

Streamlining Regulation of Agricultural and Veterinary Chemicals

Comments by

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SUMMARY

The proposal for streamlining regulation of agricultural and veterinary chemical products is welcomed. It addresses many of the issues that cause concern in obtaining approvals and registrations of substances regulated by the Australian Pesticides and Veterinary Medicines Authority.

The proposals to clarify requirements is most welcome. However, it is suggested that APVMA provide clear guidance to underlying requirements rather than publishing prescriptive requirements. Computerised decision-making (Proposal 6) is strongly supported as a means of communicating requirements.

An effective computerised decision-making tool can help communicate requirements and facilitate the provision of required data in an accessible format. However, the decisions made by a computer should be able to be reviewed by APVMA and should be eligible for internal review if challenged by an applicant (either after an initial review by APVMA or in response to an initial decision made by the computer).

Further efficiencies can be obtained by use of external experts as assessors (Proposal 2). These assessors should be experts in their field rather than APVMA accredited assessors. The experts should not have been involved in preparation of data under review or in any other way be associated with the application under consideration other than in providing independent expert review.

The proposal to allow computer-based decision-making is strongly supported as this could provide much needed guidance to the regulated community. Such decision-making systems could flag the need for a 'conventional' application and provide guidance as to what information is required. Significant increases in efficiencies could be achieved by such systems.

Furthermore, the use of computerised decision-making and other published guidance material (including training provided by APVMA) should help ensure applications submitted to APVMA are of an acceptable standard, assessment reports prepared by external assessors are usable and, overall, should lead to improved efficiencies within APVMA.

Irrespective of the guidance and training, there can be disagreements about the information that is required to 'satisfy' APVMA. Where APVMA determines additional information is required and the applicant agrees, the possibility to supply readily available information during assessment (Proposal 5) and, if not readily available, to obtain provisional registration that allows the additional information to be obtained without refusing the application (Proposal 1) is strongly supported.

Computer systems should be extended to guidance on labelling and other matters. At present, many holders find the advice on labelling difficult to comprehend and follow (Proposal 11). Computer systems can be used to clarify information required thereby achieving the objectives stated for Proposal 11.

Finally, where any decision, whether computerised or manual, is made on information that is knowingly false, misleading or incorrect, APVMA should be able to take action to suspend or cancel the approval or registration obtained on the basis of such information. However, the decision to suspend or cancel an

approval or registration should be tempered by reason; it would be inappropriate to cancel an approval because of an error in, say, the way an address is expressed as occurred following the introduction of the 2014 reforms.

Comments on: The Agricultural and Veterinary Chemicals Legislation (Streamlining Regulation) Bill 2018

INTRODUCTION

The Department of Agriculture and Water Resources has released for consultation proposals for amendment to the regulation of agricultural and veterinary chemicals with a view to streamlining regulation of agricultural and veterinary chemicals in Australia.

Competitive Advantage is a consultancy service providing assistance to organisations intending to commercialise or supply chemicals in Australia and various other countries.

Our comments on the proposals are contained in this document.

COMMENTS

Proposal 1 – Provisional registration or variation with conditions for efficacy (provisional registration of chemical products)

The explanatory document states APVMA cannot register a chemical product unless it is satisfied that the product meets the safety criteria, the efficacy criteria and the trade criteria.

The term 'satisfied' is not defined.

The explanatory document further states the objective of the proposed amendment is to 'provisionally register products, or provisionally register new uses of existing chemical products (vary product registrations), by allowing information about the efficacy of a product to be provided after registration, as a condition of registration'.

The proposal to provisionally register products on the condition that additional data are provided within an agreed, specified time is supported and welcomed.

The current regulatory process inhibits registration by requiring a complete data package, including local efficacy data, to be provided at the time the application for registration is submitted to APVMA.

As the term 'satisfied' is not defined or explained, differences of opinion as to what is considered sufficient to 'satisfy' the regulator can result in applications being refused because additional data might be requested by

APVMA when the applicant might believe the data requirements have been satisfied.

Rather than refusing an application it might be appropriate to agree additional information to be generated after the product is 'provisionally' registered¹.

Similarly, some additional data might be required in relation to a storage stability study. Again, rather than refusing the application, it might be possible to agree a plan for the applicant to generate and provide the requested data.

Overseas data, data for related products and/or laboratory data might be sufficient to indicate the product 'satisfies' the requirements. If APVMA disagrees the available information is sufficient, APVMA is currently required to refuse the application as there is no process, at present, by which the registration can be placed on hold while additional data are obtained.

Provisional registration should not be limited to efficacy data alone. Provisional registration should be available for any data that is not critical in determining the immediate or specific use of the proposed product.

