PSGR

New Zealand Charitable Trust

2024 UPDATE

For over 25 years the Physicians and Scientists for Global Responsibility New Zealand Charitable Trust (PSGRNZ) has produced reports and submitted to government Bills and Inquiries.

All PSGRNZ's submissions are available to the public on our website PSGRNZ.org.nz. You can find us on LinkedIn. To find us on Twitter, YouTube, Substack, LinkedIn, &/or Instagram just use our handle @PSGRNZ (you won't find us if you forget to put the 'NZ' in).

This Update is a 'go-to' summary of our recent work.

The only consistent PSGRNZ social media 'handles' we could secure are @PSGRNZ – which is why we will more frequently refer to *PSGRNZ* – to reduce confusion when searching online. Note, our full name is Physicians and Scientists for Global Responsibility New Zealand Charitable Trust.

THANK YOU!

Thank you to the many members who have supported us with advice, insight and corrections for our research papers and submissions this year. This voluntary support is essential to achieve quality by the final draft.

SUBMISSIONS

We've made a couple of major submissions since we last sent out our newsletter. Our summaries of submissions can be read from page 3 onwards.

MEMBERSHIP

Please – without members PSGRNZ cannot do this work! We've kept our fees deliberately low because your membership is important to us.

Membership information: **HERE**.

Email: info@PSGR.org.nz

KiwiBank Tauranga 38-9001-0432703-00

Charity registration no. CC29935



IN MEMORIUM

Trustees and colleagues of PSGRNZ were greatly saddened with the passing of dear friend and colleague Dr Mike Godfrey, LRCP.MRCS (England) and MBBS (London) (1938-2024).

Dr Mike was a founding member of PSGRNZ. Mike's remarkable powers of observation, sense of humour, polymath mind and vast knowledge of human biology, heavy metal toxicity and biochemistry ensured that Mike was a valuable asset in all PSGRNZ endeavours.

Mike also played a key role for two decades, supporting researchers by patiently scanning PSGRNZ research papers and releases, for missing information, bad grammar and simple errors. The hours Mike put into supporting this work will be long remembered.

Mike was an early adopter of infra-red breast thermal imaging (thermography) technology, a non-touch and non-invasive method of potential early detection of breast cancer. As of 2024, some 9,000 women (and some men) had elected to include thermography as part of their breast health monitoring strategy. Mike's daughter Truly, continues Mike's legacy, managing their business, Clinical Thermography NZ.

Godfrey, M. and Godfrey, P. (2023) Breast Thermography: A 20-Year Retrospective Review of Infra-Red Breast Thermal Imaging in New Zealand and Its Potential Role in Breast Health Management. Advances in Breast Cancer Research, 12, 129-141. https://doi.org/10.4236/abcr.2023.124010



PSGRNZ ADVOCACY

WHITE PAPER: DIGITAL ID'S & CBDCS (2024)

PSGRNZ (2024) <u>Stepping Back from the Brink: The Programmable Ledger.</u> Four democratic risks that arise when Digital IDs are coupled to Central Bank Digital <u>Currencies.</u> Bruning, J.R., ISBN 978-0-473-71618-9. <u>2</u> page summary | Press release | Executive summary

This discussion paper questions what the broader impacts might be, should the RBNZ secure the power to release central bank digital currencies (CBDCs).

This paper draws attention to the requirement for a Digital Identity to secure CBDCs, the potential loss of privacy this would involve, and the increase in government surveillance. The paper discusses the Reserve Bank of New Zealand's already broader-than-most-central-banks powers, and the increase in powers that the RBNZ would secure from being able to release CBDCs. It questions whether Parliamentary oversight would erode if such powers shifted to the RBNZ

PSGRNZ asked that the public of New Zealand and their representatives make time to ask whether CBDCs open up a Pandora's box that produces real risks for civil, constitutional and human rights. Our concerns include:

- Knowledge that Digital IDs coupled to CBDCs enhance all-of-government oversight over private activity including through back-door arrangements.
- 2. Programmable smart contracts can be used at scale to achieve targeted political objectives and limit rights and freedoms, carrying real risk for abuse.
- That due to the complexity of the digital infrastructure, there is little possibility for parliamentary oversight.
- 4. A risk of an inevitable shift in delegation of responsibilities to the Bank of International Settlements (BIS) and International Monetary Fund (IMF) through guidance, global harmonisation, and best practice arrangements, and away from sovereign governments.

