July 7, 2023

To FSANZ: <submissions@foodstandards.gov.au>

Comments on P1028 – the Infant Formula Standard

Thanks for the opportunity to make these comments.

RECOMMENDATIONS

1. Australian and NZ food policy and regulation authorities must prioritise personal and public health and citizen wellbeing as their top priority, ahead all other issues. The financial sustainability of health system depends on improving access to nutritious foods.
2. The processes of food standard setting must be made more accessible to the public and be conducted at arms-length from ultra-processed food industry lobbyists.
3. More independent, peer-reviewed, and published scientific evidence of public health outcomes must be required for approvals of industrial, ultra-processed foods, especially those novel ingredients with little history of safe use e.g. GMOs, NBTs, nanotechnology.

FOOD POLITICS

Together, three institutions make and implement food policy and food standards in Australia and Aotearoa NZ. They are the food regulator Food Standards Australia New Zealand (FSANZ)[1], the Food Ministers' Meeting[2] of state, territory, federal and NZ Ministers whose portfolios represent a variety of special interests, and the Food Regulation Standing Committee (FRSC)[3] of senior government officials who coordinate policy advice to the Food Ministers' Meeting and ensure internationally consistent approaches to food standards.

These bodies consistently acquiesce to the production, promotion and market agenda of the fake food industry, lightly regulating ultra-processed food (UPF) products to advance the interests of companies which deconstruct, degrade and denature the human food supply.

The UPF industry lobbying organisation, the Australian Food and Grocery Council (AFGC) is:

> "**the leading national organisation representing Australia's food and grocery manufacturing sector" which** operates "from Canberra to maintain close relationships with government and has team members located around Australia to stay connected with the industry and our members".[4] Also, "**As the peak industry body for companies that manufacture and supply food and grocery products in Australia, we engage with all levels of government and relevant regulatory**

[1] https://www.foodstandards.gov.au/Pages/defau t.aspx
[2] https://foodregu at on.gov.au/ nternet/fr/pub_sh ng.nsf/Content/Forum
[3] https://foodregu at on.gov.au/ nternet/fr/pub_sh ng.nsf/Content/FRSC
[4] https://www.afgc.org.au/about-afgc/your-team

> **bodies as a trusted advisor to inform them of member needs and other evidence when developing policies.**"

The AFGC's nine-member Board are senior executives of companies that sell their UPF products nationally and into global markets. AFGC staff have extensive government, regulatory and industry experience and connections which may even amount to conflicts of interest. For instance, the lead on Nutrition and Regulation held several roles at FSANZ including Principal Microbiologist and was then **Principal Scientist at the Department of Agriculture, Fisheries and Forestry (DAFF), including a three-year posting to Beijing as Counsellor (Agriculture) at the Australian Embassy, among other DAFF positions.** The AFGC's lead on Government and Media Relations worked for s**everal years in political offices across State and Federal Governments gaining a deep understanding of government processes, he established the government relations function in the nation's principal standards body (FSANZ?) and "was required to distil the complex technical work of the organisation to bureaucrats and political decision-makers in all state jurisdictions across the Commonwealth."**

AFGC does not appear to disclose its members but it has a long list of associate members which contribute their skills and products to the UPF industry.[5]

UPF FOOD

The Time commentary 'Why Ultra-Processed Foods Are So Bad for You' correctly asserts:

> "At their core, ultra-processed foods are industrial concoctions with ingredients that make them harmful, including a host of synthetic additives: salt, sugar and oils combined with artificial flavors, colors, sweeteners, stabilizers and preservatives."[6]

The global pandemics of obesity, gastro-intestinal illness, and consequential non-communicable diseases such as Type 2 diabetes, are a UPF and UP drink scandal. Food technologists in the junk food companies formulate products to create dependence on and addiction to their cheap and nasty products. They deconstruct whole foods to their basic chemical and molecular parts, modify and re-assemble them with processing aids and additives into food-like shapes and textures - salt, sweet, colours, and flavours – to maximise the market for their "edible junk." Marginalised communities across the world, often lacking access to even basic medicines and other necessities, can still buy a Coke or M&Ms.[7]

The British Medical Journal also confirms the urgent need for public health action on UPF and beverages as increasing scientific evidence confirms strong links between their consumption and big increases in the incidence of non-communicable diseases everywhere.

They conclude:

> "Increasing awareness of the health harms of ultra-processed foods provides the opportunity for a shift in global dietary public health policy away from a strict focus on individual nutrients and dietary behaviours, towards the wider social, economic, commercial, and political drivers of the overproduction and overconsumption of some types of food over others. This approach should also ensure that the most vulnerable and food insecure also benefit. Coordinated action at local, national, and

[5] https://www.afgc.org.au/about-afgc/assoc ate-member-d rectory
[6] https://t me.com/6245237/u tra-processed-foods-d et-bad/
[7] https://thefern.org/b og_posts/back-forty-they-on y-want-you-to-be_eve- ts-food

transnational levels will be required to seize these opportunities and equitably improve dietary public health."[8]

There are scant signs that Australasian food regulators are responsive to this and a multitude of other compelling evidence that UPFs are the direct cause of epidemics of loss of wellbeing, impose ill-health and bring death, here and around the globe.

