Submission to the inquiry into the independence of regulatory decisions made by the Australian Pesticides and Veterinary Medicines Authority (APVMA)

Friends of the Earth Australia

23rd November, 2018

Many thanks for the opportunity to make a submission to this inquiry. We would welcome the opportunity to present to the Inquiry panel.

Through our dealings with the APVMA over the years we have been deeply concerned by its pro-industry bias. The APVMA's vision is summarised in its 2015 draft Regulatory Science Strategy:

"Australians have confidence that agricultural and veterinary chemicals are safe to use." [1]

This 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.

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.

We recommend that the Federal Government:

1) Urgently review and overhaul the APVMA's funding arrangements and entire culture.
2) Implement strict measures to prevent conflicts of interest in its advisory committees;
3) Implement the precautionary principle with clear guidelines preventing regulatory approvals or declarations of safety when there is significant uncertainty, large data gaps or a lack of peer reviewed science available;
4) Ensure that industry-funded science never forms the primary or exclusive basis for regulatory approval;
5) Ensure that corrupt or fraudulent science isn't used in making decisions that affect the broader public. This requires not only criminal penalties but significantly greater oversight and enforcement;
6) Require the mandatory reporting of toxicology test results for all chemicals, as has already been implemented in some countries for clinical trial data.[2]
7) Instruct the APVMA and FSANZ to conduct formal reviews of glyphosate and order Monsanto (now Bayer AG) to make all internal scientific documentation relating to the carcinogenicity of glyphosate publically available. Gaps in knowledge should be identified and filled with peer-reviewed science.
8) Re-establish the Agricultural and Veterinary Chemicals Re-approval and Re-registration scheme that was axed by the Abbott Government (with ALP support).
9) Initiate a similar Senate inquiry into the independence of regulatory decisions made by FSANZ.

We will now address the terms of reference:

a) the responsiveness and effectiveness of the APVMA's process for reviewing and reassessing the safety of agricultural chemicals in Australia, including glyphosate, and how this compares with equivalent international regulators

Of particular concern is the APVMA's alignment with industry, exhibited through both the 'approvals' process and the slowness with which the agency responds to substantial evidence that certain chemicals should be reviewed or removed from the market.

The APVMA and its predecessor the National Registration Authority were late in removing organochlorines and organophosphates (e.g. Fenthion Oct 2014), so current the current problems with the agency are not new. Many of these problems appear to be historical, political and structural in nature. The APVMA still appears to be unable to reign in a multitude of pesticides that remain problematic in terms of human and environmental impacts such as neonicotinoids. Waterways are of particular concern, despite APMVA's efforts to "mitigate" their impacts. e.g. Diuron in Great Barrier Reef catchments.

In Europe, pesticides have to be proven safe to human health and the environment in order to be allowed onto the European market. It is the responsibility of industry to provide the data showing that a pesticide can be used safely. Australia does not have the same system as Europe and the APVMA does not apply the same precautionary approach.

The APVMA implicitly shifts from a safety first to a market first approach by conflating the notion that no evidence of harm is the same as evidence of safety. This kind of regulatory sleight of hand has serious implications. It means that intervention will only occur once 'sufficient' evidence is provided to justify intervention. This occurs rarely.

Chemical review and reassessment

Even when chemicals are banned under other regulatory systems of other countries, the APVMA allows use to continue while the chemical is reviewed. Many of these reviews have continued for over a decade.[3] This reveals a structural failure. For example, Friends of the Earth and the Australian public were promised a review would be undertaken on the herbicide simazine in 2008. The agency reported that the chemical had been added to its Priority Candidate Review List, and that the Office of Chemical Safety was given a Work Order at the beginning of the 2008/9 financial year to perform a phase-1 assessment of the compound, with their report expected in early 2009. Nearly 10 years later the review still hasn't be completed.

As the National Toxics Network has noted, many existing chemicals in use in Australia have been grandfathered in without assessment or adequate data.[4] In order to ensure a 'safety first' approach to the use of agricultural chemicals, there must be explicit requirements that they be demonstrated as safe – not simply that - based solely on company data - they exhibit no evidence of harm.

