CropLife AUSTRALIA

SUBMISSION IN RESPONSE TO APVMA DRAFT REGULATORY GUIDELINES

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INTRODUCTION

CropLife Australia (CropLife) is the peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia. The Australian Pesticides and Veterinary Medicines Authority (APVMA) draft regulatory guidelines (the guidelines) are intended to be a comprehensive risk framework for agricultural and veterinary chemicals and as such CropLife and our members have a strong interest in any proposed amendments.

Over the last three years, CropLife has advocated for the preparation and completion of the guidelines well in advance of the commencement on 1 July 2014 of the amended *Agricultural and Veterinary Chemicals Code Act 1994*. Whilst it could be argued that there has been sufficient time for the APVMA, it is a completely unrealistic timeframe for registrants. It has not recognised the practicalities of preparing and submitting an application for a new active constituent or chemical product, let alone provided a reasonable timeframe in which registrants can prepare and train relevant staff to ensure they are able to seamlessly transition to the new scheme. The capacity to comprehensively review the guidelines has been significantly impacted by:

- The short consultation period;
- The size of the guidelines and no documented changes to refine areas of review;
- The lack of an all-inclusive single version (either electronic or hardcopy) of the guidelines at the start of the consultation process;
- The hardcopy version eventually provided was found to be missing in excess of 200 pages of data guidelines; and
- A significant number of tools and legislative instruments still yet to be developed

Concerns also remain that the guidelines are not sufficiently detailed to provide the necessary information or guidance on process for the wide range of potential applications the APVMA will need to assess. It will not be possible for applicants to adequately prepare high quality applications without a full understanding of the tests that will be applied and the information that will be necessary to satisfy regulatory requirements. As such, CropLife expects the guidelines to be a dynamic document, enabling issues in regards to comprehensiveness, readability, and errors that come to light over time, to be rectified as soon as identified.

CropLife concedes that the development and implementation of reform outcomes resulting in a new regulatory program have been a significantly extra burden on the APVMA and that both the required resources and timeframes of introducing the new system were not reasonably accounted for by the Department of Agriculture.

CropLife reserves the right to revise or otherwise alter its position in relation to any issue as it considers additional information that is not available at this time. The consequences of all changes cannot be fully considered in the time available for comment on the draft.

1. GENERAL CONCERNS/RECOMMENDATIONS

1.1 Transitional arrangements

There is a lack of certainty within the APVMA as to what the transitional arrangements are for applications submitted prior to 1 July 2014. The common questions resulting from the information sessions and posted on the APVMA website state that an application (for approval, registration or variation) submitted before 1 July 2014 will only be determined under the old legislation if a notice under section 11A has been issued in relation to that application before 1 July 2014. **CropLife recommends** that the APVMA publicly confirm the transitional arrangements (including fee clarification) and ensure all APVMA staff are informed to guarantee consistency in interactions with industry and the general public.

1.2 Online Portal

Whilst CropLife understands that the online portal is not expected to be functional in time for implementation of the guidelines, **CropLife recommends** the following functions that will improve user experience:

1. Print option – the ability to print an application once it is submitted electronically would ensure the hardcopy kept by the registrant is the same as that received by the APVMA.

2. 'Off-line' applications – the development of an application is a time consuming process. Enabling registrants to develop applications 'off-line' will assist registrants in completing applications when an internet is not available.

1.3 Efficacy coordinator

CropLife commends the APVMA in the creation of in-house Health and Environment Coordinators, which have led to improved efficiency, consistency and clarity in assessments conducted by the Department of Health and the Department of Environment. **CropLife recommends** expanding this function to creating an Efficacy Coordinator, which would lead to similar benefits in efficacy assessments.

1.4 Evaluation planning

CropLife understands that evaluation planning is to occur after an application has been accepted. **CropLife recommends** that evaluation planning outcomes be made available to the registrant once determined, allowing registrants to plan accordingly.

1.5 Fees

Whilst the fees and time frames for the Items and Modules that apply from 1 July, 2014 have been clearly communicated, there are issues surrounding the fee structure that have not been well articulated by the APVMA in the draft regulatory guidelines. Some examples are as follows:

- What part, if any, of the fees will be refunded for refused applications?

