Submission to the Policy Discussion Paper (Nov 2010)

Better Regulation of Agricultural and Veterinary Chemicals

February 2011

This submission is also supported by:

Australian Gene Ethics www.geneethics.org

National Toxics Network Inc.
PO Box 173
Bangalow NSW 2479

T| 02 66871 900
E| info@ntn.org.au
www.ntn.org.au

ABOUT NTN

The National Toxics Network (NTN) is a community based network working to ensure a toxic-free future for all. NTN was formed in 1993 and has grown as a national network giving a voice to community and environmental organisations across Australia, New Zealand and the South Pacific on a wide range of toxic pollution issues. NTN is the Australian focal point for the International POPs Elimination Network (IPEN). NTN also participates in the work of the international Pesticide Action Network (PAN).

NTN has had a long history of involvement working to improve the regulation of AgVet chemicals in Australia to ensure the best regulatory outcomes for the protection of the environment and public health from exposure to pesticides.

Dr Mariann Lloyd Smith, NTN's senior advisor, was a member of the interim committee, which established the Community Consultative Committee for the then National Registration Authority (NRA), now the Australian Pesticides and Veterinary Medicines Authority (APVMA). She also participated in the agriculture department's committee to establish a national pesticide use database, which unfortunately did not occur.

Dr Lloyd Smith was a key contributor to the development of the national waste management plans for organochlorine pesticides. As Co-Chair of IPEN she also works to ensure that Australia meets its obligations as a signatory to the *Stockholm Convention on Persistent Organic Pollutants* which has listed pesticides which were once registered and used in Australia including: aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, hexachlorobenzene, mirex, toxaphene, chlordecone, alpha hexachlorocyclohexane, beta hexachlorocyclohexane, lindane, pentachlorobenzene and most recently, endosulfan which has been proposed for listing and is in the final stages of assessment under the Convention.

NTN has also provided several representatives to serve terms on the APVMA's Community Consultative Committee (CCC) on behalf of Australian environment groups. Jo Immig, NTN's Coordinator served two terms on the CCC and played a significant role in reforms to the *NSW Pesticides Act* which saw the introduction of mandatory training, record keeping and notification requirements.

GENERAL COMMENTS

As an organisation that strives to represent the interests of the community and environment, NTN values the important role that community consultation plays in shaping government policy and regulations.

We welcome the Gillard Government's election commitment for Better Regulation of Chemicals and the opportunity to make a submission in response to the Policy Discussion Paper. We note that there will be further opportunities for the community to input into this process.

We also note that running concurrently to this process is the COAG reform proposal for a single national framework for AgVet chemical regulation. NTN has already made submissions to this process, and we have also expressed our disappointment at the community consultation process, which we believe has been significantly deficient to date given the importance of the reform proposals.

NTN supports the general assessment in the Foreword to the Policy Discussion Paper that "The Australian Government recognises the system is not working as effectively as it should and is looking at options for reform to better protect human health and the environment; and increase the authority's efficiency and effectiveness".

While Australian farmers may well be amongst the most innovative and efficient in the world, NTN believes that they, along with consumers and the environment, have been let down by a regulator and government that has failed to keep pace with community expectations, breakthroughs in the science of toxicology and, substantial changes in regulatory approaches to pesticides in other countries.

While NTN supports many of the proposed reforms in the Policy Discussion Paper, our support is contingent on seeing the details of each proposal. In particular, how they will be implemented in legislation and importantly how they will be resourced.

A concern that we have held for many years is that the APVMA's budget is totally inadequate for its functions. The undue influence the industry has on the APVMA through the cost recovery process is of real concern to the community. Industry views the APVMA as a service provider, but the APVMA is a regulator and its activities must be carried out at arms length from industry.

1. Implementing complete risk frameworks for AgVet chemicals assessment and review

NTN supports the development of a complete and overarching risk framework for AgVet chemicals, however there are no details about how aligning the level of risk with the level of assessment would actually work to drive better outcomes for the protection of the environment and community health from pesticide exposures.