The evidence of harm is well-documented and strong, for UPF's association with ovarian and breast cancers,[9] a higher risk of cerebrovascular disease, depression, and all-cause mortality,[10] obesity and associated illnesses.[11]

FSANZ website page on 'Diet quality and processed foods' updated in September 2020 opens with an acknowledgement that:

> "A nutritious diet is important to the health and wellbeing of Australian and New Zealand consumers. Large studies around the world have reported that diets of lower quality (e.g. high in sugar, salt, and saturated fats) are associated with an increased risk of early death from cardiovascular disease and cancer."

But then FSANZ negatively critiques the systems developed to evaluate the nutritional status of various diets and concludes with an 'analysis' that fobs off the reader with the unsubstantiated claim that FSANZ:

> "carried out a significant amount of work comparing studies linking diet and health outcomes," which "limited our analysis to consideration of mortality, cardiovascular disease, cancer, obesity and metabolic syndrome." Then it lamely concludes with the unsupported example that "people with diet quality scores in the lowest 25% in food/nutrient scoring systems have about the same increased risk of adverse health outcomes as people in the highest 25% of ultra-processed food consumption."[12]

As a result of this weak excuse for FSANZ inaction, we cannot rely on its assurance that:

> "FSANZ will continue to monitor the emerging literature on diet scoring systems and NOVA."

"There is now a considerable body of evidence supporting the use of UPFs as a scientific concept to assess the 'healthiness' of foods within the context of dietary patterns and to help inform the development of dietary guidelines and nutrition policy actions."

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[8] BMJ 2020;369:m2391 | do : 10.1136/bmj.m2391

[9] eC n ca Med c ne 2023;56: 101840 |On ne 31 January 2023 https://do .org/10. 1016/j.ec nm.2023. 101840

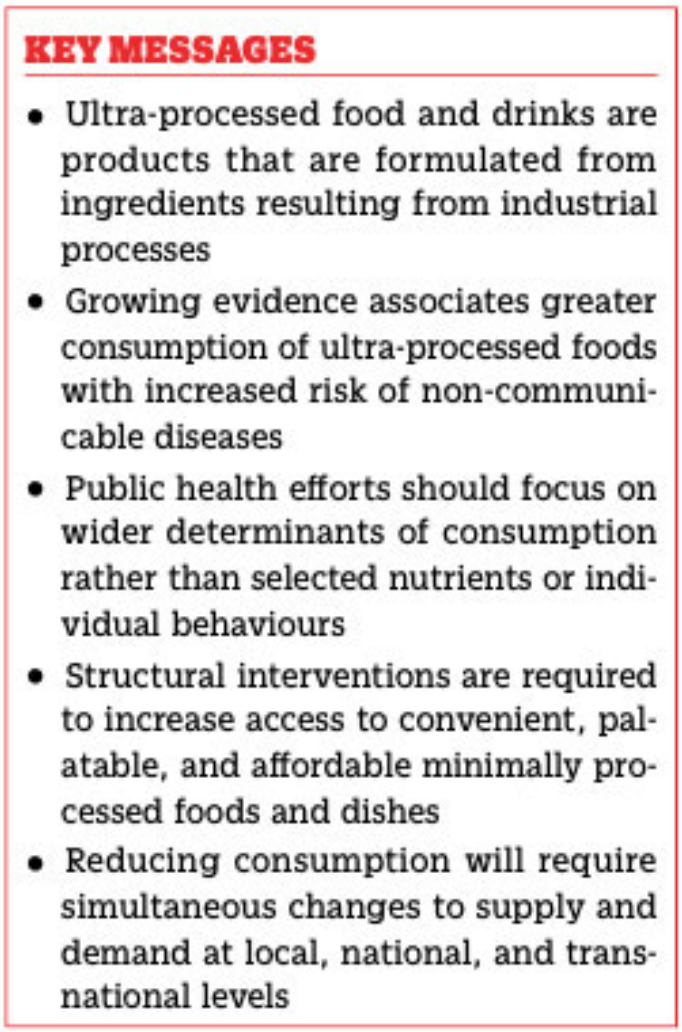
[10] Br t sh Journa of Nutr t on (2021), 125, 308–318 do :10.1017/S0007114520002688

[11] Advances n Nutr t on 14 (2023) 718–738 https://do .org/10.1016/j.advnut.2023.04.006