- What portion of the module fee will be waived for applications where certain part(s) have already had a supportive assessment conducted (as part of an overall previously refused application, or where the part has been assessed under Item 25)?

Also, through discussions with the APVMA it became apparent that new modules need to be developed to cover situations where completed (supportive) assessments are provided for individual parts (with the relevant data) with a submission. In these situations, **CropLife recommends** a reduced fee to cover the data protection and finalisation process only.

1.6 Refused applications

The draft regulatory guidelines do not currently provide sufficient detail on refused applications and how they will be handled. Applications refused based on one part or parts being defective, should continue being evaluated (with the agreement of the applicant), even with the knowledge that the ultimate result will be a refusal.

1.7 Holders

Significant questions still remain with regard to holders, applicants, nominated agents and authorised agents. **CropLife recommends** providing succinct definitions, particularly explaining any differences between 'person' and 'company' and the nomination process.

1.8 Co-formulant composition

Co-formulants may not be manufactured by the registrant and the composition of co-formulants is strictly confidential to the supplier. For chemical products containing co-formulants, the chemistry evaluator may decide that the composition of co-formulants must be assessed to enable registration, which may involve the Office of Chemical Safety, Department of Health. Providing the composition of co-formulants to the APVMA when manufactured by a third party can be difficult and time consuming and may lead to applications being refused due to the statutory timeframes imposed by amended legislation.

To provide registrants with predictability as to whether the composition of a co-formulant is going to be required during evaluation prior to submitting an application, **CropLife recommends** establishing a list of 'approved' co-formulants that have been evaluated as part of an application.

1.9 Reference number for information submitted before an application is lodged

In regards to the above concerns, information to be submitted in support of an application may not be in the possession of the registrant. To ensure the required information is given to the APVMA within 7 days of lodging an application, the registrant may need to request a third party to submit the information before an application is lodged.

As such, there is a definite requirement to suitably track information given to the APVMA before an application is lodged. **CropLife recommends** the allocation of reference numbers for information submitted before an application is lodged, that can be entered into the online portal when lodging an application.

1.10 Conditional registration

CropLife recommends that the APVMA consider utilising amendments to the legislation that allow for the implementation of conditional registrations. Conditional registrations are any time limited registration that has conditions attached. Conversion to a full registration is 'conditional' upon the conditions imposed by the APVMA being met.

The major benefits of conditional registration include:

1. Reduced total cost of registration (including time to market)

- There are products for which small plot trials are not practical, e.g. pheromones. Their mode of action is, however, well known and effects could have been demonstrated elsewhere. At present, such products need large scale trial permits that can require assessment of data. It would be better if the assessment was done as part of the registration, the registration was conditional upon the area treated being limited and data being provided to the APVMA within a specified time. This would have the advantage of the APVMA needing to review the application once rather than initially as a permit application and then again as a registration application.

- If there is substantial information available to support use of a product but the information does not fully conform to APVMA requirements, a conditional registration could allow the product to be commercialised while data conforming to requirements is generated, provided to and assessed by the APVMA. There would be no need to delay commercialisation waiting for the required data to be generated but the APVMA would still receive the required data and would be able to assess those data.

2. Reducing the possibility of applications being refused as a result of minor data requirements or other requirements that are unlikely to prevent a product being ultimately registered

    - The APVMA will be required to refuse applications if there are data gaps that cannot be filled within the available time.
    - These data gaps might be some confirmatory efficacy data, some additional stability data, additional method validations, etc. The data gaps could be that one or more studies were not conducted in accordance with APVMA requirements, e.g. a storage stability study conducted in packaging larger than that proposed for the commercial pack or analytical methods used percent area rather than a standard. At present, the registration is delayed until data conforming to APVMA requirements are provided to and assessed by the APVMA. Under the new legislation if, say a stability study will require longer than the available time, the APVMA would be required to refuse the application.
    - Granting a conditional registration subject to the required data being supplied within a realistic timeframe would avoid the need to refuse the application.

