gene ethics
working for a GM-free future
ABN: 67 104 140 918
PO Box 400, Emerald Vic 3782
T: 03 5968 2996 E:
info@geneethics.org

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Committee Secretary
Senate Standing Committee on Rural and Regional Affairs
PO Box 6100
Parliament House
Canberra ACT 2600
T: 02 6277 3511
E: <rrat.sen@aph.gov.au>

Re: comments on the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

Thanks for this opportunity to make a submission to the Senate Standing Committee on Rural and Regional Affairs inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018. Please accord us an opportunity to also be heard in defence of our case for AgVet chemical regulation that fully respects the public interest.

Our comments respond to the government's Explanatory Memorandum, which we assume is a fair and balanced representation of the intention and effects of all the Bill's clauses.

Recommendations:

We ask the Senate Inquiry to consider, support and recommend that the Bill not be passed as now drafted. We propose and recommend instead, the following priority goals for action:

1. Consolidate, redraft and rationalize into a single piece of legislation, the quagmire of Legislation and Regulations that are now used to administer AgVet chemical affairs;
2. Restore the Chemicals Reassessment and Re-registration Act cancelled in 2014, to establish a comprehensive, effective and efficient chemical reassessment and re-registration regime;
3. Embed the Precautionary Principle[1] in APVMA legislation, regulation and practice, to prioritise effective hazard and harm prevention for human and animal health and our environments;
4. Move the onus of proof for the safety and efficacy of all toxic chemicals and veterinary medicines off regulators and civil society, onto applicants, patent owners and producers of AgVet chemicals;
5. Facilitate the timely participation of the interested and informed public, and civil society advocates, in the APVMA's regulatory affairs, including membership of the Governance Board;
6. Transfer Ministerial and Departmental responsibility for the APVMA from Agriculture to Health or Environment, where protecting public, health, safety and the environment are core business;
7. Develop a labelling standard in consultation with users, against which to measure the adequacy of all farm and domestic AgVet chemical labels, for clarity, comprehension and compliance;
8. Prioritise old registered chemicals (including glyphosate) for review using the EU model, first re-assessing chemicals that failed EU, US or Canadian assessment and are deregistered there;

[1] The precautionary principle is defined in S391(2) of the EPBC Act as follows: "lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage."

9. Inquire into all the independent evidence of glyphosate and GBH toxicity, teratogenicity and carcinogenicity, then introduce precautionary regulations and amended labels;
10. Replace the APVMA's regulatory science regime with genuine scientific methods, processes and principles, to eliminate best guesses and gap-filling from the regulator's decision-procedures;
11. Require or commission research on the risks, hazards and costs of registered AgVet chemical use;
12. Fund long term epidemiological studies of agrochemical residues in the human and animal food supplies, biomonitor the human population, and explore longer term impacts such as cancers;
13. Prioritise occupationally exposed workers, pregnant women and their children for biomonitoring;
14. Prohibit pre-harvest spraying of chemical dessicants on food crops, to reduce residues in food;
15. Require Bt endotoxins produced in GM plants to be included in pesticide use calculations;
16. Research and report on the health and environmental costs of AgVet chemical use and exposure, as a counterpoint to a CropLife consultant's benefit narrative.[2]
17. Develop enforceable, best practice, minimum standards and benchmarks, to replace all guidelines;
18. Require peer-reviewed data to be submitted, to validate all company-generated and commissioned data and to ensure that corporate trial results are replicable and verifiable;
19. Publish full applications, complete raw data and all documentation of technical assessments;
20. Expand cost recovery from the chemical industry to Treasury but, like the OGTR and some others, fund the APVMA from a Federal Budget appropriation to operate effectively and efficiently;
21. Make AgSafe programs mandatory not voluntary, including DrumMuster, so that toxin containers and AgVet chemical residues are safely and securely reused and recycled.

Comments on the Explanatory Memorandum

1. (the Bill) will amend the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act), the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) and the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act).

