



**SUPPLEMENTARY SUBMISSION IN RESPONSE TO
POLICY DISCUSSION PAPER**

***BETTER REGULATION OF AGRICULTURAL AND
VETERINARY CHEMICALS***

**ANTICIPATED COSTS FROM IMPLEMENTATION OF A
RECONSIDERATION SCHEME**

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INTRODUCTION

This submission is additional to that made by CropLife Australia (CropLife) on 20 December 2010. This supplementary submission specifically outlines the likely costs that will ultimately be incurred by users of agricultural chemicals should proposals for a re-registration scheme proceed. While the ultimate cost of these proposals is dependent upon the final form of the proposal, CropLife has made conservative assumptions regarding the likely cost of implementation.

However, when indirect costs are taken into account, the final impact of the re-registration proposals is likely to significantly exceed the direct costs that have been identified in this submission.

ANTICIPATED COSTS FROM IMPLEMENTATION OF RECONSIDERATION

CropLife anticipates significant costs to registrants will accrue through the implementation of a re-registration scheme. These additional costs are likely to significantly exceed any benefits that might accrue in terms of worker safety, community or environmental protection. CropLife anticipates that costs will be incurred both through:

- The direct costs to registrants; and
- The indirect costs to users and the community resulting from reduced choices, increases in pest pressure and reductions in competition.

These costs must be fully considered once final details of the proposal are understood.

■ Direct costs

The actual cost imposed on registrants by a registration scheme will be dependent upon the precise details and construction of any reconsideration program. Critically, it will depend upon whether the scheme is initiated on an active constituent or product basis. While current chemical reviews are conducted on an active constituent basis, the Discussion Paper seems to suggest that a reconsideration scheme would operate to reconsider individual products. Assuming that a reconsideration process would require product reviews approximately every ten years, it would require the APVMA to process approximately 900 chemicals each year to work through the entire catalogue of APVMA products.

A nominal application fee of \$500 per product¹ would impose an additional \$450,000 per year on registrants. However, the cost to registrants is not limited to application fees for reconsiderations. The bulk of the cost is incurred through preparation, negotiation and internal liaison necessary to adequately and accurately answer any questions raised through the re-application process. Even questions that may be perceived as relatively simple and straight forward (such as “Does this product meet contemporary standards?”) may require significant internal research and analysis to determine whether there are additional standards that need to be met, or if current data would satisfy those standards. Should the reapplication fee exceed \$500, or the frequency of reconsideration be greater than ten years, the potential industry-wide impact would be significantly greater.

Table 1: Potential Cost of Stage 1 Reconsideration: Application Fees

Cost	Reconsideration Frequency					
	1 year	2 year	3 year	5 year	7 year	10 year
\$ 500	\$ 4.5m	\$ 2.25m	\$ 1.5m	\$ 0.9m	\$ 0.64m	\$ 0.45m
\$ 1,000	\$ 9.0m	\$ 4.5m	\$ 3.0m	\$ 1.8m	\$ 1.29m	\$ 0.9m
\$ 1,500	\$ 13.5m	\$ 6.75m	\$ 4.5m	\$ 2.7m	\$ 1.93m	\$ 1.35m
\$ 2,500	\$ 22.5m	\$ 11.25m	\$ 7.5m	\$ 4.5m	\$ 3.21m	\$ 2.25m
\$ 5,000	\$ 45.0m	\$ 22.5m	\$ 15.0m	\$ 9.0m	\$ 6.43m	\$ 4.5m

¹ CropLife expects that even for a simple check-box re-registration procedure, fees should be fully cost recovered. A fee of \$500 would be likely to reflect the true cost of each re-registration. Current annual fees to maintain a registration are \$430.

CropLife estimates that the internal cost of preparing responses to any questionnaire about a product being reconsidered would be approximately \$5,000 per product reconsideration process. Costs would be incurred through identification of appropriate and relevant ‘contemporary standards’, conducting literature searches to identify whether ‘contemporary standards’ have been met, completion of re-registration forms and procedures, and ongoing communication and liaison from the APVMA. However, it is difficult to estimate the actual cost in the absence of a clear understanding of what registrants will be required to do to meet the requirements of the scheme. CropLife could envisage an average cost per product that exceeds this figure. Similar to application fees, the total cost borne by registrants will be dependent upon the work required and the frequency of the reconsideration process.