It's evident that there is a low level of public trust in the countries where CBDCs have been rolled out, including in China and Nigeria. It's also evident from an Australian trial that cashless economies can adversely impact low-income groups, increasing people's compliance burdens, while reducing their autonomy.

PSGRNZ recommended a minimum six-year moratorium of any CBDC trial. Please read and share!

FLUORIDE - COGNITIVE & IQ RISK?

PSGRNZ continues to work with groups across New Zealand to shed light on the problematic evidence used by the Director-General of Health (D-G) to justify ordering that territorial authorities fluoridate water.

At a glance:

- No risk assessment of fluoride or hydroxyfluorosilic acid (HFA) to human & environmental health.
- NZ children have higher urinary fluoride levels than adults
- ➡ Fluoride/HFA emitted into environment never assessed for bioaccumulation and toxicity.
- Select committee processes have failed to discuss the safety of fluoride. Safety seen as 'out of scope'.
- Scientific reviews used by government not fit for risk assessment, as no methods declared.
- Office of Prime Minister & Cabinet (OPMCSA) peer reviewers limited to oral/dental health expertise.
- No transparent and accountable public review on the safety of fluoride has been undertaken.
- S.116E only requires a marginal decrease in cavities.
- S.116E − no requirement to assess the safety of fluoride or HFA.
- S116.E stipulates water to be dosed with fluoride, not HFA.

In a recent presentation to the Tauranga City Council, trustee Jodie Bruning questioned whether the courts have not 'twigged' that a transparent and impartial risk assessment, an important administrative law convention, had not been undertaken. Bruning outlined that the reviews from the Office of the Prime Minister's Chief Science Adviser lacked the robustness of science fit for policy.

The looming threat of large fines has had an effect on governance, with local government officials in narrowing their gaze to exclusively focus on the legal implication of the D-G's order, while failing to consider health risk required by other legislation. This includes:

- Water Services Act 2021 states that 'safe' drinking water can only be established when other causes are considered together with the consumption or use of drinking water.
- Local Government Act 2002 which requires that officials must 'identify and assess any other public health risks relating to the drinking water services supplied to the community.'

It appears that the D-Gs order cannot be considered alongside other legislation designed to protect health.

The Director-General of Health points to 3 publications to justify the safety of fluoride:

- Gluckman & Skegg (2014). <u>Health effects of</u> <u>water fluoridation: A review of the scientific</u> evidence.
- No author. Office of the Prime Minister's Chief Science Adviser (2021). <u>Fluoridation: an update</u> on evidence - 02 June 2021. (October Update)
- Cochrane Review. Iheozor-Ejiofor Z, et al (2015). <u>Water fluoridation for the prevention</u> <u>of dental caries</u>. Cochrane Database of Systematic Reviews.

Process-based, transparent risk assessment is an important administrative law convention. It ensures that the public trust the regulatory process, and the decisions regulators make.

Scientific evidence used in policy-making for both medicines and for toxic emissions to the environment should be of a high standard. This would involve full disclosure of the authors, an impartial process for selecting that science, a transparent methodology and disclosure of why or why not scientific studies were categorised as fit for purpose. Peer reviewers should be impartial, such as trained toxicologists and epidemiologists, and should not have an interest in one exclusive risk subset.



The 2021 review cited by the D-G fits none of this. The 2014 review did not contain a methodology, and the sole risk-based consideration in the Cochrane review concerned the risk of fluorosis.

In a recent <u>High Court case</u> (November 2023), it was ruled that the Director-General of Health was found to have failed consider the Bill of Rights Act (BORA).

However, the judge did not require that the directive to fluoridate be rescinded, pending the D-G's assessment of whether fluoridation was a reasonable

limit on the right to refuse medical treatment under the BORA.

As of September 2024, the D-G has not released the BORA consideration.

For 50+ years, 50% of the population has been exposed to fluoridated water, and consequently, local authorities have released fluoridated council water into the environment.

The NZ Environmental Protection Authority has never undertaken a comprehensive risk assessment to quantify the toxicity of fluoride to humans, and to environments that wastewater treatments release fluoride (hydroxyfluorosilic acid - HFA) into. To our knowledge, resource consents have not been required.

