



22 December 2011

Agvet Chemicals - Early Harvest and APVMA Reforms Team
Agricultural Productivity Division
Department of Agriculture, Fisheries and Forestry

GPO Box 858
Canberra ACT 2601

To whom it may concern,

Please find attached a preliminary submission from CHOICE on the Australian Government's proposed reforms to agricultural and veterinary chemicals legislation.

Should you require any further information or clarification, please do not hesitate to contact me.

Kind regards

A handwritten signature in black ink, appearing to read "Matt Levey".

Matt Levey
Head of Campaigns - CHOICE

Unlocking the power of consumers

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CHOICE SUBMISSION

Better Regulation of Agricultural and Veterinary Chemicals

ABOUT CHOICE

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.

To find out more about CHOICE's campaign work visit www.choice.com.au/campaigns and to become a CHOICE campaigns supporter sign up at www.choice.com.au/ccu.

Overall, CHOICE strongly supports the policy intent of the bill. In particular we think the re-registration process, the shut the gate provisions, the new compliance toolkit and the capacity to appoint another agency to collect agricultural and veterinary chemical levies will substantially enhance the effectiveness and efficiency of the regulatory system.

However the success of some of these measures depends on the effectiveness of the new risk management framework and we have concerns that the bill does not provide an adequate anchor for the development of a framework that will promote human health and environmental protection in line with the expectations of Australians and consistent with global standards.

We have sought to assess the bill against its capacity to deliver on the policy intent articulated in the Explanatory Guide. We have not fully assessed the bill in all its complexity and detail but there are four headline issues we wish to flag at this early stage. They are:

- 1. The lack of guiding principles for risk framework in the legislation;**
- 2. The introduction of a new legal test for re-registration;**
- 3. The s14 5) b) discretionary items; and**
- 4. Confusing terminology used in the bill.**

We also wish to note that **the legislation is exceedingly complex**. Locating provisions and working how they interact with existing requirements has been timing consuming and tortuous. We doubt we have comprehended the full extent of changes. If stakeholders cannot understand the bill or its intent then that reflects poorly on a regulatory system designed to protect the public. While we think the new provisions should be enshrined in law as soon as possible, something has to be done over a longer period of time to deal with what we regard as the unnecessary complexity of this bill.

1 - Risk-based framework

Policy intent: To provide for the development and application of a risk-based framework to guide the assessment and reconsideration of chemicals, in particular guide the scale of assessment.

We do not think the bill delivers on this policy intent. **This is a centrepiece reform and the legislation provides no guidance on the principles that would underpin such a framework. In the absence of guiding principles, we cannot see how the risk management framework will be anything more than a restatement of the status quo.**

The risk based framework will underpin the effectiveness and capacity of the regulatory system to meet the expectations of the Australian community and ensure that only safe chemicals have market access. It will be the foundation of improvements to the:

- Initial registration system;
- Re-registration system;
- Chemical review system; and
- Complete chemical portfolio review.

We understand that the APVMA will develop and consult on the risk-based framework and that it will be a flexible document. However the **core principles** on which the framework is to be based **must** in our view **be articulated in the legislation** and **must go beyond existing requirements**. Otherwise, this reform will be little more than a restatement of the status quo and will not change outcomes for the community.

We think this is so important that it would be appropriate to **place the principles in the objects of the Act**. While the object of the Code is to register and control chemicals based on risk, the objects need to provide guidance by way of principles that would underpin a risk-based scheme. This would include the following:

The object of the code is to make provision for the evaluation, approval and control of the supply and manufacturer of agvet chemicals within a risk based framework that:

- Puts the protection of human health and the environment above plant protection;
- Submits high-risk chemicals to greater regulatory oversight including shorter registration periods;
- Acknowledges that some hazards present an unacceptable risk that cannot be managed;
- Requires the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified;
- Acknowledges the need for a precautionary approach in the face of legitimate scientific uncertainty; and
- Defines high-risk chemicals to include those that are carcinogenic, mutagenic, persistent, bio-accumulative or toxic to reproduction, as the EU system does.

A statement of principles like this would guide the APVMA in the development of the risk framework and provide greater capacity than the existing Act does to remove dangerous chemicals from the

market. Without a statement of principles like this, we cannot see how the risk framework will be any more than a restatement of the status quo.

