Submission to the APVMA – Regulatory Science Strategy

17th February, 2016

We welcome the opportunity to comment on this draft Regulatory Science Strategy.

Introduction

The purpose of this document is unclear. It does not appear to be directed towards either regulatory amendments or internal reform, but rather seems to be a justification of the current practices of the APVMA.

As a strategic document it lacks both the rigour and clarity of the regulatory science strategies of other regulators such as the US Food and Drug Administration.[i] It fails to identify concrete steps, their purpose, the time frame in which the initiatives will be implemented, or how the effectiveness of the strategies will be measured.

The Vision

The APVMA's vision is disturbing. "Australians have confidence that agricultural and veterinary chemicals are safe to use," is not about preventing environmental harm or protecting human safety but the perception of safety. If the public believes that the APVMA is doing its job that tells us nothing about whether agricultural chemicals are, in fact, safe.

Regulatory Science

Regardless of the purpose of the document or the use to which it will be put, the APVMA's attempt to validate its concept of 'regulatory science' must be questioned and opposed.

.While it is true that regulatory bodies are not scientific bodies and must make both regulations and decisions based on science, that does not make the decisions or process followed by regulators 'science' in any sense of the word. It is Orwellian double speak intended to allow the APVMA to hide behind a patina of 'regulatory science' when it is making political or 'pragmatic' decisions.

The real question is actually how well does the APVMA use science in its regulatory role and obligations, in particular to "ensure that the health and safety of people, animals, crops and the environment are protected?" (p. 1)

Unfortunately, it is the view of many environmental NGOs - including Friends of the Earth - that the APVMA is failing to fulfill its environmental health and human safety obligations.

The concept of 'regulatory science' put forward by the APVMA speaks to these failings and is disturbing. The proposed definition – a pragmatic application of the scientific method – is a scientifically meaningless definition that provides gigantic loopholes through which poor and scientifically unjustifiable decisions can continue to be made.

The APVMA's approach to uncertainty and ignorance (i.e. the unknown) is particularly poor. As the draft strategy states:

> *"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."* (p. 3)

This is not justifiable either scientifically or ethically. Responding to a lack of information or data by making an ill-informed decision is an abrogation of the obligations of the APVMA to actually work to protect the environment and human health. The APVMA has the authority to seek and demand more information (see e.g. section 8B, Agvet Regulations). The Authority's failure to do so cannot be considered scientific in any way. A more apt definition is corporate capture.

Lack of Precaution

While the draft strategy doesn't even mention the precautionary principle (or the principles of Ecologically Sustainable Development, which include the precautionary principle and to which Australia ostensibly adheres[ii]), the APVMA's definition of 'regulatory science' clearly reflects a rejection of the precautionary principle. Precaution in the face of uncertainty or ignorance is not a radical notion. In fact it is the best way to protect environmental and human health when data gaps exist. Nor is the principle unworkable,[iii] but the APVMA clearly rejects it in this document and in practice. In doing so, the APVMA further embraces its 'business first' approach to chemicals and approvals.

In the absence of precaution, the agrochemicals industry benefits from the poor science it produces - as this becomes the basis for decisions – i.e. approvals.

Unfortunately, this lack of precaution is evident in the APVMA's approach to assessment, regulation, oversight, monitoring and enforcement.

At the assessment stage, the APVMA assesses only individual chemicals and not the combined, synergistic, cumulative and long term impacts on human health and the environment. In assessing the safety of chemicals, the APVMA does not assess the safety of whole formulations but solely so-called 'active ingredients' - despite the evidence that many 'inactive' ingredients can have significant impacts on the nature and scale of the chemical's impacts.

In the case of nanomaterials, the Authority has ignored the evidence that nanopesticides are now in widespread use and so these remain unregulated.

We are concerned that the refusal of the APVMA to insist that data gaps are filled will inevitably result in approval rewarding industry for not exercising the kind of due diligence that should be demanded of them.

There is no reason from a legal perspective that regulators should be prevented from insisting on additional information before making a decision. In fact, there is ample evidence that this is the only rational 'scientific' approach for regulatory bodies dealing with either environmental or human impacts of activities which the agency is charged with regulating.

Notably, this power is often used by the Department of Environment as part of the Environmental Impact Assessment process.

Corporate capture

The APVMA's assessments frequently rely solely on company data – data that science tells us is significantly less reliable than independent science.

In setting maximum residue levels (MRLs) for chemicals, the APVMA appears to be driven first and foremost by the needs of industry. The introduction of genetically engineered crops has led to the increased use of certain chemicals at higher levels, and the APVMA has raised MRLs in response to industry requests.[iv]

The APVMA's approvals are rarely reviewed. Standards or thresholds that should trigger review simply don't exist and peer reviewed data that calls into question an APVMA approval is frequently ignored. The absence of such standards is neither scientific nor ethical. The ignoring of data on the health and environmental impacts of Atrazine is a typical example of ignoring a substantial body of peer reviewed literature in favour of industry and industry generated data. No doubt the APVMA will respond to the health concerns raised regarding glyphosate in the same way.