However, the D-G and the OPMCSA have, to date, dismissed the only published cognitive neurodevelopmental assessment of the risk of fluoride to developing brains in the world. Unlike the OPMCSA papers, the process (methods) of selecting studies and evaluation of risk has been transparently declared.

New Zealand children have been found to have higher levels of fluoride in their urine, but this has never been considered by the OPMCSA, nor in any policy documents, nor in any legislative processes.

When the D-G requested that Parliament amended the Health Act 1956, Parliament complied. However, the new legislation, specifically, section 116 E may be unfit for purpose due to two at least two failures - the failure to require that a risk assessment is undertaken, and a failure to require officials to weigh the benefits of any small cavity reduction with other known risks of fluoride. This might include (but is not limited to):

- ⇒ Skeletal fluorosis.
- Pediatric fractures.
- Arthritis/osteoarthritis.
- Developmental and IQ risk.

The Ministry of Health's latest campaign began in 2017 with the Health (Fluoridation of Drinking Water Amendment Bill). However, in both the 2016/17 Select committee report, and a later 2021 Health Committee report, public concerns about the safety of the fluoridation of drinking water were dismissed by Government Committees. Committees noted that people discussing safety concerns were not relevant as they did not speak directly to the text of the bill.

For 50+ years, 50% of the population has been exposed to fluoridated water, and consequently, local authorities have released fluoridated council water into the environment. Yet the New Zealand Environmental Protection Authority has never monitored fluoride/hydrofluorosilicic acid (HFA) emissions to understand environmentally relevant levels, nor conducted a risk assessment to review the scientific knowledge on human and/or environmental health risks.

HFA is not a pharmaceutical grade chemical, but a toxic slurry. It is a highly corrosive compound. What occurs when HFA is released as wastewater into rivers?

With no formal and impartial regulatory process, it appears that all claims that the 'benefits outweigh the risks' are flimsy. The primary 'scientific' source arises from claims by the OPMCSA. However, no methodological review was undertaken in 2021, and the peer review committee was experts in oral and dental health with experts in toxicology absent.

The OPMCSA (2021) downplayed an earlier draft of the US National Toxicology Program (NTP) Assessment for Developmental Neurotoxicity.

AUGUST 2024 NTP MONOGRAPH

NTP Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review

In August 2024 the final draft of this globally authoritative review was released NTP <u>Monograph on the State of the Science Concerning Fluoride Exposure and Neurodevelopment and Cognition: A Systematic Review</u>. NTP Monograph 08. National Toxicology Program Public Health Service U.S. Department of Health and Human Services.

The NTP review found with moderate confidence that higher than 1.5 mg/L of fluoride exposures were consistently associated with lower IQ in children. The authors noted that associations between lower total fluoride exposures and children's IQ remain unclear, and that because people receive fluoride from multiple sources, individuals with optimally fluoridated water may have total exposures higher than the concentration of their drinking water.

The NTP noted that the moderate confidence conclusions may be relevant to people living in optimally fluoridated areas, meaning that children in these areas may have total exposures in the risk range.

FLUORIDE: TIMELINE / RECOMMENDATIONS

With years of to-ing and fro-ing in New Zealand on the safety of fluoride, PSGRNZ have put together a fluoride timeline (with links):

- ⇒ Fluoride Timeline PDF
- ➡ Fluoride Timeline Easy online reading.

Last year PSGRNZ trustees presented to Whangarei District Council, Bay of Plenty Regional Council, the Tauranga City Commissioners and management.

ORAL & DENTAL HEALTH: POLICY Ongoing education programs for x2 daily brushing & flossing at kindergarten, primary & secondary level.

Ensure that education includes information emphasising the association of tooth decay with ultraprocessed foods & sugar-sweetened beverages. Increase funding for cooking and home-economics education. Make this education compulsory from years 7-9. Reduce focus on baking, and increase focus on preparing savoury, meat and vegetable based meals.

Supply: Free toothbrushes & toothpaste at kindergarten, primary & secondary level. Encourage children to drink water after meals.

