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Agvet Chemicals (Better Regulation Reforms)

Senate Inquiry into Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Comments for consideration of the Senate committee.

Inadequacies of consultative process

I was disappointed that my investment in attending the initial DAFF consultative meetings to make representations about the bill, were not taken into consideration at that time. To have no minutes taken at those meetings is totally inadequate. Then to find none of the science based commentary which had been provided to DAFF, included in the draft, demonstrated that the donation of my time for the community to assist DAFF, had been time wasted. I do hope that this letter will not be similarly a waste of time.

Better protection of human and environmental health

The Australian Government states that it is committed to reform the regulation of agricultural and veterinary chemicals to improve the efficiency and effectiveness of the current system and provide better protection for human health and the environment.



There is ample evidence that the current system is failing to stop vast off-site movement of registered products into waterways. (Brodie, et al., 2012) (Brodie & Waterhouse, 2012) (Mitchell et al, 2005) (Schafer, et al., 2011) (Shaw, et al., 2010). There is also ample evidence to demonstrate that the levels which are being exported from AgVet use, are causing toxic impacts on the environment. (Mannusson et al, 2010) (Schafer et al, 2007) (Schafer, et al., 2012) (Teh, Deng, Werner, Teh, & Hung, 2005).

Mixture effects not adequately covered

The current reform proposals does indeed recognise the complexity of agricultural and veterinary chemical regulation but does not address the complexity of the 'real life' exposure effects of agricultural and veterinary chemical mixtures (both direct and indirect). (Kortenkamp, Backhaus, & Faust, 2009) demonstrated that mostly exposures of toxins are additive, but are difficult to exactly predict, with synergism and antagonism(less often) reported. The costs of trying to research every combination given the myriad of products in use is not practicable. Therefore the focus must move to a more precautionary approach that removes the risks of exposures in the first instance.

Other authors have articulated clearly the problems with the current regulatory framework. (Hartung, 2009) (Leist, Hartung, & Nicotera, 2008). The improvements suggested by these authors do not feature in the draft. Until the contemporary scientific knowledge is embraced by regulation, then preventable harm will continue to occur to human health and the environment, at a very substantial cost to the nation.

If the Australian Government was committed to the better protection of human health and the environment, then these above issues have to be addressed. A risk management strategy, as proposed, for singly assessing active ingredients can in no way address these issues.

Structural issues with defining highly hazardous pesticides

The Australian Government – APVMA and the Office of Chemical Safety – need to define highly hazardous pesticides (HHP) in line with international definitions; the community of Australia has already clearly articulated that persistent, bioaccumulative and toxic (carcinogens, chemicals that produce reproductive and developmental harm) agricultural chemicals have no place in the Australian market and should not be registered for any use. Substitution by less harmful chemicals is severely hindered by the current approach to HHP.

The approach of placing products on a list for review that then takes > 10years to get to and complete reviews is not acknowledging the downside risk of the continued use of the product being harmful. The regulatory structure which requires risk mitigation measures to be trialled before removal of the product, eliminates the option to be risk averse. A precautionary approach is required where product use is suspended, whilst safety is proved. Rather than the current status quo, where the product use is continued, until toxicity is proven and Australia is forced via international conventions such as POP's Copehagen to move to remove use.

Why, for instance, were the previously identified most hazardous pesticides (e.g. Chlorpyrifos and other organophosphates) not removed from registration with substitution of less harmful products? This

single measure would greatly decrease costs to the Australian government (and taxpayer) and allow for increased confidence by the community that indeed the Australian government has human health and environmental protection at the foremost of its regulatory reform. The neurotoxicity of organophosphates to developing childrens brains is now established. (Eskenazi, et al., 2007)It is poor public health policy to allow continued exposure. Lymphoma rates are climbing and Australian studies demonstrate that pesticide exposure is epidemiologically associated with disease occurrence (Fritschi, et al., 2005).

Low dose (endocrine, genotoxic, immunotoxic, epigenetic) exposure effects not adequately covered in reform draft

The current reform also does not address low dose effects (at levels below current laboratory detection), endocrine disrupting chemicals (many with non monotonic response curves), immune modifying effects and the genotoxic effects many of these chemicals produce (epigenetic effects can also be considered genotoxic in their effect)¹ (Edwards & Myers, 2007) (Kelly, Poulin, Tompkins, & Townsend, 2010) (Hamlin & Guillette Jr, 2010) (Soto & Sonnenschein, 2010) (Skinner, Manikkam, & Guerrero-Bosagna, 2010) (Tierney, Baldwin, Hara, Ross, & Scholz, 2010).

“With epigenetics, we are therefore left in a similar bind as we are with endocrine disruptors. Some are going to be more harmful than others, and some we will not need to worry about. Right now, however, for the most part all we can do is identify compounds which make these epigenetic changes. Taking a lead from endocrine disruption, the precautionary thing to do would be to limit exposure to substances which have the potential to cause harm via an epigenetic mechanism, until those substances have been proven safe by test methods appropriate to demonstrating that safety.”¹

“Sound science” (to use industry and Government terminology) would have allowed for the inclusion of these matters, as it is the Governments remit to interpret all the science and produce honest and effective regulatory reform.

