



**A National Scheme for Assessment, Registration and Control
of Use of Agricultural and Veterinary Chemicals**

**Submission to the
Consultation Regulation Impact Statement**

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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.

1. Opening remarks

Overarching framework

It is our view that the missing component of these reforms and the Better Regulation reforms is 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
- 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
- PBT (persistent bio-accumulative and toxic) chemicals
- VPVT (very persistent, very toxic) chemicals
- Mutagenic chemicals
- Carcinogenic chemicals

The policy framework should explicitly acknowledge that:

- these classes of chemicals are not acceptable in Australia
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- they will be targeted for priority review against modern science
- if registered they will be required to submit to frequent review, and
- certain chemicals will be deregistered where low-risk substitutes are available.

Precautionary principle

CHOICE supports strong application of the precautionary principle in the regulation of agvet chemicals. The responsibility should be on manufacturers and importers to prove safety, before market access is granted. Lack of evidence of harm is not evidence of safety. To ensure that Australia is not lagging behind other countries and to assure consumers that government is acting to protect their safety we must place the precautionary principle at the heart of our agvet regulatory framework and should act swiftly when new evidence comes to light that may raise concerns about the safety of approved chemicals.

The regulatory framework should place protecting human health and the environment above plant protection and should make explicit reference to the precautionary principle as one of the guiding principles of ecologically sustainable development.

The legislation should direct the regulator to apply the precautionary principle when undertaking risk assessment and management decisions.

This could be done in the same way as section 391 of the Environment Protection and Biodiversity Conservation Act 1999 (Cth), which provides that the Minister “must take account of the precautionary principle” in making certain decisions under that Act. The precautionary principle is defined in section 392 is defined as the principle “that 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.”

It is our view that application of the precautionary principle to human health risks only (as proposed in Option 2) will not meet the public’s expectations for protection of the environment from pesticides.

Option 1 is supported.

Resourcing

The best designed system in the world will suffer if not adequately resourced. Whatever system is adopted the funding must be adequate. To date neither the pre-market activities administered by the APVMA are adequately funded nor are the post market activities administered by the states.

Given the enormous public interest in reviewing the existing chemical portfolio in a timely manner we think one off government funding should be provided for this task. If European analysis can be applied here the cost benefit of the reduction in chemical related disease will significantly outweigh the upfront cost of government funding of the initial ten year review program.



However the costs of periodic re-registration should be built into the ongoing funding model as they will become a standard regulatory cost.

We now address the proposals in detail as per table 1.

In respect of the matters that were canvassed in the Better Regulation review our views are unchanged and we attach our submission to that process.

Governance

In line with the Productivity Commission's recommendation CHOICE prefers a single national regulator encompassing both pre and post market regulatory functions.

However of the options put forward in the RIS CHOICE prefers Option 2.

We want consistent control of use across the country so that all communities are equally protected. Of the proposed options only option 2 could be relied on to deliver consistent national outcomes across all post market activities and over the medium and long term. A single national agency would facilitate the setting of national approaches to compliance and enforcement activities which would provide greater clarity and certainty for users and registrants who often wear the flack of inappropriate uses of their products.

It is our view that approaches harmonized legislation alone will deliver consistency on paper but not consistent implementation. A national body to set priorities and determine strategy is needed to deliver consistent outcomes. Further there is a long history in this country of harmonized legislation diverging with the passage of time.

A single national regulator for control of use would enable a close relationship between pre market chemical processes and post market activities as a significant step towards a seamless system with effective feedback loops.

We prefer that service delivery be contracted on a long term basis to state governments. Compliance and enforcement of statutory instruments is a government function. It would not be appropriate to involve to contract agronomist who are more likely to have multiple allegiances to those who provide them with work.

Facilitation of registration of low risk products

We support a program that facilitates the registration of low risk chemicals. Definitions and product groupings of low risk chemistry are best ascertained by reference to an overarching strategy on sustainable use of pesticides.

This strategy would clearly set out Australia's attitude to certain classes of chemical from the low risk biopesticides to high risk POPs, PBTs, carcinogens and endocrine disruptors and registration processes would be tailored to the level of risk.

For low risk products we support the definition used by the Health Canada program and we support the proposals to provide either expedited review or reduced data pathways and fees in certain circumstances.



We note the US EPA reduced risk program requires much less data for the registration of biopesticides and on average biopesticides can be registered within a year compared to three years for conventional pesticides.

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.

Minor use, permits and permissible uses

The issues raised under these headings in our view confuse the issues of minor use and the permit system. That is permits and permissible uses are being used to address the minor use problem, rather than a policy solution consistent with a science based framework.

What needs to be considered is a broader solution to the minor use problem so that chemicals used in horticulture and other minor uses are ones that are properly assessed and safely used.

