



australian network of environmental defender's offices

Submission on *Better Regulation of Agricultural & Veterinary Chemicals* Discussion Paper

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The Australian Network of Environmental Defender's Offices (ANEDO) consists of nine independently constituted and managed community environmental law centres located in each State and Territory of Australia.

Each EDO is dedicated to protecting the environment in the public interest. EDOs provide legal representation and advice, take an active role in environmental law reform and policy formulation, and offer a significant education program designed to facilitate public participation in environmental decision making.

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ANEDO submission on the *Better Regulation of Agricultural and Veterinary Chemicals* Discussion Paper

February 2011

The Australian Network of Environmental Defender's Offices Inc (ANEDO) is pleased to provide comment on the Department of Agriculture, Fisheries and Forestry (DAFF) Policy Discussion Paper: *Better Regulation of Agricultural and Veterinary Chemicals*. ANEDO is a network of 9 community legal centres in each state and territory, specialising in public interest environmental law and policy.

The Discussion Paper calls for comment on a series of proposed statutory and administrative reforms to the Australian Pesticides and Veterinary Medicines Authority, which is responsible for regulation up to the point of sale. ANEDO recognises that this reform process is occurring simultaneously with the COAG proposal for a single national framework for the regulation of agvet chemicals beyond the point of sale, in which process we also hope to have the opportunity to provide comment.

Our key recommendation is that the regulatory regime for agvet chemicals needs to be reformed to more effectively implement the principles of ecologically sustainable development (ESD), in particular, to mandate a precautionary approach to the management of agvet chemicals.

We address the following issues:

1. Scope and purpose of the review
2. Process and format
3. Precautionary versus risk management approach
4. Monitoring and funding
5. Responses to specific reforms proposed
6. Recommendations

1. Scope and purpose of review

In his Foreword to the Discussion Paper, Minister Ludwig states that the consultation process is “the first step in delivering on the Gillard Government’s election commitment to introduce reform to the sector...”¹ The ALP’s 2010 Election Policy Platform states that “Labor is committed to the strict control of pollutants and toxins in the environment, including the minimisation of the production, import and use of harmful substances, the development of alternative technologies and, where possible, the elimination of harmful substances.”² This undertaking, and the Minister’s stated commitment to implement it, give rise to a legitimate expectation that the APVMA review will lead to better environmental outcomes in relation to pesticide regulation.

¹ Joe Ludwig, Minister for Agriculture, Fisheries and Forestry, PDP, Foreword.

² Accessed at <http://www.alp.org.au/australian-labor/our-platform>, Ch. 9, para. 107.

It is our understanding that the Prime Minister's commitment was made, in part, in response to ongoing concerns about the performance of the APVMA in responding to human health and environmental issues. As far as we are aware, these concerns include:

- The perceived conflict of interest inherent in the Federal regulator being funded by the industry it is set up to regulate, giving rise to the perception that it has been "captured" by industry interests;
- The length of time it can take for pesticide reviews to be completed;
- The lack of input from community and environmental groups in decision-making;
- The continued registration and use of pesticides in Australia which have been de-registered in other broadly comparable jurisdictions;
- The absence of any independent system of monitoring the real-world health and environmental impacts of pesticides following registration;
- The lack of transparency and questions about the risk assessment of so-called inert or non-active (but still potentially hazardous) ingredients in pesticide formulations; and
- The total load and increasing number of pesticides in the Australian environment.

In his Foreword, Minister Ludwig goes on to state that the reforms "aim to cut unnecessary red tape for farmers and business and encourage the development of modern, cleaner and safer chemicals." The proposed reforms now appear to be largely focused on encouraging greater efficiencies in APVMA operations and thus lower costs to industry.

ANEDO's primary interest is in whether the proposed reforms will lead to a strengthened regulatory framework that fosters improved environmental outcomes with regard to pesticide use.

EDO offices have been involved in responding to a variety of pesticides issues, including the following:

- Community concerns in the NSW Northern Rivers region regarding the potential negative impacts on human and environmental health of off-target spray drift from a variety of agricultural industries, for example, macadamia farms in particular, given their proximity to rural residential dwellings and rural villages;³
- Fish kills in the Noosa River and fish larvae deformities in a fish hatchery on the Noosa River adjacent to a macadamia farm;
- Coral dieback on the Great Barrier Reef attributed, in part, to pesticide runoff from cane farms in coastal catchments in north Queensland; and
- EDO Tasmania has assisted community members with concerns about the lack of access to information regarding herbicides for which research permits have been granted; and calling for investigation into the causes of large scale oyster deaths on the East Coast of Tasmania in catchments dominated by agricultural and forestry uses.

