PSGR

Physicians & Scientists for Global Responsibility

October 3rd, 2021

Submission

Hazardous Substances and New Organisms (Hazardous Substances Assessments) Amendment Bill

Submitted to the:

Committee Secretariat
Environment Committee
Parliament Buildings
Wellington
en@parliament.govt.nz

Address

PO Box 16164
Bethlehem
Tauranga 3147
New Zealand

Email

info@psgr.org.nz

Website

www.psgr.org.nz

Phone

Ph+64 27 505 0808

PSGR would welcome an opportunity to speak to this submission.

Physicians and Scientists for Global Responsibility Charitable Trust (PSGR) work to educate the public on issues of science, medicine, technology (SMT). PSGR work to encourage scientists and physicians to engage in debate on issues of SMT, particularly involving genetics and public and environmental health.

We urge New Zealand to transition towards making better use of international regulators. The sheer volume of chemicals that require assessment are beyond the capacity of a single national regulator. Over 6,000 chemicals constitute the bulk of chemical emissions, of these 62% are hazardous to health.[1] The result of this is that there are substantial gaps in knowledge that require international co-operation to address.

The Cabinet paper[2] which sought approval for the Amendment Bill noted that the changes are 'aimed for better protection of human health, safety, and the environment'. This bill can ensure assessment and reassessment processes can more effectively protect 'human health, safety, and the environment.'

This submission makes several recommendations:

- We support the amendment as stated in the RIA: enable the EPA to apply data, information, assessments, and decisions from trusted regulators with a consideration of the New Zealand context (with consultation in its discretion, except in particular circumstances).[3]
- The purpose of the bill must be to protect human and environmental health and future text can be deepened to ensure that the use of discretion by the Authority is required to support the purpose.
- We highlight a weakness in the current approval and assessment process, in systemic deficiencies which result in regulatory decision-making defaulting to decisions that support industry claims.
- We are concerned that where a review is triggered by an international decision, the current absence of human and environmental monitoring and research efforts will inevitably result in political controversy that is likely to tilt decision-making to favour industry claims over protection.
- The absence of a strong scientific community has left hazardous substances regulation dependent upon offshore, unpublished industry data. There are no feedback loops which demand that local effects and exposures to human and environmental health are integrated in deliberation.
- Currently cost-benefit scenarios favour productivity claims. Cost-benefit analyses used in regulatory assessment are currently unable to account for ecosystem deterioration, and off-target impact.
- We recommend that a stronger application of the precautionary principle is applied. Uncertainty is a prevalent in risk management. Particular attention can be paid to emphasising uncertainty in legislation and the obligation to act precautionarily to protect environmental and human health, and that in terms of environmental health this may reflect a species-specific protective stance.
- Decisions from trusted regulators may be applied to change the status of a chemical or tighten controls in favour of human and environmental health. However, the downgrading or loosening of controls should trigger a formal risk assessment or reassessment process and public consultation.
- That the future Methodology is structured to prioritise European decisions. The European Commission places the precautionary principle at a high level in policy and regulation. Hazard-based European decisions may more appropriately navigate uncertainty due to the recognition that it is largely unknown at what level disease states triggered by exposure to mutagenic, carcinogenic, reprotoxic and endocrine disrupting substances commence.

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[1] United Nations Environment Programme, 2019. Global Chemicals Outlook II From Legacies to Innovative Solution

[2] MfE. Parker. June 30 2020. Policy approval for proposed amendments to the Hazardous Substances and New Organisms Act 1996 2zkv166sx 2020-06-30 09:31:04

[3] Regulatory Impact Assessments on proposed amendments to the Hazardous Substances and New Organisms Act 1996. https://www.treasury.govt.nz/sites/default/files/2021-07/ria-mfe-hsnoa-nov20.pdf p.19

(A) Increasing pollution from substances banned in Europe

1) We recommend that decisions made by an overseas body as an international regulator can inform the New Zealand Environmental Protection Authority (NZEPA) and enable the NZEPA to take steps to protect human and environmental health. However, decisions must involve placing more stringent controls around toxic substances or withdrawing approval of a substance. Where overseas decisions are considered by the authority as having potential to weaken controls or reauthorise a toxic, bioaccumulative substance, a full risk assessment must be required