3. Facilitating registration of minor uses

    - Registration of minor uses is hampered by the cost and data requirements.
    - Products for niche use patterns or markets may not justify the cost of registration for situations that would not provide a reasonable return on investment in a reasonable time.
    - Use of overseas data, scientific arguments, etc could allow the APVMA to be reasonably 'satisfied' a product could be used.
    - Products could then be registered conditional upon confirmatory data being provided to the APVMA within a specified time, i.e. Australian producers would have access to products that would otherwise not be available due to the small size of the market.
    - Existing products could be conditionally registered for minor uses subject to confirmatory data being provided to the APVMA.

Such use of conditional registration would enable the product to be registered instead of continuing to be sold under permit, which commonly needs to be renewed, i.e. there is an incentive for the registrant to add the use to the label and may reduce resource requirements within the APVMA.

2. SPECIFIC CONCERNS/RECOMMENDATIONS

2.1 Principles of good regulatory science practice

6. – Advice from agencies, technical service providers and international sources, page 344
This section needs to be amended to clarify that the advice provided by agencies, technical service providers and international sources will be critically considered before a decision is made on whether to include it in regulatory decision making.

2.2 Make an application

4. – Putting your application together – approval, registration, variation, page 29
The APVMA information sessions correctly highlighted the impact of regulation 5A, being that any information supporting an application must be given to the APVMA within 7 days of lodging an application. The regulatory guidelines are distinctly silent on this requirement. **CropLife recommends** amending the regulatory guidelines to further explain the requirements and timelines associated with lodging an application.

11. - Application aid tool, page 58
The guidelines state that the tool to assist registrants lodging an application, Application aid, will not be available until 1 July 2014. To assist registrants prepare for the implementation of Application aid, **CropLife recommends** that the APVMA publicly provide updates on its expected functionality and availability as soon as possible.

2.3 Information and assistance

2. - General assistance, page 94
Pre-application assistance is only going to be available to applicants with pending applications. CropLife is concerned that there is no provision to cover the discussions CropLife members have historically held with the APVMA years in advance of a new, complex and innovative application. These discussions have enabled the eventual registration of particularly innovative products that the APVMA would not have otherwise been capable of assessing, particularly considering the introduction of statutory timeframes. **CropLife therefore recommends** the inclusion of 'General assistance' with no scheduled fees, to ensure this practice continues.

2. - General assistance, page 94
CropLife is concerned that it will take 10 working days to respond to a query. This is a ridiculous length of time that will potentially lead to costly delays for applicants. **CropLife recommends** reducing the time to respond to a query to 3 days.

4.1 & 4.2 - Technical assessment, page 324 & 325
In certain situations, registrants with complex applications may decide to request a technical assessment (Item 25) due to the additional flexibility and certainty it provides. CropLife understands that the technical assessment can then be used in support of an application. Unfortunately, the description of a technical assessment in the guidelines does not sufficiently explain when a technical assessment can be requested and why a registrant would consider doing so**. CropLife recommends** expanding the definition of a technical assessment within the guidelines to ensure both APVMA staff and potential applicants can fully understand its uses. As previously stated, CropLife understands that a technical assessment can be used in support of an application. The regulatory guidelines should detail whether a technical assessment needs to be re-submitted as part of an application to have it assessed as part of an application. The impacts on data protection also need to be detailed. In this situation, the fees for a technical assessment have been paid. Registrants should not be required to pay the full fee if re-submission is required (i.e. a reduced fee should apply to cover data protection/finalisation only)

2.4 Reconsideration

7. – What happens if the reconsideration involves protected information, page 571
If mediation fails to reach an agreement as to the terms of compensation, an arbitrator is appointed. CropLife understands that the arbitrator must make a determination as to which proposal is most reasonable to allow the APVMA to use the protected information for the purposes of reconsideration. The guidelines do not clearly specify that the arbitrator must make a determination as to which proposal is most reasonable, unless fresh proposals are determined to be unreasonable. **CropLife therefore requests** further clarification regarding arbitration.

2.5 Agricultural – Approval of a new active constituent

1.1.3 - Stability data, page 1043
The identity of degradation products is now required. Further detail is required to clarify that this does not apply to all degradation products, only those that are toxicologically significant.

