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Inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*

Thank you for the opportunity to make a submission to the Senate Standing Committees on Rural and Regional Affairs and Transport inquiry into the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014.*

To follow is our formal submission on the Consultation document in two sections. The first section is context and background. The second section specifically addresses the questions raised in the Consultation Paper, which we believe are also relevant to this inquiry.

We urge the Government to re-consider the key proposed amendment to remove the re-approval and re-registration scheme due to commence in July 2014. If the scheme is removed we ask that the Government gives the Australian community a reassurance there will be no net loss of protections for human health and the environment as a result of any changes made to the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013.*

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SUMMARY

WWF and NTN have been actively involved with the AgVet reform processes for well over three years. We're extremely disappointed the proposed amendments seek to undo a critical public health and environmental protective aspect of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* [Amendment Act 2013].

The proposal to remove the re-approval and re-registration scheme, due to commence in July 2014, we believe will undermine the APVMA's core legislative responsibility, that is to regulate pesticides with the protection of human health and the environment from risks associated with pesticides and products as their first priority.

We reject the Government's contention that the existing provisions in relation to the APVMA's *ad hoc* chemical review program [renamed 're-consideration' under the Amendment Act 2013] are adequate to ensure the Regulator can efficiently and effectively respond to risks associated with currently registered pesticides.

The National Registration Scheme (NRS) in Australia wasn't introduced until 1996 and there are still many pesticides and products on the market that were 'grandfathered' into the scheme and have never been assessed against today's regulatory and scientific standards. Without a systematic process for risk assessment, the community, environment and trade will remain unprotected from un-quantified risks associated with poorly assessed pesticides.

We disagree with the contention that the introduction of the re-approval and re-registration scheme is a duplication of regulation. Comparable risk-based regulatory regimes in the USA and Canada have legislated re-registration schemes specifically targeted to manage the problem of older pesticides on the market that have not been subject to current regulatory standards.

The Government's amendments by and large appear to have been designed to appease the AgVet chemical industry and agricultural end-users of pesticides, while ignoring the concerns of other legitimate stakeholders as well as dismissing years of public consultation that went into designing the re-approval and re-registration scheme.

The AgVet chemical industry has perpetuated misinformation about the objectives and costs associated with the re-approval and re-registration scheme. This has only served to muddy the waters for other stakeholders, such as farmers and consumers, who should be demanding the safest and most effective products from their regulator.

1. BACKGROUND

1.1 Changing Regulatory Environment

The APVMA are currently conducting consultation sessions in relation to the Draft Regulatory Guidelines[1] that will come into effect in July 2014 as a result of the passage of the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* [Amendment Act 2013] passed by the 43rd Parliament in June 2013.

A first-principles review of the Australian Pesticides and Veterinary Medicines Authority's (APVMA) cost recovery arrangements[2] is also underway. While the scope of that review does not include consideration of the APVMA's regulatory activities, it's important to note that some of the proposed amendments outlined in the Consultation Paper may have implications for APVMA's cost-recovery arrangements.

The cooperative National Registration Scheme for Agricultural and Veterinary Chemical (NRS) is currently subject to a Council of Australian Governments' (COAG) reform process which has been ongoing since 2006. The COAG process has the specific agenda of establishing a single national framework for the regulation of Agricultural and Veterinary Chemicals [AgVet chemicals][3].

The APVMA is currently subject to a complex and rapidly changing regulatory environment. Rather than introduce even more uncertainty, we believe the Government should allow the Regulator to implement the raft of reforms introduced with the Amendment Act 2013 and review their impacts in five years.
The Coalition's *Policy for a Competitive Agriculture Sector* (August 2013) specifically names 'Safe and Efficient Chemical Registration' as a priority.

1.2 Government's Agriculture Policy and Election Commitment

The Coalition's *Policy for a Competitive Agriculture Sector* (August 2013) specifically names 'Safe and Efficient Chemical Registration' as a priority.

The Coalition Agriculture Policy states:

> *The Coalition will resolve Labor's failed attempt to improve chemical registration through reform of the agriculture and veterinary chemicals legislation to improve efficiencies…..*
>
> *The new Labor legislation for the chemical regulator ignored stakeholder concerns and added more red tape by adding a reregistration system. It will lead to a significant increase in unnecessary regulation, and increase in the cost of chemical registration by one third and adds another layer of red tape.*

The legislation referred to in the Coalition's Policy is the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* [Amendment Act 2013] passed by the 43rd Parliament in June 2013.

