The premise of this proposal is based on a single case report. Reacting to a single idiosyncratic case is the response of a dysfunctional regulator, not one that practices pragmatic risk management

> *“The potential risks to consumer safety posed by the above phenomena have been highlighted by recent deaths in Australia that have been linked to sports supplements (that were not included in the ARTG as medicines). In 2018, the death of a woman in Western Australia was attributed to an underlying metabolic disorder where her body was unable to metabolise her high protein diet that included protein-rich foods and various sports supplement protein powders[1].*

The above case in described in the background to the outcome document footnoted above.

> *“Background*
>
> *The roundtable was convened by the Australian Government Department of Health on behalf of the Food Regulation Standing Committee (FRSC) after the Australian Government Minister for Health wrote to the Acting Chair of FRSC in relation to the death of a young woman in Western Australia. The young woman’s death was attributed to an underlying metabolic disorder - Urea Cycle Disorder - where her body was unable to metabolise her high protein diet (including protein rich foods and various sports supplement protein powders).*
>
> *The Minister asked FRSC to convene a roundtable to investigate whether there are opportunities at the commonwealth and/or state and territory levels to enhance the safety of consumers who choose to use sports supplements.”*

The woman didn’t know she had a rare genetic disorder that stopped her body from properly breaking down protein. The condition caused a build-up of ammonia that poisoned her blood.

Anybody who is prone to anaphylactic shock or other allergic reactions don’t know until they know. Regulating based on extremely rare idiosyncratic reactions is not the actions of a responsible regulator. The woman was eating a very high protein diet including lean steak and egg whites. Egg whites are one of the highest protein containing foods. Does the TGA proposed to declare egg whites a therapeutic product because the can be promoted and used for a therapeutic purpose?

What about spinach? Science has shown that [redacted] was onto something and for many decades spinach was been n promoted as a muscle building vegetable. Does the TGA propose declaring spinach as a therapeutic good?

[1] Deloitte, *Department of Health Sports Supplements Roundtable: Report on Discussions and Next Steps* (August 2018).

The regulatory response proposed by the TGA was not an outcome of the forum used by the TGA to justify this proposal. To remove any claim that that might be a false statement, here are some comments and outcomes and weightings given by that forum.

[redacted], Food Standards Australia New Zealand (FSANZ)

- Food safety is a priority for the food regulatory system. Food standards are developed for the general population and are not designed to fully protect all consumers at all times. They cannot seek to manage rare adverse effects in the population and focus on risk management, not risk elimination.

[redacted] was spot on, although his comments should apply to any regulatory response. Any standards are developed for the general population and are not designed to fully protect all consumers at all times. They cannot seek to manage rare adverse effects in the population and focus on risk management, not risk elimination.

The TGA apparently does not understand that nothing it does can eliminate risk. Fake therapeutic products are alive and well in Australia. Just ask an of the manufacturers of well known brands such as [redacted] about Counterforte products. The pack looks genuine… even have TGA List numbers… but they are fake.

https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/sport-sup-action-plan

The outcomes of the review are of great interest if only for the fact that none of them involved the TGA trying to muscle in on the regulation of these products.

Options to Improve Consumer Safety

After an extended group discussion, participants worked in small groups to consider options for improving the safety of consumers who use sports supplements.

Each small group presented a summary of their ideas and options to the broader group roundtable participants – allowing discussion, questions and counter-issues to be raised. This part of the roundtable was particularly productive and conducted with goodwill.

Participants were advised, and acknowledged, that evidence-based, best practice regulatory evaluation would need occur before any options could be formally recommended to government.

There was a clear and unanimous view within the roundtable that all parties were willing to work together to improve product safety and would be willing to continue further engagement to develop options.

The following ideas and options were raised during the roundtable and attracted broad support within roundtable participants. No significant objections were raised by any roundtable participant in response to any of the following options.

Full review of Standard 2.9.4 – Formulated Supplementary Sports Foods

- This may include a review of the definition of a sports supplement. A new definition may pull more products under the Code to minimise the number of products that fall into the FMI.
- The maximum permitted levels of caffeine and its derivatives to be a consideration in this review. Potential maximum levels of other permitted ingredients would also be considered. This could also relate to product risk tiers.
- Consideration of including a warning statement on products to the effect of – Medical or dietetic advice should be sought prior to consuming this product.

This option had the strongest level of support.

Compliance and Enforcement

- Increase the enforcement capacity for regulators and increase the ability for enforcement officers to efficiently remove non-compliant products from the market.
- Give consideration to closing import loopholes.

This option had strong support, with all parties expressing a desire to see dangerous products and unethical businesses removed from the market.

