PSGR

Physicians & Scientists for Global Responsibility

New Zealand Charitable Trust

PO Box 16164
Bethlehem 3147
info@psgr.org.nz
www.PSGR.org.nz
mob: 027 505 0808

Submission to the Environmental Risk and Innovation - Ministry for the Environment:

Hazardous substances assessments: Improving decision-making.

September 29, 2019

1. Physicians and Scientists for Global Responsibility welcomes the proposal by Ministry for the Environment (MfE) of the 'trusted regulator' approach. New Zealand's low rate of reassessment to ban toxic chemicals does not fit the perception that New Zealand is a safe and nourishing food supplier, and it risks the slow decay of international goodwill that New Zealand is a trusted food source.

2. Regulatory science is extraordinarily political, but this does not mean that it should use lack of resourcing to delay protections of public and environmental health. As such, many issues that have been represented by the public over previous decades are ignored by regulators. Consultation is framed in such a way that the terms of reference retain contested issues outside of consultation. All too frequently the wider scrutiny of the published literature is simply not undertaken, and the few reassessments that happen are pushed through, with little participation from the wider public and independent scientific or public health community, - and with heavy reliance on industry data to facilitate the process. Reassessment rarely happens in New Zealand. When it does happen, it reflects industry influence, rather than best practice regulation.

3. We have separated the submission into Part 1 which illustrates the gaps and entrenched problems in assessment and Part 2 which attempts to directly respond to the 50 questions contained within the MfE document (MfE, 2019).

4. Part 1.

5. Discussion documents and consultation to the public frequently leave scientifically important, but politically controversial issues outside the term of reference. Without resourcing, monitoring and a regulatory environment that is evidence based, unbiased and utilises best practice, the New Zealand government and staff cannot protect human or environmental health.

6. The HSNO Act (Pesticides) requires updating, as Catherine Iorns has suggested (Iorns, 2018, p. 11). Particular criticisms of the current hazardous substances/risk assessment system include:

    i. the extrapolation from animal testing to humans is inadequate and relies on models and assumptions that may not be accurate, and some of which have been questioned;

ii. the "dose-response relationship" cannot be assumed at low-dose levels; for some chemicals it is neither linear nor algorithmic but more of a "U" shape, with serious effects at extremely low levels of exposure;

iii. testing will typically only focus on the pesticide's primary mechanism and not on other side effects; for example, neurotoxicity testing of organophosphates usually only requires consideration of one mechanism, that of cholinesterase inhibition, and fails to test for developmental neurotoxicity, despite the considerable and expanding literature illustrating the non-cholinergic neurotoxic effects;

iv. testing for developmental immunotoxicity is generally not carried out, nor are allergic, inflammatory or autoimmune effects looked for;

v. endocrine disruption is not tested for; this takes a long time to show up, can occur at very low-level exposures, and can be passed through to future generations; for example the damaging impact of pesticides on mammary gland development can have an impact on the development of breast cancer later in life;

vi. children and the foetus are especially vulnerable to single, low doses; the high dose protocols fail to consider exposures that are environmentally relevant especially to the unborn and newborn, and fail to target various organ systems at critical stages of development from foetal life through to adulthood;

vii. risks are estimated for a single chemical at a time, so chemicals are tested in isolation when people and the environment are in reality exposed to mixtures of various chemicals, including adjuvant chemicals that are added to the pesticide active ingredient; testing thus generally fails to consider the impact of ubiquitous exposure on society as a whole;

viii. existing body burdens of chemicals and cumulative effects are ignored in determining safe exposures;

ix. some individuals are particularly sensitive to different chemicals such that adverse effects show up at lower doses than are considered acceptable for the average person; plus different individuals react differently to interactions of combinations of chemicals;

7. A 2018 'Risk Assessment Methodology Consultation' to the public (NZEPA, 2018) did not discuss the issues in the paper by Iorns. The current discussion document that this paper is attempting to respond to, also leaves these scientific issues, and the substantial body of scientific literature that demonstrates that pesticides may be riskier than current risk assessment methodologies demonstrate, outside the terms of reference.

8. As the discussion document noted, application fees contribute about 11% of the costs of HSNO applications. Current application fees for assessing new applications act as an indirect subsidy for the chemical industry. Conventionally, the regulator does not undertake a literature review, and the data scrutinised is selected and supplied by industry. This is clearly not in the public interest that the assessment process is funded by the taxpayer but the data is predominantly selected by the industry seeking authorisation.

9. Problematically, chemicals in the environment do not tend to be monitored to ensure they are within environmental exposure limits or tolerable exposure limits for human health, the controls set by the NZEPA are not monitored and so they are not able to be enforced.

10. The problem of environmental chemical toxicity is increasing, and the global chemical market is predicted to double by 2030. The International Council of Chemical Associations estimated the total number of industrial chemicals in commerce globally at 40,000 to 60,000, with 6,000 of these chemicals accounting for more than 99 per cent of the total volume' (UNEP, 2019).

11. **Human Health Risk**. Over half of the pesticides in the New Zealand environment may be suspected carcinogens ('t Mannetje, 2019). New Zealand and Australia have the highest incidence of cancer in the world, not merely from our exposure to the sun. Cancer incidence is supported by a high rate of hormonally related breast and prostate cancers; but also is the second highest relating to cancers of the digestive tract – the colon and rectum. (Bray, et al., 2018) The cost of endocrine disruption as a driver of disease including cancer, fertility and neurological disfunction runs into the hundreds of millions (Attina, et al., 2016) (Hunt, Sathyanarayana, Fowler, & Trasande, 2016), yet in New Zealand such discussion, or resourcing to research and regulate endocrine disruptors appears outside of regulatory consideration. Further, science is drawing attention to toxicity and the microbiome, and the sex specific differences that may result in greater risk to one sex (Lozano, et al., 2018).

12. **Environment Risk**. Earth is in the sixth major extinction event and agrichemicals are major drivers of insect declines. Scientists believe that the current rate of species decline could progress into extinction. A recent paper estimated 'the current proportion of insect species in decline (41%) to be twice as high as that of vertebrates, and the pace of local species extinction (10%) eight times higher, confirming previous findings' (Sánchez-Bayo & Wyckhuys, 2019). Toxic chemicals can pollute sediment and threaten water quality and riparian habitats. Indigenous freshwater species including kākahi (freshwater mussels); whitebait (īnanga), eels (tuna) and crayfish (kōura) are in decline or under threat (Dunn, et al., 2018) (Goodman, et al., 2013). These depend on healthy ecosystems. Three-quarters of New Zealand's thirty-nine native fish species are threatened with extinction (Weeks, et al., 2015) (OECD, 2017a).