> **Reviewing, updating and consolidating all previous AgVet Chemical legislation and regulations, to bring them into the 21st century, should be a top priority.**
>
> The APVMA's constant problems and ineffectualness appear to stem from the government's repeated attempts to tweak old and outdated laws and regulations while the APVMA has engaged in perpetually making plans for reform that are not fully implemented.
>
> The Australian National Audit Office's (ANAO) 2017 performance audit report on the implementation of pesticide and veterinary medicine regulation reform finds that the review processes failed to deliver real reforms.[3]
>
> For instance, the APVMA could have embraced the AgVet Chemicals Re-approval and Re-registration scheme as a great opportunity to clear the decks of old and dangerous chemicals, in the interests of farm worker and public health and safety, and the environment. It may have been a chance to substantially reduce the large number of registrations and active constituents with which the APVMA deals. The old, dangerous and superseded toxics, for which safety data and testing are manifestly deficient, could have been prioritized for phase out. It was also an opportunity for the onus of proof to be transferred back onto the registrants, as they must give robust and modern evidence for the safety and efficacy of all those registered chemicals.

[2] Deloitte Access Economics (2018) Economic activity attributable to crop protection products, P1. Commissioned by CropLife Australia. https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf Deloitte candidly states, "This study is not a cost-benefit analysis and does not consider or compare the relative magnitudes of costs in relation to the benefits; for example, costs to the environment and potential health implications of their use."

[3] Pesticide and Veterinary Medicine Regulatory Reform, Australian National Audit Office (ANAO). https://www.anao.gov.au/work/performance-audit/pesticide-and-veterinary-medicine-regulatory-reform

But instead, the ANAO audit report finds that the APVMA had listed the "Re-registration scheme not Repealed" among the risks to implementing its reform program, and it notes:

> "The treatment established to manage this risk was the development of a contingency plan in the event that the re-registration and re-approval legislation was not repealed. This risk was rated 'Moderate', increased to 'Extreme' (February 2014 to September 2014), reduced to 'High' (September 2014 to May 2015) and subsequently to 'Low' in May 2015."[4]

This blinkered misreading of the risks and benefits of the scheme, particularly through a lack of meaningfully engagement with the interested public and civil society groups, squandered the chance to secure real and enduring positive change, for everyone's benefit.

2. The Bill will also repeal the Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014

We fully support this repeal and the re-establishment of the Chemicals Re-approval and Re-registration scheme.

Repeal should logically herald a new commitment to establishing and implementing the AgVet Chemicals Re-approval and Re-registration Act. As we told the Senate's APVMA Independence Inquiry hearing on December 7:

> "The APVMA regulates over 11,500 AgVet chemical products managed by over 900 registrants. We want them all reviewed over the next 15 years under an orderly and rigorous Re-approval and Re-registration scheme like that scheduled to start but cancelled in 2014. This must include a complete review of all the chemical labels on which the whole scheme so much depends."

The review of all previously approved chemicals is long standing unfinished business that is needed to clear the decks for a leaner and lighter system like that proposed. This should be a manageable task considering, for instance, that over 500 registrations are for different glyphosate-based formulations that all contain various strengths of the same active ingredient. As the onus would be on registrants to produce rigorous, convincing, contemporary data to prove each chemical's safety and efficacy, some of the burden would be lifted from the APVMA and its assessors.

Additional resourcing would be required to ensure that all the re-application, re-assessment, re-approval and re-registration processes could be commenced and completed in the fifteen-year timeframe. This should be far more manageable than industry's insistence that the APVMA fast track thousands of new actives into the market, with very short time frames.

3. The Bill will improve the effectiveness and efficiency of the national system for regulating agricultural and veterinary (AgVet) chemical products.

Effectiveness and efficiency have merit, but only provided they do not compromise our regulator's core mission – to protect human and animal health and safety, and all other organisms in the environment.