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[1] http://www.apvma.gov.au/about/work/better_regulation/regulatory_guidelines_faq.php
[2] http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/first-principles-review-of-the-apvmas-cost-recovery-arrangements
[3] http://www.daff.gov.au/agriculture-food/ag-vet-chemicals/domestic-policy/history-of-coag-reforms

The Amendment Act 2013 contains a raft of reforms, all of which aim to improve the efficiency and effectiveness of the AgVet chemical regulatory system and provide better protection for human health and the environment. The majority of the new provisions in the Amendment Act 2013 are not being challenged by the proposed amendments.

The Proposed *Agricultural and Veterinary Chemicals Legislation Amendments Consultation Paper* [Consultation Paper] states:

> *The Australian Government has committed to 'easing the burden imposed on the Australian economy and agricultural sector by reducing red and green tape on business by at least $1billion per year'.*

The burden the Government believes is imposed on the economy and agricultural sector by the introduction of the Amendment Act 2013 reforms, in particular the re-approval and re-registration scheme, has not been quantified in any detailed way in the Consultation Paper.

While the Government does give an estimate of an 'increase in the cost of chemical registration by one third', it's unclear how this estimate was derived, over what time period the extra costs would be incurred, whether that estimate also includes other costs as a result of the raft of changes to the registration system and, what is it one third greater than.

The Coalition Agriculture Policy states:

> *'The new Labor legislation for the chemical regulator ignored stakeholder concerns".*

The Amendment Act 2013 underwent extensive stakeholder consultation and Parliamentary processes before becoming law.

Before the Bill was passed by the Parliament it was referred to the *Senate Rural and Regional Affairs and Transport Legislation Committee* on the (29/11/2012), with a Committee report released on the (27/02/2013).

It was referred to the *Standing Committee on Agriculture, Resources, Fisheries and Forestry* on the (29/11/2012) with a Committee report released on the (12/03/13).

In its evidence given to the *House Standing Committee on Agriculture, Resources, Fisheries and Forestry Inquiry,* the Department of Agriculture, Resources, Fisheries and Forestry's (DAFF) submission to the inquiry stated:

> *The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Bill.*
>
> *Three rounds of public consultation were conducted on the reforms and associated Bill. The first round of public consultation occurred from mid November 2010 to early February 2011 about the policy discussion paper, Better Regulation of Agricultural and Veterinary Chemicals ...*
>
> *Further public consultation with an exposure draft of the legislation occurred from 15 November 2011 to 29 February 2012 ...*

> *The Bill was revised and released again as a revised exposure draft in September 2012. The revised Bill included amendments to address issues raised during the previous round of consultation.*

This statement by DAFF suggests a considerable effort was made to consider all stakeholder views.

1.3 Stakeholder Support for Re-approval and Re-registration Scheme

Given the broad stakeholder support from the environment, health, union, academic, state authorities and consumer sectors for the introduction of a re-approval and re-registration scheme, it does appear that the *Proposed Agricultural and Veterinary Chemicals Legislation Amendments*, with their specific focus on the removal of the re-approval and re-registration scheme, is an election commitment made by the Government to AgVet chemical registrants and agricultural end-users of pesticides rather than the broader Australian community.

For instance, the *Senate Rural and Regional Affairs and Transport Legislation Committee* report states:

> *3.1 Witnesses generally supported reform of the current system for the approval and registration and review of agricultural chemicals and veterinary medicines (agvet) chemicals. The Queensland Department of Agriculture, Fisheries and Forestry for example, submitted that it supports a number of the bill's provisions, including the introduction of a periodic review of a chemical's safety through a re-registration and re-approval scheme.*

The *House Standing Committee on Agriculture, Resources, Fisheries and Forestry Inquiry* report states:

> *3.21 The current system of registration and approval is ad-hoc.* ***It is noted that some chemicals and products used in Australia have never been assessed against modern standards and may have been in use for over 40 years.*** [emphasis added]
>
> *3.22 Some 9,500 chemicals products and some 2,200 active constituents are listed on the NRS (National Registration Scheme). As a result, the Government believes that a systematic method of review is warranted. DAFF justifies the need for this mandatory system, stating that the Bill responds:*
>
> > *... to community concerns by ensuring that approved or registered chemicals continue to meet appropriate health and safety standards by implementing a re-approval and re-registration scheme to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses.*

Given the broad support for a re-approval and re-registration scheme and the extensive public consultation that took place, it is extraordinary the Consultation Paper also foreshadows a back-up plan to remove the scheme, should the required amending legislation not have passed the Parliament before July 2014, when the scheme is due to come into effect.

