CropLife Australia

August 2021

Improving access to agricultural and veterinary chemicals

Exposure Draft - Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021

INTRODUCTION

CropLife Australia is the national peak industry organisation representing the agricultural chemical and plant biotechnology (plant science) sector in Australia. CropLife represents the innovators, developers, manufacturers and formulators of crop protection and agricultural biotechnology products. CropLife's membership is made up of both patent holding and generic Australian and international companies and accordingly, CropLife advocates for policy positions that deliver whole of industry benefit. The plant science industry provides products to protect crops against pests, weeds and diseases, key to the nation's agricultural productivity, sustainability and food security. The plant science industry is worth more than $20 billion annually to the Australian economy and directly employs thousands of people across the country.[1]

CropLife is pleased to provide input to the *Agricultural and Veterinary Chemicals Code (Extension of Protection Periods and Limitation Periods) Order 2021* (the Order). It is essential to ensure the incentives offered actually deliver on the stated goal of delivering new or minor use registrations to Australia's farmers, ensuring they are not disadvantaged compared to those in our major ag trading nation competitors. While many of the provisions in the Exposure Draft certainly have the potential to accomplish the addition of new uses, there will need to be substantial evaluation of the incentives and limitations placed on them to prevent "gaming" or manipulation of the data protection periods to delay the addition of uses or prevent competitors from entering the market. As currently stated, these potential circumstances both exist.

Additionally, as phrased, a large portion of products in the system would already qualify for many of the crop/pest combinations enabling extended data protection, suggesting there may be data protection period extended without adding a significant amount of new uses.

The plant science industry

The plant science industry's crop protection products include fungicides, herbicides and insecticides critical to maintaining and improving Australia's agricultural productivity to meet future global food security challenges. Each of these products is rigorously assessed by the Australian Pesticides and Veterinary Medicines Authority (APVMA) to ensure they present no unacceptable risk to users, consumers, the environment and the trade of agricultural produce.

In 1995, it took the assessment of an average of 52,500 compounds to develop one effective crop protection chemical active constituent. It now requires the assessment of more than 140,000 compounds and expenditure of more than $400 million over an 11-year period to bring just one successful crop protection product to the market. More than one-third of this cost directly relates to compliance with regulation and registration requirements. Without access to these tools, farmers could lose as much as 50 per cent of their annual production to pests, weeds and diseases.

[1] https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf

A Deloitte Access Economics report released in 2018, 'Economic activity attributable to crop protection products', estimates that up to $20.6 billion of Australian agricultural output (or 73 per cent of the total value of crop production) is attributable to the use of crop protection products.[2]

Crop protection products are crucial to modern integrated pest management techniques and systems used by farmers. Access to fewer crop protection tools would facilitate faster development of resistance among targeted pests, diminishing the efficacy of remaining chemical options. The economic impact of weeds alone is estimated to be over $4.8 billion each year, or $13 million per day.[3]

The current regulatory system for agricultural chemicals in Australia is scientifically competent, technically proficient and globally recognised. CropLife's only significant concerns with the current system relate to inefficiencies and unnecessary overlaps. The regulation of crop protection products in Australia must be efficient and effective so that Australian farmers have access to the innovative tools the plant science industry provides. This will improve the ability of Australian farmers to be sustainable, productive and internationally competitive.

[2] *https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf*

[3] *https://invasives.com.au/wp-content/uploads/2019/01/Cost-of-weeds-report.pdf*

ITEM 2: INCENTIVISING THE REGISTRATION OF CERTAIN USES

2.1 Extensions to protection and limitation periods

Extensions to particular protection periods (data protection) and limitation periods to incentivise the registration of certain uses is a concept wholeheartedly endorsed by CropLife and has been a policy and advocacy position for many years. As such, CropLife supports the incentives stated, such as introducing particular kinds of prescribed uses of chemicals, to gain extensions to protection periods and limitation periods similar to approaches applied internationally. While we support provisions extending data protections, the described mechanisms must be thoroughly evaluated to ensure they do encourage more uses to be included in the product registration and on the label, through the initial registration or a variation to the registration.

As stated, while we are supportive of the initiative in general, we have substantial concerns with the delivery of the protection periods.

Regarding the provision that applications be made at least three years before the protection period or limitation period ends (if applicable) (new subsections 34KA(3) and 34MA(3) of the Agvet Code, to be inserted by the Bill), a notification or flag on PUBCRIS will need to be introduced to clearly indicate that an eligible application has been made. The APVMA currently has the requirement to publish summaries of applications made, but we are aware of instances where applications haven't been clearly published and the current system is not searchable. As such, we feel it cannot be relied upon in its current form.