Academics from James Cook University used the Great Barrier Reef (GBR) as a case study for evaluating the effectiveness of pesticide regulation in Australia and concluded that

"the only regulatory action taken to date – restricted conditions of use for particular chemical products introduced by the Queensland Government – has occurred outside of the dedicated regulatory regime for managing pesticide risks. Other lower profile and less-studied Australian water bodies are likely to be even less protected. The ad hoc, case-by-case and very slow chemical review process administered by Australia's national pesticide regulator has not effectively assessed or addressed chemical risks to the GBR. Some failures of the current system would be addressed by a systematic re-registration program of the kind in place in the European Union and United States… Australia's national regulator has considered the risks posed by only one chemical. The case-by-case review of chemicals has not allowed for the assessment of additive effects."[5]

The current *ad hoc* regime for reassessing the safety of agrochemicals is completely inadequate. We note that our key trading partners the EU and USA now mandate regular agricultural chemical reviews.

In 2013, the Coalition government repealed Labor's Agricultural and Veterinary Chemicals Re-approval and Re-registration scheme, which would have required chemicals to be re-registered every 15 years.[6] In many cases, this would have required reassessment of existing chemicals using contemporary testing methodologies.

Under intense lobbying from chemical companies and big agricultural interests, Labor back-flipped and supported the Liberal changes to their own reforms. That year both the Nationals ($42,500) and Labor ($22,300) got donations from the agrochemical industry's peak body CropLife to the tune of $42,500 and $22,300 respectively.

The repeal of the scheme means that some of the organophosphates pesticides registered in the 1960s and 1970s have never been reassessed to see if, given advances in knowledge, they are still safe. This means that Australia continues to sanction the use of recognised highly hazardous pesticides (HHP), banned in many nations of the world on food crops and in locations where human exposures are unavoidable.[7]

The Agricultural and Veterinary Chemicals Re-approval and Re-registration scheme should be re-established immediately to ensure that agrochemicals get systematically re-evaluated to ensure that they are safe for agricultural and food use.

Data gaps should be filled

The APVMA's approach to uncertainty and ignorance (i.e. the unknown) is particularly poor. As its draft regulatory science 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."*[8]

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.

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.

The APVMA has abandoned 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,[9] but the APVMA clearly rejects it.

In the absence of precaution, the agrochemical 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.

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.[10]

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.

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.[11]

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[12] without understanding or surveilling the impacts of those decisions.

Glyphosate

The APVMA is responsible for setting maximum residue levels (MRLs) for the use of chemicals on plants. These are largely based on agronomic and trade considerations. In the last decade the MRL for glyphosate has risen on a number of foods, including a 15 fold increase in the permitted residue in cotton seed oil and a 10 fold increase in the amount of glyphosate in canola oil.[13] This MRL has almost certainly been raised due to the increased use of glyphosate on the two GM crops grown in Australia – and not because new evidence has emerged that glyphosate is harmless at higher exposure levels.

Furthermore, a 2017 study found that glyphosate caused non-alcoholic fatty liver disease in rats following chronic exposure doses of Roundup herbicide at levels far lower than Australian Acceptable Daily Intake levels.[14]

Extraordinarily, the APVMA decided not to place glyphosate under formal reassessment in response to the IARC finding that glyphosate is a probable carcinogen.[15] A significant component of the APVMA's refusal to review glyphosate have been the conclusions reached by both the US Environmental Protection Agency (EPA) and the European Food Safety Authority (EFSA) that glyphosate isn't a carcinogen.[16] Documents that Monsanto has been forced to release as a result of litigation[17] reveal that the decisions of both the EPA and EFSA were apparently compromised.

These documents suggest that the EPA official responsible for evaluating glyphosate for carcinogenicity was in collusion with Monsanto.[18] This same official provided information to EFSA that formed part of the rationale for EFSA's dismissal of a study demonstrating a "statistically significant increased incidence of malignant lymphoma" in mice exposed to glyphosate.[19]

If an unequivocal finding of the World Health Organisation isn't even sufficient to justify a formal review, what level of evidence is required before the APVMA will act?

An independent and transparent review on the safety of glyphosate and its residues in food is clearly needed.