In the event of that outcome, the Consultation document outlines the Government's proposal to introduce a new Regulation to ensure the re-approval and re-registration scheme never commences:

> *New Regulations would be required as a transitional measure in the circumstances that the Amendment Bill is not given assent prior to 1 July 2014. The regulations would set end dates 15 years into the future (in effect 'turning off' re-registration for the*

maximum possible period) and to turn off the 12 month notice of the end of an approval of registration..(p 8)

1.4 Re-registration Schemes in Comparable Jurisdictions

Systematic pesticide re-registration programs are part of the regulatory system in other comparable risk-based jurisdictions.

The USA and Canadia both have re-registration programs focussed on older pesticides on the market. In the USA, those pesticides registered before 1984 are the focus and for Canada, those registered before 1995.

In both programs there is a stated intention that those older pesticides need to be assessed to ensure they meet current scientific and regulatory standards. The situation in Australia is very similar.

The National Registration Scheme (NRS) did not come into effect until 1996. Those pesticides and products used prior to the NRS were 'grandfathered' into the scheme without thorough assessment.

There are pesticides on the market today that have never been assessed according to today's scientific and regulatory standards. By removing the re-approval and re-registration scheme, those pesticides and products will continue to be used on the market without a contemporary risk assessment, potentially placing the community and environment at risk.

USA
The 1988 amendments to the US *Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) authorized EPA to conduct the pesticide re-registration program – a comprehensive review of the human health and ecological effects of pesticides first registered before 1984, to ensure that they met current scientific and regulatory standards.

Through the re-registration program, EPA called in and reviewed supporting scientific studies, completed human health and ecological risk assessments, and developed risk mitigation measures as needed using current science, transparency, and input from stakeholders and the public. The results of EPA's reviews were summarized in Re-registration Eligibility Decisions (REDs)[4].

CANADA
The Pest Management Regulatory Agency (PMRA) of Health Canada is responsible for registering pesticides in Canada. To ensure the safety of Canadians, Health Canada launched the *Pest Management Regulatory Agency (PMRA) Re-evaluation Program* in 2001 to examine 401 active ingredients registered before 1995.

This review program will ensure older pesticides that no longer meet modern standards are removed from the Canadian market and the use instructions on product labels are updated to best protect users, bystanders and the environment. Under current legislation, all products will be re-evaluated on a 15-year cycle.[5]

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[4] Pesticide Re-registration Facts http://www.epa.gov/oppsrrd1/reregistration/reregistration_facts.htm
[5] Health Canada Re-evaluation program http://www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/regist-homolog/_re-eval/index-eng.php

2. CONSULTATION PAPER QUESTIONS AND ANSWERS

1. Implementing the election commitment to remove re-registration

Legislation is required to remove re-approval and re-registration. Amendments to the Agricultural and Veterinary Chemicals Code Act 1994 (Agvet Code) are needed to:

- *remove end dates for approvals and last renewal dates for registrations so that approvals will no longer end after a particular period and registrations may be renewed perpetually*
- *remove redundant provisions that allow applications to re-approve and re-register active constituents and chemical products*.

Questions for consultation:

(a) What are your views about these proposed changes to legislation?
(b) Do you consider that any of these changes should be retained? If yes, what should be retained and why?
(c) Do you consider additional amendments are required to remove re-registration? If so, what are they?
(d) What changes do you consider are required to the regulatory system in light of these amendments?

Response (a)-(d)

WWF and NTN do not support the proposed changes to the legislation. We believe the Australian community and the environment will be less protected from pesticide risks if these amendments are made.

We support the retention of the legislated re-approval and re-registration scheme in the Amendment Act 2013. The scheme was developed after extensive consultation and has broad stakeholder support.

It would address the problem associated with the 'grandfathered' pesticides onto the National Registration Scheme in 1996, many of which remain on the market without risk assessment against contemporary standards.

The scheme provides a systematic assessment of the entire pesticide inventory, while the continuation of an ad hoc re-consideration program is likely to miss real risks and will not improve consumer confidence in the regulator.

The concept of 'perpetual registration' as proposed by the amendments is deeply concerning. Pesticide products are by their nature highly hazardous products, designed to kill living organisms. They are subject to rapidly changing health and environmental standards as well as new data in relation to the toxicology of chemicals and their impacts on people and the environment. They should be reviewed regularly against changing use patters and contemporary standards.