2.2 Proposed approach

Relating to the proposal that the extensions would operate by providing that information with an existing protection period, or new or existing limitation periods that relate to items 1, 2, 3, or 4 of the table at subsection 34M(1) of the Agvet Code, which may be extended for up to five years if certain requirements are met, we suggest that items 5 and 6 also need to be captured. As written, a situation could arise where an applicant submits in year 6 with a variation application and gets registration in year 7 for uses that would add five years limitation, but because this is indicated to only apply to the first 4 items, the original underlying dataset would have its limitation period extended to 15 years in total. You would, however, only get five years on the new data submitted with the variation application (so it expires 12 years after the original registration), which will become confusing to administer.

Item 3 of Table One indicates a novel means of extending limitation periods to generic or otherwise orphaned products. In concept we support this, however, the means by which this is accomplished requires a registrant to take an existing product with all data protection expired but copy the formulation onto a new registration number with a slightly different name, along with new use patterns and secure up to 10 years use limitations. If this is the intent, we suggest it would be more transparent to just include variation applications from the start.

The proposal that an application under section 26B of the Agvet Code (prescribed variations) would be an additional eligible application for extending an existing protection or limitation period is somewhat perplexing, as this is required to be made if certain details on the Register are found to be incorrect. The industry is unaware of any such event that could ever trigger an extension to data protection. Without a defined reason to include this, it just creates additional complication and requires the APVMA to develop systems and processes to cater to something that will never be used. The well documented failure of the 'interchangeable determination' regulations is a classic example of the impact ill-conceived regulations can have. These mistakes cannot continue to occur as they waste resources and distract the APVMA from higher priority reforms.

Where the information provided in connection with a variation application is deemed to be less valuable than the original information, there are no proposed extensions for this information. It is puzzling that the underlying data from the original submission is proposed to be limited for a longer period than the new data submitted for a variation. Variation applications are never stand alone. They rely on the originally submitted data. It only makes sense that they stay aligned with expiration dates for limitation periods. To do otherwise will make it seem like the limitation period on the later added use has expired (i.e., if the extension is to add wheat, no study titles in the data protection list will actually say wheat so it could be incorrectly assumed that the limitation period for wheat has expired).

Where the government proposes to restrict the extensions to information given in connection with agricultural chemical products in the first instance, the proposed order will establish the framework for expanding this to active constituents and veterinary chemical products in the future. Clarity is requested to discern whether "first instance" qualifies only the first applicant who submits. At worst, this risks encouraging incomplete, poor-quality submissions to be made that waste the APVMA's time and which will not deliver on the promise of better access to industry.

The worked examples of how extensions are to be applied do raise further concerns about the complexity of the process. The examples given illustrate some of the needless complexity. As written and demonstrated, a product could end up with limitation periods expiring for the data associated with the variation applications at two different times. This will be essentially meaningless, as the uses wouldn't be available to a third-party until the original data's extended period of protection expires.

2.3 Proposed extension periods

Clarity around the uses on crop groups (as established by the APVMA) is also requested. Frequently, there are situations where there is a legitimate reason the whole group can't be included. For example, several herbicides are safe for cereals other than oats. In these cases, it is currently unclear if the product will still qualify for the extension, or if it will be ineligible because the whole group is not represented. Specific triggers for exemptions would be welcomed, without submitting a "crop group" that limits to one crop on the group, exempting all others.

The limitation periods proposed on priority uses determined through the collaborative forum established under the Improved Access to Agricultural and Veterinary Chemicals Initiative are also confusing and poorly presented. At minimum, the list should have the scientific names for all pests listed to avoid confusion and prevent gaming the system. For example, Tea tree has a general 'psyllid' listing but there are many 'psyllids'. You could be eligible for extended data protection by registering a psyllid that is a pest in a different crop that isn't actually of concern for tea tree. In this case, the benefit to growers is not realised, but by the procedure listed, would still qualify for a limitation period extension.

Further, as the crops/pests' tables are currently listed, there are several pests listed by their common name, each associated with an extended limitation period on the same crop. They all, however, have the same scientific name. By this current table, it would be possible to obtain 18 months extension of limitation period on the same species. Lastly, a clear definition of "suppression" vs "control" would be a valuable addition to these priority uses. It is neither currently clear which claim would trigger the extended limitation period, nor what those terms specifically delineate.

