PSGR

Physicians & Scientists for Global Responsibility

August 7, 2022

Submission

Public consultations on the Food Regulatory System Strategic Plan 2023-2026. Ref: ANON-NESK-81CH-5

Submitted to the:

Department of Health and Aged Care

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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.

The Physicians and Scientists for Global Responsibility welcome the opportunity to submit to the public consultation on the Food Regulatory System Strategic Plan - 2023-2026.

This response concerns feedback relating to the Consultation Paper.

> The Australia New Zealand Food Regulatory System: A world-class collaborative food regulatory system focused on improving and protecting public health and safety.
>
> Horizon Scan to support the System Strategic Direction for 2023-2026 Consultation Paper.[1]

The aim of this consultation paper is the first step of a new reform process, 'most significant reform and modernisation effort' since the inception of the Australia New Zealand Food Regulatory System (the System) in the 2000's. 'The Horizon Scan takes a broad view of the wide food system challenges and opportunities.'

The consultation asks these 3 questions.

> Q1. Are the trends, issues, risks, and opportunities affecting the broader food system accurately captured in the Horizon Scan? If you answered no, which matters have not been captured?
>
> Q2. To what extent are there activities underway within your organisation, to manage these issues and risks and to leverage these opportunities?
>
> Q3. What opportunities do you consider exist for future work or partnerships, for mutual benefit?

Submitted online:

Q1. Are the trends, issues, risks, and opportunities affecting the broader food system accurately captured in the Horizon Scan? If you answered no, which matters have not been captured?

This document does not focus on the capacity of the food regulatory system to be handicapped by inadequate processes of risk assessment that then result in a failure to feedback to the market in a circular loop system of reinforcement to ensure food remains safe and nutritious.

We quote:

> 'Our regulatory system is the response to these market failures. The objectives of the new laws and the agencies empowered to enforce them is not only to stop the damage and prevent future harm; it is to maintain and strengthen the free market system. Although many advocates of free market economics refuse to acknowledge this dynamic, law and regulations are the underpinnings of our economic system. They define market structure and property rights while attempting to ensure that property rights don't intrude on our civil liberties. Without the regulatory apparatus of the state, our modern economy could not exist. The state fosters a safe space for market growth.' (Michaels, D. 2020)

[1] https://consultations.health.gov.au/preventive-health-policy-branch/strategic-planning-cycle/supporting_documents/Horizon%20scan%2026%20June%202022_Final.pdf

The highest level objective of the Authority[2]

> *18 Objectives of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures*
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> *(1) The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:*
>
> *(a) the protection of public health and safety; and*
>
> *(b) the provision of adequate information relating to food to enable consumers to make informed choices; and*
>
> *(c) the prevention of misleading or deceptive conduct.*

The key priorities[3] are:

- Reducing foodborne illness, particularly related to Campylobacter and Salmonella
- Supporting the public health objectives to reduce chronic disease related to overweight and obesity
- Maintaining a strong, robust and agile food regulation system

Stakeholders, identified by the Horizon Scan are:

- consumers and consumer representative organisations
- public health professionals and researchers
- industries involved in each part of the food supply chain
- regulators across all levels of government in Australia and New Zealand

The Consultation Paper has discussed trends and issues, rather than focussing on distinct challenges for the Joint Food Regulation System.

Existing regulatory practices revolve around industry supplying data for regulation and from reliance on industry scientists with significant practical expertise. We recognise how and why the Horizon Scan document has focussed on broader food-scape issues rather than overriding obligation to provide safe and nutritious food. It is because such a focus would involve a substantial alteration to regulatory cultures and practices that would politically challenge relationships with commercial industries. However, this position where one stakeholder holds disproportionate power, emasculates, or de-fangs the regulator, who then cannot achieve its highest objective of protecting public health and safety.

The regulatory system is made up of laws, policies, standards and processes. A key feature of the System is shared accountability, with all stakeholders responsible for the mitigation of risks.

However, in the 21st century, there is one stakeholder group– the industry sponsor, and industry associations -with disproportionate power in managing and supplying flow of scientific information

[2] Food Standards Australia New Zealand Act 1991
[3] Maintaining a strong, robust and agile food regulation system

that effectively, control how and what regulatory agencies consider in relation to potential risk of this technology and how judgement occurs.

