# School of Public Health Faculty of Health Sciences University of Adelaide

International Evidence and Experiences in Regulatory Approaches Targeting Nutritional Aspects of Population-Level Obesity Prevention

Thesis submitted in fulfillment of the requirements for the degree of Doctor of Philosophy

Jana Sisnowski

Adelaide, Australia
3 February 2016

# **Contents**

Abs	tract		i		
Thesis declaration					
Ack	Acknowledgements				
Pub	Publications and presentations				
Abbreviations, acronyms, and definitions  1. Introduction					
1.	Introd	luction	1		
2.	Research Context				
	2.1.	The burden of disease from overweight and obesity	5		
	2.2.	The socioeconomic burden of overweight and obesity	9		
	2.3.	Complex aetiology: links between consumption patterns,	11		
		obesity, and related risk factors			
	2.4.	Shifting targets in prevention: from individual behaviour to	16		
		population-wide contributors			
	2.5.	Policy context and prioritisation	21		
	2.6.	Summary	23		
3.	Theo	retical frameworks	37		
4.	Regulatory approaches to obesity prevention: A systematic overview of				
	current laws addressing diet-related risk factors in the European Union				
	and the United States				
	4.1.	Introduction	46		
	4.2.	Declaration of authorship	47		
	4.3.	Journal article	48		
	4.4.	Postscript	60		
5.	Improving food environments and tackling obesity: a realist systematic				
	review of the policy success of regulatory interventions targeting				
	population nutrition				
	5.1.	Introduction	63		
	5.2.	Declaration of authorship	64		
	5.3.	Manuscript	65		

6.	Targeting population nutrition through municipal health and food			
	policy: Implications of New York City's experiences in regulatory			
	obesity prevention			
	6.1.	Introduction	86	
	6.2.	Declaration of authorship	87	
	6.3.	Journal article	88	
	6.4.	Postscript	100	
7.	Translating innovative public health legislation into policy action: does			
	the new South Australian Public Health Act offer a blueprint for			
	systematic regional government engagement in obesity prevention?			
	7.1.	Introduction	104	
	7.2.	Declaration of authorship	105	
	7.3.	Manuscript	106	
8.	Discus	sion and conclusion	121	
9.	Appendices			
	9.1.	Appendix 1: Supplementary materials chapter 4	131	
	9.2.	Appendix 2: Supplementary materials chapter 5	151	
	9.3.	Appendix 3: Supplementary materials chapter 6	162	

# **Abstract**

High prevalence of overweight and obesity remains a pressing health concern for most industrialised nations. As preventive approaches based on individuals' capacity for behaviour change have largely failed to impact population weight, governments have begun to implement policies to regulate food environments with a view to improving nutrition and health outcomes. This thesis comprises four studies, presented as two peer-reviewed journal articles and two manuscripts, examining the evidence and experiences generated by Organisation for Economic Cooperation and Development jurisdictions' regulatory targeting of the nutritional aspects of obesity prevention.

Article 1 provides an overview of regulatory approaches addressing dietary risk factors for obesity enacted in the United States and the European Union since 2004. The findings from a systematic search of primary and secondary legislation databases demonstrate that such approaches are currently limited in reach and scope. No jurisdiction has enacted a comprehensive suite of complementary actions addressing different components of the food environment; however, the existence of discrete interventions indicates some political will for innovation.

Article 2 employs a realist review perspective to systematically investigate the effect of "real-world" policies addressing population nutrition. The review examines: (1) the effect of interventions on average BMI/weight and calorie intake or proxy measures and (2) indicators measuring parameters on assumed causal pathways to changed consumption patterns. Results drawn from peer-reviewed articles and grey literature reports demonstrate that isolated regulatory interventions reliably improve intermediate outcomes, but fail to affect consumption at levels of clinical significance.

Article 3 is a case study of obesity prevention in New York City. Combining a documentary review and key informant interviews, the analysis demonstrates that there is scope to redefine municipal responsibilities for public health. In particular, results indicate that policy change in the emerging and contested field of regulatory obesity prevention needs strong political leadership. Executive-driven nutrition policy is shown to offer an expedient mechanism to protect expert-designed measures from the influence of competing interests. The analysis also demonstrates

the importance of building community support, the value of incremental change, and the impact of contentious public discussion on social norms around nutrition.

Article 4 considers how local governments can prepare for systematic engagement in population-level obesity prevention, using the 2011 South Australian Public Health Act as an example. Analysis shows that South Australia can potentially employ a range of levers to address food environments and nutrition under this legislation; particularly through the Health Minister's authority to issue Codes of Practice relating to specified industries or activities based on health concerns. The operationalization of this and other legal instruments for nutritional obesity prevention should be supported by a greater focus on whole-of-government responsibility for public health in general purpose legislation.

Together, these studies give a nuanced picture of the current state of regulatory obesity prevention as it relates to nutrition policy and food environments. As well as indicating directions for future research, particularly regarding the long-term effects of existing interventions and the assessment of new policy approaches, this body of work provides insights and clear recommendations for future food and obesity prevention policy.

Thesis declaration

I certify that this work contains no material which has been accepted for the award

of any other degree or diploma in my name, in any university or other tertiary

institution and, to the best of my knowledge and belief, contains no material

previously published or written by another person, except where due reference has

been made in the text. In addition, I certify that no part of this work will, in the

future, be used in a submission in my name, for any other degree or diploma in any

university or other tertiary institution without the prior approval of the University of

Adelaide and where applicable, any partner institution responsible for the joint-

award of this degree.

I give consent to this copy of my thesis when deposited in the University Library,

being made available for loan and photocopying, subject to the provisions of the

Copyright Act 1968.

The author acknowledges that copyright of published works contained within this

thesis resides with the copyright holder(s) of those works.

I also give permission for the digital version of my thesis to be made available on

the web, via the University's digital research repository, the Library Search and also

through web search engines, unless permission has been granted by the University

to restrict access for a period of time.

Jana Sisnowski

Adelaide, 3 February 2016

iii

# Acknowledgements

As part of the *HealthyLaws* grant, this PhD project was supported by the Australian National Preventive Health Agency. I also gratefully acknowledge additional funding from the Ian Wilson Liberal Foundation and the Adelaide Graduate Centre that enabled me to undertake research in New York City.

Many people have contributed to making the three years of my PhD candidature an enjoyable experience. First and foremost, I am grateful to my primary supervisor, Jackie Street, who gave me the opportunity to undertake doctoral research in Australia and provided an exceptionally supportive environment. I appreciate the time and thought you have given to my projects.

Thank you to the other two members of my supervisory panel, Annette Braunack-Mayer for steering me through the final stretch and Lizzie Handsley for being available throughout my candidature to assist with all things legal. I also gratefully acknowledge Chris Reynolds, Tracy Merlin, and Danny Broderick who contributed their expertise to manuscripts as well as the rest of the *HealthyLaws* team.

Thank you to my fellow PhD candidates and officemates, Ali, Lucy, Edi, Emma, and Ash, whose friendship made all that time spent in the office entertaining. Somewhat ironically, my PhD candidature will forever be synonymous with mad cupcake runs, well stocked junk food pantries, and elaborate lunch plans. Paul deserves credit for saving me countless times by sorting out my computer troubles and interrupting dull days with good-natured mockery.

Thank you to my family-away-from-home, Emilie, Kate, Jana R., Lovisa, Farid, and Bjørn for a myriad of adventures and emotional support even when I didn't realize I needed it; to Sabine for two epic trips and a nostalgic return to Nancy; to Ingrid for remaining in touch three continents and five countries later; and to Katie and Arlie for never failing to lift my spirits during the final months of this PhD.

Finally, thank you to my family, for continuing to support my country-hopping ways. I am particularly grateful to those family members that have braved the 15,000km odyssey to Australia, some of you twice in three years: Mami & Papi, Joscha, Anke & Gerhard, Katja & Thorsten. I hope you'll keep coming back. Oma, I know that the letters will keep coming.

# **Publications and presentations**

# 1. Peer-reviewed journal articles

<u>Sisnowski J</u>, Handsley E, Street JM. Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States. *Health Policy*. 2015;119(6):720-731. doi:10.1016/j.healthpol.2015.04.013.

<u>Sisnowski J</u>, Street JM, Braunack-Mayer A. Targeting population nutrition through municipal health and food policy: implications of New York City's experiences in regulatory obesity prevention. *Food Policy*. 2016;58:24-34. doi:10.1016/j.foodpol.2015.10.007.

#### 2. Manuscripts

<u>Sisnowski J</u>, Merlin T, Street JM. Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition.

<u>Sisnowski J</u>, Handsley E, Reynolds C, Broderick D. Translating innovative public health legislation into policy action: does the new South Australian Public Health Act offer a blueprint for systematic regional government engagement in obesity prevention?

#### 3. Presentations based on peer-reviewed abstracts

<u>Sisnowski J, Street J, Merlin T. Regulating population nutrition to tackle obesity:</u> preliminary results from a systematic review of real-life policy interventions. South Australian State Population Health Conference 2015, Adelaide, 31 October 2015.

Sisnowski J, Braunack-Mayer A, Street J. Taking a bite out of the Big Apple: NYC policy approaches to nutritional obesity prevention. Population Health Congress, Hobart, 7-9 September 2015.

<u>Sisnowski J</u>, Handsley E, Tooher R, Street J. Targeting dietary risk factors- current overseas policy approaches to obesity prevention. Public Health Association of Australia 43rd Annual Conference, Perth, 15-17 September 2014.

# 4. Other presentations

Street J, <u>Sisnowski J</u>. HealthyLaws, HealthyViews: Community views on the use of regulation and law for obesity prevention in children. Rudd Center for Food Policy and Obesity at Yale University (now University of Connecticut), New Haven, CT, 22 September 2014.

# **Abbreviations and acronyms**

The following is a list of frequently used abbreviated terms. All terms are written in full the first time they appear in both narrative text and manuscripts.

ABS Australian Bureau of Statistics

Australian National Preventive Health Agency (defunct as of

ANPHA June 30<sup>th</sup>, 2014)

BMI Body Mass Index

CDC Centers for Disease Control and Prevention (United States)

DOHMH New York City Department of Health and Mental Hygiene

EEA European Economic Area

EU European Union

International Network for Food and Obesity/non-communicable

INFORMAS diseases Research, Monitoring and Action Support

IOTF International Obesity Taskforce

NCD Noncommunicable Disease

National Health and Nutrition Examination Survey (United

NHANES

States)

WHO Regional Office for Europe Nutrition, Obesity, and NOPA

Physical Activity database

NYC New York City

OECD Organisation for Economic Co-operation and Development

SA South Australia

UK United Kingdom of Great Britain and Northern Ireland

US/USA United States of America
WHO World Health Organization

# 1. Introduction

This thesis investigates regulatory approaches to unhealthy eating patterns in the general population. As public health experts and policy-makers have turned their attention to so-called obesogenic environments, that is physical and normative environments that are conducive to gaining and maintaining excess body weight [1,2], governments across the Organisation for Economic Co-operation and Development (OECD) and beyond have begun to take policy actions that regulate food environments with a view to improving nutrition and health outcomes. With these initiatives, a diverse body of evidence related to the nature, effects, and accompanying political processes of such approaches has begun to emerge.

When this doctoral project started in early 2013, little research had been undertaken to systematically collect and assess this evidence and formulate policy-relevant recommendations for decision-makers and public health advocates. The project was designed to address a twofold knowledge gap: firstly, effective public health responses to dietary risk factors need comprehensive, up-to-date information regarding the possible design of such approaches. This necessitates maximally comprehensive knowledge not only of the suggestions put forward on a theoretical basis in the literature, but crucially also knowledge of potential solutions that have been implemented elsewhere. Secondly, the growing body of evidence emerging from early-adopter jurisdictions has the potential to elucidate how new and often controversial food policy approaches are best moved from the conceptual stage to implementation and what kinds of effects can be expected from particular types of interventions. The experiences of these jurisdictions therefore need to be examined carefully in order to identify contributors to successful policy-making, but also, where necessary, to temper expectations regarding the short-term effects of novel food policy actions.

Accordingly, the aim of this thesis is also twofold: firstly, it endeavours to systematically identify regulatory measures directed at dietary risk factors for obesity that have been implemented across the OECD. The second step is directed at comprehensively assessing evidence from post-implementation evaluations and policy-making processes. In line with empirical evidence attesting to the contribution of food environment and food system changes to the significant rise in

obesity and overweight prevalence in Western-style economies, this research focuses on systemic dietary risk factors and matching policy levers for preventive action. Therefore, for the purpose of this thesis, the policy measures of interest are regulatory approaches to obesity prevention that take the form of primary legislation or rules enacted by the executive such as delegated legislation, executive orders, or administrative rules. Applying the popular meaning of regulation as "the act or process of controlling by rule or restriction" [3], the focus is on rule-making or rule-changing measures to the exclusion of purely programmatic interventions. In line with the emphasis on government action through the use of law, the principal actors of interest are policy-makers, both elected and non-elected, and policyinfluencers at all levels of government. In large parts of the subsequent analyses, the focus is placed on interventions that target, at least theoretically, the population at large rather than a particular age, professional, or otherwise defined group. This limitation does not imply that setting- or population-specific regulations are not essential stepping stones for more far-ranging measures or necessary to protect particular populations. However, the question at the heart of this thesis is how to extend such qualitative improvements in specific food environments to the sectors predominating in public and private life, including the food retail and food service industries.

The thesis comprises six major chapters: after this brief introduction outlining the purpose and aims of the research undertaken, chapter 2 summarises the context that underpins and informs the project and its focus on dietary risk factors amenable to regulatory intervention. Chapter 3 outlines the general theoretical perspective that guided this research. The following four chapters represent the main body of work, consisting of four complementary studies that employ different methodologies to examine the evidence and experiences generated by OECD jurisdictions' regulatory targeting of the nutritional aspects of population-level obesity prevention. As illustrated in figure 1, the research follows a multi-level approach, moving from the international space to regional and local levels and from a broad collection and examination of evidence to specific, context-dependent enquiries.



Figure 1. Chapter organisation according to a multi-level approach

This work has been submitted for publication as the respective project components have been finalised over the course of the PhD candidature. The results are presented as two peer-reviewed journal articles and two manuscripts and are reproduced as published or as prepared for submission:

- Chapter 4 reports the results of a systematic search of databases containing primary and secondary legislation to identify and explore laws that address dietary risk factors for obesity enacted in the United States, the European Union, and EU Member States since 2004.
- Chapter 5 employs a realist review perspective to systematically assess the impact of real-life regulatory interventions that aim to reduce the consumption of energy-dense foods and beverages in the general population.
- Chapter 6 is a qualitative case study of pioneering obesity prevention efforts in New York City, combining a systematic documentary review and key informant interviews.
- Chapter 7 considers how regional and local governments can best prepare their jurisdictions for systematic engagement in obesity prevention at the population level, using the 2011 South Australian Public Health Act as an example.

In the three years since this research began, the policy and research agendas have picked up steam, with a growing body of original research and research synthesis emerging from universities and public agencies. As a result, this thesis is situated in an evolving context that enables a triangulation of results as well as a comparison with complementary findings. The postscripts to chapters 4 and 6 therefore discuss key contributions to the evidence base that have emerged in the intervening years in relation to the findings of this thesis.

The final discussion and conclusion in chapter 8 brings the results from the preceding four studies together and formulates three key considerations for research and policy-making in the area. The discussion section also expands on the shortcomings of this body of work and explores how these limitations can be addressed in future research and policy.

#### References

- [1] Egger G, Swinburn B. An 'ecological' approach to the obesity pandemic. *BMJ*. 1997; 315: 477-480.
- [2] Swinburn B, Egger G, Raza F. Dissecting obesogenic environments: the development and application of a framework for identifying and prioritizing environmental interventions for obesity. *Preventive Medicine*. 1999; 29:563-570.
- [3] Garner BA, editor. Black's law dictionary. 9th ed. Eagan, MN: Thomson West; 2009.

# 2. Research Context

This chapter outlines the research context in which the PhD project takes place and the evidence on which it builds. In particular, it briefly quantifies the current disease and socioeconomic burden of overweight and obesity before summarising the complex aetiology of excess body weight as it is currently conceptualised. Finally, the chapter retraces the resulting re-orientation of public health efforts towards population-wide systemic interventions which forms the foundation of the work presented in subsequent chapters.

# 2.1 The burden of disease from overweight and obesity

Obesity is defined as "a state of excess adipose tissue mass" [1], resulting from the storage of excess energy by fat cells growing in size as well as in number in adipose tissue depots of the human body. [1,2] Body mass index (BMI) expressed as weight(kg)/height(m)<sup>2</sup> has been established as a generally reliable approximation of body fatness [3,4] and is widely used as the most common measurement of obesity and overweight. [1,5-7] Although the exact distinction between overweight and obesity remains debated [1,5], a BMI at or above 30 is commonly used as a threshold for obesity [5-8] and has been endorsed as such by the World Health Organization (WHO), along with a BMI of 25 as the cut-off point for overweight. [5] General consensus holds that the respective thresholds for overweight and obesity need to be determined in relation to excess morbidity and mortality. [1,5] As a result, the link between obesity as defined by current cut-off points and the increased frequency of adverse health outcomes has been criticized as not accurately capturing the health risks starting at a BMI of 25 [5,8] or even at a BMI of 22 in some populations. [5] A meta-analysis involving data from 2.88 million subjects found an average increase of 18% in the risk of death for obese individuals compared to those of normal weight and a 29% increase for those with a BMI equal to or exceeding 35. [9] The same study also found a slightly decreased risk of mortality for subjects in the overweight, but not obese category. [9] However, as only mortality is measured, this finding is not incompatible with higher rates of morbidity starting already in the overweight category.

Obesity is not widely considered a disease in itself, but rather a state [1,8], condition [2] or disorder [7] that acts as a major risk factor for a myriad of diseases such as cardiovascular disease, type II diabetes, diseases of the gallbladder, non-alcoholic fatty liver disease, reproductive disorders, pulmonary abnormalities such as sleep apnoea, osteoarthritis, hernia, gout and certain cancers. [1,7] Some professional societies such as the Obesity Society [10] and, more recently, the American Medical Association (AMA) have decided to consider obesity a disease. [11] Overturning the recommendation of its own scientific council, the AMA plenary agreed on a resolution stating that:

"The suggestion that obesity is not a disease but rather a consequence of a chosen lifestyle exemplified by overeating and/or inactivity is equivalent to suggesting that lung cancer is not a disease because it was brought about by individual choice to smoke cigarettes." [11]

The division within the leading body of US physicians from across all medical disciplines over whether or not to use the term 'disease' in relation to obesity is part of a larger discussion juxtaposing individual and societal responsibility. While the ultimate causes of obesity remain the subject of much scientific discussion (cf. section 2.3) and likely involve multiple pathways with genetic, hormonal, and neurological components [1,8], authoritative sources [1,2,6-8] such as Black's Medical Dictionary limit themselves to noting that:

"Whatever the causes of obesity, the fact remains that energy intake (in the form of food and drink) must exceed energy output (in the form of activity and exercise) over a sufficiently long period of time." [7]

Internationally, overweight and obesity prevalence has increased markedly since the early 1970s. [12] Evidence from the United States suggests that in addition to a substantive increase in overall prevalence, there is an even more important increase in the prevalence of severe obesity as a subset of general excess weight. [13] The OECD which brings together 34 high-income economies including Australia, Canada, most of the European Economic Area (EEA), New Zealand, and the United States, reports that, across all member states, the majority of the population is currently overweight or obese. [14] Based on a mix of self-reported and measured height and weight data, the OECD further estimates that an average of 18% of the adult OECD population falls into the category of obesity according to the above

WHO definition. Obesity prevalence ranges from just around 4% in countries such as Korea and Japan (both providing measured data), 10% in Norway, Switzerland, and Italy (all self-reported data) to 28% in Australia and Hungary, 31% in New Zealand, 32% in Mexico and 35% in the United States (all measured data). Australian data was collected by the Australian Bureau of Statistics (ABS) as part of the National Nutrition and Physical Activity Survey component of the 2011-12 Australian Health Survey. The ABS reports that over 80% of survey respondents agreed to have their height and weight measured [15], suggesting that the prevalence estimate is likely to be largely correct. According to the ABS data, Australia also exceeds the OECD average of combined adult overweight and obesity prevalence with 63.4%. [16] This figure represents a sustained increase from 61.2% in 2007-08 and 56.3% in 1995. [16] With this trend, Australia diverges from some of the other OECD member states. The OECD reports a stabilisation of obesity rates in Italy, England, and the United States and slower rates of increase in Canada, Korea, and Spain. [14] Nevertheless, no OECD member state has experienced a decline of obesity or overweight. This underscores that the epidemiological magnitude of excess body weight remains a pressing problem both in countries with large sustained epidemics such as the US and in countries with relatively low, but accelerating prevalence such as France. Australia's case of high and increasing prevalence is particularly concerning.

OECD data summarising the prevalence of measured overweight and obesity among children aged 5 to 17 years reinforces this observation: the 2010 OECD average of 21% in girls and 23% in boys is far exceeded by, among others, Italy, New Zealand, and the US. [14] As the chart below illustrates, particularly high prevalence of childhood overweight is found in some countries with comparatively low or moderate adult obesity prevalence.

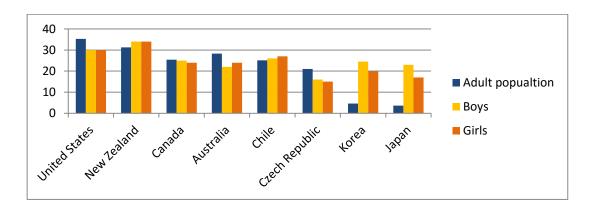


Figure 2: Childhood overweight and obesity in relation to population-wide obesity prevalence in selected OECD countries based on measured prevalence adapted from OECD data [18]

Despite evidence from several countries that childhood overweight and obesity prevalence has remained stable over the last decade or recently begun to level off in certain jurisdictions [14,18-20], generally high prevalence in children remains a major cause for concern. Research has shown that adult and childhood obesity are linked over the lifespan and inter-generationally. Not only are overweight and obese children more likely to become more severely overweight or obese adults [21,22], but children born to obese mothers also have a higher risk of developing childhood and adult overweight. [23,24] The decision of mothers to breastfeed or formula-feed infants and the food choices of breast-feeding mothers also appear to influence the development of children's food preferences. [25] Breast-fed infants have been found to be more accepting of solid foods that differ from their natural early preferences for sweet and salty tastes [25,26] and tend to mirror their mothers' food preferences. These findings have been attributed to flavours of the mothers' diet being transmitted not only prenatally, but also through breast milk.[25,27] This evidence indicates that beyond the positive correlation between parental overweight and excess weight development of their offspring [28], prenatal and early postnatal experiences have a role in conditioning the eating behaviours of the next generation.

Most importantly, the pivotal role of parents in shaping their children's environment and acquired behaviour [26-30] such as their food selection [24] raises concerns of a vicious cycle where today's children grow into overweight and obese adults that in turn influence the weight of the next generation. The US Institute of Medicine therefore concludes that "an obese adult population is an incubator, biologically and environmentally, for childhood obesity". [30, p. 19]

Marked disparities in the prevalence of obesity and associated chronic disease have been observed between races and ethnicities in countries such as the United States [19] and Australia. [31,32] In women, but not in men, obesity prevalence also increases with lower socioeconomic status. [33,34] Socio-economic differentials, often strongly correlated with race or ethnicity [35], raise social justice issues and highlights the role of modifiable socioeconomic risk factors, themselves intertwined with a range of historical, political, social, and economic circumstances. [36] However, time trends across population strata suggest that excess body weight cannot be reduced to a health problem that predominantly affects particular subpopulations: studies based on US population data show that past increases in obesity were generally similar across racial and socioeconomic strata. [37,38] With the exception of a few sub-groups for whom baseline differences persisted and even increased, for instance for Black women compared to White and Hispanic women in the US [39], a general narrowing of baseline disparities between populations of different educational attainment or socioeconomic status has been observed. [37,38] This trend is attributable to relatively higher increases in the middle and high status groups decreasing initial disparities towards worse overall health across the population. [39]

To summarise, the epidemiological evidence unequivocally presents overweight and obesity as a considerable burden of disease that affects populations with unequal impact, but in consistently significant ways. Despite persistent racial and socioeconomic disparities, high current prevalence rates and nearly uniform increases in prevalence across all segments of the population warrant a commensurate public health response. The burden and distribution of obesity attests to its manifestation as a generalised epidemic which calls for corresponding whole-of-society solutions.

## 2.2 The socioeconomic burden of overweight and obesity

A range of economic implications are associated with being overweight and obese, capturing individual as well as societal costs. Research indicates that obese people incur 25% higher health expenditures than those of normal weight in any given year, contributing 1-3% of total health expenditures in most OCED member states and 5%-10% in the United States. [40] Based on data from 1996 to 1998,

Finkelstein and colleagues estimate that overweight, but not obese Americans generate an average excess medical cost of almost 15% compared to their normal weight peers. [41] For obese Americans, this figure climbs to 37%. A 2011 systematic review of 33 US studies estimating direct medical costs of overweight and obesity reported similar figures, with a pooled estimate of \$498 (10%) for the incremental cost of overweight and \$1,662 (43%) for the incremental cost of obesity per person in 2008. [42] In Australia, a 2010 study estimated the total direct costs generated by the overweight and obese share of the population at \$10.7 billion per year in excess of the costs incurred by those of normal weight. An additional \$35.6 billion was spent on government subsidies such as disability pensions and unemployment benefits for individuals in the overweight and obese categories. [43]

Major indirect costs of obesity, summarised in a 2008 review of 31 studies, include excess costs generated by absenteeism, disability, premature mortality, and low productivity. [44] Based on a nationally representative sample of the US working population, the yearly economic and societal cost of absenteeism due to obesity in the US is estimated to range from \$3.38 billion or approximately \$79 per obese person to \$6.38 billion or approximately \$132 per obese person. [45] For women with a BMI between 35 and 40, it rises to up to \$1,033 [45] In Europe, a German study found that overweight and obese women took considerably more sick leave than their normal weight colleagues, incurring an estimated €2.18 billion in excess costs. [46] While excess healthcare costs and costs associated with lost productivity and increased welfare payments are primarily borne by society at large, adverse economic consequences of obesity also impact individuals directly. For instance, the OECD reports that obese individuals earn up to 18% less than their non-obese counterparts. [40] Baum and Ford have found that obese employees, and obese women in particular, suffer a wage penalty of 1% to 6%. This differential persists even when controlling for lower productivity due to health limitations, experience, and anticipated excess claims to employer-offered health insurance. [47] Cawley, by contrast, reports a negative correlation only for white females. [48] He attributes flat or inconclusive findings in every other race and gender combination in part to evidence that the most adverse impact of obesity on self-esteem has been observed in white women. [48]

Cawley's tentative explanation points towards the psychosocial consequences of obesity which are often intertwined with economic factors. Overweight and obese

individuals are confronted with a social stigma in informal social settings as well as in education, employment, and health care. [49] Stigmatization is believed to contribute not only to increased rates of low self-esteem, and mental health disorders, such as anxiety and depression, but also to suboptimal socioeconomic outcomes. [49,50] A correlation between overweight and the social and economic characteristics of adolescents and young adults has also been documented. Using a large 1980s cohort study, Gortmaker and colleagues observed no measurable effect of weight status on self-esteem, but found that overweight females completed on average 0.3 years less schooling, were 20% less likely to be married, and had household incomes of \$6,710 less per year than their non-overweight peers. [51] Except for a slightly lower chance of getting married, effects were flat for overweight men. [51]

From a socioeconomic point of view, overweight, obesity, and resulting ill health generate considerable costs that are borne at both individual and societal levels. Consideration of increasingly adverse future impacts on individual and societal social wellbeing, economic growth and social insurance system capacities should therefore add to the burden of disease as a forceful impetus for preventive action.

# 2.3 A complex aetiology: links between consumption patterns, obesity, and related risk factors

As previously established, there is broad scientific consensus that overweight and obesity are ultimately attributable to an energy imbalance where energy intake continuously exceeds energy expenditure. However, the relative weight given to the two sides of the equation differs widely. This is obvious even in medical dictionary accounts of the causes of obesity. Taber's Cyclopedic Medical Dictionary, for instance, asserts that

"An inactive lifestyle plays a minor role in the development of obesity, but it is unclear whether people are obese because they are inactive or are inactive because they are obese. For the majority of obese people, the explanation must lie in an excessive energy intake." [2]

Stedman's Medical Dictionary gives a different account:

"Although faulty eating habits related to failure of normal satiety feedback mechanisms may be responsible for some cases, many obese people neither consume more calories nor eat different proportions of foodstuffs than nonobese persons." [8]

In 1997, Egger and Swinburn coined the term obesogenic environment as part of their effort to build an ecological model similar to the epidemiological triad applied to infectious diseases. [51] Proponents of this idea point to categories of environmental obesogenic influences rather than estimating relative contributions to weight gain. In addition to individual physiological and behavioural characteristics of the 'host', the physical, economic, political, or sociocultural environments at micro and macro levels are considered key settings that affect both food intake and physical activity. [52]

With declining levels of physical work following widespread automatisation, technical progress has been identified by many as a central barrier to populations maintaining healthy weight levels. [54,55] However, empirical evidence suggests that the decline in average energy expenditure predated the rise of overweight and obesity prevalence: Cutler and colleagues found that energy expenditure decreased markedly between 1965 and 1975, but remained stable over the following decades. [56] Conversely, studies of the changing consumption patterns of the American population indicate that caloric supply and intake have risen considerably in parallel with the increasing prevalence of overweight and obesity. Putnam and colleagues report that average caloric supply rose by an average 300 calories per day between 1985 and 2000 after remaining stable for decades before. [57] Others have found similar and even higher increases in average energy intake and identified snack foods, sugar sweetened beverages (soft drinks) and food consumed at fast food restaurants as some of the main sources for this trend. [58,59] Meanwhile, Hill and colleagues estimate that the observed changes in the prevalence of obesity in the United States could be attributed to an average increase of daily caloric intake of no more than 50-100 calories. [60] Katan and Ludwig suggest that the added intake of approximately 370 calories per day accounts for the average increase in BMI observed in a nationally representative cohort of women between the first National Health and Nutrition Examination Survey (NHANES) in 1971 and the fourth NHANES which concluded in 2002. [61] Examining the relative effects of energy expenditure and energy intake across the Western OECD countries, Bleich and

colleagues concluded that more than 80% of the change in obesity prevalence was attributable to excess energy intake. [62]

The United States NAHNES indicates a decline in average daily calorie intake from food and beverages between its 2003/2004 and 2009/2010 iterations, amounting to 92 calories less from beverages and 117 calories less from foods for children and 44 and 42 calories less, respectively, for adults. [63] A steady decline occurred over the entire period irrespective of economic fluctuations, with some of the largest decreases in calorie intake seen in groups considered at risk for ill health, including Mexican-American children and children from families with low-income or only high school/level education. [63] However, based on the average the estimates of average excess calorie intake discussed above, this reduction is not large enough to reverse current obesity levels. At the same, time low fruit and vegetable intake presents another, related challenge for population nutrition: a review of sixteen prospective cohort studies found a combined 5% reduction in the risk of mortality for each additional daily serving of fruit and vegetables up to a threshold of five servings. [64] Yet, only 13% and 9% of US adults meet national recommendations for daily fruit and vegetable consumption, respectively. [65] Similarly, while almost half of Australian adults appear to eat fruit at recommended levels, only 5.5% reported consumption patterns corresponding to the minimum recommended intake of both fruit and vegetables. [66]

While the available empirical evidence clearly points to increased energy intake as the main cause of widespread overweight and obesity across the Western developed world and, increasingly, at a global level [67,68], the underlying reasons for changing consumption patterns are less straightforward. A range of technological changes in the way foodstuffs are manufactured and distributed are highlighted in the literature:

"The obvious possible drivers of the epidemic are in the food system: the increased supply of cheap, palatable, energy-dense foods; improved distribution systems to make food much more accessible and convenient; and more persuasive and pervasive food marketing." [69]

Changes in average inflation-adjusted food prices and the cost of energy-dense foods in particular are cited as key factors. [69,70] In parallel with real price decreases, the consumption of refined grains, added sugars and fats has risen

substantially. [71,72] Some scholars dispute the central role ascribed to food price changes on the grounds that it overestimates price elasticity and fails to explain why people consume more calories instead of diverting expenses saved on food or adjusting calorie sources towards the disproportionally cheaper energy-dense food. [73] Zimmerman points to marketing practices instead, arguing that "extensive advertising, new product development, increased portion sizes, and other tactics of food marketers [...] have caused shifts in the underlying demand for total food calories." [73, p. 286] Indeed, there is ample evidence that the size of pre-packed food and restaurant meals has steadily risen in parallel with obesity prevalence. [74,75] In addition, the consistent proclivity of humans to increase their caloric intake with increased quantities of food offered independently of hunger and satiety is well documented. [76-82] Moreover, food technology has changed the way in which foods and beverages are prepared and preserved. The food industry has taken advantage of the opportunities new technologies have presented in order "to create products whose formulations fit like keys into the psychological and physiological locks that keep consumption within reasonable limits." [73, p. 293] In an article published in the New York Times Magazine in February 2013, the notion of 'sensory-specific satiety' is described as the food industry term used to characterise the properties of hyper-palatable foods high in fat, sugar and/or salt and with carefully engineered textures designed to override satiety signals. [83] The same article quotes a former president and chief operating officer for Coca-Cola in the Americas, highlighting the existential importance of sustained overconsumption for the profitability of the company:

"How many drinkers do I have? And how many drinks do they drink? If you lost one of those heavy users, if somebody just decided to stop drinking Coke, how many drinkers would you have to get, at low velocity, to make up for that heavy user? The answer is a lot. It's more efficient to get my existing users to drink more." [83]

This perspective is in line with the finding that energy-dense foods are perceived as more palatable mainly due to their sweet taste and fatty texture and therefore generally preferred to foods of low energy density, but higher effects on satiety. [84] Against this backdrop, these nutrients have been implicated in the aetiology of obesity beyond their higher contribution of energy per unit. Taubes hypothesizes that "excess fat accumulation is caused fundamentally by the effect of dietary

carbohydrate on insulin" [85, p. 98] as the primary hormone regulating the human metabolism. He suggests that it may not necessarily be an imbalance of total calories consumed and expended, but rather the shift towards a substantially greater intake of carbohydrates, particularly various forms of sugars, which is accountable for the collective weight gain of societies over the past decades. [86,87]

Likewise, dietary fat has been implicated in causing obesity beyond its caloric contribution. Long standing recommendations of low-fat diets from health authorities such as the US Surgeon General may have resulted in a replacement of fat by higher carbohydrate intake. [86] However, new findings indicate that "the focus on fat intake may have been overemphasized at the expense of total energy." [88, p. 135] It is suggested that fat ought instead to be "seen through its effects on total energy intake" [88, p. 135], i.e. its role in making foods more palatable and therefore encouraging overconsumption. Sugar, on the other hand, has recently been linked to features of the metabolic syndrome in the absence of obesity. Citing figures that "20% of obese subjects are metabolically normal, whereas as many as 40% of normal-weight people manifest specific components of metabolic syndrome" [89], Lustig has brought to public attention [87,90] research indicating that fructose, increasingly consumed due to the popularity of sweeter, cheaper highfructose corn syrup, especially in the US, plays an independent role in the pathogenesis of hypertension, non-alcoholic fatty liver disease and insulin resistance. [91,92] The evolving understanding of nutrition and nutrients has led to marked changes in official government advice, with the 2015-2020 US Dietary Guidelines abandoning the longstanding recommended cap on total dietary fat intake [93] and the WHO recently publishing its first guidelines on sugar intake. [94]

To further complicate the complex aetiology of obesity, emerging research suggests that macro-level changes in food supply might not only affect the metabolic regulation of individual energy balance, but also interact with human neurochemical functions. Observations from animal studies suggest that intermittent exposure to high quantities of dietary sugar and fat stimulates the reward system in a way that resembles the effect of addictive substances on neural pathways: rats that binged on sugar or fat showed an increased release of the neurotransmitter dopamine. [95-98] As a result, the idea of an addiction to highly palatable processed foods akin to conventional substance dependencies has been proposed as the underlying cause for

persisting excessive calorie intake. [99,100] The possibility of such effects in humans has been demonstrated in imaging studies of obese individuals which showed a lower density of dopamine receptors. [97,101] However, it appears that changes in tolerance, at least in rats, occur only after overconsumption has been established as a pattern [98] and should already have resulted in overweight. These findings might therefore explain seemingly self-perpetuating features of overweight rather than its origins. Moreover, evidence from rat models does not show that steady overconsumption of highly palatable food results in addiction-like behaviours and neural changes. Instead, this effect was frequently observed in rats that were starved and subsequently binged on feed [e.g. 95], a condition that seems unlikely to be a general rule in humans.