Tooth decay experienced by low-income communities vastly outstrips the claimed reduction in dental caries. The cost-benefit ratio will never be black and white. The supply of toothbrushes and toothpaste to low income communities, and general education would lessen suffering, and likely lessen treatment costs.

PSGR

Providing scientific & medical information & analysis in the service of the public's right to be independently informed on issues concerning genetics, including genetic engineering & biotechnology, & other relevant matters of science & technology.

GENE EDITED FOOD: NOT A GMO?

In 2024 Food Standards Australia New Zealand (FSANZ) opened a second P1055 consultation, stating:

'P1055 is a proposal to amend the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology' to:

- make it clear which foods are genetically modified (GM) foods for Code purposes
- accommodate new technologies
- regulate foods according to the risk they pose.'

(1) In this Code, genetically modified food means (a) a food that is: (i) an organism that contains *novel DNA; or (ii) derived from an organism that contains novel DNA; or (iii) cells that contain novel DNA; or (iv) derived from cells that contain novel DNA; and (b) does not include any of the following: (i) a *substance used as a food additive (ii) a *substance used as a processing aid: (iii) a *substance used as a nutritive subs (iv) a substance used to: (A) support the growth and viability of cells during cell culture; or (B) process cells during cell culture (v) food that is derived from part of a grafted plant, where that part does not contain novel DNA or novel protein; (vi) food derived from a null segregant. (2) In this section, a null segregant means an organism, cell or cells that: (a) is descended from an organism, cell or cells that contain *novel DNA: and (b) does not contain novel DNA

The questions in the consultation involved whether the changes would produce the intended regulatory outcome. They concerned small technical details and the consumer perceptions of such details. However, they did not ask if the public considered whether the proposed new definitions would pose risks to health, and reduce consumer confidence.

Table 3. Intended regulatory outcomes under the revised approach at 2nd CFS

Food or substance	Intended regulatory outcome
Food from an organism or cells that contains novel DNA in its genome	GM food unless subject to exemption
Processed food ingredients from an organism or cells that contain novel DNA in their genome	GM food unless subject to exemption
Food from a null segregant	Not a GM food (exempt)
Substances used as a food additive (FA), processing aid (PA) or nutritive substance (NS)	Not GM food (exempt) FA, PA and NS are subject to pre-market regulation under
	other parts of the Code
Food from a genome edited organism that does not contain novel DNA in its genome	Not a GM food
	May be subject to regulation as a novel food if the food is considered to have characteristics that warrant a safety assessment by FSANZ, having regard to criteria set out in subsection 1.1.2—8 of the Code
Food derived from the part of a grafted plant that does not contain novel DNA or novel protein	Not a GM food (exempt)
	May be subject to regulation as a novel food if the food is considered to have characteristics that warrant a safety assessment by FSANZ having regard to criteria set out in section 1.1.2—8 of the Code
Precision fermentation product from a microorganism that contains novel DNA in its genome	GM food unless subject to exemption
Cell-cultured food derived from a cell line that contains novel DNA in its genome	GM food
Substances used to support the growth and viability of cells or process cells in culture as part of the production of cell-cultured food	Not a GM food (exempt)
	Whether the substances are a FA, PA or NS will need to be determined on a case by case basis. FA, PA and NS are subject to pre-market regulation under other parts of the Code and are themselves exempt from the GM food definition.

FSANZ did not ask for feedback on whether the 'intended regulatory outcome' would ensure that the object and goals of their over-riding legislation would be achieved.

This is deeply concerning, as FSANZ recognises that the current (July 2024) proposal involves a 'paradigm shift' away from process-based regulation which considered that if genetic modification was used in the process of developing a new organism, it must be declared, and undergo pre-market safety assessment.

Paradigm shift – but no media coverage.

FSANZ noted in July 'There appears to be an opportunity for consumer education.' The FSANZ call was released July 30, but until an article by Jodie Bruning (trustee) was published in September in <u>The Spectator</u>, no mainstream media in New Zealand or Australia had dug into the implications of the FSANZ 2024 'paradigm shift' proposal which was open to the public for consultation.