2) The NZEPAs focus in recent decades on processing applications, has not been appropriately balanced by scientific knowledge on the effects of current pesticides in the environment, monitoring, and enforcement.[4] The focus on processing applications and re-authorisation of chemicals, using data created by the industry applicant, with relatively few comprehensive risk assessments triggered by the NZEPA[5], has resulted in the authority that weights consideration to non-disclosed industry produced literature, while failing to take into account the real world effects of pesticide emissions into the environment and which has not lifted its gaze to international best practice.

3) Europe moves quickly when pesticides are toxic and persistent in the environment. European banned (not authorised) pesticides contaminate local freshwater[6] and groundwater.[7] Pesticide mixtures in soil and water bodies are accumulating, contaminating environments to a degree that alarm scientists.[8] [9] [10] [11]

4) New Zealand currently has more suspected carcinogens emitted into the environment than in Europe or the USA. Many of these chemicals are not authorised for use in the European Union.[12]

(B) Why turn towards Europe?

5) We recommend that European Commission institutions, including the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA) are recognised as trusted regulators.

6) European decisions should be preferentially weighted because firstly, they place the precautionary principle at a high level in European legislation which states that 'preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay.' [13]

7) Secondly because of the related hazard based regulatory model. The hazard-based model recognised that once a substance is classed as harmful carcinogenic, mutagenic and reprotoxic (CMR) it is no longer safe means that Europeans can move more swiftly to ban and heavily restrict substances. We specifically state this because European decisions are hazard based, with a much stronger focus on recognising

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[4] Environmental Protection Authority Annual Report for the year ended 30 June 2019.
[5] Regulatory Impact Assessments on proposed amendments to the Hazardous Substances and New Organisms Act 1996. P.10
[6] Hageman et al 2019. Current- Use Pesticides in New Zealand Streams: Comparing Results from Grab Samples and Three Types of Passive Samplers. Environmental Pollution, 254, 112973. https://doi.org/10.1016/j.envpol.2019.112973
[7] Close & Humphries 2019. National Survey of Pesticides and Emerging Organic Contaminants (EOCs) in Groundwater 2018. CSC19016 Institute of Environmental Science and Research Limited
[8] Silva et al 2019. Pesticide residues in European agricultural soils – A hidden reality unfolded. Science of The Total Environment. 653:1532-1545
[9] Tang & Maggi 2021. Pesticide mixtures in soil: a global outlook. Letter. Environ. Res. Lett. 16:044051
[10] Raffa & Chiampo 2021. Bioremediation of Agricultural Soils Polluted with Pesticides: A Review. Bioengineering. 8:92
[11] Navarro et al 2021. Pesticide Toxicity Hazard of Agriculture: Regional and Commodity Hotspots in Australia. 55:2;1290-1300 DOI: 10.1021/acs.est.0c05717
[12] 't Mannetje A. The carcinogenicity of pesticides used in New Zealand. NZMJ, 2020; 133(1526): 76-88.
[13] Article 191 (ex Article 174 TEC) Official Journal of the European Union 7.2.2106

potential issues such as formulation toxicity[14] and endocrine disruption.[15] [16] It is not evident that cost-benefit analyses are considered a component of risk assessment.

(C) Navigating Uncertainty

8) Moments of uncertainty in risk assessment are not rare, but instead is a pervades decision-making in risk assessment.[17] This is because where and how exposure from a substance effects a biological organism is different, based on organism maturity, nutrition and the exposures of ancestors, or preceding generations. Guidelines and processes often guide regulatory scrutiny towards industry data which can overtly bias decision-making in favour of the industry applicant.[18] [19] For decades, these processes have not sufficiently kept up with the science relating to the greater vulnerability of infants and children, as well as juvenile invertebrates and vertebrates.[20] [21]