In a review of the idea of 'food addiction', Ziauddeen and colleagues highlight the difficulty of applying animal models to humans and point out that even for recognized addictive substances the percentage of drug users that become dependent is usually small. [102] They further caution that there is "no universally agreed evidence of an addictive agent and that eating behaviour is necessarily part of a continuum." [102, p. 20] While they do not reject the idea that among the overweight and obese population there is a "behavioural phenotype with significantly disordered eating behaviour" [102, p. 21], they question the validity of this theory due to a large overlap in receptor levels between obese and normal weight participants. [100] The authors therefore urge caution in basing any public health action on 'food addiction' as an explanatory model for high human obesity prevalence. Nevertheless, Ziauddeen and colleagues still argue that "it is worth giving some consideration to the ideas that are being suggested for policy change such as restrictions on high-fat and high-sugar foods." [102, p. 26] This stance is supported by the unequivocal evidence presented earlier that the rise in obesity coincides with a considerable rise in average caloric intake mostly from 'junk' food sources and fundamental changes in food technologies and food industry practices.

# 2.4 Shifting targets in prevention: from individual behaviour to populationwide contributors

Current scientific debates aside, debate regarding the appropriate public health response to the high prevalence of overweight and obesity have long pitted

proponents of personal responsibility and advocates of greater government stewardship against each other. While a growing number of scholars advocates for greater use of governments regulatory power in the name of population health [e.g., 103-106], belief in the free market, including free commercial speech, and respect for consumer autonomy have been invoked against alleged government 'paternalism':

"The notion that obesity is caused by the irresponsibility of individuals, and hence not corporate behavior or weak or counterproductive government policies, is the centerpiece of food industry arguments against government action. Its conceptual cousin is that government intervention unfairly demonizes industry, promotes a "nanny" state, and intrudes on personal freedoms." [107]

The scientific community's discussion following the introduction of a ban on transfats in New York City restaurant food that came into force in 2007 illustrates some of the clashing viewpoints. Trans-fats are not independently linked to overweight or obesity, but "provide no known benefit to human health" and are associated with high LDL cholesterol and heart disease. [108, p. 424] Although small quantities of trans-fats occur naturally, industrial hydrogenation is by far the most common source of trans-fats in foodstuffs. [109] In a commentary, Resnik argued against trans-fat bans not primarily on the grounds that they restrict individuals' autonomous choice, but because he considered them the beginning of a slippery slope towards ever more comprehensive market regulation. [110] He claimed that such an intervention does not represent the least restrictive solution. [100] In this, he followed the traditional or neoclassical approach to economics which assumes that human behaviour is fundamentally rational and driven by the desire to maximize utility. [111] In this framework, individuals are considered fully rational and aware of both present and future implications of their choices. Thus, obesity may be a trade-off people are willing to accept. The neoclassical model accepts government interventions only to address fundamental market failures, but rejects public health improvements as a primary goal. Reasons for acceptable government intervention include insufficient or misleading consumer information, for instance when consumers are forced to make nutritional decisions in the absence of any calorie or nutrient information; external costs, that is costs to third parties or society at large resulting directly from a product or service that are not captured by price;

and cases where consumers act irrationally and need to be protected from themselves. [111] However, considering that the free market is generally considered a positive societal force and consumer rationality is the default assumption, justified government interventions in the neoclassical model are usually limited to just one group:

"While society may trust adults to accurately weight the costs and benefits of a high-calorie diet or a sedentary lifestyle, we may wish to intervene for paternalistic reasons to influence the decisions of children." [111, p. 132]

Proponents of less neoclassical economic models acknowledge that individuals are unlikely to be rational at all times and have a tendency to consistently discount the future. [112] Behavioural economics recognizes that "people make systematic errors in decision-making and suffer from self-control problems" and therefore see a role for government in structuring "choices in such a way that people make more optimal choices for reasons unrelated to obesity concerns". [112, p. 149] Consequently, alternative conceptions of consumer behaviour promote government regulation beyond the provision of information and price manipulations to restore the equilibrium of the market and accept health prevention and improvement as legitimate goals. [110-112]

The peer commentaries that accompanied Resnik's opinion piece make ample reference to the free market and rational autonomy being an illusory construct that ignores societal and psychological influences on consumers. [113-119] In particular, they highlight the role of the food industry in actively curtailing free consumer choice to its benefit. [115]

Despite the suggestion that macroeconomic systems disfavour healthy eating patterns, whole-of-population approaches to nutrition have been rare. To date, systemic action for the prevention of overweight and obesity- whether as part of actual policy or in trials- has primarily been focused on school-aged children and adolescents [120,121] and rolled out in settings such as schools or healthcare where some degree of paternalism can be justified. However, even if one accepts that children should be a priority target due to their higher vulnerability and the lifelong impact of paediatric obesity, the limited effectiveness of school-based interventions should be cause for concern. [122, 123]

The limitations of setting and sub-population specific interventions are evident when considering that children consume only 19% to 50% of their total daily caloric intake at school. [124] Moreover, as Magnusson explains, rather than focusing on populations deemed to be at high risk of developing chronic disease or disease risk factors, interventions targeting the general population are likely to be more successful in reaching the largest number of individuals with varying levels of risk:

"Where the absolute risk of the population is too high [...] it is not the case that the only ones to benefit from prevention policies are those who have the highest relative risk by virtue of being on the far right hand tail of the distribution. [...] Although interventions may benefit the smaller number of people at highest risk, the greatest benefit may be among the much larger number of people in the middle part of the disease distribution who are exposed to a relatively low risk." [125, p. 216]

As a result, approaches that reach the general population by targeting components of the general focus environment have become increasingly popular in the academic literature. Legal approaches, as a way to mandate standards and enforce compliance, have been particularly extensively analysed. [e.g. 126-134] Gostin names six nutrition-related functions of law: (1) Enforcing disclosure through labelling requirements, (2) tort liability, i.e. litigation on case-by-case basis against food industry by the government or private citizens, (3) regulation of food marketing, (4) taxation, (5) school and workplace policies and the (6) prohibition of foods or food components. [126] With the exception of number 2, these are areas for action that governments can address through legislation and regulation. Starting with Brownell's call in 1994 for the introduction of excise taxes on foods with little nutritional value [135], the academic literature has put forward inventive regulatory designs intended to maximise public health benefits and circumvent legal and political constraints. [e.g. 136-139] Examples include the exploration of local government authority to supplement standards set at higher jurisdictional levels: for instance, the nationwide requirement for calorie posting in chain restaurants and vending machines introduced by the US Affordable Care Act could be enhanced by subsidiary governments to include non-chain restaurants. [139] In addition, information provision could mandate a stronger form of "nudging" [140,141] through requirements to display physical activity equivalents alongside calorie

counts, or by instructing food outlets to order menu items by caloric value to capitalise on default choices. [139]

With a small number of exceptions [e.g. 142], much of the debate around policy options and their effectiveness rested on experimental and modelling studies at the time when this research began. These include evidence of price elasticities as well as evidence from modelling and experimental studies that suggest that large excise taxes levied on products such as sugar-sweetened beverages or high-calorie snack foods hold promise. [143,144] Over the time period of this research project, new policy approaches have been implemented and others extended to new jurisdictions. This has given rise to a growing body of work evaluating the effectiveness of real-world interventions. Chapters 4 and 5 of this thesis analyse systematically the patterns of enactment and the effectiveness of these interventions to the extent that evaluation results are available.

At the same time, movement towards more holistic assessment of overall government policy with respect to population nutrition has begun to emerge. One such initiative is the International Network for Food and Obesity/noncommunicable diseases Research, Monitoring and Action Support (INFORMAS), operating under the auspices of the International Obesity Task Force (IOTF). [145] INFORMAS considers dietary priorities and matching policy levers sufficiently developed to serve as building blocks of comprehensive national and international food policy and obesity prevention regimes, arguing that "a vision of what success would look like [...] has been widely agreed by international organizations, expert panels, professional societies and civil society organizations concerned with obesity and NCD prevention." [146, p.158] In this vein, INFORMAS has developed and pilot-tested the Healthy Food Environment Policy Index as a monitoring tool for government performance. [147] The instrument is based on a set of best practice indicators spread over seven aspects of the food environment that are amenable to policy action as well as measures of policy context. [147] However, INFORMAS themselves point out that more information is needed on the impact of many of the interventions considered best practice. [145] As a result, the Healthy Food Environment Policy Index represents a collection of policy approaches that have never been collectively implemented nor fully assessed in their individual impact on nutrition and health.

## 2.5 Policy context and prioritisation

Developments at the international level have reinforced regulatory measures as potential policy instruments to address the externalities and adverse health impact of obesity. In May 2004, the World Health Assembly (WHA), the decision-making body of the World Health Organization (WHO) representing all 194 WHO member states, endorsed the Global Strategy on Diet, Physical Activity and Health. [148] Unlike international treaties concluded under the WHO constitution such as the Framework Convention on Tobacco Control, WHO strategies are sets of recommendations that represent soft law instruments rather than binding international law. Nonetheless, coming from the only truly global health governance body, WHA decisions can reasonably be considered as expressing a degree of global consensus regarding scientific evidence and resulting policy recommendations.

The strategy recognises the adverse health outcomes associated with "elevated consumption of energy-dense, nutrient-poor foods that are high in fat, sugar and salt". [148, para. 10] Among its stated objectives is the goal to "reduce the risk factors for noncommunicable diseases that stem from unhealthy diets [...] by means of essential public health action and health-promoting and disease-preventing measures". [148, para. 18(1)] Crucially, in addition to the traditional calls for improved consumer information, the strategy explicitly mentions "fiscal measures, including taxes, to influence availability of, access to, and consumption of, various foods". [148, para. 42(2)] Governments are recognised as central actors:

"The role of government is crucial in achieving lasting change in public health. Governments have a primary steering and stewardship role in initiating and developing the Strategy, ensuring that it is implemented and monitoring its impact in the long term" [148, para. 36]

The growing recognition of chronic diseases and their associated risk factors as major public health concerns and a priority for policy-making is not only evident internationally, but also at country level. In Australia, interest in population health solutions for non-communicable disease determinants is reflected at Commonwealth level in terms of stated policy and research priorities: in 2008, obesity was added to the list of National Health Priority Areas which are selected based on their significant societal costs and their potential, if tackled in a targeted

and effective fashion, to generate significant and widespread health gains. [149] The current gap between obesity as the clearly recognised precursor of a growing disease burden and the development and implementation of appropriate counterstrategies at the population level has led to obesity also being designated a key research area. Like its 2013-2015 predecessor [150], the current National Health and Medical Research Council (NHMRC) Corporate Plan 2015-2016 [151] commits to supporting research that translates evidence into policy and practice. It also features a targeted call for research related to obesity prevention. A short-lived boost for noncommunicable disease prevention occurred in 2009, when the then Commonwealth government followed a recommendation by the National Preventative Health Taskforce and established the Australian National Preventive Health Agency (ANPHA), the funder of the research project of which this PhD thesis is a part. ANPHA made overweight and obesity prevention a cornerstone of its program and its mission explicitly included the development and improvement of public policies that have the potential to address lifestyle risk factors such as obesity. However, the organization was dismantled with the 2014-15 federal budget after a change of government.

In addition to changes in the infrastructure supporting policy-relevant research, Australian policy action has been limited. At the national level, the health star rating system, introduced in 2014 as an innovative interpretative nutrition labelling scheme was not made mandatory and has been criticised for design flaws. [152] At sub-national level, calorie posting on chain restaurant menus is required in only three out of eight states and territories. Meanwhile, novel approaches discussed in various jurisdictions have not yet been implemented: In the Australian Capital Territory (ACT), the Healthy Weight Action Plan calls for several regulatory options to be explored, including limitations to marketing directed at children near schools, playgrounds and child care centres; a requirement for supermarkets to provide at least one checkout lane without unhealthy foods and drinks; and the regulation of sugar-sweetened drink sales. [153] Similarly, proposals for exclusion zones around schools for new fast food outlets and chain restaurant advertising put forward by two Adelaide Councils [154,155] have not come to fruition. However, as discussed in chapter 7, the state of South Australia has put in place pioneering public health legislation that has the potential to underpin and enhance inventive ways to regulate for obesity prevention in the future.

# 2.6 Summary

In summary, obesity and related chronic disease remain pressing public health concerns with a considerable impact on individuals' physical, social, and economic well-being and long-lasting consequences for national resources. While the exact relative contribution of individual nutrients and the involvement of addiction-like pathways remains subject to scientific debate, there is clear evidence that shifts in the food environment are causally related to the considerable increase in overweight and obesity over the last decades. Accordingly, governments at all jurisdictional levels have recognised nutrition and obesity prevention as priorities. However, government action is only slowly moving towards the types of systemic interventions rooted in law that are advocated in the academic literature. The scarcity of evidence regarding the prevalence of such approaches, their effectiveness, and the policy-processes that facilitate progress represent the point of departure for this thesis and are addressed in the subsequent chapters.

#### References

- [1] Flier JS, Maratos-Flier E. Chapter 77.Biology of Obesity. In: Longo DL, Fauci AS, Kasper DL, Hauser SL, Jameson, JL, Loscalzo J, editors. Harrison's Principles of Internal Medicine. 18<sup>th</sup> ed. New York: McGraw-Hill; 2012.
- [2] Stedman, TL. Stedman's Medical Dictionary. 27<sup>th</sup> ed. Baltimore: Lippincott Williams & Wilkins; 2006.
- [3] Khosla, T, Lowe, CR. Indices of obesity derives from body weight and height. British Journal of Preventive & Social Medicine. 1967;21(3):122-128.
- [4] Keys A, Fidanza F, Karvonen MJ, Kimura N, Taylor HL. Indices of relative weight and obesity. *Journal of Chronic Diseases*. 1972;25(6):329-343.
- [5] World Health Organization. Obesity: preventing and managing the global epidemic. 2000. WHO Technical Report Series No. 894.
- [6] Marcovitch H., editor. Black's Medical Dictionary. 41<sup>st</sup> ed. London: A&C Black; 2005.
- [7] Marcovitch H., editor. Black's Medical Dictionary. 42<sup>nd</sup> ed. London: A&C Black; 2009.

- [8] Venes D, editor. Taber's Cyclopedic Medical Dictionary. 22<sup>nd</sup> ed. Philadelphia: F.A. Davis Company; 2013.
- [9] Flegal KM, Kit BK, Orpana H, Graubard BI. Association of all-cause mortality with overweight and obesity using standard body mass index categories: a systematic review and meta-analysis. *JAMA*. 2013;309(1):71-82.
- [10] TOS Obesity as a Disease Writing Group, Allison DB, Downey M, Atkinson R L, Billington CJ, Bray, GA et al. Obesity as a disease: a white paper on evidence and arguments commissioned by the Council of The Obesity Society. *Obesity*. 2008;16:1161-1177.
- [11] Pollack A. A. M.A. Recognizes Obesity as a Disease. New York Times. 2013. Available from: <a href="http://www.nytimes.com/2013/06/19/business/ama-recognizes-obesity-as-a-disease.html?r=0">http://www.nytimes.com/2013/06/19/business/ama-recognizes-obesity-as-a-disease.html?r=0</a> [last accessed 18 June 2015].
- [12] Jolliffe D. Continuous and robust measures of the overweight epidemic: 1971-2000. *Demography*. 2004;41(2):303-314.
- [13] Bleich S, Cutler D, Murray C, Adams A. Why is the developed world obese? Bureau of Economic Research Working Paper. 2007; w12954.
- [14] OECD. Obesity Update. 2014. Available from: <a href="http://www.oecd.org/els/health-systems/Obesity-Update-2014.pdf">http://www.oecd.org/els/health-systems/Obesity-Update-2014.pdf</a> [last accessed 14 December 2015].
- [15] Australian Bureau of Statistics. Australian Health Survey: Users' Guide, 2011-13: Body Mass and Physical Measurements. 2013. Available from: <a href="http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/9C2B28A7F682FD6FCA2">http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/9C2B28A7F682FD6FCA2</a> 57B8D00229E9B?opendocument [last accessed 14 December 2015].
- [16] Australian Bureau of Statistics. Australian Health Survey: First Results, 2011-12: Overweight and obesity. 2013. Available from:

  <a href="http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/034947E844F25207CA257">http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/034947E844F25207CA257</a>
  <a href="mailto:A30014BDC7?opendocument">AA30014BDC7?opendocument</a> [last accessed 14 December 2015].
- [17] OECD. Obesity Update. 2014. [Download the data] Available from: <a href="http://www.oecd.org/health/obesity-update.htm">http://www.oecd.org/health/obesity-update.htm</a> [last accessed 14 December 2015].
- [18] Nichols MS, Silva-Sanigorski AD, Clearly JE, Goldfeld SR, Colahan A, Swinburn BA. Decreasing trends in overweight and obesity among an Australian population of preschool children. *International Journal of Obesity*. 2011;35:916-924.

- [19] Ogden CL, Carroll MD, Kit BK, Flegal KM. Prevalence of childhood and adult obesity in the United States, 2011-2012. *JAMA*. 2014;311(8):806-811.
- [20] Van Jaarsveld CH, Gulliford MC. Childhood obesity trends from primary care electronic health records in England between 1994 and 2013: population-based cohort study. *Archives of Disease in Childhood*. 2015;100(3):214-219.
- [21] Biro FM, Wien M. Childhood obesity and adult morbidities. *American Journal of Clinical Nutrition*. 2010;91(5):1499-1505.
- [22] Freedman DS, Khan LK, Dietz WH, Srinivasan SR, Berenson GS.
  Relationship of childhood overweight to coronary heart disease risk factors in adulthood: The Bogalusa Heart Study. *Pediatrics*. 2001; 108: 712-718.
- [23] Sebire NJ, Jolly M, Harris JP, Wadsworth J, Joffe M, Beard RW, et al. Maternal obesity and pregnancy outcome: a study of 287,213 pregnancies in London. *International Journal of Obesity and Related Metabolic Disorders*. 2001;25:1175-1182.
- [24] Salsberry PJ, Reagan PB. Taking the long view: the prenatal environment and early adolescent overweight. *Research in Nursing & Health*. 2007;30:297-307.
- [25] Birch LL. Development of food preferences. *Annual Review of Nutrition*. 1999;19:41-62.
- [26] Espinoza N, Ayala GX, Arredondo EM. Interventions targeting childhood obesity involving parents. In: O'Dea JA, Eriksen M, editors. Childhood Obesity Prevention-International Research, Controversies, and Interventions. New York: Oxford University Press; 2010. p. 300-308.
- [27] Mennella JA, Jagnow CP, Beauchamp GK. Prenatal and postnatal flavor learning by human infants. *Pediatrics*. 2001;107:E88.
- [28] Keith SW, Redden DT, Katzmarzyk PT, Boggiano MM, Hanlon EC, Benca RM et al. Putative contributors to the secular increase in obesity: exploring the roads less traveled. *International Journal of Obesity*. 2006;30(11):1585-1594.
- [29] Birch LL, Ventura AK. Preventing childhood obesity: what works? *International Journal of Obesity*. 2009;33:74-81.
- [30] IOM Committee on an Evidence Framework for Obesity Prevention Decision Making. Bridging the Evidence Gap in Obesity Prevention: A Framework to

- Inform Decision Making. Washington, D.C.: The National Academies Press; 2010.
- [31] Australian Bureau of Statistics. Australian Aboriginal and Torres Strait
  Islander Health Survey: First Results, Australia, 2012-13. 2013. Available
  from:
  <a href="http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/A07BD8674C37D8">http://www.abs.gov.au/ausstats/abs@.nsf/Latestproducts/A07BD8674C37D8</a>
  38CA257C2F001459FA?opendocument [last accessed 9 January 2016].
- [32] Australian Bureau of Statistics. 4364.0.55.003 Australian Health Survey:

  Updated Results, 2011-2012 .Table 7.3 Body Mass Index by selected
  population characteristics Australia. 2013.

  <a href="http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4364.0.55.003201">http://www.abs.gov.au/AUSSTATS/abs@.nsf/DetailsPage/4364.0.55.003201</a>

  1-2012?OpenDocument [last accessed 9 January 2016].
- [33] Australian Institute of Health and Welfare. Who is overweight? Available from: <a href="http://www.aihw.gov.au/who-is-overweight/">http://www.aihw.gov.au/who-is-overweight/</a> [last accessed 9 January 2016].
- [34] Ogden CL, Lamb MM, Carroll MD, Flegal KM. Obesity and socioeconomic status in adults: United States, 2005-2008. 2010. NCHS Data Brief No. 50.
- [35] Burchard EG, Ziv E, Coyle N, Gomez SL, Tang H, Karter AJ et al. The importance of race and ethnic background in biomedical research and clinical practice. *New England Journal of Medicine*. 2003;348(12): 170-1175.
- [36] Braveman P. A health disparities perspective on obesity research. *Preventing Chronic Disease*. 2009;6(3):A91.
- [37] Zhang Q, Wang Y. Trends in the association between obesity and socioeconomic status in U.S. adults: 1971 to 2000. *Obesity Research*. 2004; 12(10):1622-1632.
- [38] Wang Y, Beydoun MA. The obesity epidemic in the United States- gender, age, socioeconomic, racial/ethnic, and geographic characteristics: a systematic review and meta-regression analysis. *Epidemiologic Reviews*. 2007;29(1):6-28.
- [39] Ljungvall A, Zimmerman FJ. Bigger bodies: Long-term trends and disparities in obesity and body-mass index among U.S. adults, 1960-2008. *Social Science & Medicine*. 2012;75:109-119.
- [40] OECD. Obesity Update 2012. Available from: http://www.oecd.org/health/49716427.pdf [last accessed14 June 2015].

- [41] Finkelstein EA, Fiebelkorn IC, Wang G. National medical spending attributable to overweight and obesity: how much, and who's paying? *Health Affairs*. 2003;22(3):219-226.
- [42] Tsai AG, Williamson DF, Glick HA. Direct medical cost of overweight and obesity in the USA: A quantitative systematic review. *Obesity Reviews*. 2011;12(1):50-61.
- [43] Colagiuri S, Lee CMY, Colagiuri R, Magliano D, Shaw JE, Zimmet PZ et al. The cost of overweight and obesity in Australia. *Medical Journal of Australia*. 2010;192:260-264.
- [44] Trogdon JG, Finkelstein EA, Hylands T, Dellea PS, Kamal-Bahl SJ. Indirect costs of obesity: a review of the current literature. *Obesity Reviews*. 2008;9:89-500.
- [45] Finkelstein EA, Fiebelkorn C, Wang G. The costs of obesity among full-time employees. *American Journal of Health Promotion*. 2005;20:45-51.
- [46] Lehnert T, Stuhldreher N, Streltchenia P, Riedel-Heller SG, König HH. Sick leave days and costs associated with overweight and obesity in Germany. *Journal of Occupational and Environmental Medicine*. 2014;56(1):20-27.
- [47] Baum CL, Ford WF. The wage effects of obesity: a longitudinal study. *Health Economics*. 2004;13:885-889.
- [48] Cawley J. The Impact of Obesity on Wages. *Journal of Human Resources*. 2004;39451-474.
- [49] Puhl R, Brownell KD. Bias, discrimination, and obesity. *Obesity Reviews*. 2001;9:788-805.
- [50] Kottke TE, Wu LA, Hoffman RS. Economic and psychological implications of the obesity epidemic. *Mayo Clinic Proceedings*. 2003;78:92-94.
- [51] Gortmaker SL, Must A, Perrin JM, Sobol AM, Dietz WH. Social and economic consequences of overweight in adolescence and young adulthood. *New England Journal of Medicine*. 1993;329(14):1008-1012.
- [52] Egger G, Swinburn B. An 'ecological' approach to the obesity pandemic. *BMJ*. 1997;315:477-480.
- [53] Swinburn B, Egger G, Raza F. Dissecting obesogenic environments: the development and application of a framework for identifying and prioritizing environmental interventions for obesity. *Preventive Medicine*. 1999;29:563-570.

- [54] Philipson TJ, Posner RA. The Long-Run Growth in Obesity as a Function of Technological Change. 1999. NBER Working Paper No. 7423.
- [55] Lakdawalla D, Philipson T. The Growth of Obesity and Technological Change: Theoretical and Empirical Examination. 2002. NBER Working Paper No. 8946.
- [56] Cutler DM, Glaeser EL, Shapiro JM. Why have Americans become more obese? *Journal of Economic Perspectives*. 2003;17(3):93-118.
- [57] Putnum JJ, Allshouse JE. Food Consumption, Prices and Expenditures, 1970-97. 1999. Statistics Bulletin No. 965.
- [58] Nielsen SJ, Siega-Riz AM, Popkin BM. 2002. Trends in energy intake in US between 1977 and 1996: similar shifts seen across age groups. *Obesity*. 2002;10(5):370-378.
- [59] Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA*. 2003;289(4):450-453.
- [60] Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: Where do we go from here? *Science*. 2003;299(5608):853-855.
- [61] Katan MB, Ludwig DS. Extra calories cause weight gain-but how much? *JAMA*. 2010:303(1):65-66.
- [62] Bleich S, Cutler D, Murray C, Adams A. Why is the developed world obese? *Annual Review of Public Health*. 2008;29:273-295.
- [63] Ng SW, Slining MM, Popkin BM. Turning point for US diets? Recessionary effects or behavioral shifts in foods purchased and consumed. *American Journal of Clinical Nutrition*. 2014;99(3):609-616.
- [64] Wang X, Ouyang Y, Liu J, Zhu M, Zhao G, Bao W, et al. Fruit and vegetable consumption and mortality from all causes, cardiovascular disease, and cancer: systematic review and dose-response meta-analysis of prospective cohort studies. *BMJ*. 2014;349:g4490.
- [65] Moore LV, Thompson FE. Adults Meeting Fruit and Vegetable Intake Recommendations-United States, 2013. *Morbidity and Mortality Weekly Report*. 2015;64(26):709-713.
- [66] Australian Bureau of Statistics. Profiles of Health, Australia, 2011-13: Daily intake of fruit and vegetables. 2013. Available from: http://www.abs.gov.au/ausstats/abs@.nsf/Lookup/by%20Subject/4338.0~201

- 1-13~Main%20Features~Daily%20intake%20of%20fruit%20and%20vegeta| bles~10009 [last accessed 22 December 2015].
- [67] Swinburn B, Sacks G, Ravussin E. Increased food energy supply is more than sufficient to explain the US epidemic of obesity. *American Journal of Clinical Nutrition*. 2009; 90:1453-1456.
- [68] Vandevijvere S, Chow CC, Hall KD, Umali E, Swinburn BA. Increased food energy supply as a major driver of the obesity epidemic: a global analysis. *Bulletin of the World Health Organization*. 2015;93(7):446-456.
- [69] Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie MI, et al. The global obesity pandemic: shaped by global drivers and local environments. *Lancet*. 2011; 378: 804-14.
- [70] Drewnowski A. Obesity and the food environment: Dietary energy density and diet costs. *American Journal of Preventive Medicine*. 2004; 27(3); 154-162.
- [71] Finkelstein EA, Ruhm CJ, Kosa KM. Economic Causes and Consequences of Obesity. *Annual Review of Public Health*. 2005; 26: 239-257.
- [72] Putnam JJ, Allshouse, J, Kantor LS. U.S. per capita food supply trends: more calories, refined carbohydrates, and fats. *Food Review*. 2002;25:2-15.
- [73] Zimmerman FJ. Using Marketing Muscle to Sell Fat: The Rise of Obesity in the Modern Economy. *Annual Review of Public Health*. 2011;32:285-306.
- [74] Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977-1998. *JAMA*. 2003;289:450-453.
- [75] Young LR, Nestle M. 2002. The contribution of expanding portion sizes to the US obesity epidemic. *American Journal of Public Health*. 2002;92(2):246-249.
- [76] Wansink B. Can package size accelerate usage volume? *Journal of Marketing*. 1996;60:1-14.
- [77] Wansink B. Environmental factors that increase the food intake and consumption volume of unknowing consumers. *Annual Review of Nutrition*. 2004;24:455-479.
- [78] Wansink B, Cheney MM. Super Bowls: serving bowl size and food consumption. *JAMA*. 2005;293(14):1727-1728.
- [79] Wansink, B., Painter, J. E. and North, J. Bottomless Bowls: Why Visual Cues of Portion Size May Influence Intake. *Obesity Research*. 2005;13:93-100.

