

FOOD REFORMULATION FOR NCD- PREVENTION: REGULATORY OPTIONS AND POTENTIAL BARRIERS

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In the context of NCD prevention, reformulation means reducing the salt, sugar, fat, or overall calorie content of processed foods. Reformulation has the potential to be a powerful public health intervention, because it involves making changes to unhealthy foods upstream in the food supply: improving population diets without individual consumers needing to change their behaviour. However, questions remain as to which regulatory approaches will be most effective at spurring the food industry to reformulate. The prevailing view has been that governments should persuade and encourage companies to reformulate ‘voluntarily’. However, there is emerging evidence that the most effective voluntary reformulation schemes are those with a high degree of government involvement, monitoring and oversight. This suggests that mandatory reformulation — ie, the highest degree of government involvement, through legislated mandatory nutrient limits — may well be a promising approach. While voluntary reformulation has wide support, it is criticised for being weak, ineffective and open to regulatory capture. Mandatory reformulation offers the possibility of a stronger regulatory approach and a level playing field for industry, but critics are wary of its impact on free choice. Mandatory nutrient limits may also constitute technical barriers to trade. This article considers food reformulation as a policy goal, before exploring these regulatory options and the criticisms of each.

I INTRODUCTION

Around the world, unhealthy diets have become a major contributor to disease, death and disability.¹ Diets characterised by high consumption of salt, sugar, fat and overall energy, and low consumption of fruits, vegetables and whole grains, are a leading risk factor for obesity as well as for diet-related noncommunicable diseases (NCDs). These include cardiovascular disease, stroke, type-2 diabetes, and certain cancers, and account for 40 per cent of all NCD deaths, or one in five deaths worldwide.² Over the past two decades, governments around the world have become increasingly concerned about the significant health, social and economic costs of unhealthy diets, prompting increased interest in policy interventions.³ Governments wishing to take preventive action on diet-related NCDs can now draw upon a well-documented ‘menu’ of policy options.⁴

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¹ David Stuckler and Karen Siegel, *Sick Societies: Responding to the Global Challenge of Chronic Disease* (Oxford University Press, 2011); World Health Organization, *Global Status Report on Noncommunicable Diseases* (2014).

² Amanuel Alemu Abajobir et al, ‘Global, Regional, and National Comparative Risk Assessment of 84 Behavioural, Environmental and Occupational, and Metabolic Risks or Clusters of Risks, 1990–2016: A Systematic Analysis for the Global Burden of Disease Study 2016’ (2017) 390 *The Lancet* 1345.

³ Christina A Roberto et al, ‘Patchy Progress on Obesity Prevention: Emerging Examples, Entrenched Barriers, and New Thinking’ (2015) 385 *The Lancet* 2400.

⁴ See, for eg, C Hawkes, J Jewell and K Allen, ‘A Food Policy Package for Healthy Diets and the Prevention of Obesity and Diet-related Non-communicable Diseases: The NOURISHING Framework’ (2013) 14(Suppl 2)



However, as Hawkes and colleagues have demonstrated, the bulk of policy actions that are implemented tend to be those ‘downstream’ interventions primarily targeting eaters’ behaviour.⁵ These include food-based dietary guidelines, health promotion campaigns and nutrition labelling. Though widely implemented,⁶ experts assess these behavioural interventions as ‘weak’⁷ and ‘limited in reach and scope’,⁸ and their impact on shifting population diets as ‘patchy’⁹ and ‘poor’.¹⁰ In order to bring about population-wide dietary change (and so halt the growth of obesity and diet-related NCDs) such interventions will need to be supported by policies that target the wider food environment and the food supply itself.¹¹ Food reformulation — changing the composition of processed foods to make them healthier — is an increasingly popular policy goal, which aims to tackle poor diets upstream, in the food supply. However, the question of how best to achieve this policy goal remains contested. The food industry and many governments have tended to prefer ‘voluntary’ approaches to reformulation, which can run the gamut from companies’ purely voluntary actions, to co- and quasi-regulatory arrangements between industry and government. Such schemes are relatively cheap to implement, but are criticised for being ineffective and open to industry capture. By contrast, the public health community has advocated a mandatory approach to reformulation, in the form of legislated upper limits on particular nutrients in particular foods. Mandatory nutrient limits offer a stronger regulatory approach, but are criticised for limiting personal and commercial freedoms, and may also function as technical barriers to trade.

This article begins by setting out the background and rationale of food reformulation as a policy goal (Section II), before introducing different regulatory approaches to achieving this goal (Section III). Section IV focuses on what is described as ‘voluntary’ reformulation, despite featuring varying degrees and kinds of state involvement. It gathers evidence of this prevailing approach at both the national and international levels, before dealing with criticisms of the approach. In essence, critics argue that voluntary reformulation policies are ineffective and undermined by industry conflicts of interest. Instead, evidence suggests that the more effective voluntary reformulation policies are those that take on features of traditional, ‘command-and-control’ regulation, such as government oversight and specific timelines and targets. This challenges the widespread understanding of ‘mandatory’ and ‘voluntary’ reformulation as binary options. Rather, they should be seen as points on a regulatory spectrum or continuum.¹²

Obesity Reviews 159; World Health Assembly, *Follow-up to the Political Declaration of the High-level Meeting of the General Assembly on the Prevention and Control of Non-Communicable Diseases*, WHO Doc WHA66.10 (27 May 2013) Annex: ‘Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020’ (*Global Action Plan for NCDs*); Ffion Lloyd-Williams et al, ‘Smorgasbord or Symphony? Assessing Public Health Nutrition Policies Across 30 European Countries Using a Novel Framework’ (2014) 14 *BMC Public Health* 1195, doi:10.1186/1471-2458-14-1195.

⁵ Hawkes, Jewell and Allen, above n 4. See also Roberto et al, above n 3.

⁶ For instance, more than 100 countries have developed or are developing some kind of food-based dietary guidelines: Food and Agriculture Organization of the United Nations, *Food-based Dietary Guidelines* (2018) <<http://www.fao.org/nutrition/education/food-dietary-guidelines/regions/en/>>. In addition, 59 countries have mandatory nutrition labelling: European Food Information Council, *Global Update on Nutrition Labelling* (2016).

⁷ Tim Lang and Geoff Rayner, ‘Overcoming Policy Cacophony on Obesity: An Ecological Public Health Framework for Policymakers’ (2007) 8(Suppl 1) *Obesity Reviews* 165.

⁸ Jana Sisnowski, Elizabeth Handsley and Jackie M Street, ‘Regulatory Approaches to Obesity Prevention: A Systematic Overview of Current Laws Addressing Diet-related Risk Factors in the European Union and the United States’ (2015) 119 *Health Policy* 720, 727.

⁹ Roberto et al, above n 3.

¹⁰ Boyd Swinburn et al, ‘Strengthening Accountability Systems to Create Healthy Food Environments and Reduce Global Obesity’ (2015) 385 *The Lancet* 2534, 2534.

¹¹ Hawkes, Jewell and Allen, above n 4.

¹² Lawrence O Gostin and Lindsay F Wiley, *Public Health Law: Power, Duty, Restraint* (3rd ed, University of California Press, 2016) 208.

Section V introduces ‘mandatory nutrient limits’, a small but growing group of regulations whose aim is mandatory reformulation, and examines the reasons why countries may choose to introduce these. To date, the major objection to mandatory nutrient limits is that they are freedom-limiting, as I have discussed elsewhere.¹³ However, as mandatory nutrient limits gain acceptability through greater use, it will be increasingly important to consider other barriers to their implementation. The precedent of tobacco control has demonstrated the importance of considering the impact of international trade rules on innovative NCD prevention policies.¹⁴ As such, this article concludes by considering whether mandatory nutrient limits may constitute technical barriers to trade (TBTs) under World Trade Organization (WTO) rules,¹⁵ an issue which has not been dealt with extensively in the literature. Unlike voluntary standards, mandatory technical regulations must be complied with, and non-compliant products may not enter the market. As such, mandatory regulations are more likely than voluntary standards to be *prima facie* considered TBTs.¹⁶

Interest in reformulation, in all its regulatory permutations, is growing. As more and more countries implement reformulation policies, we will have greater access to evidence regarding their effectiveness. However, it is equally important to gather the *regulatory* evidence. Voluntary and mandatory approaches to reformulation come with different benefits, burdens, and barriers, and these should factor into the relative feasibility and acceptability of each as a policy option.