³ One recent outcome of this involvement is *Getting the Drift: a community guide to pesticide use in the NSW Northern Rivers*, published by the EDO NSW Northern Rivers office in conjunction with the National Toxics Network. (A second, expanded edition of this booklet will be published in 2011.)

ANEDO is aware of other environmental issues related to pesticide use and/or misuse, including the alleged impact of pesticide residues in estuaries on oyster populations in commercial oyster farms on the NSW Northern Rivers. However, ANEDO recognises that the full impacts of pesticides on terrestrial and marine ecosystems are likely to be largely unknown, given the absence in Australia of any system of regular, independent and transparent environmental monitoring of pesticide residues in soils, watercourses and native animals – especially where there is no direct economic interest in doing this monitoring (unlike the oyster industry). In other words, it is impossible to know what impacts long term, low dose pesticide exposures may be having on native plants and animals because we do not know what these exposures are. We therefore believe that any meaningful reform process should include the implementation of such a monitoring system as a high priority.

As noted, ANEDO's primary interest is in whether the proposed reforms will lead to a strengthened regulatory framework that fosters improved environmental outcomes with regard to pesticide use. These outcomes include:

- Reducing the total pesticide load in Australian air, soils and water (streams, aquifers and oceans) and animals;
- Eliminating the use of particular pesticides for which there is considerable evidence of adverse environmental impacts;
- Encouraging the use of less- or non-toxic alternatives to synthetic pesticides;⁴ and
- Providing the policy context for greater uptake of integrated pest management and biological approaches to agriculture.

ANEDO is concerned that aside from the proposal to institute a periodic re-registration scheme, we believe there is little evidence in the Discussion Paper of reforms that would lead to better environmental outcomes. For example, there is a lack of detail describing how streamlined assessment processes will ensure environmental outcomes are not compromised, and a lack of detail on specific improved compliance and enforcement provisions that may lead to improved environmental outcomes. We comment on the proposed reforms below and make recommendations.

2. Process and format

A detailed response is made difficult by the fact that the Discussion Paper does not clearly distinguish between the APVMA's statutory duties pursuant to the *Agricultural and Veterinary Chemicals Code Act 1994* ("the Agvet Code") and its administrative processes. It is unclear for instance, whether the proposed risk framework is to be implemented through legislation or some other means. We therefore submit that draft legislation be made publicly available for consultation that clearly indicates what details will be the Act, Code or related subordinate instrument or policy.

Likewise, the Discussion Paper does not clearly distinguish between the existing regulatory framework and the proposed reforms. For instance, the provenance of the set

⁴ For instance, the EU pesticide strategy "aims to encourage low-input or pesticide- free cultivation, in particular through raising user awareness, promoting the use of codes of good practice and making financial means available for applied research and training": EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

of objectives in paragraph 1, page 7 is unclear. They do not appear in the Agvet Code. It is not clear whether: they exist somewhere else in the regulatory framework; they are proposed to be included in amended legislation; or they are informal objectives that have been identified only to guide the reform process. It is critical that this is made clear with further detail provided on how the objective to protect the environment will be implemented in practice.

3. Precautionary versus risk management approach

While there is no clear statement of the APVMA's approach to risk management in its legislation, on its website, or in the Discussion Paper, the APVMA's current approach appears to be to allow the registration, and not require the de-registration following review, of pesticides if the hazards identified in the risk assessment process can be managed through appropriate risk management strategies such as label instructions or user training requirements. However, in the absence of real-world testing prior to registration, to avoid ongoing adverse environmental impacts this approach depends on a stringent regime of testing the residues and impacts of pesticides in the environment. This does not currently happen in any Australian jurisdiction.

The effects of the APVMA's current approach to risk management may be seen in the fact that many pesticides currently registered in Australia have been "grandfathered" from before the current national registration system was introduced in the mid-1990s, and have not required any review to ensure they comply with contemporary toxicological standards and community expectations. Also, the APVMA does not appear to assess whether there are other, less toxic pesticides already available on the market when doing its risk assessment for registration (the principle of "substitution").