- [80] Diliberti N, Bordi PL, Conklin MT, Roe LS, Rolls BJ. Increased portion size leads to increased energy intake in a restaurant meal. *Obesity Research*. 2004;12:562-568.
- [81] Rolls BJ, Roe LS, Kral TV, Meengs JS, Wall DE. Increasing the portion size of a packaged snack increases energy intake in men and women. *Appetite*. 2004;42(1):63-69.
- [82] Rolls BJ, Roe LS, Meengs JS, Wall DE. Increasing the portion size of a sandwich increases energy intake. *Journal of the American Dietetic Association*. 2004;104(3):367-372.
- [83] Moss M. The Extraordinary Science of Addictive Junk Food. New York Times. 2013. Available from:

  <a href="http://www.nytimes.com/2013/02/24/magazine/the-extraordinary-science-of-junk-food.html?pagewanted=all&r=0">http://www.nytimes.com/2013/02/24/magazine/the-extraordinary-science-of-junk-food.html?pagewanted=all&r=0</a> [last accessed 27 October 2015].
- [84] Drewnowski A. Energy Density, Palatability, and Satiety: Implications for Weight Control. *Nutrition Reviews*. 1998; 56: 347-353.
- [85] Taubes G. Response to Dr George Bray's review of Good Calories, Bad Calories. *Obesity Reviews*. 2009;10(1):96-98.
- [86] Taubes G. Good Calories, Bad Calories. Fats, carbs, and the controversial science of diet and health. New York: Anchor Books, 2011.
- [87] Taubes G. Is sugar toxic? New York Times. 2011. Available from: <a href="http://www.nytimes.com/2011/04/17/magazine/mag-17Sugar-t.html?pagewanted=all&\_r=0">http://www.nytimes.com/2011/04/17/magazine/mag-17Sugar-t.html?pagewanted=all&\_r=0</a> [last accessed 27 October 2015].
- [88] Richards MK, Paeratakul S, Bray GA, Popkin BM. Current theories regarding the influence of diet and the control of obesity. In: Wilson T, Temple NJ. editors. Nutritional Health: Strategies for Disease Prevention. Totowa, NJ: Humana Press. 2001. p. 135-150.
- [89] Lustig RH. Fructose: It's "Alcohol Without the Buzz". *Advances in Nutrition*. 2013;4(2):226-235.
- [90] Lustig RH. Fat Chance: Beating the Odds against Sugar, Processed Food, Obesity, and Disease. New York: Hudson Street Press, 2013.
- [91] Lustig RH, Schmidt LA, Brindis CD. Public health: The toxic truth about sugar. *Nature*. 2012;482(7383):27-29.

- [92] Lim JS, Mietus-Snyder M, Valente A, Schwarz JM, Lustig RH. The role of fructose in the pathogenesis of NAFLD and the metabolic syndrome. *Nature Reviews Gastroenterology & Hepatology*. 2010;7(5):251-264.
- [93] Mozaffarian D, Ludwig DS. The 2015 US Dietary Guidelines: Lifting the Ban on Total Dietary Fat. *JAMA*. 2015;313(24):2421-2422.
- [94] World Health Organization. Guideline: sugars intake for adults and children. 2015. Available from:

  <a href="http://www.who.int/nutrition/publications/guidelines/sugars\_intake/en">http://www.who.int/nutrition/publications/guidelines/sugars\_intake/en</a> [last accessed 29 December 2015].
- [95] Corwin RL, Avena NM, Boggiano MM. Feeding and reward: perspectives from three rat models of binge eating. *Physiology & Behavior*. 2011;104(1):87-97.
- [96] Avena NM, Rada P, Hoebel BG Evidence for sugar addiction: behavioral and neurochemical effects of intermittent, excessive sugar intake. *Neuroscience & Biobehavioral Reviews*. 2008;32(1):20-39.
- [97] Avena NM, Rada P, Hoebel BG. Sugar and Fat Bingeing Have Notable Differences in Addictive-like Behavior. *Journal of Nutrition*. 2009;139(3):623-628.
- [98] Kenny PJ. Reward mechanisms in obesity: new insights and future directions. *Neuron*. 2011;69(4):664-679.
- [99] Thornley S, McRobbie H. Sickly sweet. Sugar, refined carbohydrate and global obesity. New York: Nova Science Publishers, 2012.
- [100] Ifland JR, Preuss HG, Marcus MT, Rourke KM, Taylor WC, Burau K, Jacobs WS, Kadish W, Manso G. Refined food addiction: a classic substance use disorder. *Medical Hypotheses*. 2009;72(5):518-526.
- [101] Gearhardt AN, Yokum S, Orr PT, Stice E, Corbin WR, Brownell KD. Neural correlates of food addiction. *Archives of General Psychiatry*. 2011;68:808-816.
- [102] Ziauddeen H, Fletcher PC. Is food addiction a valid and useful concept? *Obesity Reviews*. 2013;14(1):19-28.
- [103] Nestle M, Jacobson MF. Halting the obesity epidemic: a public health policy approach. *Public Health Reports*. 2000;115(1):12.
- [104] Mello MM, Studdert DM, Brennan TA. Obesity-the new frontier of public health law. *New England Journal of Medicine*. 2006;354(24):2601-2610.

- [105] Gortmaker SL, Swinburn BA, Levy D, Carter R, Mabry PL, Finegood DT, Huang T, Marsh T, Moodie ML. Changing the future of obesity: science, policy, and action. *Lancet*. 2011;378(9793):838-847.
- [106] Gearhardt AN, Bragg MA, Pearl RL, Schvey NA, Roberto CA, Brownell KD. Obesity and public policy. *Annual Review of Clinical Psychology*. 2012;8:405-430.
- [107] Brownell KD, Kersh R, Ludwig DS, Post RC, Puhl RM, Schwartz MB, Willett WC. Personal responsibility and obesity: a constructive approach to a controversial issue. *Health Affairs*. 2010;29(3):379-387.
- [108] Institute of Medicine. Dietary reference intakes for energy, carbohydrate, fiber, fat, fatty acids, cholesterol, protein, and amino acids (macronutrients). 2005. Available from:

  <a href="http://www.nal.usda.gov/fnic/DRI/DRI Energy/energy\_full\_report.pdf">http://www.nal.usda.gov/fnic/DRI/DRI Energy/energy\_full\_report.pdf</a> [last accessed 22 August 2015].
- [109] EFSA. Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids. 2007.

  Available from: <a href="http://www.efsa.europa.eu/en/efsajournal/pub/81.htm">http://www.efsa.europa.eu/en/efsajournal/pub/81.htm</a> [last accessed 22 August 2015].
- [110] Resnik D. Trans fat bans and human freedom. *American Journal of Bioethics*. 2010;10(3):27-32.
- [111] Cawley J. The economics of obesity. In: Cawley J, editor. The Oxford handbook of the social science of obesity. New York, NY: Oxford University Press; 2011. p. 120-137.
- [112] Downs JS, Loewenstein G. Behavioral economics and obesity. In: Cawley J, editor. The Oxford handbook of the social science of obesity. New York, NY: Oxford University Press; 2011. p. 138-157.
- [113] Rice T. The behavioral economics of health and health care. *Annual Review of Public Health*. 2013;34:431-447.
- [114] Boddington P. Dietary choices, health, and freedom: Hidden fats, hidden choices, hidden constraints. *American Journal of Bioethics*. 2010;10(3):43-44.
- [115] Gostin LO. Trans fat bans and the human freedom: A refutation. *American Journal of Bioethics*. 2010;10(3):33-34.

- [116] Kirkwood K. Lipids, liberty, and the integrity of free actions. *American Journal of Bioethics*. 2010;10(3):45-46.
- [117] Wilson J, Dawson A. Giving liberty its due, but no more: Trans fat, liberty, and public health. *American Journal of Bioethics*. 2010;10(3):34-36.
- [118] Nobis N, Gardner M. Cut the fat! Defending trans-fat bans. *American Journal of Bioethics*. 2010;10(3):39-40.
- [119] Keane M. Public Health Interventions Need to Meet the Same Standards of Medical Ethics as Individual Health Interventions. *American Journal of Bioethics*. 2010;10(3):36-38.
- [120] Story M, Nanney M, Schwartz M. Schools and obesity prevention: creating school environments and policies to promote healthy eating and physical activity. *Milbank Quarterly*. 2009;87(1):71-100.
- [121] Lankford T, Hardman D, Dankmeyer C, Schmid T. Analysis of state obesity legislation from 2001 to 2010. *Journal of Public Health Management and Practice*. 2013;19:S114.
- [122] Birch LL, Ventura AK. Preventing childhood obesity: what works? *International Journal of Obesity*. 2009; 33: 74-81.
- [123] Waters E, de Silva-Sanigorski A, Burford BJ, Brown T, Campbell KJ, Gao Y, et al. Interventions for preventing obesity in children. *Cochrane Database of Systematic Reviews*. 2011:12;CD001871.
- [124] Gleason P, Suitor C. Food for Thought: Children's Diets in the 1990s.
  Princeton, N.J.: Mathematica Policy Research; 2001. Available from:
  <a href="http://www.mathematica-mpr.com/publications/PDFs/childdiet.pdf">http://www.mathematica-mpr.com/publications/PDFs/childdiet.pdf</a> [last accessed 22 August 2015].
- [125] Magnusson RS. How law and regulation can add value to prevention strategies for obesity and diabetes. In: Baur LA, Twigg SM, Magnusson RS, editors. A modern epidemic: expert perspectives on obesity and diabetes. Sydney: Sydney University Press; 2012. p. 207-244.
- [126] Gostin LO. Law as a tool to facilitate healthier lifestyles and prevent obesity. *JAMA*. 2007;297(1):87-90.
- [127] Magnusson RS. What's law got to do with it part 1: A framework for obesity prevention. *Australia and New Zealand Health Policy*. 2008;5:10.

- [128] Magnusson RS. What's law got to do with it Part 2: Legal strategies for healthier nutrition and obesity prevention. *Australia and New Zealand Health Policy*. 2008;5:11.
- [129] Gostin LO, Pomeranz JL, Jacobson PD, Gottfried RN. Assessing laws and legal authorities for obesity prevention and control. *Journal of Law, Medicine & Ethics*. 2009;37(Suppl 1):28-36.
- [130] Pomeranz JL, Gostin LO. Improving laws and legal authorities for obesity prevention and control. *Journal of Law, Medicine & Ethics*. 2009;37 Suppl 1:62-75.
- [131] Gostin LO, Friedman EA, Gebauer T, Grover A, Hassim A, Ooms G, Siem H, Sridhar D, Waris A. A framework convention on obesity control? *Lancet*. 2011;378(9809):2068-9
- [132] Pomeranz JL, Brownell KD. Portion sizes and beyond-government's legal authority to regulate food-industry practices. *New England Journal of Medicine*. 2012 Oct 11;367(15):1383-1385.
- [133] Ahmed HM. Obesity, fast food manufacture, and regulation: revisiting opportunities for reform. *Food and Drug Law Journal*. 2009;64(3):565-75.
- [134] Pomeranz JL, Teret SP, Sugarman SD, Rutkow L, Brownell KD. Innovative legal approaches to address obesity. *Milbank Quarterly*. 2009;87(1):185-213.
- [135] Brownell KD. Get slim with higher taxes. New York Times, December 15, 1994. Available from: <a href="http://www.yaleruddcenter.org/resources/upload/docs/press/ruddnews/OpEdN">http://www.yaleruddcenter.org/resources/upload/docs/press/ruddnews/OpEdN</a> <a href="YTimesTaxes1994.pdf">YTimesTaxes1994.pdf</a> [last accessed 24 October 2015].
- [136] Mermin SE, Graff SK. A legal primer for the obesity prevention movement. American Journal of Public Health. 2009;99(10):1799-1805.
- [137] Harris JL, Graff SK. Protecting children from harmful food marketing: options for local government to make a difference. *Preventing Chronic Disease*. 2011;8(5):A92.
- [138] Pomeranz JL. Advanced policy options to regulate sugar-sweetened beverages to support public health. *Journal of Public Health Policy*. 2012;33(1):75-88.
- [139] Bleich SN, Rutkow L. Improving obesity prevention at the local level-Emerging opportunities. *New England Journal of Medicine*. 2013;368(19):1761-1763.

- [140] Thaler RH, Sunstein CR. Nudge: Improving decisions about health, wealth, and happiness. New Haven, CT: Yale University Press; 2008.
- [141] Oliver A. Is nudge an effective public health strategy to tackle obesity? Yes. *BMJ*. 2011; 342:d2168.
- [142] Dumanovsky T, Huang CY, Nonas CA, Matte TD, Bassett MT, Silver LD. Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labelling: cross sectional customer surveys. *BMJ*. 2011;343:d4464.
- [143] Powell LM, Chriqui JF, Khan T, Wada R, Chaloupka FJ. Assessing the potential effectiveness of food and beverage taxes and subsidies for improving public health: a systematic review of prices, demand and body weight outcomes. *Obesity Reviews*. 2013;14(2):110-128.
- [144] Thow AM, Jan S, Leeder S, Swinburn B. The effect of fiscal policy on diet, obesity and chronic disease: a systematic review. *Bulletin of the World Health Organization*. 2010;88(8):609-614.
- [145] Swinburn B, Sacks G, Vandevijvere S, Kumanyika S, Lobstein T, Neal B, et al. INFORMAS (International Network for Food and Obesity/non-communicable diseases Research, Monitoring and Action Support): overview and key principles. *Obesity Reviews*. 2013;14(S1):1-2.
- [146] Kumanyika S. INFORMAS (International Network for Food and Obesity/non-communicable diseases Research, Monitoring and Action Support): summary and future directions. *Obesity Reviews*. 2013;14(S1):157-164.
- [147] Vandevijvere S, Swinburn B. Pilot test of the Healthy Food Environment Policy Index (Food-EPI) to increase government actions for creating healthy food environments. *BMJ Open.* 2015;5(1):e006194.
- [148] World Health Assembly. Global strategy on diet, physical activity and health. Geneva: 2004. Available from:

  <a href="http://apps.who.int/gb/ebwha/pdf\_files/WHA57/A57\_R17-en.pdf">http://apps.who.int/gb/ebwha/pdf\_files/WHA57/A57\_R17-en.pdf</a> [last accessed 15 November 2015].
- [149] Australian Institute of Health and Welfare. National Health Priority Areas.

  Available from: <a href="http://www.aihw.gov.au/national-health-priority-areas/">http://www.aihw.gov.au/national-health-priority-areas/</a> [last accessed 2 December 2015].

- [150] National Health and Medical Research Council. NHMRC Strategic Plan 2013-2015. Available from:

  <a href="http://www.nhmrc.gov.au/\_files\_nhmrc/publications/attachments/nh160\_nhm">http://www.nhmrc.gov.au/\_files\_nhmrc/publications/attachments/nh160\_nhm</a>
  <a href="rec-strat\_plan\_201315.pdf">rec-strat\_plan\_201315.pdf</a> [last accessed 2 December 2015].
- [151] National Health and Medical Research Council. NHMRC Corporate Plan 2015-2016. Available from:

  <a href="https://www.nhmrc.gov.au/">https://www.nhmrc.gov.au/</a> files <a href="mailto:nhmrc/publications/attachments/nh168">nhmrc/publications/attachments/nh168</a> NH

  <a href="mailto:MRC">MRC</a> corporate plan 2015 2016.pdf [last accessed 2 December 2015].
- [152] Lawrence M, Pollard C. A year on, Australia's health star food-rating system is showing cracks. The Conversation. Published 13 July 2015. Available from: <a href="http://theconversation.com/a-year-on-australias-health-star-food-rating-system-is-showing-cracks-42911">http://theconversation.com/a-year-on-australias-health-star-food-rating-system-is-showing-cracks-42911</a> [last accessed 12 December 2015].
- [153] ACT Government. Healthy Living Food Environment. 2014. Available from: <a href="http://www.act.gov.au/healthyliving/food-environment">http://www.act.gov.au/healthyliving/food-environment</a> [last accessed 26 April 2016].
- [154] Australian Broadcasting Corporation. Marion council in South Australia investigates banning junk food advertising near schools Published 30 September 2015. Available from: <a href="http://www.abc.net.au/news/2015-09-30/marion-council-investigates-banning-junk-food-advertising/6815358">http://www.abc.net.au/news/2015-09-30/marion-council-investigates-banning-junk-food-advertising/6815358</a> [last accessed 12 December 2015].
- [155] Adelaide Advertiser, Peterson H. Ban fast food restaurants from near schools, Charles Sturt Council says. Published 4 March 2013. Available from: <a href="http://www.adelaidenow.com.au/news/south-australia/ban-fast-food-restaurants-from-near-schools-charles-sturt-council-says/story-e6frea83-1226589796329">http://www.adelaidenow.com.au/news/south-australia/ban-fast-food-restaurants-from-near-schools-charles-sturt-council-says/story-e6frea83-1226589796329</a> [last accessed 12 December 2015].

#### 3. Theoretical framework

The main focus of this chapter is the underpinning theoretical perspective for this thesis. The chapter starts by summarising the development of the concept of evidence-based health policy from its origins in evidence-based medicine. It then turns to a discussion of ways in which this paradigm applies to the specific challenge of systemic obesity prevention. In particular, the approaches to evidence and evaluation advanced by Brennan, Brownson, and Pawson [1,16,17], in conjunction with the IOTF's decision-making model [10], serve as examples of established frameworks for successful policy-making in population nutrition and obesity prevention.

A number of methodological and theoretical approaches are relevant to the specific studies presented in this thesis and are introduced in more detail in the following chapters. Although this chapter sets aside study-specific methodological considerations to focus on the overarching theoretical orientation, they are briefly summarised here for completeness. The realist approach to systematic reviews championed by Pawson and colleagues [1] underpins the systematic review in chapter 5 and Kingdon's streams model [2] guides the analysis of the New York case study in Chapter 6. In chapter 6, a case study methodology [3] was selected to allow the in-depth exploration of policy-making processes in New York City and iterative thematic analysis [4] was used for interview data. The systematic review in chapter 6 employs a narrative synthesis to summarise effects across different study designs, policy interventions, and settings. Chapter 7 as a commentary is a critical exploration of the legal and political implications of pursuing nutrition policy under the 2011 South Australian Public Health Act.

Across all its components, this thesis draws on the notion of evidence-based health policy. This concept developed from the extension to population health of the principle of evidenced-based medicine, combined with a greater emphasis on increased public accountability. [5] Evidenced-based medicine has been defined as the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." [6, p. 71] An early definition of this concept in relation to population health was put forward in 1997:

"...the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of communities and populations in the domain of health protection, disease prevention, health maintenance and improvement (health promotion)" [7. p. 190]

The role of evidence in health policy decision-making is markedly different from the concept of evidence-based medicine which is designed to guide decision-making in clinical settings. The two areas differ considerably in terms of "what is considered evidence, what is appropriate evidence, where does the evidence come from, who provides the evidence, and does all evidence count, or count with the same weight". [8, p. xvii] Evidence-based medicine favours randomised controlled trials and systematic reviews as the gold standard. [9] Conversely, in health policy, randomization is rarely feasible, cause and effect chains are complex and often indirect, and controlled environments, if possible, might be a poor predictor for real-life human behaviour. [10-14]

This is especially true for large scale preventive interventions that do not rely on direct cause and effect relationships. These types of intervention often involve "long, complex causal pathways [that...] can be affected by numerous characteristics of the population, health system, or environment". [14, p. 401] Preventive interventions that indiscriminately target "personal behaviours in the society at large" [10, p. 24] through law and policy present the additional difficulty that the desired impact might emerge only gradually or might be cumulative rather than attributable to one specific intervention. [10] In fact, the push towards basket approaches to obesity prevention and healthy eating, for instance through the NOURISHING framework that has been developed and promoted by the World Cancer Research Fund International [15], amplifies the problem: as governments are urged to adopt complementary measure acting on particular aspects of food environments and systems, all the while maintaining behaviour change and health promotion programs [15], differentiation between the effects of individual interventions will become even more challenging. The fact that the ultimately desired effects in form of health gains emerge slowly and are difficult to track presents a problem not only for policy-makers seeking to forecast policy success, but also for conventional ways of assessing and judging effectiveness at the postimplementation stage.

Against the backdrop of such considerations, Victora, Habicht, and colleagues [11,14] suggest a more judicious balance of adequacy, plausibility and probability in assessing the impact of public health interventions. The three components capture different aspects of program success and require different types of evidence:

"Probability statements are based strictly on RCT results. Plausibility statements are derived from evaluations that, despite not being randomized, are aimed at making causal statements using observational designs with a comparison group. Adequacy statements result from demonstrations that trends in process indicators, impact indicators, or both show substantial progress, suggesting that the intervention is having an important effect." [14, p. 400]

While adequacy may be measured in reaching immediate programming goals or associated trends such as the decline of obesity incidence or prevalence, changes in nutritional intake or other relevant parameters, plausibility asks whether there is a logical pathway connecting intervention and outcome. Crucially, where such pathways are long and convoluted, "evaluations based solely on adequacy criteria, or on a combination of adequacy and plausibility, may have sufficiently high internal validity for some outcomes to lead to correct decisionmaking." [14, p. 405]

The translation of these conceptual re-orientations into the practice of policy development and policy assessment has given rise to several concrete recommendations put forward by Brennan, Brownson, and colleagues [16, 17] with regard to health policy and Pawson and colleagues [1] in relation to complex policy interventions in general. Brennan and colleagues focus on the evaluation of policy interventions directed at the prevention of childhood obesity. In line with the considerations by Victora and Habicht, they are responding to the "overemphasis on evidence related to internal validity- evaluation design, methods, and efficacy- as compared with external validity- intervention design, implementation, and applicability" [16, p. 203] inherent to the conventional approach to evidence in health by suggesting an alternative classification of evidence for policy. As figure 3 illustrates, the four levels encompass a range of evidence from different sources and of varying methodological complexity. The framework refrains from designating any form of evidence as low quality, thereby opening the door for innovative interventions to move up tiers as their effects are evaluated and their approaches

replicated elsewhere. Consequently, an initial low tier status does not hinder potential progress into mainstream policy repertoires, but rather encourages more and more thorough evaluation as approaches advance and spread. Crucially, the proposed evidence hierarchy is not limited to health and behavioural outcomes, but also extends to intermediate policy or economic goals as measures of policy success.

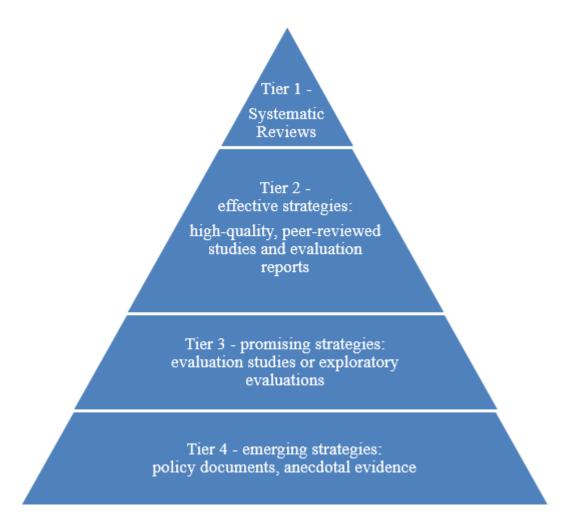


Figure 3 Levels of evidence in public health policy (adapted from [16])

The assessment of policy interventions along a continuum of outcomes is also a key feature of the realist systematic review approach proposed by Pawson and colleagues. [1] The realist approach combines a concrete application of adequacy and plausibility considerations in form of a focus on program logic and intermediate outcomes with range of evidence of varying provenance and methodological complexity. In chapter 5 of this thesis, this model is put into practice as a natural extension of evidence-based public health policy and the resulting requirements for demonstrations of policy effectiveness.

While these considerations focus on the post-implementation phase, it is essential to note that successful policy interventions begin with agenda-setting and political decision-making. In Brownson and colleagues' conceptualisation of evidence-based public health policy [17], the first component is therefore the process of policy development and adoption, followed by policy content and, finally, policy outcomes. These three components span the entire policy life cycle, from initial conception and progression through the decision-making process to evaluation at the post-implementation stage. When adding the two earlier phases to the concept of evidence based health policy, the underlying process is further complicated by the fact that, unlike medicine, public health is often subject to high-level political decision-making. Although evidence such as results from clinical trials often informs policy, for instance through decisions on insurance inclusions, these issues are usually delegated to specialist public bodies. Public health measures, by contrast, especially if subject to legislation, are more likely to be dealt with at the highest levels of government and to encompass a larger number of sectors.

Evidence-based public health policy thus brings together two groups: the researchers and other subject matter experts who generate evidence; and the policy-makers who design and implement public health policy. Numerous authors have contrasted the mindsets of the two groups- worlds apart in terms of goals, constraints and operating procedures [18-20]- and have highlighted the resulting difficulties in putting evidence-based health policy into practice. Noting that policy is concerned with the construction of realities and context-dependent responses, whereas "the world of evidence-based medicine is about deconstructing, stripping away of contexts, controlling for bias, and searching for universal truths (or at least an average population)" [20, p. 7], Lin suggests looking at evidence-based health policy as the meeting of three competing rationalities. She distinguishes between cultural, political and technical rationality, where the former encompasses heterogeneous societal views and the latter represents research evidence. [20]

In recognition that there are essentially two chasms to be bridged - one within the expert community regarding the expectations towards and relative value of different types of evidence and one between experts and policy-makers - Swinburn and colleagues on behalf of the IOTF set out to develop an evidence-based decision-making framework geared towards obesity prevention. [10] They single out five key issues to be successively addressed in the successful development of anti-obesity

interventions grounded in evidence and acceptable to those in the non-expert realm: (1) the necessity to make the case for policy action; (2) the identification of causes, contributors, and the resulting points of intervention; (3) the definition of possible interventions and their respective contexts; (4) the prospective evaluation of potential measures; and (5) the selection of a comprehensive policy program combining complementary interventions. [10]

A range of different types of research evidence and information from other sources are considered relevant to the policy-making process. In terms of research evidence, diverse study designs are deemed acceptable and expected to yield complementary data: [10]

- Observational epidemiology and results from monitoring and surveillance activities.
- Data from experimental studies and results of evaluations of actual programs or policies.
- Extrapolated data: modelled analysis of intervention effectiveness, costeffectiveness, or single variables such as uptake/reach.
- Indirect or assumed evidence such as the assumption that continued high spending on food and beverage marketing suggests an effect on consumption.
- Parallel evidence of intervention feasibility and effectiveness from similar health areas such as tobacco control.

Other types of evidence put forward by Swinburn and colleagues are less likely to be based on research findings and might be more adequately categorized as information or views. In addition to the following items, parallel and indirect or assumed evidence might also fall into this category when used in a more anecdotal fashion: [10]

- Theory and program logic.
- Informed opinion from both experts and stakeholders.

Swinburn's model also takes into account the varied types of research evidence that evidence-based population health demands and incorporates the context-specific

information, values, and vested interests that characterise the political rationality component of evidence-based health policy. In addition, the idea of learning from policy innovation elsewhere, be it another jurisdiction or a related field such as tobacco control, is present throughout this framework and can be introduced either as research evidence or as less formal anecdotal evidence. Crucially, the generic list of evidence, information, and opinions that would ideally guide policy-making is also intended to help identify research gaps [10] that make it harder for obesity prevention measures to succeed in the policy-making process.

To conclude, the paradigms and frameworks discussed in this chapter are fundamental to the direction and methodologies of this thesis. While the systematic review in chapter 5 makes the most direct use of the proposed approaches by employing a realist-informed method of collecting and appraising evidence of policy effectiveness, the rest of this work is equally steeped in the appreciation of the evidence-based public health paradigm for non-traditional evidentiary sources. In addition to quasi-experimental and simple pre-post studies quantifying the success of interventions, the types of evidence presented include policy prevalence in chapter 4 and qualitative evidence related to political processes in chapters 6 and 7. Overall, these theoretical developments away from evidence-based medicine enable this work to focus on a differentiated assessment of regulatory approaches to obesity prevention and to highlight the value of legal and bureaucratic preparedness for political change.

#### References

- [1] Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review-a new method of systematic review designed for complex policy interventions. *Journal of Health Services Research & Policy*. 2005;10(suppl 1):21-34.
- [2] Kingdon JW. Agendas, Alternatives and Public Policies. 2nd ed. New York, NY: Longman; 1995.
- [3] Yin, RK. Case Study Research: Design and Methods. 4th ed. Thousand Oaks, CA: Sage Publications; 2009.
- [4] Given, LM. The Sage Encyclopedia of Qualitative Research Methods. Los Angeles, CA: Sage Publications; 2008.

- [5] Duckett SJ. Foreword. In: Lin V, Gibson B, editors. Evidence-based health policy. Problems & possibilities. Melbourne: Oxford University Press; 2003. p. xv-xvi.
- [6] Sackett DL, Rosenberg WM, Gray JA, et al. Evidence-based medicine: what it is and what it isn't. *BMJ*. 1996;312:71–2
- [7] Jenicek M. Epidemiology, evidence-based medicine, and evidence-based public health. *Journal of Epidemiology and Community Health*. 1997;7:187-197.
- [8] Lin V, Gibson B. Introduction. In: Lin V, Gibson B, editors. Evidence-based health policy. Problems & possibilities. Melbourne: Oxford University Press; 2003. p. xvii-xxvi.
- [9] Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ*. 1996; 313(7057):570-571.
- [10] Swinburn B, Gill T, Kumanyika S. Obesity prevention: a proposed framework for translating evidence into action. *Obesity Reviews*. 2005;6:23-33.
- [11] Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *International Journal of Epidemiology*. 1999;28(1):10-18.
- [12] Kroke A, Boeing H, Rossnagel K, Willich SN. History of the concept of 'levels of evidence' and their current status in relation to primary prevention through lifestyle interventions. *Public Health Nutrition*. 2004;7:279-284.
- [13] Kellam SG, Langevin DJ. A framework for understanding 'evidence' in prevention research and programs. *Preventive Science*. 2003;4:137-153.
- [14] Victora CG, Habicht JP, Bryce J. Evidence-based public health: moving beyond randomized trials. *American Journal of Public Health*. 2004;94:400-405.
- [15] Hawkes C, Jewell J, Allen K. A food policy package for healthy diets and the prevention of obesity and diet-related non-communicable diseases: the NOURISHING framework. *Obesity Reviews*. 2013;14 Suppl 2:159-168.
- [16] Brennan L, Castro S, Brownson RC, Claus J, Orleans CT. Accelerating evidence reviews and broadening evidence standards to identify effective, promising, and emerging policy and environmental strategies for prevention of childhood obesity. *Annual Review of Public Health*. 2011;32:199-223.

- [17] Brownson RC, Chriqui JF, Stamatakis KA. Understanding Evidence-Based Public Health Policy. *American Journal of Public Health*. 2009; 99(9):1576-1583.
- [18] Choi BC, Pang T, Lin V, Puska P, Sherman G, Goddard M et al. Can scientists and policy makers work together? *Journal of Epidemiology and Community Health*. 2005;59(8):632-637.
- [19] Brownson RC, Royer C, Ewing R, McBride TD. Researchers and policymakers: travellers in parallel universes. *American Journal of Preventive Medicine*. 2006;30:164-172.
- [20] Lin V. Competing rationalities: evidenced-based health policy? In: Lin V, Gibson B, editors. Evidence-based health policy. Problems & possibilities. Melbourne: Oxford University Press; 2003. p. 3-30.

# 4. Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States

This article is an inventory of current regulatory approaches to obesity prevention, intended to provide researchers, policy-makers, and public health advocates with a comprehensive overview of the status quo. As outlined in Chapter 2, the dietary risk factors for obesity and associated chronic disease on which this thesis focuses are inextricably linked to the food production and distribution systems. Therefore, this work focuses on nutritional levers in the two principal markets of the Western industrialized world, the United States of America and the European Economic Area, with the latter comprised mostly of the European Union and its member states. The study investigates which types of interventions have been put into law and determines their respective prevalence across US and EAA jurisdictions. As the first piece of work undertaken in the framework of this PhD project, it provides the foundation for a subsequent case study of New York City regarding the policy processes involved in innovative use of the law for obesity prevention and a systematic review of the effects of regulatory interventions such as those identified here.

A postscript in section 4.4 briefly relates the findings presented here to complementary research published since the conclusion of the study.

The supplemental materials referred to in the article are available in appendix 1 (pp. 131-150).

### Statement of Authorship

Title of Paper	Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States					
Publication Status	✓ Published       ✓ Accepted for Publication         ✓ Submitted for Publication       ✓ Publication Style					
Publication Details	Sisnowski J, Handsley E, Street JM. Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States. <i>Health Policy</i> . 2015;119(6):720-731. doi:10.1016/j.healthpol.2015.04.013.					