II FOOD REFORMULATION: DEFINITION AND RATIONALE

In the general context of food manufacturing, reformulation refers to changing the chemical or nutritional composition of processed foods for any reason — eg, to make them look or taste better, or because of supply chain requirements.¹⁷ However, in the context of diet-related NCDs, reformulation means changing the composition of processed food *in order to make it healthier*.¹⁸ Here, reformulation aims to:

- Remove trans fatty acids (TFAs, also known as trans fats), which cause coronary heart disease;
- Limit salt/sodium, overconsumption of which is linked to high blood pressure and strokes;
- Limit sugar, which is linked to high blood sugar, diabetes and dental caries; and/or

¹³ Jenny Claire Kaldor, ‘What’s Wrong with Mandatory Nutrient Limits? Rethinking Dietary Freedom, Free Markets and Food Reformulation’ (2018) 11 *Public Health Ethics* 54.

¹⁴ Tania Voon, Andrew D Mitchell and Jonathan Liberman (eds), *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues* (Routledge, 2014).

¹⁵ *Agreement on Technical Barriers to Trade* (‘TBT Agreement’), opened for signature 15 April 1994, 1868 UNTS 120 (entered into force 1 January 1995), Preamble.

¹⁶ World Trade Organization, *Technical Information on Technical Barriers to Trade* <https://www.wto.org/english/tratop_e/tbt_e/tbt_info_e.htm>.

¹⁷ Amandine Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010) 237.

¹⁸ *Ibid*; European Food Information Council, ‘Food Innovation and Reformulation for a Healthier Europe — A Challenging Mission’ (2010) 74 *Food Today* <<http://www.eufic.org/library/food-today-archive/year/2010/>>; National Heart Foundation of Australia, *Rapid Review of the Evidence: Effectiveness of Food Reformulation as a Strategy to Improve Population Health* (2012) 2.

- Reduce the overall energy content or density of a product (measured in calories or kilojoules). Energy imbalance, ie, when an individual consumes more energy than they expend, including through the consumption of energy-dense foods, is linked to obesity.

In theory, reformulation can also involve adding food components associated with NCD prevention (eg, fruit, vegetables, whole grains, fibre). However, while there are examples of individual companies making such changes to their products,¹⁹ there are few examples of policy or regulation to achieve this.²⁰ Therefore, in this paper, I use the term ‘reformulation’ to mean *removing or reducing trans fats, saturated fats, salt, sugar or energy density*.

Salt, sugar and fat are added to foods during processing and manufacture for a variety of reasons.²¹ Salt, for instance, can act as a preservative, as an agent in baking, or as a flavour enhancer. Fat contributes to the ‘mouth feel’ and texture of baked and fried foods, enhancing their palatability.²² In the case of very highly processed (or ‘ultra-processed’) foods, ingredients have undergone such a degree of refinement, extrusion and re-composition that their original tastes and textures are long gone: here, salt, sugar and fat are added back in, to make their taste acceptable.²³ Compared to whole grains, fruits, and vegetables, sugar and fat are relatively cheap ingredients (often due to mismatches between incentives for agricultural production and dietary goals) and so adding sugar and fat rather than whole grains etc increases profit margins.²⁴ Regardless of *why* they are added, the fact that they have been added provides the entry point for policy intervention: at food production, rather than at consumption.

Unlike policies that aim to change our consumption behaviours, reformulation seeks to change the nature of the available food. That is to say, it targets the supply, rather than the demand, side of dietary choice. Its rationale is that: (a) relatively minor changes to commonly consumed foods can have a major effect on population health; and (b) these changes can be made at the level of manufacturing, rather than food choice or behaviour.²⁵ Like other population-based policy approaches, reformulation derives its power from targeting what Geoffrey Rose described as a ‘mass influence acting on the population as a whole’.²⁶ Making small, barely perceptible changes to our environments, Rose argued, could shift the distribution of disease, and thus the overall health of the community, without needing to convince each individual to change his or her behaviour.²⁷ When a food is reformulated, ‘the consumer does not have to

¹⁹ Marlene B Schwartz and Kelly D Brownell, ‘Actions Necessary to Prevent Childhood Obesity: Creating the Climate for Change’ (2007) 35 *Journal of Law, Medicine and Ethics* 78, 83.

²⁰ Fortification is a related, but different, concept, relating to chronic micronutrient deficiencies rather than NCDs: see Mark Lawrence, *Food Fortification: The Evidence, Ethics, and Politics of Adding Nutrients to Food* (Oxford University Press, 2013).

²¹ Major exceptions include certain cuts of meat and certain oils, which are very high in naturally occurring saturated fat.

²² Michael Moss, *Salt, Sugar, Fat: How the Food Giants Hooked Us* (Random House, 2013).

²³ Ibid; Carlos Monteiro, ‘The Big Issue Is Ultra-processing. [Commentary]’ (2011) 2 *World Nutrition* 22; Gyorgy Scrinis and Carlos Augusto Monteiro, ‘Ultra-processed Foods and the Limits of Product Reformulation’ (2017) *Public Health Nutrition* 1.

²⁴ World Health Organization, ‘Diet, Nutrition and the Prevention of Chronic Diseases: Report of a WHO Study Group’ (WHO Technical Report Series No 797, 1990), 127–8.

²⁵ Boyd Swinburn, ‘Sustaining Dietary Changes for Preventing Obesity and Diabetes: Lessons Learned from the Successes of Other Epidemic Control Programs’ (2002) 11 (Suppl 3) *Asia Pacific Journal of Clinical Nutrition* S598, S601.

²⁶ Geoffrey Rose, ‘Sick Individuals and Sick Populations’ (1985) 14 *International Journal of Epidemiology* 32, 33.

²⁷ Geoffrey A Rose, *The Strategy of Preventive Medicine* (Oxford University Press, 1992) 97. For this reason, reformulation is sometimes described as ‘stealth health’.

modify drastically his or her habitual dietary food pattern',²⁸ but nevertheless benefits from an improved diet. Population-based policies 'tend to be sustainable, affect the whole population (including those who are difficult to reach), become systemic (affect default behaviours), and reverse some of the environmental drivers'.²⁹ And, unlike a medical approach that involves identifying and targeting only high-risk individuals, population-based prevention 'can be expected to generate much-needed health gains while entirely or very largely paying for themselves through their reduction of future health-care costs'.³⁰

Ideally, health policy is based on the strongest possible evidence. In the case of medical interventions, this would mean a prospective, double blind, randomised controlled trial. However, obtaining the same 'gold standard' of evidence in public health policy is much more difficult. This is especially true of nutritional epidemiology, where disentangling dietary factors from other closely related factors (eg, other health behaviours, wealth, or education levels) can be particularly challenging.³¹ Advocates of reformulation therefore draw on a mix of evidence to argue that the intervention is both effective and cost-effective. This includes modelling studies, case studies, and systematic reviews. So, in a modelling study of interventions to reduce salt intake, Cobiac and colleagues found that 'Programmes to encourage the food industry to reduce salt in processed foods... are an excellent investment; they improve population health and will reduce health sector spending in the long term'.³² In Mauritius, reformulation to reduce the saturated fat in cooking oil was associated with a significant fall in cholesterol levels over five years.³³ Reformulation to limit TFAs in Denmark, initially through voluntary measures and then using government regulation, was associated with a significant decline in cardiovascular disease.³⁴ And in a systematic review, Downs and colleagues found that reformulation eliminated TFAs from the food supply more effectively than labelling.³⁵ In a recent systematic review on the effectiveness of policies to reduce population salt consumption, Hyseni and colleagues found reformulation (along with multi-component interventions) to be the most powerful intervention.³⁶

²⁸ Joop van Raaij, Marieke Hendriksen and Hans Verhagen, 'Potential for Improvement of Population Diet Through Reformulation of Commonly Eaten Foods' (2009) 12 *Public Health Nutrition* 325, 326.

²⁹ Boyd A Swinburn et al, 'The Global Obesity Pandemic: Shaped by Global Drivers and Local Environments' (2011) 378 *The Lancet* 804, 810.

³⁰ Michele Cecchini et al, 'Tackling of Unhealthy Diets, Physical Inactivity, and Obesity: Health Effects and Cost-effectiveness' (2010) 376 *The Lancet* 1775, 1781.

³¹ Elizabeth Loder, 'Food for Thought' (2015) 351 *British Medical Journal* h4249, doi:10.1136/bmj.h4249.

³² Linda J Cobiac, Theo Vos and J Lennert Veerman, 'Cost-effectiveness of Interventions to Reduce Dietary Salt Intake' (2010) 96 *Heart* 1920, 1922. See also Marissa Collins et al, 'An Economic Evaluation of Salt Reduction Policies to Reduce Coronary Heart Disease in England: A Policy Modeling Study' (2014) 17 *Value in Health* 517.

³³ Ulla Uusitalo et al, 'Fall in Total Cholesterol Concentration over Five Years in Association with Changes in Fatty Acid Composition of Cooking Oil in Mauritius: Cross Sectional Survey' (1996) 313 *British Medical Journal* 1044.

