the safety assessment criteria.

Banned in comparable overseas markets

1.18 Submitters expressed concern about the use of chemicals that have been banned elsewhere but are still used in Australia. Comparable jurisdictions have since banned some of the chemistries still widely used in Australia, because they did not meet contemporary health and environmental standards.

1.19 Paragraph 47A(1)(a) of the Bill *Varying duration-decisions of foreign regulators*, read in association with the Draft Regulations, provide a process to vary approval periods based on the actions of other jurisdictions, but conditions which require more than one foreign country to prohibit the use of a chemical based on a health or an environmental concern are too restrictive.

1.20 Given that the list of ‘*regulators that are prescribed by the regulations*’ in the draft regulations does not include all European Union member states, this section is very limited in its scope. The reason for the exclusion of EU members is unclear because as WWF note:

Given that the decisions and supporting documents such as risk assessments from the EU are always provided in English, language should not be an issue when considering all EU member countries.⁵

1.21 WWF recommended that when action is taken in any of the jurisdictions prescribed under the regulations to prohibit the use of a chemical, based on health or environmental concerns, ‘then that chemical will go to the top of the list in Australia and the registrant will be given notice, following the process in the Bill, that the registration will not be re-approved.’⁶

1.22 The 7 year time frame in Schedule 2, section 47A is also too restrictive. Given that Australia still has pesticides registered that have long been banned in other countries because, after risk assessment, they failed to meet contemporary health and safety standards and the public’s expectations, there is no justification why these same

4 WWF Australia and National Toxic Network, *Submission 25*, p.6

5 WWF Australia and National Toxic Network, *Submission 25*, p.5

6 WWF Australia and National Toxic Network, *Submission 25*, p.5

pesticides should be considered safe to use in Australia because those bans have been in place for more than 7 years.

Recommendation 3

1.23 Strengthen the relationship between actions taken by foreign jurisdictions and Australian decision making.

Onus on chemical companies to prove their products remain safe at regular intervals

1.24 The onus is still on the APVMA to prove safety because no minimum data requirements have been established within Schedule 2, *Re-approvals and Re-registrations* for industry to comply with.

1.25 As a result, the APVMA is reliant on data and testing from the manufacturer and the APVMA does not have explicit powers to quickly remove a chemical or product if there are data gaps in relation to its toxicology or uses in Australia.

Recommendation 4

1.26 Reverse the onus of proof so that chemical companies have to address data gaps in order to maintain registration.

Addressing regulatory burdens

1.27 Some submitters such as the Animal Health Alliance outlined concerns that some chemicals also have to go through a Therapeutic Goods Authority (TGA) registration process. This can result in an extra level of regulatory red-tape that they felt was unnecessary.⁷ In future reforms the Government should consider excluding chemicals that have been subject to a TGA assessment from this registration process or introducing some other method of data sharing and decision making that helps streamline this process.

1.28 Other submitters raised concerns about the minor use permits and off-label use.

1.29 While we would not seek to undermine the risk-assessment process, and have some concerns about anything other than the most targeted and clearly specified off-label use, we appreciate some of the concerns of growers such as those raised in the Australian Mushroom Growers Associations and the National Farmers Federations' submissions that touch on regulatory burden.⁸

1.30 In the review process the Australian Greens would like to see included an examination of the minor use and off-label use that looks at ways to ensure that while the registration and assessment processes are rigorous, that the regulatory burdens associated with minor and off-label use on growers is not unreasonably onerous.

7 Dr John O'Brien, Managing Director, Jurox Pty Ltd, representing the Animal Health Alliance, *Committee Hansard*, 4 February 2013, p. 13.

8 Australian Mushroom Growers Association, *Submission 35*, p. 2; National Farmers Federation, *Submission 31*, pp 2–3.

Conclusion

1.31 In conclusion, this reform is essential, but it is important that the re-registration process and subsequent reviews of chemical use achieve the ultimate goal of managing risk to human life and the environment, and are based on scientific analysis, take account of decision made in other countries and the actions of the APVMA are not hampered in its risk assessments by a lack of data or a lack of definitional clarity. A definition of unmanageable risk will also help focus the review on efficiently and effectively excluding chemicals that present an unacceptable level of harm. The Bill should be amended to address the issues raised above.

Recommendations

Recommendation 1

Include a definition of unmanageable risk in the objects and the assessment triggers of the Bill.

Recommendation 2

Include a reference to the degradation products and metabolites as part of any reference to toxicity within the safety assessment criteria of the Bill.

Recommendation 3

Strengthen the relationship between actions taken by foreign jurisdictions and Australian decision making in the Bill and the regulations.

Recommendation 4

Reverse the onus of proof in the Bill so that chemical companies have to address data gaps in order to maintain registration.

**Senator Rachel Siewert
Australian Greens Senator for Western Australia**