The system entails some checks and balances that the industry tags 'red tape' mainly because

[4] Ibid. ANAO, P53

regulatory processes do not apply the precautionary principle and the onus of proof is displaced from the applicants and registrants, where it belongs, onto the regulators. If unambiguous principles were codified and routinely applied in the APVMA's work, some essential 'red tape' now needed to restrain industry's over-reach may be reviewed.

4. The Bill will:

a. Enable the use of new, simpler regulatory processes for low risk chemical products (to simplify the approval of active constituents and labels, and the registration of certain products)

We oppose this proposal.

The inherent flaw in this promise is the lack of objective measures and a general paucity of good data to establish that certain chemicals are of low enough risk to justify simpler regulatory processes.

Given the public relations, advertising, and other claims made for its safety, we presume glyphosate may be one chemical that could be regulated under this simplified regime. Yet contemporary evidence plainly shows that regulators, users and the general public were systematically and effectively misled, misinformed and misguided over glyphosate's genuine harm and hazard profile for the past 50 years![5]

b. provide the Australian Pesticides and Veterinary Medicines Authority (APVMA) and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application

We do not agree with this provision.

The Explanatory Memorandum and the Bill fail to disclose the scope, scale and substance of the "certain types of new information" that the APVMA and industry want "more flexibility to deal with". Members of the public have a right to know what is envisaged.

The memo asserts that, "Deferring commencement for 6 months is necessary to allow the associated regulations and other legislative instruments to be developed for these measures, including consultation on these instruments," but on past experience, such consultation will be exclusively with the corporations, which stand to gain directly from the APVMA having the proposed discretionary powers.

c) provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products—particularly those uses (minor uses) with insufficient commercial return for chemical companies to normally add to the product label

Limitation and protection periods raise serious questions of restraints on public access to information and data submitted in support of applications and chemical reviews. The interested public requires unfettered access to applications and all data, preferably without having to resort to Freedom of Information requests.

The APVMA should operate more openly and transparently. Intellectual property laws should adequately restrain commercial competitors from submitting another registrant's proprietary information in support of their own applications.

d) support computerized decision-making by the APVMA

[5] Gillam, C. Whitewash – the story of a weed killer, cancer, and the corruption of science, Island Press, Washington DC USA, 2017.

We do not support computer use for APVMA "decision-making".

Doing "an administrative check of an application" or other routine checking task does not strictly fall within the realm of 'decision-making'. In online forms, for instance, requiring certain fields to be completed or boxes to be checked is acceptable but decision-making goes to making sense of the information put in the comment field or what the checked boxes mean beyond, for example, allocating the application to a particular division within the organisation, where it would receive expert human consideration, adjudication and decision-making.

We are not comfortable that the APVMA appears to gain the sole discretion to, "introduce computerised decision-making where the APVMA considers that this is appropriate, and is intended to establish a flexible legislative regime …" Public participation in such decisions is essential. The APVMA must be much more than merely a service and approval provider for AgVet chemical industries, agribusiness and other commercial interests.

Likewise, "the use of an expert system to make a decision—as opposed to helping a decision-maker make a decision—should be legislatively sanctioned to ensure that it is compatible with the legal principles of authorised decision-making," appears to be a big step towards delegating substantial decision-making powers to algorithms. We reject this.

Then replacing a machine-made decision, where the APVMA considers it to be wrong, "without the need for formal administrative review," also suggests a lack of access for those advocating for the public interest.

Unless humans routinely checked computer-generated decisions within short time frames, we see no reason for a cap of 60 days to be imposed on reversing or modifying such decisions.

e) provide for a legislative instrument made by the APVMA to prescribe a scheme in the future that would allow applicants and the APVMA to use accredited third party providers to undertake assessment services

We do not concur with the proposal to allow applicants "to use accredited third party providers to undertake assessment services."

This smacks of applicants being able to pick and choose those who will assess their proposals. There is a significant body of evidence that such corporate-generated data is likely to be inherently unreliable and must therefore be viewed sceptically.