Data collection and better understanding of the problem

- Consider better and more consistent reporting is needed to understand the nature of the problem and adverse events. This could include reporting to the TGA or to health departments.
- Data from industry would also be helpful.
- Undertake more work to understand the issue and what regulatory options are available to address the issue.

This option had strong support – with industry participants indicating they could also share information on emerging trends (positive and negative) based on their interactions with consumers.

Education campaigns targeted at:

- Critical care professionals – to support health care professionals to maintain their knowledge and skills in identifying and managing a patient with a metabolic condition.
- Health professionals – to encourage general health professionals to enquire whether sports supplements have been consumed when determining the cause of a reaction.
- Consumers and agents who sell/recommend products – to educate all consumers, manufacturers and suppliers (online and retail) of the potential risks of consuming sports supplements. This includes targeting users and the specific industry. The need for carefully planned communication messages was recognised, as warning consumers not to take supplements is unlikely to be engaging, consumers that are seeking a competitive advantage may be more likely to take risks to achieve their desired outcome.
- Gym owners and personal training educators - to educate personal trainers that they should be providing only basic health eating information, not specific advice on taking sports supplements. Advice should be sought from a qualified health professional prior to recommending sports supplements.

This option had the strong support but noting the risk of alienating consumers if the message was poorly pitched.

Risk tiers

- This would see products classed into specific groups aligned with an agreed risk level. For example, higher risk products (such as those with very high caffeine levels) may be placed behind the counter and require advice prior to purchase.
- Concerns were raised on this matter as to the equality between a retail business versus an internet business.
- Further concerns were raised that if domestic products are placed behind a counter, consumers will purchase products online which may be less likely to be compliant.

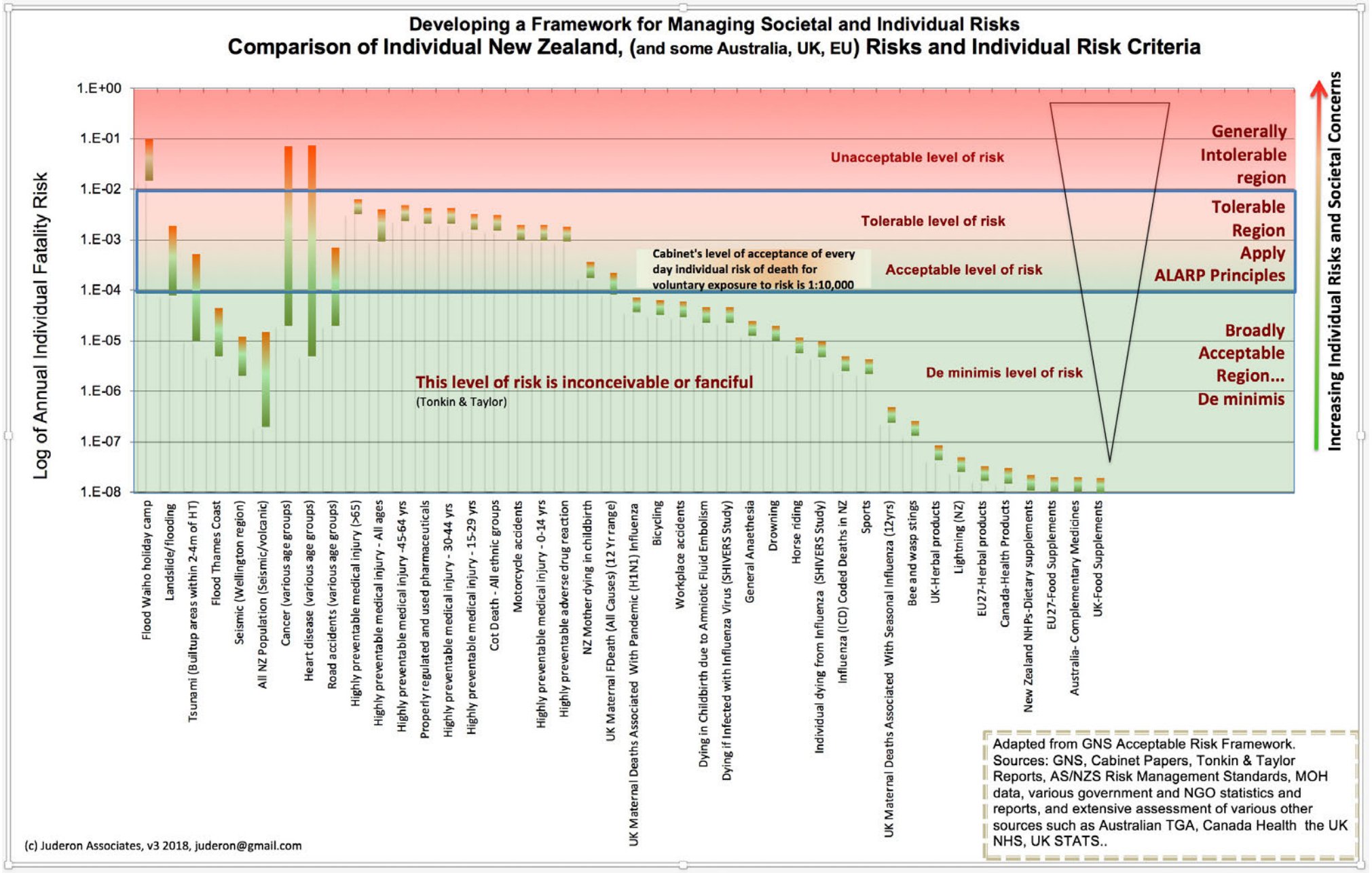
> *This option had support in-principle, noting that further policy work would be required to consider the effectiveness of such an option and means of implementing it without undue regulatory burden.*