13. An under-resourced science knowledge base

i. **Industry Dominates**. Due to the relatively small funding base for public and environmental health initiatives to provide independent scientific data in New Zealand, New Zealand lacks the sufficient knowledge and resourcing in the public sector to contest heavily resourced industry interests, including AgCarm, Federated Farmers and various horticultural and arable farming lobby groups.

ii. **Staff culturally allied with industry**. The historical dependence on industry data has meant that NZEPA staff communicate more frequently with industry. Further, staff attend international forums where international standards are decided with input from industry. For example, at a recent Codex meeting attended by Ministry for Primary Industries staff, discussion on endocrine disruption could not achieve consensus so the topic was dropped as 'there was no

consensus to take on the proposal for new work' (Codex Almentarius Commission, 2019). No representatives from the New Zealand public health sector attended.

iii. **When civil society advocates – it is ignored**. Organisations, public health academics and political parties have criticised NZEPA decisions but this has been ignored by the regulator. Civil society organisations seeking to draw attention to the toxicity of agrichemicals are under-resourced and funding to support organisations seeking to draw attention to chemical pollution in the environment is extraordinarily hard to acquire. During the organophosphate and carbamate insecticides group assessment, Pesticides Action Network Aotearoa released the book Poisoning our Future: Children and Pesticides – however due to the small resources of this organisation this book was largely unknown to the public and did not receive substantial media attention that might shape a more precautionary approach (Watts, 2013). Dr Meriel Watts has had to draw funding from offshore, there is no-one in public academia with a similar mandate to research and draw attention to broad aspects or risk from environmental chemical mixtures, and in particular, pesticides.

iv. **No resourcing – no knowledge**. There is little monitoring in New Zealand, either in the environment, or biomonitoring of humans. Data is not collected to understand the total tonnages that are sold into the New Zealand environment. The current Reassessment list contains many chemicals banned in Europe and a recent study has drawn attention to the mixtures of chemicals that are present in freshwater (Hageman, et al., 2019). New Zealand academic and research institutions lack the capabilities to analyse the mixture toxicity to estimate whether chronic exposures of these mixtures are drivers of the dramatic decline observed in New Zealand aquatic vertebrates. A recent AgCarm sponsored report (NZIER, 2019) cites the claimed benefits of pesticide use, but there is simply no public funding to balance such claims to address the potential risk to soil, air, water or public health.

v. **Diffuse chemicals require monitoring in order to scientifically assess risk**. Toxic chemicals drive disease and biodiversity decline and chemical use is predicted to increase (UNEP, 2019). The European Environment Agency notes that diffuse agrichemicals are major contributors to freshwater pollution (EEA, 2018), and the OECD has noted that the toxic risk from diffuse chemicals requires bottom up monitoring if diffuse pollution is to be adequately addressed. New Zealand lacks these monitoring capabilities and the current MfE National Environment Standards policy consultation process has ignored the problem of diffuse chemical contamination in freshwater and sediment.

14. Endocrine Disruption

i. There is scientific consensus that endocrine disruption from toxic chemicals, including pesticides, represents a significant health threat (Gore, et al., 2015) (Demeneix & Slama, 2019). Endocrine disrupting chemicals contribute to disease and damage neurological function (Attina, et al., 2016). The New Zealand machinery of government has yet to address the toxic risk from endocrine disrupting chemicals in the New Zealand environment and there are no apparent specialists in endocrinology with expertise on toxic chemicals working in public and environmental health. It is not surprising that regulators are slow to require data as a necessary (rather than voluntary) component of risk assessment. Endocrine disrupting chemicals can interfere with the hormone system at parts per billion and parts per trillion, far

below the levels that the chemical industry study for safety (Vandenberg, et al., 2013). The problem of endocrine disruption underpins increasing awareness that many chemicals including pesticides are dangerous at the levels considered safe by regulators, including the NZEPA (Kortenkamp A., 2014) (Lee, 2018).

ii. The risk of endocrine disrupting substances is particularly acute in regards to prenatal and neonatal exposures, and exposures to young children. Infants and children consume more than adults by bodyweight, and have vulnerable development windows where they are more likely to be harmed. It may take years for the harm to be observable. (Watts, 2013)

iii. The European Commission is taking steps to ensure endocrine disruptors are regulated and public and environmental health is protected. Sweden has sued the European Commission for delays and the pressure from public and environmental health groups are significant (IEEP, 2019). A framework has been released and it is understood it will be based on application of the precautionary principle and that it should be horizontally applied across sectors (E.C., 2018).

iv. There are gaps, for example cumulative effects are not considered, biological thresholds may be difficult to establish, resulting in the fact that no safe level of exposure. The European REACH regulation recognises endocrine disrupting chemicals as substances of very high concern, at the same level of carcinogens, mutagens and reprotoxicants. The European Chemicals Agency (ECHA) has started listing EDCs, albeit slowly.

v. A recent European paper contained recommendations which recommended the development of ‘a set of trans-sectorial and harmonized regulations to minimize human and environmental exposure to endocrine disruptors’. The paper suggested that EDCs can be categorised into known, presumed and suspected EDCs. (Demeneix & Slama, 2019, pp. 97-98)

15. Formulation ingredients should not be kept secret

i. Another key issue considered a voluntary, rather than essential component of risk assessment is the greater toxicity of the retail formulation that the public is exposed to. Risk assessment in New Zealand is based around the toxicity of the active ingredient, yet the formulation is developed for enhanced toxicity (Mesnage & Antoniou, 2018) and frequently, crops will have multiple formulations applied to them (Evans, Martin, Faust, & Kortenkamp, 2016).

ii. Glyphosate-based herbicides have never formally undergone risk assessment in New Zealand. There has only been a carcinogenicity study which was heavily criticised for relying on industry data (Douwes, et al., 2018). A series of papers have shown that the formulation of glyphosate is much more toxic than the active ingredient (Myers, et al., 2016) (Mesnage, Defarge, de Vendomois, & Seralini, 2015) and that the ingredients in the formulation include the heavy metals cadmium, lead and arsenic, as well as petroleum distillates (Defarge, de Vendômois, & Séralini, 2018). Pesticides and heavy metals act synergistically, enhancing toxicity (Singh, Gupta, Kumar, & Sharma, 2017).

iii. Despite the New Zealand focus on sediment, the Ministry for Environment, and the NZEPA have are yet to scrutinise the greater risk to sediment quality as the active ingredient,

breakdown metabolites and heavy metals can remain in sediment for long periods of time. Our own drinking water standards confirm this (MoH, 2018).

