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GENE TECHNOLOGY BILL 2024 (GT BILL).

RECOMMENDATIONS – PHYSICIANS & SCIENTISTS FOR GLOBAL RESPONSIBILITY NEW ZEALAND.

1) That this Gene Technology Bill 2024 (GT Bill) is withdrawn.

This Bill cannot assure risk-proportionate regulation, and the text of the Bill does not require this. The regulator will be straightjacketed by the wide variety of exempted gene editing techniques and gene edited organisms and by being legally bound [50] to grant mandatory medical authorisation. The Regulator has no powers to (a) review the exempt techniques and organisms (including undeclared accidents and failures) for risk; (b) monitor and trace all gene edited organisms; and (c) surveil public and published literature to identify new knowledge on all risks associated with gene editing technologies. The Technical & Māori Advisory Committee powers are extremely restricted.

2) The Hazardous Substances and New Organisms Act 1996 (HSNO) can remain the administering legislation for all GMOs, including gene edited (GE) technologies and techniques.

a) Risk-tiering of genetically modified organisms (GMOs) including GE organisms can be placed inside HSNO.

b) HSNO clauses [4-8] require the Regulator to consider ethics-based principles.

c) The GT Bill skirts obligations by merely suggesting Regulators must have 'regard' for certain conventions.

d) The GT Bill uses statute to set aside broad Treaty obligations, which appear to be proxied into the Māori Advisory Committee that is expected to sufficiently and comprehensively address cultural/legal/ethical issues.

e) Both hazard and exposure assessments are required to characterise overall risk. These are ignored in GT Bill.

f) HSNO has a well thought out Controls section, the GT Bill ignores this.

3) Work to amend HSNO with risk-tiering inside the Act and no exempt activities, *only* commence after:

a) GE-related legislative changes by our major export markets, including the European Commission have been finalised to ensure New Zealand harmonises with key premium markets, adopts best practice guidelines for GE organisms in food, and is not 'caught short' with banned or unknown GE organisms in export products.

b) The Parliamentary Commissioner for the Environment undertakes a fully funded review to assess: Environmental Protection Authority (EPA) costs of pre-market risk assessment; the history of open-air trials in New Zealand; and the financial resourcing necessary for the EPA to risk assess, monitor and trace GMOs outdoors and in food.

c) Independent assessment of GE agriculture, assessing consumer demand, long-term yields, and on and off-target risks, including risk of transfer of risk assessment obligations from biotech developers to food businesses.

d) Transdisciplinary assessment (ethics, law, culture, biology) of the utility of a Bioethics Council (see Royal Commission on Genetic Modification 2001, recommendation Ch.14) that would act as an advisory body, provide guidelines on biotech issues which interface with social, ethical and cultural factors, and promote transparency.

4) To be 'risk-proportionate' the Regulator must have the powers to assess the risk (the probability of harm) with the potential severity of harm.

A hazard is the potential of an organism to cause harm to human and animal health and/or the environment. This is then integrated with an estimated likelihood and magnitude of adverse effects.

a) None of these standard risk assessment processes are discussed in the GT Bill. Hazards cannot be mitigated if an assessment has not taken into account exposure and context, in order to assess the probability of harm. Regulators must understand how an organism may be hazardous in a practical context, in the first place. Comparative hazard analyses which ignore use-patterns, are unfit for purpose.

b) This legislation can never be 'risk-proportionate' if classes of gene editing (GE) techniques and GE organisms are predetermined as indistinguishable and exempt or very-low risk and non-notifiable.

5) **All modifications to GE organisms must be assumed to be heritable, as GE organisms can reproduce.**

This immediately places all GE organisms (including exempt classes) in a class of 'persistent' and potentially 'bioaccumulative' technologies and contaminants. GE technologies enable rapid scaling up of the production of new organisms. This far exceeds what could happen with conventionally-bred organisms.

6) **All gene editing technologies are powerful mutagens,** including technologies that would be exempt in the GT Bill.

7) **There has never been a Regulator that automatically presumes a previously-regulated substance/organism would be 'safe' for all time and therefore write it out of regulatory oversight.**

Humanity has a long history finding out that previously stated 'safe' technologies are instead, harmful and/or deadly.

8) **All GE techniques and GE organisms must be regulated, based on the modification/editing 'process' by which they are produced.**

The potency of the mutagenic process, the potential for reproduction, and the potential of commercial scaling cannot be underestimated. This is the basis of the case for regulation. If gene editing tools are used, this is regarded as a genetic modification process. All organisms should then be assessed on a case-by-case basis.