#### **Principal Author**

Name of Principal Author (Candidate)	Jana Sisnowski
Contribution to the Paper	Designed the study and search strategy, performed the database searches, analysed the search results, drafted the manuscript, responded to reviewers, approved the final manuscript, acted as corresponding author.
Overall percentage (%)	80%
Signature	Date 11/01/2016

#### **Co-Author Contributions**

By signing the Statement of Authorship, each author certifies that:

- i. the candidate's stated contribution to the publication is accurate (as detailed above);
- ii, permission is granted for the candidate in include the publication in the thesis; and
- iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Elizabeth Handsley					
Contribution to the Paper	Provided comments on drafts of the manuscript, read and approved the final manuscript.					
Signature	Date 22/01/2016					

Name of Co-Author	Jackie Street
Contribution to the Paper	Contributed to the design of the overall research project within which this study was conducted, provided comments on drafts of the manuscript, read and approved the final manuscript.
Signature	Date 11. 1. 2016

ELSEVIER

Contents lists available at ScienceDirect

#### **Health Policy**

journal homepage: www.elsevier.com/locate/healthpol



Review

## Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States



Jana Sisnowski<sup>a,\*</sup>, Elizabeth Handsley<sup>b</sup>, Jackie M. Street<sup>a</sup>

- <sup>a</sup> School of Population Health, University of Adelaide, 178 North Terrace, Adelaide, SA 5005, Australia
- <sup>b</sup> School of Law, Flinders University, Bedford Park, SA 5042, Australia

#### ARTICLE INFO

Article history:
Received 4 July 2014
Received in revised form 13 April 2015
Accepted 21 April 2015

Keywords: Legislation as topic Prevention and control Nutrition policy Overweight Obesity

#### ABSTRACT

High prevalence of overweight and obesity remains a significant international public health problem. Law has been identified as a tool for obesity prevention and selected high-profile measures have been reported. However, the nature and extent of enacted legislation internationally are unclear. This research provides an overview of regulatory approaches enacted in the United States, the European Union, and EU Member States since 2004. To this end, relevant databases of primary and secondary legislation were systematically searched to identify and explore laws addressing dietary risk factors for obesity.

Across jurisdictions, current regulatory approaches to obesity prevention are limited in reach and scope. Target groups are rarely the general population, but instead sub-populations in government-supported settings. Consumer information provision is preferred over taxation and marketing restrictions other than the regulation of health and nutrition claims. In the EU in particular, product reformulation with industry consent has also emerged as a popular small-scale measure.

While consistent and widespread use of law is lacking, governments have employed a range of regulatory measures in the name of obesity prevention, indicating that there is, in principle, political will. Results from this study may serve as a starting point for future research and policy development.

© 2015 Elsevier Ireland Ltd. All rights reserved.

#### 1. Introduction

There is a broad consensus that overweight and obesity, recognized internationally as a health problem of "epidemic proportions" [1], are ultimately attributable to an energy imbalance where energy intake continuously exceeds energy expenditure. The idea of an obesogenic environment [2] identifies physical, economic, political,

and sociocultural environments as key factors adversely affecting both food intake and physical activity [3].

Empirical evidence points to increased energy intake as the main cause of widespread overweight and obesity [4,5], with caloric supply and intake having risen considerably in parallel with overweight and obesity prevalence [6,7]. Snack foods, sugar-sweetened beverages, and food consumed at fast food restaurants have been identified as some of the main sources for this trend [8,9] and several studies concluded that observed average excess energy intake is sufficient to account for all or most prevalence increases in the US [10,11] and Western OECD countries [12].

<sup>\*</sup> Corresponding author. Tel.: +61 883131689. E-mail address: jana.sisnowski@adelaide.edu.au (J. Sisnowski).

Changing consumption patterns have been attributed to shifts in the food system, including "increased supply of cheap, palatable, energy-dense foods; improved distribution systems to make food much more accessible and convenient; and more persuasive and pervasive food marketing" [13]. Although some scholars dispute the central role ascribed to food price changes [14,15], the consumption of refined grains, added sugars and fats has risen substantially [16] in parallel with real price decreases [17]. Marketing practices, including new product development and increased portion sizes [9,18], may also have changed both calorie supply and demand.

The importance of the wider societal and economic environment in shaping nutrition at population level implies a role for governments to intervene through laws aimed at creating health benefits [19]. In the US, states and local jurisdictions have emerged as leaders [20] in considering and implementing laws aimed at preventing obesity and improving population-wide nutrition [21]. Yet, policy analyses at state level reveal lawmakers' preference for measures that, while politically palatable, are limited in scope and execution [22–27].

Legislative measures elsewhere include Denmark's short-lived "fat tax" [28] and Hungary's "public health product fee" [29]. In general, these have been reported mostly anecdotally [30,31], albeit generating considerable interest from international media [32–35]. Less headlineworthy, more incremental policy changes receive little attention, making it difficult for policy-makers in other jurisdictions to discern trends and assess potentially transferable measures.

This paper provides a systematic overview of current regulatory approaches addressing the dietary causes of overweight and obesity in the European Union (EU) and its 28 Member States and at US federal level. The direction the world's two biggest economies [36] take on contentious policy issues such as the prevention of dietrelated chronic disease necessarily has a global signaling effect, especially to fellow OECD countries with close trade links and similar socioeconomic structures. Our intention is to provide researchers and policy-makers with a starting point for future enquiries into regulatory interventions to address dietary risk factors for overweight and obesity. The information presented here may form the basis for further research into the nature and implications of these approaches, inform political discussions around feasibility and acceptability of different regulatory options, and guide future policy development.

#### 2. Methods

#### 2.1. Terminology

Our approach engages two separate meanings for the term "regulation": one denoting subordinate or delegated legislation issued by the executive branch of government, and the other, popular meaning of "the act or process of controlling by rule or restriction" [37]. We restricted our search to regulatory measures that (1) limit or discourage excessive caloric intake and (2) are stipulated by law. This includes semi-mandatory regulation, such

as arrangements in which a legislature or government agency formally sets rules or approves rules drawn up by some combination of public and private bodies. These rules are mandatory for participants, while participation itself remains voluntary and enforcement arrangements vary. By contrast, purely self-regulatory schemes, statements of intent or desirability, and pilot programs are not within the scope of this definition.

#### 2.2. Search strategies

To identify relevant laws across jurisdictions, we searched appropriate government databases for primary and delegated legislation. In the absence of a database covering all 28 EU Member States, regulatory measures in the EU were identified through the Technical Regulations Information System (TRIS). TRIS collects notifications, in English, under Directive 98/34/EC: member states are required to notify all provisions related to agricultural and industrially manufactured products that could be considered barriers to the functioning of the internal market [38]. We also searched the WHO European Database on Nutrition. Obesity and Physical Activity (NOPA) as a complementary source. NOPA is a monitoring tool to which all members of the region are invited to contribute [39]. Some of the data submitted, notably policy documents and legislative and regulatory pieces, are made publicly available in their original language alongside a short summary in English. However, EU funding to maintain the database ran out in 2013 and updates for 2013 were incomplete due to staff shortages [personal communication February 2014].

All searches were conducted in English for the years 2004–2013. The earlier search limit coincides with the 2004 Global Strategy on Diet, Physical Activity and Health, which indicated an emerging international consensus on the need to tackle adverse health outcomes associated with energy-dense, nutrient-poor diets [40].

We derived search terms from the five nutrition-related functions of law identified by Gostin, namely: (1) enforcement of disclosure through labeling requirements, (2) regulation of food marketing, (3) taxation, (4) school and workplace policies and (5) prohibition of certain foods or food components [41]. We refined and complemented these terms using relevant Medical Subject Headings and subheadings. Finally, we adjusted our search terms to encompass those sectors and settings for government intervention suggested by Magnusson, including "primary production, manufacture, retail, catering and advertising of food" [42]. Table 1 details the final search strategy.

#### 2.3. Eligibility criteria

Results were assessed for relevance based on title and, where available, category/subject matter and summary/abstract. Accompanying statements of grounds submitted through TRIS were also used to establish relevance. We excluded policy areas representing distal factors without direct bearing on caloric intake such as laws relating to agricultural subsidies, state aid to food producers, and government intervention in agricultural markets, including all provisions related to trade such as

**Table 1** Databases and search strategies.

Jurisdiction	Database	Search strategy		
European Union European Union Member States	Technical Regulations Information System (TRIS) WHO European Database on Nutrition, Obesity and physical	((TI~ ((obes* OR overweight OR nutrition* OR sugar* OR fat* OR label*OR calori* OR food* OR lunch OR breakfast OR snack* OR drink* OR beverage* OR vending) OR ((nutrition* OR sugar* OR fat* OR label*OR calori* OR food* OR lunch OR breakfast OR snack* OR drink* OR beverage*) AND tax))) OR (TE~ ((obes* OR overweight OR nutrition* OR sugar* OR fat* OR label* OR calori* OR food* OR lunch O breakfast OR snack* OR drink* OR beverage*) AND tax))) AND OR ((nutrition* OR sugar* OR fat* OR label* OR calori* OR food* OR lunch OR breakfast OR snack* OR drink* OR beverage*) AND tax)))) AND Date_of_document >= 01/01/2004 <= 31/12/2013 AND DTS_SUBDOM = LEGISLATION, Search language: English Single keyword searches for the years 2004–2013, conducted separately for title and text, by year where results exceeded the maximum number of hits Search combining country (28 current EU MS+Iceland, Norway, Switzerland), topic (nutrition-related and obesity-related), and years (2004–2013)		
United States	activity (NOPA)			
Congressional legislation	THOMAS (Library of Congress)	Advanced bill text search by word(s)/phrase; include variants applied: obesity + overweight + nutrition + sugar + fat + label + labeling + calorie + food + diet + lunch + breakfast + snack + drink + beverage + vending Limitations: 108th Congress (2004 only) to 113th Congress (2013 only), enrolled bills only		
Federal regulation	Federal Register (US Government Printing Office)	Advanced search, restricted to 'rules and regulations' and "presidentia documents' for executive orders overweight OR nutrition OR sugar OR fat OR label OR labeling OR calorie OR food OR diet OR lunch OR breakfast OR snack OR drink OR beverage OR vending		

tariffs, trade agreements, quotas, licenses, and refunds. These limitations in the name of study focus and feasibility notwithstanding, we note evidence that low prices of commodities such as sugar, milk, and certain crops have facilitated the trend toward excess consumption of high calorie foods and beverages [16,43]. However, considering the deeply entrenched economic and structural interests behind agricultural subsidies and the uncertain price response to agricultural policy changes [43], levers closer to the end-consumer seem currently more promising from a policy and health impact perspective. Specific provisions to supply or subsidize commodities for large sub-populations tied to agricultural subsidies were therefore retained in recognition of their direct impact on caloric intake.

Regulatory measures relating exclusively to trans-fats or sodium/salt content were excluded, as both are independently linked to chronic disease without obesity as a necessary mediating risk factor [44,45]. Items pertaining primarily to food safety, standardization, or quality control, rather than reduction of caloric intake, were included only where obesity-related grounds were evident from the legal text or statement of grounds.

#### 3. Results

The majority of search results fall into just two of the five categories of Gostin's functions of law, namely consumer information through labeling requirements and school and other setting- or program-specific nutrition policies. Two

further fields of legal activity are only partially represented: firstly, marketing restrictions are often semi-regulatory in nature and mostly designed to protect children. Marketing directed at the general population is mainly regulated through limiting the health and nutrition claims allowed on foodstuffs. These regulations do not necessarily engage weight-related health concerns. Secondly, rather than prohibiting certain foods or ingredients, more limited food reformulation has been the preferred approach and, along with taxation, direct regulation of food marketing is rarely found. In addition, instead of definite patterns, the results show a wide geographical spread of activities across all categories. No jurisdiction has comprehensively targeted all areas and no clear role model becomes apparent. However, in combination with EU law applicable to all Member States and associated countries, a concentration of the most numerous and potentially most consequential activities can be observed in France, the UK, and several Scandinavian countries.

The following section reviews the most important laws identified according to the broad categories of intervention described above. Where additional references are given in brackets, the law in question is invoked only for comparative purposes. For a quick overview of actors and interventions, Table 2 provides a simplified summary of the results by jurisdiction and category. Full search results are provided online. Since our search extended only to December 2013, key developments that occurred during the analysis stage of this research, in the first half of 2014, are addressed in Section 5 (Methodological Limitations).

**Table 2** Jurisdictional activities by interventional category (2004–2013, based on search results).

Jurisdiction	Nutrition labeling		Food marketing		Food standards		Product reformulation	Taxation
	Informative	Interpretative	Advertising	Health claims	Institutions	Programs		
European Union	<b>√</b>			<b>√</b>		√	$\checkmark$	
Austria								
Belgium			$\checkmark$					
Bulgaria								
Czech Republic								
Croatia								
Cyprus								
Denmark		<b>√</b> *						(√)
Estonia					$\checkmark$			
Finland								
France			$\checkmark$		$\checkmark$		$\checkmark$	$\checkmark$
Germany							$\checkmark$	
Greece				$\checkmark$				
Hungary					$\checkmark$			$\checkmark$
Iceland		<b>√</b> *	$\checkmark$	$\checkmark$				
Ireland								
Italy							$\checkmark$	
Latvia				$\checkmark$				
Lithuania								
Luxembourg								
Malta								
Netherlands		√*					$\checkmark$	
Norway		√*	√*					
Poland					$\checkmark$			
Portugal								
Romania					$\checkmark$			
Slovakia								
Slovenia					$\checkmark$			
Spain							$\checkmark$	
Sweden		<b>√</b> *						
Switzerland								
United Kingdom		<b>√</b> *			$\checkmark$			
United States	$\checkmark$			$\checkmark$	$\checkmark$	$\checkmark$		

Brackets indicate repealed laws and asterisks denote semi-mandatory regulations. Note that all EU laws apply in EU and EEA Member States in addition to any individual country-level laws. This table summarizes the search results and therefore does not include missing data discussed in Section 5 (Methodological Limitations).

#### 3.1. European Union

EU law provides a broad framework of dietary intakerelated laws that directly contribute to and/or could more explicitly be adapted for obesity prevention. Union lawmaking has the potential to both constrain and enable additional obesity prevention efforts in individual Member States.

#### 3.1.1. Consumer information through nutrition labeling

With Regulation 1169/2011/EU on the Provision of Food Information to Consumers, the Union introduced a mandatory standardized presentation and content format for nutrition labeling with application obligatory from December 2016. Until then, nutrition labeling remains voluntary at EU-level unless nutrition-related health claims are made (Directive 90/496/EEC, OJ L 276, 6.10.1990, p. 40). For all packaged and most unpackaged foods, operators have the choice between indicating only energy value or energy value and total fat, saturated fat, sugars, and salt in the "principal field of vision". A full nutrition declaration has to be provided in any field of vision for prepackaged foods: energy value and fat, sugar, and salt content must be expressed per 100 ml or 100 g and may additionally be indicated per portion or per Guideline Daily Amount (GDA)

percentage. The same applies to the declaration of energy value in the principal field of vision, while the optional four nutrients may be added in one of the three forms depending on how total energy value is expressed. The Regulation also mandates that GDA expression needs to supply a reference to overall daily adult reference intake of 8400 kJ/2000 kcal.

#### 3.1.2. Marketing

Marketing practices are constrained by rules imposed on the use of health and nutrition claims, complemented by requirements for clear consumer information in related fields such as food additives. The use of diet-related claims of beneficial nutritional or physiological effects is regulated by Regulation 1924/2006/EC on Nutrition and Health Claims Made on Food. It provides the legal basis for a Union claims register.

The recitals recognize the concern that claims may "mask the overall nutritional status of a food product, which could mislead consumers when trying to make healthy choices". As a result, the Regulation mandates the imposition of minimum conditions for the use of claims based on the overall nutritional profiles of food-stuffs or categories thereof. It also mandates that claims incorporate an accompanying statement "indicating the importance of a varied and balanced diet and a healthy

lifestyle". The legislation set a deadline of January 2009 for the Commission to establish these general minimum nutritional value requirements, but this had not eventuated by the end of the study period. The impact of this may be observed in a 2013 decision (Commission Regulation 1018/2013/EC) in response to Member State concerns over sending a "conflicting and confusing message to consumers, particularly in light of national dietary advice to reduce sugars consumption". The claim "carbohydrates contribute to the maintenance of normal brain function" was allowed only under restricted conditions, including a limitation of eligibility to products that also meet the "low sugars" or "no added sugars" claims. Similarly, Commission Regulation 1047/2012/EC changed the conditions for the claims "reduced saturated fat" and "reduced sugars" in order to prevent reformulation running counter to regulators' intentions. Industry had previously responded to the regulation by replacing saturated fats with trans-fats and sugar with fat. The regulator reacted by mandating that the sum of saturated fats and trans-fats be 30% below, and trans-fat content similar to, comparable products to qualify for "reduced saturated fat" status. Similarly, the calorie value of "reduced sugars" products is now required to be equal or below that of comparable products.

Consumer understanding of overall nutritional value is also a concern for legislation regulating other aspects of food composition: *Regulation1925/2006/EC on the Addition of Vitamins and Minerals to Foods*, for instance, expresses concern that consumers not be misled about the "nutritional merit of a food". The legislation provides for the exclusion of certain foods in addition to requiring compulsory nutritional labeling under an exemption from the still applicable voluntary scheme.

#### 3.1.3. Food reformulation

Regulation 1333/2008/EC on Food Additives represents an example of regulatory action making small inroads into calorie reduction: it is the legislative basis for a suite of Commission regulations approving food additives with explicit references to obesity-related grounds such as "the need for new products which are energy-reduced to be placed on the market" or otherwise enabling and facilitating the manufacture of products with lower caloric value (e.g. Commission Regulations 913/2013/EU, No 723/2013/EU, No 1049/2012/EU).

In an instance of directly imposed reformulation, *Directive 2012/12/EU relating to Fruit Juices* prohibits the use of added sugar in fruit juices and bans the claim 'with no added sugars'. It may be replaced with the interim message "from 28 April 2015 no fruit juices contain added sugars". Rather than forcing manufacturers to reduce sugar content, the "new directive incorporates the current industry practice" [46].

#### 3.1.4. Setting-specific nutritional standards

The European Union's regulation of the nutritional content of its food programs, which include a long-running School Milk Scheme, a School Fruit Scheme and an EU food distribution program, is uneven.

The two school programs have their current legal basis in Regulation 1308/2013/EU, known as the Single Common

Market Organization (CMO) Regulation. Its predecessor, the 2007 Single CMO Regulation, made no mention of noneconomic motivations for the supply of school milk, but new implementing rules set in 2008 (Commission Regulation 657/2008/EC) invoke the "fight against obesity". They also cite "existing health and nutritional tendencies" as the reason for including a wider range of milk-based products, including flavored milk with up to 7% added sugar, a limit not previously specified. The rules applying prior to the overhaul had been last revised in 2007 to end reimbursement rates favoring full-fat over reduced-fat milk (Commission Regulation 1544/2007/EC). By contrast, Council Regulation 13/2009/EC which added the School Fruit Scheme indicated a nutritionally more stringent approach by excluding from EU co-financing "unhealthy products", defined in the implementing rules as any products containing added sugar, fat, salt, or sweeteners. The new Single CMO Regulation frames both school programs in language combining the economic motivations of the Common Agricultural Policy (CAP) in "stabilizing markets" with promoting "healthy eating habits".

In contrast to the emergence of explicit health concerns in the school programs, the re-orientation of the EU food distribution toward nutritional content has been more subtle. The scheme was initially exclusively based on surplus food from intervention stocks (Council Regulation 3730/87/ECC, OJ L 352, 15.12.1987, p. 1.) but was separated out of the CAP and transformed into a primarily market purchase-based program with Regulation 121/2012/EU regarding Distribution of Food Products to the most Deprived Persons in the Union. This allows greater flexibility in regulating nutritional content of national food programs, with Member States mandated to "choose the food products on the basis of objective criteria including nutritional values".

#### 3.1.5. Regulatory measures targeting the management of obesity

In addition to primary preventive regulatory measures, several measures could be considered geared toward secondary and tertiary prevention, i.e. reduction or stabilization of overweight or non-medical treatment of obesity. *Regulation 609/2013/EU* incorporates changes introduced by the Claims Regulation which allows claims referring to a "reduction of hunger" or an "increase of the sense of satiety", but maintains the original prohibition of references to the rate or amount of weight loss. Since it came into force, numerous applications related to weight loss have been rejected under its provisions (e.g. Commission Regulations 432/2011/EU, 383/2010/EU, 984/2009/EC).

#### 3.2. EU Member States

Member States and additional European Free Trade Association (EFTA) members have considered, implemented, and at times revoked an array of regulatory approaches. In the areas of nutrition information and food reformulation in particular, the supremacy of Union law restricts the maneuvering space for Member States, but additional policies with regulatory character have nevertheless been developed.

#### 3.2.1. Consumer information through nutrition labeling

The EU Food Information to Consumers Regulation, described in Section 3.1.1, continues to restrict additional nutrition labeling at Member State level to voluntary participation schemes. Six countries, Denmark, Iceland, the Netherlands, Norway, Sweden, and the UK, notified semimandatory schemes in which the respective jurisdictions set labeling format and conditions of use.

The most widely adopted is a Nordic nutrition labeling scheme which uses a keyhole symbol to identify healthier choices. Eligibility is determined by a system of cut-off points for maximum fat, sugar, and salt and minimum dietary fiber. Adjustments to the scheme in the last 10 years have seen it jointly adopted by Sweden (2008/444/S), Denmark (2008/440/DK), and EFTA members Norway (2008/9024/N) and Iceland (2012/9008/IS). Denmark has since notified the extension of the labeling system to the certification of catering establishments and for use on recipes (2011/314/DK).

The Netherlands approved a new industry-owned and administered food choice logo and the accompanying nutritional criteria for its use. The logo consists of a green tick mark reading "healthier choice within this product group" for basic foodstuffs and a blue tick mark reading "conscious choice within this product group" for foodstuffs defined as non-basic (2012/414/NL).

The most comprehensive semi-mandatory nutrition labeling system in force was notified in 2006 when the UK was still weighing the respective advantages of different "Voluntary Front of Pack Signpost Nutrition Labelling Systems" (2006/38/UK). Eventually launched in 2013 [47], it provides for the green, amber, and red coding of nutrient values which are subject to separate per 100 ml/g criteria for total fat, saturated fats, sugars, and salt in foodstuffs and beverages. The red categories additionally specify overriding per portion cut-off points.

#### 3.2.2. Marketing

Few statutory regulations address marketing practices for unhealthy food, but Norway recently notified a proposed ban on the marketing of such foods to children (2013/9005/N) with the express purpose "to promote health by preventing obesity and diet-related diseases in the population". The criteria intended to determine whether marketing is directed at children employ the term "may particularly appeal to children", indicating that marketing does not have to exclusively target children to come within scope. Crucially, the proposal establishes a clear definition of what constitutes "energy-dense, salty, sweet or nutrient-poor foods": for instance, fast food may not exceed 225 kcal/950 kJ of energy or 4 g of saturated per 100 g of ready-to-eat product. Additional laws with direct reference to the marketing of unhealthy food and beverages were filed in the NOPA database: from Belgium comes a Decree of the Flemish Government to add specific provisions on advertising and sponsorship aimed at children and young people to the code for advertising and sponsorship on radio and television and from Iceland the 2011 Media Law. The Icelandic law stipulates that "in commercial communications and teleshopping it shall be prohibited to [...] encourage minors to consume foods and beverages containing nutrients and substances with a nutritional and physiological effect, excessive intakes of which in the overall diet are not recommended, in particular fat, trans-fatty acids, salt/sodium and sugars". However, neither regulation contains a full definition of these categories.

At the intersection of labeling and marketing sits France's requirement for health messages to accompany advertising of items "containing added sugar, salt or synthetic sweeteners or manufactured foodstuffs" (2004/329/F). The messages, with separate messages for infant and toddler foods and marketing directed at children, advise healthy eating and exercise, for example, "Stay healthy: avoid eating too much fat, sugar and salt" (2006/480/F). Non-compliant advertisers are taxed 1.5% of their annual marketing budget, benefiting the National Institute for Prevention and Health Education.

#### 3.2.3. Setting-specific nutritional standards

Four countries, the UK, Poland, France, and Hungary, have notified laws to TRIS regulating the school food environment

The UK introduced mandatory nutrition standards for school food in England (2007/226/UK), Scotland (2008/32/UK) and Wales (2013/76/UK): all three prescribe rules for the composition and nutritional content of school lunches, including total daily energy value as well as minimum and maximum values for key nutrients. Requirements for foods provided outside school lunches are also specified.

Poland (2012/637/PL, 2013/509/PL) banned the distribution, sale, and on-premises marketing of certain high-sugar foods and beverages in educational institutions.

In France, three regulations establish general frameworks on the nutritional quality of school food (2010/758/F 2010/697/F) and food served in universities, prisons and childcare, healthcare, social and socio-medical establishments (2011/564/F). All three regulate meal component content and frequency with the goal of reducing sugar and fat. The 2004 Health Law that introduced the legal basis for mandatory health promoting messages to accompany advertising for unhealthy foods and beverages also stipulated a ban on vending machines carrying the same categories of items in French schools from September 2005.

Meanwhile, Hungary (2005/475/HU) mandates that institution directors obtain the endorsement of the school health service prior to allowing vending machines or food retailing on their premises.

Another three laws addressing the school food environment were submitted to NOPA: according to WHO's content analysis of the legal texts in their original language, Romania's Ministerial Order No. 1563 approves a list of foods that are banned from preschools and schools. Slovenia's 2013 Law on School Nutrition prohibits vending machines in primary schools and Estonia's Regulation on Health Protection Requirements for Catering Facilities specifies that school lunches are to cover 30–35% of daily energy and nutrient needs in schools and 85–90% in kindergartens.

#### 3.2.4. Food reformulation

Food reformulation, aimed at reducing added sugar and to a lesser extent reducing fat, has been a major focus of notified activities, but the scope has been limited. For instance, between 2007 and 2013, four exemptions from EU law were filed to allow lower than standardized sugar content in jams and jellies, some with the explicit goal to prevent "obesity by promoting healthy eating" (2008/107/D) and "as part of the fight against obesity" (2008/218/F). However, it is made very clear that the adjustment was following industry wishes: Germany explains that the regulation follows established manufacturing practice, France refers to "market trends" and the UK claims "to provide manufacturers with freedom and flexibility and to avoid stifling innovation" (2013/649/UK).

Under the title "Urgent measures to promote the country's development through a higher level of health protection" (2012/559/I), Italy notified a mandatory increase in the percentage of fruit juice contained in certain beverages from 12% to 20%. The accompanying notification invokes a "broader strategy, aimed at reducing inappropriate behaviour and promoting healthy eating, together with legislation aimed at providing incentives for the industry to produce food products with reduced fat and sugar content, regulate commercial promotion aimed at young children and ensure healthy food", none of which have been the subject of a notification from Italy in the time period under review.

Citing "current consumer trends, leaning towards the purchase of products that adhere to scientific nutritional recommendations", Spain submitted two Royal Decrees on revised quality standards for a variety of bakery products, confectionery and sweets (2009/589/E, 2010/187/E) that allow reformulation towards reduced sugar and fat content.

The Netherlands also submitted a proposal to set the maximum fat content of lean minced meat "in such a way that a contribution is made towards preventing excess weight and reducing the intake of saturated fats" (2007/34/NL).

#### 3.2.5. Taxation

Only three countries notified far-reaching legislation intended to change food purchasing behaviors in the general population. France established an indexed tax of €7.16 per hectoliter on sugary drinks and drinks containing artificial sweeteners (2011/597/F) to "increase the price of sugary drinks, the uncontrolled consumption of which encourages weight gain, in order to encourage consumers to drink them less".

Hungary's "public health product fee" (2011/340/HU) expressly aims to reduce "the domestic consumption of products involving health risks", while "creating a new budgetary resource for the financing of public health services". The legislation established categories of prepackaged foods and beverages taxable if they exceed certain added sugar, caffeine, or salt thresholds. The original tax rates were subsequently increased, certain product categories broadened and new ones added (2011/599/HU, 2013/622/HU).

Denmark imposed, and subsequently abolished, an excise tax based on saturated fat content (2011/19/DK) and permanently shelved a similar proposal based on sugar content (2011/651/DK). In parallel to the reasoning in Hungary, the twofold objective of the laws was to "benefit the health of the population and to acquire funding for targeted public expenditure". It was intended that the sugar tax would increase existing chocolate and ice cream duties by 25% and 50%, respectively. The fat tax imposed a levy per kilogram of saturated fat on a range of foodstuffs, including meat, dairy, oils and fats, if they exceeded the saturated fat threshold.

#### 3.3. United States

A major US focus has been federally assisted nutrition programs. Changes to the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and schemes targeting child nutrition dominate American regulatory obesity prevention efforts. In the time period under review, no law mandating food reformulation appears to have been enacted. Similarly, the search did not find any new federal provisions restricting food marketing practices or taxing unhealthy foods and beverages. This may indicate an absence of such laws or a lack of updates of laws possibly enacted prior to the search period. However, a suite of new rules has been proposed in 2014, i.e. outside the search limit, that would overhaul nutrition labeling and continue to implement statutory provisions of previously enacted congressional legislation regarding nutrition standards in federally assisted programs. These items feature briefly in Section 4.

#### 3.3.1. Consumer information through nutrition labeling

Provisions in the 2010 Patient Protection and Affordable Care Act make nutrition labeling mandatory country-wide for standard menu items offered in chain restaurants with 20 or more locations. On menus and menu boards, total calorie value per item must be indicated and a statement regarding recommended average daily caloric intake must be prominently displayed. Per item calorie value disclosure also applies to operators owning more than 20 vending machines and to restaurant items not displayed on a menu or menu board.

#### 3.3.2. Marketing

Similar to the EU, US marketing practices are addressed by regulation of health and nutrition claims, primarily in relation to specific product categories such as meat (e.g. Final Rules 75FR82147, 70FR33803).

#### 3.3.3. Nutrition standards

The 2010 Healthy, Hunger-Free Kids Act includes Title II Reducing Childhood Obesity and improving the diets of children, mandating changes to school food and food assistance programs. The act provides an update of meal patterns and nutrition standards for the long running, federally legislated school lunch and school breakfast programs based on National Academy of Sciences recommendations. This mandate has been carried out by Final Rule 77FR4088

which sets calorie ranges and saturated fat and sodium limits. In addition to these nutrient requirements, new meal patterns are also prescribed and include fruit, grains, meat or meat substitutes, and milk as mandatory food components. Food type specifications also differ from previous standards in that five different sub-groups of vegetables need to be served and all grains have to be 51% whole grain. Final Rule 77FR4088 also changes previous provisions (2004 Child Nutrition and WIC Reauthorization Act) with regard to beverages accompanying school meals from allowing a variety of milk to only fat-free milk or unflavored low-fat milk.

Further the 2010 Act requires that all additional foods sold in schools ("competitive foods") meet Dietary Guideline-consistent standards to be established through regulatory action. Interim Final Rule 78FR39067 implements this provision: it sets nutrient requirements, including absolute calorie limits as well as relative maximums for total fat, saturated fat, and sugar. In addition, all foods must fall into one of three categories, namely be a "whole grain-rich" product, contain a defined amount of fruit and/or vegetables, have fruit, vegetables, dairy or protein as its first ingredient; or until 2016 may qualify by virtue of high calcium, potassium, vitamin D, or dietary fiber content. Beverages other than milk are restricted to drinking water or non-sweetened juice, with the exception of high schools where beverages meeting certain definitions of "calorie-free" are allowed. Age-dependent maximum portion sizes are specified for all beverages except water.

In addition to the above, the 2008 Food, Conservation and Energy Act or Farm Bill, made permanent a new school-based Fresh Fruit and Vegetable Program that had previously been trialed.

Child nutrition outside the school setting is addressed in the framework of the Child and Adult Care Food Program (CACFP) and the WIC. The 2010 Healthy, Hunger-Free Kids Act makes changes to both programs: meals and snacks served in care homes and institutions under the CACFP must be Dietary Guideline-complaint and "promote the health of the population served by the program [...] as indicated by the most recent relevant nutrition science" (Subtitle B, Sec. 221, 2(g)B(i)). Nutrition requirements are to be reviewed at least every 10 years. Similar to the school programs, milk needs to meet Dietary Guideline-consistent and drinking water must be provided. In addition to the mandatory nutrition standards that have yet to be established by regulatory action, the legislation calls for guidance to be issued to "states and institutions [...] to encourage [...] foods that are recommended for increased serving consumption" (Subtitle B, Sec. 221, 3(B)(u)(3)(B)(i)) such as fruits and vegetables, whole grain products and low-fat meat and dairy products.