While the proposal to introduce a re-registration system would go some way to correcting this issue, the proposed reforms still represent a fundamentally different approach to other jurisdictions that have adopted a precautionary approach.⁵ For instance, in the EU,

Each active substance has to be proven safe in terms of human health, including residues in the food chain, animal health and the environment, in order to be allowed to be marketed. It is the responsibility of industry to provide the data showing that a substance can be used safely with respect to human health and the environment.⁶

As a result of this process, which was completed in 2009, more than two-thirds of the pesticides which were approved for use before 1993 have now been withdrawn from sale in the EU. While there may be a variety of reasons for some of these chemicals being voluntarily withdrawn by manufacturers, the fact that "about 70 substances failed the review and have been removed from the market, because the evaluation carried out did not show safe use with respect to human health and the environment"⁷ reflects the difference in approach.

⁵ The precautionary principle is defined in section 391(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."

⁶ EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

⁷ EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

By contrast, there are currently “6313 registered agricultural chemical products and 3315 registered veterinary chemical products based on 1866 approved active constituents” in Australia, and the numbers are increasing slightly each year.⁸ In contrast to the European Union (EU),⁹ the APVMA has no mandate to reduce either the number or total load of pesticides in the Australian environment.

Likewise, where a registered pesticide is under review by the APVMA, these reviews can take an inordinately long time – for example, up to 14 years and counting for parathion-methyl. This is unacceptable for a chemical which is recognised as a cholinesterase inhibitor, suspected endocrine disruptor and possible carcinogen,¹⁰ and which the APVMA acknowledges is the subject of concerns regarding its “potential for adverse environmental effects, including its high toxicity to bees”.¹¹ Again by contrast, some 75% of decisions regarding about 1000 active ingredients then in use in the 27 nations of the EU were taken in the 4 years between 2005 and 2009.¹²

While the EU Directive underpinning its approach does not refer specifically to the precautionary principle, this principle is implicit in the Directive’s requirement that any particular pesticide must not be authorised for use unless it can be shown that:

- “(ii) “it has no unacceptable effect on plants or plant products;
- (iii) it does not cause unnecessary suffering and pain to vertebrates to be controlled;
- (iv) it has no harmful effect on human or animal health, directly or indirectly (e.g. through drinking water, food or feed) or on groundwater;
- (v) it has no unacceptable influence on the environment, having particular regard to the following considerations:
 - its fate and distribution in the environment, particularly contamination of water including drinking water and groundwater,
 - its impact on non-target species...”¹³

In comparison, the Object of the Agvet Code is:

- “...to make provision for and in relation to:
 - (a) the evaluation, approval, and control of the supply, of active constituents for proposed or existing agricultural chemical products or veterinary chemical products; and
 - (b) the evaluation, registration, and control of the manufacture and supply, of agricultural chemical products and veterinary chemical products.”¹⁴

The effect of this Object is demonstrated by the fact that the APVMA’s typical response to a product review is “to tighten controls on two to three hundred products a year and

⁸ Data supplied by Dr Simon Cubit, Manager, Public Affairs, APVMA, by email to Mark Byrne, EDO NSW Northern Rivers, dated 13 December 2010.

⁹ EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

¹⁰ See http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC35122.

¹¹ http://www.apvma.gov.au/products/review/current/parathion_methyl.php.

¹² EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.

¹³ EU Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, Article 4: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31991L0414&model=guichett.

¹⁴ From section 1, Agvet Code.

to deregister a handful of active constituents.”¹⁵ In other words, it attempts to manage risk where possible by tightening controls such as label directions and training requirements, rather than by de-registering a product.

In view of the risks involved – especially to matters of national environmental significance under the *Environmental Protection and Biodiversity Conservation Act 1999* (EPBC Act) including the World Heritage-listed Great Barrier Reef – the current approach to pesticide regulation in Australia is clearly inadequate for environmental protection. ANEDO therefore believes that the most fundamental reform that should occur is to more effectively implement the principles of ecologically sustainable development (ESD), including the precautionary principle, into the Agvet Code. Australia has had a National Strategy for ESD since 1992, and it is an integral part of many instruments of Federal, State and Territory legislation, most notably the EPBC Act (Section 3A). The time is well overdue for it to be applied to the regulation of pesticides.