16. Why Europe should be the 'trusted regulator'

i. If New Zealand is to protect human health and environment, it must do so using best practice risk assessment. Regulatory responsiveness to data that indicates human health harm, and the problem of accumulation in the environment can be observed by Europe's response to chemicals that are accumulating in the New Zealand environment. Responsiveness reflects the degree of public or industry pressure that will drive the political position.

ii. Regulators are guided by outdated references that are often many decades old and intimate pesticides aren't in the environment at significant levels (MoH, 2018). There has been little funding for toxicology and monitoring of pesticides in New Zealand freshwater environments.

iii. However a recent wide ranging study detected the chemicals *diazinon, chlorpyrifos, thiamethoxam, imidacloprid, atrazine* –across New Zealand. In many cases, mixtures of these chemicals were present (Hageman, et al., 2019).

iv. In Europe these chemicals are heavily regulated or banned from use.

i. Canada and Australia

By comparison *diazinon, chlorpyrifos, thiamethoxam, imidacloprid, atrazine* are all registered for use Canada through the regulator Health Canada (Health Canada, 2016). In Australia, the Australian Pesticides and Veterinary Medicines Authority has authorised *diazinon, chlorpyrifos, thiamethoxam, imidacloprid, atrazine* for use (APVMA, 2019).

ii. The United States Environmental Protection Agency

a. The USEPA (USEPA, 2019) has *diazinon, chlorpyrifos, thiamethoxam, imidacloprid, atrazine* approved for sale.

b. The United States Environmental Protection Agency (USEPA) has recently been heavily criticised for handling of neonicotinoid insecticides, glyphosate-based herbicides, chlorpyrifos and dicamba. A recent study noted that the USEPA lags significantly behind the European Union, but that the USA also permits pesticides banned or phased out in Brazil and China. The paper suggested that much of the problem sits with inadequate legislation.

> '[Federal Insecticide, Fungicide, and Rodenticide Act] FIFRA gives the US EPA significant discretion on which pesticides it ultimately decides to cancel and makes the US EPA-initiated, non-voluntary cancellation process particularly onerous and politically fraught. This, in part, has led to an almost exclusive reliance on industry-initiated, voluntary cancellation of pesticides in the USA' (Donley, 2019).

c. China has recently taken steps to reduce chemical pollution. China is phasing out some toxic pesticides to improve food safety and reduce soil pollution (Patton, 2017). Many of the selected pesticides remain available in New Zealand. China is undertaking research to investigate taxation and subsidy 'ecological compensation policy' schemes to assist transition (Liu & Xie, 2018).

Pesticide	List	EU	USA	BRA	CHN
2,4-DB		3	3	1	1
Bensulide		1	3	1	0
Chloropicrin		1	3	0	2
Dichlobenil		1	3	1	4
Dicrotophos	W	1	3	1	0
EPTC		1	3	1	0
Norflurazon		1	3	1	0
Oxytetracycline	A	1	3	1	4
Paraquat	R2	1	3	2	1
Phorate	W, R2	1	3	1	2
Streptomycin	A	1	3	1	3
Terbufos	W	1	3	3	1
Tribufos (DEF)		1	3	1	0

Fig. 2 Pesticides Used in the USA and Banned in at Least Two of Three Other Agricultural Nations. The first column gives the common pesticide name. The second column indicates whether the pesticide is on an international list of concern (W=World Health Organization (WHO) "extremely" or "highly" hazardous pesticide [79]; R2 = Rotterdam Convention Annex III list, Recommended [73]; A = WHO "critically" or "highly" important antibiotics [53]). Columns 3–6 indicate the pesticide status in the European Union (EU), the United States of America (USA), China (CHN) or Brazil (BRA). 1 = Banned; 2 = In process of complete phase out; 3 = Approved; 4 = Not approved/ voluntarily withdrawn; 0 = Not in database/unknown. Red = banned/ phasing out; Green = approved; Orange = Not approved/unknown

Figure 1 USA Lags Behind Other Nations in Banning Harmful Pesticides. Donley 2019

iii. Food and Agricultural Organisation - World Health Organisation (FAO-WHO) Joint Meeting on Pesticides Residues (JMPR)

a. The FAO-WHO JMPR committees are trade based, and in general, rely on industry supplied data to form the bases of toxicological assessment. This is a trade-based organisation with no democratic accountability. It was FAO-WHO JMPR committees conducted the toxicological evaluations (FAO-WHO, 2006) and then the pesticide residue trials that initially authorised glyphosate-based herbicides to be applied on food crops (FAO-WHO, 2005), entailing an increase in maximum residue levels that Codex then adopted in 2006 (Codex, 2019). The USA followed suit soon after. The 2016 FAO-WHO JMPR (FAO-WHO, 2016) assessment excluded a wide body of science that might have indicated glyphosate on food crops.

b. While the participation of 'experts' to FAO-WHO Joint Meeting on Pesticide Residues (JMPR) and Codex committees are publicly promoted (Codex, 2018) it is difficult to access and understand meeting participation as the process is opaque and outside of public scrutiny. The events are heavily attended by industry and the country representatives are usually agriculture and primary industries focussed rather than having public health expertise. New Zealand staff from the Ministry for Primary Industries, and at times the NZEPA attend these meetings.

c. It is due to the lack of democratic accountability, the participant expertise that is related to agriculture and facilitation of innovation in the agricultural field, rather than expertise in public health, including endocrinology and carcinogenicity, or in environmental health, that the FAO-WHO is not recommended as a trusted regulator for the NZEPA and MfE.

d. (The International Agency for Research on Cancer (IARC) is a separate UN WHO agency, located at Lyon, France.)

iv. European Commission

a. In Europe the neonicotinoid insecticides thiamethoxam and imidacloprid are limited to use in greenhouses, field use is not permitted due to risk to pollinators (EC, 2019). Neonicotinoids

are a global surface waters contaminant (Sánchez-Bayo, Goka, & Hayasaka, 2016). Europe has recently ruled that there is no safe exposure to chlopyrifos due to its neurotoxicity at low levels (EC, 2019). The ecotoxic diazinon (EFSA, 2006) and endocrine disruptor and groundwater pollutant atrazine (E.C., 2004) have been banned for over ten years.

b. These five chemicals form an excellent benchmark with which to identify regulatory response to risk in the international regulatory environment. In addition, the persistent groundwater pollutant hexazinone, commonly detected in New Zealand groundwater (Close & Humphries, 2014), and banned in Europe for that very reason, will also be added to the benchmark group of diazinon, chlorpyrifos, thiamethoxam, imidacloprid, atrazine – to evaluate regulatory responsiveness. It is acknowledged that chemicals act differently in different environments, however all of these chemicals have been 'controversial' – public and environmental health scientists outside the regulatory theatre have expressed concerns that these chemicals confer significant human and environmental health harms for a long time.

