Submission To: Senate Standing Committee on Rural and Regional Affairs and Transport.

Subject: Inquiry into the APVMA.

FROM: LOCAL ENVIRONMENTAL ACTION FORUM. ESPERANCE WA

Date: 23 October 2018.

L.E.A.F *We are an independent local environmental group based in Esperance Western Australia. We are concerned about the human and environmental health of our district. The area is a major cropping area where our farmers have increasing reliance of chemical input for their operations.*

Abstract

There are over 8000 registered chemicals in Australia which are part of a four trillion dollar globally expanding market. It has been shown on numerous occasions that many of these products have some deleterious effect on human health and the environment. The enormous volumes that some of these chemicals are now being used on a global scale is reason for concern.

We acknowledge that many of these compounds play a major role in our agricultural production systems, but we are of a view that it is time for a fundamental shift away from the thinking of an industrial agricultural systems chemically reliant to an ecological one that has the promise of a more sustainable future with a healthier environment, healthier food and human population. The technical solutions of the future will need to be smarter, more targeted less risk to human health. The “sledge hammers” of the past won’t be acceptable in this emerging necessary paradigm. This paradigm will be driven by the need to create healthy foods and healthy people and the economic benefits that it brings.

A s a general premise we consider the guiding ideology of a regulating authority should be that of using a ***Precautionary Principal*** regarding human and environmental health rather than a **substantiative** one, especially if there is a lack of research.

Main Points.

- Open and transparent decision making. Arm’s length from industry.
- Human and environmental health should be the overriding principle of operation.
- The Precautionary Principle of risk assessment be adopted.
- All of society are the stakeholders.
- A wide range of expertise is needed in the regulatory process including BIOETHICISTS, ECOLOGISTS, SYSTEM MODELLERS, ECONOMIC MODELLERS and COMMUNITY INPUT**.**
- APVMA and its decision making should be under regular independent external review.
- APVMA task should be not to speed up the use of chemicals but to be certain they are safe and don’t incur future costs to the environment and human health.

- APVMA needs to recognise that an ecological approach is needed for agriculture and horticulture in order to produce healthy foods and store carbon in our soils.
- APVMA needs to review its position urgently on glyphosate including its adjuvants considering global concerns from reputable experts and institutions.
- Glyphosate and its adjuvants use needs to be restricted around schools and in the public domain until it is proven beyond reasonable doubt it is safe.
- The use of glyphosate to spray off crops prior to harvest should be restricted.
- Some countries are going to phase out Glyphosate. Considering this and questions over safety the position of Glyphosate and its adjuvants in Agriculture and Horticulture needs urgent review.

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a. The Responsiveness and effectiveness of the APVMAS process.

1.Open & Transparent Decision Making.

Most of the users of Agriculture and Vetinary Chemicals in the public domain would not be aware of the processes of the regulator rather there is a tacit acceptance that the regulator is working for the public good.

The APVMA doesn't list on its website the composition of the expert panels or the process how weighted decisions are made. For example, what makes a risk acceptable?

What is required on a national or international level are completely independent research institutions such as the International Ramazani Institute Non-Profit Social Cooperative to provide independent evaluations.

2.Obligation to Publicly Educate.

Many of us are not aware of the science of toxicology regulation or are we able to determine if it has a wider enough scope to access the risks that the integration of a new product may present. It is not explained. The public need this to be open and transparent to generate mutual respect for the decisions made.

3.We are all stakeholders.

The APVMA website to the uninitiated gives the impression that it exists for the convenience of the companies and agricultural industries. The site frequently refers to "stakeholders" as if it is some type of exclusive commercial club. We would present the notion that every Australian is a stakeholder as to the effect of many of the chemicals in the environment or in our foods.

Even the terms of reference to this enquiry is talking about the ***timely ticking off delivering*** the next compound is an indication of how much the industrial model is inground in our thinking. The criteria should be safety not time.

4.Constructively Tensioning the Decision-Making Process

APVMA from our observation seems to be the final authority if a chemical can be registered and used. By the nature of its function it must work closely with industry and as such could be seen by the public as not being impartial.

The Canadian system seems to put the weight of registration on the health Department. We would consider that a final decision be made as to the acceptance of a product be made by a Health Department and finally signed off by the Minister for Agriculture. The **tensioning of the decision-making process** both on a national and international basis is a necessary method to maintain performance and high-level decision making. This process can be complemented by including a wide range of skills on the expert panels. The science-based panel should be leading people in their field that can demonstrate no commercial or other affiliations with industry. We would like to see broader expertise on these panels such as **Bio Ethicists** and **Ecologists**

5. International Collaboration.

Effective, transparent exchange of information between international regulatory bodies would be essential but again would need a broad suite of disciplines so that the processes are under continual enquiry. Toxicology ***specialisation*** brings its own risk that it could lose sight of real-world situations.