The proposal also lacks a policy position on the implication of adding one or more crop groups, as well as a priority use relevant for those crop groups. For example:

- Adding Pome Fruits and Stone Fruits would allow a 12-month extension (6 months for each)
- Adding Alternaria (from a Pome Fruit listing) and Botrytis (from a Cherry listing) would allow a 12-month extension (6 months for each)
- But what if Pome Fruit and Stone Fruit were added as crops with uses for Alternaria and Botrytis, would the extension be 24 months?

CropLife supports the reflection of the proposed crop group related periods in the difference in effort required by applicants to generate data to support a particular crop group as per the 'extrapolation and data waiver guidance within crop groups' table that is set out in the APVMA's document *Representative crops and extrapolation principles for risk assessment and data waivers*. The regular review of the Order to include relevant new priority uses established through the collaborative forum and to remove priorities that have been addressed, is likewise supported. The suggested 12-month phase-out period, however, would likely be too short of a timeframe to allow for the potential need to do two seasons of trials to establish efficacy. In light of this, it could take two to three years before an application could be properly prepared. Such a short phase out will disincentivise investment in new uses.

Similarly, some of the provisions for the limitation periods on particularly small market crops may not capture the extra effort in generating data. This has been recognised in the 18 months extension for some spices and edible fungi. As currently laid out, considerable effort could be employed in navigating a "course of least effort" to establish the maximum data protection or limitation on use period, without noticeably addressing the shortfalls in product availability for specific crop and pest examples. The aim is to incentivise new uses and increase access to chemicals.

Further to this, we suggest more provision to prevent the gaming/manipulating of new use applications to product registrations may be needed. At worst, new uses could be delayed from registration, as registrants calculate their maximum limitation periods. This ability to game the proposed system runs counter to the stated *intent* of the Order, which is to incentivise new uses. Further incentives on a "point scoring" system could be included to incentivise the earlier introduction of new and minor uses, such as a multiplier effect for the addition of uses earlier in the 10-year limitations on use period.

2.4 Ending an extended period or limitation period

CropLife also supports the proposal that the Order allow for ending the protection or limitation period extension (such as where the use that led to the extension is removed). This will be a good preventative measure to ensure the protection and limitation periods are not manipulated unfairly, either through the lodging of junk applications or poor data, which prevent the entry of other registrants, or as stipulated in the example, the removal of prescribed crops or pests from the label once protection or limitation periods have been extended.

Indeed, this is but one of the examples by which the system could be "gamed" by registrants more interested in obtaining the protection and limitation periods than extending new uses to Australian farmers. CropLife agrees it would be prudent to ensure the APVMA has a mechanism to deal with this or other circumstances where it would be appropriate to end the extension period.

2.5 Application summary

CropLife supports the concept of "springboarding" whereby competing chemical companies use knowledge of the expiry date of a protection period or a limitation period to determine when they may be able to submit an application, referencing that information, to progress the development of their own generic products or innovative re-formulations and new use patterns. As noted previously in this submission, however, this system is not currently working reliably enough to inspire confidence. The only way this is fair and equitable is if a flag is raised on PUBCRIS that an eligible application has been made.

Hence, the proposal to amend regulations to provide for the summary of the variation application to include an indication that the existing protection period or limitation period may be extended as a result of granting the application is supported but must be bolstered.

ITEM 5: DETAILS THAT DIFFER FROM THE REGISTERED PARTICULARS

Standards for minor differences in constituents, concentration, composition and purity

CropLife agrees that during manufacturing processes there can be reasonable variations in the constituents contained in a chemical product (such as trace amounts of another constituent in the end product) as a result of both the concentration of constituents in a chemical product and the composition or purity of constituents in a chemical product.

CropLife maintains these minor differences may be entirely reasonable, particularly where they do not affect the safety or efficacy of the registered chemical product. The Crop Protection and Stewardship Committee of CropLife has, for considerable time, been actively engaged with the APVMA on this subject. Given that proposed regulation 41 does not allow for fundamental changes in a product's constituents, concentration, composition or purity, CropLife will work with the APVMA to develop the standards for minor formulation variations, so they come into effect shortly after the regulations are enacted.

ITEM 6: EXCLUSION OF AGVET CHEMICALS FROM REGULATION

CropLife supports enhanced means such as this to refine the APMVA product category regulatory scope. Indeed, reducing the APVMA's product category regulatory scope is necessary to improve efficiency quickly and dramatically in the core registration operations of the APVMA. Dairy sanitisers, anti-fouling paint, swimming pool chemicals and cleaners should not be regulated by the APVMA. If necessary, these product types can be more appropriately regulated by another agency. Removing these products from the APVMA's regulatory scheme will allow it to focus its resources on its core business of assessing, approving and registering agricultural and veterinary active constituents and products.