Equal playing field for community contributed science and industry science access to decision makers

Perhaps the Government needs to clearly define, in plain English, what it precisely means by “better protection of human health and the environment” and ensure legislation continues to conform to this and not disregard community expectations, and fly in the face of mounting scientific evidence that current regulation is failing to prevent serious endocrine disruption and epigenetic impacts.

How has DAFF received the view of the community in regard to this matter?

¹http://healthandenvironmentonline.com/?utm_source=GraphicMail&utm_medium=email&utm_term=NewsletterLink&utm_campaign=

Is the view of “communities”, and the science they continue to present, getting as much weight as the view of the chemical industry?

If not why not, as it is the communities (environment and human) that suffer the adverse consequences of the failure of the Australian Government (through APVMA and the Office of Chemical Safety) to ensure regulatory reform “protects” human health and the environment.

As a clear example of the imbalance, I have ten’s of ministerial letters in response to my request to make scientific representations on pesticides to the Minister for Agriculture which have been declined. Yet Croplife Australia meets with the minister regularly.

Inadequate protection of unborn foetuses and children

It is commonly known that the foetus and the child are among the most vulnerable sub-populations and require therefore the most protection.² Engagement of all disparate “communities” is therefore fundamental to this process.

Indeed the World Health Organisation has warned that; “... *chronic, noncommunicable diseases are rapidly becoming epidemic worldwide. Escalating rates of neurocognitive, metabolic, autoimmune and cardiovascular diseases cannot be ascribed only to genetics, lifestyle, and nutrition; early life and ongoing exposures, and bioaccumulated toxicants may also cause chronic disease.*”³ In fact WHO has stated that children worldwide should be protected from persistent organic pollutants as they are not safe for children at any exposure and the risk of any exposure cannot be safely managed.

No longer should international trade standards be more rigorous than these for the domestic market; our environment and people deserve to have the highest standards implemented. If a pesticide is not acceptable in another country on 'imported' foodstuffs, it should not be considered safe here.

A “managed risk” strategy, with no effective outcome monitoring, nor, adequate disclosure of public health data, cannot deliver good public health outcomes.

The Adverse Experience Reporting Program (AERP) run by APVMA is an adhoc community reporting system that is grossly inadequate as insufficient financial or expert resources are given to those that report with this process.

² <http://www.panna.org/current-campaigns/kids-health>;
<http://www.panna.org/publication/generation-in-jeopardy>

³ <http://www.ncbi.nlm.nih.gov/pubmed/22315626>

The APVMA expect investigative detail in the reports and along with the long delay before there is any reply to the initial reporting, follow up is generally ineffective and unhelpful in this process.

I have first hand experienced the demonstrably deficient process. APVMA chose to use reviewers who were less expert, than the veterinarian notifying the APVMA. This was the case with Sunland Fish Hatchery. APVMA requested them to undertake, less comprehensive reviews, using restricted terms of reference. The approach of not consulting the reporting veterinarian is contrary to the National Veterinary codes of conduct which require all information to be provided to the second opinion provider. APVMA did not do this for the numerous Sunland Fish Hatchery AER's. International experts including Professor Andrew Hewitt visited the property and said that spraying cannot be conducted safely at that site with the equipment being used, where buffer vegetation codes of practice have not been implemented- yet APVMA took no action to improve labelling, remove unsafe products. Professor Mac Law, internationally recognised as the leading toxicological aquatic veterinary pathologist, agreed with the Qld Government case pathologist, Dr Roger Chong, that the lesions in the affected fishes were likely due to exposure to agrichemicals.

Yet, APVMA strangely disagreed with all these expertise, and have filed all these AER's, with no action taken. So it is clear that the AER process is utterly dysfunctional.

Adequacy of data to support registration and re-registration

Where an agricultural and veterinary chemical has no data to ensure its safety to human and environmental health, including to native Australian wildlife and fish, then it should not be permitted or registered. All current internationally acknowledged science should be included in APVMA's "safety" assessments; nothing less is acceptable.

It is good to see the introduction of a re-registration program, however it should require all products to supply contemporary data, to ensure that newly discovered toxicological impacts (eg EDC; epigenetic; immunotoxic) are detected, controlled and eliminated. The proposed program does not compulsorily require contemporary data to be submitted to demonstrate ongoing safety.

Response to International removal of products for safety reasons

When an agricultural and veterinary chemical has registration or re-registration cancelled for safety reasons, such as was the case with Endosulfan, the Australian Government should not allow for a 1-year sell-out period for stock in trade. This is blatantly at odds with "better protection of human health and the environment", as it is then knowingly selling and using products which are known to be unsafe.

Please consider these matters carefully as they are of the utmost importance to the health of our future generations.

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