We note that ESD is specifically referred to in the preamble of the *Agricultural and Veterinary Chemicals Act 1994*,

(b) that the principle of ecologically sustainable development requires a regulatory system that is designed to ensure that the use of such products today will not impair the prospects of future generations;

however, we submit that the principles must be operationalised and more effectively implemented through administration of the code and subordinate instruments.

4. Monitoring and funding

The APVMA is currently “funded by fees, charges and levies imposed on the industry it regulates”.¹⁶ In view of the need, expressed above, for a system of environmental testing to occur for registered pesticides, it is essential that the APVMA’s funding base be expanded. Funding this new system from Consolidated Revenue is appropriate in view of the public interest involved. However, it may be more appropriate for such testing to be done by a body independent of the APVMA such as SEWPaC or the CSIRO.

Independent of the scientific monitoring issue, the APVMA’s funding base should be decoupled from the revenue raised from industry. At present, the more pesticides are sold in Australia, the higher the APVMA’s income. While it may be appropriate in some circumstances to utilise industry funds – consistent with the polluter pays principle – funding independent of industry is necessary.

5. Responses to specific reforms proposed

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

- It is not clear how this proposed reform differs from the existing “overarching risk framework for agvet chemicals.”
- It is not clear what criteria will be used to determine the level of risk, and in particular what weighting will be given to the various components listed — ie,

¹⁵ Quote from email from Dr Simon Cubit, Manager, Public Affairs, APVMA, to Mark Byrne, EDO NSW Northern Rivers, dated 13 December 2010.

¹⁶ http://www.apvma.gov.au/news_media/community/2010-15_funding.php.

public health; occupational health; chemistry and manufacture; residues and trade; and efficacy and safety as well as the environmental component.

- It is noted that SEWPaC's 2009 Environmental Risk Assessment Guidance Manual for agricultural and veterinary chemicals,¹⁷ which is intended to form the environmental component of the proposed risk assessment process, applies Data Requirements for Environmental Effects Assessment relating only to fish, Daphnia and algae, with no reference to the 70% of Australian plant and animal species that are endemic.
- ESD and Public policy objectives and community concerns should be included as relevant considerations in the risk framework.

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

- This section is focused on hastening application processing time frames, and does not provide any detail on improving the *quality* of assessments in terms of achieving improved environmental outcomes. The reforms need to explain how any streamlining of assessment guarantees that environmental outcomes will not be compromised.

3. Enhancing the agvet chemical review arrangements

- As noted above, some reviews currently take an inordinate length of time. Manufacturers should be given a maximum of 1 year to respond to requests for missing data, and the entire review process should take no longer than 2 years.
- The proposal for a compulsory re-registration system is supported. The maximum period between registrations should be 5 years for high risk pesticides and 10 years for low risk pesticides.
- The factors that would inform this process appear to be administrative checks in the first instance (Annex 1) rather than scientific criteria as required by EU regulatory re-registration. Further, they do not currently include input from community or environmental groups or any overarching policy framework - this should be rectified.
- The ad hoc chemical review program that would operate concurrently also needs timeframes for reviews to be completed in between re-registration processes as required.

4. Using overseas assessments to their full extent

- The legislation should be changed to *require* the APVMA and its regulatory partners to examine and consider work conducted by comparable overseas agencies” in making their decisions, rather than simply *encourage* this.
- “Comparable overseas agencies” should be specified.
- The absence in the Agvet Code of criteria relating to bioaccumulation, long-range environmental transport and any other matters specified in the *Stockholm Convention on Persistent Organic Pollutants* and the *Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International*

¹⁷ .

http://www.ephc.gov.au/sites/default/files/CMgt_NChEM_ERAGM_for_Industrial_Chemicals_200902.pdf.

Trade represent breaches of Australia's current international legal obligations. Rather than giving "consideration" to legislative changes to introduce these, these obligations should be clearly implemented into domestic law as a matter of urgency, since Australia ratified the former in 2004 and the latter in 2003.