9) The production of science geared to sustain uncertainty in order to prevent regulation is a key tactic used by organisations who produce controversial substances which potentially harm human and environmental health. There is a tendency for regulators to delay regulation until harm is obvious, and supportive legislation to prevent harm in the first place is essential if health is to be protected.[22]

10) Professor David Michaels, who served as Assistant Secretary of Labor for the Occupational Safety and Health Administration (OSHA) has noted that when the scientific literature starts to accumulate and provide evidence that a substance is harmful, there is rarely an about turn. He has also observed that where there is absence of social movements to counteract industry-regulator relationships regulatory policy tends to follow in the direction established by industry.[23]

11) Parliamentary Commissioner for the Environment has noted the parlous state of to the political environment of pesticide regulation.[24] Lacking secure positions in environmental pollution research, scientists will be unlikely to risk their political and professional reputation submitting to consultations or challenging decisions in the regulatory sphere.

12) New Zealand lacks a robust scientific community that exists independently from the regulated industries, that has capacity to engage in public consultations, and where there is evidence of harm or of a foreign regulator making a safer or more precautionary stance, contesting regulatory decisions. Regulatory environments are supremely political. In environments lacking actors with sufficient scientific expertise and authoritative clout to contest decisions, it is unlikely that regulators will pay attention to and review

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[14] EFSA More et al 2019. Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals. EFSA Journal e050634

[15] European Commission 2020 Commission Staff Working Document Fitness Check on endocrine disruptors. SWD(2020) 251 final Brussels

[16] ECHA/EFSA 2018. Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. EFSA J. 2018;16(6):5311.

[17] Scott D. Application of the Precautionary Principle During Consenting Processes in New Zealand: Addressing Past Errors, Obtaining a Normative Fix and Developing a Structured and Operationalised Approach (LLM Thesis, Victoria University of Wellington, 2016).

[18] Cordner et al 2019. Guideline levels for PFOA and PFOS in drinking water: the role of scientific uncertainty, risk assessment decisions, and social factors. Journal of Exposure Science & Environmental Epidemiology (2019) 29:157–171

[19] Robinson et al 2020. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. European Journal of Risk Regulation. DOI:10.1017/err.2020.18

[20] Encarnação et al 2019. Endocrine disrupting chemicals: Impact on human health, wildlife and the environment. Science Progress 102:1;3-42

[21] Sapbamrer & Hongsibsong 2019. Effects of prenatal and postnatal exposure to organophosphate pesticides on child neurodevelopment in different age groups: a systematic review. Environmental Science and Pollution Research (2019) 26:18267–18290

[22] Scott D. Application of the Precautionary Principle During Consenting Processes in New Zealand.

[23] Michaels, D. (2020). The Triumph of Doubt. Dark Money and the Science of Deception. Oxford University Press.

[24] Parliamentary Commissioner for the Environment 2020. A review of the funding and prioritisation of environmental research in New Zealand

published peer reviewed literature outside the data selected by industry actors (as applicants) that is intended to secure approval.

(D) How do foreign decisions not only trigger – but catch up – to out of date regulation?

13) The RIA emphasises that the HSNO Act requires that decisions take into account the sustainability of all native and valued introduced flora and fauna, the intrinsic value of ecosystems, public health and considers the relationship of Māori, and their culture and traditions with ancestral lands.

14) Interacting and historic issues plague New Zealand risk assessment and hazardous substance approval processes. This raises the question of providing the NZEPA with directive influence in the construction of the Methodology Order.

15) Examples are provided in order to demonstrate the recurring potential for the NZEPA to favour industry data and in moments of uncertainty to act in favour of industry applicants:

a) A recent consultation to produce a 2020 Risk Assessment Methodology for Hazardous Substances revealed a narrow range of consultation, while expert industry submittors contributed, there were no basic or applied scientists with relevant lab-based research skills available to feed into policy development. This effectively constrains the scope of consultation. As a result, the 2020 Risk Assessment Methodology does not consider the potential for environmental and human health data to feedback into the regulatory sphere. The document prioritises linear modelling instruments that fail to take account of persistence and real-world impacts in Aotearoa New Zealand. Our science deficit compounds this problem.