1.1.4.1 - Manufacturer and manufacturing site, page 1043
The name and street address currently provided for the manufacturer and manufacturing site clearly identify where a product is manufactured. Adding an arbitrary administrative burden to this process by now requiring GPS coordinates is unwarranted as it does not provide any greater ability to verify a site of manufacture. This information is not readily available and represents an unnecessary requirement with no added benefit.

2.6 Agricultural – Registration of an agricultural chemical product

1.1.4 - Formulation composition, page 1045
Certificates of analysis for each constituent in a formulation are not easily sourced and would only provide details on non-active constituents relevant to a specific batch of the material. Certificates of analysis are also likely to show a narrower range for the constituent parameters than that which could be supplied, according to the technical specification. A technical specification would provide sufficient information about the constituent, as the supplier will be manufacturing the constituent to comply with the technical specification. CropLife considers the current process of providing the Safety Data Sheets and technical specifications to be more effective and efficient in providing the required information on formulation composition. CropLife is also concerned that the complexity involved in arranging for a number of non-active constituent suppliers to provide certificates of analysis in a timely manner will result in applications being far too readily rejected due to statutory timeframes.

2.7 Agricultural – Approval of a new source of an active constituent

2.1.14 - Analytical reference standards, page 1052
The provision of reference standards is currently only required for a new active constituent, not a new source. **CropLife recommends** amending this section to align with existing requirements.

2.8 Agricultural – Generation of storage stability data for agricultural chemical products

2.6 - testing intervals, page 1042
Testing every 6 months for real-time testing is not practical, nor is the information readily available in global data sets. **CropLife recommends** amending this section to requiring initial and then annual testing for long-term studies.

2.8 - Containers, page 1042
Extrapolation of stability to sizes greater than 50 per cent in volume should be possible for some formulation types i.e. pack size would have little effect on solid formulations. **CropLife recommends** adding some flexibility to this section.

3.1.5 - Persistent Foaming, page 1042
Current CIPAC method for persistent foaming is MT 47.3. This section requires amendment to reflect current methods.

3.1.6 - Suspensibility, page 1042
MT 184 is a revision of methods MT 15.1, MT 161, MT 168 and MT 177. This section requires amendment to reflect current methods.

3.2 - Parameters to be tested in stability trials, page 1042
The introductory paragraph states that the relevant physical chemical properties of each formulation type should be monitored before and after storage. Previous APVMA advice determined that the 'Low temperature stability' test parameter for liquid formulations such as SL, LS, OL, UL, EC, DC, EW, ES, ME, SE, SC, FS, OD is only applicable before storage and does not need to be repeated after storage. **CropLife recommends** amending this section to remove all the 'Low temperature stability' test clauses from the relevant tables, or at least indicating on the tables that this clause is only applicable before storage.

3.2 – Parameters to be tested in stability trials, page 1042
Current CIPAC method for persistent foaming is MT 47.3 and for suspensibility, MT 184 is a revision of methods MT 15.1, MT 161, MT 168 and MT 177. This section requires amendment to reflect current methods.

2.9 Agricultural chemical products – Toxicology (Part 3)

2.2.1 - Submission, page 1036
More specific detail is required on the scientific arguments the OCS may consider of sufficient regulatory value as to grant a data waiver.

2.2.4 – OECD format, page 1036
The template provided in Section 4 should be the primary format for submitting data packages. As such, **CropLife recommends** that the OECD format should be referred to as an acceptable format, not the preferred format.

3.0.3 – Toxicokinetics and metabolism, page 1036
A default dermal absorption value of 100% is excessively conservative and out of step with other regulatory authorities. For example, the European Union's default absorption values are: • 25% for products containing > 5% AI, • 75% for dilutions containing ≤ 5% AI

3.0.8.1 – Chronic toxicity studies, 1036
The requirement to use both a rodent and non-rodent species with rats and dogs preferred is out of step with other regulatory jurisdictions, such as the EU and USA, where a 1-year dog study is no longer a requirement.

2.10 Agricultural chemical products – Residues (Part 5A)

2.1 – Residue studies, page 1037
The use of terms such as "confidence" and "probable sources of variation" are ambiguous and open to interpretation. CropLife recommends rephrasing to be more prescriptive.