17. Drinking Water

i. The problems with the FAO-WHO (Geneva based) and Codex (Rome based) process step into inferior WHO standards for drinking water, as it is the FAO-WHO industry supplied studies that are used to determine risk and appropriate levels of exposure for populations.

ii. New Zealand regulators (MoH, 2018) have conventionally relied on World Health Organisation standards for Drinking water (WHO, 2017).

iii. WHO standards can result in New Zealand drinking water suppliers not monitoring drinking water for chemicals and underestimation of toxicity.

iv. For example, the WHO 2017 drinking water standards for glyphosate rely as principle references on 1994, 1998 and 2005 evaluations. The 2004 drinking water standards, copied and pasted into the current 2017 standards (WHO, 2017) rely on the a 26 month study of glyphosate in rats to arrive at a NOAEL of 32mg/kg bodyweight per day. This is an unpublished 1981 Monsanto feeding study, and it forms the basis of the WHO drinking water standards (Lankas, 1981). The Lankas study has been critiqued in a previous paper which was critical of NZEPA reliance on unpublished industry data (Bruning & Browning, 2017). This single study has formed the basis for assessment in the European Union and previously the WHO-FAO before the latter lowered residue levels to increase exposure.

v. The WHO then state:

> 'Because of their low toxicity, the health-based value derived for AMPA alone or in combination with glyphosate is orders of magnitude higher than concentrations of glyphosate or AMPA normally found in drinking-water. Under usual conditions, therefore, the presence of glyphosate and AMPA in drinking-water does not represent a hazard to human health. For this reason, the establishment of a formal guideline value for glyphosate and AMPA is not deemed necessary.' (WHO, 2017, p. 374)

vi. New studies in the published literature that demonstrate that glyphosate may be toxic below levels that regulators recommend have been ignored (Myers, et al., 2016). Contrary to

regulatory claims there is evidence glyphosate is ubiquitous in the environment and that the chemical and its metabolite can accumulate in freshwater environments (McKnight, Rasmussen, Kronvang, Binning, & Bjerg, 2015) (Villeneuve, Larroudé, & Humbert , 2011). Glyphosate in 'surface waters in the EU appears to be lower, but consistently occurring' (Székács & Darvas, 2018).

European Drinking Water Standards consistently safer than WHO-FAO standards

vii. However, the European Union standards are stricter which would create additional protections for the New Zealand public. The EU in a proposal memorandum, recently rejected WHO recommendations to remove toxic chemicals including polycyclic aromatic hydrocarbons, benzene and mercury from European directives for monitoring, and similarly to increase maximum values (permitting higher exposures) of other contaminants. Further, thyroid harming disinfectant products although recommended by WHO, were set at sufficiently lower levels than that proposed by WHO. Similarly, the EU set lower levels for polyfluoroalkyl substances (PFAS) than recommended by WHO, and set maximum levels for the PFAS group (0.50 μg/l). Europe also requires that the sum of all pesticides in drinking water cannot exceed 0.50 μg/l. (E.P., 2019)

viii. Other chemicals banned in Europe and not permitted in EU drinking water, yet remaining on the NZEPA Priority Chemicals List include: Alachlor, Amitrole, Bioresmethrin, Brodifacoum, Carbaryl, Carbendazim, Cyfluthrin, Cyhalothrin, Diazinon, Dichlobenil, Dichlorvos, Fenitrothion, Fenthion, Flocoumafen, Paraquat, Propargite, Propoxur, Trifluralin.

ix. Of these WHO 2017 drinking water standards still maintains tolerable allowances for EU banned chemicals alachlor and trifluralin. The EU banned chemicals dichlorvos carbaryl, diazinon, fenitrothion, propoxur included in the WHO 2017 drinking water standards but do not have guideline values as the WHO presumes these chemicals occur in drinking-water sources at concentrations well below those of health concern.

x. These EU banned chemicals are not included in WHO drinking water standards: Amitrole, Bioresmethrin, Brodifacoum, Carbendazim, Cyfluthrin, Cyhalothrin, Dichlobenil, Fenthion, Flocoumafen, Paraquat, Propargite.

xi. In New Zealand, pesticides require monitoring if they have an established MAV – maximum acceptable value. If they are not assigned a MAV there is no requirement to monitor in drinking water. Alachlor, diazinon and trifluralin have MAV's assigned to them.

xii. There is no New Zealand MAV established for amitrole, bioresmethrin, brodifacoum, carbaryl, Carbendazim, Cyfluthrin, Cyhalothrin, Dichlobenil, Dichlorvos, Fenthion, Flocoumafen, Paraquat, Propargite, Propoxur. Fenitrothion 'could' have a MAV.

xiii. The neonicotinoids thiamethoxam and imidacloprid do not have MAVs assigned and are not required to be tested in drinking water

Part 2. Answering the 50 questions

From the Discussion Document: Hazardous substances assessments: Improving decision-making

Proposal 1: (3.1.1) Making better use of international information

Option 2: Apply trusted regulator's information

Option 2C: Apply full assessments or decisions with New Zealand lens

1. Do you agree that the EPA should make better use of international information during assessments and reassessments of hazardous substances?

Yes.

2. Do you agree with the criteria for defining who is a trusted regulator?

We do not agree as the current criteria is narrow and does not provide guidance to best regulatory practice.

In order to protect public and environmental health so that the purposes of the HSNO Act may be best achieved it is not sufficient to simply suggest collegial regulatory jurisdictions such as Australia or Canada. These regulators are not best practice.

In order to protect human and environmental health the regulator with the most transparency, use of the most up to date considerations (such as endocrine disruption and oxidative stress) and who is legally required to transparently consider the published scientific literature in a transparent approval and assessment process must be used.

- A 'trusted regulator' must be best practice so that New Zealand does become hitched to a 'race to the bottom' regulatory environment.
- There will not always be replacement chemicals, and banning of toxic chemicals must not be delayed in the hope there will be a safer replacement.
- The European Food Safety Authority (EFSA) should act as trusted regulator as there are legislative mechanisms in place requiring that EFSA consider the published scientific literature and consider the toxicity of the full formulation.
- Other regulators, such as the WHO-FAO consider activities mandated within EU legislation discretionary, and lack the democratic accountability of the EU. This is because the EU is closely scrutinised by well-established public health and environmental organisations.
- The USA lags behind Europe, China and Brazil in banning hazardous pesticides.
- Best practice sends signals out to both trading partners and other agricultural nations
- Conventionally regulators have based authorisations and risk assessments around data supplied by industry. This remains problematic as industry will select data favourable to authorisation. Europe is required to consider the literature outside of industry data.

The current regulatory idea of 'reliability' does not guarantee safety and protect public and environmental health. Current notions of 'reliability' involve the use of data quality systems that are inadequate and insensitive. Much of the data is hidden via commercial confidentiality agreements and the problematic laboratory management system titled 'good laboratory practice'(GLP). GLP

‘does not evaluate the scientific quality and reliability of a study (Buonsante, Muilerman, Santos, Robinson, & Tweedale, 2014, p. 140) (Myers, et al., 2009).