b) In addition, the Risk Assessment Methodology does not provide guidance nor outline how a precautionary stance might be engaged to protect the environment. The Methodology ignores the potential for low level mixtures to cause harm to trophic environments.[25]

c) Current cost-benefit analyses are unable to sufficiently address the pollution at scale of the soil and water biomes. Instead, the focus on GDP and productivity remains central to claims for authorisation or re-authorisation of toxic and persistent chemicals.[26] We note this because in selecting overseas regulators it is critical that 'like manner' make way for best practice. New Zealand has no formal policy or guidelines concerning the health effects of endocrine disruptors.

d) The new 2020 Risk Assessment Methodology for Hazardous Substances emphasises the role of the applicant in providing data to the NZEPA. The Methodology demonstrates that cost-benefit analyses are weighted to favouring industry claims for productivity (rather than for example, considering pressure on ecosystems':

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[25] NZEPA 2020. Risk Assessment Methodology for Hazardous Substances. https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Risk-Assessment-methodology/Risk-Assessment-Methodology-for-Hazardous-Substances-How-to-assess-the-risk-cost-and-benefit-of-new-hazardous-substances-for-use-in-New-Zealand-v2.docx

[26] E.g. NZEPA commissioned Sapere December 2018 Economic assessment of paraquat use in New Zealand https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203301/c34071b227/APP203301-Appendix-B-Sapere-economic-and-benefits-assessment.pdf

e) 'The applicant, or their consultants and advisors, are in the best position to collect and present this information, as they have the best knowledge about the benefits of making their product available in New Zealand.'[27]

f) The speed of new approvals and authorisations have not been balanced by environmental stewardship. New Zealand's weighting to favour industry applications and industry claims – economic well-being – has effectively downplayed or sidelined the Authorities obligation to consider its obligation to safeguard the life-supporting capacity of air, water, soil and ecosystems, and the social and cultural wellbeing of people and communities. The current culture has meant that no discussion of accumulation and persistence can be had to consider the capacity to protect water, soil and ecosystems for future generations.

g) While environmental exposure levels (EELs) and human tolerable exposure levels (TELs) are imagined in the HSNO Act, in reality, levels have not been established in such a way that produces clear national standards, or levels to monitor. As a result, there is no effective enforcement mechanism.

h) New New Zealand drinking water standards for pesticides lack any consideration of toxicity risk from low level mixture effects, whereas European legislation provides a minimum total exposure level in drinking water.[28]

16) Current approval processes have enabled for example, a range of strange activities to be undertaken:

a) The NZEPA has authorised toxic new versions of glyphosate-based herbicides that are not approved anywhere in the world.[29] [30]

b) The NZEPA is extraordinarily slow to place controls on neonicotinoid insecticides. When Europe banned outdoor use of a toxic and persistent insecticide in 2018, New Zealand commenced a call for information at that time. However, in mid-2021 it is still uncertain at what stage risk assessment, which commenced in 2021, may conclude, and if the insecticide may be similarly restricted, in order to protect soil and aquatic insects. Regulatory environments have been slow to recognise the potential for chemicals in the same class to compound risk[31], yet class-based regulation is possible.[32] The Regulatory Impact Assessment (RIA) discusses the cost of risk assessment, however newly invented Calls for Information[33] for controversial substances appear another layer of cost, when they could be incorporated in risk assessment. Europe never authorised treatment of pasture grass seed with these neonicotinoid insecticides, whereas in New Zealand, packaging is not even labelled.

