



**Submission
to DAFF
on the
Better Regulation of Agricultural and
Veterinary Chemicals
Policy Discussion Paper**

December 2010

57 Carrington Road Marrickville NSW 2204
Phone 02 9577 3333 Fax 02 9577 3377 Email ausconsumer@choice.com.au
www.choice.com.au

The Australian Consumers' Association is a not-for-profit company limited by guarantee.
ABN 72 000 281 925 ACN 000 281 925



CHOICE exists to unlock the power of consumers. Our vision is for Australians to be the most savvy and active consumers in the world.

As a social enterprise we do this by providing clear information, advice and support on consumer goods and services; by taking action with consumers against bad practice wherever it may exist; and by fearlessly speaking out to promote consumers' interests - ensuring the consumer voice is heard clearly, loudly and cogently in corporations and in governments.

Executive Summary

CHOICE strongly supports the majority of the proposed reforms.

They are moderate, long overdue reforms and bring Australia up to date and in line with the two main systems of risk regulation globally.

In addition there are three things we think these reforms should deliver.

1. an overarching strategy for pre and post-market chemical regulation which sets out the future direction for the industry;
2. an improved governance framework; and
3. more resourcing for the APVMA.

Overarching framework

We support a risk based strategy and but think it would work best within an overarching agricultural and veterinary chemical strategy that would guide both pre and post-market regulatory activities as well as drive innovation and development of low-input or non-chemical alternatives.

Elements of this framework would include:

- Commitment to put the precautionary principle at the heart of chemical regulation
- Commitment to put protection of human health and the environment above plant protection
- Clear direction on Australia's attitude to certain classes of chemicals

choice

- Acknowledgement that risk management is a policy process and there are other legitimate factors eg community values that must be considered along side science
- Encouragement of low-input or pesticide free farming including integrated pest management, organic production
- National consistency and improved controls in relation to chemical use

Whatever overarching framework is adopted clear direction must be provided in relation to how Australia intends to deal with certain classes of chemicals.

These include:

- POP (persistent organic pollutant) chemicals
- endocrine disruptors (for the European framework see http://ec.europa.eu/environment/endocrine/index_en.htm)
- PBT (persistent bio-accumulative and toxic) chemicals
- VPVT (very persistent, very toxic) chemicals
- Mutagenic chemicals
- Carcinogenic chemicals - note the US Delaney clause

The policy framework should explicitly acknowledge that:

- these classes of chemicals are not acceptable in Australia
- will be targeted for priority review against modern science and
- certain chemicals will be deregistered where low-risk substitutes are available will be deregistered.

The framework needs to acknowledge that risk **management** involves considerations beyond science. The European model of risk regulation that recognizes risk management is a policy process of which science is one input. It allows the consideration of other legitimate factors at the risk management stage. These include social values, economic considerations, ethical and environmental factors among other things.

Improved governance

The proposals to establish a science panel and replace the Advisory Board with at call expert advisers needs more thought.

Scientists are highly specialized and a broad panel from which the APVMA can draw on a needs basis may work better.

A science panel needs to advise on scientific issues. Many of the functions allocated to the proposed panel are governance functions.



The proposal to replace the Advisory Board with at-call expert advisers is a bad one and we strongly oppose it.

Rather we think the Advisory Board's membership needs reworking to improve community input (particularly in relation to environmental issues) and expand independent scientific input.

Additionally the Advisory Board should have an explicit role in making risk management decisions in relation to individual chemicals.

However our preferred model is that the Advisory Board be replaced with a Commission which would function like other *Financial Management Act* regulators.

A full-time Commissioner (the current CEO) would head the organization and would be assisted in governance and decision making functions by several part-time Commissioners. The Commission as a whole should have the following skills, of which individual Commissioners should hold one of more:

- administrative decision making,
- regulatory expertise,
- consumer protection,
- public health,
- environment protection,
- regulatory science and
- industry knowledge.