Similarly, bans or limits on use of certain chemicals overseas are rarely followed. When a review is conducted it is rare to see more than an in-house whitewash in which the safety of the chemical is asserted. Atrazine, for example, remains on the market, despite a ban in the EU and significant peer reviewed data indicating that there is no safe level of exposure.

The failure to review is compounded by a lack of oversight, surveillance and enforcement.

At a more general level, the APVMA has allowed thousands of tonnes of poorly assessed chemicals to enter the food chain and environment annually[v] without understanding or surveilling the impacts of those decisions.

No measurable outcomes

In this context it is not surprising that the 'strategies' presented here are weak and unambitious aspirational goals accompanied with a suite of aspirational undertakings that are not specific, timebound or measurable.

The case studies don't provide evidence of anything. For example, the case study of the science fellows and visiting scientists doesn't provide any examples of how this initiative has resulted in better science, better assessment or better outcomes.

Similarly, the regulatory science network is touted as an outcome, but no outcomes are even claimed.

Enhancing stakeholder communication and engagement

The claim that the "APVMA needs to engage with the public in order to raise the general level of awareness and understanding about the assessment process for agricultural and veterinary chemicals, especially its focus on human health and the environment," implicitly claims that the lack

of trust in the APVMA is simply due to a misunderstanding. This is a common view in regulatory agencies, but the suggestion that better explanations or more sophisticated messaging will increase the level of trust in agencies is misplaced. Certainly, in the NGO sector that works on agricultural and food issues, these ongoing attempts are little more than spin and it is time for regulators to recognise that they are distrusted on the basis of their performance.

Friends of the Earth supports the suggestion that "The APVMA must ensure that credible and independent scientific information is accessible to stakeholders so that they are better able to make informed decisions about issues that might affect them." (p. 8) However, in order for this to occur, the APVMA must have independent science available – which it frequently doesn't. One way to help address this impasse would be for the APVMA to release the full data upon which it relies in giving approvals and assurances of safety.

Case Study – 'Our Science'

The paper claims that the Our Science web page provides the risk analysis framework. However, this is nothing but a simplistic diagram illustrating how the broad concepts of risk assessment, risk management and risk communication overlap. It conveys nothing about which risks are given priority and which aren't; and how the authority deals with uncertainty or complete ignorance in its assessments.

Enhancing our capability to identify and respond to emerging regulatory issues.

This section notes that the APVMA will "develop and test model frameworks for the assessment and regulation of products of emerging technologies."

Despite identifying the emergence of nanopesticides and despite a 2007 study that identified some of the gaps in the regulatory system, the APVMA has ignored the appearance of nanopesticides in Australia and failed to develop a regulatory framework to allow it to assess the unique risks associated with nanopesticides.

Rather than develop a framework, the APVMA advises each company proposing to use nanomaterials in agricultural chemicals to contact the APVMA for advice on how to proceed. An ad hoc system of assessing emerging technologies is a recipe for failure.

RNA interference case study

The RNA interference technology case study is disturbing. CSIRO has a vested interest in developing the technology, and hence is less likely to advocate a precautionary approach to the new technology. Yet it appears that the APVMA has not consulted with independent scientists concerned with the use of RNAi technologies in agriculture and food.

Conclusion.

The regulation of food and agriculture in Australia is now so compromised by extreme free market deregulatory ideologies that this paper isn't particularly surprising. However, it is a paper disappointingly lacking in analysis of the current state of science and regulation within the APVMA. If this is regulatory science, it needs to end.

[i] FDA (2013). Strategic Plan for Regulatory Science.
http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm268095.htm
[ii] Intergovernmental Agreement on the Environment (1992). Section 3.5.1.
https://www.environment.gov.au/about-us/esd/publications/intergovernmental-agreement
[iii] Stirling, A and Gee D. (2002). Science, Precaution and Practice. Public Health Reports, **117**:521-533
[iv] See, e.g., the MRLs for glyphosate on canola seeds, which has increased 10 fold since 2005.
https://archive.apvma.gov.au/archive/gazette/2003/04/gazette0304p22.php;
https://www.comlaw.gov.au/Details/F2016C00073
[v] Australian Academy of Technological Sciences and Engineering (2002). Pesticide use in Australia.
http://www.atse.org.au/Documents/Publications/Reports/Climate%20Change/Pesticide%20Use%20in%20Aust%202002.pdf