The risk framework must have the precautionary principle[1] at its core. The regulation of AgVet chemicals in Australia also needs a policy context and a strategy that is explicit about the need to reduce the use and reliance on pesticides, as is the case with the European Commission's (EC) action on pesticides. For example, the EC proposes that by 2014 all member states would need to create the conditions for implementing integrated pest management (IPM)[2].

Under the European Commission Directive 91/414/EEC for the community-wide review of all AgVet chemicals for instance:

> Each substance had to be evaluated as to whether it could be used safely with respect to human health (consumers, farmers, local residents and passers-by) and the environment, in particular groundwater and non-target organisms, such as birds, mammals, earthworms, bees.[3]

In 2009, the EC completed its review of existing pesticides that were on the market before 1993. This program concerned about 1,000 active substances and led to the removal from the market of more than two thirds of these substances. All reviewed pesticides have undergone a detailed risk evaluation with respect to their effects on humans and on the environment.

If these pesticides are not safe to use in the European Union, then the Australian public is justified in asking why they are still being used here.

While we understand there may be differences in use regimes and environmental conditions that need to be considered, if a pesticide has failed the basic test for

[1] The precautionary principle is defined in S391(2) of the EPBC Act as follows: "lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage."
[2] See *Sustainable Use of Pesticides: A Strategy to Ensure the Safer Use of Pesticides* http://ec.europa.eu/environment/ppps/strategy.htm
[3] EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

its safety to human health and the environment, then it should no longer be on the market in Australia. By keeping these dangerous and outdated chemistries on the Australian market, innovation is stifled because there are no incentives for change.

Australia needs a policy directive that sets the scene for a regulatory system that preferences low risk products; provides disincentives for the registration of high-risk products; and, has an efficient and effective process for the swift removal of high-risk products from the market.

Policy guidance around complete risk frameworks should also acknowledge and provide strategies for:

- Meeting Australia's obligations under international conventions
- Meeting the regulatory challenges of changing paradigms in toxicology
- Assessment of endocrine-disrupting chemicals
- Assessment of epigenetic effects and chemicals
- Removing mutagenic and carcinogenic chemicals

The risk framework also needs to acknowledge that risk management incorporates considerations beyond science. For example, the European model of risk regulation recognizes that risk management is a policy process of which science is one input along with social values and ethical and environmental factors.

We support the publishing of risk manuals and standards as proposed as it is consistent with open government and the community right to know.

2. Improve the quality and efficiency of AgVet chemical assessment and registration processes

We have no objections to improving the quality and efficiency of assessment and registration, as long as equal consideration is also given to the efficiency and effectiveness of any re-registration program, chemical reviews and removing dangerous pesticides from the market.

2.1 Lodging applications

We have no objection to this proposal and believe that it would provide a more level playing field for smaller and less experienced applicants.

2.2 Assessing applications

While we understand the objective is to cut unnecessary workload to improve assessment efficiency, we are concerned about how the determination of 'low risk' would be made in order to exclude assessment of efficacy and trade implications.

The example provided for excluding trade risks associated with veterinary products sounds reasonable on the face of it, however there may be instances where this isn't the case e.g. the use of tick products on livestock destined for export?

We have some reservations about excluding efficacy even in 'low risk' products despite our desire to see genuine low risk products move more quickly through the regulatory process.

We do not want to see a proliferation of products that exploit a 'low risk' category by making efficacy claims that can't be substantiated or, that do not provide the customer with clear advice on the effective usage of the product (eg quantity to use) to achieve the desired outcome under Australian conditions.

On the other hand, we do not want onerous requirements for data placed on registrants of genuine low risk products. A balance needs to be struck and could take into consideration such things as whether the product is registered in other comparable jurisdictions for similar purposes.

2.3 Assessment timeframes

We support the proposals to reform timeframes for assessment. However, we question whether extra payment is appropriate for priority processing in a risk-based system. We would rather see an accelerated assessment process on the basis of genuine low-risk, as long as the criteria to determine 'low risk' are acceptable.

3. Enhancing the AgVet chemical review arrangements

The loss of confidence in Australia's regulatory system as a result of the ad hoc nature and long delays associated with the chemical review process is a very significant issue.