A Commission would:

- Deepen the expertise in the governance of the organization
- Provide a strong governance structure to support the direction for the APVMA as it matures as a regulator
- Provide strong governance to implement these reforms, particularly the complex process of setting up and executing the re-registration process
- Provide a separation between risk assessment (science) and risk management (science plus other factors) in the decision making framework of the organisation as FSANZ does.

Resourcing

We are concerned about three things.

- The low level of funding overall
- Lack of indexing of funding
-



- Industry influence on the funding and Cost Recovery Impact Statement process

The APVMA needs more funding and funds need to be collected at arms length from the industry. The APVMA is a regulator, not an industry service provider, and the regulated community is largely responsible for paying for the risk it creates.

We now address the proposals in detail.

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

CHOICE supports the development of an overarching agricultural and veterinary medicines framework based on risk.

We suggest this would have two limbs:

- 1) A strategic framework which sets out the Government's policy direction on chemicals; and
- 2) Detailed rules that implement the intent of the framework.

In relation to the strategic framework we refer you to the European framework on Sustainable Use of Pesticides

<http://ec.europa.eu/environment/ppps/objectives.htm>.

Our preferred elements for an Australian framework include:

- Commitment to put the precautionary principle at the heart of chemical regulation
- Commitment to put protection of human health and the environment above plant protection
- Clear direction on Australia's attitude to certain classes of chemicals (see below)
- Acknowledgement that risk management is a policy process and there are other legitimate factors such as community values that must be considered along side science
- Encouragement of low-input or pesticide free farming including IPM and organics
- National consistency and improved controls in relation to chemical use

In Europe these elements are implemented via regulation EC1107/2009.

http://www.eppo.org/PPPRODUCTS/information/2009_1107_EU-e.pdf

choice

Key policy dimensions set out in the preamble of this regulation are:

- A **high** level of human health and environmental protection (clause 8)
- Application of the precautionary principle (clause 8)
- Onus on industry to demonstrate products are safe (rather than on government to prove they are not safe) (clause 8)
- Promotion of non-animal testing methods (clause 11)
- Need for detailed procedures to be laid down in regulations to achieve predictability, efficiency and consistency (clause 12)
- Separation of risk assessment from risk management (clause 12)
- Strict deadlines (clause 14)
- Approval periods proportionate to risk to a maximum of 15 years (clause 15)
- Capacity for interim review (clause 16)
- Incentives to bring low risk substances to market (clause 17)
- Identification of classes of chemicals for substitution with actives that require less risk mitigation (clause 19)
- Human health and environment has priority over plant protection (clause 24)
- Capacity to impose conditions on use having regard to sustainable pesticides framework (clause 29)
- Giving priority to non-chemical and natural alternatives including IPM wherever possible (clause 35)

Precautionary principle

We support all these elements in the new Australian risk based framework and in particular support application of the precautionary principle.

The precautionary principle is already encapsulated over 40 Australian laws including federal environment, fisheries management and gene technology laws. For a full list see:

<http://www.federationpress.com.au/pdf/Peel,%20The%20Precautionary%20Principle,%20Appendix%20A.pdf>

Chemical classes

Whatever overarching framework is adopted clear direction must be provided in the framework in relation to how the regulator will deal with certain classes of chemicals.

These include:

- POPs chemicals
- endocrine disruptors (for the European framework see http://ec.europa.eu/environment/endocrine/index_en.htm)



- PBTs - persistent bio-accumulative and toxic
- VPVTs - very persistent, very toxic
- Mutagenic
- Carcinogenic chemicals - note the US Delaney clause

Our view is that the policy framework should explicitly acknowledge that these classes of chemicals are not acceptable in Australia. They will be targeted for priority review against modern science and, where substitutes are available, will be deregistered.

Risk management

The risk framework also needs to acknowledge that risk **management** involves considerations beyond science. We prefer the European model of risk regulation that recognizes that risk management is a policy process of which science is one input.

It allows the consideration of other legitimate factors at the risk management stage. These include social values, economic considerations, ethical and environmental factors among other things.

We note in Europe risk assessment and risk management is functionally and institutionally separate with Europe's risk assessment agency EFSA reviewing the science, but member states and the European Commission responsible for risk management decisions.