The chemical companies will be driven by the market model and present their justifications from there view point. Who presents alternative views that may be better for the environment and human health.? The regulator needs broad expertise to make reasoned decisions.

6. A new approach is needed.

Around 2012 it appears that some of the international regulatory agencies underwent a review of their activities. Australia may have something to learn from adjustments made. It may also be far better to create our own unique independent, suitably distanced from industry, transparent regulatory body instead of copying mistakes of others.

“Industrial “agriculture where the silver bullet from a chemical company is the next new chemical or biotech solution needed seems to be self-defeating. What is needed is the return to an ecological approach to agriculture, so we can build healthy soils, healthy landscapes, healthy food and healthy people.

The ecological ‘technology” of the future is one that will work with the environment and not against it. It will be smarter and more targeted.

6. 1 The focus on LD50 scale for describing the toxicity of chemicals.

It is our view that there has been too much focus on the **Lethal Dose Scale** (LD50) only to discuss the toxicity or acceptability of chemicals. The scale doesn’t pick up the longer-term effects of the chemical, on the environment, bio accumulation problems and synergy’s with other compounds added or found in the environment. The scale needs to be used along with other parameters. For example, DDT has a LD 50 of approx. 800 while some of Glyphosates adjuvants are 600. The furore over DDT was because of its bio accumulation and effects on egg shells.

7.Adjuvants.

Adjuvants: the compounds that are added to the parent chemical to enhance its effect are not clearly listed on the label. It is not clear that the LD 50 describes the toxicity or any synergies that may exist. Additives such as POEA, organosilicon surfactants, propylene glycol, glycerine are added to enhance the effect of the chemical.

It needs to be made clear if the adjuvants are part of the chemical’s toxicity assessment.

POEA for example is five times more toxic than glyphosate.

8 Glyphosate.

The **APVMA** has rigorously defended its position on its web site regarding the registration of glyphosate in Australia providing it is used at label rates despite what appears some unassailable truths from a non-technical point of view. Apart from this enquiry there didn't seem any attempt to review its position rather it leaped to defending the status quo.

Some of these facts are.

- Total use to date from time of release of 8.6 billion kilograms Glyphosate used to Feb 2016. Projected **value** in 2022 $9.91 billion dollars US. The highest volume of chemical used is set to escalate due to intended release of glyphosate dependent GMOs and excess production capacity by the Chinese of glyphosate.
- August 2018 Californian Court made judgement against Monsanto in the Dewayne Johnson case.
- Decision against Monsanto in the Dewayne Johnson case upheld Oct 2018.
- 2015 Classification by International agency for Cancer Research as a group 2a probable carcinogen
- Defined as a Highly Hazardous Pesticide. FAO/WHO Joint Meeting on Pesticide Management as implemented by Mozambique (Come et al 2013).
- 2010 Monsanto patented the product as an antimicrobial.
- Professor Jack Heinemann University of Canterbury New Zealand Finds that the use of glyphosate can accelerate antibiotic resistance 100,000 times.
- The European Food Safety Authority described glyphosate persistent in soil as being low to high and that of its break down product AMPA being three years. This dispels the current myth that it breaks down readily.
- (Poletta et al 2009) DNA damage in the broad snouted caiman reported after the use of Roundup.
- 2009 Benachour & Seralini demonstrated that glyphosate, Roundup, POE and the metabolite AMPA cause cell death in human umbilical, embryonic and placental cells at dilutions far below those used in agriculture. They demonstrated the synergistic effects of the adjuvants.
- German government knew since 1998, that glyphosate
  causes birth defects. After analysing the industry data reported by the German authorities 1998. draft assessment report, independent scientists
  concluded: "a substantial body of evidence demonstrates that glyphosate and Roundup cause teratogenic effects and other toxic effects on reproduction", including heart, kidney, skeletal, lung and cranial problems (Antoniou et al 2012).
  Glyphosate adversely affects a number, but not all, of enzymes in the cytochrome P450 (CYP) 'superfamily' (McLaughlin et al 2008)
- The Argentinean state of Chaco where GM soy and rice crops are heavily sprayed with glyphosate birth defects increased four-fold in the year 2000 to 2009.

This is a very small sample of a range of studies or observations that should at least raise some concerns regarding this product. Granted a lot more research is needed. The facts of record volume usage, its potential to accumulate in the soil, its potential to disrupt the human biome, The **IARC** finding that it is a group 2a carcinogen plus the Dewayne Johnson court case should raise questions about unqualified support by APVMA for this compound This failure in many ways mirrors what is wrong with the regulatory process.