[12] https://www.foodstandards.gov.au/consumer/nutr t on/Pages/D et-qua ty-and-processed-foods.aspx

Table 1 Nova classification of foods based on the extent and purpose of processing[7]

Group	Name	Definition	Example products
1	Unprocessed or minimally processed foods	Edible parts of plants or animals and fungi, algae, and water; or these foods altered by processes such as removing inedible or unwanted parts, drying, crushing, grinding, fractioning, filtering, roasting, boiling, pasteurisation, refrigeration, freezing, placing in containers, vacuum packaging, or non-alcoholic fermentation	Fresh, squeezed, chilled, frozen, or dried fruits and vegetables, including pulses; grains, grits, flakes, or flour; meat, poultry, fish, and seafood; couscous and polenta; tree and ground nuts and other oil seeds without added salt or sugar; spices and herbs; plain yoghurt; tea and coffee
2	Processed culinary ingredients	Substances obtained directly from group 1 foods or from nature by processes such as pressing, refining, grinding, milling, and spray drying	Salt; sugar and molasses; honey and syrup; vegetable oils; butter and lard; starches extracted from corn and other plants
3	Processed foods	Relatively simple products made by adding group 2 substances to group 1 foods. Processes include various preservation or cooking methods and, in the case of breads and cheese, non-alcoholic fermentation	Canned or bottled vegetables and fruits; salted or sugared nuts and seeds; salted, cured, or smoked meats; canned fish; fruits in syrup; cheeses and unpackaged freshly made breads
4	Ultra-processed food and drink products	Formulations of ingredients, mostly of exclusive industrial use, that result from a series of industrial processes, many requiring sophisticated equipment and technology. These include the fractioning of whole foods into substances, chemical modifications of these substances, assembly of unmodified and modified food substances using industrial techniques such as extrusion, moulding and pre-frying, frequent application of additives whose function is to make the final product palatable or hyper-palatable (cosmetic additives), and sophisticated packaging, usually with synthetic materials	Carbonated drinks; ice cream, chocolate, confectionery; mass produced packaged breads and buns; margarines and spreads; biscuits, pastries, cakes, and cake mixes; breakfast cereals, cereal and energy bars; energy drinks; milk drinks, fruit yoghurts, and fruit drinks; meat and chicken extracts and instant sauces; infant formula milks and other baby products; health and slimming products such as meal substitutes; many ready to heat products, including pies, pasta dishes, and pizza; poultry and fish nuggets, sausages, burgers, and hot dogs; and instant soups, noodles, and desserts



the bmj | BMJ 2020;369:m2391 | doi: 10.1136/bmj.m2391

FSANZ's consumer 'information' page on processed foods[13] is similarly opaque and unhelpful. The UPF industry must no longer be allowed to co-opt our food 'guardians' into stalling comprehensive reviews of the evidence of harm from UPFs. Those responsible for food policy and regulation must mobilise genuine public health programs to stem the scourge of UPFs, in the interests of community-wide public health and wellbeing.

INFANT FORMULAS ARE UPF

Infant formulas are also UPFs so reviewing FSANZ's unreferenced, unsupported and uninformative 'analysis' of industrial UPF substances[14] was a necessary introduction. Infant formulas play an important role for the industry, as a Trojan horse that introduces people to life-long acceptance and consumption of UPFs. Follow-on formulas, processed baby foods, and weaning foods are also predominantly UPFs that play a key role in younger community members becoming hooked for life on low-nutrient substitutes for real food.

Major flaws in FSANZ's approach to feeding the vulnerable infants who do not have the enormous benefits of being breast fed.

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[13] https://www.foodstandards.gov.au/consumer/genera_ssues/Pages/processed-foods.aspx
[14] https://www.foodstandards.gov.au/consumer/nutr t on/Pages/D et-qua_ty-and-processed-foods.aspx

1. Though FSANZ mentions breastfeeding and requires formula labels that mention it as desirable, FSANZ and our governments should more proactively advocate for the natural practice. FSANZ and industry messaging are not unequivocal and readily default to infant formula as a satisfactory alternative to breastmilk. The assumption that breast-milk and formula are functionally equivalent is not backed up with compelling evidence. FSANZ should be proactive advocates for the health and well-being that a wholesome food supply provides, which would also decrease the demand for and cost of treating diet-related illnesses later.