PSGRNZ reviewed FSANZ literature and the outcome of the previous consultations, concluding that the questions in the FSANZ consultation were unfit for purpose; and that it was unlikely that FSANZ would take account of public submissions that contradicted the FSANZ apparent consensus position, proposed in FSANZ documents and clarified in a 2nd September Webinar. As the public raised concerns, FSANZ staff deferred to the explanatory consensus position. All the public examples where genetic alterations might occur, following gene editing, were dismissed as 'also occurring in nature' unless there was novel DNA or a novel protein present, and so would not be a GMO.

This latter section of the webinar was not published.

PSGRNZ drew attention to 2 previous consultations where FSANZ did not declare the weight of public response for or against their line of questioning:

664 responses were made in 2018, and discussed in the <u>Preliminary report: Review of food derived using</u> new breeding techniques – consultation outcomes.

1736 submissions were made in the 2021 consultation, which was summarised in the <u>Safety assessment: full technical report</u>. P1055 – <u>Definitions for gene</u> technology and new breeding techniques.

Of course, gene edited staple foods, such as wheat could have a rearranged genome but no novel DNA, and therefore not require pre-market assessment.



Following this research PSGRNZ sent in a <u>submission to</u>
<u>FSANZ</u> (published in full for online reading on <u>our</u>
<u>Substack</u>) that included a preface speaking to these concerns, in addition to responding to the questions. which were directly concerned with achieving a technical outcome. Our concerns included:

- Likelihood much public input would be dismissed by FSANZ failing to transparently disclose the weight of public opinion (expert and non-expert).
- Claim that GMOs that do not contain novel DNA or a novel protein/s are substantially equivalent to conventionally bred food when all reviews have failed to disclose a transparent methods to ensure that all types of risk have been accounted for and considered.
- Proof that FSANZ ignored expert evidence by experts that GMOs that would not be categorised as GMO can potentially produce unintended effects and off-target genomic changes.
- ➡ Failure of FSANZ to call attention to <u>fundamental</u> <u>differences in the scale and pace of biotechnology development.</u> The incentivisation of market release of patented GMO products comes from stronger IP rights than developers using conventional breeding techniques can access. FSANZ did not address this.
- The 'substantial equivalence' claim is a technique historically applied by the biotechnology industry to infer that GMOs are as safe as conventionally bred foods. This tactic has enabled regulators to avoid comprehensive risk assessment.
- Merging premium food producers with ultraprocessed producers as one category.

CBDCS: The Reserve Bank of New Zealand (RBNZ) held a <u>Digital cash in New Zealand Digital Cash (CBDC)</u>
<u>Consultation</u> and PSGRNZ responded (published here).

P1055: Food Standards Australia New Zealand (FSANZ) has proposed to <u>amend the definitions</u> for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). PSGRNZ responded to the <u>first round</u> in 2021. Our response to this <u>second call for submissions here</u>.

MEDIA: Trustee Jodie Bruning has had articles published which reference PSGRNZ (these are *not approved* PSGRNZ publications).

CBDCs -

On the Edge of the Programmable Ledger

<u>Don't be misled – Judging the risk from Central Bank</u> <u>Digital Currencies in isolation is a rookie mistake.</u>

<u>The RBNZ CBDC survey – an artifact constructed to deny dissent</u>

FLUORIDE -

Fluoride – is risk assessment up to scratch?

<u>A challenge for Sarfati – Is medicated drinking water justified?</u>

GENE EDITING -

<u>Is our food safety authority failing the fairness and impartiality test?</u>

TOXICS -

Agricultural and horticultural products regulatory review: Is the review set up to fail?

<u>Downplaying pesticide risks undermines real risks</u> <u>sprayers face</u>

HEALTH -

The Silent Shame of Health Institutions

The 'Re-Education' of New Zealand Medical Doctors



PSGRNZ ADVOCACY

PSGRNZ INTERVIEWS

IN CONVERSATION WITH SCIENTISTS & DOCTORS

Audio: Podcast Spotify – search PSGRNZ

Audio: PSGRNZ.Substack.comVideo: YouTube – search PSGRNZ

We've been conducting interviews with scientists and doctors who are advocating for game changing approaches to how we *do* science, how we treat illness and how we *protect* human & environmental health. These interviews seek to draw attention to complex topic areas that are narrowly served by conventional science funding, research & medical approaches.

Click on the image below to go to the video to watch or listen on Spotify or Substack – PSGRNZ.

All interviews are fully referenced and high quality. Please share with patients, colleagues & friends.

