Representing **the best** of the plant science industry

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28 April 2017

Dr Rebecca Doolan
Regulatory Reforms Team
Therapeutic Goods Administration
PO Box 100
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Dear Dr Doolan

CropLife Australia (CropLife), the national peak industry organisation representing the agricultural chemical and biotechnology (plant science) sector in Australia provides the following comments on the Scheduling Policy Framework review and associated consultation paper.

The delays and unpredictability associated with poison scheduling have long been a serious concern of the plant science sector, as it leads to unnecessary delays to the introduction of new and innovative crop protection products to the Australian market. All too often, and for reasons outside of the applicant's control, one of the three lodgement deadlines for scheduling applications a year are missed, delaying the introduction of critical crop protection tools that Australian farmers desperately need. Many crop protection products have short annual application windows and the four-month delay until the next lodgement deadline is effectively an entire farming season.

Poison scheduling is a necessary and useful undertaking, ensuring adequate controls on how medicines and chemicals are made available to the public. CropLife's concerns are specifically regarding the inefficiency and unpredictability of the process, which not only delay the introduction of new and innovative products into the Australian market, but are also out of step with the Global Joint Reviews (GJRs) process. Agricultural chemical products associated with GJRs are registered and available for use in all GJR international jurisdictions other than Australia. This is solely due to unnecessary processes and structural delays associated with poison scheduling in Australia. These unnecessary and costly delays in product availability will continue until the scheduling system significantly improves its timeliness and predictability.

The *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009* provided for revised scheduling arrangements that commenced on 1 July 2010. This included the conferral of the power to make amendments to the Standard for the Uniform Scheduling of Medicines and Poisons, more commonly known as the Poison Standard (the Standard), to the Secretary of the Department of Health or their delegate. Decisions not deemed sufficiently straightforward to enable a delegate-only decision continued to be referred to the Advisory Committee on Chemicals Scheduling (ACCS) for advice and recommendation to the Secretary of the Department of Health (or delegate) on the level of access required for medicines and chemicals.

These amendments had the commendable intention of increasing the number of delegate-only scheduling decisions, allowing straightforward decisions to occur outside of the regular ACCS process and thereby markedly improving the timeliness and predictability of the process. Unfortunately, this amendment failed to deliver on its intent. Delegate-only decisions are not legally enforced until the Standard is amended and this only occurs after ACCS has met at one of its three meetings a year to finalise proposals to amend the Standard, following its exhaustive and time consuming public consultation process.

Expediting the legal standing of delegate-only decisions by enabling amendment to the Standard outside of the regular ACCS process is a necessary refinement to streamline the scheduling process for agricultural chemicals, which is disappointingly missing from the consultation paper. **CropLife recommends** amendments to enable delegate-only decisions to be considered legally enforced when made, enacting the intention of the revised scheduling arrangements that commenced on 1 July 2010. Delegate-only decisions would continue to be considered by ACCS, providing the opportunity for revision. The risk of a change to scheduling following consideration by ACCS and the associated cost of relabelling would be assumed by the applicant.

The consultation paper also fails to address the time lag between the final decision of the ACCS and the publication of the updated Standard. Reducing this time lag through the introduction of a mechanism such as electronic publication or webpage, would streamline scheduling processes by several months. As an example, for the July 2017 scheduling meeting, the final decision is due 31st October 2017. The publication date is 1 February 2018, which is an additional three (3) months later. This delay is unnecessary given that the final decision has already been made. Fixing this aspect alone could also save time in the Australian Pesticides and Veterinary Medicines Authority's (APVMA) registration process.

It is important to note that the purpose of the 2010 revised scheduling arrangements was to address these poison scheduling efficiency issues. It is only through a technical drafting error in the legislative amendment, that we now have these unintended delays. The scheduling system is not working as efficiently as the Government intended and we are only seeking a simple correction to legislation so it operates as originally envisioned. This is a matter that CropLife has been pursuing for some time and attached for your reference is a copy of our letter to the then responsible Minister, Senator the Hon Fiona Nash, Minister for Rural Health.

The consultation paper policy recommendation to consider a chemicals scheduling delegate within the APVMA has strong merit. A chemicals scheduling delegate within the APVMA would mean that agricultural chemical products would only require consideration by ACCS, in the first instance, if the delegate deemed it not sufficiently straightforward, or if the applicant disputed the delegate decision. Given that there are specific guidelines on how to schedule a product, this outcome should not be an issue. The regular ACCS process would continue to perform its role in the background. While CropLife supports this policy recommendation in principle, improvements to APVMA internal processes and enabling delegate-only decisions to be considered legally enforced when made are necessary for any benefit to be realised.

Introducing a chemicals scheduling delegate within the APVMA would also benefit from amendment to the current policy on changes to existing entries in the Standard. At present, changes to existing entries in the Standard can only be considered by the ACCS, not the delegate. The associated extended timeframe acts as a deterrent for applicants to introduce less toxic formulations to the Australian market. New formulation types that exhibit lower toxicity than the formulation that created the entry in the Standard should be encouraged, and enabling a process to streamline changes to existing entries would provide this. **CropLife recommends** amendments to allow delegate-only decisions for changes to existing entries in the Standard.