Personally, I have very little involvement in the Australian therapeutic products industry. No doubt many will have concerns about the TGA trying to eliminate risk rather than allow pragmatics regulatory responses such as labelling, education and improved “smart” monitoring. For example, if Sports Drug agencies are concerned about banned substances being present in food, then let them introduce standards and a certification programme for sports people to use… assuming of course that counterfeit products won’t emerge in the marketplace.

But one positive aspect of this proposal is that it reinforces New Zealand industry’s gross dislike of the Australian TGA regime, and makes it so much easier to ensure that New Zealand politicians reject Australia’s obnoxious regime.

When I was first introduced to the Complementary Medicine industry in Australia (and the Natural Health Product industry in New Zealand) the TGA was trying to impose its regime on New Zealand. My first contacts in Australia’s TGA were the likes of [redacted] That was in 1998-2002. They may have moved on, but has the regulatory practice of the TGA really changed that much post [redacted]?

In short, the proposal will make it easier to motivate New Zealanders to continue rejecting Australia’s obnoxious regulation of safe and effective natural health products. What is proposed is not modern risk management practice.


Developing a Framework for Managing Societal and Individual Risks
Comparison of Individual New Zealand, (and some Australia, UK, EU) Risks and Individual Risk Criteria
Log of Annual Individual Fatality Risk
1.E+00
1.E-01
1.E-02
1.E-03
1.E-04
1.E-05
1.E-06
1.E-07
1.E-08
Unacceptable level of risk
Tolerable level of risk
Acceptable level of risk
De minimis level of risk
Cabinet's level of acceptance of every day individual risk of death for voluntary exposure to risk is 1:10,000
This level of risk is inconceivable or fanciful
(Tonkin & Taylor)
Generally Intolerable region
Tolerable Region Apply ALARP Principles
Broadly Acceptable Region... De minimis
Increasing Individual Risks and Societal Concerns