Some examples of where provisional data could be useful include:

- Additional storage stability data.
 - Storage stability data generated in other countries commonly does not have all the elements requested by APVMA. Provided some indication of acceptable shelf-life is available and provided APVMA requested data can be generated within a relatively short period of time, and the applicant agrees to generate the data, the product should be provisionally registered on condition that the missing data be generated and submitted within an agreed period.
- Additional efficacy data or crop safety data.
 - Applicants should be permitted to generate data to address any specific points raised by APVMA in relation to efficacy or target safety when other information indicates the product would be safe and efficacious if used at least in specific situations (i.e. certain, specified, but not all, requested crops).
- Limited environmental safety data where the product can be used without risk to the questioned situation.
 - As an example, questions may arise about toxicity to a specific non-target organism in certain locations.
 - The use of the product could be restricted in those 'at-risk' locations until required data are collected, provided to APVMA and assessed by APVMA.

¹ Pre-Application Assistance requests rarely provide definitive advice as to the data required to satisfy APVMA. Pre-Application Assistance responses commonly give broad rather than specific advice as Pre-Application Assistance requests, if submitted prior to initiating studies, will not include the data that needs to be assessed to determine if the data are adequate or if additional data are required.

There should be no restriction, other than the fit and proper person requirements, for products that could be eligible for provisional registration.

A restricted chemical product, if used in the way it would be used when registered, should not be prevented from registration because, for example, there might be a question about control of a single species on the proposed label.

New products, new modes of action, etc should be eligible for provisional registration if there is suitable justification.

As an example, if a product is used successfully in other countries in the same or similar situations and additional data are required to confirm to APVMA the efficacy of the product, the history of use overseas might support provisional registration subject to local data confirming efficacy and target situation safety.

It is suggested that provisional registration be allowed where there is sufficient information to indicate the suitability of the product in the proposed situations.

Provisional registration should not be a means for dealing with poor quality applications.

It is suggested that provisional registration be granted only where adequate justification is provided in the application.

Provisional registration will not adversely impact on currently registered products. All products should be eligible for provisional registration if this will lead to registration.

The criteria for allowing provisional registration should be clearly articulated to the regulated community so there is transparency and consistency in the granting of provisional registrations.

In relation to transparency and consistency, I do not agree that provisional registration should be at APVMA's discretion. Applicants must be able to understand how the decision to provisionally register is made and why an application might not be eligible for provisional registration.

The need for a provisional registration might be identified in a Pre-Application Assistance response where APVMA suggests additional, specified data be generated.

Specifically:

- Provisional registration allows an application for registration to be progressed without the need to refuse the application because APVMA considers specific additional data are required when the applicant considered the information available or provided was sufficient. Provisional registration will save time and cost for applicants.
- Provisional registration should be available for any data that APVMA believes it requires to finalise registration of a product. This could include chemistry data, efficacy data, certain environmental data as well as other data.
- Provisional registration should be available to all product types.
- In agreeing to a provisional registration, applicants and APVMA should agree to a project plan that will:
 - Identify the information required; and
 - When such information should be made available to APVMA although it needs to be recognised that plans for generating data might be delayed because of external factors such a drought, floods, lack of pest, etc.
- Provisional registration should be an option to generate data identified during assessment of an application as well as being identified during pre-application assistance.

Proposal 2 – An accreditation scheme for assessors in the future (accreditation of assessors)

The proposal to use external assessors is strongly supported.

The explanatory document states the objectives for external assessors includes increasing the efficiency of application processing and providing applicants with more control over data assessment timeframes and costs.

The explanatory document further states that assessors will need to be accredited by APVMA and that APVMA would provide a framework for assessors which could specify matters such as insurance, conflict of interest and data handling protocols and that APVMA would need to be compensated for functions performed by APVMA.

The need for a formal accreditation system of external assessors is questioned.

Using only accredited assessors may impede development of new technologies as the accredited assessors available at any given time might not be 'qualified' for a new technology or type of product introduced at that time.

Assessors should be people competent in their area and able to comment on the relevant data.

An external assessor should be independent. They should not have been involved in the preparation of the data under review or in preparation of the registration application nor should they be directly associated with the applicant e.g. work in the applicant organisation.

Clear guidance as to the requirements should be provided by APVMA so that:

- Applicants can prepare applications in accordance with the guidelines; and
- External assessors can address the requirements when preparing an assessment report.

Guidelines for data assessment should include training and regular updates on requirements.

Regular dialogue between APVMA and external assessors, including potential assessors, would benefit APVMA, the external assessors and the regulated community.

Computerised decision-making systems (Proposal 6) could significantly assist in ensuring data are presented in a way that facilitates assessment by external assessors as well as ensuring data and assessment reports are provided in a form that allows efficiencies within APVMA's overall assessment of the application and the applicant's preparation of the data.