Meanwhile, the supplemental foods provided to eligible mothers and young children through the WIC program are also required to be reviewed at least every 10 years. The 2004 Child Nutrition and WIC Reauthorization Act required that the foods made available under the scheme be updated after a review by the Institute of Medicine. Interim Rule 72FR68966, applicable from 2009, implements this mandate.

The nutritional status of another vulnerable group, older persons, is targeted by Final Rule 71FR74618 which implements previous statutory provisions to make permanent the Senior Farmers' Market Nutrition Program, modeled after a similar program under WIC.

At the general population level, the Supplemental Nutrition Assistance Program (SNAP), formerly known as food stamps, has its current legal basis in the 2008 Food and Nutrition Act and was re-authorized most recently during the search period by the 2008 Farm Bill. It exhibits the same range of purposes as the EU's most recent food assistance program, claiming "to strengthen the agricultural economy; to help to achieve a fuller and more effective use of food abundances; [and] to provide for improved levels of nutrition among low-income households". SNAP does not appear to consider nutritional value since "any food or food product for home consumption except alcoholic beverages, tobacco, and hot foods or hot food products ready for immediate consumption" is covered.

#### 4. Discussion

The current regulatory approaches most prevalent in the EU and US are generally limited in reach and scope. Target groups are often not the general population, but subpopulations in settings where the government can claim responsibility for the health of these populations during the time they spend under its care. Regulatory changes addressed to the food manufacturing industry were mainly confined to one product type, frequently incorporating already-existing practice or industry requests. Although health concerns are often invoked, they do not appear to take precedence over industry interests and broad claims of a contribution to obesity prevention sit oddly with the very limited scope of reformulation. An overarching concern for the economic bottom line may also be inferred from the fact that, rather than targeting consumption levels or patterns, reformulation may operate unbeknown to consumers unless industry qualifies for and considers advantageous the use of health or nutrition claims. Nonetheless, the frequency of limited reformulation efforts in the EU and the language used in accompanying policy statements reflect government attraction to these comparatively non-contentious approaches and possibly increasing industry acquiescence in an attempt to prevent more sweeping legislation, such as taxation. It is unlikely decision-makers would be attracted to more far-reaching, population-wide measures without clear evidence of success, but with Denmark's fat tax discontinued after just 1 year and Hungary's "public health product fee" only introduced in 2011, there has been little time for incremental health effects to accumulate and become practically signif-

Overall, the patterns described above appear consistent with trends gauged from more in depth studies at US state level where subject matter and associated political palatability seem instrumental in predicting the introduction and adoption of legislation. A study examining enactment of US state legislation addressing childhood obesity found that bills on school nutrition were the most frequently proposed measure, while other specific

nutrition-related topic areas such as soda and snack taxes and menu and nutrition labeling were introduced less often and not enacted once in the period under review [22]. A follow-up study observed a positive association of relatively uncontroversial and inconsequential content (such as walking/biking trails, model school policies and studies or task forces) with bill adoption [23]. It also demonstrated a positive association between enactment and variables hinting at political palatability such as multiple sponsors or bipartisanship, and a negative association with variables indicating significant policy change such as new laws and laws generating revenue, which are similarly the types of laws least frequently observed in the EU and at US federal level. Likewise, a study of population-wide obesity legislation by setting found that most proposed legislation related to schools, with initiatives applying community-wide proposed and enacted much less often [26].

The reluctance of policy-makers to intervene on economically significant matters underlines the importance of new regulatory possibilities at subsidiary levels. Yet, the European Food Information to Consumers Regulation may serve as an example of higher order law limiting national obesity prevention efforts. During the legislative process, concrete opportunities to complement the display of nutritional data with more explicit promotion of healthy nutrition were foregone: several amendments explicitly allowing additional mandatory nutrition labeling at Member State level, including color schemes such as traffic light labeling, were defeated in the European Parliament [48]. As a result, unless action is taken at Union level, semi-mandatory labeling regulation, combining voluntary participation with government-set or -approved mandatory rules, will remain the most stringent standard possible across the EU. Moreover, the European Parliament also passed rigid criteria to be met by voluntary participation schemes at Member State-level. Unlike Nordic and Dutch labeling which positively highlights overall nutritional value and is presented as a broad nationally based nutrition claim in accordance with the Claims Regulation. the UK scheme positively and negatively judges nutrient content, a differentiation that is not foreseen by the Claims Regulation. The newest technical guidance issued in June 2013 explains that the colors in that scheme do not represent claims, but a form of additional expression under the Food Information to Consumers Regulation [47]. Since then, the scheme has been the subject of at least two critical parliamentary questions in the European Parliament [49,50] and several protest notes by Italy to the Council of the European Union [51] questioning the scheme's compliance with the regulation, particularly the provisions that additional schemes be "objective and non-discriminatory; and their application does not create obstacles to the free movement of goods". While the Commission maintains that the scheme appears to be within the scope of the regulation [52–54], the current dispute foreshadows the clash between public health concerns and vested economic interests that is likely to define the Commission review of potential harmonization of additional labeling in 2017 and any Member State action in the meantime.

#### 5. Methodological limitations

Although we designed our search strategies to maximize comprehensiveness, the overview in this article is not exhaustive. The purposely broad search terms take into account the challenge of locating mandatory provisions that are not explicitly acknowledged as related to obesity prevention, yet this breadth resulted in several thousand hits per database which could only be scanned for relevance rather than examining full text. Minor provisions embedded in major or omnibus-style pieces of legislation or regulation might therefore be underreported.

In addition, systematic searches at EU Member Statelevel present their own set of difficulties in the absence of a common legal database. Despite being rooted in a legal obligation, TRIS contains only measures that countries deem relevant for submission and NOPA contributions are entirely voluntary: one such relevant intervention that has not been notified, but was identified from the literature [31], is Finland's recent excise duties on sweets and ice cream and increased soft drink tax rate [55,56]. More generally, consistent notification to TRIS in areas such as school food regulation and regulation of marketing to children may be lacking: school nutrition policies only concern a small market segment and most advertising regulations have co-regulatory character at best rather than representing full statutory regulation required for inclusion in this study. Conversely, these two areas have attracted the interest of supranational institutions as relatively uncontroversial, provided they are directed at the protection of minors. Two recent in-depth reports by the European Commission [57] and WHO-Euro [58] are available to complement the necessarily limited findings presented in this study: the EU report shows that, while mandatory interventions have indeed been undernotified, half of all national school food polices do not set any mandatory standards. Similarly, the WHO report confirms our findings that statutory regulation of food and beverage advertising, even to children, is a rare occurrence in Europe. WHO concludes that "the majority of the EU countries rely on general advertising regulations, which do not specifically address the promotion of HFSS food and beverage products to children, and on self-regulatory mechanisms which may or may not include specific controls to limit the promotion of such products to children", with additional statutory provisions specific to nutrition found only in Ireland. [58] Even approaches that scale back the degree of government coercion further than the at least semi-mandatory regulations covered in this paper are rare, despite appearing more politically feasible. A unique case falling somewhere between semi-mandatory and entirely self-regulated is the UK's linking of the industry-written and enforced, non-statutory BCAP code [§32.5, 59] to statutory instruments, overseen by communications regulator Ofcom. These institute a ban on the advertisement in or adjacent to programming directed at children of foods and beverages deemed unhealthy based on a score-based nutrient profiling scheme [60,61].

Considering that TRIS submissions occur at advanced draft stages, it is also impossible to follow up on implementation details and possible subsequent repeal unless these

are also notified. For instance, the cancelation of Denmark's fat tax has been widely reported [33,34] and it appears that Norway chose to trial an industry-led, self-regulatory regime on food advertising for children for at least the next 2 years despite notifying its draft law to the EU in 2013 [62].

Our search method also could not take into account regulatory developments that have not yet reached approval stage, or that were discarded or defeated during the legislative or administrative decision-making process. In the first quarter of 2014, US executive agencies initiated a suite of regulations that are much more far-reaching than previous initiatives at federal level. Among these are the revision of the Nutrition and Supplement Facts Labels and the overhaul of one-sitting serving sizes, published as proposed rules in March 2014 (79FR11879, 79FR11989). Also on the official regulatory agenda (79FR895) are a proposed rule regarding meal pattern revisions for the Child and Adult Care Food Program and the finalization of regulatory provisions updating the nutritional content of WIC food packages and implementing the Affordable Care Act menu labeling requirements.

Finally, as mentioned in Section 1, the geographical and jurisdictional scope of this paper is necessarily limited. For instance, the number of municipalities and similar administrative units across Europe and the United States is simply too large and their governments too diverse linguistically and legally to allow for systematic examination. Nonetheless, various levels of government from municipalities to sovereign states, individually or cooperatively, are currently involved in obesity prevention. A number of local governments such a New York City under Mayor Michael Bloomberg and a few Californian municipalities have emerged as trailblazers in enacting innovative laws aimed at reducing calorie intake. New York policies include the first instance of menu labeling in chain restaurants, an attempted portion size cap on soda sold in a range of food service establishments, and the successful introduction of nutrition standards for city procurement [63-65]. Berkeley voters made headlines when they approved the first 1-cent-an-ounce tax on soft drinks in the US in November 2014 [66] and zoning laws, often within the remit of local government, have been employed, among others, to keep fast food chains at least 500 feet from schools in Detroit and to ban chain restaurants from certain areas in several Californian municipalities [67]. At the same time, industry has successfully subverted other initiatives such as San Francisco's attempt to ban toy incentives from kid's meals has been circumvented by McDonald's charging a separate 10 cents passed on to the company charity [68].

#### 6. Conclusion

This overview of current laws and regulations indicates that a range of strategies to reduce caloric intake at the population level have been considered and implemented. At the aggregate level, most broad areas of intervention proposed in the academic literature have been tackled in at least one jurisdiction. However, few countries have built a comprehensive obesity prevention regime of multiple, complementary measures spanning different sectors and settings. The ultimate goal from a public health perspective,

the reduction of average caloric intake and a resulting decrease of obesity prevalence, will require patience on the part of policy-makers and action in the face of incomplete knowledge of implementation results. Nonetheless, knowing what measures have been undertaken elsewhere allows researchers and policy-makers to study potential exemplars with a view to emulating successful policies and improving or combining existing approaches to increase overall effectiveness in preventing obesity.

#### Conflict of interest

The authors have no conflicts of interest.

#### **Authors' contributions**

JMS contributed to the design of the overall research project within which this study was conducted. JS designed the research strategy, performed the database searches completed the first draft of the paper. JMS and EH provided comments on drafts of the manuscript which JS incorporated following discussion. All authors reviewed and approved the final version.

#### Acknowledgements

The authors would like to gratefully acknowledge the *HealthyLaws* research team for their valuable advice at all stages of the project.

This project was conducted as part of the study *Healthy-Laws – Public Perspectives in Public Health Law*, funded by the Australian National Preventive Health Agency (ANPHA), project ID: 182BRA2011. ANPHA had no role in the study design; the collection, analysis, and interpretation of data; or the writing of the manuscript. JMS is also supported by an NHMRC Capacity Building Grant (565501) and holds an Australian National Preventive Health Agency Fellowship (20STR2013F).

#### Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.healthpol.2015.04.013.

#### References

- United Nations. Political declaration of the high-level meeting of the general assembly on the prevention and control of noncommunicable diseases. New York: UN; 2009.
- [2] Egger G, Swinburn B. An" ecological" approach to the obesity pandemic. BMJ 1997;315(7106):477.
- [3] Swinburn B, Egger G, Raza F. Dissecting obesogenic environments: the development and application of a framework for identifying and prioritizing environmental interventions for obesity. Preventive Medicine 1999:29:563–70.
- [4] Swinburn B, Sacks G, Ravussin E. Increased food energy supply is more than sufficient to explain the US epidemic of obesity. American Journal of Clinical Nutrition 2009;90:1453–6.
- [5] Cutler D, Glaeser E, Shapiro J. Why have Americans become more obese? Journal of Economic Perspectives 2003;17(3):93–118.
- [6] Putnam JJ, Allshouse JE. Food consumption, prices and expenditures, 1970–1997. Statistical Bulletin no. 965. Washington, DC: Economic Research Service, US Department of Agriculture; 1999.

- [7] Putnam JJ, Allshouse J, Kantor LS. U.S. per capita food supply trends: more calories, refined carbohydrates, and fats. Food Review 2002:25:2–15
- [8] Nielsen SJ, Siega-Riz AM, Popkin BM. Trends in food locations and sources among adolescents and young adults. Preventive Medicine 2002;35(2):107–13.
- [9] Nielsen SJ, Popkin BM. Patterns and trends in food portion sizes, 1977–1998. Journal of the American Medical Association 2003;289:450–3.
- [10] Hill JO, Wyatt HR, Reed GW, Peters JC. Obesity and the environment: where do we go from here? Science 2003;299(5608):853–5.
- [11] Katan MB, Ludwig DS. Extra calories cause weight gain-but how much? Journal of the American Medical Association 2010;303(1):65-6.
- [12] Bleich S, Cutler D, Murray C, Adams A. Why is the developed world obese? Annual Review of Public Health 2008;29:273–95.
- [13] Swinburn BA, Sacks G, Hall KD, McPherson K, Finegood DT, Moodie ML, et al. The global obesity pandemic: shaped by global drivers and local environments. The Lancet 2011;378(9793):804–14.
- [14] Chou SY, Grossman M, Saffer H. An economic analysis of adult obesity: results from the behavioural risk factor surveillance system. Journal of Health Economics 2004;23(3):565–87.
- [15] Zimmerman FJ. Using marketing muscle to sell fat: the rise of obesity in the modern economy. Annual Review of Public Health 2011;32:285–306.
- [16] Finkelstein E, Ruhm C, Kosa K. Economic causes and consequences of obesity. Annual Review of Public Health 2005;26:239–53.
- [17] Drewnowski A. Obesity and the food environment: dietary energy density and diet costs. American Journal of Preventive Medicine 2004;27(3):154–62.
- [18] Young LR, Nestle M. The contribution of expanding portion sizes to the US obesity epidemic. America Journal of Public Health 2002;92(2):246–9.
- [19] Mello M, Studdert D, Brennan T. Obesity the new frontier of public health law. New England Journal of Medicine 2006;354:2601–10.
- [20] Magnusson R. Conceptualising policy options for obesity prevention response to "Counteracting obesity: developing a policy framework to guide action". International Journal of Public Health 2008;53(6):317-9.
- [21] Diller P, Graff S. Regulating food retail for obesity prevention. Journal of Law Medicine & Ethics 2011;39(Suppl. 1):89–93.
- [22] Boehmer TK, Brownson RC, Haire-Joshu D, Dreisinger ML. Patterns of childhood obesity prevention legislation in the United States. Preventing Chronic Disease 2007;4(3).
- [23] Boehmer TK, Luke DA, Haire-Joshu DL, Bates HS, Brownson RC. Preventing childhood obesity through state policy, predictors of bill enactment. American Journal of Preventive Medicine 2008;34(4):333-40.
- [24] Cawley J, Liu F. Correlates of state legislative action to prevent child-hood obesity. Obesity 2008;16(1):162–7.
- [25] Eyler AA, Nguyen L, Kong J, Yan Y, Brownson R. Patterns and predictors of enactment of state childhood obesity legislation in the United States: 2006–2009. American Journal of Public Health 2012;102(12):2294–302.
- [26] Lankford T, Hardman D, Dankmeyer C, Schmid T. Analysis of state obesity legislation from 2001 to 2010. Journal of Public Health Management and Practice 2013;19:S114–8.
- [27] Niggel SJ, Robinson SB, Hewer I, Noone J, Shah S, Laditka SB. Adult obesity prevalence and state policymaking in the United States: is problem severity associated with more policies? The Social Science Journal 2013;50(4):565–74.
- [28] Smed S. Financial penalties on foods: the fat tax in Denmark, Nutrition Bulletin 2012;37(2):142–7.
- [29] European Commission. 98/34 Procedure (TRIS) Database. Entry 2011/340/HU: Act No . . . of 2011 on the public health product tax; 2011.
- [30] Holt E. Hungary to introduce broad range of fat taxes. The Lancet 2011;378(9793):755.
- [31] Mytton OT, Clarke D, Rayner M. Taxing unhealthy food and drinks to improve health. BMJ 2012;344:e2931.
- [32] Cheney C. Battling the couch potatoes: Hungary introduces 'Fat Tax'. Spiegel Online International; 2011, September. Available from: http://www.spiegel.de/international/europe/battling-the-couch-potatoes-hungary-introduces-fat-tax-a-783862.html [cited 12.02.14].
- [33] The Economist. A fat chance. The Danish government rescinds its unwieldy fat tax; 2012, November. Available from: http://www.economist.com/news/europe/21566664-danish-government-rescinds-its-unwieldy-fat-tax-fat-chance [cited 12.02.14].

- [34] Australian Broadcasting Corporation. Denmark to scrap world's first fat tax; 2012, November. Available from: http://www.abc. net.au/news/2012-11-11/denmark-to-scrap-world27s-first-fat-tax/ 4365176 [cited 12.02.14].
- [35] Daley S. Hungary tries a dash of taxes to promote healthier eating habits. New York Times 2013, March. Available from: http://www.nytimes.com/2013/03/03/world/europe/hungary-experiments-with-food-tax-to-coax-healthier-habits.html [cited 12.02.14].
- [36] International Monetary Fund. World economic outlook database; 2014, April. Available from: http://www.imf.org/external/pubs/ ft/weo/2014/01/weodata/index.aspx [cited 14.05.14].
- [37] Garner BA, editor. Black's law dictionary, 9th ed. Eagan, MN: Thom-son West; 2009.
- [38] European Commission. A guide to the procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society services. Luxemburg: European Communities; 2005.
- [39] World Health Organization Regional Office for Europe. WHO European database on nutrition, obesity and physical activity (NOPA). Available from: http://data.euro.who.int/nopa/about.aspx [cited 30.01.15].
- [40] World Health Organization. WHA57.17: global strategy on diet, physical activity and health. Geneva: WHO; 2004.
- [41] Gostin LO. Law as a tool to facilitate healthier lifestyles and prevent obesity. Journal of the American Medical Association 2007;297(1):87–90.
- [42] Magnusson RS. What's law got to do with it Part 2: legal strategies for healthier nutrition and obesity prevention. Australia and New Zealand Health Policy 2008;5(1):11.
- [43] Elinder LS. Obesity hunger agriculture: the damaging role of subsidies. BMJ 2005;331(7528):1333-6.
- [44] Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Willett WC. Trans fatty acids and cardiovascular disease. New England Journal of Medicine 2006;354(15):1601–13.
- [45] Karppanen H, Mervaala E. Sodium intake and hypertension. Progress in Cardiovascular Diseases 2006;49(2):59–75.
- [46] Council of the European Union. Council approves new rules for fruit juices. Available from: http://www.consilium.europa.eu/uedocs/ cms.data/docs/pressdata/en/lsa/128843.pdf [cited 05.05.14].
- [47] UK Department of Health. Press release: final design of consistent nutritional labelling system given green light; 2013, June. Available from: https://www.gov.uk/government/news/final-design-of-consistent-nutritional-labelling-system-given-green-light [cited 21.04.14].
- [48] European Parliament. Procedure file: document reference 2008/0028(COD), food information to consumers. Amendments 272, 291. Available from: http://www.europarl.europa.eu/oeil/popups/ficheprocedure.do?lang=en&reference=2008/0028%28COD%29 [cited 29.05.14].
- [49] European Parliament. Recommendation from the Department of Health of the United Kingdom on using the hybrid system for the labelling of foods. Parliamentary questions, 15 November 2012, E-010443-12. Available from: http://www.europarl.europa. eu/sides/getDoc.do?pubRef=-//EP//TEXT+WQ+E-2012-010443+0+ DOC+XML+V0//EN [cited 29.05.14].
- [50] European Parliament. Food labelling: UK traffic-light system. Parliamentary questions, 26 September 2013, E-011011-13. Available from: http://www.europarl.europa.eu/sides/getDoc.do?type=WQ&reference=E-2013-011011&language=EN [cited 29 05 14]
- [51] Council of the European Union. "Hybrid" nutrition labeling system recommended in some Member States- Information from the Italian delegation. Document Number 5899/14. Available from: http://register.consilium.europa.eu/doc/srv?l=EN&f=ST%205899% 202014%20INI [cited 29.05.14].
- [52] European Parliament. Answer given by Mr Borg on behalf of the Commission. Parliamentary questions, 17 January 2013, E-010443. Available from: http://www.europarl.europa.eu/sides/ getAllAnswers.do?reference=E-2012-010443&language=EN [cited 29.05.14l.
- [53] European Parliament. Answer given by Mr Borg on behalf of the Commission. Parliamentary questions, 6 November 2013, E-011011/2013. Available from: http://www.europarl.europa.eu/ sides/getAllAnswers.do?reference=E-2013-011011&language=EN [cited 29.05.14].
- [54] Council of the European Union. Press release: 3295th council meeting, competitiveness. Document number 6653/14. Available from: http://gr2014.eu/sites/default/files/COMPET%2020.2.2014\_ Conclusions.pdf [cited 29.05.14].

- [55] Finnish Ministry of Finance. Excise duty. Available from: http://www.vm.fi/vm/en/10\_taxation/05\_excise\_duty/index.jsp [cited05.03.14].
- [56] Finnish Customs. Excise taxation. Customer Bulletin No. 16; 2013. Available from: www.tulli.fi/en/finnish\_customs/publications/ excise\_tax/excise\_taxation/006.pdf [05.03.14].
- [57] Storcksdieck genannt Bonsmann S, Kardakis T, Wollgas J, Nelson M, Caldeira S. Mapping of National School Food Policies across the EU28 plus Norway and Switzerland. JRC Science and Policy Report. Luxembourg: Publications Office of the European Union; 2014. Available from: https://ec.europa.eu/jrc/sites/default/files/lbna26651enn.pdf [accessed Feb 1st 2015].
- [58] World Health Organization Regional Office for Europe. Marketing of foods high in fat, salt and sugar to children: update 2012–2013. Available from: http://www.euro.who.int/\_data/assets/pdf.file/0019/191125/e96859.pdf?ua=1 [accessed 01.02.15].
- [59] Advertising Standards Authority. UK Code of Broadcast Advertising (BCAP Code). Available from: http://www.cap.org.uk/Advertising-Codes/Broadcast.aspx [cited 30.01.15].
- [60] Ofcom. Television advertising of food and drink products to children: final statement; 2007. Available from: http://stakeholders.ofcom.org.uk/binaries/consultations/foodads\_new/statement/statement.pdf [cited 30.01.15].
- [61] UK Department of Health. Policy paper: the nutrient profiling model; 2011. Available from: https://www.gov.uk/government/ publications/the-nutrient-profiling-model

- [62] Meehan S. Norwegian Government drops draft law to ban food advertising to children. Asociación Nacional de Anunciantes website. Available from: http://andapty.com/9-noticias/13-norwegiangovernment-drops-draft-law-to-ban-food-advertising-to-children [cited 30.01.15].
- [63] Farley TA. The role of government in preventing excess calorie consumption: the example of New York City. Journal of the American Medical Association 2012;308(11):1093–4.
- [64] Frieden TR, Bassett MT, Thorpe LE, Farley TA. Public health in New York City, 2002–2007: confronting epidemics of the modern era. International Journal of Epidemiology 2008;37: 966–77.
- [65] Gostin LO. Bloomberg's health legacy: urban innovator or meddling nanny? Hastings Center Report 2013;43(5):19–25.
- [66] O'Connor L. Nation's first soda tax passes in Berkeley, fails in San Francisco. Huffington Post 2014, November. Available from: http://www.huffingtonpost.com/2014/11/04/bay-area-soda-tax\_n\_6104000.html [cited 30.01.15].
- [67] Mair SJ, Pierce MW, Teret SP. The city planner's guide to the obesity epidemic: zoning and fast food; 2005. Available from: http://www. publichealthlaw.net/Zoning%20City%20Planners%20Guide.pdf [cited 30.01.15].
- [68] Huffington Post. San Francisco happy meal toy ban takes effect, sidestepped by McDonald's. Huffington Post 2011, November. Available from: http://www.huffingtonpost.com/2011/11/30/ san-francisco-happy-meal-ban\_n\_1121186.html [cited 30.01.15].

#### 4.4 Postscript

Similar findings have been reported in studies using different methodologies. For instance, taking a broader subject matter interest, a review of nutrition policies in 30 European countries confirmed that regulatory action targeting nutrition in the general population is a rare occurrence. [1] Specifically, the mandatory reformulation of products was found to be mostly related to salt and trans fat content, two nutrients that are independently linked to adverse health outcomes. Mandatory regulation more directly related to obesity prevention was found to be reasonably common only with regard to restrictions on marketing to children and aspects of setting-specific nutrition, predominantly in schools. [1] By contrast, education campaigns and non-binding policy pronouncements, guidelines, and cooperation agreements with the food industry were determined to be widespread. [1] In a second study, Roberto and colleagues adopt a global view and anecdotal approach to confirm that legal approaches to improving the food environment and food systems remain exceptions. [2]

In addition, an observation that could only be mentioned in passing in this study has been the subject of extensive academic debate. As noted in the article which forms the basis of this chapter, the European Union has played a double edged role, on the one hand legislating in areas such as labelling and program food standards at a level that is presumably superior to most national provisions, while on the other hand preempting more advanced complementary initiatives such as the UK's traffic light labelling. As such, the EU presents an interesting combination of both solution and problem to higher-level public health governance in the field of noncommunicable disease prevention. Alemanno and Garde describe what they term an "embryonic EU lifestyle policy" [3] that covers the three risk factors smoking, alcohol consumption, and unhealthy diets, but employs different policy levers to address each area. Tobacco has been the subject of EU regulation and, with alcoholic beverages and energy, is the only product category to which EU legislation on excise duties applies. [4] By contrast, unhealthy diets have been addressed primarily through soft law. This includes strategic pronouncements and infrastructure such as the EU Platform on Nutrition, Health and Physical Activity as a stakeholder consultation forum and the High Level Group on Nutrition and Physical Activity for intergovernmental exchange between EEA members. [4] However, tangible progress in rule-making has stopped at the measures around food information provision to consumers and subsidised school milk and fruit schemes described above.

Alemanno and Carreño attribute the rescinding of the Danish fat tax in part to claims of cross-border shopping that left domestic food retail reeling and circumvented the purpose of the tax. [4] In response, they examined the possibility that the EU enact a Union-wide scheme mandating ingredient or product-based taxes on public health grounds. [4] The authors concluded that the treaties that form the legal basis of the European Union generally exclude both health and fiscal policies from EU competencies. In addition, EU's responsibility for harmonising internal taxation is limited to instances where the functioning of common market is interrupted due to national legislation. [4] As a result, in order for the EU to exercise its harmonising competencies, a large number of EEA members would have to independently implement significant excise taxes in the first place. This is clearly not a realistic scenario at the current stage. Moreover; it seems difficult to make the case that the cross-border price differences due to taxation have a distorting effect in an economic area where taxation, cost of living, and average income vary widely.

In summary, the limited used of laws and regulations for obesity prevention described in this chapter is a finding that has been replicated at the global level. The double edged role of the European Union as both an important legislator and an inhibitor of innovative country-level regulation has been underlined in legal analyses that stress national willingness to act in the fields of health and taxation as a pre-condition for supra-national policy.

#### References

- [1] Lloyd-Williams F, Bromley H, Orton L, Hawkes C, Taylor-Robinson D, O'Flaherty M et al. Smorgasbord or symphony? Assessing public health nutrition policies across 30 European countries using a novel framework. BMC Public Health. 2014;14:1195.
- [2] Roberto CA, Swinburn B, Hawkes C, Huang TT, Costa SA, Ashe M, et al. Patchy progress on obesity prevention: emerging examples, entrenched barriers, and new thinking. *Lancet*. 2015; 385(9986): 2400-2409.

- [3] Alemanno A, Garde A. The emergence of an EU lifestyle policy: The case of alcohol, tobacco and unhealthy diets. *Common Market Law Review*. 2013;50(6):1745-1786.
- [4] Alemanno A, Carreño I. 'Fat Taxes' in Europe and Beyond A Legal and Policy Analysis Under EU and WTO Law. *European Food and Feed Law*. 2013;2:97-112.

# 5. Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition

6.

This manuscript systematically reviews the evidence produced by real-life policy interventions targeting different aspects of the food system. In assessing the implementation process, nutrition impact, and health impact of these measures, it complements the evidence on policy prevalence presented in the previous article by qualifying 'policy success' along a continuum of outcomes.

The full results table and the supplemental materials accessible through the PROSPERO database are also available in appendix 2 (pp. 151-161).

# Statement of Authorship

Title of Paper	Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition	
Publication Status	☐ Published       ☐ Accepted for Publication         ☐ Submitted for Publication       ☐ Publication Style	ion
Publication Details	Sisnowski J, Merlin T, Street JM. Improving food environments systematic review of the policy success of regulatory intervention	

# **Principal Author**

Name of Principal Author (Candidate)	Jana Sisnowski
Contribution to the Paper	Designed the study and search strategy; performed the database searches; analysed the search results; drafted the manuscript.
Overall percentage (%) Signature	80% Date 25/61/2016

# **Co-Author Contributions**

By signing the Statement of Authorship, each author certifies that:

- i. the candidate's stated contribution to the publication is accurate (as detailed above);
- ii. permission is granted for the candidate in include the publication in the thesis; and
- iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Tracy Merlin	
Contribution to the Paper	Assisted with the development of the systematic review protocol; assisted with database search strategies; commented on drafts of the manuscript,	
Signature	Date 25 1 2016	
Name of Co-Author	Jackie Street	

Name of Co-Author	Jackie Street
Contribution to the Paper	Reviewed a sub-set of search results for inclusion in the review; acted as second assessor of study quality; commented on drafts of the manuscript.
Signature	Date 26.1.2016

Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition

# 1. Introduction

Regulatory measures that aim to improve population nutrition have become an increasingly popular tool in the public health strategy against obesity. As an increasing number of approaches are tested in real-life, a new dimension of evidence has become available to inform future policy-making more realistically (1) than modeling exercises and researcher-manipulated studies in controlled settings (2, 3). However, evaluations of early efforts have not been systematically and comprehensively examined. Although one recent systematic review (4) analyzed the evidence of natural experiments in the areas of physical activity and nutrition, it relied on a search of PubMed only and excluded outcomes measured directly in the food environment. It reported mostly null results across the categories of interest to this study and did not identify any studies on fiscal policies or food supply measures (4). Evaluations of policy interventions are methodologically challenging as they are necessarily observational and involve long and often indirect cause-and-effect chains that occur in parallel with a myriad of other changes in the population and environment (4-6). Preventive interventions that target environments rather than individual behaviors present the additional difficulty that the desired impact might emerge only gradually or cumulatively in conjunction with other interventions (7). These considerations suggest that only measuring ultimate outcomes of interest, such as changes to nutritional patterns or body weight, is not an adequate indication of policy success or failure. Instead, the impact of real-life public health interventions may be more appropriately assessed by substantiating a logical pathway connecting intervention and outcome, and by demonstrating realization of immediate program

goals or the presence of more distal jurisdiction-wide trends in average weight or nutritional intake. (6, 8)

# 2. Methods

To review current research evaluating real-life policy interventions addressing obesity, we use a realist review approach (9) which focuses on program mechanisms to provide a more nuanced assessment of policy success or failure. Specifically, we investigate the effect of statutory provisions of a regulatory nature that aim to reduce the consumption of energy-dense foods and beverages in the general population. The outcomes of interest align with the program logic outlined above: we collected data regarding (i) the effect of these interventions on average BMI or weight and on calorie intake and related proxy measures and (ii) indicators measuring parameters on the assumed causal pathway to changed consumption patterns, including measures of the degree of program implementation and non-behavioral consumer responses such as awareness and knowledge. In recognition that new rules may be evaluated on the basis of process indicators alone, we allowed all methodological approaches with some measure of comparison, including studies of implementation progress with an assumed baseline of zero. A review protocol was developed and registered on the International Prospective Register of Systematic Reviews (PROSPERO) prior to commencement of this study. It is available under the registration number CRD42015025276 and provides a comprehensive account of the methods used. As summarized in figure 1 and in line with a realist review approach, our search and selection methods were informed by the likely program logic of interventions in the principal areas identified in the literature as possible regulatory levers (10, 11).