> "You don't have to look far for real-life examples of poorly conducted or intentionally misleading industry research."[6]

Even when data is generated in more neutral situations and for non-commercial purposes,

> "for most study designs and settings, it is more likely for a research claim to be false than true."[7]

We are also uncomfortable with the APVMA outsourcing its assessment services.

We disagree that, "The APVMA's legislative instrument will provide community confidence in the assessors of AgVet chemical products as it could, for example, specify requirements for experience, insurance, conflict of interest measures and data handling protocols."

[6] Besley, JC *et al.* (2017) People don't trust scientific research when companies are involved, *The Conversation*, May 8, 2017. https://theconversation.com/people-dont-trust-scientific-research-when-companies-are-involved-76848
[7] Ioannidis, J.P. (2005) Why most published research findings are false. *PLoS Med*. 2(8):e124. Epub 2005 Aug 30. https://www.ncbi.nlm.nih.gov/pubmed/16060722

As the APVMA continues to distance its work from the interested public and its advocates, community confidence will be even harder to win, especially with an added layer of distance and complexity that outsourcing would impose. For instance, how would the ex-employees of present or former APVMA applicants, such as Monsanto, be prevented from gaining accreditation as the assessors of chemicals for which they were formerly applicants?

Typically, a bureaucratic fix is proposed for the problems that outsourcing would itself create, when the Memo proposes that, "The instrument could also include requirements for an audit and compliance program." Examples of such checks and balances failing to deliver on their promises are legion. In the end, ICACs or Royal Commissions are then required to shut down the chicanery and shams. Surely more efficiency, effectiveness and rationality would result from investments in the APVMA's own expertise, instead of outsourcing evaluations.

f) labeling risk communication about chemical products by improving the transparency of voluntary recalls

We advocate more stringent and mandatory recall, deregistration and public notification provisions than those proposed in this section.

The APVMA must have powers to mandate, monitor and enforce to rules on all AgVet chemical recalls and must exercise its powers with due diligence. Mandated rules should apply not only to registrant-initiated voluntary recalls but also to APVMA mandatory recalls and de-registrations.

The APVMA must be notified of all registrant-initiated recalls, without exception, to ensure all recalls are effectively implemented. Effective, efficient and comprehensive publicity and notifications are essential so that all users, and those who may hold stocks of recalled chemicals, are advised of the precautionary actions they must take.

g) harmonise the need to inform the APVMA of new information (where it relates to the safety criteria) so that the same obligations apply to all holders and applicants

We agree with harmonising the requirements to report new evidence and information "that shows the constituent or product may not meet the safety criteria, trade criteria or efficacy criteria" among all licence holders and applicants. This is provided that the change does not in any way compromise strict reporting rules.

It is not clear why the substantial penalties that apply to recalls should not also apply to other infringements of the Act and its Regulations, such as withholding new relevant information or evidence from the APVMA.

The timeliness, form and means of making such notifications should be specified in the Act. Is there a standard form for making such reports and a clear repository for this vital information? How long after a scientific paper or an expert committee's report is published do holders or applicants have to notify the APVMA?

For instance, what responsibility and timing did all the registrants of glyphosate-based herbicides have to report the IARC conclusion in March 2015 that the chemical is 'probably carcinogenic to humans' (Group 2A)?[8]

In the same monograph IARC also reclassified the insecticides malathion and diazinon as 'probably carcinogenic to humans' (Group 2A) and the insecticides tetrachlorvinphos and parathion as 'possibly carcinogenic to humans' (Group 2B).

[8] IARC Monographs Volume 112: evaluation of five organophosphate insecticides and herbicides, International Agency for Research on Cancer (IARC), March 20, 2015

Did any registrants notify the APVMA of the IARC findings? What responsibility did they have to notify APVMA, when and in what form?