³⁴ Steen Stender, Arne Astrup and Jørn Dyerberg, 'A Trans European Union Difference in the Decline in Trans Fatty Acids in Popular Foods: A Market Basket Investigation' (2012) 2 *BMJ Open* e000859, doi:10.1136/bmjopen-2012-000859.

³⁵ Shauna M Downs, Anne Marie Thow and Stephen R Leeder, 'The Effectiveness of Policies for Reducing Dietary Trans Fat: A Systematic Review of the Evidence' (2013) 91 *Bulletin of the World Health Organization* 262.

³⁶ Lirije Hyseni et al, 'Systematic Review of Dietary Salt Reduction Policies: Evidence for an Effectiveness Hierarchy?' (2017) 12(5) *PLoS ONE* e0177535, doi:10.1371/journal.pone.0177535.

III REGULATORY APPROACHES TO REFORMULATION

If reformulation is the policy goal, then how is it to be achieved? Reducing salt, sugar, fat, or calories in the food supply means first influencing food manufacturers to act in a certain way. This is because — other than in states where food production is nationalised — government is not directly responsible for the food supply. Rather, it regulates the food industry, which in turn produces the food supply. Traditionally, governments achieved this through legislation and regulations: formal rules backed up by penalties for their breach.³⁷ Today however, many aspects of food regulation have become ‘de-centred’,³⁸ with governments seeking to facilitate or encourage, rather than coerce, a particular outcome. As in many industries, traditional command-and-control regulation in the food industry has been supplemented, and in many cases supplanted, by ‘softer’, arm’s length forms of regulation including guidelines and standards (rather than laws) and self-regulation (rather than government regulation).³⁹

A review of the literature suggests that different policy approaches, involving different types and degrees of state involvement, can encourage food reformulation. These can be understood using terms from two influential taxonomies of public health policy intervention, namely Gostin’s seven models,⁴⁰ and the ‘Nuffield Ladder’,⁴¹ of interventions. So, governments wishing to spur reformulation by food manufacturers may adopt:

- A ‘pure’ market approach to reformulation, ie ‘do nothing’ in a Nuffield sense,⁴² leaving companies to respond to consumers’ demands for healthier foods. This may play out at the level of individual companies (eg, multinational PepsiCo making a strategic commercial decision to decrease the salt, sugar and fat in its snack foods),⁴³ or across an industry (eg, Australian manufacturers significantly reduced TFAs across the food supply during the 1990s, in response to consumer demand).⁴⁴
- A hybrid market and policy approach to reformulation, whereby government actions prompt a change in consumer expectations and demands. Informational policies, in the form of health promotion campaigns, education, or dietary guidelines, can help to shift consumer preferences — to which markets then respond. For example, after governments issued advice to consume low-fat dairy foods during the 1980s and 1990s,

³⁷ Modern food laws date from the late 19th century, a legacy of the Industrial Revolution and the profound changes it brought about in the food supply; see: Christopher Reynolds, *Public and Environmental Health Law* (Federation Press, 2011).

³⁸ Julia Black, ‘Critical Reflections on Regulation’ (2002) 27 *Australian Journal of Legal Philosophy* 1; Ian Bartle and Peter Vass, ‘Self-regulation within the Regulatory State: Towards a New Regulatory Paradigm?’ (2007) 85 *Public Administration* 885.

³⁹ Tim Lang, David Barling and Martin Caraher, *Food Policy: Integrating Health, Environment and Society* (Oxford University Press, 2009); Tim Lang and Michael Heasman, *Food Wars: The Global Battle for Mouths, Minds and Markets* (2nd ed, Routledge, 2015); David Levi-Faur, ‘The Global Diffusion of Regulatory Capitalism’ (2005) 598 *Annals of the American Academy of Political and Social Science* 12.

⁴⁰ Gostin and Wiley, above n 12, 28–33, 207–16. The seven models of traditional public health intervention are: the power to tax and spend; alteration of the informational environment; alteration of the built environment; alteration of the socioeconomic environment; direct regulation; indirect regulation through the tort system; and deregulation. Gostin and Wiley also point to newer models of intervention from the ‘new governance’.

⁴¹ Nuffield Council on Bioethics, *Public Health: Ethical Issues* (2007). The Nuffield Ladder’s intervention steps, which overlap to some degree with Gostin’s, are: do nothing and simply monitor the situation; provide information; enable choice; guide choice through changing the default; guide choice through incentives; guide choice through disincentives; restrict choice; and eliminate choice.

⁴² *Ibid.*

⁴³ John Seabrook, ‘Snacks for a Fat Planet: Pepsico Takes Stock of the Obesity Epidemic’ *The New Yorker* (online), 16 May 2011 <<http://www.newyorker.com/magazine/2011/05/16/snacks-for-a-fat-planet>>.

⁴⁴ Bill Shrapnel, ‘Should Trans Fats Be Regulated?’ (2012) 69 *Nutrition and Dietetics* 256.

manufacturers around the world significantly increased the number and types of low-fat dairy products available for sale.⁴⁵

- *A policy approach with indirect effects on reformulation*, such as labelling (especially interpretative front-of-pack labelling) or fiscal policies (taxes or subsidies). In these cases, while the measure does not regulate food composition as such, manufacturers reformulate in order to achieve a more favourable label or minimise costs. In the Netherlands, for example, adoption of a ‘healthy choice’ front-of-pack logo prompted manufacturers to reformulate their products, especially in relation to sodium and dietary fibre.⁴⁶ In Hungary, one study showed that 40 per cent of manufacturers had reformulated their products in order to avoid the ‘junk food tax’.⁴⁷
- *A government-led, ‘voluntary’ approach with direct effects*, exemplified by ‘new governance’⁴⁸ tools such as self-regulatory, co-regulatory, or quasi-regulatory reformulation policies. Here, food composition is directly targeted, but the measures are imposed voluntarily by the food industry, with varying degrees of government involvement. In the UK during 2003–2011, industry and government worked together to develop and implement standards on salt reduction, described as ‘voluntary with the threat of regulation/legislation’.⁴⁹
- *A policy approach with direct effects*: mandatory nutrient limits, whereby governments set and enforce food composition requirements, leading to reformulation. The mandatory TFA limit in Denmark⁵⁰ is a good example (discussed further below).

Only the last two involve efforts by government to influence food composition *directly*. As such, they represent a paradigm shift from the weaker, indirect or behavioural policy approaches described above, which have been criticised as ineffective. These newer approaches, targeting the food supply directly, are the focus of this article. In the nutrition policy literature, the distinction between the two strategies is often expressed as ‘voluntary’ versus ‘mandatory’. However, it is important to emphasise that ‘voluntary reformulation’ in this (policy) context does not refer to the *purely* voluntary, commercial decisions of food manufacturers. Rather, voluntary reformulation is used to describe a range of policy approaches with varying degrees of government oversight, stopping short of laws or regulations. Indeed, given the heterogeneity of the approaches used, the main purpose of the term ‘voluntary’ seems to be to distinguish them from traditional, command-and-control regulation. A more accurate — though unwieldy — formulation would be ‘government action to encourage private sector action’.⁵¹ In many of these cases, firms agree to comply voluntarily with standards or guidelines set by government, under threat of regulation if they do not, and the schemes are

⁴⁵ Barbara Santich, ‘Paradigm Shifts in the History of Dietary Advice in Australia’ (2005) 62 *Nutrition and Dietetics* 152; DK Sandrou and IS Arvanitoyannis, ‘Low-Fat/Calorie Foods: Current State and Perspectives’ (2000) 40 *Critical Reviews in Food Science and Nutrition* 427.

⁴⁶ Ellis L Vyth et al, ‘Front-of-Pack Nutrition Label Stimulates Healthier Product Development: A Quantitative Analysis’ (2010) 7 *International Journal of Behavioral Nutrition and Physical Activity* 65.

⁴⁷ Anikó Bíró, ‘Did the Junk Food Tax Make the Hungarians Eat Healthier?’ (2015) 54 *Food Policy* 107.

⁴⁸ Gostin and Wiley, above n 12, 207–16.

⁴⁹ F J He, H C Brinsden and G A MacGregor, ‘Salt Reduction in the United Kingdom: A Successful Experiment in Public Health’ (2014) 28 *Journal of Human Hypertension* 345, 351.

⁵⁰ M R L’Abbé et al, ‘Approaches to Removing Trans Fats from the Food Supply in Industrialized and Developing Countries’ (2009) 63(Suppl 2) *European Journal of Clinical Nutrition* S50.