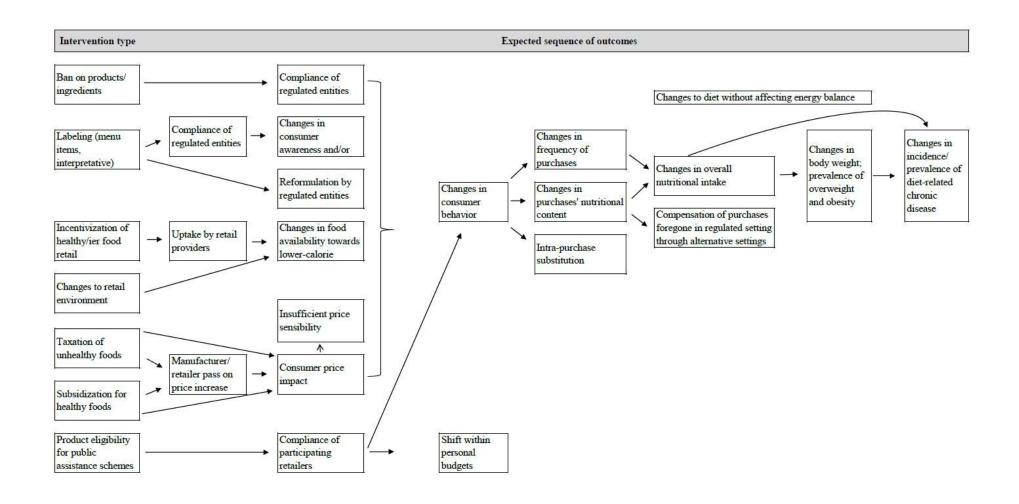


Figure 1 Assumed pathways from interventions to health outcomes

# 2.1. Data sources

We systematically searched 16 databases that span academic research as well as research undertaken by public agencies and other public or private organizations. In addition, we hand-searched the reference lists of all articles that met the inclusion criteria detailed below. A full overview of the search strategies used in the following databases is available in the document attached to the review protocol in PROSPERO.

# 2.2. Study selection

We considered all studies published between 2004, the year WHO member states first acknowledged a role for market-related regulatory interventions for obesity prevention in the Global Strategy on Diet, Physical Activity (12), and October 31<sup>st</sup>, 2015 for inclusion in this review, with no initial restriction on the language of publication.

We included all full-scale policy interventions designed to improve population nutrition, regardless of whether the outcome(s) reported was related to the food environment or to behavioral patterns. Eligible studies examined (i) an enacted statutory intervention (ii) that applied to the entire population of its jurisdiction and (iii) that targeted the consumption of energy-dense foods and beverages. These criteria exclude all interventions that are not part of a full-scale, jurisdiction-wide policy such as pilot programs and private sector or NGO actions without a change of primary or secondary legislation. Differential sales taxes and low-level soda taxes, usually enacted solely as means to raise revenue [13], were excluded due to the missing link to public health. In addition, we excluded all interventions aimed only at children or other defined or implicit sub-groups (e.g. school-based programs or the US Special Supplemental Nutrition Program for Women, Infants, and Children), but retained those that provide a social safety net open to anybody in demonstrated need

(e.g. the US Supplemental Nutrition Assistance Program (SNAP)/ food stamp program).

After removal of duplicates, we screened 25,323 items for relevance according to the inclusion criteria. The first reviewer (JS) initially assessed each title and, where available, abstract. A subset of 10% of the initial search results was again reviewed for eligibility according to the inclusion criteria by a second reviewer (JMS). Where study eligibility was disputed, the co-authors reached a consensus decision. The first reviewer then retrieved and assessed the full text of 295 articles that had been determined to possibly meet the inclusion criteria in the first round of screening. In addition to studies reporting on the evaluation of one specific intervention matching the inclusion criteria, we also retained eleven systematic reviews whose inclusion criteria overlapped at least partially with ours. We reviewed the reference lists of these reviews for additional eligible studies before excluding the reviews themselves from further analysis. Together with the hand-searching of the reference lists of all included studies, this process yielded an additional seven eligible articles. The same two reviewers independently assessed the 48 selected studies for methodological quality prior to inclusion in the review using the appraisal tools for Quality Assessment of Before-After (Pre-Post) Studies With No Control Group (14) and for Quality Assessment of Observational Cohort and Cross-Sectional Studies (15) developed by the National Heart, Lung, and Blood Institute. At this stage, we excluded a further three studies which reported evaluation outcomes, but did not detail or reference the underlying methodology. The flow diagram in figure 2 summarizes the database search and study selection process.

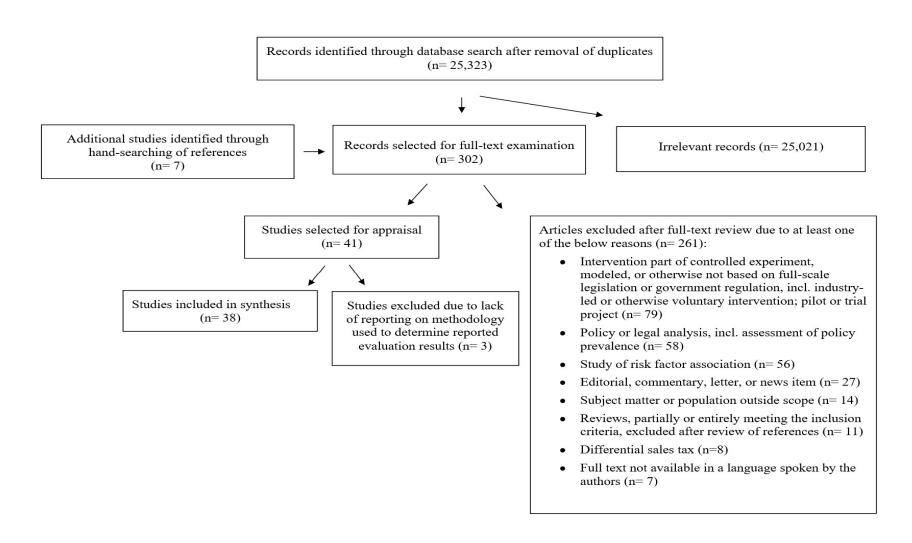


Figure 2 Summary of search and selection process

# 2.3. Data extraction

We grouped studies according to type of intervention reported and extracted the following details for each reference: setting, study design, time post-implementation, main population and, where applicable, sub-populations, results for the primary outcome, and, where applicable, results for any secondary outcomes reported.

### 3. Results

The 38 studies (16-53) span six different types of interventions: a majority (n= 19) report on calorie posting on chain restaurant menus, followed by food infrastructure (n=7), subsidies for healthy food purchases (n=5), taxation of unhealthy foods and beverages (n= 5), government food standards (n=1), and nutrition labeling of products (n=1). Approximately 84% of included studies (n=32) assess interventions implemented in the United States. Evaluation strategies varied and resulted in different endpoints, often with multiple strategies used in one report to quantify the success of program implementation and the effects on behavior. The results table in the annex provides a detailed overview of the included studies. In the following, we summarize the results in a narrative meta-synthesis.

# 3.1. Menu labeling

Calorie posting on menus at chain restaurants has been the most comprehensively examined intervention of the approaches identified in this study. Our examination of 19 individual studies included predominantly pre-post designs and repeat cross-sectional surveys with a control group, with sample sizes ranging from a few hundred participants (16,23,29,32) to over 100 million transactions (17). Studies measuring average calorie intake, based on verified purchases or self-reported consumption and not restricted to one chain, suggest that menu labelling using calorie per item does

not impact on consumer purchasing behavior. (21,23-27,29,31-33) However, two studies reported a differential post-implementation drop in average calories ordered. Both took place at only one regulated chain. The first used two outlets of a nonidentified fast food chain in Philadelphia and control locations in neighboring states, resulting in a total sample of 648 verified purchases. This study reported a 9% drop, equivalent to 151 food calories less purchased on average compared to non-regulated jurisdictions (16). The second study was limited to the Starbucks chain in New York City, with Boston and Baltimore as control locations (17) It was one of two evaluations (17,26) in which a chain agreed to share its sales data. Starbucks sales data showed a drop of 6% to an average order of 232 calories post-implementation (17). However, the caloric value of average purchases at Starbucks were much lower than at other regulated chains both pre- and post-implementation. For instance, in the other single chain study, customers at regulated outlets purchased an average of 1,556 calories (16) and the average entrée in King County contained 777 calories at 18 months post-labelling before adding any side orders (18). This suggests that the Starbucks study may not be representative of the regulation's impact in the broader fast food sector. Interestingly, the Starbucks study also observed that the company's aggregate sales revenue remained stable post-implementation and even increased by 3% at stores located near a Dunkin Donuts (17). Assuming that the increase in sales near rival outlets indeed represents a shift of customers rather than new customers, it seems that the chain attracts more health-conscious consumers away from equally regulated competitors. Taken together, these two observations call into question the external validity of the Starbucks study.

Intermediate outcomes on the logical pathway to consumption were frequently measured as the sole endpoint (19,20,22,31) or as a secondary outcome (16,21,23-25,27,29,32,33). Variables such as self-reported noticing of calorie labels and self-

reported usage in ordering varied by location and study: for instance, the average share of consumers reporting having noticed calorie labeling at the end of the respective post-implementation observation period ranged from 38% to 76% in Philadelphia (25,16), from 58% to 59% Washington State (19,27), and from 54% to 64% in NYC (24,20). Similarly 57% of adolescents in NYC (23) and 87% of parents ordering for their children in Washington State reported noticing calorie labels after their introduction (32). Across all studies, the share of customers who reported using the calorie information in purchasing decisions was far below the share noticing it. Among those making use of the labeling, uptake tended to vary by sub-population, but showed few consistent trends across studies. For instance, in a Washington State study women, high income earners, and whites had greater odds of using menu labeling (19) and in a second Washington State study usage differences were found between women and men, but not between races or ethnicities (27). In NYC, men were likely than women to report using the information (20), with the opposite finding reported in another study also conducted there (21).

The idea that an effect might occur outside the restaurant setting and therefore be undetectable in cross-sectional studies was investigated four months after Philadelphia's introduction of menu labeling (26). Program logic indicates that potential fast food consumers might respond to the new labeling by reducing the number of restaurant visits without changing the amount of calories at each visit. However, the study found no reduction in the number of fast food restaurant visits by either consumers intercepted at a fast food restaurant or by those questioned in a random-digit dialing phone survey (26). While there was no statistically significant association in either direction, trends across several sub-groups suggest that if there was an effect, it would more likely tend towards an increased number of average visits post implementation (26). By contrast, one study provided evidence of a slight

increase in the successful translation of information provision to nutrition knowledge: in NYC, no statistically significant differential change in correct estimates of recommended daily calorie intake was reported post-implementation (22). However, the share of respondents correctly estimating the caloric value of their purchase rose from 15% to 24% in NYC while declining from baseline in the control city of Newark, resulting in a statistically significant differential change during the postimplementation period (22). In Philadelphia, differential changes in the accuracy of estimates of calories purchased were statistically significant only in customers with at least some college education and in those ordering small meals, perhaps a sign a greater health consciousness (31). In addition, it appears that at least in Washington State, where King County implemented a new menu labeling regulation, chain restaurants responded to the change through modest reformulation of their menus, thus bypassing consumer decision-making on the pathway to reduced calorie intake (18). On average, entrées contained 41 calories less at 18 months after enactment of the new rule compared to at six months, a 5% drop to 777 calories per entrée (18). A comparison of menus between chains operating in regulated jurisdictions and chains operating only in non-regulated jurisdictions showed that the availability of healthier food options increased by 8% at regulated chains, but remained constant at control chains (28). No difference in average caloric content was found between regulated and control menus (28). Another King County study looked at the wider restaurant environment post-implementation and found few qualitative changes to the food environment other than compliance with the regulation compared to a control jurisdiction (30). Overall, these studies implied broad compliance with the regulations, but showed only small spillover effects into other aspects of the restaurant food environment.

One study from Australia provides insights into the possible effect of policy innovation across jurisdictional borders. Conducted in the year before and 11 months after New South Wales (NSW) became the first state to introduce mandatory menu labeling, the article reports nationwide trends for the five fast food chains with the largest numbers of outlets in Australia (34). The study design neglected to compare NSW with the non-regulated states and is therefore of little use to assess the implementation of the regulation in NSW. However, the study reported that the average total nutrition information available in stores rose significantly across the nation while the number of outlets with no nutrition information available dropped by 31% to just two stores in the sample. This finding attests to the power of policy diffusion through convergence of practice in nationally and internationally operating food business.

# 3.2. Improvement of food infrastructure

Studies reporting on the success of changes to the food infrastructure are limited to the three US jurisdictions of Philadelphia, NYC, and South Los Angeles in Los Angeles County. Philadelphia and NYC both introduced programs to improve the quality of corner stores. The Get Healthy Philly program showed progress when measured in form of an aggregated score, but individual measures of the availability of healthier food found inconsistent trends and few statistically significant pre-post changes (35). Similarly, NYC's Healthy Bodegas program showed no consistent trend toward the purchase of healthier items (36).

NYC's Green Carts program which made available up to 1,000 permits for mobile vendors of fresh produce in disadvantaged neighborhoods did also not result in any statistically significant increase in reported fruit and vegetable consumption (38). Evaluation observations also indicated that vendors tended to cluster along public

transport, commercial, and other hubs within their designated zones and thereby largely bypassed the most disadvantaged neighborhoods (39,40). In addition, not all 1,000 permits created by specific legislation were taken up: two evaluations found approximately 50% of permits active on paper (37,38), but when attempting to locate all vendors, only 166 carts could be located (37).

Meanwhile, South Los Angeles' ban on new free-standing fast food chain outlets also showed limited effectiveness in improving the food environment. Four and a half years after implementation, only 10% of food outlets operating at the time of the study had opened under the new rule (41). This indicates limited reach of a law applying only to new businesses in a fairly stable food environment. Not surprisingly, after controlling for individual and collective characteristics, the study found no statistically significant differences in diet and BMI changes in comparison to control jurisdictions (41).

# 3.3. Subsidies for healthy foods

The studies examining the use of subsidies centered on the US Supplemental Nutrition Assistance Program (SNAP), formerly known as food stamps, and local efforts to incentivize their use for the purchase of healthy foods. At the aforementioned Green Carts in NYC, the use of SNAP benefits was associated with an average of \$3.86 more spent compared to cash payment (43). The Health Bucks program in NYC and the Philly Food Bucks program in Philadelphia both offer \$2 vouchers per \$5 in SNAP benefits spent at farmers' markets. Both programs resulted in increased SNAP sales at farmers' markets (42,46). In addition, vendors in NYC reported a high degree of satisfaction with the impact of the program on their business (45). Although voucher users in Philadelphia were 2.6 times more likely to report increased fruit and vegetable consumption since becoming market customers than

non-voucher users (46), health survey data in NYC showed no differential increase in self-reported fruit and vegetable consumption after introduction of the program compared to control neighborhoods (44).

# 3.4. Taxation of unhealthy foods and beverages

Taxation of unhealthy foods and beverages expressly for public health purposes represents the only category not dominated by US evidence. All five studies in this category investigate European approaches. The French beverage tax of 7.16 euros per hectoliter (0.076 euros per liter) was found to have been passed through fully to retail prices for soda and partially for other taxed beverage categories at six months postimplementation (47), thereby validating the first step on the logical pathway to reduced consumption.

Three studies (49-51) quantifying the effects of the now abolished Danish tax on saturated fat content concluded that the intervention had an effect on consumption levels as measured by proxy sales and purchasing data. A study based on a panel of 2,000 households found that purchases of butter, butter blends, margarine and oils decreased by 10%-15% in the first nine months post-implementation (50). However, this was at least partially attributed to hoarding prior to the entry into force of the new tax (50). A study of sales data collected from different retail chains owned by Coop Denmark showed different price developments for the three product groups (minced beef, cream, and sour cream) up to one year post-implementation (51). Prices of minced beef and cream were higher post-implementation, but no consistent pattern was observed for sour cream prices. In addition, price changes were stronger for the medium-fat and weakest for the low-fat varieties of minced beef and cream (51). Matching the price changes, sales changes suggested there was a decrease of 4-6 % in the intake of saturated fat from minced beef and cream, while no significant effect

was found for sour cream (51). Another study examined sales data for twelve taxed foodstuffs over the entire 15 months of the tax's existence (49). It reported a total decrease in sales across product categories by 0.9%, but an increase by 1.3% pre-implementation and post-abolition of the tax. Sales changes were estimated to translate into a population-wide increase of heart disease by 0.2%-0.5% due to a decrease of both saturated fat and unsaturated fat intake (49). Although an estimate and a very small effect size, this result illustrates that targeting specific nutrients in a wide range of foodstuffs may entail unintended changes in consumption patterns that mitigate or negate intended effects.

In Hungary, a broad-based junk food tax was estimated to have reduced purchases of processed foods, which were mostly taxed, by 3.4%, while purchased quantities of unprocessed foods increased by a statistically insignificant 1.1% at 16 months postimplementation (48).

# 3.5. Procurement standards for public institutions

The only full-scale evaluation of a jurisdiction setting standards for the nutritional quality of items available to its employees and the general public is that of the Healthy Beverage Executive Order enacted by the city of Boston (52). Two years post-implementation, unhealthy beverage availability and average caloric content per beverage declined considerably compared to the pre-implementation period and compared to control sites. These sites were owned by the city and the state of Massachusetts and not covered by the order. However, positive trends of a lesser magnitude were also observed at the comparison sites, particularly the ones owned by the city rather than the state, indicating that a larger trend or a signaling effect beyond the direct intervention may have contributed to the changes.

# 3.6. Nutrition labeling of products

The only study identified that assesses nutrition labeling on products originated in New South Wales, an Australian state (53). Reporting that only 7% of 350 product samples matched the exact nutritional information given on the label in a laboratory test (53), this study is narrowly focused on compliance. However, as interpretative labeling approaches are increasingly considered, it does raise the question to what extent nutrition labeling can be enforced beyond adherence to design and presentation rules and what constitutes an acceptable margin of error for consumer information.

# 4. Discussion and conclusion

These findings indicate that isolated regulatory interventions frequently result in improvements of the most proximal outcomes, measured in the food environment and situated at the very beginning of the logic model. However, the interventions assessed here fail to achieve an effect on consumption that could plausibly be considered as clinically significant. This is a differentiation between different levels of policy success and failure that was not highlighted in previous work (4).

When compared to just a few examples of effect estimates put forward during policy development and decision-making processes, it is clear that current interventions are falling short of the public health impact hoped for by policy-makers and predicted by many researchers. For example, in New York City, the Department of Health estimated that the new calorie posting rule would lead to "at least 150,000 fewer New Yorkers [becoming] obese, [and] at least 30,000 fewer cases of diabetes" (54) over five years. However, with the exception of the study focused on Starbucks, the New York City-based studies profiled here failed to find statistically and clinically insignificant calorie reductions. (21-24,33) Moreover, a recent look at the sustained impact of the intervention, published just after the cutoff date for this review, concluded that even minimal improvements in consumer awareness appear to have

diminished over time (54). Meanwhile, the Danish forecast that a fat tax would eventually add 5.5 days to the average Dane's lifespan (55) will remain unrefuted given the quick abolition of the measure, but appears tenuous given the early evaluation results. Similarly, one of the evaluations of New York City's Green Cart program reported that the city originally estimated that the generated increased intake of fruits and vegetables would measurably improve the health status of 75,000 individuals and avert loss of at least 50 lives a year (37). However, program administrators concluded that the direct impact of the intervention on morbidity and mortality would be too difficult to quantify and the program evaluators observed that direct health-enhancing arguments for Green Carts subsequently faded (37).

This is not to say that these interventions may not deliver cumulative behavioral and health effects in the long-term, especially where they act in parallel with complementary interventions and change social and political perceptions of nutrition. In this context, it is notable that recent studies at national level and in hotspots of obesity prevention activities such as New York City find both a shift in the attitudes of consumer towards sugary drinks and an actual reduction in average soft drink consumption (57-59).

Some of the interventions discussed above may also be not consequential enough to have a meaningful impact on consumption: a recent review of regulation targeting sugar-sweetened beverages argued that policies are squandering potential for more pronounced behavioral impact by restrained design, possibly to appease industry and political opponents (60). Indeed, very few of the above interventions match the designs identified in the literature as the more effective approaches, be it displays of physical activity equivalents instead of plain calorie counts (61) or excise taxes amounting to price increases of at least 15-25%, equivalent to the long advocated

penny per ounce tax (62-64). In 2015, Berkeley, California, passed a tax on sugar-sweetened beverages that matches the magnitude suggested by public health experts and in 2014, Mexico implemented a tax of one peso per liter which, if passed on to consumers, comes close to the recommended level with a 10% increase in price. Two early evaluations, published just after the cut-off date for this review, report that in both locations, the taxes were generally passed on, with higher price increases relative to taxation levels reported for Mexico compared to Berkeley (65,66). The study in Berkeley employed comparison cities for control of pre-post trends and reported pass-through rates of 69% for soda and 47% for all taxed products (65). Neither jurisdiction reported deleterious effects on the prices of non-taxed beverages such as bottled water, with the exception of slight price increases for diet soda in Berkeley (65,66). These two fiscal interventions warrant close attention from the experts and policy-makers as they represent rare examples of current policy recommendations being put into practice.

Some limitations must be taken into account when interpreting the results of this systematic review. Firstly, despite an expansive search of a variety of databases and broad inclusion criteria, it is likely that some evaluations of real-life interventions are not available through academic and gray literature repositories. It is reasonable to suppose that in many instances, especially in lower level jurisdictions and in middle and low-income countries, no formal evaluation of relevant policies would have been undertaken and/or reported. As a result, only a small number of studies from outside the OECD were identified, with several articles describing interventions in Ghana (67) and the Pacific island region (68,69) excluded at the appraisal stage due to the unavailability of detailed evaluation processes and results. These limitations underline the need to make methodically sound evaluations a routine component of

policy implementation and highlight the usefulness of some form of centralized repository for comprehensive evaluation reporting that is accessible globally.

Secondly, our study purposely used appraisal tools tailored to observational study designs that are amenable to evaluating real-life policies. As outlined in the introduction, real-life policy experiments do not always fully align with the methodological expectations of evidence-based health sciences, particularly when compared to targeted prevention delivered in health care settings. This issue was raised in relation to the study by Dumanovsky and colleagues who employed a simple pre-post study design to quantify the effect of menu labeling in New York City (21). Criticized for the chosen study design (70), the authors responded that the methodology needs to match both the reality of a policy in progress and the limited resources of a public agency carrying out its own evaluation while stymied by the refusal of industry to share its sales data (71). Despite some reservations about these study designs expressed in the literature, studies using conventional cross-sectional designs or simple pre-post designs posed little difficulty for appraisal and data extraction. Conversely, studies that evaluated implementation processes were problematic to appraise and summarize. Aspects of design, common in the evaluation of food infrastructure interventions such as the corner store programs in Philadelphia and NYC and NYC's Green Cart program, complicated the assessment of studies examining food infrastructure improvements and food subsidization programs. These aspects included the use of descriptive approaches, a mix of different study designs of varying quality within single reports and, in at least one case, a muddling of baseline and post-implementation data (35). The difficulties that we encountered suggest that scholarly assessment of study quality and the reality of policy-making in perennially resource-constrained health departments occasionally collide. As a result, even more differentiated appraisal tools need to be used for evaluation in recognition

that studies with descriptive approaches can be useful for charting implementation progress by ensuring that program logic is in place.

To conclude, our review underlines that the immediate expectations associated with the examined types of regulatory interventions need tempering. At this point in time, the policy examples discussed above primarily deliver proof of feasibility: the fact that they survived the policy-making process and have been mostly successful in reaching immediate program goals should enhance the political palatability of such approaches even if, at the time of examination, there has been little demonstrated impact on risk factors and health outcomes. Policy-makers should therefore not dismiss such recent policy experiments as failures, but pursue the example of these jurisdictions as necessary building blocks for more stringent and comprehensive nutrition policy and obesity prevention regimes.

# References

- (1) Shemilt I, Marteau TM, Smith RD, Ogilvie D. Use and cumulation of evidence from modelling studies t inform policy on food taxes and subsidies: biting off more than we can chew? BMC Public Health. 2015;15(1):297.
- (2) Eyles H, Mhurchu CN, Nghiem N, Blakely T. Food pricing strategies, population diets, and non-communicable disease: a systematic review of simulation studies. PLoS Medicine. 2012; 9(12):e1001353.
- (3) Powell LM, Chriqui JF, Khan T, Wada R, Chaloupka FJ. Assessing the potential effectiveness of food and beverage taxes and subsidies for improving public health: a systematic review of prices, demand and body weight outcomes. Obesity Reviews. 2013;14(2):110-128.
- (4) Mayne S, Auchincloss A, Michael Y. Impact of policy and built environment changes on obesity-related outcomes: a systematic review of naturally occurring experiments. Obesity Reviews. 2015;16(5):362-375.

- (5) Reeve B, Ashe M, Farias R, Gostin L. State and municipal innovations in obesity policy: why localities remain a necessary laboratory for innovation. American Journal of Public Health. 2015;105(3):442-450.
- (6) Victora CG, Habicht J-P, Bryce J. Evidence-based public health: moving beyond randomized trials. American Journal of Public Health. 2004;94(3):400-405.
- (7) Swinburn B, Gill T, Kumanyika S. Obesity prevention: a proposed framework for translating evidence into action. Obesity reviews. 2005;6(1):23-33. Swinburn B, Gill T, Kumanyika S. Obesity prevention: a proposed framework for translating evidence into action. Obesity Reviews. 2005;6(1):23-33.
- (8) Habicht J-P, Victora C, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. International Journal of Epidemiology. 1999;28(1):10-18.
- (9) Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review–a new method of systematic review designed for complex policy interventions. Journal of Health Services Research & Policy. 2005;10(suppl 1):21-34.
- (10) Magnusson R. What's law got to do with it? Part 2: Legal strategies for healthier nutrition and obesity prevention. Australia and New Zealand Health Policy. 2008;5(1):11.
- (11) Gostin LO. Law as a tool to facilitate healthier lifestyles and prevent obesity. Journal of the American Medical Association. 2007;297(1):87-90.
- (12) World Health Organization. Global Strategy on Diet, Physical Activity and Health. 2004. Available from: <a href="http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy\_english\_w">http://www.who.int/dietphysicalactivity/strategy/eb11344/strategy\_english\_w</a> <a href="eb.pdf">eb.pdf</a> [last accessed 2 October 2015].
- (13) Kim D, Kawachi I. Food Taxation and Pricing Strategies to Thin Out the Obesity Epidemic. American Journal of Preventive Medicine. 2006;30(5):430-437.
- (14) National Heart, Lung, and Blood Institute. Quality Assessment Tool for Before-After (Pre-Post) Studies With No Control Group. Available from: <a href="http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/before-after">http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/before-after</a> [last accessed 12 January 2016].

- (15) National Heart, Lung, and Blood Institute. Quality Assessment Tool for Observational Cohort and Cross-Sectional Studies. Available from:

  <a href="http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort">http://www.nhlbi.nih.gov/health-pro/guidelines/in-develop/cardiovascular-risk-reduction/tools/cohort</a> [last accessed 12 January 2016].
- (16) Auchincloss AH, Mallya GG, Leonberg BL, Ricchezza A, Glanz K, Schwarz DF. Customer responses to mandatory menu labeling at full-service restaurants. American Journal of Preventive Medicine. 2013;45(6):710-719.
- (17) Bollinger B, Leslie P, Sorensen A. Calorie Posting in Chain Restaurants. American Economic Journal: Economic Policy. 2011;3(1):91-128.
- (18) Bruemmer B, Krieger J, Saelens BE, Chan N. Energy, saturated fat, and sodium were lower in entrees at chain restaurants at 18 months compared with 6 months following the implementation of mandatory menu labeling regulation in King County, Washington. Journal of the Academy of Nutrition and Dietetics. 2012;112(8):1169-1176.
- (19) Chen R, Smyser M, Chan N, Ta M, Saelens BE, Krieger J. Changes in awareness and use of calorie information after mandatory menu labeling in restaurants in King County, Washington. American Journal of Public Health. 2015;105(3):546-553.
- (20) Dumanovsky T, Huang CY, Bassett MT, Silver LD. Consumer awareness of fast-food calorie information in New York City after implementation of a menu labeling regulation. American Journal of Public Health. 2010;100(12):2520.
- (21) Dumanovsky T, Huang CY, Nonas CA, Matte TD, Bassett MT, Silver LD. Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labelling: cross sectional customer surveys. BMJ. 2011;343:d4464.
- (22) Elbel B. Consumer estimation of recommended and actual calories at fast food restaurants. Obesity (Silver Spring). 2011;19(10):1971-1978.
- (23) Elbel B, Gyamfi J, Kersh R. Child and adolescent fast-food choice and the influence of calorie labeling: a natural experiment. International Journal of Obesity. 2011;35(4):493-500.
- (24) Elbel B, Kersh R, Brescoll VL, Dixon LB. Calorie labeling and food choices: a first look at the effects on low-income people in New York City. Health Affairs. 2009;28(6):w1110-w21.

# 6. Targeting population nutrition through municipal health and food policy: Implications of New York City's experiences in regulatory obesity prevention

This article complements the evidence from the previous chapter regarding the nature and frequency of different types of regulatory interventions targeting dietary risk factors for obesity across major OECD jurisdictions. Using a case study methodology, this study adds an in-depth examination of the political processes and strategies that had an impact on policy development, decision-making, and implementation of obesity prevention and food policy measures in New York City. Due to it being a local rather than a national or supranational jurisdiction, New York City was not included in the preceding overview of regulatory activities (chapter 4). The results from that study indicated limited relevant regulatory activity at higher levels of governance, prompting interest in the experience of lower-level jurisdictions that had succeeded in formulating and enacting innovative approaches. New York City has been a trailblazer in implementing or attempting to implement a suite of such policies. These activities as well as the responses from various stakeholders have been covered extensively in the media and in the academic literature. Therefore, this particular jurisdiction presents a useful case study subject that provides an understanding of not only what types of approaches were enacted, but crucially how successes where achieved and the nature of barriers encountered. Together with knowledge of what types of approaches are already being implemented in comparable settings, it is possible to formulate recommendations on how to optimise policy development and implementation processes for obesity prevention through legislation and regulation. This constitutes an essential piece of information for governments at equivalent and higher levels that seek to take regulatory action on dietary risk factors.

A postscript in section 6.4 briefly relates the findings presented here to complementary research published since the conclusion of the study.

The supplemental materials referred to in the article are available in appendix 3 (pp. 162-195). Also provided are the ethics application, including the recruitment and information materials used in this case study, and the confirmation of ethics approval.

# Statement of Authorship

Title of Paper	Targeting population nutrition through municipal health and food policy: implications of New York City's experiences in regulatory obesity prevention	
Publication Status	Published Submitted for Publication	Accepted for Publication Publication Style
Publication Details	health and food policy: implication	Mayer A. Targeting population nutrition through municipal as of New York City's experiences in regulatory obesity -34, doi: 10,1016/j.foodpol.2015.10,007.

# **Principal Author**

Name of Principal Author (Candidate)	Jana Sisnowski
Contribution to the Paper	Conceptualised the study; led the ethics approval process; identified and recruited participants; conducted the interviews and document review; analysed the results; drafted the manuscript; responded to reviewers; approved the final manuscript; acted as corresponding author.
Overall percentage (%)	80%
Signature	Date 11/01/2016

# **Co-Author Contributions**

By signing the Statement of Authorship, each author certifies that:

- i. the candidate's stated contribution to the publication is accurate (as detailed above);
- ii. permission is granted for the candidate in include the publication in the thesis; and
- iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Jackie Street
Contribution to the Paper	Co-conducted three interviews; coded a subsection of interviews for quality control; commented on drafts of the manuscript; reviewed and approved the final manuscript.
Signature	Date # 1. 2016

Annette Braunack-Mayer
Provided comments on drafts of the manuscript; reviewed and approved the final manuscript.
Date 12.01.0016



Contents lists available at ScienceDirect

# **Food Policy**

journal homepage: www.elsevier.com/locate/foodpol



# Targeting population nutrition through municipal health and food policy: Implications of New York City's experiences in regulatory obesity prevention



Jana Sisnowski\*, Jackie M. Street, Annette Braunack-Mayer

University of Adelaide, School of Public Health, 178 North Terrace, SA 5005 Adelaide, Australia

### ARTICLE INFO

Article history: Received 29 May 2015 Received in revised form 6 October 2015 Accepted 28 October 2015

Keywords: Nutrition policy Health policy New York City Obesity Prevention

### ABSTRACT

Obesity remains a major public health challenge across OECD countries and policy-makers globally require successful policy precedents. This paper analyzes New York City's innovative experiences in regulatory approaches to nutrition. We combined a systematic documentary review and key informant interviews (n = 9) with individuals directly involved in nutrition policy development and decisionmaking. Thematic analysis was guided by Kingdon's three-streams-model and the International Obesity Task Force's evidence-based decision-making framework. Our findings indicate that decisive mayoral leadership spearheaded initial agenda-change and built executive capacity to support evidence-driven policy. Policy-makers in the executive branch recognized the dearth of evidence for concrete policy interventions, and made contributing to the evidence base an explicit goal. Their approach preferred decision-making through executive action and rules passed by the Board of Health that successfully banned trans-fats from food outlets, set institutional food standards, introduced menu labeling requirements for chain restaurants, and improved access to healthy foods for disadvantaged populations. Although the Health Department collaborated with the legislature on legal and programmatic food access measures, there was limited engagement with elected representatives and the community on regulatory obesity prevention. Our analysis suggests that this hurt the administration's ability to successfully communicate the public health messages motivating these contentious proposals; contributing to unexpected opposition from food access and minority advocates, and fueling charges of executive overreach. Overall, NYC presents a case of expert-driven policy change, underpinned by evidence-based environmental approaches. The city's experience demonstrates that there is scope to redefine municipal responsibilities for public health and that incremental change and contentious public discussion can impact social norms around nutrition.

© 2015 Elsevier Ltd. All rights reserved.

### Introduction

During Michael Bloomberg's 12 year tenure as mayor, his administration actively promoted New York City (NYC) as a trail-blazer of international significance in chronic disease prevention (Bloomberg, 2011; DOHMH, 2012c). Successive City Health Commissioners and Department of Health and Mental Hygiene (DOHMH) staff have publicly outlined city policy choices aimed at improving population nutrition and advocated for complementary interventions at higher jurisdictional levels (Brownell and Frieden, 2009; Dowell and Farley, 2012; Farley, 2012; Farley

E-mail addresses: jana.sisnowski@adelaide.edu.au (J. Sisnowski), jackie.street@adelaide.edu.au (J.M. Street), annette.braunackmayer@adelaide.edu.au (A. Braunack-Mayer).

et al., 2009; Frieden et al., 2008). Some regulatory proposals did not pass judicial scrutiny (Pigott, 2014) or were rejected at higher jurisdictional levels (USDA, 2011; Farley and Dowell, 2014). Others have been replicated: for example, calorie posting imposed on chain restaurants has been brought to federal level in slightly modified form (Nestle, 2010). Descriptive accounts and early evaluations of new rules directly connected to obesity prevention or to healthy food access more generally have been published by public agencies and academics (e.g. Angell et al., 2012; Baronberg et al., 2013; Dannefer et al., 2012a,b; Dumanovsky et al., 2010, 2011; Freudenberg et al., 2010; Fuchs et al., 2014; Tan, 2009; Vadiveloo et al., 2011). However, the broad NYC experience as a comprehensive policy effort has remained largely unexamined. We therefore provide an overview of barriers and facilitators to policy-making for obesity prevention. Our findings, while case-specific, can

<sup>\*</sup> Corresponding author.

inform political discussions and guide other jurisdictions on the feasibility and acceptability of different regulatory options.

### Material and methods

We used a case study methodology which is well suited to "retain the holistic and meaningful characteristics of real-life events" (Yin, 2009: 4) while using a wide range of evidence. Given that this study focusses on the policy-making processes around NYC's dietary obesity prevention efforts and the factors that shaped their content, we have concentrated on accounts from policy-makers, notably civil servants and appointed and elected leaders who possess knowledge of all stages of the policy-making process. External stakeholders' influence is reflected in the documentary review and policy-makers' accounts. The choice of NYC as our case study and the subsequent selection of interviewees followed a non-probability, purposive sampling approach (Given, 2008).

The two-stage data collection process comprised a document review and key informant interviews. The document review encompassed research articles and policy documents from 2002, when Mayor Bloomberg took office, to August 2014. As summarized in Fig. 1, systematic searches of PubMed, GreyLit, and the DOHMH website for documents pertaining to NYC-specific obesity prevention policies located 114 relevant records that were included in the subsequent analysis.

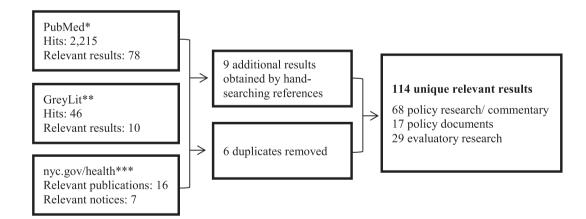
Review data informed development of the key informant interview schedule and complemented evidence from interviews. Qualitative research does not have consistent standards for sample size (e.g. Morse, 1995; Patton, 2002) and recommendations vary widely (e.g. Back, 2012; Brannen, 2012; Miller, 2012). The theoretical endpoint of data collection and analysis and a gauge of internal study validity is data saturation, described by Morse (1995, p. 147–148) as "data adequacy' operationalized as collecting data until no new

 Table 1

 Institutional affiliation (former or current) of interviewees.

New York City Department of Health	4 interviewees
and Mental Hygiene (DOHMH)	
New York City Board of Health	2 interviewees
City Hall	2 interviewees
City Council	1 interviewee
3	

information is obtained [and resulting in] enough data to build a comprehensive and convincing theory". However, as Patton (2002, p. 246) notes, "sampling to the point of redundancy is an ideal, one that works best for basic research, unlimited timelines, and unconstrained resources." He suggests that "qualitative sampling designs specify minimum samples based on expected reasonable coverage of the phenomenon given the purpose of the study and stakeholder interests" (Patton, 2002, p. 246). Among the considerations determining adequate sampling size are research scope and purpose (Back, 2012; Brannen, 2012; Miller, 2012), but also target audience characteristics (Brannen, 2012) and project resources (Miller, 2012). In this case study, we applied these principles to determine that four key government institutions involved in health and food policy (see Table 1) needed to be represented in our sample by interviewees who individually or collectively covered the entire Bloomberg mayoralty. Interviewees were selected based on their professional role. Authorship of articles and reports and/or mention in policy documents identified during the review allowed us to establish an initial list of twelve possible participants. We then used snowball sampling to identify an additional four participants involved in relevant policy processes. Sixteen interview requests were submitted: nine requests were granted (see Table 1), two participants declined and five did not respond to multiple requests. In line with Morse's (1995, p. 148) suggestion that "the tighter and more restrictive the sample and more clearly



### **Search Strategies:**

- \*\* Simple full text search for "obesity" with additional keyword "New York"" (2002-2014)
- \*\*\* Search of categories "Notices" and "Publications" (topics "Diabetes", "Food Service and Safety", "NYC Public Health", "Nutrition and Exercise", "Overweight and Obesity", 2002-2014)

Fig. 1. Document review process.

delineated the domain, the faster saturation will be achieved", this sample allowed us to comprehensively examine the views and processes inside city government. Continuous triangulation with the results from the preceding document review helped focus the interviews and together, these multiple, varied sources of evidence produce the type of in-depth exploration of a clearly defined subject matter that Yin (2009) cites as a key advantage of the case study methodology All interviews, seven face-to-face (50–70 min each) and two by email, were conducted between September and December 2014. Prior to interview, all participants were informed about project aims and confidentiality arrangements and provided written consent. Ethics approval (H-2014-122) was obtained from the University of Adelaide.

Data analysis followed an inductive thematic approach from open to selective coding (Liamputtong and Ezzy, 2005). Initial line-by-line coding identified initial theoretical strands, which were organized into descriptive themes from which analytical themes were developed (Thomas and Harden, 2008). The interview schedule was updated iteratively throughout the research process. All transcripts were initially coded by JS. JMS independently coded the first four interviews, with differences compared and discussed to engender coding reliability. These and additional methodological details are documented in the online Supplementary data.

### Theoretical framework

We use two complementary frameworks to underpin our approach. Firstly, we draw on Kingdon's (1995) multiple-streammodel which offers a process-oriented representation of the key forces and actors in policy-making. Focusing on agenda-setting, the process preceding legislative or executive decision-making, Kingdon (1995) conceptualizes successful policy-making as the result of a brief coupling of otherwise largely independent streams of problem identification, policy solution, and politics. A focusing event, electoral change, or a rapid shift in public opinion open up a limited window of opportunity seized by "policy entrepreneurs [who] hook solutions to problems, proposals to political momentum, and political events to policy solutions" (Kingdon, 1995: 182). Kingdon (1995) argues that thematic agenda-setting occurs suddenly in the political stream, whereas potential solutions are developed incrementally in the policy stream. Similarly, in the expert-driven policy stream, consensus is achieved through "processes of persuasion and diffusion [in which] ideas survive scrutiny according to a set of criteria" (Kingdon, 1995: 159), whereas political agreement is reached by bargaining around varied interests. Assuming that solutions are flexible and predate political opportunity, he suggests that the entrepreneurs "try to make linkages far before windows open so they can bring a prepackaged combination of solution, problem, and political momentum to the window when it does open" (Kingdon, 1995:

Secondly, we draw on the International Obesity Task Force's (IOTF) evidence-based decision-making framework (Swinburn et al., 2005). To complement Kingdon's focus on parallel processes with a modeling of policy-making as a sequence of actions. The framework identifies five consecutive key actions for successful development and implementation of obesity policies: (1) making a case for policy action, (2) identifying causes, contributors, and corresponding intervention levers, (3) defining possible interventions and their contexts, (4) prospectively evaluating potential measures, and (5) developing a comprehensive policy program combining complementary interventions (Swinburn et al., 2005). Together, these two conceptual models provide a comprehensive explanatory framework for the processes and components of policy-making.

### Results and discussion

A number of major themes relevant to successful policy development and implementation in the area of nutrition-related obesity prevention emerged from the interviews and document review (see the online appendix for a categorized overview of publications identified). Drawing upon Kingdon's and the IOTF's frameworks, we begin with an analysis of the drivers of policy initiation, followed by a discussion of the role that evidence played in policy design and justification. We then explore feasibility considerations and expert-driven decision-making as two pivotal constants during the Bloomberg era. The place of regulatory obesity prevention within the wider health and social policy agenda is discussed with particular emphasis on stakeholders' diverging views on food access. Finally, we review the limitations of New York's expertdriven regulatory approach to obesity prevention and present lessons-learned as well as recommendations offered by policymakers there.

Executive leadership and agency expertise as a catalyst for policy development

All sources agree that Mayor Bloomberg's personal interest and political investment in chronic disease prevention was instrumental in establishing and advancing a policy agenda in this area. His election and tenure were clearly identified as a window of opportunity:

"You need the political will to get it done; in other words, you would need a mayor as well as a commissioner [or] other appointed official, to be able to say, this is the policy that needs to be developed and this is why. [...] We did always think of Bloomberg as the public health mayor, and we knew that we were there in what I call the golden age of public health in New York City."

[Interviewee 5, DOHMH]

Bloomberg meets Kingdon's description of a prototypical policy entrepreneur whose "defining characteristic, much as in the case of a business entrepreneur, is their willingness to invest their resources - time, energy, reputation, and sometimes money" (Kingdon, 1995: 123). Indeed, Bloomberg's election drew together the political and policy streams: a member of the political realm, he hooked the political will to explore and enact regulatory action to the policy stream. However, rather moving directly into concrete decision-making, the initial years were devoted to internal capacity building. This finding appears at odds with Kingdon's proposition that pitch-ready policy solutions need to be available as soon as a political event opens a window of opportunity. Instead, in this case, a policy entrepreneur, whose election in itself represented a window of opportunity, initially set about creating conditions for policy change. An integral part of this strategy was the installation of lower-level policy entrepreneurs to drive the effort at a technical level. Thus, commitment to and expertise in chronic disease prevention was built throughout the health department hierarchy: the first Health Commissioner of the Bloomberg era, Thomas Frieden, handpicked by the Mayor (Colgrove, 2011), was repeatedly described as the fulcrum for concrete policy change. Additionally, an expanding workforce brought skills and experience, and departmental re-organization consolidated the focus on chronic disease prevention. A Division of Disease Prevention and Health Promotion was swiftly created under the new administration and later divided into bureaus. For the first time, staff was allocated specifically to several high-burden chronic diseases such as diabetes (Colgrove, 2011) and specialized programs and bureaus were created, including the Physical Activity and Nutrition

Program that became part of the new Bureau of Chronic Disease Prevention and Control and "grew by leaps and bounds [...] under the Bloomberg Administration" (Interviewee 5, DOHMH). Current DOHMH expertise covers the whole spectrum of obesity prevention, as one participant explained:

"The Bureau [...] encompasses all the obesity work, and includes the policy work [...], a research and evaluation unit [...], a programmatic unit [...] and a communications unit. [...] Because there is now a policy unit, the way that the department is structured around this, I think [it] streamlines a lot of things and it is a very nimble unit."

[Interviewee 3, DOHMH]

Against this backdrop of organizational change, interviewees disagreed about the future of NYC obesity prevention. Some regarded the end of the Bloomberg era as synonymous with the end of innovative public health interventions:

"We had this window. We had to take it. [...] I knew that when Mayor Bloomberg left that our power would disappear."

[Interviewee 1, DOHMH]

Others pointed out the continuity in terms of expertise and commitment at agency level and changes in institutional awareness and knowledge on nutrition:

"I think that there has been a shift nationally and locally on these issues. [...] The rationale and the knowledge no longer just live with us. It's a lot easier to have those conversations even within the agency these days because we've done all this work, but because they're a part of the conversation to begin with."

[Interviewee 2, DOHMH]

Accordingly, despite Bloomberg's pivotal role as catalyst and enabler of policy change, institutional reform preceded policy development and had a lasting impact on policy priorities.

Evidence-driven framing of the problem and possible intervention points

As reflected in the IOTF's framework, building a case for action on obesity was a starting point for NYC policy-makers. All interviewees identified problem severity, particularly the high and increasing prevalence of obesity and related chronic diseases, as the driving force behind policy initiation. The consistent and heavy use of evidence by NYC policy-makers has been noted previously, particularly their critical evaluation of published research and collection of local epidemiological data (Laugesen and Isett, 2013). Local studies include the annual Community Health Survey and the NYC Health and Nutrition Examination Survey whose first iteration in 2004 found high prevalence of metabolic syndrome and obesity (Jordan et al., 2012). This reinforced an earlier study's findings that 53% of New York City adults, and particularly Harlem, Bronx, and central Brooklyn residents, were overweight or obese (DOHMH, 2003). The problem statements introducing the rules on trans-fats (DOHMH, 2006a), calorie posting (DOHMH, 2006b, 2008a,b), and sugary drinks portion size (DOHMH, 2012a,d) made extensive reference to obesity prevalence. In addition, other observational data indicating shifting consumer behavior, including a national shift towards prepared food, were used to define areas for intervention. Locally, DOHMH studies analyzed food environments and consumption patterns, primarily in neighborhoods with particularly dire health indicators. Prominent characteristics identified include the limited availability of healthy foods and beverages, coupled with cost and quality concerns, the ubiquity of unhealthy foods, and high consumption of sugary beverages (e.g. Adjoian et al., 2014; Alberti and Noyes, 2011; Bassett et al., 2008; Dannefer et al., 2012a,b; DOHMH, 2011; Elfassy et al., 2014; Rehm et al., 2008).

Within the IOTF framework (Swinburn et al., 2005), identifying potential points of intervention (issue 2) and instruments with which to respond (issue 3) are underpinned by the choice to view obesity as an issue amenable to successful local government intervention (Swinburn et al., 2005). Kingdon conceptualizes this as the differentiation between condition and problem, subject to a "perceptual interpretative element" (Kingdon, 1995: 110). In NYC, this involved understanding obesity as not only a problem for the federal government, but also for local government. Accordingly, interviewees consistently viewed obesity as a societal problem requiring a systemic response. City government was seen to be in a position to change the food environment, with regulatory action considered an effective and expedient tool. This shifting focus is also evident in the City's strategic health agenda: the inaugural 2004 'Take Care New York' outlines individual-level actions, while the 2012 version privileges government action on socioeconomic levers, such as the food environment (DOHMH, 2004; Frieden, 2004a,b; Summers et al., 2009). As one interviewee explained, the concentration on regulatory competencies followed an early "across-the-board effort within the Health Department to update the Health Code" (Interviewee 5, DOHMH) to align with evidence. The administration's perception that regulatory measures could be used to address chronic disease risk factors was reinforced by parallel evidence from successful tobacco control measures:

"Having achieved [tobacco control] as the first priority under the Bloomberg administration around public health I think gave confidence and maybe more political will- hey, this worked, and we should maybe think about that for obesity. [...] The fact that they were able to operationalize it successfully kept that partnership [between Mayor and Health Commissioner] going and created leverage and political will."

[Interviewee 5, DOHMH]

In summary, epidemiological evidence, often collected at city level, underpinned the framing of obesity as a societal problem and served to identify possible intervention points within that paradigm.

Choosing interventional targets: the primacy of feasibility

Despite substantial evidence of high prevalence of obesity and associated risk factors, interviewees noted that regulatory response measures were selected without much knowledge of their potential impact:

"We were really charting the course of trying to implement what people were saying on paper should be done around policy and practice to prevent obesity, but we didn't have a blueprint."

[Interviewee 5, DOHMH]

Policy design therefore relied on program logic and practical feasibility. To mitigate risks in making policies with incomplete evidence, the IOTF advocates a portfolio approach (issue 5), i.e. mixing interventions based on varying anticipated effectiveness and projected overall impact (Swinburn et al., 2005). This follows from resource-intensive small-scale interventions, typically directed at high-risk groups, usually coming with good evidence of effectiveness. By contrast, potentially high-impact population-wide approaches remain largely untested and often involve longer and more contextualized pathways between intervention and desired outcome. Selecting a mix of interventions serves two purposes: it helps address the multi-faceted causes and mediators of

obesity. It also counterbalances risks associated with implementing promising population-wide interventions whose outcomes are estimated mostly through extrapolation and logic (Swinburn et al., 2005). As a result, the IOTF considers such prospective evaluation (issue 4) challenging (Swinburn et al., 2005). However, the NYC experience suggests that the selection of a comprehensive portfolio can be even more difficult. Two reasons account for this: firstly, the explicit shift to population-wide interventions operates independently from interventions targeting small high-risk groups. Secondly, a mix of measures as the ideal theoretical endpoint undervalues incremental policy-making essential to innovation: evaluation results and political experiences need to feed back into and act as stepping stones for future policy-making. Accordingly, a case-by case attitude driven by a sense of urgency characterized the Bloomberg administration's approach:

"I'd like to say that it had a whole sequenced strategic plan but it didn't. We had lots of ideas, ones we felt we had a decent chance of success, which would have a big impact, we tried. We all- I certainly during my time- had this intense sense of time being [...] So, no, we didn't think too much about it- this works, what will we do next."

[Interviewee 1, DOHMH]

The trans-fat restriction proposal offers an example of the line of reasoning used in the absence of conclusive evidence. With data on population-wide health impact lacking, DOHMH argued that removing a problem should naturally translate into positive health impact: with the increased share of calories consumed away from home, the prohibition of trans-fats would substantially reduce associated harmful effects. The notice of adoption estimates that between 6% and 23% of coronary heart disease cases could be prevented and cites precedent in Denmark to alleviate concerns that the new rule would harm industry (DOHMH, 2006a). Authoritative opinion such as recommendations by the Department of Agriculture and the American Heart Association, as well as prior political action at federal level indicating general support for similar measures, featured in policy documents (DOHMH, 2006a) and interviewees' accounts:

"[A] very sound rich body of scientific literature, [including] at the time a fairly recent article by Mozaffarian [(Mozaffarian et al., 2006)] that laid out the impact on coronary heart disease, led to identifying trans-fat as something that the department wanted to focus on. In addition, the F.D.A. had a couple of years prior required the labelling on nutrition facts panels of trans-fat. Prior to that it would've been less feasible, though doable."

[Interviewee 2, DOHMH]

After accompanying programmatic interventions to facilitate the switch were put in place and deadlines pushed back at industry request, the rule quickly met targets (Angell et al., 2012). The ability to isolate trans-fats accounts for a large part of policy selection and success:

"We recognized that trans-fats weren't contributing to the obesity problem. They were a nutritional problem – probably not the biggest nutritional problem in America, but they were one that you could isolate off because it was an artificial chemical that shouldn't have been in the food supply in the first place and we could just ban it. You couldn't do that with saturated fats. You couldn't do that with sugar."

[Interviewee 1, DOHMH]

Similarly, with regard to the proposal to limit sugary drinks portion size to 16 oz (0.5 l), interviewees pointed to the ease with which sugar-sweetened beverages could be isolated given their lack of nutritional value and major calorie contribution:

"[A] concern I had about the rule, but which I think the health department did a very good job of allaying [was,] if I go to the movies and buy a 24 ounce soda and a large popcorn, there are more calories in the popcorn than in the soda. And the response was, there is some nutritional value in popcorn, there is no redeeming nutritional value in high fructose corn syrup, it's pure calories."

[Interviewee 4, Board of Health]

This same argument could not be applied to calorie posting where consumer choice was highlighted:

"Not that that was the rationale that was used, but this concept of consumer education and transparency, here we're providing information so that consumers could make better, more informed choices in the hopes that that would reduce calorie consumption."

[Interviewee 2, DOHMH]

While the problem statement put forward (DOHMH, 2008a, 2006b) is almost identical to the trans-fat rule, the original justification for calorie posting largely sidestepped estimates of its impact on consumption. Instead, the rationale is presented as a response to consumer acceptance of federally mandated nutrition labels on pre-packaged foods and supportive opinion polls (Frieden, 2004a). Rather than discussing the unclear anticipated effect on obesity, these arguments appear to justify the proposed intervention as in step with societal expectations, "probably reassur[ing] the board that its moves were not so far out in front of public opinion as to threaten its institutional legitimacy" (Mello, 2009: 2018). Only in the revised proposal extending the scope to all chain restaurants did additional DOHMH research prompt a more ambitious estimate of anticipated effects on consumption. The reenactment followed a successful lawsuit brought by the New York State Restaurant Association that found the previous version pre-empted by federal law (Holwell, 2007, 2008), In its re-submission to the Board of Health, DOHMH (2008a) drew on research on Starbuck's voluntary introduction of a rudimentary form of calorie posting that found just under one third of consumers noticing the new information, with purchases by this segment of customers averaging 48-52 fewer calories (Bassett et al., 2008). This resulted in the estimate that the new rule would lead to "at least 150,000 fewer New Yorkers [becoming] obese, [and] at least 30,000 fewer cases of diabetes" (DOHMH, 2008a: 7) over five years.

Overall, policy development was consistently anchored in research evidence. However, policy-makers also demonstrated a willingness to take a leap of faith where concrete outcomes could only be predicted based on extrapolation and assumptions. Similarly, the administration actively contributed to closing the evidence gap by conducting in-depth evaluations.

Balancing expert policy and decision-making with community involvement

Removing agenda-setting, policy development, and formal decision-making from the usual legislative realm and instead positioning regulatory responsibility with the Board of Health made the policy process largely expert-driven.

"Any time that anywhere legislative people tried to use a legislative process, it opened up the process to lobbying and industry groups coming and interrupting that process. [...] One of the reasons why we were able to get things done is because we had local regulations in place, and we were not beholden to elected officials and as much of the politic process."

[Interviewee 5, DOHMH]

Rather than representing any particular interests outside the health realm, the Board is required by law to be made up of five medically-qualified members, plus five with advanced health-relevant degrees (New York City Charter). Consequently, regulatory decision-makers belong to the same community of experts as those who develop the policy proposals and likely hold similar views.

"Most of us keep abreast of the developments in medicine and public health, and are well aware of the role that sugary beverages have played in the obesity epidemic. And we reviewed, as part of the rule making process, a lot of the background documents, a lot of the scientific studies."

[Interviewee 7, Board of Health]

However, keeping all aspects of policy-making within the expert realm and moving quickly to maximize the number of initiatives attempted during the exceptionally supportive and expert-inclined Bloomberg mayoralty entailed sacrifices: where time was judged too short to build public support for regulatory actions that would not be subjected to direct electoral or legislative scrutiny, a lack of community engagement ultimately emerged as a threat. Interviewees described policy development as "very guarded" (Interviewee 5, DOHMH) until a fully fleshed out policy would be floated and rapidly prepared for formal decision-making. Some participants argued that a degree of institutional secrecy was justified:

"New York City is a media center and especially after the early successes in tobacco, the press was always looking at us ready to write a story. There is nothing we could develop [...] without fear that it might leak out in the development process and we would get an embarrassing story and end up really hurting our ability to get it done. So everything was done with the greatest secrecy and determination that no one who wasn't in the Department could hear about this until the plan was fully finished."

[Interviewee 1. DOHMH]

Others pointed out that these isolationist tendencies came at the expense of preparatory work, especially where policies were perceived or portrayed as unfairly targeting minority populations as was the case with the proposals related to sugary drinks:

The smoking stuff, for all the initial grumbling, got great press. And I think they got a little cocky, didn't do their political homework well enough. [...] The problem was not with group politics, but with public perception [...]. They might have done better to have spent six months or a year in a public relations kind of campaign and doing more public education on the subject. It would have been great to have some African-American athlete or celebrity be a spokesperson for this kind of proposal."

Lack of community support impacted most on the failure to address sugary beverage consumption through a state tax, exclusion from SNAP (Supplemental Nutrition Assistance Program/food stamp) benefits that was rejected by the federal government, and the portion cap rule. Predictably, lobbying efforts by the beverage industry were perceived as a major stumbling block in swaying public opinion and gaining legislative support. While usual industry arguments on personal choice and responsibility were widely expected, industry efforts to capitalize on the diversity of NYC constituencies caught policy-makers by surprise.

"The group that surprised and disappointed us the most were the minority groups. On the food stamp proposal in particular, the hunger advocates came out very vocally against that. We were presented as somehow we were being mean to poor people. [...] With the portion cap, I was really shocked and terribly disappointed at the civil rights groups that came out against it [such as] the NAACP [National Association for the Advancement of Colored People]."

[Interviewee 1, DOHMH]

During the public comment periods for the three rules that came before the board, the joint original proposal on trans-fat and calorie posting received approximately 2,200 comments, with 99% supportive of the trans-fat proposal and 97% supportive of calorie posting (DOHMH, 2006a, 2006b). By contrast, the sugary drinks portion size rule yielded approximately 32,000 comments in support and 6000 in opposition (~84% positive) (DOHMH, 2012b). Despite the fact that, in all cases, written comments and oral testimony were coordinated by public health advocates and researchers, much greater participation on the sugary drinks rule. particularly in opposition, highlights clear differences in reception. The overall regulatory strategy's inability to overcome jurisdictional limitations, namely food retail being partially regulated by New York State (DOHMH, 2012b), ultimately contributed to the initial ruling finding the regulation "arbitrary and capricious" (Tingling, 2013). While this aspect was not confirmed in subsequent decisions (Pigott, 2014; Renwick, 2013), the three courts agreed that executive overreach invalidated the rule.

Interviewees commented on widespread lobbyist and media misrepresentation of the rule as a soda ban and industry behavior partially motivated at least one Board member to vote in favor of the sugary drinks portion cap:

"The industry people were so obnoxious and so offensive that they lost me entirely. [...] The other thing that really bothered me is they really did a good job, from a political and public relations point of view, buying off minority politicians."

[Interviewee 4, Board of Health]

In summary, the expert-driven approach helped focus policy design on research evidence without dilution by private interests, but policy-making in relative isolation from public debate also enabled public discussion to be seized by industry.

Regulatory obesity prevention within the wider health and social policy agenda

The use of government regulation to change consumption prompted reservations based on a perceived dichotomy with equitable access to healthy food:

"There is such a powerful socioeconomic gradient associated with obesity and access to healthier alternatives, both in terms of foods and in terms of life circumstances between lower income communities and upper income communities. [...] So, I would prefer a world for obesity in which we were in the position [of providing] more positive assistance for people eating more healthily."

[Interviewee 4, Board of Health]

"The Mayor looked a lot at this through the concept of food choices in a somewhat punitive way, let's limit access to this and that. [...] Where we saw things slightly differently is I'm a big advocate, as was the Council, for food access. I believe that partially why people make bad choices is [...] because they don't have any other choice."

[Interviewee 6, City Council]

Similarly, the federal Department of Agriculture ultimately rejected the SNAP exclusion request by reference to its "longstanding tradition of supporting and promoting incentive-based

solutions to the obesity epidemic" (USDA, 2011). DOHMH viewed food access and obesity prevention as complementary, but not identical issues:

"That whole concept of food deserts caught on at that time [...], so there was an interest in the City Council, there was an interest in the Deputy Mayor's Office and so they created this Food Policy Coordinator really around increasing access to healthy foods, not so much obesity prevention. Later, the two themes sort of merged, but that came from a totally different direction"

[Interviewee 1, DOHMH]

Evidence regarding the relationship between food insecurity and obesity prevalence is mixed: local studies demonstrated an association of obesity with socioeconomic status (Black and Macinko, 2010: Black et al., 2010) and an association between neighborhood socioeconomic status and fast food/convenience store density (e.g. Gordon et al., 2011; Kwate et al., 2009). At the same time, research has not found any consistent, populationwide association between food insecurity and the relationship between obesity and food outlet density appears more complex than hypothesized (e.g. Karnik et al., 2011; Stark et al., 2013; Viola et al., 2013; Yaemsiri et al., 2012). Nevertheless, the food environment was addressed: while the City Council passed the first zoning laws incentivizing supermarkets in low-income areas, DOHMH undertook other, less publicized regulatory changes, including to school food (Perlmanm et al., 2012), nutrition in child care facilities (DOHMH, 2006c) and children's camps (DOHMH, 2012e) and through Executive Order No. 1225 (Office of the Mayor, 2008) applying food standards to city food procurement (Lederer et al., 2014). Both the executive and the legislative branch claim responsibility for early rule changes and programs around access to healthy foods: DOHMH interviewees highlighted their Healthy Bodegas Initiative and the Health Bucks program supplementing food stamps spent at NYC greenmarkets with additional fruit and vegetable vouchers. This program built on an initiative, funded by the City Council since 2006, to facilitate the use of electronic food stamps at greenmarkets. Despite such complementary executive and legislative initiatives, the relationship with DOHMH was judged uneven by the City Council. Part of the dissonance appears due to the general absence of horizontal coordination. Local health departments' capacity to initiate and coordinate "cross-agency conversations and policymaking [in order to] insert health concerns into a vast range of policymaking activities within their jurisdictions" (Pomeranz, 2011: 1193) has been increasingly stressed, often by reference to NYC. Yet, instead of a systematic approach, engagement in obesity prevention,

"in an informal way,  $[\ldots]$  happened just when ideas got floated around City Hall.  $[\ldots]$  But there wasn't any formal adoption of Health in All Policy."

[Interviewee 1, DOHMH]

The aforementioned executive order that mandated the establishment of city food standards also added a Food Policy Coordinator to the Deputy Mayor's office. The new role brought together representatives from City Hall, the Departments of Health and Education, the City Council, and others to work together on policy proposals and develop the food standards. Thus, half-way through the Bloomberg mayoralty, the lack of health-in-all-policies-approaches in food policy was partially resolved, albeit without extending the principle to other health concerns and government sectors. The Coordinator became a focal point for whole-of-government representation and advocacy, recognizing that while

"DOHMH is widely understood to have the content expertise on this issue [...], this role focuses on building collaboration between and among about 15 agencies who have some operational role in food [and] on cooperation with New York State and [...] similarly situated food policy advisors in cities nationwide."

[Interviewee 9, City Hall]

An early internal review concluded that "although most of the City's food programs are developed within specific agencies, the Food Policy Coordinator appears to have been able to promote coordination between different agency initiatives, reduce programmatic overlap, improve inter-agency communications, and ultimately help bring the initiatives to fruition". (NYC Center for Economic Opportunity, 2008: 103). One initiative established 1000 permits for Green Carts, mobile food vendors providing fruits and vegetables to underserved areas (Rules of the City of New York; DOHMH, 2008b). It encountered unexpectedly harsh opposition from bodega owners and other businesses. The Food Policy Coordinator was credited in part with the eventual passage of this bill, making it "more palatable to Council members because it was part of a larger, coherent City food policy" and leveraging "relationships with community based organizations [that] were critical in the development of a coalition of more than 100 organizations that supported the Green Cart legislation" (NYC Center for Economic Opportunity, 2008: 6). Conversely, an Obesity Task Force, also convened by the Food Policy Coordinator, assembled representatives from across the executive, but not the City Council. Plans outlined in its 2012 report (NYC Obesity Task Force, 2012) included a range of activities related to healthy food access, but focused on the sugary drinks portion cap for which legislative support was lacking. In addition, there was a preference for executive solutions where legislative political will could have been leveraged:

"[For] the trans-fat issue and the calorie count, we had Council members that wanted to pass legislation to do that. [...] After the Board did it, we actually passed legislation to codify [trans-fats only; a bill proposing alternative nutrition information provision was introduced], so that if a future mayor wanted to get rid of it they would have to actually repeal it."