It is a fundamental failure in the regulatory process that there is no systematic re-registration process, as well as an effective ad hoc process for chemical review in between as new information becomes available about products on the market or there are advancements made in the science of toxicology.

From the community's perspective it is clear that a lot of time and effort goes into ensuring the APVMA is efficient and effective at getting products onto the market, however the same standards do not apply at the other end when products need to come off the market or be given new instructions for safer use.

NTN strongly supports the intention of the proposed reform, and believes it will be essential to rebuilding community confidence in the regulatory process as well as delivering real outcomes for the protection of health and the environment.

We support the setting of timeframes for data submission in the review process, as long as the timeframes are reasonable in terms of community expectations and any extensions are managed with the protection of community health and the environment uppermost.

But we don't believe we need to re-invent the wheel in designing the re-registration system. Registration review systems have operated in European Union since 1994 and in the USA since 2006.

NTN is of the view that the comprehensive EU risk assessment and authorisation procedure is the best regulatory approach for Australia to model a re-registration system on. Most companies that supply products onto the Australian market will have already gone through that process in the EU.

The EU's risk assessment and authorisation procedure required registrants to prove their safety in accordance with current standards. The chemicals that are no longer authorised in Europe either did not, or could not, pass that risk assessment process.

Even for the chemicals that failed the process because of incomplete dossier, there was not even basic data to adequately assess their heath and environmental impacts and so they are assumed to be a risk until proven otherwise, which is an example of the precautionary principle in action.

The review of existing pesticides in the EU was completed in 2009. Of some 1,000 active substances on the market in at least one Member State before 1993, 26%, corresponding to about 250 substances, have passed the harmonised EU safety assessment. The majority of substances (67%) have been eliminated because dossiers were not submitted, were incomplete or withdrawn by industry, or the chemical failed the test.[4]

[4] EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009

We agree there needs to be a tiered approach and a process for determining which registrations undergo review first, however we are concerned that a time-consuming process to develop this system would continue to undermine the community's confidence in the regulatory process.

There are many pesticides no longer permitted for use in the EU that are being widely used in Australia[5]. A good starting point would be to look at how the EU prioritized pesticides and for Australia to first consider the pesticides that failed the EU process.

There are also many products in Australia that have 'off label' permits and these pesticides should also be assessed as a priority because there is a substantial increase in their use without adequate data to support it. There is potentially a role for the proposed 'independent science panel' in refining the prioritization process for re-registration.

Another important aspect to consider alongside the re-registration system is managing what happens when pesticides are removed from the market. The EC strategy for sustainable pesticide use[6] for instance is encouraging the uptake of integrated pest management in Member States, along with other incentives and support for the reduced use and reliance on pesticides.

The Australian government needs to ensure that policies, strategies and resources are in place to help farmers make the transition to agricultural production systems that are less dependent on pesticides and are in the best interests of community health and the environment.

4. Using overseas assessments to their full extent

It has been a key frustration that overseas assessments and regulatory decisions are not better utilized and NTN supports moves to improve the situation. Determining what overseas agencies have applied a 'comparable' and 'compatible' approach is of course the controversial aspect of the proposed reform.

The difference between comparable international regulators is the policy framework within which risk analysis is conducted. The EU regulation for instance, uses the precautionary principle to underpin the basis of their risk

[5] *A List of Australia's Most Dangerous Pesticides* (2010) NTN/WWF www.ntn.org.au
[6] See *Sustainable Use of Pesticides: A Strategy to Ensure the Safer Use of Pesticides* http://ec.europa.eu/environment/ppps/strategy.htm

assessment process. NTN supports the adoption of the precautionary principle into the Australian risk assessment framework.

NTN strongly supports the inclusion into the legislation contemporary scientific and technical standards that relate to AgVet chemicals and the criteria that apply under all international conventions and treaties that Australia is a signatory to. In fact, we'd argue that it's negligent this isn't already occurring given the obligations Australia has as a signatory to the various conventions including the Stockholm, Rotterdam, Basel and Waigani Conventions.