Table 2: Potential Cost of Stage 1 Reconsideration: Costs to Registrants

Cost	Reconsideration Frequency					
	1 year	2 year	3 year	5 year	7 year	10 year
\$ 5,000	\$ 45.0m	\$ 22.5m	\$ 15.0m	\$ 9.0m	\$ 6.43m	\$ 4.5m
\$ 7,500	\$ 67.5m	\$ 33.8m	\$ 22.5m	\$ 13.5m	\$ 9.64m	\$ 6.75m
\$ 10,000	\$ 90.0m	\$ 45.0m	\$ 30.0m	\$ 18.0m	\$ 12.9m	\$ 9.0m
\$1 5,000	\$ 135m	\$ 67.5m	\$ 45.0m	\$ 27.0m	\$19.29m	\$ 13.5m

CropLife estimates that the costs of internal processing by registrants (assuming 900 products per year at \$5,000 per product) would result in an additional \$4.5m cost being borne by registrants.

Finally, for those products that may require new data or information before a re-registration is permitted, significant costs will be incurred. Generating new data is an expensive and time consuming process. Generating the required data for a minor use of an agricultural product would generally cost at least \$100,000. However, if new data surrounding the environmental effects or toxicology of a product are required, the cost of data generation could be significantly greater.

Should 2% of all products require additional data to be generated each year, this could result in an additional \$1.8m per year (assuming a 10-year reconsideration period). However, the actual cost of this data will be dependent upon both the number of products requiring additional data to be generated and the cost of generating that data. Should fewer products require data generation, the annual cost could be proportionately lower.

Table 3: Potential Cost of Reconsideration: Generating Additional Data

Cost of Data	Percentage of Products Requiring New Data			
	1%	2%	5%	10%
\$ 100,000	\$ 9.0m	\$ 18.0m	\$ 45m	\$ 90m
\$ 150,000	\$ 13.5m	\$ 27m	\$ 67.5m	\$ 135m
\$ 250,000	\$ 22.5m	\$ 45m	\$ 113m	\$ 225m
\$ 500,000	\$ 45m	\$ 90m	\$ 225m	\$ 450m

Total direct costs to registrants are therefore likely to be at least \$6.75m per annum², representing an approximate increase of 25% in total cost recovered fees imposed on registrants. Depending on the construction of the program, costs to registrants could conceivably be much greater.

² Assuming a 10-year reconsideration period, \$500 application fee, \$5000 in costs to registrants in preparing reconsideration documentation, and 2% of products requiring additional data to be generated

Between 1995 and 2008, the discovery, development and registration costs for a new active ingredient have increased from \$152m per active ingredient to \$256m per active ingredient³. Increases in development costs account for nearly 80% (\$79m) of this increase. Greater development costs occur due to registrants needing to develop additional data to demonstrate that products meet current regulatory standards. This data indicates that the cost to the industry to develop new data for an active ingredient that comes under review through the reconsideration process could be \$79m.

In addition, the opportunity costs from registrants supporting existing registrations rather than innovating, developing and registering new, safer and softer agricultural chemical products will be significant. Australia's farmers will be denied access to the chemical tools that they need to meet ongoing sustainability and productivity challenges.

Further, as this increase in cost is passed down the chemical supply chain, distributors and retailers will need to increase their prices by more than the actual increase in price to maintain an adequate margin for the product. As a result, the actual cost to farmers will be greater than the \$6.75m estimate.

While registrants will incur large ongoing costs from complying with the requirements of a reconsideration scheme, government will also incur costs in administering the new scheme along with assessing and considering data submitted by registrants. The impact on the APVMA's current registration performance must also be considered.

While industry will incur large, ongoing costs from complying with the requirements of a reconsideration scheme, governments will also incur costs through increased administration, and increased assessment and review of new data developed by registrants. This may have a detrimental impact on the APVMA's performance of its current risk assessment and registration functions.

■ Indirect Costs to users, consumers and the environment

While significant costs will be borne by registrants, these are likely to be exceeded by the indirect costs imposed upon users and consumers from imposition of a re-registration scheme. Given the current limited detail surrounding the *Better Regulation* proposals, estimations are difficult. However, CropLife expects that prior to any decision taken to formally implement these proposals, a full assessment of the likely costs and benefits must be made.