Principles such as those above will assist in dealing with the current difficulties with the administration of the code in relation to reviews. For example, the current rules require an endless cycle of risk mitigation. In the case of endosulfan, exceedingly complex risk mitigation measures resulted in a situation where growers were unable to implement the rules and state regulators were unable to enforce the rules because the requirements were so complex no-one could understand them. We are concerned that without a statement of principles which can guide the risk management framework, this approach will be perpetuated with chemicals currently under review, for example diuron and other dangerous chemicals. Such principles will put appropriate constraints around the current endless cycle of risk management. In particular, they will help define the limits of risk management.

If the risk management framework does not provide greater capacity to remove dangerous products from the market, it will have failed as a reform.

2 - The review of the chemical portfolio and the re-registration program

Policy objective: A mandatory scheme for the continuation of approvals and registration with time periods for market access based on risk.

We applaud the introduction of a re-registration scheme but Chapter 2 introduces a **new, unknown legal test** for this process.

Under the bill, the test for continuation of registration is “no reason to doubt”. The Explanatory Guide says re-registration would be based on the principle that registration would continue if there was “no reasonable grounds, founded in evidence, to doubt that the product poses an unacceptable risk” S51F (2)(b). However, for both initial registration and reconsideration (or what is commonly known as review), the test is that the APVMA must be “satisfied”, for example under s14 1) the APVMA must grant an application “if it is **satisfied** of all the matters...”.

The “no reason to doubt” is a new legal construct, one that is not known in administrative law. We are concerned that it could require considerable litigation for its meaning to be settled. It would be a particularly undesirable start to the new re-registration scheme and could in fact delay its roll out should a dissatisfied registrant choose to challenge the scheme in the courts. We think a new test will undermine the objective of an efficient and effective system that provides consistency, certainty and predictability of outcomes.

Therefore we support extension of the existing “satisfied” test to the new re-registration process.

3 - Terminology - continuation and reconsideration

As mentioned above, the current legislation is lengthy and complex and the draft bill is going to add substantially to the complexity. Many provisions in the existing legislation are confusing and some the new provisions are going to add to that confusion.

We have two key issues here:

i) At present, terms used in the bill are not used by stakeholders. We think the draft bill presents an opportunity to align the bill with common usage.

ii) More critically, we think the proposed term “continuation” of registration for what is essentially a re-registration process is confusing at best and misleading at worst as it presumes continuation of registration when in fact continuation is only one of four possible outcomes for the process.

i. Terms not used by stakeholders

Stakeholders refer to the current “**reconsideration**” process (Division 4 of the Ag Vet Chemicals Code Act 1994) as the chemical “review” program and the proposed “**continuation**” of approvals and registration process (schedule 2 of the exposure draft) as the “re-registration” process.

The draft bill presents an opportunity to align terminology with common usage and rename the current re-consideration provisions as “chemical review”.

This frees up the term **reconsideration** and we think it would be a good alternate name for the schedule 2 of the exposure draft in place of “continuation”. Alternatively “re-registration” could be used.

ii. Why we object to term continuation for the re-registration process

There are four outcomes from the so-called “continuation” process – continuation, conditions, cancellation and review.

Heading the section on continuation is a presumption for one of the four possible outcomes. This is confusing at best and misleading at worst.

The term in common use is re-registration, but reconsideration could serve equally well if the current sections of the code were renamed review in accordance with common use.

In respect to the objections to the term re-registration, we note both the words “re” and “registration” are in the Macquarie Dictionary and if the word was used in the legislation it would in a short space of time be added to the dictionary. If concerns persist with the term “re-registration”, then we suggest replacing it with the term “re-consideration”, and renaming the reconsideration sections as “review”. This would align all terminology with common use.

We would have “registration/reconsideration” every 7 – 15 years, and “review” when required.

4 - What the APVMA must and may have regard to: s14 (5)

s14 (5) (a) and (b) of the Chemicals Code sets out the matters that the APVMA must and/or may have regard to in granting or refusing an application for registration. The substantive change here is that some matters are considered to be mandatory considerations and others are considered to be discretionary. While the reasoning behind this is understandable, in some cases it is not appropriate to afford such a wide discretion.