2. Reducing red-tape by allowing for less frequent renewal of registrations

Legislation is required to reduce red tape by providing for less frequent registration renewals.

Questions for consultation:

(e) What views do you have about reducing the frequency of renewals?

(f) What renewal period option do you prefer?

i. Annual or a multiple year renewal, would apply to all registrations?

ii. Different periods for different types of products?

iii. Allow choice between annual or multiple year renewal?

Response (e)–(f)

It's possible the proposed amendment may reduce red tape and have merit, however it's difficult to assess its impact because of the uncertainty around the impact of the proposed amendment and the outcomes of the APVMA's cost recovery arrangements review. Questions that come to mind incude:

- What is the current rationale for annual renewals and what would change if there were less frequent renewals?
- Is an annual renewal an opportunity for the APVMA to ensure products are what they say they are and that manufacturing standards are being adhered to?
- What happens if the APVMA needs to de-register a chemical or product within the period of time it has been granted renewal? Would they have to refund the unused portion of the renewal?
- Is annual renewal actually a 'burden' for the APVMA and/or registrants? How much 'red tape' would changing it actually reduce?
- Would moving to less frequent renewals, or choice around options, be more complex to administer and increase the burden on the APVMA?
- If renewal fees are set in relation to the APVMA's annual costs, will it make forward planning more difficult for the APVMA or easier?
- How would paying multiple renewal fees in advance be able to adequately take into account the changing cost structures in say 5-7 years time?

3. Addressing concerns with chemical product quality

Legislation is required to improve the APVMA's ability to secure information about the safety of chemicals supplied in the market.

Questions for consultation:

g) Do you consider amendments should be made to allow APVMA to gather information about products supplied in the market?
h) Are the matters about which the APVMA would be able to require information appropriate? (see paragraphs 99(3)(a) to (k) on page 22 of the exposure draft Bill)
i) Is the safeguard that prevents the APVMA from requiring information unless it believes it is reasonably necessary to protect human, animal, plant or environmental health or safety or trade adequate? Is the safeguard necessary?

Response (g)

We fully support giving powers to the APVMA to gather information about products supplied in the marketplace, as this is their legislated regulatory responsibility. We appreciate that chemical sales and manufacturing processes have changed dramatically since the AgVet Code was first drafted, however we do not believe the proposed amendment will solve the problem.

The Consultation Paper says that the re-approval and re-registration scheme gives the APVMA an opportunity to ensure the quality of chemical products.

The Consultation Paper states:

> "Removing re-registration removes an opportunity for the APVMA to confirm that chemical products supplied to the market are the same as the product evaluated and registered by the APVMA" (p10)

The Consultation Paper also states:

> "This can be addressed in part by improving the ability of the APVMA to require a person who supplies an agvet chemical product in Australia to provide information (for example, a chemical analysis) about the product they are supplying". (p10)

A key component of the re-approval and re-registration scheme then is that it gives the APVMA the opportunity to do its job equitably and systematically and to ensure the product on the market is the same product it evaluated and registered.

If that scheme is removed, the APVMA could only do its job ***in part*** with much the same hurdles it already faces in securing information about chemical quality.

Given the problematic nature of chemical product quality in today's marketplace, it would be prudent to give the APVMA the best opportunity of ensuring product quality via a systematic re-approval and re-registration scheme, not the continuation of an ad hoc approach based on suspicions.

Response (h)

The matters listed for information requests by the APVMA in the Exposure Draft Bill: 32 Subsections 99(1) to (5) of the Code set out in the Schedule, appear to be comprehensive, however only the Regulator would know the real scope of the information required for its purposes.

Response (i)

Instead of ***Reasonable suspicion that the product does not meet APVMA requirements*** **[emphasis added]** which is the test that existed before the introduction of the re-approval and re-registration scheme, the Consultation Paper suggests in the absence of the re-approval and re-registration scheme:

> 'The power is only to apply is the APVMA considers the information is necessary to protect human, animal and environmental health and safety or protect trade'.

The Exposure Draft *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2012* proposes in:

32 Subsections 99(1) to (5) of the Code set out in the Schedule:

> "This section applies if the APVMA reasonably believes [emphasis added] that it is necessary to exercise powers under this section:
>
> (a) to protect the health and safety of human beings; or
> (b) to protect animals, plants or things, or the environment; or
> (c) to prevent significant prejudice to trade or commerce between Australia and places outside Australia.