5. Establishing an independent science panel and 6. Enhancing the provision of expert advice

- The aim of these reforms appears to be to justify eliminating the advisory board. For example it is unclear why a panel of *scientific* experts is needed to report annually on the APVMA's progress in "reducing the backlog of reviews and improving the efficiency of assessments", as this advisory function could be carried out by the APVMA advisory board. Similarly, the CEO of the APVMA can already obtain ad hoc advice from "expert advisors" under current arrangements. ANEDO therefore does not support these proposals, since oversight by a broadly representative board should be an integral part of the proper regulation of pesticides.
- ANEDO recommends that the advisory board be reinstated to its former formal role as the APVMA's governing body, and that it be strengthened by the inclusion of a representative from a peak environmental NGO and independent scientific representatives. The current framework is unbalanced as industry already has two dedicated Industry Liaison Committees.¹⁸

7. Improving legal interaction with the APVMA

- ANEDO supports clarification of appeal processes.
- Merits review should not be available for scientific decisions requiring a recall, only judicial review where there has been a flaw in the process. This is consistent with a precautionary approach.
- Moratoriums on the sale and use, or the de-registration, of high risk registered pesticides under existing legislation are likely to produce better environmental outcomes than seeking the power to prevent manufacturers and/or distributors from obtaining a stay of the APVMA's decision in the AAT.

8. Improving the APVMA's compliance enforcement capacity

- ANEDO supports this proposal. An enhanced range of enforcement and compliance provisions should be included in the legislation, and accompanied by a clear compliance strategy and sufficient resources to ensure monitoring, compliance and enforcement activities are carried out effectively and therefore provide an appropriate deterrent.

Annex 1: Summary of the proposed tiered and targeted approach for introducing a reapplication, review and re-registration scheme for agvet chemicals

- ANEDO supports the proposal to institute a re-registration process for all approved pesticides, provided maximum interval for the process is 5 years for high risk pesticides and 10 years for low risk ones; that the stages prior to

¹⁸ http://www.apvma.gov.au/about/committees/il_committee.php

review take no longer than 1 year; and that the review stage takes no longer than 2 years.

However, we would like to see a full list of the questions proposed to be applied in stage 1 (Reapplication), which should include, *inter alia*:

- “Has your product been de-registered or withdrawn from sale in any other countries?”
- “Is there any scientific data to indicate that your product is a carcinogen/endocrine disruptor etc?”
- “Has any non-industry-funded research been undertaken on the effects of your product on terrestrial or marine plant or animal species or ecosystems?”

6. Recommendations

The *Agricultural and Veterinary Chemicals Code Act 1994* should be amended to:

1. Include provisions operationalising the principles of ecologically sustainable development (ESD) as an overarching object.
2. Require new pesticides to be assessed using a precautionary approach, similar to the EU system.
3. Pursuant to the implementation of ESD, introduce the following objectives for pesticide regulation:
 - a. Reduce the total pesticide load in Australian air, soils and water (streams, aquifers and oceans).
 - b. Eliminate the use of particular pesticides for which there is considerable evidence of adverse environmental impacts.¹⁹
 - c. Encourage the use of less- or non-toxic alternatives to synthetic pesticides.²⁰
4. Introduce a statutory maximum period for the interval between scheduled pesticide reviews of 5 years for high risk pesticides and 10 years for other pesticides.
5. Introduce a statutory maximum period for completion of all pesticide reviews (scheduled or non-scheduled) of 2 years.
6. Fund the APVMA from consolidated revenue in addition to industry fees to ensure its independence.
7. Include provision for a comprehensive, regular and independent system of national environmental monitoring.
8. Include a representative of an appropriate environmental organisation on the APVMA Advisory Board.
9. Introduce a statutory system of independent, regular and transparent real-world environmental monitoring of pesticide impacts.
10. Require every single ingredient, whether active or “inert”, to be specified on product labels, with all material safety data sheets available on the APVMA website.

¹⁹ Noting that “weight of evidence” may be an inappropriate standard in view of the dominance of industry-funded research into pesticide impacts.

²⁰ For instance, the EU pesticide strategy “aims to encourage low-input or pesticide-free cultivation, in particular through raising user awareness, promoting the use of codes of good practice and making financial means available for applied research and training”: EU Action on Pesticides, Fact Sheet, European Commission Directorate-General for Health and Consumers, March 2009.