2.7 – Fate of residues during storage, page 1037
Internationally, a timeframe of 30 days of deep-frozen storage is considered acceptable without any storage stability data. For example, OECD 506, para.4 states: "If MOR samples are always analysed within 30 days of their storage in frozen conditions, applicants can omit conducting a freezer storage stability study provided justification is given e.g. basic physical chemical properties data show residues are not volatile or labile".

2.11 – Special requirements for seed dressing, page 1037
The requirement to determine the fate of seed dressings to be used on cereal seeds when fed to livestock is out of step with international guidelines e.g. Codex/JMPR and OECD. Seed treated with a seed dressing should not be fed to livestock and therefore feeding studies using treated seed should be considered unnecessary. CropLife suggests revisiting the former Standing Committee on Agriculture's special requirement for seed dressings to be used on cereal seeds.

2.11 Agricultural chemical products – Occupational Health and Safety (Part 6)

2.2 – Data summary, page 1027
Registrants would benefit from an understanding of the exposure models that the OCS will use to evaluate the risk to domestic users/bystanders/public.

2.4.4 - Dermal absorption, page 1027
Refer comments for Agricultural chemical products – Toxicology (Part 3), 3.0.3. Toxicokinetics and metabolism.

2.12 Agricultural chemical products – Environment (Part 7)

1. - Introduction, page 805
The Environment Protection Branch of the Department of the Environment evaluates environmental data on behalf of the states or territories, who then advise the APVMA. CropLife believes the APVMA could more efficiently deal with environmental aspects of pesticide applications by having greater flexibility. Therefore, **CropLife recommends** that the APVMA consider editing the data guidelines for Agricultural chemical products – Environment, removing specific references to the Department of Environment to give this flexibility in the future.

2. – Overview of the assessment process, page 805
The reliability of the source/reference is considered a key factor in this context to minimise potential waste of resources due to the use of 'false positive endpoints'. **CropLife recommends** introducing points raised in 4.1.1 – Quality of submitted studies here to emphasise its importance.

2. – Overview of the assessment process, page 805
A clear definition on what is considered a '*major*' and/or '*significant*' metabolite is required.

4.1.6 – Formulation data, page 805
Exemptions should be considered where toxicity is modified by the formulation (e.g. slow release, encapsulated formulations, and granules). In such cases, formulation data may be more relevant for the risk assessment.

4.2.1.5 - Combination toxicity testing, page 805
There is inconsistent wording for combination toxicity throughout the data guidelines. **CropLife recommends** amending Part 7 section 4.2.1.5 Combination toxicity testing, to be consistent with Part 3, page 1036: 3.0.13.3 Toxicity of mixtures and 2.5 Extrapolation of data.

6. - Format for submission of Part 7 environment data, page 805
The Environment guideline recommends submissions in OECD format. The OECD format should be referred to as an acceptable format, not the preferred format. For consistency across all application parts the APVMA should provide a clear document template consistent with that provided in other application parts. This is particularly important where a less comprehensive application may only need to address particular data points. **CropLife recommends** that a template for dossier submissions should be provided, not a reference to another organisation (i.e. OECD).

2.13 Agricultural chemical products – Pesticides efficacy and crop safety general guideline (Part 8)

2.1.7 – Pilot, pivotal and commercial-scale studies, page 978
In the development of new products/formulations, 'pilot' studies where more consecutive applications than the final label will recommend are applied to determine optimum rate and ensure efficacy is due to the new product and not influence/biased by the performance of other actives. 'Pivotal' data use patterns are designed primarily for resistance management, not efficacy and the presence of other rotational chemistry can influence the net result and not reflect the performance of the product being presented. Data reflecting the rotational nature of use patterns is important, but should not overshadow the importance of evaluating the proposed new product on its own merits. As such, "pilot" data should have more or equal weight in the evaluation of new products since they demonstrate the true efficacy of a product.

2.1.8 – Optimal rate, page 978
This section defines optimal rate as being the lowest rate that provides acceptable efficacy. Acceptable efficacy from a statistical viewpoint maybe 95% or 98%, but from a commercial/farmer viewpoint efficacy may need to be 100% if pest freedom is required. As such, the wording should be changed to commercially acceptable efficacy.