Over this same period the capacity of regulatory agency scientists, has been progressively eroded to a box-ticking process, following out-dated modelling conventions and linear considerations perspective, as their resources and ongoing skills-development continue to erode in relation to the resources available to industry-paid scientists with a vested interest in getting the product to market. Civil society has been witness to, over these decades. an accelerated expansion in release of novel technologies with scalar risks. In addition, over this same period the degree and complexity of additives, contaminants and pollutants in food has surged.

Over this same period the capacity for independently funded, public sector scientists to explore risks relating to food safety, food technology, food ingredients and the combinatory effect of synthetic contaminants to produce food that is not nutritious and safe, has been substantially eroded. This has arisen from managerial cultures, tight funding environments and limited funding avenues to conduct public interest basic science.

Yet the 'A world-class collaborative food regulatory system focused on improving and protecting public health and safety' paper has not discussed these issues.

We submit that the greatest challenges that fundamentally arise in modern regulatory environments, is in the assurance in the integrity and veracity of science and scientific knowledge that is applied to ensure that civil society are exposed to safe and nutritious food.

We suggest that the key issue for the global food regulatory system is in shifting into a proactive stewardship role where scientists have autonomy to recognise the changing nature of risk relating to food in the 21st century.

Therefore, key issues, for reform include guidance and strategies to deal with scientific uncertainty in the 21st century, the consequences of underfunding, reliance on out-of-date and inadequate modelling and guidelines; and the failure to establish pathways to access and prioritise independent science that has no political or financial conflict of interest, in relation to a regulatory decision-at-hand.

We are not alone in our perspective that regulatory agencies have been unable to meaningfully tackle the implications of ongoing releases and emissions from industrial production. A recent paper by Stockholm Institute scientists, Persson et al. 2021, Outside the Safe Operating Space of the Planetary Boundary for Novel Entities, stated:

> ‘The increasing rate of production and releases of larger volumes and higher numbers of novel entities with diverse risk potentials exceed societies’ ability to conduct safety related assessments and monitoring. We recommend taking urgent action to reduce the harm associated with exceeding the boundary by reducing the production and releases of novel entities, noting that even so, the persistence of many novel entities and/or their associated effects will continue to pose a threat.’

Meaningful integration of knowledge relating to the capacity of technologies to disrupt the endocrine system has not occurred, yet this information is over 25 years old. A recent paper drew attention to the institutional silence on risk from exposures to endocrine disruptors.[4]

These issues and more, contribute to the systemic impotence of governance and regulatory authorities in the face of increasing health risk, which includes the diagnosis of complex chronic diseases at younger and younger ages; increasing population-level vulnerability to infectious diseases; and concerning shifts relating to intelligence, mental illness and resilience.

The capacity of regulators to steward technologies and protect health, is central to the success of the democratic and free-market system. As Professor David Michaels has stated:

> 'Our regulatory system is the response to these market failures. The objectives of the new laws and the agencies empowered to enforce them is not only to stop the damage and prevent future harm; it is to maintain and strengthen the free market system. Although many advocates of free market economics refuse to acknowledge this dynamic, law and regulations are the underpinnings of our economic system. They define market structure and property rights while attempting to ensure that property rights don't intrude on our civil liberties. Without the regulatory apparatus of the state, our modern economy could not exist. The state fosters a safe space for market growth.' (2020)

The PSGR briefly discuss the areas of concern below that we consider are inadequately parsed in the document, or of low priority, but of significant concern: The deployment of the Precautionary Principle, the consequence of long-term systemic underfunding of regulatory institutions; the absence of practical, cultural and financial pathways for regulators to receive feedback and information from local independent scientists and scientific communities; and the consequent vulnerability to lobbying that arises from these issues.

PRECAUTIONARY PRINCIPLE

Questions of ethics and risk remain largely outside the regulatory framework. This leaves regulators without a moral compass to guide them when decisions are complex, ambiguous and uncertain. However, regulators almost always work in profoundly uncertain environments.

Science is process driven, yet the regulatory environment is, contrary to perception, distinctly subjective. This occurs when regulators exercise a choice not to do certain work; or to pay attention to new knowledge; or provide clear decision-making in relation to uncertain and complex matters. This means that regulators can default to linear decisions. This is a subjective choice, to look away from complexity. We are aware that systemic underfunding exacerbates expedience.