The assessment of costs must include:

- A consideration of the costs that are likely be incurred by farmers due to:
 - *Increased product costs*: Increases in the costs imposed upon registrants to maintain existing products will result in price increases for agricultural chemical products. Price rises will have an impact on farmers when deciding what pest control measures they should employ to control pest, weeds and diseases. Increases in the costs of critical farm inputs will have a detrimental impact on the income of farming communities.
 - *Reduced product choice*: If implementation of a reconsideration program occurs, CropLife expects that some agricultural chemical products will be withdrawn from the market as the cost of maintaining a registration is likely to exceed the economic return that would result from that product. This will particularly impact on horticultural and other minor uses where, due to the very small markets, the return on investment by registrants can be marginal. This could result in more agricultural industries having no products to control pests and withdrawing production.

Further, CropLife expects that increases in the cost of maintaining registrations will have a greater impact on generic, as opposed to proprietary products. As proprietary products often cost more than generic products (to recover research and development costs), the loss of generic products will increase the cost of chemical inputs to farmers.

³ PhillipsMcDougall, *Research and Development; Cost and Return*, AgriFutura No. 125, March 2010, p2

- *Weakened resistance management strategies:* Every year, experts from CropLife member companies develop strategies to manage resistance to agricultural chemicals. These strategies are widely disseminated and promoted by groups such as the Grains Research and Development Corporation, Horticulture Australia, Landmark, *ChemCert*, the Australian Wine Research Institute and several state farmer associations. Resistance management is a critical element of integrated pest management strategies. Resistance management relies of a variety of chemical products and modes of action to prevent and delay resistance developing in agricultural pests, weeds and diseases. A loss of product choices may result in chemical modes of action being lost from resistance strategies. If this occurs, CropLife would expect to see greater issues of resistant pests developing around Australia.

The ultimate impact on resistance management strategies will, of course, be dependent upon the potential that new products with new modes of action become available and mitigate the loss of other modes of action.

It should be remembered that CropLife member companies have made significant investments in developing the current resistance management strategies based on chemicals and modes of action currently available in Australia. The potential cost of developing new resistance management strategies should not be ignored.

- *Reduced pesticide market competition:* Increasing regulatory costs and barriers to market entry will decrease market competition in agvet chemicals, thereby increasing costs.
- A consideration of the costs that are likely to be incurred by consumers due to:
 - *Increased food costs:* Increasing production costs for agricultural produce will ultimately increase the prices paid by consumers for food.
 - *Increased food imports:* Reduced options for pest, weed and disease control may result in some crops no longer being able to be profitably grown in Australia. This may mean consumers resorting to produce grown overseas for some minor or specialty crops.
- A consideration of the costs that are likely to be incurred by the environment due to reduced options for controlling weeds of national significance and other environmental pests and weeds.

While CropLife has not been able to estimate the costs that are likely to be incurred by users of agricultural chemical products, we expect it to be much greater than the cost imposed by registrants in maintaining current product registrations. These indirect costs must be accounted for when preparing a regulatory impact statement for these proposals.

The experience from other countries may be indicative of the likely impact in Australia. Implementation of hazard-based criteria under EU91/414 and the Water Framework Directive in the United Kingdom may result in the loss of key chemicals required to control weeds in cereal and oilseed crops. The economic cost from the loss of essential chemicals is estimated to be £1.2bn (A\$1.95bn)⁴. If key chemistries necessary to treat significant pests, weeds and diseases in Australian major crops were lost, CropLife would expect similar economic costs on Australian growers.

CONCLUSION

CropLife cannot support an ineffective and duplicative reconsideration system while there remain other more efficient options available to government that will meet the public policy goals announced in its election platform but will not impose such significant burdens on Australia's agricultural sector. CropLife stands ready to work with the government on delivering these better outcomes but cannot support a change that contradicts the government's own stated objectives for reform.

Ultimately, Australia's farmers, as the users of agricultural chemical products will bear the cost of these proposals through increased prices for agricultural chemical products and reduced product choice. The potential flow-on effects of reduced agricultural productivity and international competitiveness will result in prohibitive impacts on Australian agriculture that far outweigh any benefit.

⁴ http://www.hgca.com/document.aspx?fn=load&media_id=5196&publicationId=5580