Removing the regulatory duplication of whole viable seeds is also required. Whole viable seeds that are genetically modified with incorporated pest and/or disease control, are currently regulated by the Office of the Gene Technology Regulator, Food Standards Australia New Zealand, the Therapeutic Goods Administration and the APVMA. Exclusion of whole viable seeds from regulation as an agvet chemical is a necessary and viable solution with significant efficiency gains, without compromising human health or environmental safety.

To accomplish this, it is recommended that Schedule 3, Part 3 of the Agvet Code be additionally amended to create a subsection that excludes whole viable seed and propagation materials for grafting or planting and declares them to be non-agricultural chemical products.

A technology is being developed overseas that improves the efficiency of the well understood process of applying an electrical current to a plant in order to destroy the plant[4]. This efficiency gain is via the application of conductive liquid at the front of the applicator that lowers the energy required when the electrical current is applied at the rear of the applicator. This technology has application in fallows, pasture renovation, interrow weed control, preventing seed set of resistant weeds prior to harvest and crop desiccation. There may also be some benefit in the control of other pests such as ergot in ryegrass or insects that congregate at the top of a plant where the electrical current is applied.

Whilst the electrical current per se would be excluded from the definition of an agricultural chemical product (as it wouldn't be defined as a substance), the conduction fluid appears likely to require registration in Australia and not Europe due to the 'indirect' wording in the definition. Rather than disincentivise Australian growers getting access to this technology, an exemption should be established now. Suggested wording for the exemption is "Any conductive substance used in conjunction with electrical current as a method of destroying any plant or destroying, stupefying, repelling, inhibiting the feeding of, or preventing infestation by or attacks of, any pest".

[4] *https://crop.zone/*

Similarly, in Australia the CSIRO is developing a sprayable biodegradable polymer as an alternative to non-biodegradable plastic sheeting[5]. Whilst the primary function of this technology is to prevent water loss, it also provides weed (and possibly other pest) suppression so could be captured by the definition of an agricultural chemical product. An exemption does exist for a 'physical barrier to a pest' but this excludes substances 'released into the environment' so would not apply to this technology. Suggested wording for the exemptions is "Any substance which is a biodegradable polymer applied to the soil that presents a physical barrier to a pest or plant".

Several other innovative technologies are expected to have similar potential to be captured by the current definition of an agricultural chemical product, so it is suggested a specific request be made during the next round of consultation to receive suggestions for further exclusions that can be considered by the Department.

[5] *https://www.csiro.au/en/research/production/materials/sprayable-biodegradable-polymer-membrane*

CONCLUSION

CropLife and our members are supportive of provisions to extend data protection and limitations on use in exchange for the addition of new or minor uses to product labels. In the current structure, however, there are substantial concerns that the potential exists for companies to "game" or manipulate the system.

The structure for additional data protection measures is complex, convoluted and difficult to navigate. In many cases it is difficult to understand how the pest species/crop combinations were reached.

Owing to both this complexity and lack of clarity surrounding the incorporation of many of these data protection and limitation extension periods, CropLife recommends more in-depth consultation with both the APVMA and the Industry. This would serve to better facilitate a streamlined process by which new uses and innovative formulations may be rewarded with extended data protection provisions, as well as allow for these processes to be introduced at the APVMA without adding needlessly complex and burdensome administration. As previously indicated, CropLife's significant concerns with the current system relate to inefficiencies and unnecessary overlaps. We do not wish for these measures to add to this inefficiency.

Perhaps most importantly, however, is that this process must now be expedited. As these provisions are public and the broader industry is aware of the forthcoming changes, they must be reviewed and implemented with all possible haste. For many reasons, we do not wish registrants to begin strategically withholding applications. Firstly, this will result in the opposite of the intended outcome, meaning delayed applications for new uses, while registrants calculate means of obtaining the maximum possible data protection and limitation periods. Secondly, a delay here, while registrants watch the process unfold, would mean that once the amendments are implemented the APVMA could be comprehensively overwhelmed with applications.

CropLife and our members have constructively engaged for years in all previous reform agendas and proposed specific initiatives to improve the regulatory system, both in its effectiveness and its efficiency. Despite our frustration with the slow process and lack of proper implementation of these reforms, we remain committed to continuing to work constructively with the Federal Government to ensure Australia has the world's best agricultural chemical regulator.