We completely dismiss the assertion by CropLife made in their submission that, "The Stockholm process is increasingly becoming a forum for political campaigns against particular chemistries. In circumstances where decisions are not made on the basis of sound science, the APVMA should not be obliged to consider the outcome of the process". [7]

This is an outrageous slur for CropLife to make. The Convention processes are scientific, rigorous, transparent and accountable. Some would argue that any 'politics' that has been brought to the Stockholm Convention process has actually been driven by AgVet chemical corporations desperate to hold onto their old toxic chemistries at any price.

It is unconscionable that any modern regulatory agency would allow the registration, or the continued registration, of any pesticide that is toxic, persistent, bio-accumulative and has long range transport in the environment.

5. Establishing an independent science panel

NTN does not support this proposal in its current form. We do not believe it should be the role of an independent science panel to 'report annually on APVMA's progress with reducing the backlog of reviews and improving the efficacy of assessments'. A science panel needs to advise on scientific matters, which is where their expertise lies.

NTN strongly objects to the proposal to replace the Advisory Board with an independent science panel and/or expert advisor/s on a 'as needs' basis. The Advisory Board plays an important role in ensuring a wide range of stakeholder views are heard by the APVMA (see 6 below).

[7] See http://www.daff.gov.au/agriculture-food/food/regulation-safety/ag-vet-chemicals/better-regulation-of-ag-vet-chemicals/responses-to-the-discussion-paper

An independent science panel would be a very useful initiative to assist the APVMA with science functions including:

- Developing the process for defining the risk categories for the re-application and re-registration process and chemical review program
- Peer-reviewing research
- Reviewing contentious assessments
- Providing advice on emerging scientific issues that impact the work of the APVMA such as developments in the science of toxicology and ecotoxicology, endocrine disruption etc

The independence of the scientists on the panel is paramount and the selection criteria to ensure their independence will be critical. The community will not want to see another opportunity for industry representatives to exert their influence and will not support the panel unless it is truly independent.

6. Enhancing the provision of expert advice

NTN strongly objects to the proposal of replacing the Advisory Board with expert advisor/s to the CEO on a 'as needs' basis. The Policy Document provides no evidence that makes the case that the Advisory Board is not delivering for the organization, or, that experts on a 'as needs' basis would be as useful or cost-effective.

The Advisory Board has an important role to play in providing representation for a range of stakeholders that can give useful guidance to the CEO on a wide range of issues relating to all aspects of the APVMA's responsibilities.

The expert adviser proposal would also reduce community input, further diminishing community confidence in the regulator. Community groups do not have the capacity to monitor and provide the sort of detailed advice the CEO might need on an ad hoc basis. Community input is best facilitated within an ongoing framework where meetings are held regularly and community participation is properly resourced.

Axing the Advisory Board would also remove the capacity for stakeholder representatives to initiate areas of concern and advice, which we understand has been one of its most important capacities over a period of great upheaval and change for the APVMA.

The operation of the Advisory Board and its capacity to discuss issues from a variety of perspectives, with its historical knowledge of the organisation and the issues is invaluable. It is an efficient and cost effective way for the CEO to obtain expert

advice. It could be argued that seeking those views from experts on a 'as needs' basis could be more expensive and less effective.

NTN believes there is scope to rebalance the representation on the Advisory Board to ensure it provides equitable representation for all stakeholders. Industry currently have disproportionate representation on the Advisory Board, and, it also has representation via its dedicated Industry Liaison Committee and Regulation Liaison Committee. It could well be more cost effective to remove these committees and provide a fairer representation on the advisory board, including an independent scientific expert as well as an environment representative on the Advisory Board.

7. Improving legal interaction with the APVMA

NTN is not able to provide a legal perspective, however we generally support changes that give more options to the regulator to enforce decisions that are in the best interest of the community and protect the environment, while also providing procedural fairness. Presumably other agencies that have effective recall mechanisms could provide a model.

8. Improving the APVMA's compliance enforcement capacity

NTN supports the proposal to provide the APVMA with a modern graduated compliance regime. This is long overdue. It does raise issues around resourcing, as the best suite of compliance tools is useless unless they are actually being applied.