It is also essential that the interested public and advocacy groups have a clear role in, and path to, notifying the APVMA of new evidence and information as it becomes available. Regulators' responsibilities to review and respond to such advice, in consultation with those who submit it, should also be unambiguously spelt out.

h) provide a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process

The APVMA should develop a scientific framework for measuring variations in AgVet chemical products, so objective judgments can be made about whether any deviation from the standard formula that the APVMA has approved is minor or major.

A similar system should be developed for the adventitious presence of contaminants.

We are unsure if the APVMA requires independent random batch testing of AgVet chemical products but, if not, it should.

i) provide the APVMA with more proportionate options for dealing with false or misleading information, and clarify what information must be included on a label

We fully support and advocate a complete public review of the laws and regulations that mandate the minimum content, design and legibility features of the labels on all farm and domestic AgVet chemicals. Clarity, comprehension and precautionary user compliance should be among the labelling criteria.

We also concur with broadening, "the circumstances where a more proportionate APVMA response (suspension or cancellation) is available," as a sanction for providing false or misleading information.

The Explanatory Memorandum asserts that, "The label, and the instructions for use in the label, are … vital to ensuring the safe and effective use of the chemical product." This is because, "Chemical products can be extremely hazardous to people, plants, animals and the environment if they are not used in accordance with the instructions for use on the label."[9]

We assume that the false or misleading information referred to can include the claims and information offered to the public in advertising, promotions, advice, etc, not merely the 'mischief' on which these provisions appear to focus. We are dissatisfied that when the APVMA deals with false or misleading information, the public continues to have no role (section 34P of the AgVet Code). Such matters are of keen public interest and concern so the AgVet chemicals regulatory scheme must be responsive if it hopes to win the public trust and confidence that it lacks.

For instance, Monsanto repeatedly claimed in its advertising and promotions that Roundup herbicide is biodegradable. But in 1996, the Attorney General of the State of New York, Consumer Frauds and Protection Bureau, and Environmental Protection Bureau charged that Monsanto's claim constituted False Advertising Regarding the Safety of Roundup Herbicide (Glyphosate). The claim was prohibited, at least in New York State.[10] [11]

[9] Parliament of the Commonwealth of Australia, Explanatory Memorandum to the Streamlining Regulation Bill, 2018, P57.
[10] In the matter of Monsanto Company, respondent. Assurance of discontinuance pursuant to executive law § 63(15). New York, NY, November, 1996. https://big.assets.huffingtonpost.com/fraud.pdf
[11] ABC TV, Four Corners, The Monsanto Papers, Monday October 8, 2018. https://www.abc.net.au/4corners/the-monsanto-papers/10352384

Matters of holder non-compliance and misinformation are of legitimate public interest so must also be published. Public exclusion is unacceptable, even more so where a member of the public or advocacy group initiated the review by alleging that a holder had submitted to the APVMA or issued to the public, false and/or misleading information about its AgVet chemicals.

j) allow the holder of a suspended product to address the reason for the suspension

Again, the process must be open and transparent to the public.

k) fix anomalies in the regulation-making powers for the labeling criteria

Again, the process must be open and transparent to the public.

l) simplify the APVMA's corporate reporting requirements

We favour the APVMA continuing to publish an annual operational plan, as a public measure of the relevance, effectiveness and efficiency of the APVMA's operation.

Other Comments

1. **We reject the new sections 14C, 14D and 14E** that propose deregulation of applications which are, "anticipated to be those that have sufficiently low associated risk as to warrant reduced supporting information requirements. … For these active constituents and chemical products it is conceivable that no technical information may be required and, as such, this mechanism could support the introduction of a means of self-approval or self-registration, where appropriate."[12]

   We question the assumption that any AgVet chemicals can be classed as low risk, especially without any supporting information or technical evidence being provided to our regulators. Under no circumstances are self-approval or self-registration acceptable.