⁵¹ Jose Brambila-Macias et al, ‘Policy Interventions to Promote Healthy Eating: A Review of What Works, What Does Not, and What Is Promising’ (2011) 32 *Food and Nutrition Bulletin* 365; Sara Capacci et al, ‘Policies to Promote Healthy Eating in Europe: A Structured Review of Policies and Their Effectiveness’ (2012) 70(3) *Nutrition Reviews* 188.

clearly positioned as government policy, i.e., action that government is taking on diet-related NCDs.⁵²

IV 'VOLUNTARY' REFORMULATION

A *The 'Persuade and Encourage' Model*

Until recently, the prevailing view has been that reformulation would be best achieved by governments taking steps to persuade, convince, encourage, support and otherwise partner with the food industry. This is usually described as a voluntary model, since firms are, ultimately, free to choose whether or not to comply. However, we might also describe it as a 'persuade and encourage' model, by reference to the actions of government. In 1990, the first report of a World Health Organization (WHO) expert study group on Diet, Nutrition and Prevention of Chronic Disease stated that '[food] companies could play an important part in developing new foods with a more appropriate nutrient content'⁵³ if convinced to do so and if provided with appropriate support for research and development. The WHO expert group drew on evidence about the intervention in North Karelia, Finland, a very successful community-based prevention program targeting cardiovascular disease.⁵⁴ One component of the North Karelia strategy had been to encourage the food industry to introduce low-fat milks and unsaturated vegetable fats.

An Australian taskforce in the late 1980s drew on similar evidence from Norway, whose approach was 'the most comprehensive adopted by any developed country, and quite unique'.⁵⁵ In contrast to other countries, the taskforce wrote, 'Norway's policy does not emphasize individual behaviour as much as it proposed to change dietary habits by changing the process of food production and distribution in order to reduce the availability of what is termed unhealthy food'.⁵⁶ Norway had achieved this 'through *liaison with* and education of primary and secondary food industries'.⁵⁷

During the 1990s, the idea that achieving a healthier food supply depended on first securing the agreement and cooperation of the food industry became the default assumption. For instance, in a 1995 article that elsewhere called for government action on obesity, James wrote:

We have had considerable success in persuading the food industry to change the fatty acid composition of the diet to reduce the impact of CHD. ... [But] the Government's target at the moment is for an average population fat intake of 35% simply on the basis that to put it any lower would incur such objection and lack of cooperation from the food industry that nothing might develop.⁵⁸

⁵² See for example Kathy Trieu et al, 'Salt Reduction Initiatives around the World — a Systematic Review of Progress Towards the Global Target' (2015) 10(7) *PLoS ONE* e0130247, doi:10.1371/journal.pone.0130247.

⁵³ World Health Organization, 'Diet, Nutrition and Prevention', above n 24, 129.

⁵⁴ *Ibid* 130–1.

⁵⁵ Nutrition Taskforce of the Better Health Commission, *Towards Better Nutrition for Australians* (1987) 70.

⁵⁶ *Ibid*.

⁵⁷ *Ibid* 74 (emphasis added). Hetzel and McMichael likewise drew on the Norwegian example to argue that national dietary guidelines could be used 'as a reference point for the individual citizen, for the food industry, and for agriculture': Basil S Hetzel and Tony McMichael, *The LS Factor: Lifestyle and Health* (Penguin, 1989) 52.

⁵⁸ W P T James, 'A Public Health Approach to the Problem of Obesity' (1995) 19 *International Journal of Obesity* S37, S44 (emphasis added).

And even in their ‘new frontier’ article on the emerging role of law in obesity prevention (often cited as the first American journal article on the subject), Mello and colleagues nevertheless judged persuasion and encouragement to be more effective than regulation, when it came to changing the food supply:

[T]he success of government regulation of the food industry will probably fall short of what industry could accomplish alone if it were strongly motivated to do so. Efforts to encourage self-regulation and corporate responsibility could go far toward improving the healthfulness of foods sold.⁵⁹

As described below, ‘persuade and encourage’ has achieved policy salience at both the national and international levels.

B ‘Persuade and Encourage’ in National Policy

At the level of national policy, ‘persuade and encourage’ has translated into a range of government approaches and schemes to engage the food industry and encourage voluntary reformulation. At least 25 countries have voluntary salt reduction schemes in place, with several more having voluntary targets only for bread (which is a significant source of added salt in the diet).⁶⁰ Four countries have voluntary TFA limits,⁶¹ and several more have co- and quasi-regulatory policies encouraging reformulation across the food supply, including in relation to sugar and total fat.⁶²

As noted above, apart from being not mandatory, there is wide variation in their regulatory form and features, particularly in relation to the degree of government involvement and the formality of any commitments by the food industry. Some are loose, open-ended arrangements, described as ‘platforms’, ‘forums’ or ‘mechanisms’ to facilitate discussion and cooperation between government and industry representatives (eg, Australia’s Healthy Food Partnership, or the European Union (EU) platform for action on diet, physical activity and health).⁶³ Under the United Kingdom (UK) government’s Responsibility Deal, food companies are encouraged to make specific ‘pledges’, including on reformulation.⁶⁴ In the United States (USA), the National Salt Reduction Initiative describes itself as a ‘partnership’ between local, state and national health authorities and various food companies.⁶⁵ The French government implemented

⁵⁹ Michelle M Mello, David M Studdert and Troyen A Brennan, ‘Obesity — the New Frontier of Public Health Law’ (2006) 354 *The New England Journal of Medicine* 2601, 2607 (emphasis added).

⁶⁰ Jacqui Webster et al, ‘Target Salt 2025: A Global Overview of National Programs to Encourage the Food Industry to Reduce Salt in Foods’ (2014) 6 *Nutrients* 3274.

⁶¹ Downs, Thow and Leeder, above n 35.

⁶² World Cancer Research Fund International, *NOURISHING Framework* <<http://www.wcrf.org/int/policy/nourishing-framework>>; Lloyd-Williams et al, above n 4.

⁶³ Department of Health (Aust), *Healthy Food Partnership* <<http://www.health.gov.au/internet/main/publishing.nsf/Content/Healthy-Food-Partnership-Home>>; European Commission, *EU Platform for Action on Diet, Physical Activity and Health* <http://ec.europa.eu/health/nutrition_physical_activity/platform_en>.

⁶⁴ Department of Health and Social Care (UK), *Healthy Lives, Healthy People* (30 November 2010) <http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_121941> 30.

⁶⁵ New York City Health Department, *National Salt Reduction Initiative Goals and Summary* <<https://www1.nyc.gov/assets/doh/downloads/pdf/cardio/cardio-salt-factsheet.pdf>>.

a National Program for Health and Nutrition, under which 35 companies signed commitments between 2008 and 2013.⁶⁶

Others involve more tangible, quasi-regulatory features and requirements. Argentina's *Menos Sal, Mas Vida* (Less Salt, More Life), for instance, was a public–private partnership (PPP) that involved the Minister of Health signing a voluntary agreement with the industry.⁶⁷ The UK's salt reduction program (2003–2011, then replaced by the Responsibility Deal), an early and highly successful example of voluntary salt reduction, is usually described as a government-led, voluntary scheme,⁶⁸ or as 'voluntary with the threat of regulation/legislation'.⁶⁹ This notion that voluntary action takes place in the shadow of potential regulation is a common theme in the persuade and encourage model. For instance, in its 2009 report, *Weighing It Up: Obesity in Australia*, the House of Representatives Standing Committee on Health and Ageing expressed the view that regulation should only be used if voluntary approaches did not succeed: 'industry should first be encouraged to undertake self-regulation. However ... should industry fail to make concrete changes in relation to ... reformulation, then the Federal Government should explore potential regulatory changes'.⁷⁰

C 'Persuade and Encourage' at the International Level

The persuade and encourage model has also received strong normative support from the WHO, because a voluntary or partnership model of food industry change is consistent with the WHO's Ottawa Charter philosophy of multisectoral action for health.⁷¹ Most recently, the WHO Commission on Ending Childhood Obesity (ECHO) found that 'real progress can be made by constructive, transparent and accountable engagement with the private sector'.⁷² Specifically, the ECHO recommendations include a call for countries to engage with the food manufacturing sector in developing 'initiatives ... to reduce fat, sugar and salt content, and portion sizes of processed foods'.⁷³ This recommendation is consistent with WHO policy guidance since its 2004 Global Strategy on Diet, Physical Activity and Health (DPAS).⁷⁴

The DPAS emphasised the central role of governments in creating healthy environments and facilitating healthy choices, but also encouraged the participation of the food and drinks industries in NCD prevention. It stated: 'bringing about changes in dietary habits will require the combined efforts of many stakeholders, public and private'.⁷⁵ In stark contrast to the WHO's stance towards tobacco manufacturers, the private sector 'could become partners with governments and nongovernmental organizations in implementing measures... to encourage

⁶⁶ Clementina Sebillotte, 'Efficiency of Public–Private Co-regulation in the Food Sector: The French Voluntary Agreements for Nutritional Improvements' (Working Paper No ALISS 2013–03, Alimentation et Sciences Sociales, December 2013).