The foundation of modern science, published in the scientific literature, is that to be meaningful it must be replicable and reproduceable. Scientifically credible risk assessment must act transparently, and place the public interest before commercial interests. The current crisis of trust in regulators has its foundations in the hidden nature of regulatory risk assessment. This is currently being challenged in international courts, as the regulatory failure to take account of chemical formulations much more toxic than the declared active principle are becoming evident. If NZEPA is to maintain legitimacy it is critical that industry data is not privileged.

What other criteria should we consider?

The criteria that should be considered require regulatory risk assessment to undertake the following:

- Literature review of the published scientific literature
- Toxicity studies supplied of the full formulation for all endpoints
- Inclusion of endocrine disruption as an endpoint
- Inclusion of oxidative stress
- Greater consideration of prenatal and neonatal toxicity
- Recognition of the toxicity and risk as emissions to the environment from adjuvant ingredients
- Toxicological data available to the public for scrutiny

3. Do you agree with the proposed principles and considerations of using information from trusted regulators (see section 2.1.1)? What other principles should we consider?

It is recognised that much of this may already been undertaken.

4. Which jurisdictions/agencies do you think we should regard as trusted regulators? Why?

The European Food Safety Authority / European Commission is the only relatively safe regulator. This is because it is exposed to the most public scrutiny. To illustrate the problem of reliance on non-EU jurisdictions, the following case study of aminocyclopyrachlor is provided.

Case Study: aminocyclopyrachlor

Authorisation for the aminocyclopyrachlor (NZEPA, 2019) is in process, and the data gaps and problems reveal the weaker regulatory environment of New Zealand, but also the countries that have approved the herbicide for use. Initially marketed as a broadleaf herbicide, the product is intended to kill wilding pines.

Aminocyclopyrachlor has an ecotoxic (9.1) rating, and should be assigned an environmental exposure limit (EEL). However New Zealand doesn’t test for agrichemicals in surface waters to understand if EELs are exceeded.

(a) Synthetic Auxins – oxidative stress

Aminocyclopyrachlor is a synthetic auxin in the pyrimidine-carboxylate sub-class. The mode of action of these herbicides is to mimic the naturally occurring plant hormone, indole-3-acetic acid (IAA). Synthetic auxins are highly toxic and accumulate in groundwater (Munira, Farenhorst, Sapkota, Nilsson, & Sheedy, 2018). Synthetic auxins include 2,4-D, clopyralid, MCPA and dicamba.

In aquatic ecosystems synthetic auxins can accumulate and reach several trophic levels. The synthetic auxins can damage cellular energy metabolism at low concentrations. In animals, 'the effects include impaired energy metabolism resulting from the inhibition of mitochondrial enzymes; inhibition of enzymes that produce polyamines required for protein synthesis; inhibition of DNA synthesis; and induction of hepatic enzymes involved in detoxification and lipid peroxidation'. The impact of synthetic auxins is sub-lethal – 'A decline in oxygen utilization leads to a low supply of ATP for the maintenance of cellular homeostasis and increased oxidative stress'. (Salvo, Malucelli, Da Silva, Alberton, & De Assis, 2015). Oxidative stress is a driver of disease (Kaur & Thakur, 2018). However studies such as these, indicating that the applicant product may exert similar risk as other chemicals in its class, will not be supplied by applicants.

(b) European Union: not authorised because of persistence?

It is not approved in the European Union. This may be due to data gaps, no data has been supplied for endocrine disrupting effects. It is likely that Bayer is attempting to get early adoption in weaker regulatory regimes because of its risk in water.

Aminocyclopyrachlor does not bind readily to soil, it is considered 'moderately to highly mobile', is 'degraded slowly in soil and aquatic media through microbial activity' and has half-life greater than 100 days (Bayer CropScience, p. 44). Synthetic auxins pollute groundwater, and the capability to detect the chemicals may be dependent on laboratory instrumentation and methods used. Synthetic auxins don't tend to be detected in New Zealand groundwater. In a European study the degradation products, metabolites of phenoxyacetic acid herbicides were detected as often as the parent active ingredient (McManus, Moloney, Richards, Coxon, & Danaher, 2014).

No data on metabolites appears to have been supplied to the NZEPA. European assessments tend to identify metabolites. Only one long term study was supplied to the NZEPA for aquatic vertebrates. If used in the same manner as conventional forestry herbicides, aminocyclopyrachlor will accumulate, like the forestry chemicals terbuthylazine, hexazinone and atrazine, in New Zealand groundwater (Close & Humphries, 2014).

As a synthetic auxin, aminocyclopyrachlor may cause oxidative stress at low, chronic levels and exposures to vertebrates in aquatic ecosystems may be significant due to the persistent nature of the herbicide. In comparison, neither Health Canada, the Australian APVMA or New Zealand provide comparable guidance.

(c) Drinking water gaps

WHO drinking water guidelines (WHO, 2017) do not include aminocyclopyrachlor. Europe has raised concerns that mixtures of synthetic auxins may contaminate drinking water. Current regulatory procedures in New Zealand do not sufficiently include consideration of metabolites that may be present in drinking water, in addition to the parent compound. There are insufficient mechanisms to understand whether drinking-water testing identifies metabolites (for example, that are listed in European toxicological assessments) which are not clearly determined through the WHO drinking water process. Further, appropriate and transparent mechanisms are not in place to ensure mixture effects are considered, as well as accumulative risk from chemicals (and metabolites) in the same pesticide class.

It appears New Zealand may be a backdoor entrant for products the EU won't consider safe. The product has a long half-life, will it persist in groundwater with other forestry herbicides that currently

pollute groundwater? There has been no declaration of the toxicity assessment of the adjuvant ingredients, and it is known that adjuvants are primary drivers of toxicity, which would also be applied to the New Zealand environment.

The comment on endocrine disruption is inadequate and specific tests should be undertaken of the full formulation to assess endocrine effects. Conventional toxicology data are unsuitable for guidance on endocrine disrupting potential (Vandenberg, et al., 2013).

5. What information should we regard as trusted?

As discussed earlier, studies that have been hidden under confidentiality agreements using the GLP should not be trusted. GLP is a laboratory management system designed to prevent misconduct and fraud. GLP is not considered a guarantee of reliable or valid science (Myers, et al., 2009).

The problem of hidden data and the pressure placed on regulators to ignore data demonstrating toxicity has been brought to light in successive glyphosate law suits in the USA where jurors have determined that non-Hodgkin's lymphoma arose after exposure to glyphosate (Baum, Hedlund, Aristei & Goldman, 2019) (USR2K, 2019). The General Court of the European Union recently decided that the public had a right to access to industry data conventionally kept hidden due to 'commercial confidentiality'. The court considered that the public right to examine data relating to 'emissions into the environment' was *'deemed to be in the overriding public interest, compared with the interest in protecting the commercial interests of a particular natural or legal person, with the result that the protection of those commercial interests may not be invoked to preclude the disclosure of that information'* (General Court of the European Union, 2019).