2. Many ingredients that FSANZ approves for inclusion in formula are UPFs derived from fermentation processes, many with novel genetically manipulated and gene edited organisms that have no history of safe use. Typical of a general lack of evidence for the safety and efficacy of these substances is FSANZ's admission of uncertainty and evidence gaps as to the health effects of 2'-FL and LNnT.[15]

   "**FSANZ notes that the low number of relevant clinical trials constrains the assessment of beneficial health effects** of 2'-FL and LNnT **and the estimation of the magnitude of those effects**. **Acknowledging the limitations in the body of evidence**, FSANZ concludes that for infants: a) the addition of synthetic 2'-FL and LNnT to infant formula leads to a Bifidobacterium enriched microbiota that is more similar to that observed in breastfed infants than in those fed unsupplemented formula. However, the size of **the effect of 2'-FL and LNnT on bacterial populations is difficult to estimate**. **Evidence for a link between the presence of 2'-FL and/or LNnT in human milk or formula and any specific health outcome is limited to secondary outcomes of one randomised control trial and observational studies of lower quality**. b) there is a consistent body of indirect evidence to demonstrate a credible mechanism for 2'-FL inhibition of the binding of pathogenic Campylobacter jejuni to intestinal epithelial cells, and limited, largely indirect, evidence for a reduction of intestinal colonisation by C. jejuni and the incidence of diarrhoea. **There are no studies which test this.** For young children: a) evidence that a bifidogenic effect occurs in children fed formulated supplementary foods for young children (FSFYC) supplemented with synthetic 2'-FL and/or LNnT **is very limited**. There is no reason to expect that the previously demonstrated effect in infants would not occur in young children. b) **As with infants there is no direct evidence that inhibition of binding of C. jejuni occurs in children fed formulated supplementary foods** for young children (FSFYC) supplemented with synthetic 2'-FL. The Independent Expert Advisory Group (IEAG) for A1155 concluded that:
   - the approach to the assessment taken by FSANZ is appropriate
   - there is a bifidogenic effect; but that **there is limited evidence in humans to estimate the size of the effect or to link the bifidogenic effect to a beneficial health outcome**
   - there is a dose response effect in relation to the competitive inhibition by 2'-FL of binding of C. jejuni to its epithelial cell receptor; but **this inhibitory effect at a cellular level cannot be linked causally to a reduction in infection rates in infants or children** because, for obvious reasons, C. jejuni challenge studies in humans are unethical." **(our emphasis)**

[15] https://www.foodstandards.gov.au/code/app cat ons/Documents/A1155%20Rev ew%20SD2%20Benef c a %20 effects.pdf

Despite these uncertainties and lack of evidence, the substance produced with GM microbes was approved for addition to infant formula. The Review Report said:

"The assessment also concluded **insufficient evidence exists** to substantiate an immune modulating effect, improved intestinal barrier function, or protective effects against allergic responses for 2′-FL and LNnT.

• **Permitting these oligosaccharides benefits trade and international harmonisation, and supports innovation in the food system and thus provides net benefits to the community.**

So FSANZ counts UPF trade, Codex regulations, and food technology innovation as beneficial to the community despite massive uncertainties about the health impacts on emerging generations of citizens.

3. Industrial infant formulas introduce children and parents to a life-time of uncritical acceptance of ultra-processed foods, responsible for global health pandemics. Families with limited resources are more likely to default to cheap and nasty products instead of the fresh produce that would enable their children to reach full potential. FSANZ should resume promoting the Healthy Food Pyramid as the basis of personal and community health and wellbeing but FSANZ now advances the interests of globalised UPF industries, well ahead of public health and citizen wellbeing.

4. FSANZ food regulation uses a reductionist, chemistry and food technology approach. Instead of applying the scientific model that has been used for a century as the benchmark for good scientific practice and assessment, it uses 'regulatory science' that uncritically accepts applicant's biased and incomplete data, to favour the interests of the UPF industry and its trashy products. 'Safety' is narrowly defined in FSANZ assessment and data gaps are filled with best guesses. The issues are treated as technocratic even though FSANZ and governments also have responsibility for Health and Wellbeing - including personal and community wellbeing in the broadest sense.

   In SD1 - Safety and Food Technology – FSANZ advises that it:

   "has developed three principles to guide consideration of the risk management approach for food additives. … **The principles are: (1) the protection of infant health and safety; (2) the number of food additives used in infant formula products should be the least number necessary to achieve the required technological functions; and (3) consideration of harmonisation with international standards."**

5. Individual ingredients are assessed in isolation from other contents of UPF concoctions. Yet untested interactions and cumulative effects may be significant contributors to both negative or positive impacts of ingesting these products but the research is sparse and FSANZ has little interest in commissioning it or requiring applicants to do so.

6. Post-approval, longitudinal, monitoring and testing for efficacy, healthfulness and compliance of the commercial products must be part of the robust regulation of the infant formula regime. Without independent analysis it would be a long while before any adverse impacts were identified and ameliorated. Some infants may have health or other conditions that put them at particular risk.

7. Labelling should be required for all formula ingredients, using text rather than numbers or symbols. Those made with fermentation or other processes using genetically modified, other novel organisms, nanotechnology and other vanguard technologies without a history of safe use must be clearly identified as such.