⁶⁷ Luciana Castronuovo et al, 'Analysis of a Voluntary Initiative to Reduce Sodium in Processed and Ultra-processed Food Products in Argentina: The Views of Public and Private Sector Representatives' (2017) 33(6) *Cadernos de Saúde Pública* 2.

⁶⁸ Karen Charlton, Jacqui Webster and Paul Kowal, 'To Legislate or Not to Legislate? A Comparison of the UK and South African Approaches to the Development and Implementation of Salt Reduction Programs' (2014) 6 *Nutrients* 3672, 3677.

⁶⁹ He, Brinsden and MacGregor, above n 49.

⁷⁰ House of Representatives Standing Committee on Health and Ageing, Parliament of Australia, *Weighing It Up: Obesity in Australia* (2009) 80.

⁷¹ World Health Organization, *Ottawa Charter for Health Promotion* (1986).

⁷² Commission on Ending Childhood Obesity, World Health Organization, *Report of the Commission on Ending Childhood Obesity (Echo)* (2016).

⁷³ *Ibid.*

⁷⁴ World Health Organization, *Global Strategy on Diet, Physical Activity and Health* (2004).

⁷⁵ *Ibid* [61].

healthy eating'. The food industry was encouraged to make its products healthier: to '[l]imit the levels of saturated fats, trans-fatty acids, free sugars and salt in existing products; continue to develop and provide affordable, healthy and nutritious choices to consumers; [and] consider introducing new products with better nutritional value'.⁷⁶

The DPAS has since been replaced by the WHO's Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020,⁷⁷ but 'persuade and encourage' remains an important tenet. One of the overarching principles of the GAP is multisectoral action: 'coordinated multistakeholder engagement for health both at government level and at the level of a wide range of actors ... and partnership with relevant civil society and private sector entities'.⁷⁸ Objective 3 of the GAP is 'to reduce modifiable risk factors for noncommunicable diseases and underlying social determinants through creation of health-promoting environments', including the promotion of a healthy diet. WHO is agnostic as to *how* that might be achieved: member states are urged to 'develop *guidelines, recommendations or policy measures* that engage different relevant sectors, such as food producers and processors' to reduce salt, sugar and overall calories, and to replace trans and saturated fats with unsaturated fats.⁷⁹

D *Voluntary Reformulation: Criticism and Barriers*

Although voluntary reformulation schemes come in a wide array of regulatory forms, there is an emerging literature arguing that these forms are not created equal. In particular, there is growing evidence that a reformulation scheme's degree of voluntariness is inversely correlated to its effectiveness. Persuading and encouraging, or even partnership with the food industry, is not sufficient. Rather, certain structuring conditions need to be met in order for partnerships with the food industry to be effective for public health. These conditions include concrete timelines and targets, transparency, incentives for compliance, and consequences for non-compliance — in short, higher degrees of government involvement.

So for instance, an assessment of reformulation goals under the Australian Healthy Food Partnership (then known as the Food and Health Dialogue) noted that while industry 'participants negotiated, agreed and committed to take action on a series of modest, time-bound targets', compliance was patchy.⁸⁰ This was 'likely to be, in part at least, due to other shortcomings of the [reformulation] program, such as the lack of monitoring and the absence of media publicity and public awareness of food company actions'. Similarly, an early assessment of the calorie reduction initiative under the UK's Public Health Responsibility Deal⁸¹ noted that 'inadequate monitoring minimises industry (and Government) accountability' and that 'no sanctions exist to drive compliance'.⁸² Without 'clear targets, industry cooperation and strong government leadership', the voluntary, collaborative nature of

⁷⁶ Ibid.

⁷⁷ World Health Assembly, *Global Action Plan for NCDs*, above n 4.

⁷⁸ Ibid.

⁷⁹ Ibid 32; although it should be noted that the updated Appendix 3 to the Global Action Plan (2017) now contains specific recommendations on actions that can benefit from regulatory/legislative implementation.

⁸⁰ Tamara Elliott et al, 'A Systematic Interim Assessment of the Australian Government's Food and Health Dialogue' (2014) 200 *Medical Journal of Australia* 92.

⁸¹ Clare Panjwani and Martin Caraher, 'The Public Health Responsibility Deal: Brokering a Deal for Public Health, But on Whose Terms?' (2014) 114 *Health Policy* 163.

⁸² Ibid 170.

the arrangement ‘undermined its potential as a public health policy tool and hindered its ability to deliver at a population level’.⁸³

The persuade and encourage approaches rest on a belief that, given the right information, support or incentives, the food industry will be sufficiently motivated to change its products. To many public health observers, this belief is at best optimistic, and at worst deluded. They argue that the making, selling and advertising of highly processed foods, high in sugar, salt and fat, is not *incidental* to the industry’s activities — rather, it is the very basis of its profitability.⁸⁴ Accordingly, schemes that involve governments partnering with industry to improve public health are doomed to fail, because the interests of these two stakeholders are fundamentally not aligned.⁸⁵ In such cases, self-, co- or quasi-regulation is simply a smokescreen for inaction or, worse, a way of blocking or co-opting government regulation.⁸⁶ Moreover, as Scrinis and Monteiro have noted recently, at an ecological level, voluntary reformulation efforts do nothing to challenge unhealthy food consumption patterns, and may in fact legitimise them.⁸⁷

On the other hand, cases of successful voluntary reformulation are characterized by a high degree of government oversight and corporate accountability. The UK’s 2003–2011 efforts on salt reduction mentioned above are widely hailed as a successful example of voluntary reformulation, in terms of achieving targets. Though voluntary, companies’ actions to reduce salt took place against a backdrop of strong scientific leadership, repeated monitoring and evaluation of population salt intake, a salt reduction strategy with progressively lower targets, ministerial support including the threat of regulation, clear nutrition labelling, and a high profile consumer awareness campaign.⁸⁸ The success of the UK’s voluntary salt reductions is attributed to all of these components, acting in concert.⁸⁹ Drawing on this case study and others, as well as frameworks derived from regulatory theory, Reeve and Magnusson have recently proposed a systematic framework under which governments can become progressively more involved as and when voluntary schemes prove ineffective.⁹⁰ They describe this as ‘regulatory scaffolding’, and suggest three domains in which governments can operate to make self-regulatory schemes more robust. These are:

⁸³ Ibid 171.

⁸⁴ Kelly D Brownell and Kenneth E Warner, ‘The Perils of Ignoring History: Big Tobacco Played Dirty and Millions Died. How Similar Is Big Food?’ (2009) 87 *The Milbank Quarterly* 259; Monteiro, above n 23; David Stuckler and Marion Nestle, ‘Big Food, Food Systems, and Global Health’ (2012) 9(6) *PLoS Medicine* e1001242, doi:10.1371/journal.pmed.1001242; Moss, above n 22; R Moodie et al, ‘Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-processed Food and Drink Industries’ (2013) 381 *The Lancet* 670.

⁸⁵ Stuckler and Nestle, above n 84; Moodie et al, above n 84; Kaare R Norum, ‘Pepsico Recruitment Strategy Challenged’ (2008) 11 *Public Health Nutrition* 112; Carlos A Monteiro, Fabio S Gomes and Geoffrey Cannon, ‘The Snack Attack’ (2010) 100 *American Journal of Public Health* 975; Panjwani and Caraher, above n 81.

⁸⁶ Bryan Thomas and Lawrence O Gostin, ‘Tackling the Global NCD Crisis: Innovations in Law and Governance’ (2013) 41 *Journal of Law, Medicine and Ethics* 16, 24.

⁸⁷ Scrinis and Monteiro, above n 23.

⁸⁸ He, Brinsden and MacGregor, above n 49; Charlton, Webster and Kowal, above n 68.

⁸⁹ He, Brinsden and MacGregor, above n 49; Charlton, Webster and Kowal, above n 68.

⁹⁰ Belinda Reeve and Roger Magnusson, ‘“Legislative Scaffolding”: A New Approach to Prevention’ (2013) 37 *Australian and New Zealand Journal of Public Health* 494; Roger Magnusson and Belinda Reeve, ‘“Steering” Private Regulation? A New Strategy for Reducing Population Salt Intake in Australia’ (2014) 36 *Sydney Law Review* 255; Roger Magnusson and Belinda Reeve, ‘Food Reformulation, Responsive Regulation, and “Regulatory Scaffolding”: Strengthening Performance of Salt Reduction Programs in Australia and the United Kingdom’ (2015) 7 *Nutrients* 5281; Belinda Reeve and Roger Magnusson, ‘Food Reformulation and the (Neo)-Liberal State: New Strategies for Strengthening Voluntary Salt Reduction Programs in the UK and USA’ (2015) 129 *Public Health* 351.