External assessment by assessors who are suitably qualified, but not necessarily accredited by APVMA, would improve efficiency of the regulatory process by ensuring acceptable applications are submitted and applicants have increased confidence that their applications will be accepted by APVMA.

Proposal 3 –Prescribed approvals and registrations (approval and registration for active constituents, chemical products or labels)

The explanatory document proposes a streamlined approach to new approvals and registration by use of a self-declaration or self-regulation process.

The explanatory document proposes the simplified, streamlined process would apply to active constituents, chemical products and labels where minimal or no assessment of technical information is required.

It is noted the process would be suitable for products such as those of lower regulatory concern.

The proposal is supported but it is suggested that clear criteria for eligible applications be provided by APVMA.

Furthermore, the proposal that APVMA have powers to cancel any approval or registration for which such approval or registration relied on false, misleading or incorrect information intentionally provided to APVMA is strongly supported.

For a system of self-declaration or self-regulation to work there needs to be strong enforcement action to ensure false, misleading or incorrect information is not intentionally provided to the regulator.

Proposal 4 – Data protection incentives for certain uses of chemical products (limits on use of information)

No comment is made on this proposal.

Proposal 5 – Prescribe certain information that can be taken into account if provided during an assessment (information to be taken into account in determining applications)

The proposal for defined types of information to be provided during assessment is supported.

The explanatory document states that prior to 2014, it was possible to provide additional information during the process of registration. Since then, 'new' information cannot be provided.

The explanatory document argues this encourages applicants to lodge complete applications and improves the efficiency of APVMA's assessments.

While the current process might improve the efficiency of APVMA's assessments, the lack of clarity of requirements can impose undue burdens on applicants.

Applicants might believe they have provided adequate support for their application but APVMA might request additional information. In most cases, if the applicant cannot convince APVMA the additional information is not critical, the application will be refused and will need to be re-submitted after the additional data are provided. This causes delays and increases costs to applicants.

Prescribing the type of information that can be provided during assessment plus the option to generate data under a provisional registration (Proposal 1) will give applicants significantly greater confidence when applying for registrations and approvals.

Proposal 6 – Provide for computerised decision-making (computerised decision-making)

The explanatory document proposes allowing use of computerised decision-making. The document refers to the use of computer programs to make decisions under the *Therapeutic Goods Act 1989*.

Computerised decision-making tools, if available to applicants, would help ensure clear guidance is provided to the regulated community and would very much simplify the entire regulatory process.

Computerised decision-making is used in many fields including human health. As an example, blood tests are often initially evaluated by computer before being checked by an appropriately qualified pathologist. With at least some systems, the pathologist can change the decisions made by computer and, if appropriate, can add information to allow better decisions to be reported by the software in future.

The regulated community and the regulator would benefit from a system that allows:

- First-pass decisions to be made by the computer; and
- There being an ability to modify those decisions if necessary; and
- The decision process used by the systems being able to be updated as required; and
- Both the regulator and the regulated community having access to the systems.

The proposal to allow APVMA to substitute an incorrect decision made by a computer is supported. However, it is suggested that the amended decision be eligible for internal reconsideration.

Computer based decision-making cannot be so prescriptive that updating and modification of decisions is not possible. In some cases, the decisions might not apply to a specific technology or data type. As an example, toxicity testing is moving to methods that involve fewer animals. If a computerised decision-making system uses the reported end-point to progress an application but APVMA questions the methods used to obtain reported result, there should be an option to have any amended decision reviewed internally rather than requiring AAT to adjudicate on a technical matter.

Intelligently designed computer-based systems would define the required end-points and would identify points of concern. They would help external assessors (Proposal 2) assess data and would allow APVMA to focus on those points indicated by the software as requiring attention.

Proposal 7 – Improve the transparency of voluntary recalls (voluntary recalls)

No comment is made on this proposal.

Proposal 8 – Require relevant information to be provided in relation to label approvals and variations (notification of new information)

The proposal to require the same public health and environmental protection safeguards for providing relevant information that currently apply under section 160A to apply to applicants for any and all applications, including applications for label approvals and variations to approvals and labels, is supported.

Proposal 9 – Standards for registered chemical product constituents (definition of registered chemical product)

The proposal to allow a range for each ingredient in a formulation is supported.

Currently, an application for registration requires the nominal or target concentration of each constituent to be listed in the application. In contrast, other countries (e.g. USA) require the nominal, upper and lower limits to be stated.

Without specifying the upper and lower limits there is a risk that, over time, formulations can be gradually changed until they drift outside acceptable limits. Specifying upper and lower limits would provide certainty about the permitted levels for each ingredient in a formulation.