The recommended business improvement measure to improve decision transparency and information sharing, specifically the recommendation to develop a mechanism to allow early information sharing between the APVMA and the scheduling secretariat, should be of some benefit. Improving awareness of a product's proposed timing of use could help avoid situations too frequently experienced by registrants of agricultural chemical products. Australian farmers are regularly unable to access desperately needed products, for an entire season in many situations, when one of the three ACCS meeting deadlines per year are unnecessarily missed, delaying scheduling by four (4) months.

Finally, the Scheduling Policy Framework requires further amendment to remove unnecessary discrimination of agricultural chemicals, compared to their pharmaceutical chemical counterparts. As it stands, applicants for pharmaceutical chemicals can submit applications, including assessments undertaken internally or by an external consultant, for scheduling directly to the scheduling delegate. Whereas, agricultural chemical scheduling applications must be made directly to the APVMA for assessment and evaluation prior to the application then being referred to the Department of Health for scheduling. **CropLife recommends** aligning agricultural chemicals with pharmaceuticals by enabling either the APVMA or the applicant to make scheduling submissions. In some situations, this will provide the registrant with more control on when submissions are made for scheduling and therefore reduce the risk of missing key deadlines.

Implementing our recommendations will assist in delivering genuine improvements in efficiency and predicably in the scheduling of agricultural chemical products. Please do not hesitate to contact CropLife's Director of Agricultural Chemical Policy, Mr Alastair James, should you require clarification or elaboration on any aspect of this submission.

Yours sincerely

(SIGNED)

Matthew Cossey
Chief Executive Officer

Attach:

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16 November 2015

Senator the Hon Fiona Nash
Minister for Rural Health
PO Box 6100
The Senate
Parliament House
CANBERRA ACT 2600

Dear Minister

I write to raise my serious concern with the delays and unpredictability associated with poisons scheduling, which is resulting in substantial additional and unnecessary delays to the introduction to the Australian market of new and innovative crop protection products. In some specific cases, poisons scheduling alone has delayed the introduction of crop protection tools that farmers desperately need by in excess of eight months. Revisions to scheduling arrangements to increase the number of delegate-only decisions were meant to streamline this process, but technicalities appear to have completely undermined that promised efficiency.

Scheduling is a national classification system that controls how medicines and chemicals are made available to the public. Medicines and chemicals are classified into Schedules according to the level of regulatory control over the availability of the medicine or chemical required to protect public health and safety. It is an inefficient and unpredictable process that not only delays the introduction of new and innovative products into the Australian market, but is also out of step with Global Joint Reviews (GJRs). Agricultural chemical products associated with GJRs are registered and available for use in all involved international jurisdictions other than Australia, solely due to unnecessary delays associated with scheduling. These embarrassing situations will continue until the scheduling system significantly improves its timeliness and predictability.

The *Therapeutic Goods Amendment (2009 Measures No. 2) Act 2009* provided for revised scheduling arrangements that commenced on 1 July 2010. This included the conferral of the power to make amendments to the Poisons Standard (the Standard) to the Secretary of the Department of Health or their delegate. Decisions not deemed sufficiently straightforward to enable a delegate-only decision are referred to the Advisory Committee on Chemicals Scheduling (ACCS), a statutory committee under the Therapeutic Goods Act 1989, for advice and to make recommendations to the Secretary of the Department of Health (or delegate) on the level of access required for medicines and chemicals.

These amendments had the laudable intention of increasing the number of delegate-only scheduling decisions, allowing straightforward scheduling decisions to occur outside of the regular ACCS process and thereby markedly improving the timeliness and predictability of the process. It has, however, come to light that delegate-only decisions do not at all expedite the process. This is due to delegate-only decisions not being legally enforced until the Standard is amended. The Standard only gets amended after ACCS has met at one of its three meetings a year to finalise proposals to amend the Standard, following its exhaustive and time consuming public consultation process. Missing a deadline for an ACCS meeting can lead to delays to new and innovative products entering the Australian market by up to, and sometimes in excess of 8 months.

CropLife has regularly expressed concern to the Office of Chemical Safety within the Department of Health (the Department) about the time taken for poisons scheduling decisions to be made and the impact this has on the availability of new and innovative tools that Australian farmers desperately need. It is devastating that the revised scheduling arrangements have not achieved the improvements in timeliness and predictability that were expected. With the Department having primary responsibility for scheduling policy, I believe it is crucial that it take a leading and active role in correcting this unnecessary regulatory burden and internationally embarrassing situation. Accordingly, I respectfully request and urge you to directly involve yourself in ensuring this issue is corrected as a matter of urgency.

We would be happy to meet with you to discuss this further and provide greater context to our request. Please do not hesitate having your office contact my Policy Manager - Agchem Regulation and Stewardship, Mr Alastair James, if we can be of assistance to you and your team.

Yours sincerely

Matthew Cossey
Chief Executive Officer

cc. *The Hon. Barnaby Joyce, Minister for Agriculture and Water Resources*
Ms Kareena Arthy, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority