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Re: our comments on APVMA regulatory science strategy draft

Thank you for the opportunity to comment on this document. We seek further opportunities to participate fully in APVMA processes and decision-making.

Recommendations:

1. Remove regulatory science from the regulator's operating systems.
2. Introduce the precautionary principle into APVMA legislation, regulation and practice.
3. Adopt new scientific processes and principles to replace regulatory science.
4. Cease making baseless assumptions to fill gaps in scientific data and understanding.
5. Develop standards, benchmarks and minimum requirements to replace guidelines.
6. Enable well-designed experiments to be required to fill data gaps.
7. Publish all applications and documentation of technical assessments.
8. Require peer-reviewed publications to substantiate company-generated data.
9. Accept only evidence from experiments that are reproducible and falsifiable.
10. Make applicant fees for service and cost recovery payable to Treasury.
11. Fund the APVMA from a Treasury Budget allocation like that for the OGTR.
12. Improve processes for timely participation in regulatory affairs for the interested and informed public, and civil society advocates.
13. Establish a Senate Inquiry (or Royal Commission) to inquire, without fear or favour, into all the evidence of glyphosate toxicity and carcinogenicity.
14. Reinstate the comprehensive chemical review regime cancelled in 2014.
15. Refund the cancelled program to monitor agrochemical residues in the food supply.

Discussion:

The APVMA fails farmers, citizens, the environment and public health by ignoring realistic community expectations, new scientific evidence in toxicology and ecology, and evolving regulatory regimes that strengthen synthetic chemical regulation in other countries.

APVMA proposes only guidelines that will inevitably remain weak, open to biased interpretation and unenforceable. We recommend that standards, benchmarks and minimum requirements be developed to replace its guidelines. These would enable genuinely scientific assessments to replace the so-called 'regulatory science' that the APVMA now practices.

The APVMA's independence is critical. Yet its budget is inadequate to fulfill its many

complex functions and dependence on levies from the chemical industry creates a clear and unacceptable conflict of interest. Industry levies should be paid to Treasury, with the APVMA funded by a Budget allocation to pay for the services it provides to all parties including, most importantly, the citizens and shoppers of Australia.

Agribusiness and the few large agrochemical and GM companies remaining have undue influence on the APVMA through cost recovery. Just five mega corporations will control the global industrial seed, agrochemical and food supplies. ChemChina's acquisition of Syngenta will create the world's second biggest agrochemical and seed conglomerate behind newly merged Dow/Dupont. Monsanto would still be the biggest GM seed company.[1] This concentration of ownership is against the public interest.

We expect the APVMA to be an objective and impartial referee on disputed issues, with its regulatory activities conducted at arms length from industry. Industry views the APVMA as a service provider and exercises undue influence over its decisions.

1. The consultation draft says: "Regulatory science involves a **pragmatic** application of the scientific method for the purpose of making a decision about whether to allow something (e.g. chemicals) to be used within the defined legislative framework and timeframes."

Gene Ethics is dismayed that APVMA uses the conceptually lax and practically flawed notion of 'regulatory science', as defined here, to reach its decisions. The scientific method has an internally consistent and rigorous methodology and rationale that philosophers and scientists have developed and refined over at least the past millennium. It has withstood the test of time, peer-review and informed public criticism to be universally accepted as the way to conduct scientific work, to progress towards a robust understanding of how the world's systems function, including our understanding of risks, hazards and harms.

By departing from the scientific method, APVMA compromises its objectivity, credibility, authority, and decisions.

We consider it essential, instead, that the APVMA makes a **'precautionary' rather than 'pragmatic'** application of the scientific method. The Precautionary Principle is defined and described with precision in many international and national laws. For instance, in the EU one account says:

> "The Precautionary Principle is a strategy to cope with possible risks where scientific understanding is yet incomplete, such as the risks of nano-technology, genetically modified organisms and systemic insecticides.
>
> The Precautionary Principle is defined as follows:
>
> When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.
>
> Morally unacceptable harm refers to harm to humans or the environment that is
> - threatening to human life or health, or
> - serious and effectively irreversible, or
> - inequitable to present or future generations, or

[1] http://www.bloomberg.com/news/articles/2016-02-03/chemchina-offers-to-purchase-syngenta-for-record-43-billion

- imposed without adequate consideration of the human rights of those affected.

> The judgement of plausibility should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review. Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.
>
> Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process."[2]

Precaution has the great merit and strengths of focusing on prevention rather than treatment, ongoing analysis, and participation.

2. The consultation draft continues: "What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of **existing scientific knowledge** and, where necessary, **assumptions to address data gaps or uncertainty.** Regulatory scientists **do not generate new lines of enquiry to answer questions**, instead relying on available information (provided by applicants or in the literature) to make a decision one way or another."

This passive and selective approach allows applicants for chemical registration to submit a suite of sub-standard, unpublished and un-peer-reviewed information (not scientific evidence) in support of their claims.

The best-guess approach of using 'assumptions' to fill data and knowledge gaps, and to resolve uncertainty, is so lacking in rigour that it would be laughable if it were not so serious. Failure to require additional, independently generated, data to generate essential knowledge and improve confidence is completely irresponsible and flouts APVMA's duty to protect the public interest.

> Our questions to the APVMA include: On what grounds has the APVMA ever reject an application to register a chemical? What applications for chemical registration have been rejected? When were these applications rejected?

The agrochemical industry and agribusiness have captured government and the APVMA. Clear evidence of this was passage of the Agricultural and Veterinary Chemicals Legislation (Removing Re-approval and Re-Registration) Amendment Bill 2014, regrettably passed with ALP support. Agriculture Minister Barnaby Joyce killed off the safety review scheme for agricultural pesticides that was to have begun on July 1, 2014.

According to the Minister, his irresponsible decision saved the chemical industry just $1.3 million while: "Agvet chemicals contribute to 68 per cent of all crop production in Australia and are critical to our nation's $47.9 billion per annum farming industry."[3] Killing the safety assessment scheme was a miniscule saving.

Yet it continues the chronic impacts of older chemicals on public health and safety, and

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[2] http://www.precautionaryprinciple.eu/

[3] http://www.agriculturemin ister.gov.au/Pages/Media-Releases/agvet-chemical-reform-reduces-burden-on-australian-farmers.aspx

the environment. Hundreds of registered pesticides were approved up to 50 years ago, long before modern safety testing methods were available. They need a contemporary review to improve safety for farmers, farm workers and shoppers who eat the foods. Other users of these chemicals also remain at risk. Many chemicals still used in Australia are banned overseas because of their toxicity. This is unacceptable.

The general chemical review would have required new scientific evidence but would not have affected the availability or price of those chemicals that were found to be really safe to use. The reviews would also have reassured us that the allowable chemical residues in food are safe, which now relies on outdated evidence and an unscientific (divide by 100) method of setting Maximum Residue Limits for each active ingredient in food. MRLs derived from Good Agricultural Practice, set to meet the requirements of the agrichemical industry and agribusiness, ignores evidence of the cumulative, synergistic and whole of life impacts of multiple agricultural chemicals – not even including the adjuvants used with the active ingredients. The Minister also defunded a program of chemical residue monitoring in the food supply, after the first year of a five-year program.

The lack of a modus operandi that is grounded in the Precautionary principle leaves the APVMA exclusively serving agribusiness and the chemical industry while ignoring the public interest.

3. The draft goes on: “Regulatory agencies have to consider the findings of conventional (or basic) scientific research and apply any relevant findings to regulatory science which then directs the tasks of regulators in conducting risk assessments of applications for approval to market new pesticide and veterinary medical products.”

Using assumptions to fill substantial knowledge gaps is just grossly irresponsible. We again counsel the APVMA and the government to apply the Precautionary Principle. It is a robust concept and strategy written into many international and Australian laws, to effectively minimise possible risks where scientific understanding is incomplete, as it always is.

The exception is where there is strong or irrefutable evidence of harm but such evidence is often delayed until long after a chemical, pollutant or organism has been released for an extended time and much harm has already been done. Big pharma, agrichemical, mining and tobacco companies are renowned for burying negative evidence until they have cost recovered and made profits sufficient to easily bear the costs of any compensation claims for the damage they do. Even then they will fight rearguard actions to exhaust their claimants and avoid paying up.

The premature deployment of new technologies and their products is not a rational, humane or acceptable way for our governments to regulate toxic industries on the public’s behalf. The APVMA and our other regulators must not be allowed to routinely licence pollution.

The consultation draft provides a case study of **Genomic Recombination** which amply demonstrates the great weaknesses of relying on assumptions to make critical decisions. It shows clearly that even a widely held belief can be wrong. Especially under the influence of forces that human activity unleashes, we know vanishingly little about how the living world functions. Precaution is therefore an essential mindset and method.

The default position for consideration of a new chemical application should be that it would be rejected unless it meets published benchmarks and standards that are set in advance

against which to evaluate the proposal. In the absence of such objective measures, every case-by-case assessment will be ad hoc, lack objectivity and be riskier than it should.

4. Then the draft says: "We need to demonstrate that we have considered the best possible scientific advice, and explain the basis for our decisions to a public which includes those who have limited knowledge of the assessment process that underpins APVMA decisions."

This patronises the many informed and interested citizens who have legitimate concerns about the APVMA's standards, methodologies and decisions who seek to engage in an orderly dialogue with the government, Authority and its staff. We are held at arms length as not being 'stakeholders' since the APVMA appears to define its clients and constituents as the industry and agribusiness.

It says: "The APVMA needs to engage with the public in order to raise the general level of awareness and understanding …" and: "respond promptly to enquiries from the public …" and: "explain the basis for our decisions to a public which includes those who have limited knowledge …" and: "building public confidence in the APVMA."

Yet the APVMA nowhere mentions the general public online and sees its stakeholders as exclusively industry and farmers (agribusiness).[4]

- We will use existing mechanisms for feedback from stakeholders on regulatory science quality.
- We will seek stakeholders' views on a wide range of scientific regulatory issues, most often via the APVMA website.

5. The APVA case study on RNAi is to produce: "insecticides to protect plants, either by genetic modification of the plant to incorporate the machinery to synthesise RNAi molecules specifically directed against insect predators, or by topical application (spraying) of RNA molecules to the plant; most plants are able to absorb double-stranded RNA molecules which are subsequently processed to miRNAs and then distributed throughout the plant."

There will be need for a new approach to regulating these novel entities. For instance, these authors say: "New methods are needed to identify RNAi crops and measure the environmental persistence of small RNAs."[5] CRISPR, ZFN and the products of synthetic biology will also demand assessment and regulation which should be prepared for now.

Again, the APVMA fails to take the interested and informed public into its confidence and enable any participation at all, when it reports that: "In cooperation with researchers at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the APVMA has started to consider the issues which may need to be taken into account in regulating pesticides and veterinary medicines based on PTGS. The APVMA has contributed to several CSIRO workshops on RNAi technology and CSIRO scientists presented a seminar at the APVMA on RNA interference – an emerging technology for controlling pests and diseases in animals and plants."

At the very least, reports of these meetings should be in the public domain. APVMA should also have entered into discussions with a wider range of experts and public interest advocates than disclosed here. The public should be apprised of work for the approval of

[4] http://apvma.gov.au/node/336
[5] http://www.kocw.net/home/common/contents3/document/wcu/2013/KyungSang/KimMinChul/1.pdf

completely new genetic manipulation techniques and other novel organisms and materials proposed for release, long before the first applications appear for public comment.

Wider discussion and much more independent research are essential as:

> "The potential hazards posed by RNA interference (RNAi)–based pesticides and genetically modified crops to non-target organisms include off-target gene silencing, silencing the target gene in unintended organisms, immune stimulation, and saturation of the RNAi machinery. … Areas that warrant future work include the persistence of insecticidal small RNAs in the environment, describing crop-based food webs to understand those species that are most exposed, sequencing genomes for species to proactively understand those that may be affected by RNAi, and substantiating that laboratory toxicity testing can accurately predict the field-level effects of this technology."[6]

6. Our Case Study: Glyphosate

A Senate Inquiry (or Royal Commission) is needed to review all the evidence about glyphosate toxicity outside the APVMA, without fear or favour. Terms of Reference should include the reinstatement of a comprehensive chemical review like that scheduled to begin on July 1, 2014. Also refunding the monitoring of agrochemical residues in the food supply. Roundup's active ingredient glyphosate is the world's most used weed killer. Over 90% of all GM crops globally resist being sprayed with Roundup's active ingredient, glyphosate.

On strong new evidence, the World Health Organisation's IARC expert committee reinstated glyphosate to the category of 'a probable human carcinogen' in March 2015. Governments, regulators and chemical users must heed these scientific findings and act. Under public pressure, the APVMA has finally agreed to review the safety of glyphosate by May or June 2016 but appears to have already prejudged the outcome when it says:

> "The APVMA, along with regulators in other countries, consider that current labels for glyphosate products contain appropriate instructions for use to keep those regularly handling glyphosate safe."[7]

That is similar to the passive and erroneous decision APVMA took when permitting two chicken vaccines that later recombined and created a new pathogen. This refuted the assumptions and preconceptions that the world's regulators held, as recounted in APVMA's own case study.

The WHO report concluded that glyphosate most threatens the health of people who spray it without adequate safety protection. Yet council workers without respirators or facemasks constantly spray our streets, playgrounds and schools with Roundup. Farmers, Landcare workers and home gardeners also liberally apply it with minimal concern for the health and safety of themselves and others. Most are conned into believing Roundup and other chemicals are safe.

State Workers Compensation Insurers recommend that all local councils review their glyphosate and other weed killer use, as work safety data sheets are long out of date.[8]

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[6] Lundgren 2013 RNAi-Based Insecticidal Crops: Potential Effects on Non-target Species BioScience Volume 63, Issue 8 Pp 657-665 http://bioscience.oxfordjournals.org/content/63/8/657.abstract

[7] http://www.abc.net.au/news/2016-02-16/councils-still-using-pesticide-that-probably-causes-cancer/7168464

[8] http://www.echo.net.au/2015/11/insurer-warns-councils-over-use-of-roundup/ and http://www.workcover.nsw.gov.au/media/publications/health-and-safety/be-aware-glyphosate-and-organophosphates-fact-sheet

They particularly warn of the danger to unprotected children, animals and adults. With community support, many councils are now reviewing chemical policies and considering other weed management systems such as weed steamers. Some unions that cover council workers have also written to councils alerting them to their liability for the harm Roundup products may do (pers comm. 2015).

The ABC story also reveals APVMA has a glaring conflict of interest. 50% of the APVMA's $33 million annual budget comes from a levy on the sales of registered chemicals, of which glyphosate products contribute $1.5 million. To serve the public interest and to restore its credibility, the companies that it regulates should not directly fund the APVMA.

Conclusions:

The APVMA should abandon regulatory science and adopt genuine scientific methodologies, including the precautionary principle. We urge the adoption of our recommendations.

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