6. Which options do you support for using information from trusted regulators for assessments of new hazardous substances? Why?

Option 2C: Apply full assessments or decisions from the European Food Safety Authority / European Commission with New Zealand lens

7. Which options do you support for using information from trusted regulators for reassessments of existing hazardous substances? Why?

Option 2C: Apply full assessments or decisions from the European Food Safety Authority / European Commission with New Zealand lens

8. Should the requirements for applying trusted regulators' information for the initial assessment to introduce a chemical to the New Zealand market be any different to a reassessment (see section 1.2 and 2.1)?

There should be additional scrutiny of the published literature because the product will have been on the market for some time.

9. Do you suggest another option? If so, please explain.

10. When applying information from a trusted regulator, should the New Zealand context always be considered? (This is currently a requirement in the HSNO Act).

Currently the New Zealand context is not sufficiently considered. Risk to human and environmental health is unable to be gauged due to the lack of scientific resourcing and data funding. If New Zealand data are supplied it is frequently industry funded, but the public science resourcing to understand New Zealand risk is dismal. If this was happening it would be recommended. But it is not.

11. Are there any other issues with using information from international regulators that the discussion document has not covered?

Please read through reference list.

Proposal 2: (3.1.2) Immediate suspension based on trusted information

'The Hazardous Substances and New Organisms Act 1996 (HSNO Act) allows the Environmental Protection Authority (EPA) to obtain any relevant information on a substance from any source when undertaking assessments and reassessments'. However in practice industry supplies the data for assessments and reassessments are rare.

12. Do you think the current threshold for suspension is appropriate (that is, significant actual or imminent danger to human health or safety or the environment from the continued use of the substance – see section 3.1.2 – 'The problem')? Why/why not?

It is not clear if there has ever been an immediate ban, usually it is clear to industry that a pesticide is unlikely to be authorised at the end of its approval period. In Europe peer reviews occur over a period of time and before the end of the approval period, giving industry suitable warning. It is exceptionally rare that a ban would occur with immediate ramifications.

As the document notes 'The criterion of "significant actual or imminent danger to human health or safety or the environment" sets a high threshold that the EPA has never been able to use to suspend a substance.' This may be due to the inadequacy of the methodology order which restricts use of precaution, making it difficult to use the precautionary principle in decision-making, as Catherine Iorns has suggested. (Iorns, 2018)

Review of the methodology and HSNO Act to more appropriately effect the precautionary principle, so that it is situated at a meta-level in decision-making, rather than as another factor considered alongside issues, would be an important step. This has also been suggested by Iorns.

Again, Europe has been able to more effectively embed the precautionary principle in decision-making.

Improvement in interpretation of the precautionary principle along European lines would ensure more effective application of an important mechanism to ensure New Zealand regulators can recognise the danger of unanticipated and irreversible effects. This might help shift the science base to recognise system risk from not only similar modes of action but also via synergies from different chemicals and heavy metals and act precautionarily. There is no work in New Zealand addressing this, unlike Europe (Napierska, et al., 2018) and pesticide mixtures are common in the New Zealand environment (Hageman, et al., 2019).

The document discussing reassessment of OPCs is arguably misleading as it does not discuss the European approach to many of these toxic chemicals.

If New Zealand was following European precedent there would be a phase out time. The current long (fifteen year) period for diazinon in New Zealand in Europe would be referred to as an extension rather than revocation or a 'phase-out'.

The example of organophosphate and carbamate insecticides is problematic as the NZEPA could have followed European precedent and been more restrictive. However the significant industry pressure may have guided the decision. The decision of the New Zealand regulator to restrict the studies considered for the OPC decision and not consider bans or restrictions in Europe was a political decision rather than a scientific decision.

Case Study: Organophosphate and carbamate insecticides group assessment APP201045

A NZEPA 2013 group reassessment extended the EU banned insecticide diazinon till 2028, and pushed through the following chemicals (bold indicates chemicals banned in Europe): **Acephate**, **Benomyl**, **Carbaryl**, **Carbofuran**, **Carbosulfan**, Chlorpyrifos (Exp 2020), Chlorpyrifos-methyl (Exp 2020), **Diazinon**, **Dichlorvos**, **Dichlofenthion**, **Dimethoate**, **Ethion**, Famphur (unknown in EU), Fenamiphos (Exp 2020), **Fenitrothion**, **Isazofos**, Maldison (Malathion), **Methamidophos**, **Methomyl**, **Omethoate**, Oxamyl (exp 2020), **Phorate**, **Phoxim**, Pirimicarb (exp 2020), Pirimiphos-methyl (Exp 2020), **Prothiofos**, **Pyrazophos** and **Terbufos** (NZEPA, 2015).

The application register indicates the heavy agrichemical industry representation that supported reauthorisation of the chemicals (NZEPA, 2019). The submissions for the NZEPA reassessment indicates the disproportionate representation of public and environmental health, versus industry interests that pay staff or contract experts to submit to this process (NZEPA, 2013).

While the NZEPA encourages public submissions to the assessment processes, it is rare that a publicly paid scientist or official would submit against reassessment. Therefore, advocates for environmental and human health are limited to organisations with the resources to submit, which are few.

In this submission (APP201045), the Sustainability Council expressed concern and were 'baffled however by the thinness of the reassessment application', suggesting that synergistic effects and neurotoxic effects should be considered and meta analyses should form an important part of the process (Sustainabiliity Council, 2013). The Pesticide Action Network (PAN) recommended phase outs, noting the inadequacy of the group assessment and including references for studies not considered within the group assessment.

PANANZ also noted that many organophosphate and carbamate insecticides are carcinogenic, endocrine disruptors, and/or neurodevelopmental neurotoxins, and pose additional risk to children. The submission stated:

'We believe that assessing so many chemicals at once is not appropriate: quite apart from the huge burden this places on non-profit organisations with non-paid 'staff', in PAN ANZ's view the chemicals and their alternatives have not been properly assessed by EPA. In fact it is stated on page 22 of the APP201045 Consultation report that "EPA staff are aware that there are more recent studies which it has been unable to incorporate into its assessment because of the timing and number of substances in this Application"' (PAN-NZ, 2013).

Proposal 3: (3.1.3) Using a trusted regulator's decision to change a hazard classification

Option 2: Adopting a trusted regulator's decision following an internal process

This would be contingent on the European Food Safety Authority/ European Commission acting as trusted regulator.

20. Do you agree with the description of this issue (that is, it is not necessary for the EPA to always follow a modified reassessment process to change a hazard classification based on trusted information – see section 3.1.3 – 'The problem')? Why/why not?

