20 December 2012

Committee Secretary
Senate Rural and Regional Affairs and Transport Legislation Committee
PO Box 6100 Parliament House
Canberra ACT 2600

Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Dear Secretary

Thank you for the opportunity to make a submission to the Inquiry. We also welcome the opportunity to present further details at a public hearing.

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WWF-Australia and the National Toxics Network (NTN) have been closely involved with the reform process from the outset. Our key concern is delivery of the Gillard Government's commitment to reforms that 'better protect human health and the environment'.[1]

Summary

We want Australians to have timely access to the safest and smartest chemistries for pest management in their homes and in agriculture. Many of the amendments in the Bill will help to improve the efficiency and effectiveness of the APVMA, which is welcomed.

However our reading of the Bill, and the details of how key reforms will operate in the Draft Regulations, does not give us confidence there will be sufficient improvement to the protection of human health and the environment as a result of these reforms.

The fact remains the APVMA has a backlog of old chemistries (which make up the bulk of the pesticide inventory in Australia) to review. These chemistries were 'grandfathered' into the national scheme without ever having full health and environment risk assessments.

Comparable jurisdictions have since banned some of the chemistries still widely used in Australia, because they did not meet contemporary health and environmental standards.

We understand Australia has unique climatic and agricultural considerations in its use of pesticide products, but if the human and environmental risks of some chemistries are unmanageable, then these products should not be permitted in Australia.

For instance, the fact that Australia was one of last countries to ban the now Stockholm Convention listed organochlorine pesticide endosulfan, is just one example of wasted resources and unnecessary exposure of the environment and people to this toxic, persistent and bioaccumulative pesticide.

[1] Better Regulation of Chemicals, Tony Burke 14.8.2010
http://www.alp.org.au/federal-government/news/better-regulation-of-chemicals/

The APVMA spent years reviewing endosulfan and constantly defended its safety and ability to be 'managed', despite the fact that it was turning up in waterways, rainwater tanks and in people's blood.

Diuron, the herbicide currently impacting the Great Barrier Reef (GBR) and catchment area is another example of an unmanageable pesticide, and yet, the APVMA recently reaffirmed its registration after years of review, and despite millions of dollars of research, which shows it cannot be managed and is causing damage to the GBR.

Having a re-registration scheme was a Gillard Government election commitment and we welcome the introduction of the re-approval and re-registration scheme (Schedule 2). This will help to bring Australia into line with other comparable jurisdictions such as the USA and the EU that have re-registration systems in place.

Re-registration should be the mechanism for quickly removing the backlog of unmanageable chemistries from the market that no longer meet the health and safety standards of today.

In its current form, Schedule 2 is unlikely to achieve this 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. We could still have the same unmanageable pesticides on the market here for many years to come.

Specific concerns:

Conflict of interest
For good reason, the regulation of pesticides in most other jurisdictions sits with either the equivalent environment or health department, or a combination of the two.

The APVMA does not have the public's confidence to make the protection of health and the environment its first priority. As a fully cost recovered agency, it's perceived as having a conflict of interest and is unduly influenced by the agrochemical industry in its decisions.

We want the APVMA to come under the responsibilities of either the health or environment ministers, or a combination of the two, so that industry's influence over the APVMA is minimized.

Protect humans and nature as a first priority
We're pleased to see greater recognition given to the protection of human health and the environment with the inclusion of *Section 1A Implementing the Code*, in particular, 1A (2) (a) which recognises human health and the environment as the first priority of the system and also acknowledges intergenerational equity.

Given that the protection of human health and the environment are the 'first priority' we would expect to see it at first under 1A *Implementing the Code* (1) before the acknowledgment of the economic rationale for implementation of the Code. Having it as (2) sends the wrong message to the public who are already highly suspicious about the independence of the APVMA.

Unmanageable risks
While 1A 2 (d), recognises 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.

If the Code is to be implemented with the intention that unmanageable chemicals and products are not appropriate, it's critical a definition of 'unmanageable risk' is explicit in the Bill, along with clauses spelling out how it will be operationalised in a transparent and accountable manner, giving certainty to the public and industry.

In this mater we want the APVMA's appetite for risk to be commensurate with the contemporary science in toxicology, regulatory approaches in other jurisdictions, and the public's expectations, and we are very concerned this is currently not the case.

For instance, 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. We feel there is no justification why these same pesticides should be considered safe to use in Australia.

According to our reading of the Bill and Draft Regulations, 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. This is absolutely unacceptable.

Implementing the Code for unmanageable risks
The bill must define what 'unmanageable risk to the health of human beings, animals and the environment' actually is. There's no point wasting regulatory resources on chemistries, which by definition, present 'unmanageable risk' based on their inherent toxicological hazards and the risk of exposure to them. By keeping these products on the market the regulator is blocking the way for newer, safer products to get to market.

In other jurisdictions, pesticides that present 'unmanageable risk to the health of human beings, animals and the environment' are recognised as a 'highly hazardous pesticides'. This doesn't mean other jurisdictions don't have risk-based regulatory systems, but rather, within their risk-based systems, they recognize that some pesticides are highly hazardous and therefore unmanageable according to the latest science and within the expectations of the community.

A conservative and 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 is:

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]

The FAO/World Health Organisation (WHO) Joint Meeting on Pesticide Management (JMPM) outlined criteria for defining highly hazardous pesticides [or unmanageable pesticides].

The JMPM adopted the following criteria in 2008. Since adopting the criteria, further discussion are taking place on whether to include other important criteria such as endocrine, disruption; inhalation toxicity; bioaccumulation, persistence and toxicity to bees.