We think serious consideration needs to be given to a program that would fund research and data generation for minor use in a similar way to the IR-4 program in the US.

However if government funds were to be applied to such a program these should be applied in a manner consistent with the sustainable use of pesticides strategy mentioned above. In practice this would mean that funds should be directed towards low risk and reduced risk options including IPM solutions.

In relation to permissible uses on crops and off label use much of the discussion focuses on irrelevant considerations. The purpose of the chemical registration process is to ensure that chemicals are only approved in a manner that is safe for users, the community and the environment. The assessment system cannot and should not consider impacts on farm productivity or compliance problems such as whether changing the system may drive chemical use underground. At any rate these are likely to be short term adjustment problems if they eventuate at all.



The approval process must remain focused on the safety of chemical use for human health and the environment. Current off-label use systems undermine this fundamental goal of the system and have arisen to deal with the minor use problem.

Therefore in addressing this problem we favour science based approaches that affirms the integrity of the chemical registration system and solutions that substantively address the problem of minor use within a reduced risk framework.

That means we do not support off label uses, nor do we support agronomists being empowered to allow off label uses.

We do support establishment of a system that would facilitate data generation for minor uses along the lines of the US IR-4 program provided any government funding was targeted at reduced risk options. Extending access across crop groupings has the capacity to fit with a science based approach.

Management of the chemical portfolio

We prefer option 2 although tempered by some processes outlined in option 1. That is:

- all chemicals on the market should go through the registration process by a defined cut off date
- periodic re-assessment should be required within a risk framework ie the higher the risk the shorter the time frame between periodic assessment
- there should be fixed time frames for data provision and fixed timeframes for completion of individual assessments.

Initial review of existing portfolio

We support a risk based approach. This means:

- the prioritisation of assessments should be based on risk;
- review timeframes for assessment should be based on risk;
- data requirements should be based on risk;
- registration timeframes should be based on risk; and
- fees should be based on risk.

Chemicals for priority review should be:

- POPs chemicals
- endocrine disruptors
- PBTs - persistent bio-accumulative and toxic
- VPVTs - very persistent, very toxic
- mutagenic
- carcinogenic chemicals
- 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

Further we suggest any chemical currently under review should be finalized within one year of the program commencing.

There should be an immediate data call-in for all chemicals on the list of 40 priority chemicals and a cut-off date set for completion of the process of no more than two years from commencement of the re-registration period.

In addition there should be an immediate data call-in on the 80 chemicals that have been deregistered in Europe but are still permitted for use here with a three year review finalization timeline.

Finally the science panel within two years of commencement should publish lists and timeframes for balance of the portfolio review.

A risk based approach also means:

- additional data would not be required for chemicals that meet current standards and
- chemicals that have been registered in the last five years could be grandfathered, thus avoiding the initial portfolio review process.

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 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.

A maximum of ten years should be allowed to complete the initial portfolio review.

As mentioned above arrangements could be made to exempt (or grandfather in) recently registered chemicals from this initial portfolio review.

A national system of use controls – regulatory powers

Anything short of a national program would not produce consistent outcomes. We agree that such a program would need to be resourced with appropriate feedback loops and integrated into existing national programs such as the Australian total Diet Survey.

Option 1 is supported.

A national system of use controls – record keeping



Records underpin successful compliance and enforcement programs and are an essential part of risk management.

To date lack of record keeping requirements have hampered investigations and increased regulatory costs. They undermine the effectiveness of the regulatory regime.

Records are currently required for a number of existing programs and uniform requirements will not push up costs for those who already adhere to good industry practice.

Moreover we support the development of a national pesticide use database and note that PSIC attempts to develop such a database have foundered. Until now sales data has been sought as a proxy for use but it would be preferable for a national database to be established. Record keeping requirements provide a foundation on which a low cost electronic system in which users upload data could be built.

Option 1 is supported

Training and licensing – fee-for-reward users

We support a national training and licensing scheme for fee-for-reward users, including an approach that involves the development of competency criteria for each occupational category, provided standards are set at a level that ensures a sound level of competence.

A national scheme would benefit workers especially those who move interstate.

We prefer option 1.

Training and licensing – farmers and other occupational users

The assumption that users have the skills to follow label instructions is flawed. Firstly label instructions for higher risk chemicals are usually complex and require high levels of literacy to comprehend. Secondly it fails to acknowledge that many users have low literacy skills.

If the regulatory system is to deliver on its promise to protect human health and the environment it must ensure an adequate base level of training and competency such as AQF 3.

Training and licensing – sales personnel and advisors

We do not support an off label use regime as discussed under permissible uses above. It undermines the regulatory system and should not continue. We question the conflict of interest in a seller providing off label use and would caution against any system that legitimized this.

If the system continues to allow off label use only trained advisors who are independent of chemical suppliers and sellers should be able to give this advice.