2.1.11 – Trial locations, page 978
The need to run trials in each major geographic or climatic area is overly prescriptive. Currently trials are undertaken in a number of different areas to demonstrate that efficacy is not dependent on environmental/climatic factors. CropLife is also concerned that extrapolations from protected cropping to open are unlikely to be acceptable. Protected cropping is an area with limited registrations, which results in increase pressure on what is registered. Adding additional barriers to registering in protected cropping situations is likely to make the situation worse. CropLife agrees that from a residue perspective, there should be a number of separate trials, but from an efficacy/crop safety perspective there should be some leeway to extrapolate based on a limited number of trials. **CropLife recommends** amending this section to enable extrapolations from open to protected and vice versa in certain situations.

2.1.12 – Cultivars, page 978
The statement that trials should be run on the most widely used commercial cultivars is overly prescriptive. Crop safety trials should include the most widely used commercial cultivars, but efficacy trials, where a single pest species is targeted e.g. SFNB in barley, cultivars should be selected based on which one will be most useful in providing the required information about chemical efficacy.

2.1.13 – Application method, page 978
Requiring 3 or 4 commercial application boom spray trials to show that efficacy with hand held booms is equal to commercial boom sprays is onerous, time consuming and may lead to applications being rejected due to exceeding statutory timeframes. Currently, providing evidence that the spray droplet size and water volume were equivalent is acceptable. Furthermore, if there is a reduction in efficacy with hand boom -vs- commercial boom the legal responsibility sits with the registrant. **CropLife recommends** amending this section to align with existing requirements.

2.1.17 – Good laboratory/trial practice, page 978
Good Laboratory Practice for efficacy trials would impose significantly higher costs on registrants to run trials that are not realistic/comparative to grower/farmer practice. **CropLife recommends** deleting this section as section 2.1.16 – Good agricultural/industry practice adequately covers requirements in this area.

3.1 – Recommendations for mixtures, page 978
The requirement of mixture recommendations to appear on both labels creates a chicken and egg situation. Even if the two product labels are submitted at the same time the review will be separate and until one is registered, there is no evidence of the supporting label claim. **CropLife recommends** amending this section so that a letter of intent or equivalent is acceptable.

3. ERRORS

Page 288
The last sentence of the second paragraph does not make sense: "If within this period you do not submit the other information specified by the legislative instrument, you are taken to have lodged your application."

Page 934
Compatibility statements: "The inclusion of general information on compatibility is not a relevant particular of a label. It and is not mandatory" should probably read: "The inclusion of general information on compatibility is not a relevant particular of a label and is not mandatory."

Page 522
Permit – 2nd paragraph: "The assessment period…..notice advising you that you application…" The second "you" should be "your"

Page 83
Application fees and assessment periods: Module 2.4 is missing.

Page 109
How to apply for pre-application assistance-"*We will only accept request*…." should be "*We will only accept a request*…."

Page 35
Paragraph repeated with almost identical information: Intended to guide you through each step of the application process. It will also provide an estimate of the timeframe and fee for application. Available from 1 July 2014. Intended to guide you through each step of the application process, the application aid will also provide an estimate of the timeframe and fee for application. Available from 1 July 2014.

Page 991
Rights to review decision, 5th paragraph: "*When we consider a decision, we must confirm, vary set aside…"* should be "*When we consider a decision, we must confirm, vary and set aside…"*

Page 988
Supplying restricted chemical products, 2nd paragraph: "A person must not supply a restricted products, or cause…." should be "A person must not supply a restricted product, or cause…."

CONCLUSION

CropLife is disappointed that the APVMA draft regulatory guidelines consultation process was not more effective, but concedes that the majority of issues were as a result of limitations on time and resources outside of the APVMA's remit. Even considering the recommendations within this submission, CropLife remains concerned that the APVMA draft regulatory guidelines do not currently provide adequate guidance to allow an applicant to submit a fully compliant application. As such, CropLife will continue to work constructively with the APVMA, post consultation period to ensure that issues in regards to comprehensiveness, readability, and errors are rectified as soon as identified.