For example, the science community and civil society have not observed a prioritising of prenatal, postnatal and risk in childhood and for young adults (developmental origins of health and disease – DoHaD) that matches or reflects the state of understanding in 21st century peer reviewed literature.

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[4] Maffini MV and Vandenberg LN (2022) Failure to Launch: The Endocrine Disruptor Screening Program at the U.S.Environmental Protection Agency. Front. Toxicology 4:908439. doi: 10.3389/ftox.2022.908439

Yet these developmental periods are when exposures to substances and technologies and set in place harm that occur for a lifetime. As the science has progressed for the production of technologies, resourcing for equivalent science has not occurred. It has remained locked in the 20th century science, while ethics have remained outside discourse. There are at least 2 ways this can be improved upon:

(a) The science to understand and clarify risk relating to individual susceptibility in complex, ambiguous and uncertain environments is available, biomarker and omics assisted technologies can highlight the importance of exposure timing, duration, intensity and the potential reversibility of exposures that carry particular risk for humans before the age of 25 years.

(b) There is an absence of guidance documents which can inform regulators on complex ethical issues and help guide decisions to ensure a precautionary stance is taken that protects infants, children and young people. Such documents can be produced with the assistance of legal experts who have published literature relating to the precautionary principle and human and environmental health. For good measure we include the definition here:

> **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 cost-effective measures to prevent environmental degradation (UNEP 1992).

SYSTEMIC UNDERFUNDING

The major challenges arise from historic, systemic underfunding of regulatory agencies which result in reduction of autonomy of regulators, dependent alliances with industry and regulatory capture. The effect is:

1. Absence of regulatory scientists who can challenge industry claims.

2. Overdependence on outdated modelling rather than incorporating new methodologies as the science changes (such data mining, use of mechanistic data to predict effect from dietary exposures. E.g. ToxCast-Based Predictive Models).

3. Historic, social and cultural dependency on the commercial industry who select and supply the data to prove that a new technology or product is safe and fit for purpose.

4. Failure, after the product has been on the market for some time, to engage sufficient resources to review the scientific literature on risk (as risk assessment), whether to a biological organism, a human, the environment or the economy.

5. Tendency to centre cost-benefit analysis around economic benefit rather than broader social, cultural and health related issues.

6. Incapacity to consider consequence and risk at scale (such as for gene editing).

7. Lack of triggers when products are persistent, bioaccumulative and toxic. Such as when dietary heavy metals or toxic pesticides aggregate in lipids.

8. A hands-off approach to the evidence of the complex relationship of dietary toxins. This particularly concerns two areas. Firstly, metabolic syndrome, and the relationship to obesity. The evidence has been accumulating and has been summarised in a reviews in Biochemical Pharmacology. (E.g. Lustig et al. 2022. Obesity I: Overview and molecular and biochemical

mechanisms. See also Obesity II & III.) Secondly, neurodevelopment and intelligence, such as a recent Op-Ed Are we getting dumber? by Scientists Barbara Demeneix and R. Thomas Zoeller, outlined.

9. New science can be harnessed, such as by incorporating biomarker assisted technologies to understand health effects; to consider the additive and synergistic effects of combinatory compounds.

E.g. Complex exposure scenarios can be evaluated through the deployment of aggregated (or multi) biomarker response technologies. These technologies are well established. They provide information on the bioavailability of contaminants under realistic exposure scenarios to show the effects (biological disruption) following exposures.

Omics technologies (adductomics, epigenomics, proteomics, metabolomics and transcriptomics) traverse a broader biological space, and can complement the traditional biomarker endpoints and play an important role in understanding mixture effects, and the early molecular events in the pathways leading to disease which to date has been largely excluded from regulatory considerations.

For example, this is evidenced in the failure of regulators to consider not only the effect of genomic changes and risk re[5]lating to herbicide tolerant species, but to estimate concurrent risk from the pesticides that the product is designed to tolerate. Multi-stacked GMO and GE crops with sequential pesticide sprays are designed to be sold into food/consumer markets with multiple pesticide sprays. The combinatory effect of edited product and chemical can be assessed with these technologies.

Data released from the FSANZ 25th Australian Total Diet Study demonstrates the multiple exposures from multiple chemicals and heavy metals. The FSANZ could engage local independent scientists to run biomarker/omics testing on rodents to identify risk.