This works for Europe because of the large number of member states. We are not arguing for risk management decisions to be taken at the political level here.

However we suggest the risk management decision making process should facilitate consideration of other legitimate factors by including experts with relevant knowledge in the decision making process. See our proposals under points 5 and 6 below.

Publishing manuals

The paper proposes that the APVMA would develop and publish risk manuals, standards and methodologies to guide decisions about the level of risk of particular products and ingredients.

CHOICE supports this proposal as it is consistent with open government. It would make the methodology clear to cognoscenti.



However it is the overarching risk framework and the policy approach to risk analysis that must be elaborated and simply articulated to the community for this process to deliver the necessary confidence boost in the integrity of the policy framework within which chemical regulation occurs.

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

2.1 Lodging applications

We have no objection to this proposal.

2.2 Assessing applications

While there is a case for tiered process for registration and review this particular initiative depends on the definition of low risk and the sort of products that are assigned to this particular category.

Where a chemical is used as part of the food chain efficacy testing is essential to ensure the lowest amount possible is used.

Where a product is not used in food production but makes a high level claim such as controlling a disease eg malaria, dengue fever efficacy testing is also warranted.

All synthetic chemical based pesticides sold into the domestic market should also be efficacy tested to ensure the lowest possible amount of the active ingredient gets into the environment.

2.3 Assessment timeframes

CHOICE agrees with the proposals to reform timeframes for assessment.

We question whether payment is the appropriate criteria for priority processing in a risk based system.

We would prefer priority status is accorded to low risk substitutes for high risk chemicals.

Any system where registrants can pay to “queue jump” should be on a 100% cost recovery basis. We have some concern that the process may favour large multi-national companies over smaller domestically based companies which have been quite innovative.



3. Enhancing the agvet chemical review arrangements

Review timeframes

We support setting strict non-negotiable timeframes for data submission in the review process.

The current loss of confidence in the regulatory system as a result of delay is hugely significant.

The question is how extensions are managed. There are two approaches globally. The first is the negotiated extension approach proposed for applications. We support that approach for applications, because in that process the applicant has an incentive to provide the data. However we oppose that approach for reviews because the applicant's motivation is to delay.

Evidence from the US and the EU is that defined rules around the extension process is administratively more efficient for both government and registrants.

The US approach has proved administratively burdensome and led to considerable time extensions. By comparison the strict deadline approach adopted by the Europeans has proved clear and efficient for all parties.

Given the history of extensive time delays in Australia it is necessary to implement strict non-negotiable rules around time frames.

The US approach would simply perpetuate the current crisis of confidence in the time taken for reviews as it may result in no change.

Re-application, review and re-registration system

Re-registration is the mechanism that has been adopted internationally to ensure chemicals on the market meet contemporary health and safety standards.

Registration review systems have operated in Europe since 1994 and in the US since 2006. This proposal brings Australia into line with global standard practice. It is a long overdue reform.

However this needs to be set within an overarching framework as articulated in point one above. For example, the system should allow the APVMA to refuse re-registration where a substitute chemical that requires less risk management and risk communication is available.



It also needs a defined process and defined timeframes.

To avoid unnecessary burden on registrants we recommend aligning the Australian re-registration processes with the European approach as virtually all companies will have already gone through that process.

In particular the Australian process should adopt the European criteria for prioritizing chemicals for review. This is a function that the science panel mentioned below could assist with.

Not only is it unnecessary to develop a new re-registration process when the European regulators have already done this it would undermine confidence in these reforms if the next five years were spent working on criteria and processes for the re-registration process.

Renewal periods should be for five, ten or 15 years depending on the nature of the active.

High risk chemicals should be reviewed against modern science after five years.

In relation to the process set out in Annex 1 we do not think step one - reapplication is adequate.

It should not be a simple self assessment process. The APVMA should develop a checklist approach that requires registrants to prove that their product complies with modern standards.

Registrants should be required to provide the APVMA with summary information at this stage about:

- Any overseas regulatory decisions about the product
- Any adverse experience reports (we note the s161 problems in this regard)¹
- All academic studies about the product with high regard being had to independent academic studies.