RNA interference

According to the APVMA's draft regulatory science strategy:

> *"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* [post-transcriptional gene silencing]"[20]

CSIRO has key patents and major commercial interests in this technology, and hence is less likely to advocate a precautionary approach.[21] Yet it appears that the APVMA has not consulted with independent scientists concerned about the use of gene silencing technologies in food and agriculture. This is a classic case of letting industry write the rules. On it's website the APVMA uncritically repeats the unsubstantiated claims of the agrochemical industry regarding this technology[22], with no mention of the safety concerns that have been raised by independent scientists[23] and regulators in other countries – such as the US Environmental Protection Agency.[24]

Nanomaterials

The APVMA's pro-industry stance is exemplified by its approach to the regulation of nanomaterials in agrochemicals. In 2014 the agency released a paper - *Regulatory Considerations for Nanopesticides and Veterinary Nanomedicines*. The paper made the implicit assumption throughout that the benefits associated with the use of nanomaterials in pesticides and veterinary medicine outweigh the risks. The paper tended to downplay the risks associated with the use of nanomaterials (usually by way of criticising relevant studies) and uncritically supports the claimed benefits.

The paper claimed there is 'general consensus' that the current regulatory framework is adequate for the moment. It is not clear where this consensus exists but in the absence of applications, assessments and surveillance, it's a meaningless thing to say. In fact, it is not clear how the current regulatory framework actually applies to nanomaterials nor is it clear that businesses seeking to use nanomaterials in agricultural products even need to apply to the APVMA for authorisation for such use.

The paper claims that those seeking to use nanomaterials in agricultural products must apply for authorisation. While there are information requirements relating to nanomaterials in the application, there does not appear to be any requirement that nano forms of existing chemicals are subject to any application requirement. The APVMA website previously claimed that "data supporting a chemical or chemical product that contains engineered nanomaterials will be independently evaluated, regardless of a conventional counterpart product being approved." Although they noted that "not all engineered or manufactured nanoscale materials are novel and will need to be assessed."[25] However, in 2014 this ostensible requirement was removed from the APVMA website and replaced with the statement that "the APVMA has not yet published any detailed guidelines specifically about the registration and regulation of products containing nanomaterials." Four years later this remains the case.

It is suggested that those proposing to register a product using nanomaterials 'should' first contact APVMA, but this is not mandatory.[26]

In the absence of any nano-specific regulations, the current regulations will only capture nanomaterials if they are new chemicals that would be subject to regulatory controls regardless of particle size. Reformulations of existing chemicals at a nano scale, nano-emulsions, nano-encapsulations and nanomaterials that are not active ingredients are not currently subject to any regulatory requirements.

In its paper on nanomaterials the APVMA accepts that change in regulations may be required in the future but lacks any clear vision of what regulatory changes may be needed and what shape and scope they may have.

In some ways, it appears that the APVMA is going backwards. In a 2012 review of agency responses to the 2007 Monash review of regulatory gaps,[27] APVMA was complimented for filling some of the identified gaps. For example, the APVMA website indicated that chemicals reformulated at the nanoscale would be treated as new substances. However this has not happened and is no longer mentioned on the APVMA website.

The Monash review also noted that all chemical registrations were going to be reviewed and that this process would capture nanomaterials in agricultural chemicals . However, the review of chemicals was abandoned by the Abbott Government.

Applications for new registrations include information requirements relating to nanomaterials, but as the APVMA has noted, these are for information only. The APVMA does not require companies to submit new applications for reformulated agricultural chemicals that contain nanomaterials.[28]

It does not appear that the APVMA has taken any active steps to determine whether nanomaterials are already in the agricultural sector, while FoE's research shows they are. The APVMA claims that there are no nanomaterials being used in agriculture because there have been no applications for approval. This barely qualifies as evidence. In light of the lack of nano-specific regulation and the lack of accepted standards and definitions, the industry's failure to apply for approval of nano-products is perfectly defensible from a legal perspective.

The APVMA's claim that there are no nanomaterials currently in use in Australian agriculture can also be disputed by examining the French register of nanomaterials. This reveals the agricultural industry to be the largest user of nanomaterials – mostly plant protection products.[29] It is therefore highly likely that nanomaterials are already being used in agricultural chemicals in Australia. Given the knowledge gaps regarding the use of nanomaterials in agriculture - and the recognised problems with methodologies for detecting nanomaterials in soils, plants and foods - satisfactory risk assessments for the use of nanomaterials in agricultural chemicals cannot currently be conducted.[30] These issues should be resolved before commercial release is permitted.