[2] http://www.fao.org/agriculture/crops/core-themes/theme/pests/code/hhp/en/

~ Formulations that meet the criteria of classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard;

~ Pesticide active ingredients (AIs) and their formulations that meet the criteria for category 1A and 1B carcinogens, mutagens or reprotoxins as used by the UN Globally Harmonized System (GHS) on chemicals classification and ***labeling****;*

~ AIs listed in Annexes A and B of the UN Stockholm Convention on persistent organic pollutants (POPs), and those meeting all the criteria in paragraph 1 of Annex D; or AIs and formulations listed in Annex III of the UN Rotterdam Convention on the prior informed consent procedure;

~ Pesticides listed under the Montreal Protocol on ozone-depleting substances;

~ AIs and formulations that have a high incidence of severe or irreversible adverse effects on human health or the environment.

Priorities for health and environment criteria
To understand how the Re-approvals and Re-registrations scheme (Schedule 2) of the Bill will work, it's necessary to look at the Draft Regulations.

Schedule 1 Amendments of the Agricultural and Veterinary Chemicals Code Regulations 1995, ['the Draft Regulations'], sections *17D Priorities for health criteria* and section *17E Priorities for environment criteria*, defines priority criteria for the purpose of re-approval and re-registration.

These criteria will be used to make regulatory decisions about market tenure for chemicals and **products;** therefore it's critical they reflect widely accepted definitions and criteria. Unfortunately we believe they do not.

This part of the regulation is also the engine room for ensuring that regulatory effort in the re-registration and re-approval process is efficient and that high-risk chemicals and products are acted on quickly, while genuine low risk products are fast tracked and given greater tenure in the marketplace, as is the Government's intention.

The proposed Draft Regulation's criteria in Section 17D are out of step with the internationally accepted FAO/WHO definition and criteria listed above.

What the Draft Regulations propose as 17(D) (2) '*high priority for health criteria'* are in fact criteria, that under the FAO/WHO definition and criteria above, are what defines a 'highly hazardous pesticide' or using the Draft Regulation's terminology, what would be a '*very* high priority' or, what is effectively an 'unmanageable' risk.

Under *Appendix 3 Re-approval and Re-registration Criteria of the Draft Regulations*, a pesticide that's effectively highly hazardous to the environment could be re-approved for 10-15 years and a highly hazardous pesticide to human health could be re-approved for 7- 10 years. We strongly believe that this is unacceptable.

A new category needs to be added to the *'Proposed Matrix for End Dates'* in Appendix 3 and to sections

17D Priorities for health criteria and section *17E Priorities for environment criteria.* This would help to ensure that the implementation of the Code according to 1A (e), for unmanageable chemicals and products, does actually occur.

What's currently defined in *17D Priorities for health criteria* and section *17E Priorities for environment criteria* as a 'high priority' needs to be re-defined as a '*very* high priority' and the subsequent categories would flow accordingly.

In the *'Proposed Matrix for End Dates'* in Appendix 3, a '*very* high priority' category needs to be added, with options ranging from 0-5 years, with five years only being granted with severe restrictions on use and only when there are no available substitutes.

Banned in comparable overseas markets
Paragraph 47A (1) (a) of the Exposure Draft Bill *Varying duration-decisions of foreign regulators* and *Division 2.5A Variation of dates for approval or registration*, 22D *Prescribed overseas regulatory action* of the Draft Regulations, provide a process to vary approval periods, but the conditions under which this occurs are too restricted.

What we want is that if *one* or more foreign countries prescribed by the regulations, have prohibited 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.

Whether the foreign country made that decision within a 7-year period is too restrictive. A scientifically sound decision based on health or environmental concerns may have been made in a country 10 or more years ago that is highly relevant to Australia, if we still permit the use of that chemical.

The list of '*regulators that are prescribed by the regulations'* (Div. 2.5A 22D) is too restrictive and must also include all European Union member states, not just the United Kingdom. The decisions and supporting documents such as risk assessments from the EU are always provided in English so language should not be an issue when considering all EU member countries.

Onus on chemical companies to prove their products remain safe at regular intervals
Schedule 2, *Re-approvals and Re-registrations* establishes a process for chemicals and products to be re-approved or re-registered. This is a welcome addition**;** however the onus is still on the APVMA to prove safety because no minimum data requirements have been established for industry to comply with. Or to put it another way, 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.

The tests to determine re-approval of a chemical and re-registration of a product are defined in Section 5A *Definition of meets the safety criteria*; 5B *Definition of meets the efficacy criteria*; and 5C *Definition of meets the trade criteria; 5D Definition of meets the labeling criteria.*

While this is better clarification and simplification of the tests products are required to meet, there is still too much discretion being given to the APVMA to determine "undue hazard" to the safety of people and the environment.

Definition of meets the safety criteria 5A (1) (a) - (d) must include: *"(d) is not, or would not be, unmanageable to the health and safety of human beings, animals and the environment according to the*

definition in XXXX".

This would ensure that the APVMA gives effect to 1A 2 (d) and would improve the efficiency of the system by ensuring time and resources are not wasted assessing unmanageable risks.
5A (2) 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 constituent.

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 are genuinely conducting a risk assessment to determine "undue hazard" to people, animals and the environment, this must be taken into consideration.

We propose the addition of the following words to 5A (2) (a):

(I) *the toxicity of the constituent, "its degradation products and metabolites", and its residues in relation to relevant organisms and ecosystems, including human beings.*

Conclusion
We would be grateful to appear at a public hearing to present these key concerns and recommendations in more detail. We will also be providing more detailed response to the proposed regulations before 21 December.

Yours sincerely

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