The modified reassessment process in New Zealand privileges the well-resourced chemical and agricultural industry players that are able to contest and challenge decisions. The lack of funding in chemical toxicology, the lack of biomonitoring of chemicals in human and environmental health, results in there being no appropriate avenues to contest industry weight. This democratic chasm is resulting in the toxicity we observe in the environment currently. The only option to protect public and environmental health is to mesh with best practice, which will also protect our market reputation as a safe and healthy best practice food producer.

21. Should the EPA be able to adopt a trusted regulator's decision to change a hazard classification? Why/why not?

Yes – if it is the European Food Safety Authority/ European Commission

22. Which option to change a classification based on trusted information do you support?

Why?

Option 2: Adopting a trusted regulator's decision following an internal process

This is contingent on the European Food Safety Authority/ European Commission acting as trusted regulator.

23. (If you choose Option 2 or 3) The EPA is planning to update the HSNO classification system to align with the Globally Harmonized System of Classification and Labelling (GHS). While this update is taking place, the EPA needs to verify the GHS classification with an HSNO classification. Should the EPA be able to adopt a trusted regulator's classification change before the update is complete? Why/why not?

Yes – if it is the European Food Safety Authority/ European Commission

24. Do you suggest another option to change a classification based on trusted information? If so, please explain.

No. This aligns with EU regulations.

Proposal 4: (3.2.1) Better consultation process to collect quality information

25. Do you agree with the description of this issue (that is, the current voluntary mechanism cannot help the EPA collect quality information for reassessments – see section 3.2.1 – 'The problem'?) If not, why not?

Reassessment delays have been of concern to the organisation for some time, as lags to restrict chemicals in the environment benefit polluting industry rather than public and environmental health.

Local non-government organisations lack the resources to comprehensively address the economic cost of toxic chemicals, whether to human or environmental health, and the cost of reassessment constitutes a formidable barrier preventing public entities pursuing reassessment of toxic chemicals. As noted in the MfE discussion document 'Since 2001, the EPA has only been able to complete 51 reassessments, and it has recently identified that a further 39 chemicals are in urgent need of review' (ME1426) (MfE, 2019).

The situation of reassessment in New Zealand is farcical. The voluntary nature of reassessment and the 'call for information' is an impossible task due to the poor resourcing outside of industry and the vested interests of the chemical industry. Industry not only have 'low interest in maintaining approvals', they have low interest in the scientific literature being researched to investigate multiple human health concerns that are demonstrated by curious scientists.

If the NZEPA is unable to fund its own reassessment then it must look to international best practice.

26. What would motivate people to give more comprehensive information for a reassessment?

This question inspires dark humour. Industry will supply data that supports industry approvals. The general public and publicly paid scientists outside the regulatory theatre in New Zealand lack resourcing to supply comprehensive data. In addition to our small population and limited taxation base, this is why New Zealand requires a trusted regulator, and deserves such a regulator to be best practice.

27. Which option do you support? Why?

This is not supported. There should be no 'call for information' for reassessment as there is no adequately resourced civil and scientific society that can adequately respond in the public interest to provide data supporting reassessment.

28. Do you suggest another option to collect quality information? If so, please explain.

Why does this process not also look to overseas jurisidictions as a trusted regulator?

29. Should the EPA have the discretion to decide what a 'lack of information' means or this needs to be prescribed in the HSNO Act/regulations? Why/why not?

Currently due to the outdated nature of the HSNO Act there is an alarming 'lack of information'.

The HSNO Act (Pesticides) requires updating, as Catherine Iorns has suggested (Iorns, 2018, p. 11) – particular criticisms of the current system include:

• the extrapolation from animal testing to humans is inadequate and relies on models and assumptions that may not be accurate, and some of which have been questioned;

• the “dose-response relationship” cannot be assumed at low-dose levels; for some chemicals it is neither linear nor algorithmic but more of a “U” shape, with serious effects at extremely low levels of exposure;

• testing will typically only focus on the pesticide’s primary mechanism and not on other side effects; for example, neurotoxicity testing of organophosphates usually only requires consideration of one mechanism, that of cholinesterase inhibition, and fails to test for developmental neurotoxicity, despite the considerable and expanding literature illustrating the non-cholinergic neurotoxic effects;

• testing for developmental immunotoxicity is generally not carried out, nor are allergic, inflammatory or autoimmune effects looked for;

• endocrine disruption is not tested for; this takes a long time to show up, can occur at very low-level exposures, and can be passed through to future generations; for example the damaging impact of pesticides on mammary gland development can have an impact on the development of breast cancer later in life;

• children and the foetus are especially vulnerable to single, low doses; the high dose protocols fail to consider exposures that are environmentally relevant especially to the unborn and newborn, and fail to target various organ systems at critical stages of development from foetal life through to adulthood;

• risks are estimated for a single chemical at a time, so chemicals are tested in isolation when people and the environment are in reality exposed to mixtures of various chemicals, including adjuvant chemicals that are added to the pesticide active ingredient; testing thus generally fails to consider the impact of ubiquitous exposure on society as a whole;

• existing body burdens of chemicals and cumulative effects are ignored in determining safe exposures;

• some individuals are particularly sensitive to different chemicals such that adverse effects show up at lower doses than are considered acceptable for the average person; plus different individuals react differently to interactions of combinations of chemicals;

30. Do you find there are barriers when applying for a reassessment? If so, what are they?

It is expected that the NZEPA will understand that the barriers to reassessment include the time-cost to civil society, but also the resistance to reassessment of controversial chemicals by industry.

The Green Party paper which systematically discussed the problems with the current approval status of glyphosate was comprehensively ignored by the NZEPA (Bruning & Browning, 2017). Later criticisms by scientists criticising were also ignored by the NZEPA (Douwes, et al., 2018).

Political actions have been instigated to remove controversial pesticides from reassessment lists. Glyphosate was on an earlier Chief Executive Initiated Reassessment list. However this list was changed and renamed to the Priority Chemicals List and glyphosate was dropped.

The current game of removing glyphosate from reassessment lists amid the international climate where glyphosate is demonstrated in successive court cases to cause cancer, demonstrates that the NZEPA is more wary of chemical industry opprobrium than that of the general public. If NZEPA were to show leadership and accept the finding of its own authority on cancer, the IARC’s recent finding of glyphosate as a probably carcinogenic, and discuss the risk in the scientific literature,

particularly of non-Hodgkin's lymphoma – for which there has been an increase – perhaps NZEPA would also be protecting farmer and applicator health.

Proposal 5: (3.2.2) Amending modified reassessments for a more targeted consultation

31. Do you agree that the current modified reassessment process does not allow flexibility in consultation? If you don't agree, why not?

The current process privileges industry supplying the data for reassessment. This is biased and unscientific as it does not require a literature review to understand new issues in risk.