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[27] NZEPA 2020. Risk Assessment Methodology for Hazardous Substances. https://www.epa.govt.nz/assets/Uploads/Documents/Hazardous-Substances/Risk-Assessment-methodology/Risk-Assessment-Methodology-for-Hazardous-Substances-How-to-assess-the-risk-cost-and-benefit-of-new-hazardous-substances-for-use-in-New-Zealand-v2.docx p.41

[28] Commission Drinking Water Directive 98/83/EC, sum of all pesticides 0.5 µg/L

[29] See application NUL3232 Nufarm. (Crucial APP203611) 27.02.2018. EPA0316 May 2015. 600g/L glyphosate present as potassium, mono-methylamine and ammonium salts for MON-0573 (Monsanto), CP67573 (Monsanto)

[30] Crucial APP203611 Approval code HSR101362, https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203611/c4686971d9/APP203611_Final_Application_Form.pdf

[31] Ullah et al 2019. Bisphenol A analogues bisphenol B, bisphenol F, and bisphenol S induce oxidative stress, disrupt daily sperm production, and damage DNA in rat spermatozoa: a comparative in vitro and in vivo study. Toxicology and Industrial Health 35:4;294-303

[32] Kwiatkowski et al 2020. Scientific Basis for Managing PFAS as a Chemical Class. : Environ. Sci. Technol. Lett. 7, 532−543

[33] E.g. glyphosate herbicides and neonicotinoid insecticides

c) Chief Executive Initiated reassessments, are based on a NZ EPA Priority Chemicals list that is derived from a NZEPA invented FRCaST modelling instrument[34] which is too narrow in scope to accurately identify hazard. This instrument does not consider pervasiveness of a chemical in the environment, nor does it look at the published literature. Risk is based on risk observed in industry supplied data.

d) It is very clear that public consultation and submissions to New Zealand's regulatory process is much more heavily dominated by industry actors, and rarely attended to, if ever, by New Zealand scientists with capacity to enter this extremely political environment. In this gap, non-government organisations, including Māori, and laypeople submit, but may rarely be heard. Public frustration in NZEPA decision-making can be seen in a recent response to feedback document where the Authority repeatedly stated 'We acknowledge that the use of certain chemicals is an emotive issue for New Zealanders'.[35] There is an absence of scientific feedback into the regulatory system and we believe this is due to the dearth of environmental research funding and the precarious funding environment for such scientists.

(E) We urge that best regulatory practice be prioritised.

17) Section 76E notes that

i) 3) The Authority must not recognise an overseas body unless the Authority has considered whether—

(a) the body operates in a manner comparable to the Authority in regulating hazardous substances; and

(b) the legislative regime regulating hazardous substances in which the body operates is comparable to this Act; and

18) We consider that there is a risk that European decisions, and regulatory outcomes may be down weighted because their decision-making processes are different. We urge that instead, European decisions are prioritised.

19) The quality of the decision-making in foreign jurisdictions is dependent upon the responsiveness of regulatory authorities to act in the public interest once the scientific literature indicates plausible harm from activities or considers that harm may be likely. The quality of decision-making is also a function of the capacity of a regulatory environment to adequately respond to new scientific evidence relating to the ways hazardous chemicals cause harm.

20) Therefore, a regulator that acts in a *like* manner, may not result in the best outcome that is protective of human and environmental health if this excludes regulators who more readily integrate new scientific practices. The capacity for a regulator to respond to new evidential pathways of risk, and act in a timely manner, before irreversible harm has occurred, is a function of the quality of engagement with science that is absent of conflicts of interest and produced by non-industry actors and the weighting of the precautionary principle in the legislation. It is evident that the regulators who can most swiftly integrate new forms of evidence concerning the methods by which environmental chemicals can disrupt metabolic

[34] FRCaST screening tool https://www.epa.govt.nz/industry-areas/hazardous-substances/chemical-reassessment-programme/priority-chemicals-list/

[35] NZEPA 2020. Response to feedback on EPA's risk assessment methodology for hazardous substances

pathways, such as the integration of new scientific biomarker and omics technologies, will be those who can most act most protectively.[36] [37] [38]

21) For example, recognition of scientific technologies that can draw attention to the drivers of and the issue of oxidative stress is central for evaluating complex disease patterns. This ensures regulation can be enacted to protect health and prevent multimorbid conditions. While the International Agency for Research on Cancer considered the potential for the herbicide glyphosate to induce oxidative stress, this was left outside a consequent cancer review. [39] [40] [41] Oxidative stress is an early step in a cascade to health harm, and hazardous substances can induce oxidative stress across the insect and animal kingdom.