If the safety of a nanomaterial cannot be ascertained then it should have no market. Safety first is a basic tenet of precaution and yet the APVMA implicitly shifts the onus onto the public to demonstrate that nanomaterials in agricultural products aren't safe. This shift effectively abandons the precautionary principle.

b. the funding arrangements of the APVMA, comparisons with equivalent agricultural chemical regulators internationally and any impact these arrangements have on independent evidence-based decision making;

"Investigations by anti-corruption commissions in Australia "have repeatedly shown that agencies with regulatory functions…are particularly vulnerable to corruption and misconduct, especially where a high degree of discretion is combined with close relationships with the industry" (Adams et al 2007)[31]

Studies of regulatory capture and institutional corruption have demonstrated that the co-option of regulatory agencies is frequent and common.[32]

In 2017-18, the APVMA received 84 per cent of its operating budget from industry fees.[33] We believe that the APVMA's pro-industry bias is due in no small part to its funding arrangements, which effectively sets up a client relationship with the very companies it is supposed to be regulating. This funding arrangement needs to be urgently reviewed and the entire culture at the APVMA to be overhauled.

David Kessler, a former head of the US Food and Drug Administration (FDA), told the *Wall Street Journa*l, "There is no doubt that user fees give the industry leverage on setting the agency's priorities. There are significant risks."[34]

Light (2013) argues that "the authorization of user fees in 1992 has turned drug companies into the FDA's prime clients, deepening the regulatory and cultural capture of the agency."[35] Similar conclusions can be drawn regarding the APVMA.

c. the roles and responsibilities of relevant departments and agencies of Commonwealth, state and territory governments in relation to the regulation of pesticides and veterinary chemicals;

Food Standards Australia New Zealand

Whilst the APVMA is responsible for setting maximum residue levels (MRLs) in crops, Food Standards Australia New Zealand (FSANZ) is responsible for setting these in food. [36] Over the last few years Friends of the Earth has accumulated a substantial body of evidence that illustrates that FSANZ has been captured by industry in a similar way to the APVMA. The ordinary outcomes from FSANZ processes, assessments and decisions provide overwhelming evidence that FSANZ serves corporate interests first. When faced with a choice between public and private interest, FSANZ supports the private interest. When faced with choice between commerce and precaution, commerce is preferred.

In setting MRLs FSANZ is informed by the Australian Pesticide and Veterinary Medicines Authority (APVMA)'s[37] MRLs for the use of chemicals on plants. These are largely based on agronomic and trade considerations.

In the last decade the MRL for glyphosate has risen on a number of foods, including a 15 fold increase in the permitted residue in cotton seed oil and a 10 fold increase in the amount of glyphosate in canola oil.[38] This MRL has almost certainly been raised due to the increased use of glyphosate on the two GM crops grown in Australia [39] – and not because new evidence has emerged that glyphosate is harmless at higher exposure levels.

In fact, recent research suggests that glyphosate may be harmful at levels far lower than Australian Acceptable Daily Intake levels.[40]

FSANZ, although responsible for protecting public health in relation to food, has made no public statement on the safety of glyphosate since the IARC report came out in mid-2015. The IARC report and conclusion is only mentioned twice on the FSANZ website,[41] on both occasions as notes in the context of approval for a GM crop resistant to the use of glyphosate. On both occasions FSANZ clearly intimates that the IARC is wrong. The response is so minimal compared to other food regulators globally that it gives the impression that FSANZ is not taking the issue seriously at all. FSANZ simply notes that the IARC "conclusion is in stark contrast to the 'non-carcinogenic' classification given to the herbicide by a number of national and international expert committees."[42]

Extraordinary, FSANZ - which is charged with assessing the safety of chemical residues in food - has done no public review on the safety of glyphosate at all and remained virtually silent on the issue.

An independent and transparent review on the safety of glyphosate residues in food is clearly needed.

Lack of coordination between agencies

There seems to be a lack of information flowing between the APVMA, environmental and health agencies, posing major challenges for managing waterway pollution. For example, how can the National Health and Medical Research Council (NHMRC) set adequate guidelines for drinking water, if they are not provided the most relevant and up to date information?

In 2016, Friends of the Earth determined that most AGVET chemicals registered for use in Australia have never been tested for in waterways and only 3.5% have ecological guidelines. Furthermore 41% of pesticides detected in Australian waterways do not have Australian Drinking Water Guidelines (ADWG).[43]

A further study published by Friends of the Earth in 2017 found widespread pollution of Victorian Waterways with pesticides is a regular occurrence, with 46 different pesticides detected in Victorian water supplies between 2007-16.[44]

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