Such work is particularly relevant for the developmental risk. With such scientific technologies in place, it is ethically and practically reasonable to engage scientists to assess the potential additive or synergistic (combinatory) effects of dietary heavy metals and pesticides for infants and children who consume higher quantities by bodyweight.

Such expertise then can feedback and inform industry actors and scientists, rather than the somewhat odd and backwards process of national regulators relying on the expertise from the industry scientists.

NO FEEDBACK LOOP FROM SCIENCE COMMUNITIES.

In addition to the absence of dedicated laboratories and scientists who can explore and challenge industry claims of safety, there is an absence of turning to, or deferring to independent scientific communities of experts for information. We also observe that regulatory scientists are handicapped by an absence of a dedicated scientific community outside the regulatory environment with block funding to explore new knowledge relating to risk from shifts in technologies relating to food and safety.

[5] https://www.foodstandards.gov.au/publications/Documents/25th%20Australian%20Total%20Diet%20Study%20appendices.pdf

Such scientists would create vital feedback loops that would inform, and challenge regulators, and supply evidence and data to counter industry claims of safety.

An absence of such scientists results in regulatory agencies and their scientists being more at risk of susceptibility to lobbying pressure.

LOBBYING PRESSURE

Regulatory capture is the process through which special interests affect state intervention in any of its forms (including through informational lobbying) (Bo 2006). Lobbyists for powerful industrial groups exercise power by influencing journals, media and relationships, particularly for example at national and global conferences, such as the WHO-FAO Joint Meeting on Pesticides Residues.

The dependency on industry to select and supply data for reauthorisation results in an inevitable to-ing and fro-ing where relationships occur, and other forms of lobbying can be carried out.

This leads to a loyalty to get the job done, improve the economy by getting new technology through. This is but one element of regulatory capture.

Q3. What opportunities do you consider exist for future work or partnerships, for mutual benefit?

Does mutual benefit relate to whom? Which stakeholder?

We submit that existing cultures and practices make it politically difficult for the Horizon Scan document to adequately acknowledge the inappropriate power of industry groups, and the conflicts of interest in the regulatory system, where one stakeholder, industry, exercises disproportionate, indeed, outsize power, in deciding which science and scientific knowledge is brought to regulators.

Trends, issues, risks, and opportunities revolve around strengthening independent knowledge production to navigate uncertain and complex environments, and for regulatory practices to respond flexibly to reflect advances in science in the peer reviewed literature.

Therefore, we submit, if the Objective of the authority in protecting public health and safety, that the reform process must revolve around the empowering of the food safety regulator to conduct risk assessment in such way that industry does not have control over the majority of science supplied for authorisation and risk assessment.

This includes advocating for the development of human and environmental health research institutes with independent block funding, where scientists and management are not involved in public-private partnerships with industry sectors. Institutional arrangements where public-private partnerships are relatively common, or where large sums of income arises from the public sector, have been identified to produce a chilling effect on the production of science which might politically or financially challenge or contradict these industries.

Independent block-funding of science to explore human and environmental health risks can dually provide a feedback loop into the regulatory sphere, and act as a training ground where regulatory science can gain expertise in real world risk, in order to reduce their reliance on industry expertise.

In addition, requiring that the regulator is equipped with laboratories and expert scientists with independent and practical experience so as to empower the regulators with a capacity to modernise regulation as the science changes; and with a power to command independent government funded institutions to produce scientific studies which may act to verify or challenge the claims of industry.

This includes the autonomy to extensively and independently review the peer reviewed literature in order to identify new knowledges relating to risk and to withdraw permissions that enable industry stakeholders to hide data behind secret commercial in confidence agreements.

The risks involve the capacity for a regulator to act before substantial harm has occurred – so as to protect public health and safety, therefore there is an opportunity to enshrine the precautionary principle at a high level in law and regulation. In addition, future work would involve training and education of management and regulatory scientists in administrative law and in application of the precautionary principle, so as to prioritise public health and safety, according to the latest scientific knowledge.

Finally, there can be no equity among stakeholders if close relationships between industry, and industry groups (lobby groups) have close and ongoing relationships between the regulator through the process of submission as sponsor or in submissions for reauthorisation.