Legal advice would need to be sought on the difference between ***reasonable suspicion*** and ***reasonably believes*** and whether the effect of this amendment would be to give the APVMA greater ease in obtaining the required information, or in fact makes it more difficult for them. We don't believe a safeguard is necessary.

4. Reducing red-tape by allowing for simpler variations to approvals and registrations

Legislation is required to allow for simpler variations of registrations or approvals – reducing the need for further assessment if certain conditions are met.

Questions for consultation:

j) What are your views about reforming provisions that allow simple variations to approvals and registrations?
k) What kinds of variations should be permitted under this simple method?

Response (j) (k)

We support the reduction of red-tape when it can be done without diminishing health and environmental safeguards. However without seeing the list of **prescribed variations** the APVMA may consider to be 'simple variations' it's not possible to support the amendment.

While some variations may appear to be simple, such as a variation to the packaging or label, they can still have significant implications for the safety of a product, or the way it's used that may not be realised unless an assessment is done by the APVMA.

The suggestion that 'simple formulation changes' could be considered a 'simple variation' does cause serious concern. Formulation changes can dramatically impact the toxicity of the active constituent and the formulated product. A different solvent or surfactant, for instance, can radically change the toxicity and hazard of a formulated product.

In fact, the whole issue of the toxicity of so-called 'inert' ingredients and the toxicology of formulated products compared to active ingredients is an area that the APVMA needs to pay far more attention, not less.

According to the Swedish Chemicals Agency in the report *Hazard and Risk Assessment of Chemical Mixtures under REACH* (2010):

> Empirical evidence on the toxicity and ecotoxicity of such chemical cocktails shows one common pattern, independent of the specific chemical composition of a particular mixture, the exposed organism or biological endpoint under observation: **the joint toxicity of a chemical mixture is always higher than the individual toxic effect of even the most potent compound present.** In particular, even low, individually non-toxic concentrations might result in a significant toxicity, if they co-occur as a chemical mixture. [emphasis added]

5. Reducing red-tape by no longer requiring annual returns about active constituents

Legislation is required to remove the obligation to report imports, manufacture and exports of active constituents that are not included in chemical products.

Questions for consultation:

l) What are your views about removing the obligation to report import, export and manufacture of technical grade active constituents?

Response (l)

As far as we are aware, the APVMA currently only collects aggregated sales figures for pesticide products in Australia, which it publishes annually in the Government Gazette.

Until this amendment appeared to remove an obligation to collect data collection on imports, manufacture and exports of active constituents, we were unaware the APVMA even had the power to collect it and we question why it has not been reporting on it.

Australia needs more data collection requirements for pesticide use, manufacture and disposal, not less. This data is vital for emergency services, health and environmental regulators, as well as the broader community.

The APVMA already lists technical grade active constituents separately in its PUBCRIS database, regardless of whether they are in products or not, so it should continue to collect data on the volumes of those chemicals imported, exported or manufactured in Australia.

There is also a concern that without a requirement to report to the Regulator, Australia could become a place where banned or restricted active constituents are trafficked to and from other countries.

6. Improving efficiency by requiring electronic lodgement of information and fees

Legislation is required to require lodgement of application forms and required data and payment of fees electronically.

Questions for consultation:

(m) What are your views about requiring electronic lodgement of application information and fees?

(n) What other information or fees should be provided only electronically, is any?

Response (m) (n)

We support electronic lodgement if it improves efficiency and exemptions can be made for those genuinely needing to lodge via alternative means.

7. Obliging access to information about chemicals that the APVMA holds

Legislation is required to oblige the APVMA to provide access to information about approvals and registrations in its files to persons eligible to receive it.

Questions for consultation:

(o) What are your views about providing companies responsible for a product with access to information about the product that the APVMA holds for a fee?

Response (o)

We support the proposal that costs need to be recovered for any service provided. We need legal clarity about any provisions that would 'turn off' access to documents the APVMA holds by third parties under the FOI Act. We're also concerned that the definition of a 'recipient' to non-confidential commercial information is being narrowed.

8. Other amendments consequential to existing reforms

A small number of other simple amendments are required to address some minor implementation issues identified in existing reform legislation.

Questions for consultation:

(p) Do you have any concerns about the consequential amendments proposed?

Response (p)

There is limited information to assess these consequential amendments. If they are genuinely minor in nature and do not diminish human health and environmental protections under the Amendment Act 2013, we have no problem with them.