The APVMA should also set up priority lists for re-registration. In addition to:

- POPs chemicals
- endocrine disruptors
- PBTs - persistent bio-accumulative and toxic
- VPVTs - very persistent, very toxic
- Mutagenic
- Carcinogenic chemicals

¹ Registrants have refused to provide s161 reports to date. The intent of the law needs to be clarified one way or another.



These could include:

- products that didn't get registered in Europe for failing to provide data against modern health and safety standards
- products deregistered elsewhere
- high volume of use of products
- products with large number of off label permits

4. Using overseas assessments to their full extent

International work shares in chemical assessment and review are already a feature of the global regulatory landscape. Regulators apply similar methods in risk assessment.

The difference between “comparable” international regulators is the policy framework within which risk analysis is conducted. Specifically, the difference is that the precautionary principle underpins risk analysis in the EU.

The precautionary principle should be adopted into our framework.

We strongly agree that Stockholm criteria should be reflected in the criteria for the registration and review of ag vet chemicals. In particular the Stockholm hazard criteria (chemicals that resist degradation, bio-accumulate or transport long range) should be grounds for refusing registration or removing a chemical from the Australian register.

Any decision to restrict in any way the use of chemical by a comparable regulator should trigger an immediate review here. The system should not allow the APVMA to wait until the re-registration period comes around.

5. Establishing an independent science panel

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

- adding an additional layer of integrity to scientific processes
- developing risk categories for the registration process including re-application and re-registration process
- recommending chemicals for priority re-registration
- providing an additional mechanism for input on contentious issues (this was previously a function of the Board prior to the Uhrig reforms. However we note the panel alone would not be sufficient for this purpose - see below)



Membership criteria should be established to ensure the scientists are truly independent of industry. The term “independent” would need definition eg an independent scientist is one who has not worked or provided research to relevant industry bodies in the last eight years.

Given that scientists tend to be highly specialized it may be that the APMVA should draw from the panel on a needs basis in much the same way FSANZ does with its science fellows.

It would not be useful to assign any functions other than science-based functions to a science panel. A number of the proposed functions for the panel are better characterized as management or governance functions eg overseeing backlogs, improving efficiency and sit better with the Advisory Board.

These are important and necessary functions and are discussed below.

6. Enhancing the provision of expert advice

The proposal removes the capacity for expert advisers to self-initiate areas of advice.

This has been one of the most important capacities of the advisory board during this very difficult period.

The expert adviser proposal would reduce community input. Community groups do not have the capacity to monitor and provide the sort of detailed advice the CEO needs on an adhoc or at call basis. Community input is best facilitated within an ongoing framework where meetings are held regularly and community participation is properly resourced.

Any reduction of community input will further tilt the balance of influence in favour of the industry, which is well resourced and capable of provide “expert” input any time.

Any reduction of resourcing for community input is inconsistent with Public Service Commission attempts for agencies to do more to assist NGOs and citizens generally become involved in government decision making. See Ahead of the Game: Blueprint for the Reform of Australian Government Administration.

It is difficult to see how the proposal would be more “cost-effective” unless the experts were rarely called on.



Advisory Board

The APVMA is an immature regulator and undergoing considerable change. It needs a wider skill base at the governance level than any one CEO could possess.

The Advisory Board -despite its limitations - has served the organization well. It has provided useful guidance to the CEO on a number of issues including the cost recovery process, the spate of recent reviews, including the efficiency and effectiveness reforms as well as a range of other strategic issues.

The collegiate operation of the Advisory Board and its capacity to discuss issues from a variety of perspectives and come to an agreed view for the CEO is in fact an efficient and cost effective way for the CEO to obtain expert advice.

The current proposal appears more a measure to deal with a constrained budgetary situation, rather than an evidence based proposal to address a systemic failure.

If budget is the problem - and we believe it is for many reasons - then that is the problem that should be addressed (see below).

There are two three limitations of the current Advisory Board model which go to its membership and role.

Membership

Community interests - especially on the environment - are underrepresented. Environmental protection is an objective of the Act and it is inexplicable that the AB lacks an environment expert.