2. **Economic activity is not a valid justification for AgVet chemical use.** CropLife's submission notes that it had, "proposed the introduction of an interim international recognition registration system. In specific situations where the proposed use pattern is the same, interim international recognition registration would enable Australian farmers to access new and innovative products based on the product's registration by a respected overseas regulator, with only necessary Australian-specific assessments conducted by the APVMA." CropLife laments that its proposal was not adopted in a form that its corporate members could support.

   We propose instead, "an interim international recognition, de-registration system". Under this scheme, all AgVet chemicals that are banned or have restricted uses in, say, two respected overseas jurisdictions would likewise be banned or restricted here. The APVMA would then accept applications for reassessment and possible re-registration in Australia. This system would serve as a means to rationally allocate APVMA resources to a Reassessment and Re-registration scheme.

3. **We oppose Croplife's weak case for deregulation** as it rests on the Deloitte Access Economics 2018 report, 'Economic activity attributable to crop protection products', commissioned by CropLife. The report "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."

   But without any data on the full direct and indirect costs and harms arising from that economic activity, the statistic is meaningless. CropLife's case lacks substance, is incomplete and should be dismissed as the Deloitte report is clear that its, "study is not a cost-benefit analysis and does not

[12] Explanatory Memorandum P9.

consider or compare the relative magnitudes of costs in relation to the benefits; for example, costs to the environment and potential health implications of their use."[13]

The Australian Government should require or commission research on the risks, hazards and costs of registered AgVet chemical use. This would be an antidote to the questionable assumption that using AgVet chemicals yields net benefits and to determine the extent to which it imposes externalised and un-recouped health and environmental costs on the whole community.

A European technical report[14] on the human health costs of the diseases and deaths that result from exposure to synthetic endocrine-disrupting chemicals estimates, "the total of costs for the selected endocrine-related diseases and conditions at €636 – 637.1 billion per year in the EU.

The health conditions investigated include:

- Reproductive and fertility problems
- Abnormalities of the penis and testicles in baby boys
- Cancer of the breast, prostate, testes
- Children's behavioural disorders, such as autism and ADHD
- Obesity and diabetes."

The report also notes that, "the total cost calculation is probably a gross underestimate despite some of the assumptions and generalisations involved in calculating it (as)

- Figures were not available for all the endocrine-related health problems.
- Some figures are estimates for costs to the health care system but do not include the costs to families arising from illness and to employers from lost working days.
- None of the figures cover the costs of misery and pain associated with these conditions."

The US Endocrine Society also reports on the substantial health impacts and costs of EDCs that various products generate, including many farm chemicals.[15] [16]

Despite these considerations, most regulators including the APVMA are insufficiently cautious when assessing new AgVet chemicals for registration. They are also far too slow to reassess and deregister chemicals, even when reliable scientific evidence of harm has accumulated to the point where it can no longer be ignored. For example, good data shows certain products (e.g. endocrine disruptors) and practices (e.g, the pre-harvest dessication of food crops) have unacceptable hazards, risks, and costs yet minimal APVMA action has resulted. Another example of the APVMA's belated response is the imminent health threats and health system costs of the routine use of antibiotics in animal husbandry that led to antimicrobial resistance now threatening us all.

Please favourably consider our representations and recommend, in the public interest, that the government refrain from streamlining APVMA processes as proposed in the Bill. Instead, please call for the implementation of our recommendations.

Bob Phelps
Executive Director

[13] https://www.croplife.org.au/wp-content/uploads/2018/04/Deloitte-Access-Economics-Economic-Activity-Attributable-to-Crop-Protection-Products_web.pdf
[14] Health Costs in the European Union – How much is related to EDCs (Endocrine Disrupting Chemicals)? Health and Environment Alliance (HEAL), June 2014, P5. https://www.env-health.org/wp-content/uploads/2018/06/health_costs_report_edcs.pdf
[15] Endocrine Society. https://www.endocrine.org/topics/edc
[16] Hormone Health Network. Endocrine Disrupting Chemicals (EDCs), September 26, 2016. https://www.youtube.com/watch?time_continue=85&v=ibfAF66JzFE