- *Regulatory content* (eg, specifying goals and targets, clarifying definitions, specific terms and conditions);
- *Regulatory processes* (eg, regulating the administration, monitoring, and review of self-regulatory processes; requiring independent audits); and
- *Enforcement* (eg, building in incentives for compliance and penalties for non-compliance).⁹¹

V MANDATORY NUTRIENT LIMITS

A What Are They?

If the way to improve voluntary schemes is, in effect, to make them *less* voluntary – then what of mandatory reformulation? Though less popular than voluntary approaches, an increasing number of jurisdictions are using mandatory regulation to spur reformulation. This regulation does not tend to specify the desired process (ie, reformulation) but rather the desired outcome: upper limits on particular nutrients in particular foods. Manufacturers must comply with these limits if they want their food to remain on the market. These *mandatory nutrient limits*⁹² now exist in 24 jurisdictions around the world, and more jurisdictions are adopting them.⁹³ Table 1 lists mandatory nutrient limits with jurisdictions where they are currently in force.

Table 1. Mandatory nutrient limits currently in force⁹⁴

Nutrient	Jurisdictions (foods to which the limit applies)
Salt/sodium	Argentina (broad range of foods), Belgium (bread), Bulgaria (bread, cheese, meat products, <i>lutenica</i>), Finland (cheese), Greece (bread, tomato products), Hungary (bread), Netherlands (bread, flour), Paraguay (bread), Portugal (bread), Slovakia (under review), South Africa (broad range of foods)
Trans fat	Argentina, Austria, Colombia, Denmark, Hungary, Iceland, Iran, Latvia, Norway, Singapore, South Africa, Switzerland, USA
Saturated fat	Ghana (meat), Mauritius (cooking oil)

Mandatory nutrient limits are traditional, command-and-control government regulations, usually implemented as national food standards (though some take the form of legislation or other rule types, such as Royal Decrees). As shown in Table 1, existing mandatory nutrient

⁹¹ Reeve and Magnusson, ‘Food Reformulation and the (Neo)-Liberal State’, above n 90. This work builds on Ayres and Braithwaite’s ‘responsive regulation’ concept, which described how the State could step back from command-and-control regulation, but nevertheless promote effective outcomes by scaling up its involvement in response to non-compliance: Ian Ayres and John Braithwaite, *Responsive Regulation: Transcending the Deregulation Debate* (Oxford University Press, 1992).

⁹² See Kaldor, above n 13.

⁹³ As of mid-2017, a further seven countries had notified the WTO of their intention to introduce mandatory TFA limits: Bahrain, Kuwait, Oman, Qatar, Saudi Arabia, the United Arab Emirates, and Yemen.

⁹⁴ Jenny Claire Kaldor, *Can Government Regulations Produce a Healthier Food Supply? A Critical Assessment of the Legal, Policy and Ethical Bases for Mandatory Nutrient Limits* (Doctoral Research in progress, University of Sydney).

limits apply to fats (primarily trans fats) and salt. At a technical level, the regulations tend to follow a familiar structure, specifying:

- The regulated food (eg, bread, oil, tomato paste, and may also specify that imported foods as well as domestic products are included);
- The nutrient to be limited (eg, sodium, industrially produced TFAs); and
- The limit to be imposed (eg, 2 per cent).

The major exception to this structure is the regulation of trans fat in the USA. In 2015, industrially produced TFAs, or partially hydrogenated oils, were removed from the US Food and Drug Administration's (FDA's) list of food additives 'generally recognised as safe' (GRAS). GRAS ingredients are not regarded as food additives for the purposes of US food law, and so may be added without prior approval.⁹⁵ Removal of GRAS status means that TFAs may no longer be added to food unless a particular use has received pre-marketing approval from the FDA.⁹⁶ Obtaining such approval would involve demonstrating 'a reasonable certainty of *no harm* of the proposed use(s)',⁹⁷ where harm includes chronic harms such as adverse effects on cholesterol and increased risk of coronary heart disease.⁹⁸ As such, the removal of GRAS status functions as a de facto mandatory nutrient limit.

In 2004, Denmark was the first government to regulate an upper permissible limit, of 2 per cent, on artificially produced TFAs. It has since been followed by nine other jurisdictions. In 2009, The Netherlands introduced government regulation on the permissible amount of salt (sodium) in bread and flour. Eight other jurisdictions followed its example, and in 2013 both South Africa and Argentina introduced mandatory sodium limits on a wide range of foodstuffs. Public health experts are now advocating mandatory limits on sugar,⁹⁹ though so far no jurisdiction has implemented these. While their number is still relatively low, mandatory nutrient limits are on the rise, both by *kind* of nutrient and also by total number: see Figure 1, below.

⁹⁵ Federal Food, Drug and Cosmetic Act of 1938, 21 USC §§201(s) (2006); Kelly D Brownell and Jennifer L Pomeranz, 'The Trans-Fat Ban — Food Regulation and Long-term Health' (2014) 370 *New England Journal of Medicine* 1773.

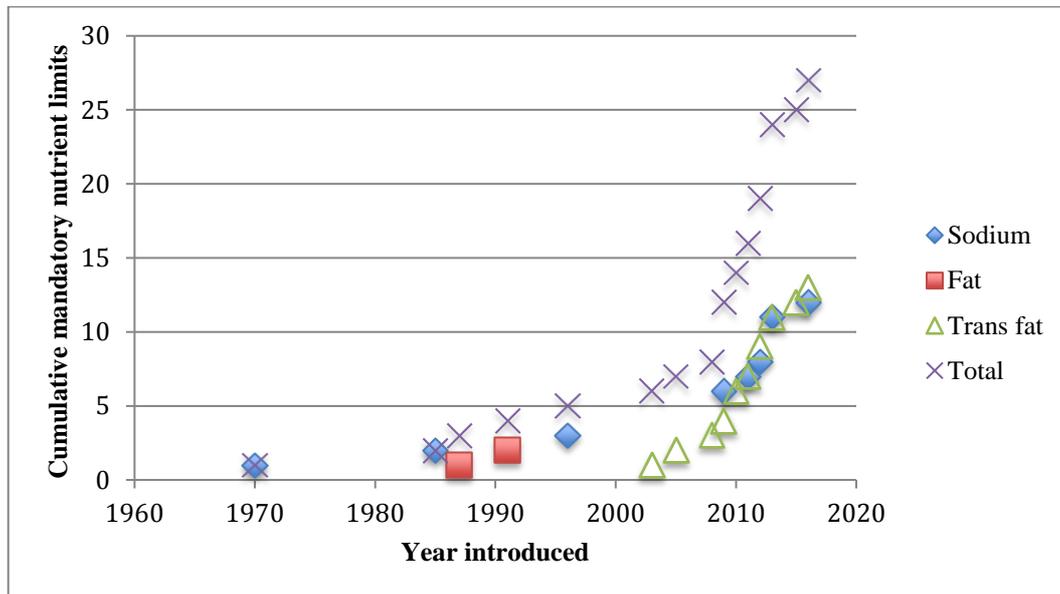
⁹⁶ US Food & Drug Administration, 'Final Determination Regarding Partially Hydrogenated Oils' (2015) 80 *Federal Register* 34650.

⁹⁷ *Ibid* [I] (emphasis added).

⁹⁸ *Ibid* [IIIA].

⁹⁹ World Cancer Research Fund International, *Curbing Global Sugar Consumption: Effective Food Policy Actions to Help Promote Healthy Diets and Tackle Obesity* (2015).

Figure 1 - Type, and cumulate number, of mandatory nutrient limits over time



B Why Do Governments Introduce Mandatory Nutrient Limits?

Mandatory nutrient limits are relatively new and have not yet received sustained scholarly attention. However, to the extent that it exists, the literature suggests that countries implement mandatory nutrient limits for a variety of reasons, summarised below. Surprisingly, these do not always support the contention that mandatory approaches should be used only if voluntary methods fail.

1 International Momentum on Diet-Related NCDs

International momentum on diet-related NCDs was an important ingredient in South Africa's decision to introduce its mandatory salt limits in a range of commonly consumed foods. In the lead up to the UN's Political Declaration of the High-Level Meeting of the General Assembly on the Prevention and Control of NCDs (2011), the South African health minister wanted to take clear, decisive action, and considered that regulation would send a strong message to the food industry.¹⁰⁰

2 The 'Level Playing Field'

A reason frequently cited for regulation as opposed to voluntary compliance is that regulation creates a level playing field for industry players¹⁰¹ — the same rules apply to all firms, and none will be forced to assess whether compliance will lend a competitive advantage or disadvantage. For this reason, some firms actually prefer regulation to self-regulatory schemes.