32. One option is to allow the EPA more flexibility in consultations, that is, a more targeted consultation. Would you support this?

This supports the industry with the greatest motivation to supply data to protect chemical authorisations. It in no way is a science-based approach, neither is it impartial.

33. Do you suggest another option? If so, please explain.

If we were following EU risk assessment, we wouldn't be in the current mess we are currently in. Most of the 'controversial' outdated substances have been banned or restricted in Europe.

Proposal 6: (3.3.2) Avoiding duplication when reassessing priority chemicals

The Options presented in this section do not appear to adequately address how this might change if a trusted regulator approach might be taken – for example how this might be addressed if European decisions were followed.

34. Do you agree that it is likely the EPA encounters a duplication of work in determining the grounds for reassessment of priority chemicals given that these chemicals have been screened using the FRCaST tool and appear on the Priority Chemicals List (PCL)? If you don't agree, why not?

The NZEPA constructed a tool to guide which chemicals require assessment - the FRCaST tool. It was passed by colleagues in Australia and Canada, a process the NZEPA claimed was sufficient as international peer review. The FRCaST tool is a weak tool for assigning risk. It doesn't require that the NZEPA select for ubiquity in the environment, nor does it review the scientific literature outside the regulatory environment to identify new knowledge of risk. As authorisations are driven by data supplied by the industry applicant, regulatory data is primarily composed of industry supplied by the applicant. This tool is inadequate for guiding public safety.

The current FRCaST tool appears to have been a tool to remove glyphosate from the old list. Glyphosate herbicide was dropped from the earlier list, it is ubiquitous in the environment, and successive court cases has demonstrated that the International Agency for Research on Cancer (IARC) accurately determined that glyphosate and its formulations probably caused cancer.

As we are sure the NZEPA is well aware, glyphosate has never undergone formal risk assessment, nor reassessment in New Zealand. A criticised carcinogenicity review is not sufficient to protect public health. (Douwes, et al., 2018)

The problem of duplication would be removed if EU precedent was followed.

35. Which option do you support? Why?

The FRCaST tool is inadequate for protection of public health and the lack of reference to scientific literature has the result of it not sufficiently forming an evidence based ground for reassessment. Further the collegial regulators used for proof of the tool, also prioritise industry data and exclude the published literature in regulatory risk assessment.

As has been stated, reassessment in New Zealand is decades behind best practice. Harmonisation with EU standards is the safest way to protect public health.

36. If you choose Option 2 (giving the PCL a statutory status, and skipping grounds for reassessment of these chemicals), how would you like the EPA to inform the public about the planned timing of PCL reassessments?

The PCL is not sufficiently evidence and science based to grant it statutory status.

37. (For those who have technical knowledge about the FRCaST) How do you think the prioritisation process should be improved to allow the skipping of grounds?

Again, the PCL has not the capability to understand risk to environmental and human health as it does not consider the published scientific literature.

38. If you choose Option 3 (adding the PCL to the HSNO list of grounds for reassessment, to streamline the process)? What are the implications to consider?

39. Do you suggest another option? If so, please explain.

As has been stated, reassessment in New Zealand is decades behind best practice. Harmonisation with EU standards is the safest way to protect public health and this would remove the duplication issue.

Proposal 7?: 3.3.3 Updating controls of existing substances

Avoiding duplication when assessing new and existing substances

The Options presented in this section do not appear to adequately address how this might change if a trusted regulator approach might be taken – for example how this might be addressed if European decisions were followed.

40. Do you agree there can be duplication of work in assessing and reassessing related substances with the same active ingredient (see section 3.3.2 – 'The problem')? If not, why not?

For some time New Zealand has referred to a decision document which will act as the authoritative approval for related substances with the same active ingredient. The problem with the NZEPA process is that reassessments are rare, and when they happen, they rely on industry supplied data. Any new substance authorisations will also use industry supplied and selected data.

This problem of 'duplication' is of minor concern. It can be solved with timely notification.

Option 2: Combining assessment and reassessment of substances with the same active ingredient

41. What option do you support? Why?

42. If you choose Option 2 (combining processes), what are the implications of the proposed combination?

43. If you choose Option 3 (postponing/declining an application, pending a reassessment), what are the implications of this option?

44. Do you suggest another option? If so, please explain.

45. Are there any other ways to promote innovation in the chemical industry, to replace chemicals being reassessed or on the Priority Chemicals List?

The questioning here should be about innovation in agriculture to reduce the use of toxic chemicals.

Proposal 8: Updating controls of existing substances

46. Do you agree that controls on existing substances should be updated quickly, to align with a more recent assessment? Why?

Many chemicals that have come through via the transfer process have never undergone comprehensive toxicological assessment, nor reassessment, such as glyphosate. Updates on transferred substances should be automatic.

47. Which option do you support, and why?

Option 3: Aligning controls with new approvals – but only if NZEPA is following European standards

The current suggestion that an application forwarded by the chemical industry with the vested interests, would then form a new approval and update existing substances is not in the public interest.

Further, the targeted consultation suggestion (p.34) does not appear to have any justified basis. Updates on older substances could be publicly notified.

48. Do you suggest another option? If so, please explain.

Harmonise with the European Food Safety Authority / European Commission and use these decisions to update older existing substances with the same active ingredient.

Proposal 9: Other considerations to enable change

49. Should a process for updating controls be introduced as described in this section? Why/why not?

The HSNO Act should not just be amended, it should be redrawn so that it is relevant to twenty-first century scientific risk, harmonising with European Commission/ European Food Safety Authority.

If this was undertaken, yes controls could be updated based on the European decision.

50. Should EPA staff (rather than a decision-making committee) have the power to make decisions, if the change is purely technical? Why/why not?

Yes – if NZEPA harmonised with the European Commission/ European Food Safety Authority

Other considerations to enable change:

Cost-benefit analysis undertaken by NZEPA cannot accurately predict the value of social, cultural and environmental benefits and should not be used to guide risk assessment. Until greater analysis outside of the regulatory theatre is undertaken it is critical that the toxicological human and environmental health impact from toxicity studies supplied that assess the toxicity of the pesticide formulation should guide risk assessment authorisation and assessment.

Cost-benefit analysis have been traditionally inadequate for gauging risk and have conventionally over-represented industry interests and ignored substantial data gaps. There are significant knowledge gaps in recognising the harm from chemical pollution to te ao Māori (MfE & Stats NZ, 2019). There are significant data gaps for mahinga kai status, as traditionally no national scientific monitoring has been available (funded) to scientifically understand chemical pressures in sediment and the low-level accumulative polluting effects on food and the capacity for the production of safe food for future generations.

As Catherine Iorns has suggested the NZEPA might adopt a more complex approach to risk assessment and incorporate effects-based risk assessment that incorporates ecosystem interdependence.

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