22) When regulatory agencies fail to take such a health effect into account, they cannot be said to be protecting health.

(F)Treaty of Waitangi – Te Tiriti o Waitangi

23) We believe there are several key issues that may be relevant to the Treaty of Waitangi /Te Tiriti o Waitangi

24) Firstly, current regulatory environment guidelines and protocols may prevent officials from acting to uphold the Treaty of Waitangi/Te Tiriti o Waitangi. Regulatory environments tend towards limiting the scope of consultation, therefore unlike Europe,[42] the NZEPA does not place substantial weight on studies looking at the total formulation emitted into the environment, which includes heavy metals and organosilicon compounds. Other measures can improve risk assessment.[43] The NZEPA does not pay particular attention to persistence of chemicals and their metabolites in the environment, nor considers the current pressure on the environment from pre-existing contaminant levels. In this environment, there is no regular testing of tuna, of endemic fish species of crustaceans including koura, which are all in decline or under threat.[44] [45] [46]

25) Secondly, this environment is possible because there is no feedback look from Aotearoa New Zealand to contest industry financed science – our environmental science system is poor.[47] Current regulatory science prevents a serious weighting of the small effects that can harm fertility or damage predator-prey relationships. There is little inspection of the systemic impact to trophic species - āta tirotiro science - and without this science, when the scientific technologies are available, the Treaty is not upheld. The

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[36] Benbrook et al 2021. Commentary: Novel strategies and new tools to curtail the health effects of pesticides. Environmental Health volume 20: 87 2021

[37] Robinson et al 2020. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. European Journal of Risk Regulation. DOI:10.1017/err.2020.18

[38] Kassotis et al 2020. Endocrine-disrupting chemicals: economic, regulatory, and policy implications. The Lancet 8:719-730

[39] Temple W. Review of the Evidence Relating to Glyphosate and Carcinogenicity. Wellington: Environmental Protection Authority 2016.

[40] Douwes, J., (2018). Carcinogenicity of glyphosate: why is New Zealand's EPA lost in the weeds? New Zealand Medical Journal, 82-89.

[41] Portier 2020. A comprehensive analysis of the animal carcinogenicity data for glyphosate from chronic exposure rodent carcinogenicity studies. Environmental Health 19:18

[42] General Court of the European Union. EFSA's decisions refusing access to the toxicity and carcinogenicity studies on the active substance glyphosate are annulled. Press Release No.25/19 https://curia.europa.eu/jcms/upload/docs/application/pdf/2019-03/cp190025en.pdf

[43] Robinson et al 2020. Achieving a High Level of Protection from Pesticides in Europe: Problems with the Current Risk Assessment Procedure and Solutions. European Journal of Risk Regulation. DOI:10.1017/err.2020.18

[44] Allibone, R., & et al. (2010). Conservation status of New Zealand freshwater fish, 2009. New Zealand Journal of, 44(4), 271-287.

[45] Dunn, N., Allibone, R., Closs, G., Crow, S., David, B., Goodman, J., . . . Rolfe, J. (2018). Conservation status of New Zealand freshwater fishes, 2017. . Wellington: Department of Conservation.

[46] Goodman, J., Dunn, N., Ravenscroft, P., Allibone, R., Boubee, J., David, B., . . . Hitchmough, R. (2013). Conservation status of New Zealand freshwater fish, 2013. . Wellington: Department of Conservation.

[47] Parliamentary Commissioner for the Environment 2020. A review of the funding and prioritisation of environmental research in New Zealand

current regulatory science system is linear and fragmented, reflecting, as Rereata Makiha has noted, tīkarokaro, or pulling apart science[48], with the result that the vulnerability of juvenile species to low level mixtures, and the intergenerational decline of species due to persistent exposures which not only produce disease and infertility, but also reduce the potential to will never be assessed.