¹⁰⁰ Charlton, Webster and Kowal, above n 68.

¹⁰¹ Stender, Astrup and Dyerberg, above n 34; Michelle M Mello et al, 'Critical Opportunities for Public Health Law: A Call for Action' (2013) 103 *American Journal of Public Health* 1979; Webster et al, above n 60; Karen E Charlton, Kelly Langford and Jenny Kaldor, 'Innovative and Collaborative Strategies to Reduce Population-wide Sodium Intake' (2015) 4 *Current Nutrition Reports* 279.

3 *The Success of Voluntary Reformulation Measures*

A surprising factor in Denmark's decision to introduce a mandatory TFA limit in 2003 was the success of the voluntary approach that was used in the first instance. As mentioned above, there is a prevailing belief that mandatory regulation is used by governments only as a final or extreme option, or even as a threat to industry if it does not take adequate voluntary action. In the case of Denmark, voluntary measures had, over ten years, achieved very significant reductions in TFA across the food supply. However, certain subgroups of the population were still consuming high TFA diets (see below). This persuaded the government that regulation was necessary.¹⁰² So in Denmark, the success of voluntary reformulation actually paved the way for widespread acceptance of regulation. The technology needed to reformulate had already been developed, industry buy-in and cooperation had already been secured, and consumers were already educated on the need for reformulation.¹⁰³

4 *The Need to Protect Vulnerable Sub-groups*

In Denmark, voluntary reformulation successfully and significantly reduced the *average* quantity of TFA across the food supply. However, there was evidence that certain pockets of the population were still consuming very high TFA diets. Moreover, these tended to be sub-groups already at greater risk of cardiovascular disease due to socioeconomic and behavioural factors. Labelling and public health awareness campaigns were deemed an ineffective way of reaching these sub-groups, as well as being impractical in the case of unpackaged takeaway foods.¹⁰⁴ Accordingly, the government decided to regulate an upper permissible limit of 2 per cent on industrially produced TFA in oils and fats. In Australia, voluntary reformulation has achieved similarly successful drops in *average* TFA consumption,¹⁰⁵ but, as in Denmark, vulnerable sub-groups remain.¹⁰⁶

5 *Policy Transfer and Trade Harmonisation*

Finally, there is some evidence that the existence of mandatory nutrient limits in some jurisdictions has led to their adoption in other jurisdictions. It is very likely that the introduction of a mandatory TFA limit in Denmark has led to the diffusion of this regulation to other jurisdictions.¹⁰⁷ Following the Danish TFA regulations, several countries have introduced regulations in almost identical format — ie, they use the same upper limit of 2 per cent, and apply it to fats and oils. These include four more EU countries, plus Switzerland and Norway, and the EU is now considering whether to adopt a mandatory limit under European law.¹⁰⁸ In this regard, one of the considerations is that, 'By setting an EU wide harmonised legal limit,

¹⁰² T Leth, H G Jensen, A A Mikkelsen and A Bysted, 'The Effect of the Regulation on *Trans* Fatty Acid Content in Danish Food' (2006) 7(2) *Atherosclerosis Supplements* 53; Steen Stender, Jørn Dyerberg and Arne Astrup, 'Consumer Protection Through a Legislative Ban on Industrially Produced *Trans* Fatty Acids in Foods in Denmark' (2006) 50(4) *Food and Nutrition Research* 155, 156.

¹⁰³ L'Abbé et al, above n 50.

¹⁰⁴ Leth et al, above n 102; Paolo M Drostby, 'The Danish *Trans* Fat Ban' (Paper presented at the Generation Excess III Conference, Centre for Science in the Public Interest, CSPI International, 2008).

¹⁰⁵ Rainer Reuss et al, 'Trans Fatty Acids in Australia and New Zealand' (2009) 16(*Australasian Epidemiologist* 20, 20; Shrapnel, above n 44.

¹⁰⁶ Australian Broadcasting Corporation, 'Big *Trans* Fat', *Background Briefing*, 15 November 2015 (Rachel Carbonell) <<http://www.abc.net.au/radionational/programs/backgroundbriefing/big-trans-fat/6936016>>.

¹⁰⁷ Tino Bech-Larsen and Jessica Aschemann-Witzel, 'A Macromarketing Perspective on Food Safety Regulation: The Danish Ban on *Trans*-Fatty Acids' (2012) 32 *Journal of Macromarketing* 208.

¹⁰⁸ European Commission, *Report From the Commission to the European Parliament and the Council Regarding Trans Fats in Foods and in the Overall Diet of the Union Population* (2015).

the approach would also minimise, or even abolish, the risk of national regulatory choices (further) fragmenting the single market'.¹⁰⁹ In South Africa, there was also some evidence of policy transfer from nutrient to nutrient: the salt limit was introduced under the same legislation that was used to regulate TFA, and so regulators already had a template for how it might be done.¹¹⁰

C *Mandatory Nutrient Limits and International Trade Rules*

Until recent years, the idea of using mandatory limits for NCD prevention has been given short shrift in the literature, mentioned only in passing as part of a taxonomy of policy approaches to unhealthy diets. Dismissed as overly paternalistic and intrusive, these measures tended to be seen as an extreme, 'far-reaching',¹¹¹ and 'contentious'¹¹² option. For instance, Resnik drew on health ethics frameworks to argue in 2010 that trans fat limits could open the door to excessive government control over consumers' freedom to choose their own diet.¹¹³ Beyond such political/philosophical objections, other — perhaps more practical — barriers to the implementation of mandatory nutrient limits have rarely been considered. However, as reformulation has increasingly become part of the policy landscape in recent years, this view is being re-evaluated.¹¹⁴

Having dealt with the 'freedom-limiting' charges against mandatory nutrient limits elsewhere,¹¹⁵ here I briefly examine one of the more practical objections. This is that mandatory nutrient limits may constitute a TBT under WTO rules. Just as the Western diet has spread around the world, NCD prevention policies are also subject to globalisation. Today, national jurisdictions are less likely to be innovating on NCD policy in isolation, but rather are looking to the guidance of the WHO in its normative role. And most recently, the WHO has recommended that countries implement mandatory limits on trans fat, and consider mandatory

¹⁰⁹ Ibid.

¹¹⁰ Kaldor, *Can Government Regulations Produce a Healthier Food Supply?*, above n 94.

¹¹¹ M ten Have et al, 'Ethics and Prevention of Overweight and Obesity: An Inventory' (2011) 12 *Obesity Reviews* 669, 675.

¹¹² Allyn L Taylor, Emily Whelan Parento and Laura Schmidt, 'The Increasing Weight of Regulation: Countries Combat the Global Obesity Epidemic' (2015) 90 *Indiana Law Journal* 257, 282.

¹¹³ David Resnik, 'Trans Fat Bans and Human Freedom' (2010) 10(3) *American Journal of Bioethics* 27. See also the Commentaries in response to Resnik: Kenneth Deville, 'Trans Fat Bans and the Dynamic of Public Health Regulation' (2010) 10(3) *American Journal of Bioethics* 46; James Wilson and Angus Dawson, 'Giving Liberty Its Due, But No More: Trans Fats, Liberty, and Public Health' (2010) 10(3) *American Journal of Bioethics* 34; Nathan Nobis and Molly Gardner, 'Cut the Fat! Defending Trans Fats Bans' (2010) 10(3) *American Journal of Bioethics* 39; Kelly D Brownell, 'Government Intervention and the Nation's Diet: The Slippery Slope of Inaction' (2010) 10(3) *American Journal of Bioethics* 1; Lawrence O Gostin, 'Trans Fat Bans and the Human Freedom: A Refutation' (2010) 10(3) *American Journal of Bioethics* 33; Paula Boddington, 'Dietary Choices, Health, and Freedom: Hidden Fats, Hidden Choices, Hidden Constraints' (2010) 10(3) *American Journal of Bioethics* 43; Kenneth Kirkwood, 'Lipids, Liberty, and the Integrity of Free Actions' (2010) 10(3) *American Journal of Bioethics* 45; Michael Keane, 'Public Health Interventions Need to Meet the Same Standards of Medical Ethics as Individual Health Interventions' (2010) 10(3) *American Journal of Bioethics* 36; Alan Rubel, 'Local Trans Fat Bans and Consumer Autonomy' (2010) 10(3) *American Journal of Bioethics* 41.

¹¹⁴ See for instance the leading text, Gostin and Wiley's *Public Health Law: Power, Duty, Restraint*; Gostin and Wiley above n 12. In the 2nd ed (University of California Press, 2008), Gostin wrote that mandatory limits are 'perhaps the most coercive, and politically divisive, form of obesity regulation' (at 512). This language is absent from the 3rd ed (2016), in which Gostin and Wiley situate mandatory trans fat limits within widely accepted principles of consumer protection law and discuss the potential for application to other nutrients (465–6).

