22 October 2012

Senator the Hon. Joe Ludwig
Minister for Agriculture, Fisheries and Forestry
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Draft Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Dear Minister

We thank you for the way you've taken on board some of our concerns in the *Exposure Draft of the Agricultural and Veterinary Chemicals Legislation and Amendment Bill 2012*.

Although the Bill is much improved, there are still some critical deficiencies in the drafting.

We understand the consultation for the Draft Regulations will occur later, however it's also necessary to flag some details here as they impact on our understanding of how fundamental sections of the Bill could operate.

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 (b) which recognises human health and the environment as the first priority and intergenerational equity and, 1A (e) which recognises unmanageable risks.

Given that the protection of human health and the environment are the 'first priority' in the implementation of the Code, we would expect to see it at the top of the list as 1A (a) not as (b) following details on the economic rationale for implementation of the Code. Having it as (b) sends the wrong message to the public who are already highly suspicious and concerned about the first priority of the APVMA in the regulation of pesticides.

Unmanageable risks

In relation to 1A (e), there is no definition of "unmanageable" risks. If the Code is to be implemented with the intention that unmanageable chemicals and products are not appropriate in Australia, it's critical that a definition of "unmanageable" is provided in the Bill and that there be clauses indicating how it will be operationalised in a transparent and accountable manner, giving certainty to industry and the public.

Despite what your Departmental advisors may claim, there is no conflict in defining 'unmanageable' risks within a risk-based system. If there were no chemicals with unmanageable risks, the APVMA would never de-register or deny approval to any chemical.

We want 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 concerned that this is currently not the case.

Australia still has pesticides registered that have long been banned in other countries because, after risk assessment, they were found to not meet contemporary health and safety standards and the public's expectations.

We feel there is no justification why these same pesticides should not also be considered unmanageable in Australia. They must be rapidly removed from the market to allow safer options to become more rapidly available. This is our key concern and the proposed Bill does not resolve this key concern.

According to our reading of the Exposure Draft Bill and Draft Regulations, some unmanageable chemicals could still 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. We want unmanageable chemicals off the market immediately or within five years at the latest.

Defining and implementing unmanageable

In order to define what unmanageable risk to the health of human beings, animals and the environment is, it's necessary to examine internationally accepted definitions and criteria that can be adopted in Australia, while still taking account of unique use and exposure scenarios in Australia.

There could also be some flexibility built into the implementation. For instance, if there are no substitutes, then it may be deemed appropriate to continue a limited registration (0-5 years) for an unmanageable chemical under highly restricted conditions.

The FAO/WHO definition and criteria for 'highly hazardous pesticides'[1] provides a conservative, widely accepted and practical approach to defining highly hazardous and unmanageable pesticides:

Highly hazardous 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 may be considered to be and treated as highly hazardous by in that country.

A highly hazardous pesticide may have one or more of the following characteristics:

- *Pesticide formulations that are included in classes Ia or Ib of the WHO Recommended Classification of Pesticides by Hazard;*

- *Pesticide active ingredients and their formulations that are included in carcinogenicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS), or are included accordingly in the WHO Recommended Classification of Pesticides by Hazard;*

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

- *Pesticide active ingredients and their formulations that are included in mutagenicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS) or are included accordingly in the WHO Recommended Classification of Pesticides by Hazard;*

- *Pesticide active ingredients and their formulations that are included in reproductive toxicity Categories 1A and 1B of the Globally Harmonized System on Classification and Labelling of Chemicals (GHS) or are included accordingly in the WHO Recommended Classification of Pesticides by Hazard;*

- *Pesticide active ingredients listed by the Stockholm Convention in Annexes A and B;*

- *Pesticide active ingredients and formulations listed by the Rotterdam Convention in its Annex III*

- *Pesticides listed under the Montreal Protocol*

- *Pesticide formulations that have shown a high incidence of severe or irreversible adverse effects on human health or the environment.*

Priorities for health and environment criteria

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 is 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.

But 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 <u>*one*</u> 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

The Exposure Draft Bill, includes Division 3A – *Re-approving and re-registering* which 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.*

This is also a welcome clarification and simplification of the tests required, but 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) - (c) 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 (e) 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) :

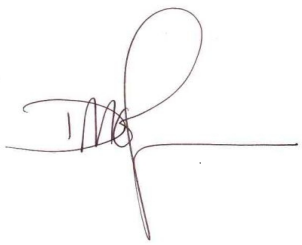
> *(I)the toxicity of the constituent, "<u>its degradation products and metabolites"</u>, and its residues in relation to relevant organisms and ecosystems, including human beings.*

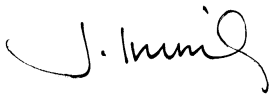
Finally, the regulation of agricultural pesticides in many foreign countries sits with either the equivalent environment or health department, or a combination of the two. We would prefer to see the APVMA come under the responsibilities of either the health or environment ministers, or a combination of the two so that industry's influence over the APVMA is minimised.

Given this is an unlikely change during these reforms, we would like to see the Ministers for Health and Environment given the powers in the legislation to trigger immediate action by the APVMA to suspend or review a chemical, if they provide reasons in writing stating their concerns.

We would be grateful to meet with you to discuss 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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