A standard for ingredients would provide some guidance to applicants as to the ranges that would be generally accepted. If the range is outside the permitted limits, the applicant should be required to explain this.

One issue of concern with guidance materials and standards is that it can be difficult for applicants to find all the required guidelines and requirements. It is suggested that a computerised decision-making process (Proposal 6) that incorporates the standards and guidelines would help applicants prepare complete applications.

Proposal 10 – Suspension or cancellation of approvals and registrations for providing false or misleading information in an application for variation or label approval (suspension or cancellation of approval or registration for provision of false or misleading information)

Suspension or cancellation of approvals for providing false or misleading information is supported

This proposal is supported provided there is an opportunity to correct information if the false or misleading information was supplied in error and the information does not cast doubt on the immediate safety or efficacy of the product or might adversely impact trade.

In contrast, intentionally providing false or misleading information should not be tolerated.

The proposal to suspend or cancel an approval or registration because 'any person' provided false or misleading information is too broad. It is not clear who might provide false or misleading information that could lead to suspension or cancellation of an approval or registration.

It is suggested that the provision to suspend or cancel an approval or registration be restricted to information provided by the holder or at the request of the holder.

Proposal 11 – Addressing an inconsistency in label particulars (supply of registered chemical products with unapproved label)

The proposal to clarify information on a label is supported.

A significant problem with current registrations is that the notice issued by APVMA for registration of a chemical product and approval of a label requires the holder to wade through a complex and confusing maze of statements:

- The Notice states:
 - *'The approval of the label is subject to the prescribed conditions set out in Attachment 3 and the additional conditions imposed by the APVMA under paragraph 23(1)(b) of the Agvet Code set out in Attachment 4'.*
 - *'The registration of this product is subject to the prescribed conditions set out in Attachment 1 and the additional conditions imposed by the APVMA under paragraph 23(1)(b) of the Agvet Code set out in Attachment 2'.*
- Attachment 3 then states the following must be included on the label:
 - *'the information recorded for the label in the relevant APVMA file under subparagraphs 21(c)(iii) and (iv) of the Code'.*

If a holder is to check the AgVet Code and/or its regulations, they are unlikely to be enlightened as to requirements. As an example:

- The AgVet Code Regulations, at reg 17(1)(j) state:
 - Particulars that are prescribed include *'particulars determined by the APVMA CEO under subregulation (2)'*; and

- The AgVet Code at Section 21(c)(iva) requires '*any other particulars prescribed by the regulations*' to be recorded by APVMA.

The reference to 'conditions' and 'particulars' and numerous cross-referencing to other references can and does result in holders becoming confused as to what information is required on the label.

The currently issued notices obfuscate rather than clarify label requirements.

Correction of the error at section 81 of the AgVet Code is welcomed. However, to improve consistency of label information, it is recommended that APVMA be required to state, when notifying a holder of a label approval, the information that:

1. Must be on the label; and
2. Should be on the label.

Providing clear guidance as to specific requirements for individual labels would reduce confusion and improve consistency and compliance.

Proposal 12 – Improving dealings with suspended approvals and registrations (variation of approval or registration during suspension)

No comment is made on this proposal.

Proposal 13 – Address anomalies in matters that can be prescribed for the statutory criteria (safety, efficacy, trade and labelling criteria)

While the proposal to address anomalies in the AgVet Code in relation to labelling criteria, overseas trials/experiments and overseas assessments is supported, the proposal to allow the making of regulations to prescribe matters that the APVMA **must** have regard to is questioned.

Technology is changing rapidly. Any prescriptive approach adopted today might not be applicable to novel technologies developed tomorrow.

It is suggested that APVMA be required to publish the underlying requirements and to suggest rather than mandate options for satisfying those requirements.

By stating the underlying requirements, the applicant has flexibility to address those requirements by the most appropriate means available. As an example, overseas trial data might provide adequate information to

indicate the product will be effective under local conditions. This information might be sufficient to obtain registration or, if APVMA ultimately considers additional data are required, to enable a provisional registration (Proposal 1) to be issued requiring confirmation the product is effective to be demonstrated under local conditions.

Proposal 14 – Simplifying APVMA corporate reporting requirements (annual operational plans)

No comment is made on this proposal.

Proposal 15 – Align the 2014 legislation review with the overarching review of agvet chemical legislation (other amendments)

No comment is made on this proposal.

Proposal 16 – Make minor and machinery changes to the Administration Act and Agvet Code (other amendments)

The proposal to remove redundant sections and to otherwise clarify and update the relevant legislation is supported.

Proposal 17 – Other Amendments from the Agriculture and Water Resources Legislation Amendment Bill 2016 (other amendments)

No comment is made on this proposal.