9) **All GE activities, including the proposed 'exempt activities', must be registered for traceability, regardless of whether the resultant GE organisms advance to pre-market assessment and release.**

a) A possible scenario is the release of undeclared 'failed' GE organisms which then contaminate export product and are identified by foreign jurisdictions as an unauthorised GE organism. This could result in rejection and/or condemnation of that shipment.

b) Developers making GE organisms are faced with laboratory challenges. A 'precise' edit may still result in subsequent unintended (domino-like) changes in the cell as it attempts to repair the damage done to the DNA. Reagents and equipment used during the GE process can carry DNA contamination from other biological organisms.

c) Exempt activities cannot be assumed to be exempt if they have not been screened for unintended changes (which developers may be unable to control). It is unscientific to believe that exempted GE organisms are free of transgenes. GE processes can introduce and contaminate genetic material from multiple species.

d) Regulators must require that all GE organisms are screened for intended and unintended DNA rearrangements.

10) **Food export companies be warned:** A European legal opinion identified that deregulation (i.e. via exemptions) would lead to a 'a transfer of the implementation of risk assessments from genetic engineering law to novel food law and thus to the food businesses'. Associated costs would then be passed on to the food business/industry.

11) **The Regulator must *not* be scientifically and ethically straightjacketed.**

a) The GT Bill proposes that for scientific information on risk, the Regulator is limited to sourcing information from: (i) Other regulators who may be similarly restricted; and (ii) The Technical Advisory Committee, which has a limited scope of reference [113-119].

b) Hazards cannot be mitigated if it is not yet known how an organism may be hazardous, and what evidence exists in the published and peer reviewed literature, and if legal evidence following legal and local and/or global court proceedings, is excluded from review.

12) **The Regulator must have powers to demand disclosure of intended *and* unintended genetic changes in all GMO organisms.**

This should be part of a mandatory thorough molecular characterisation and risk assessment of any modified organism (including all GE organisms) intended for environmental releases, or for market authorisation. This should also include the unintentional integration of novel DNA and rearrangements of the organism's own DNA, for every genetic event that has been detected in the genome of a genetically manipulated species.

13) **HSNO Act 1996 - precautionary principle clauses must remain in place.**

The Ministry for Business, Innovation and Employment (MBIE) has failed to state that with emerging technologies, there is relatively little known about the extent to which random changes following gene editing can rearrange genomes, and what changes would occur as a result of this. Such changes could not only affect the health of the edited organism/s, but also the health of any other organisms in the immediate and surrounding environments. It could also affect the biochemistry and hence the safety of plants and animals used for food. The need for precaution is also greater as technologies including AI, Nanotechnology and Synthetic biology converge with gene editing tools, while will enhance the scale and speed of releases.

a) Contamination by replicating organisms would likely be irreversible and beyond financial instruments' scope to remedy the losses.

14) **We recommend that MBIE has no role in the development of future GMO and GE policy and regulation.**

MBIE is a ministry concerned with business innovations and is not qualified to be drafting scientifically-determined guidelines and environmental regulations.

15) **We recommend a name change for GE technologies: *new genomic techniques*.**

Instead of the confusing and misleading name 'new breeding techniques', they should be called 'new genomic techniques' as is the case in Europe. This clearly shows that newer genetic technologies are being used and prevent confusion or misinterpretation by policy-makers and/or the public.

16) **Legislation (e.g. Subpart 5—Mandatory medical authorisations) based on decisions made in overseas jurisdictions, which legally bind New Zealand regulatory agencies to automatically authorise and mandate any foreign substance/s, including medical therapeutics, must be removed from, and not inserted in, any future legislation, including but not limited to, the HSNO Act 1996.**

17) IN ANY FUTURE LEGISLATION:

a) All modified/edited organisms would have pre-market process-based risk assessment on a case-by-case basis. Monitoring would be undertaken, in accordance with best global practice.

b) The Parliamentary Commissioner for the Environment would have the powers to review New Zealand risk assessment practices and compare these with best global practice.

c) All GMO production, using all current and future GE processes, is undertaken in a certified, contained facility.

d) HSNO clauses [4-8] can form the basis for principles. Insert an obligation to consider ethics-based issues, including societal values and animal welfare, and to provide call-in powers for the regulator for bioethics issues.

e) The Regulator would have the discretion to identify low- and high-risk organisms via risk categories. In order to characterise overall risks, these categories would include assessments for both hazard exposure (such as and probable use-patterns). It would also include the extent to which the applicant intends to scale up production and release following market authorisation.

f) The Regulator is given the powers to identify and review the relevant scientific literature, and provided call-in powers for these reviews. Information surveillance to include published white papers, court findings and papers used in the discovery process to analyse global risks associated with the use of all gene technology processes.