Two Part Cancer Series with Dr Anna Goodwin, retired oncologist & secondary prevention consultant.

'The science of cancer knows that it's an injury response, but the clinical management of cancer has not yet figured this out for the most part.'



Part 1: Unravelling the Biological Drivers of Cancer



Part 2: Getting your Best Cancer Outcome.

Professor Grant Schofield, Professor of Public Health at Auckland University of Technology (AUT) & Director of AUT's Human Potential Centre.

'They were right. I should never have been appointed. It's a hopeless job for someone who wants to be outspoken about public policy.'



Extending your health span to live your best (mental & metabolic) life.

Dr Simon Thornley MBChB, MPH (hons), PhD. Public Health Physician, lecturer and researcher in the department of Epidemiology and Biostatistics, University of Auckland.

'If you look at the nutrition world from an insulincarbohydrate-sugar perspective, there's no discordance between trying to improve your overall metabolic health with a diet that both helps your waistline, your pancreas & your coronary arteries.'



Having a good hard look at the evidence. On public health & locked in med school paradigms.

Professor Pablo Gregorini. Lincoln University. Head of the Centre of Excellence in Designing Future Productive Landscapes and Pastoral Livestock Production Lab. 2-part interview.



[1] Is eating meat ethical? Taking another look at climate & environment & animal production systems.



[2] What happens when we give livestock more choice in a grazing system? Animal plant choice influences human cellular health - Metabolomic profiling & phytonutrients.

Dr Jen Unwin, Chartered Clinical & Health Psychologist - 30 years UK NHS. D.Psy, FBPs, C.Psychol. PhD. Co-founder: Co-Founder: <u>Food</u> <u>Addiction Solutions (FAS) UK. 2-part interview.</u>

'It is now thoroughly embedded in the practice and all the partners are on board.

There's lots of data about lots of patients over 11 years so it's a unique data-set really, internationally.'



[1] Game-changing UK doctors' clinic. 10 years of reversing diabetes!



[2] If we don't recognise food addiction as a substance use disorder, how can we treat it?

Professor Ashley Gearhardt, University of Michigan. Clinical Science Area Chair.

'We're seeing those same behavioural indicators of addiction - the loss of control & the intense cravings. The inability to cut down, even if you know you have a life-threatening illness.'



<u>Ultraprocessed food. Can UPFs meet the same</u>
<u>benchmarks for an addictive substance as tobacco & alcohol?</u>

MOVING FORWARD - OUR FOCUS

- Honour our <u>charitable objectives</u> and keep to our <u>core mission</u>: Providing scientific & medical information & analysis in the service of the public's right to be independently informed on issues relating to human & environmental health.
- Keep a sharp eye on technologies that are implicated in the aetiology of disease or that directly drive disease.
- Highlight the methods and processes used by prominent institutions to avoid conducting transparent, scientifically rigorous and robust risk assessments for the products and technologies they are tasked with regulating.
- Shed light on the importance of public trust in good process, and the critical role rigorous, robust and transparent processes should place in securing regulatory legitimacy (and the dependency of the courts on trustworthy processes).
- Necessarily draw attention to issues that are complex, uncertain and ambiguous. This is because

- when technology butts up against human biology, the extent of potential harm will predominantly be uncertain. For example, a baby or child may have different vulnerabilities based on their developmental age and stage. Have officials considered such issues, and taken into account the long-term impact of early-stage exposures?
- Highlight the importance of the precautionary principle 'where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing costeffective measures to prevent environmental degradation.' This principle is not discussed in our government institutions, including where a precautionary approach is required by legislation. There are no policy documents supporting regulatory decision-making where there is risk of morally unacceptable harm. Morally unacceptable harm includes harm that is:
 - Threatening to human life or health; or
 - Serious and effectively irreversible; or
 - Inequitable to present or future generations; or
 - Imposed without adequate consideration of the human rights of those affected.



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URL: PSGRNZ.Substack.com

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You can find us on Substack.com or on Spotify by simply searching 'PSGRNZ'.

The final word by Professor Jack Heineman from last year's interview discussing risk and the <u>potential scalability of</u> new technologies.

'Where harm can accumulate at scale transition, that's precisely where regulation is a solution to mitigate risks.'