For example, the matters in s 14 5) b) (i) (ii) (iii) (ADI, dietary exposure, residue assessments) need not be mandatory considerations for non-food producing species but should be mandatory for all chemicals used in association with food producing species.

We think s5) b) (i) (ii) (iii) requirements should be mandatory for chemicals used with or in association with food producing species, whether the food is for human or animal consumption.

It would do no harm to also retain them in s5 b) as discretionary matters in case they are ever relevant considerations in other situations although it is difficult to think of any.

Additionally the stability of the product is integral to the functioning of the product and should be a mandatory consideration.

Issues not in the bill

Risk framework

We look forward to the release of the risk-based framework. Of particular interest to us is the criteria for assigning a registration period and the criteria for scheduling the complete chemical portfolio review.

On the latter we support a **matrix approach** that is underpinned by the principles we have set out above and therefore considers both **the hazard** inherent in the chemical **and other factors** such as:

- Volume of use (sales data could be a proxy for volume of use);
- Amount of off-label use and time since last review; and
- Overseas deregistration, especially for products that were deregistered in Europe after failing to provide requested data.

Science Panel election commitment

The bill is silent on the Science Panel. However, we would like to see a statement of the role and the appointment process for the Science Panel as soon as possible.

An independent Science Panel could be a useful initiative to assist the APVMA with the development and execution of the risk-based framework, in particular its application to the portfolio review process. The Science Panel would:

- Add an additional layer of integrity to scientific processes;
- Assist with the development of risk categories for the registration process including reapplication and re-registration process;
- Advise on the prioritisation of chemicals for the re-registration schedule; and
- Provide an additional mechanism for input on contentious scientific issues, especially where there may be the need for a precautionary approach.

CHOICE would welcome a statement on the terms of reference and membership criteria for the science panel in the very near future.

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

We do not support assigning administrative or audit functions such as monitoring backlogs to the Science Panel. The tasks of over-sighting backlogs and improving efficiency sit better with the Advisory Board.

Advisory Board

We are pleased that the Advisory Board has been retained, but we note that community expertise - especially on environmental protection - is underrepresented. We also note the absence of skills in regulatory science.

Environmental protection is an objective of the Act and at least one Board member should have this skill. Regulatory science is core business for the APVMA so we also believe this is necessary.

There are a number of ways these could be added to the appointments process. One way would be by amending subsection (e) to either allow for a board member with experience in environmental protection more generally, rather than limiting it to an environmental toxicologist, and secondly, by adding a new subsection to provide for the appointment of a person with regulatory science expertise.

Issues not yet considered

Chapter 3 – Quality and efficiency of assessment and registration

Policy objective: Measures to address the timeliness of reviews. To reduce backlog and provide for consistent completion of assessments within appropriate timeframes.

To ensure there is no undue impediment to using overseas data and assessment (where conducted by comparable agencies).

CHOICE has not yet had a chance to examine this part of the bill. However, issues we will look at include the data cut-offs or shut the gate provisions, particularly how they will work.

We strongly support the capacity to refuse applications where registrants do not provide information in set timeframes, and will look at these more closely early next year.

We are particularly interested in the interaction of s159 and 161 with shut the gate provisions.

On the question of whether extension of timeframes should be mutually agreed, we would point out that this is the US approach and it has led to the sort of lengthy delays that this reform package proposes to address. We support discretionary extensions but believe a maximum period should be provided for. This provides clarity and certainty for all stakeholders. We believe that 18 months should be the maximum extension.

Chapter 4 - Enforcement

We support the additional measures to manage and deter non-compliance. While we have not yet examined this part of the bill in detail, we wish to suggest an additional item for the compliance toolkit.

We have concerns with chemical formula and product integrity. We are aware that counterfeit products and products with impurities are more common than desirable. In addition, “label drift” – where the contents of the product are not in accordance with the label - has been a problem for years. We would like to suggest that registrants be required to provide annual certification that their products:

- Do not contain counterfeit elements;
- Do not contain impurities; and
- Contain contents are in accordance with the label.

This could be aligned with the annual sales data collection process for efficiency.

Chapter 5 - Data protection

We have not as yet examined this part of the bill.

Chapter 6 - Collecting the levy



We support allowing for other agencies to collect the levy. We have not as yet examined that part of the bill.