Independent regulatory scientists are underrepresented.

By comparison industry is over-represented.

Role

The Advisory Board is simply advisory and its agenda can be controlled by the CEO seeking advice. It has a significant role in providing advice that the CEO must have regard to but it has no ultimate responsibility and limited capacity to command the resources and information needed for effective governance (because that is not its role).

Moreover the advisory board is an ideal body because of its broad makeup to provide advice on the risk management aspect of chemical regulation. However these matters have never come before the advisory board. This was a role of the APVMA Board prior to the Uhrig reforms.



One option is to reform the Advisory Board to address the deficiencies identified above.

Our preferred option - A Commission model of governance

The Advisory Board was a creature of the Uhrig reforms.

At the time CHOICE preferred that governance of the APVMA should be undertaken by a full-time Commissioner and a few part-time Commissioners.

This is the prevailing model for Financial Management Act regulators such as ASIC, ACCC and ACMA (Communications and Media Authority) although these days the Commissioners of the larger regulators are mostly full-time. The legislation that sets up these bodies specifies the skills that must be available to the Commission collectively.

In the case of the APVMA the Commissioners collectively (including the full-time Chair) should have the following skills:

- administrative decision making,
- regulatory expertise,
- consumer protection,
- public health,
- environment protection,
- regulatory science and
- industry knowledge.

It would be expected that the Commissioners would have expertise in more than one of these areas.

A Commission would:

- Deepen the expertise in the governance of the organization
- Provide a strong governance structure to support the direction for the APVMA as it matures as a regulator
- Provide strong governance to implement these reforms, particularly the complex process of setting up and executing the re-registration process
- Provide a separation between risk assessment (science) and risk management (science plus other factors) in the decision making framework of the organisation as FSANZ does.

We note FSANZ is a *CAC Act* agency and therefore has a governing Board. The Board is responsible for risk management decision making.



7. Improving legal interaction with the APVMA

CHOICE question is whether an injunction is an appropriate remedy when a regulator is urgently seeking to protect human health and the environment.

We support removal of the right to obtain an injunction when a chemical has been recalled or suspend because human health and/or the environment is at risk.

We support however the broader right to review of the legality of the decision making process.

We also note that Europe does not allow de novo or merits reviews of risk regulation.

Europe has adopted what is known as a “deferential standard” of review for risk regulation. That is where an agency is required to undertake complex scientific assessment de-novo or merits review is not available.

Review is only available if decisions appear incorrect in light of the facts and law which were available to them at the time.

There is also a need to provide standing for the community to level playing field.

8. Improving the APVMA’s compliance enforcement capacity

We support the modernization of the APVMA’s compliance regime and making available a modern suite of enforcement tools. Provision of tools such as enforceable undertakings is long overdue.

Resourcing

Choice has made a number of representations over the last few years to the Minister and to the APVMA in the CRIS (cost recovery) process about the inadequacy of the funding arrangements for the APVMA.

We are concerned about three things:

- Low level of funding
- Lack of indexing of funding
- Industry influence on the funding and CRIS process.

The APVMA’s budget is inadequate for its functions. This is reflected in time blowouts in relation to applications and reviews. Essential post-market compliance and monitoring projects have languished over the last few years due to lack of funds - notably the adverse experience reporting project.



The budget has decreased in real terms over each of the last five years - a period in which the agency has been ill equipped financially to cope with the pace of change and the additional demands on it. In particular the CRIS process, the control of use and better regulation initiatives have been resource intensive and the APVMA has struggled to manage these reforms at the same time as conducting its core business.

We are strongly of the view that the industry's influence on the funding process must be limited. Industry is, of course, a legitimate stakeholder but we have reached a situation where the industry views APVMA funds as "their money". They view the organisation as an industry service provider and have argued for public funding of post market activities.

The APVMA is a regulator, and the regulated community should be largely responsible for paying for the risk they create.

We have argued many times that this situation must be brought under control. We have suggested one way of doing so could be if a neutral third party was responsible for the APVMA's funding arrangements including collection of revenue. We have suggested the Department of Finance as a suitable body.