¹¹⁵ Kaldor, above n 13.

limits for salt.¹¹⁶ With this global diffusion of NCD prevention policies, the need to consider international trade rules and their impact on public health is becoming more and more important, as further highlighted by recent challenges to innovative tobacco control regulations under international trade rules.¹¹⁷

TBTs are defined in the Agreement on Technical Barriers to Trade, an international treaty administered by the WTO. The aim of the Agreement is to ensure that ‘technical regulations and standards, including packaging, marking and labelling requirements... do not create unnecessary obstacles to international trade’.¹¹⁸ In order to achieve this purpose, the Agreement specifies at Article 2.2 that:

technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking account of the risks non-fulfilment would create. Such legitimate objectives are, inter alia: national security requirements; the prevention of deceptive practices; protection of human health or safety, animal or plant life or health, or the environment. In assessing such risks, relevant elements of consideration are, inter alia: available scientific and technical information, related processing technology or intended end-uses of products.¹¹⁹

The main difference between technical regulations and standards is that the former are mandatory and the latter are voluntary.¹²⁰ While goods that fail to comply with voluntary standards may still be sold (although they may experience adverse commercial consequences), failing to comply with technical regulations is a barrier to market entry.¹²¹ As such, the widely held view is that technical regulations (such as mandatory nutrient limits) are prima facie TBTs, while voluntary standards (such as measures to encourage voluntary reformulation) are not.¹²² However, despite the existence of 26 mandatory nutrient limits, there has been only one challenge on the basis that it would constitute a trade barrier. That case was not brought under WTO law, but in the European Commission (EC).

As noted above, Denmark was the first country to introduce a mandatory TFA limit. The limit was introduced in 2003, and in 2004 the EC claimed that the regulation was a breach of Denmark’s obligations under the terms of the EC Treaty relating to the free movement of goods within the EU. Articles 28–30 of the EC Treaty prohibit unjustified restriction on intra-EU trade, the ‘most restrictive’ of which is ‘a ban on the marketing of a specific product or substance’.¹²³ The EU took initial steps toward prosecution in the European Court of Justice.¹²⁴

¹¹⁶ World Health Assembly, *Global Action Plan for NCDs*, above n 4.

¹¹⁷ Benn McGrady, *Trade and Public Health: The WTO, Tobacco, Alcohol, and Diet* (Cambridge University Press, 2011); Alberto Alemanno and Amandine Garde, ‘Regulating Lifestyles in Europe: How to Prevent and Control Non-Communicable Diseases Associated with Tobacco, Alcohol and Unhealthy Diets?’ (SIEPS Reports, Swedish Institute for European Policy Studies, 2013); Moodie et al, above n 84; International Development Law Organization, United Nations Inter-Agency Task Force on the Prevention and Control of Noncommunicable Diseases, *Mission Report, Thematic Session on Law and the Prevention and Control of Noncommunicable Diseases, New York, 9 February 2016* (World Health Organization, 2017) <<http://www.who.int/ncds/un-task-force/uniatf-ncdreport02-2016.pdf?ua=1>>; Jonathan Liberman, ‘Building a Law and NCDs Workforce: A Necessity for Global Cancer and NCD Prevention and Control’ (2017) 12 *Journal of Cancer Policy* 72.

¹¹⁸ *TBT Agreement*, 1868 UNTS 120, Preamble.

¹¹⁹ *Ibid* Art 2.2

¹²⁰ World Trade Organization, *Technical Information on TBT*, above n 16.

¹²¹ *TBT Agreement*, 1868 UNTS 120, Annex 1.

¹²² Although there is some dissent on this point: see Arwel Davies, ‘Technical Regulations and Standards Under the WTO Agreement on Technical Barriers to Trade’ (2014) 41 *Legal Issues of Economic Integration* 37.

¹²³ European Commission, *Free Movement of Goods — Guide to the Application of Treaty Provisions Governing the Free Movement of Goods* (2010).

¹²⁴ Bech-Larsen and Aschemann-Witzel, above n 107.

Denmark refused to change its legislation, relying on Article 36 of the EC Treaty: trade barriers may be justified if they protect human health.¹²⁵ In such cases:

The Member State imposing a national ban on a product/substance has to show that the measure is necessary and, where appropriate, that the marketing of the products in question poses a serious risk to public health and that those rules are in conformity with the principle of proportionality [and] ... that the stated aim cannot be achieved by any other means that has a less restrictive effect on intra-EU trade.¹²⁶

In making this case, Denmark was able to present the EC with epidemiological and other evidence, and also received support from a European consumer organization.¹²⁷ The EC dropped the case in 2007.

In 2006, a Canadian national taskforce on options for TFA reduction was advised that a mandatory TFA limit 'would not conflict with Canada's international obligations under World Trade Organization agreements, in particular the Agreement on Technical Barriers to Trade', on the grounds that it would be necessary to achieve the legitimate objective of protecting public health.¹²⁸ Two factors provided confidence to the task force: first, the advice of leading scientific organizations such as the WHO, and secondly, 'the fact that other jurisdictions have adopted measures to limit the consumption of trans fats'.¹²⁹ Ten years on, the global landscape is changing fast, as increasing numbers of countries choose to impose mandatory TFA limits (see Figure 1, above). Perhaps most notable here is the USA's recent decision to remove TFA from its list of GRAS ingredients. In light of this development, a recent European report suggests that in fact *not* having a mandatory TFA limit may pose a barrier to future trade with the USA.¹³⁰

There have not yet been any test cases in relation to the trade restrictiveness of mandatory salt limits (bearing in mind that the first comprehensive salt standards, in South Africa and Argentina, were introduced in 2013 and are only now being phased in). However, it is unlikely that the lessons from TFA can be applied to salt in a straightforward manner, due to notable differences between the two nutrients. In essence, TFA is an artificial substance, added at the level of manufacturing and only found in fats and oils, which carries clear risk, and no benefit, to human health. In food law terms, this is analogous to adulteration (ie, contamination with a harmful substance).¹³¹ By contrast, salt is a naturally occurring substance, with a more complex relationship to human health, found in products throughout the food supply but also added in cooking and at the table. Countries wishing to justify the imposition of a trade barrier in the form of a mandatory nutrient limit will need to show technical, scientific, statistic and nutritional data,¹³² and the evidentiary picture for salt is far more complex than that for TFA.¹³³

¹²⁵ Stender, Dyerberg and Astrup, above n 34; European Commission, above n 123.

¹²⁶ European Commission, above n 123.

¹²⁷ Bech-Larsen and Aschemann-Witzel, above n 107.

¹²⁸ Canadian Trans Fat Task Force, *Transforming the Food Supply: Report of the Trans Fat Task Force Submitted to the Minister of Health* (Canadian Ministry of Health, 2006).

¹²⁹ Ibid.

¹³⁰ European Commission, *Report From the Commission to the European Parliament and the Council Regarding Trans Fats in Foods and in the Overall Diet of the Union Population* (2015).

¹³¹ Garde, above n 17.

¹³² European Commission, above n 123; *TBT Agreement*, 1868 UNTS 120, Art 2.2.

¹³³ Dariush Mozaffarian et al, 'Global Sodium Consumption and Death from Cardiovascular Causes' (2014) 371 *New England Journal of Medicine* 624.

VI CONCLUSION

Halting, and ultimately reversing, the impact of unhealthy diets on human health will require strong, upstream, population-based policy responses. Reformulating commonly consumed processed foods is a policy goal that holds great promise in this regard, and reformulation schemes around the world are on the rise. But the regulatory question remains: how best to achieve this goal? Regulatory options for encouraging food reformulation run the gamut from pure, market-based approaches, to command-and-control regulation in the form of mandatory nutrient limits. Until recently, the prevailing wisdom has been that governments should seek to persuade and encourage the food industry to reformulate, an approach favoured by governments and the food industry, and encouraged by the WHO. However, measures to encourage voluntary reformulation have had mixed success. The most successful have been those with a high degree of government involvement — that is, voluntary schemes with features of mandatory regulation. Alongside evidence of the growing use of mandatory nutrient limits, this is suggestive of a trend. This in turn points to the need for greater technical understanding of mandatory limits, to enable policy learning: for instance, the major barriers and drivers faced by countries seeking to implement them. This paper has sought to add to the evidence base by providing regulatory insights on both voluntary and mandatory reformulation policies. This regulatory evidence will supplement the emerging base on the effectiveness of reformulation for public health, and ultimately guide policy makers seeking to design approaches to reformulation.