26) New technologies may improve the capacity for officials to act to uphold the Treaty of Waitangi. Traditional Māori knowledge, or science has recognised the intersystem connectivity and interdependency, and new scientific methods that similarly recognise this appear compatible. New technologies can reveal multiple and often overlapping factors that lead to a decline in health and these technologies can improve predictive toxicology testing.[49] [50]

27) Finally, we consider that hazard-based regulatory risk assessment which acknowledges the difficulty of recognising a level at when harm from a carcinogenic, mutagenic, reprotoxic or endocrine disrupting substance commences; and a stronger interpretation of the precautionary principle, more closely reflect principles of Te Ao Māori (the Māori worldview).

(G) Concerns relating to the future Methodology Order

28) The RIA suggests placing discretion in the construction of the Methodology Order with the NZEPA. However historical decision-making by the NZEPA that bends towards industry at every turn, and the 2020 construction of the Risk Assessment Methodology documents suggests a regulatory agency that is unlikely to substantially change course.

29) The RIA proposed amendments to the Methodology Order (p.20):

> 100. To implement the above changes, we also propose amendments to the Methodology Order to:
>
> - set the criteria and process for identifying international regulators whom the EPA can trust (trusted regulators)
>
> - specify the assessment and reassessment processes when the EPA applies information from trusted regulators
>
> - specify other requirements on the way the EPA applies information from trusted regulators, including how the EPA will apply a part or the whole package of information
>
> - set the criteria for the EPA's discretion over consultation"
>
> - require the EPA to be more transparent about its work plan and decisions.

30) Others have commented that the Methodology Order[51] does not include a requirement to take into account Treaty of Waitangi/Te Tiriti o Waitangi, and that it offers a weak interpretation of the precautionary principle. [52]

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[48] Husband 2021. Rereata Makiha: Holding on to ancestral knowledge. E-Tangata https://e-tangata.co.nz/korero/rereata-makiha-holding-on-to-ancestral-knowledge/

[49] Hernandez et al 2019. Critical assessment and integration of separate lines of evidence for risk assessment of chemical mixtures. Archives of Toxicology 93:2741–2757

[50] Eicher et al 2020. Metabolomics and Multi-Omics Integration: A Survey of Computational Methods and Resources. Metabolites 10:202

[51] Hazardous Substances and New Organisms (Methodology) Order 1998 https://www.legislation.govt.nz/regulation/public/1998/0217/latest/whole.html#DLM254556

[52] Iorns Magellanes 2018. Permitting Poison: Pesticide Regulation in Aotearoa New Zealand. EPLJ, 456-490.

31) We are concerned as to how 'uncertainty' will be navigated and we consider this requires much deliberation outside the confines of the NZEPA. The Methodology Order requires that 'when considering submissions addressing scientific evidence or uncertainty, the Authority must take account of the scientific basis or authority for the information contained in the submission.'[53] This NZEPA Risk Assessment Methodology, positions 'uncertainty' which bases deliberation around industry data and emphasises that in uncertain situations decisions should be weighted to studies fulfilling that fit within the much critised Klimisch Score guideline, or protocol. This has lead to a disproportionate weighting to industry data emphasising 'reliability' which may not reflect the state of science relating to safety of a hazardous substance.[54]

Concluding Comments

32) We make these comments in anticipation of further consultation relating to the methodology. PSGR supports a focus in the future iteration of the methodology that emphasises the changing nature of science, and the obligation of regulatory agencies keep up to date with new evidence. This reflects the public law maxim that officials shall not close their minds to relevant considerations. This is essential, as new pathways which reveal vulnerability and risk that are not always the priority of the industry actors, the applicants that are currently charged with responsibility of submitting the data on risk assessment.

33) Therefore, a priority of an overseas body operating in a like manner may not at this stage, support the most transparent, and accountable processes of risk analysis that reflect both new scientific evidence, new technologies to understand risk and incorporate a weighting to independent data.

[53] Hazardous Substances and New Organisms (Methodology) Order 1998 S.16

[54] Kaltenhauser et al 2017. Relevance and reliability of experimental data in human health risk assessment of pesticides. Regulatory Toxicology and Pharmacology 88 (2017) 227e237