8. Is the glyphosate risk acceptable to the environment and the people in it?

If the answer to this question is no and this products registration is withdrawn then our agricultural industries will need a replacement product, strategy or method to replace it. Research and extension will be necessary.
The proponents of the chemical and biotech industries promote the view that without such products as glyphosate that agriculture would collapse. Unless we research and find alternatives to agricultural practices and offer innovations that are not a threat to human health and the environment then how do we know.?
From a public point of view, we would suspect that glyphosate has a limited life due to increased herbicide rates and the rapidity of weed resistance, so alternatives will be needed.
Similarly, if it is proven that glyphosate alters soil microorganisms and has a depressing effect on future production, is this an acceptable risk and what will be the real cost of that?
The public need to have the confidence that the regulator has human and environmental health front and centre and is arm's length from industry.

9 Polarised Debate.

We note the APVMA rejection of the IARC conclusion of glyphosate. We also note the ***Crop Life*** website and its declaration that an enquiry is not necessary despite the mounting global concern. If the regulators decision making was guided by the "***Precautionary Principle"*** rather than considering the chemical companies as the fonts of all wisdom when it comes to agricultural practice, then it would be morally right to review the situation.
The mounting global concern over the last five years about Glyphosate is coming from reputable and qualified people in the agricultural field. These are amongst many, chemists, soil scientists, microbiologists and climatologists.
Leaders such as the former governor general Michael Jeffery's call as reported by the Guardian "for farmers to embrace regenerative agriculture and cut back on chemical and non-organic fertiliser usage' in the interest of soil security must be reason for reconsideration in having a regulator whose main aim is for timely approval of compounds. It is time for change.
Given the amount of spin that is around the glyphosate controversy we need to perceive the regulator as independent from industry. We get it that agricultural chemicals are production tools but if their risk is too great then we expect the regulator to act on our behalf. Ultimately science and time will deliver the final verdict on the safety or otherwise of this compound. It would be better to see our regulator as pro – active rather than arrive at a decision when there is a crisis.

10. A Wider Responsibility.

It is fair to say that Roundup was marketed originally as breaking down quickly and comparatively safe for its operators that were applying it. Even to today its promoters' resort to comments like it is not as toxic as coffee, a BBQ or common salt. Ingrained in the public psyche is it is safe despite label precautions. Therefore, it is quite common to see the product used without caution around schools, parks and gardens and in public places. This is despite the horror stories appearing in the popular press about this product, Dewayne Johnson court case ruling and the IARC determination. As the authority that has the final say we believe it has the obligation to correct and react to misconceptions and correct them as need be.

B. Funding Arrangements for the APVMA

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1 Change the pay for service method.
This method is unlikely to produce a transparent, arm's length from industry model.

Obviously, the service of regulation and registering products must be paid for. Paying staff as salaried officers and making another government agency responsible for collecting registration fees may be a method.

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c. Role of other Federal and Government Departments.

As a general view it would appear necessary to have Federal and State Government bodies involved to gain access to regional differences.
We would consider it necessary to have a range of agencies feeding into the decision-making process particularly some of the human health, cancer councils and environmental bodies taking a more leading role.

D Timely access to safe and environmentally sustainable and productivity enhancing products.

We have no problem with an efficient system that delivers timely access to products providing it doesn't compromise safety.
We think part of the case for registration should be put forward by the company to model the benefits that a compound will be to industry and the environment.

E. APVMAs Relocation Impact on Efficiency.

We do not have any special insights in this area apart from the fact Armidale is a great spot and a University town which should offer some synergism.
We are in an era of modern digital communication that offers the ability to operate anywhere.
I understand that very little on ground research is done on chemicals by the APVMA, rather relying on external research review.
If it were to conduct actual research, then the location of this organisation would be different.

Conclusion.

L.E.A.F. recognises the need to reduce the volume and types of chemicals we introduce into the environment. It is time to change our focus from an industrially based agriculture to an ecologically based one that produces healthy food from healthy soils.
It is worthwhile remembering we are coating the planet with four trillion dollars' worth of man-made chemicals annually and soon to be an avalanche of biotech products on the basis it is safe. This is driven by the industrial model and we are expecting our environment to absorb this assault without repercussions is a form of lunacy.
The drive by industry to promote the view that without increasing amounts of biotech and chemical technology is the only way to feed a burgeoning population is in our view flawed. Especially when we consider the amount of food stuff that is wasted annually. Agricultural soils present the opportunity to store carbon to aid in climate mitigation, produce healthy food and healthy people without massive amounts of chemicals. We will need smarter ecological tools not more.

The focus of a regulator should be to protect Australians and the environment we live in. Approve targeted and specific products that are beyond doubt safe.

It is vital for Australian people to have a completely independent, free from commercial bias regulatory body that has health and the environment it's fundamental charter.

It is disappointing to see a Four Corners Television program create the need for this introspection and then the regulator and industry become highly defensive about their positions without a plan to improve.

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