Flood Waiho holiday camp
Landslide/flooding
Tsunami (Builtup areas within 2-4m of HT)
Flood Thames Coast
Seismic (Wellington region)
All NZ Population (Seismic/volcanic)
Cancer (various age groups)
Heart disease (various age groups)
Road accidents (various age groups)
Highly preventable medical injury (>65)
Highly preventable medical injury - All ages
Highly preventable medical injury -45-64 yrs
Properly regulated and used pharmaceuticals
Highly preventable medical injury - 30-44 yrs
Highly preventable medical injury - 15-29 yrs
Cot Death - All ethnic groups
Motorcycle accidents
Highly preventable medical injury - 0-14 yrs
Highly preventable adverse drug reaction
NZ Mother dying in childbirth
UK Maternal FDeath (All Causes) (12 Yr range)
UK Maternal Deaths Associated With Pandemic (H1N1) Influenza
Bicycling
Workplace accidents
Dying in Childbirth due to Amniotic Fluid Embolism
Dying if Infected with Influenza Virus (SHIVERS Study)
General Anaethesia
Drowning
Horse riding
Individual dying from Influenza (SHIVERS Study)
Influenza (ICD) Coded Deaths in NZ
Sports
UK Maternal Deaths Associated With Seasonal Influenza (12yrs)
Bee and wasp stings
UK-Herbal products
Lightning (NZ)
EU27-Herbal products
Canada-Health Products
New Zealand NHPs-Dietary supplements
EU27-Food Supplements
Australia- Complementary Medicines
UK-Food Supplements
Adapted from GNS Acceptable Risk Framework.
Sources: GNS, Cabinet Papers, Tonkin & Taylor Reports, AS/NZS Risk Management Standards, MOH data, various government and NGO statistics and reports, and extensive assessment of various other sources such as Australian TGA, Canada Health the UK NHS, UK STATS..
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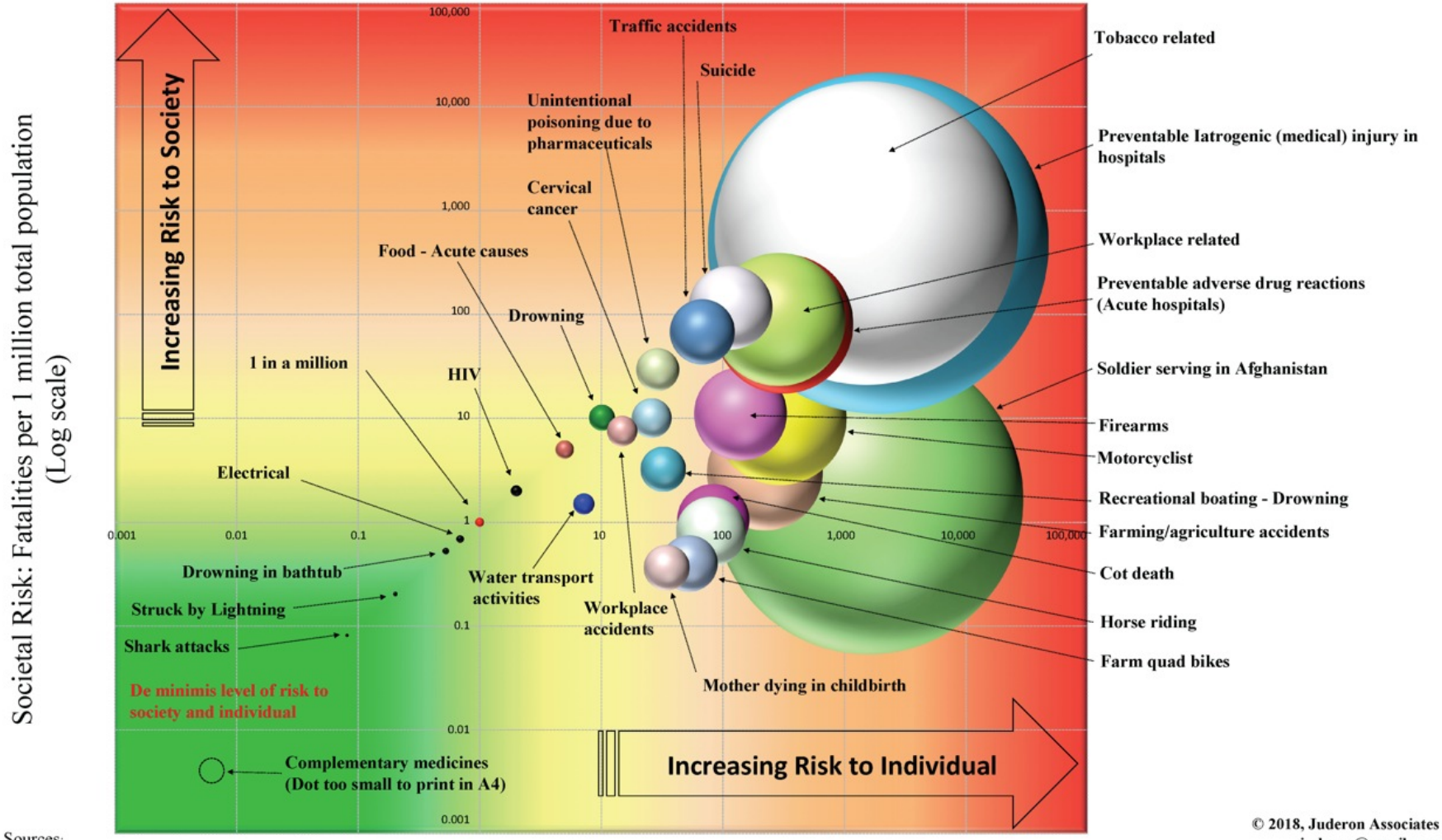
Societal vs Individual Risk of Death in Australia (v3.1)

Selected causes of death

Bubble size represents relative individual risk
Note: Log scales



Sources:
Various Australian Government and NGO databases, medical literature and reports and personal communications with the TGA

Individual Risk: Fatalities per million people exposed to risk (Log scale)