[Interviewee 6, City Council]

Overall, the perceived dichotomy between, on the one hand, obesity prevention that was seen as unfairly targeting minority populations by some and food access on the other hand put the Bloomberg administration at odds not only with anti-hunger advocates and minority organizations, but also with the City Council. Ceding some control over strategic directions and integrating the two issues through the Food Policy Coordinator helped DOHMH maximize policy outcomes where political agreement could be reached.

Limits to harnessing city regulatory powers

There was notable appreciation of the regulatory powers of the Board of Health, with one member describing it as "the most powerful government body with which I have ever been associated" (Interviewee 4, Board of Health). However, the limits of executive rule-making and city authority in a federal system were apparent. Pre-emption at state and federal level on taxation and SNAP prevented the city from enacting a sugary beverage tax and banning soda from food stamps. Similarly, the sometimes strained relationship between legislative and executive branches and court decisions overturning the sugary drinks portion size cap illustrate the limits of executive action. The final ruling by the State Court of Appeals, held that the Board "exceed[ed] the scope of its regulatory authority" and "engaged in lawmaking [that] infringed upon the legislative jurisdiction of the City Council" (Pigott, 2014), which

by all accounts would have opposed the measure. Concern that such a ruling would restrict the executive in developing innovative regulatory approaches does not appear to have been a major concern at the time: however, with the rule struck down, the general assumption that "agency rulemaking receives deferential judicial review" (Pomeranz, 2011: 1195) has been invalidated. This, in turn, may influence both future judiciary decisions and executive policymaking.

On the other hand, in the NYC context, the portion cap also shows how the failure of one policy gave rise to creative thinking about alternatives:

"There was a general thought in public health to think about other strategies besides a tax that might be effective. [...] Because the tax proposals met with such opposition the thinking was let's try something else.

[Interviewee 7, Board of Health]

All major policies were evaluated and findings published as part of the administration's commitment (Farley and Van Wye, 2012) to building the evidence base. In the short term, none of the NYC interventions substantially reduced calorie intake: measures targeting food access rather than obesity directly achieved some success in adding healthy choices to the food environment (Dannefer et al., 2012a,b; DOHMH, 2010; Fuchs et al., 2014; Kerker et al., 2014) and in increasing the use of SNAP benefits at farmers' markets (Baronberg et al., 2013). With regard to interventions that made calorie intake a direct evaluation metric, calorie posting did not change restaurant purchases, despite moderate increases in the number of patrons who reported noticing the information (Dumanovsky et al., 2010, 2011; Elbel, 2011; Elbel et al., 2009, 2011; Vadiveloo et al., 2011) and some suggestions of menu item reformulation towards lower calorie content (Nestle, 2010). Nevertheless, policies that fail to live up to their anticipated direct impact may still achieve a degree of success not captured by evaluation designs:

"[Research on the effect of calorie posting] still doesn't capture the full impact because anecdotally people have talked about changing either patterns of purchases, they used to get it every morning and now they only get it once a week, or that they saw that they purchased a large amount of calories and compensated later in the day."

[Interviewee 2, DOHMH]

Most importantly, this regulation as well as proposed policies that were not enacted or implemented such as the three soda initiatives that failed at different levels of government may have changed attitudes and behaviors more widely and ultimately contributed to positive health impacts.

"Life-expectancy expanded dramatically during the Bloomberg administration. [...] Sugary drink consumption is plummeting and we have good data on that. Childhood obesity rates are also going down in New York City right now. So a lot of things did succeed in the ultimate thing we care about, even though some of the policies themselves didn't go through."

[Interviewee 1, DOHMH]

Indeed, New York experienced a general increase in life-expectancy that outpaced national trends (Li et al., 2013) and obesity prevalence among city elementary and middle school students (CDC, 2011) and children from low-income families (Sekhobo et al., 2014) decreased across New York City. These improvements, often observed in studies with ecological design, do not allow any claim of causality in relation to food policy. However, antismoking laws and "associations with both citywide and targeted policies" (Li et al., 2013:11), including food policy,

are suggested as potential contributors to improved lifeexpectancy. Regardless of their attributable health impact, these controversial regulatory measures, including those not implemented, may have changed attitudes and behaviors simply through the extensive public and political debate they generated:

"Even though we lost all those major policies [on sugary drinks], in focus groups people now all tell us, 'oh yeah, that stuff is bad, I'm trying not to drink it'. [...] That is a success that we didn't expect, but we're pleased it happened. In general, there's a dynamic relationship between messages you hear in the media and policy change. Messages can enable policy changes to occur. Policy changes can enable the national conversation to change."

[Interviewee 1, DOHMH]

Consequently, while key interventions did not substantially alter consumption patterns or never made it to implementation, the overall policy effort may have contributed to obesity prevention. In particular, the contentious and highly politicized debates around proposals likely had a constructive effect in increasing public awareness and paving the way for future regulation.

### Recommendations proposed by NYC policymakers

Recommendations for other jurisdictions put forward by interviewees coalesced around three themes directly connected to key issues encountered during the policy-development, decision, and implementation processes. Interviewees stressed the importance of creating supportive public opinion to stave off opposition, particularly from well-resourced industry. Targeted community outreach beyond mass education campaigns was seen as a key ingredient. They also expressed the sentiment that shifting the focus from changing the behavior of consumers to changing corporate behavior could reframe interventions as a question of justice and social responsibility rather than a threat to individual choice:

"We should have had a broad-based coalition so we'd have done more community organizing around it and made the case for community groups that this is a case where this big rich industry is making money, making profits, by making you sick. You should be angry about that and you should be working with us on this."

[Interviewee 1, DOHMH]

Others agreed that community outreach was necessary, but should not be the primary occupation of health departments. Instead, they advised harnessing relationships with experts, advocates, and the media to support political decision-making and influence public opinion:

"Those relationships are critical, but it's not really the function of a public health agency to do direct community outreach- it's to engage other stakeholders to do that outreach."

[Interviewee 5, DOHMH]

"A strong relationship with the researchers, because they can speak to that as an independent voice as it goes out. A strong understanding of the media landscape, journalists and publications that understand public health and you can talk to and really explain."

[Interviewee 2, DOHMH]

Interviewees also confirmed that a favorable constellation of circumstances similar to Kingdon's three streams was instrumental in allowing measures to be formulated and implemented. In particular, political will, maximization of regulatory, expert-driven decision routes, technical expertise in the policy stream, and implementation capabilities were seen as critical components. However,

in terms of future policy action in NYC, interviewees indicated that the most conspicuous targets for regulatory action have already been addressed and other areas are more difficult to address.

"Part of the truth is so much was done, I'm not sure how much low hanging fruit, no pun intended, there still is. [...] In part maybe it's just stuff is harder and more time consuming now, and maybe there isn't as much urgency because they want to continue what we did and see what that yields."

[Interviewee 6, City Council]

With regard to other jurisdictions, interviewees suggested that policy-makers should appreciate and take advantage of the role of municipal law-making as a relatively protected space in which to establish and then diffuse a policy agenda. This is an idea that has also been stressed in previous research (Freudenberg et al., 2010; Frieden, 2004b). Decision-makers should pay particular attention to the varying areas of legal authority within both the executive and legislative branches in their respective local entities.

"I think what you want to do is figure out ways that you act very locally, because that's what a legislature can do that a mayor can't. Find ways when your mayor does something right to back it up. And then use whatever type of particular legislative power you have as a city council, in some cities that's zoning, in others it might be tax law, every city's different, and use them creatively."

[Interviewee 6, City Council]

The trailblazing function, more so than individual policy success or evidence generation, was setting a highly visible precedent redefining municipal responsibilities:

"Up until this time, everybody looked to the federal government for leadership in public health. [...] That a mayor would take on a public health agenda, nobody thought that would ever happen. That's not what mayors do- mayors fight crime and pick up the garbage."

[Interviewee 1, DOHMH]

No interviewee went so far as to suggest that regulatory intervention alone could substantially change consumption patterns. However, there was agreement on the intermediate effect of political discussion and accompanying programmatic work in changing social norms as well as strong sentiment that political responsibility for public health needs to be re-defined.

### **Conclusions**

This paper provides an in-depth analysis of obesity prevention policy-making during the Bloomberg mayoralty. During this period, DOHMH championed regulatory interventions directly targeting nutritional intake, including stringent city food standards, removing trans-fats from restaurant food, requiring calorie posting in chain restaurants, restricting sugary drinks portion size, proposing a statewide soda tax, and altering local SNAP rules. The latter three proposals were met with fierce resistance from various quarters, including minority business organizations, civil rights advocates, and the majority of the City Council. These stakeholders considered restrictive approaches inequitable or harmful to small businesses and preferred regulatory and programmatic work with a more enabling focus, such as access to healthy foods.

Basing our analysis of key Bloomberg-era policy processes on the models proposed by Kingdon and the IOTF enabled observation of two crucial differences. Firstly, the involvement of the political stream was kept to a minimum due to the administration's decision to keep decision-making largely within the domain of experts. At the same time, political will played an important role in initiating and sustaining policy development. Kingdon's model does not foresee the development of innovative policies from theoretical research evidence nor does it take into account the need to first build capabilities for such policy development to occur. Conceptualizing policy-entrepreneurs as figures that pop up occasionally only to link pre-existing elements does not capture the strategic approach taken by Bloomberg and lower-level policy entrepreneurs in changing administrative structures to sustain agenda change. Secondly, the expert decision-making routes favored by the Bloomberg administration presented the challenge of balancing institutional secrecy, maintained to protect policy development, with the need to build community and legislative support. The executive branch clearly underestimated the importance of the latter two elements. As a result, the loss of the soda lawsuit, partially attributed to legislative and public opposition, is now considered a possible inhibitor for future regulatory innovation. Nevertheless, there is also anecdotal evidence that this and other widely discussed measures changed public and policy-maker perceptions.

Our findings may serve to encourage other jurisdictions that lack Bloomberg-style leadership to explore their options for regulatory obesity prevention. In particular, other jurisdictions should look to maintaining awareness of the problem and developing tailored solutions in anticipation of a change in political circumstances. Researchers have a role in creating policy entrepreneurs through dissemination of findings to receptive policy-makers and explanation of their applicability to specific jurisdictional contexts. Our research also underscored that political action and public support for a particular public health agenda are intertwined and mutually supportive. This cautions against decoupling regulatory change from programmatic interventions and highlights the importance of community involvement through public education and participatory policy development. Inclusive policy development, while more cumbersome in the short term, may prove advantageous by changing social norms and paving the way for implementation of publicly acceptable and politically sustainable interventions. Jurisdictions seeking to extract lessons should therefore also consider the limits of regulation in isolation. Despite the international buzz generated by health department-driven precedents, decision-makers in this research clearly acknowledge the value of cross-sectoral health policy. In addition, much of the impact of the proposed and implemented regulatory changes is described as increased awareness of the problem severity and risk factors. Consequently, while NYC exemplifies innovative and pragmatic approaches to chronic disease prevention, it has not transformed conventional approaches to health policy-making nor would this be conducive to effective obesity prevention.

### Acknowledgements

The authors wish to thank all interviewees who took the time to share their insights and expertise. We also gratefully acknowledge the guidance provided by the HealthyLaws research team and advisory committee.

This project was conducted as part of the study HealthyLaws – Public Perspectives in Public Health Law, funded by the Australian National Preventive Health Agency (ANPHA), project ID: 182BRA2011. ANPHA had no role in the study design; the collection, analysis, and interpretation of data; or the writing of the manuscript. JMS is also supported by an NHMRC Capacity Building Grant (565501) and holds an Australian National Preventive Health Agency Fellowship (20STR2013F).

# Appendix A. Supplementary material

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.foodpol.2015.10.007.

### References

- Adjoian, T., Dannefer, R., Sacks, R., Van Wye, G., 2014. Comparing sugary drinks in the food retail environment in six NYC neighborhoods. J. Community Health 39, 327–335.
- Alberti, P., Noyes, P., 2011. Sugary Drinks: How Much Do We Consume? A Neighborhood Report by the Bronx, Brooklyn and Harlem District Public Health Offices. DOHMH, New York, NY.
- Angell, S.Y., Cobb, L.K., Curtis, C.J., Konty, K.J., Silver, L.D., 2012. Change in trans fatty acid content of fast-food purchases associated with New York City's restaurant regulation: a pre-post study. Ann. Intern. Med. 15, 81–86.
- Back, L., 2012. Expert voices. In: Baker, S.E., Edwards, R. (Eds.), How Many Qualitative Interviews is Enough. National Centre for Research Methods Review Discussion Paper, pp. 12–14. <a href="http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf">http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf</a> (accessed 22.09.15).
- Baronberg, S., Dunn, L., Nonas, C., Dannefer, R., Sacks, R., 2013. The impact of New York City's Health Bucks Program on electronic benefit transfer spending at farmers markets, 2006–2009. Prev. Chronic Dis. 10, E163.
- Bassett, M.T., Dumanovsky, T., Huang, C., Silver, L.D., Young, C., Nonas, C., Matte, T. D., Chideya, S., Frieden, T.R., 2008. Purchasing behavior and calorie information at fast-food chains in New York City, 2007. Am. J. Public Health 98, 1457–1459.
- Black, J.L., Macinko, J., 2010. The changing distribution and determinants of obesity in the neighborhoods of New York City, 2003–2007. Am. J. Epidemiol. 171, 765– 775.
- Black, J.L., Macinko, J., Dixon, L.B., Fryer, G.R., 2010. Neighborhoods and obesity in New York City. Health Place 16, 489–499.
- Bloomberg, M., 2011. Bloomberg Speaks on Non-Communicable Diseases at UN General Assembly. <a href="http://www.mikebloomberg.com/news/bloomberg-speaks-on-non-communicable-diseases-at-un-general-assembly">http://www.mikebloomberg.com/news/bloomberg-speaks-on-non-communicable-diseases-at-un-general-assembly</a> (accessed 16.09.14).
- Brannen, J., 2012. Expert voices. In: Baker, S.E., Edwards, R. (Eds.), How Many Qualitative Interviews is Enough. National Centre for Research Methods Review Discussion Paper, pp. 16–17. <a href="http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf">http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf</a> (accessed 22.09.15).
- Brownell, K.D., Frieden, T.R., 2009. Ounces of prevention the public policy case for taxes on sugared beverages. N. Engl. J. Med. 360, 1805–1808.
- CDC, 2011. Obesity in K-8 students-New York City, 2006–07 to 2010–11 school years. MMWR Morb. Mortal. Wkly. Rep. 60, 1673–1678.
- Colgrove, J., 2011. Endemic City. The Politics of Public Health in New York. Russell Sage Foundation, New York, NY.
- Dannefer, R., Adjoian, T., Van Wye, G., 2012. Retail audit of sugary drinks in six New York City neighborhoods. EPI Data Brief, 17.
- Dannefer, R., Williams, D.A., Baronberg, S., Silver, L., 2012b. Healthy bodegas: increasing and promoting healthy foods at corner stores in New York City. Am. J. Public Health 102, e27–e31.
- DOHMH, 2003. One in 6 New York City adults is obese. NYC Vital Signs 2(7), 1–4. DOHMH, 2004. Take Care New York 2004. <a href="http://www.nyc.gov/html/doh/downloads/pdf/tcny/tcny-policy.pdf">http://www.nyc.gov/html/doh/downloads/pdf/tcny/tcny-policy.pdf</a> (accessed 27.08.14).
- DOHMH, 2006a. Notice of Adoption of an Amendment (§81.08) to Article 81 of the New York City Health Code. <a href="https://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf">www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf</a>> (accessed 27.08.14).
- DOHMH, 2006b. Notice of Adoption of an Amendment (§81.50) to Article 81 of the New York City Health Code. <a href="http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf">http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf</a> (accessed 27.08.14).
- DOHMH, 2006c. Notice of Adoption of Amendments to Article 47 of the New York City Health Code. <a href="http://www.nyc.gov/html/doh/downloads/pdf/public/notice-hc-20060615-art47.pdf">http://www.nyc.gov/html/doh/downloads/pdf/public/notice-hc-20060615-art47.pdf</a> (accessed 27.08.14).
- DOHMH, 2008a. Notice of Adoption of a Resolution to Repeal and Reenact §81.50 of the New York City Health Code. <a href="https://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf">www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf</a>. (accessed 27.08.14).
- DOHMH, 2008b. Notice of Adoption of Amendments to Chapter 6 (Food Units) of Title 24 of the Rules of the City of New York. <a href="http://www.nyc.gov/html/doh/downloads/pdf/notice/notice-adoption-chapter6.pdf">httml/doh/downloads/pdf/notice/notice-adoption-chapter6.pdf</a> (accessed 04.11.14).
- DOHMH, 2010. New York City Healthy Bodegas Initiative: 2010 Report. <a href="http://www.nyc.gov/html/doh/downloads/pdf/cdp/healthy-bodegas-rpt2010.pdf">http://www.nyc.gov/html/doh/downloads/pdf/cdp/healthy-bodegas-rpt2010.pdf</a> (accessed 27.08.14).
- DOHMH, 2011. Consumption of Sugar Sweetened Beverages (SSBs) in New York City. EPI Data Brief, 4.
- DOHMH, 2012a. Proposed Resolution to amend Serving Sizes in Food Service Establishments (Health Code Article 81). <a href="https://www.nyc.gov/html/doh/downloads/pdf/notice/2012/amend-food-establishments.pdf">www.nyc.gov/html/doh/downloads/pdf/notice/2012/amend-food-establishments.pdf</a> (accessed 27.08.14).
- DOHMH, 2012b. Summary and Response to Public Hearing and Comments Received Regarding Amendment of Article 81 of the New York City Heath Code. <a href="http://www.nyc.gov/html/doh/downloads/pdf/boh/article81-response-to-comments.pdf">http://www.nyc.gov/html/doh/downloads/pdf/boh/article81-response-to-comments.pdf</a> (accessed 23.10.14).
- DOHMH, 2012c. Preventing Non-communicable Diseases and Injuries: Innovative Solutions from New York City. <a href="http://www.nyc.gov/html/doh/downloads/pdf/ip/un-rpt.pdf">http://www.nyc.gov/html/doh/downloads/pdf/ip/un-rpt.pdf</a> (accessed 27.08.14).
- DOHMH, 2012d. Notice of Adoption of Amendment of Serving Sizes in Food Service Establishments. <a href="http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article81.pdf">http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article81.pdf</a> (accessed 27.08.14).
- DOHMH, 2012e. Notice of Adoption of Amendments of Nutritional Requirements for Children's Camps. <a href="http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article48.pdf">http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article48.pdf</a> (accessed 27.08.14).

- Dowell, D., Farley, T.A., 2012. Prevention of non-communicable diseases in New York City. Lancet 380, 1787–1789.
- Dumanovsky, T., Huang, C.Y., Bassett, M.T., Silver, L.D., 2010. Consumer awareness of fast-food calorie information in New York City after implementation of a menu labeling regulation. Am. J. Public Health 100, 2520–2525.
- Dumanovsky, T., Huang, C.Y., Nonas, C.A., Matte, T.D., Bassett, M.T., Silver, L.D., 2011. Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labelling: cross sectional customer surveys. BMJ 343, d4464.
- Elbel, B., 2011. Consumer estimation of recommended and actual calories at fast food restaurants. Obesity (Silver Spring) 19, 1971–1978.
- Elbel, B., Kersh, R., Brescoll, V.L., Dixon, L.B., 2009. Calorie labeling and food choices: a first look at the effects on low-income people in New York City. Health Aff. 28, w1110-w1121.
- Elbel, B., Gyamfi, J., Kersh, R., 2011. Child and adolescent fast-food choice and the influence of calorie labeling: a natural experiment. Int. J. Obes. 35, 493–500.
- Elfassy, T., Yi, S., Nonas, C., 2014. Perceived access to fresh fruits and vegetables in New York City. EPI Data Brief, 49.
- Farley, T.A., 2012. The role of government in preventing excess calorie consumption: the example of New York City. JAMA 308, 1093–1094.
- Farley, T.A., Dowell, D., 2014. Preventing childhood obesity: what are we doing right? Am. J. Public Health 104, 1579–1583.
- Farley, T.A., Van Wye, G., 2012. Reversing the obesity epidemic: the importance of policy and policy research. Am. J. Prev. Med. 43, S93–S94.
- Farley, T.A., Caffarelli, A., Bassett, M.T., Silver, L., Frieden, T.R., 2009. New York City's fight over calorie labeling. Health Aff. 28, w1098–w1109.
- Freudenberg, N., Libman, K., O'Keefe, E., 2010. A tale of two obescities: the role of municipal governance in reducing childhood obesity in New York City and London. J. Urban Health 87, 755–770.
- Frieden, T.R., 2004a. Take Care New York: a focused health policy. J. Urban Health 81, 314–316.
- Frieden, T.R., 2004b. Asleep at the Switch: local public health and chronic disease. Am. J. Public Health 94, 2059–2061.
- Frieden, T.R., Bassett, M.T., Thorpe, L.E., Farley, T.A., 2008. Public health in New York City, 2002–2007: confronting epidemics of the modern era. Int. J. Epidemiol. 37, 966–977.
- Fuchs, E.R., Holloway, S.M., Bayer, K., Feathers, A., 2014. Innovative Partnership for Public Health: An Evaluation of the New York City Green Cart Initiative to Expand Access to Healthy Produce in Low-Income Neighborhoods. Case Study Series in Global Public Policy 2(22014).
- Given, L.M., 2008. The Sage Encyclopedia of Qualitative Research Methods. Sage Publications, Los Angeles, CA.
- Gordon, C., Purciel-Hill, M., Ghai, N.R., Kaufman, L., Graham, R., Van Wye, G., 2011.

  Measuring food deserts in New York City's low-income neighborhoods. Health Place 17, 696–700.
- Holwell, R. (United States District Court for the Southern District of New York), 2007. Case 1:07-cv-05710-RJH. <a href="http://www.citizen.org/documents/nysra\_distdecision.pdf">http://www.citizen.org/documents/nysra\_distdecision.pdf</a>> (accessed 16.10.14).
- Holwell, R. (United States District Court for the Southern District of New York), 2008. Case 1:08-cv-01000-RJH. <a href="http://www.citizen.org/documents/NYSRAOpinion\_1.pdf">http://www.citizen.org/documents/NYSRAOpinion\_1.pdf</a> (accessed 16.10.14).
- Jordan, H.T., Tabaei, B.P., Nash, D., Angell, S.Y., Chamany, S., Kerker, B., 2012. Metabolic syndrome among adults in New York City, 2004 New York City health and nutrition examination survey. Prev. Chronic Dis. 9, E04.
- Karnik, A., Foster, B.A., Mayer, V., Pratomo, V., McKee, D., Maher, S., Campos, G., Anderson, M., 2011. Food insecurity and obesity in New York City primary care clinics. Med. Care 49, 658–661.
- Kerker, P., Farley, S., Johns, M., Leggat, P., Nonas, C., Parton, H., 2014. Green Cart Evaluation 2008–2011. EPI Data Brief, 48.
- Kingdon, J.W., 1995. Agendas, Alternatives and Publics Policies, second ed. Longman, New York, NY.
- Kwate, N.O., Yau, C.Y., Loh, J.M., Williams, D., 2009. Inequality in obesigenic environments: fast food density in New York City. Health Place 15, 364–373.
- Laugesen, M.J., Isett, K.R., 2013. Evidence use in New York City public health policymaking. Front. Public Health Serv. Syst. Res., 2
- Lederer, A., Curtis, C.J., Silver, L.D., Angell, S.Y., 2014. Toward a healthier city: nutrition standards for New York City government. Am. J. Prev. Med. 46, 423–428.
- Li, W., Maduro, G., Begier, E.M., 2013. Life Expectancy in New York City: What Accounts for the Gains? Epi Research Report.
- Liamputtong, P., Ezzy, D., 2005. Qualitative Research Methods, second ed. Oxford University Press, Melbourne.
- Mello, M.M., 2009. New York City's war on fat. N. Engl. J. Med. 360 (19), 2015–2020. Miller, D., 2012. Expert voices. In: Baker, S.E., Edwards, R. (Eds.), How Many Qualitative Interviews is Enough. National Centre for Research Methods Review Discussion Paper, p. 31. <a href="http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf">http://eprints.ncrm.ac.uk/2273/4/how\_many\_interviews.pdf</a> (accessed 22.09.15).
- Morse, J.M., 1995. The significance of saturation. Qual. Health Res. 5, 147–149.
- Mozaffarian, D., Katan, M.B., Ascherio, A., Stampfer, M.J., Willett, W.C., 2006. Trans fatty acids and cardiovascular disease. N. Engl. J. Med. 354, 1601–1613.
- Nestle, M., 2010. Health care reform in action calorie labeling goes national. N. Engl. J. Med. 362, 2343–2345.
- New York City Center for Economic Opportunity, 2008. The Office of the Food Policy Coordinator. CEO Internal Program Review. <a href="http://www.nyc.gov/html/ceo/downloads/pdf/fpc\_prr.pdf">http://www.nyc.gov/html/ceo/downloads/pdf/fpc\_prr.pdf</a> (accessed 27.08.14).

- New York City Charter. Chapter 22, Section 553. <a href="http://codes.lp.findlaw.com/nycode/NYC/22/553">http://codes.lp.findlaw.com/nycode/NYC/22/553</a> (accessed 09.10.14).
- New York City Obesity Task Force, 2012. Reversing the Epidemic: The New York City Obesity Task Force Plan to Prevent and Control Obesity. <a href="http://www.nyc.gov/html/om/pdf/2012/otf\_report.pdf">http://www.nyc.gov/html/om/pdf/2012/otf\_report.pdf</a> (accessed 14.10.14).
- Office of the Mayor, 2008. Executive Order 122. <a href="http://www.nyc.gov/html/doh/downloads/pdf/cardio/food-executive-order-122.pdf">http://www.nyc.gov/html/doh/downloads/pdf/cardio/food-executive-order-122.pdf</a> (accessed 27.08.14).
- Patton, M.Q., 2002. Qualitative Research & Evaluation Methods. Sage, Thousand Oaks, CA.
- Perlmanm, S.E., Nonas, C., Lindstrom, L.L., Choe-Castillo, J., McKie, H., Alberti, P.M., 2012. A menu for health: changes to New York City school food, 2001 to 2011. J. Sch. Health 82, 484–491.
- Pigott, J. (New York Court of Appeals), 2014. 2014 NY Slip Op 04804 [23 NY3d 681]. <a href="http://www.nycourts.gov/reporter/3dseries/2014/2014\_04804.htm">http://www.nycourts.gov/reporter/3dseries/2014/2014\_04804.htm</a> (accessed 29.09.14).
- Pomeranz, J.L., 2011. The unique authority of state and local health departments to address obesity. Am. J. Public Health 101, 1192–1197.
- Rehm, C.D., Matte, T.D., Van Wye, G., Young, C., Frieden, T.R., 2008. Demographic and behavioral factors associated with daily sugar-sweetened soda consumption in New York City adults. J. Urban Health 85, 375–385.
- Renwick, J. (Appellate Division of the Supreme Court of the State of New York), 2013. 2013 NY Slip Op 05505 [110 AD3d 1]. <a href="http://www.nycourts.gov/reporter/3dseries/2013/2013\_05505.htm">http://www.nycourts.gov/reporter/3dseries/2013/2013\_05505.htm</a> (accessed 29.09.14).
- Rules of the City of New York. Title 24: Department of Health and Mental Hygiene, Chapter 6: Food Units. § Section 6-01: Mobile Food Units. <a href="http://rules.cityofnewyork.us/content/section-6-01-mobile-food-units">http://rules.cityofnewyork.us/content/section-6-01-mobile-food-units</a> (accessed 04.11.14).
- Sekhobo, J.P., Edmunds, L.S., Dalenius, K., Jernigan, J., Davis, C.F., Giddings, M., Lesesne, C., Kettel Khan, L., 2014. Neighborhood disparities in prevalence of childhood obesity among low-income children before and after implementation of New York City child care regulations. Prev. Chronic Dis. 11, E181.

- Stark, J.H., Neckerman, K., Lovasi, G.S., Konty, K., Quinn, J., Arno, P., Viola, D., Harris, T.G., Weiss, C.C., Bader, M.D., Rundle, A., 2013. Neighbourhood food environments and body mass index among New York City adults. J. Epidemiol. Community Health 67, 736–742.
- Summers, C., Cohen, L., Havusha, A., Sliger, F., Farley, T., 2009. Take Care New York 2012: A Policy for a Healthier New York City. City Health Information (CHI), 18 (suppl 5).
- Swinburn, B., Gill, T., Kumanyika, S., 2005. Obesity prevention: a proposed framework for translating evidence into action. Obes. Rev. 6, 23–33.
- Tan, A.S., 2009. A case study of the New York City trans-fat story for international application. J. Public Health Policy 30, 3–16.
- Thomas, J., Harden, A., 2008. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med. Res. Methodol. 8, 45–55.
- Tingling, M.A. (Supreme Court of the State of New York), 2013. 2013 NY Slip Op 306092013 NY Slip Op 30609(U). Decided March 11, 2013. <a href="https://cases.justia.com/new-york/other-courts/2013-ny-slip-op-30609-u.pdf?ts=1364862721">https://cases.justia.com/new-york/other-courts/2013-ny-slip-op-30609-u.pdf?ts=1364862721</a> (accessed 29.09.14).
- United States Department of Agriculture (USDA), 2011. Letter to the New York State Office of Temporary and Disability Assistance. <a href="http://www.foodpolitics.com/wp-content/uploads/SNAP-Waiver-Request-Decision.pdf">http://www.foodpolitics.com/wp-content/uploads/SNAP-Waiver-Request-Decision.pdf</a>> (accessed 21.01.15).
- Vadiveloo, M.K., Dixon, L.B., Elbel, B., 2011. Consumer purchasing patterns in response to calorie labeling legislation in New York City. Int. J. Behav. Nutr. Phys. Act 8, 51.
- Viola, D., Arno, P.S., Maroko, A.R., Schechter, C.B., Sohler, N., Rundle, A., Neckerman, K.M., Maantay, J., 2013. Overweight and obesity: can we reconcile evidence about supermarkets and fast food retailers for public health policy? J. Public Health Policy 34, 424–438.
- Yaemsiri, S., Olson, E.C., He, K., Kerker, B.D., 2012. Food concern and its associations with obesity and diabetes among lower-income New Yorkers. Public Health Nutr. 15, 39–47.
- Yin, R.K., 2009. Case Study Research: Design and Methods, fourth ed. Sage Publications, Thousand Oaks, CA.

#### 6.4 Postscript

The preceding article is one of two case studies originally planned for inclusion in this thesis. In addition to the work in New York City, a complementary project was initially envisaged to take place in Denmark where the fat tax had just been abolished and a planned sugar tax was never implemented. However, the funding and time constraints of a three year PhD project prevented this second case study from being conducted. In 2015, two articles were published that investigate the Danish experience in a fashion similar to the research planned as part of this work. [1,2] In addition to the Danish findings, the Bloomberg era continues to generate academic insights into the processes around nutrition policy development that both validate and extend the work described in this chapter. This postscript serves the purpose of relating this work by other authors to the conclusions drawn in the above case study.

Undertaken at the same time as the study presented in this thesis, a very similar enquiry into the New York City policy experiences independently drew similar conclusions. [3] The work also notes that cultural change likely contributed to local behaviour change regarding sugary drinks consumption and that the leadership shown in New York had a signalling effect for other jurisdictions in the USA and internationally. [3] In addition, the study confirms some of the conclusions from the case study presented in this chapter by identifying as a key lesson the necessity to balance strong executive leadership with sustained community engagement. It also agrees that opposition motivated by a variety of concerns needs be addressed more effectively through the garnering of community support and forceful communication of the public health evidence base.

The importance of the latter lessons is augmented by a recent analysis of the news media's framing of the soda portion cap rule which finds that negative framing predominated in the coverage. [4] Reporting themes changed as the policy process progressed from a focus on charges of government intrusion to greater emphasis on potential economic ramifications as well as legal and policy design concerns. [4] These findings are in keeping with the results from the stakeholder interviews reported in this chapter that the harm done by certain food and beverage product types was not accurately represented in the public debate. Public health concerns were explicitly identified as the primary motivator for the proposed intervention in

less than two thirds of the media articles examined. [4] The latter finding also matches observations in the academic literature that the negative externalities of deleterious consumption pattern hardly featured in the public debate in New York. [5] As noted in this chapter's findings, the culpability of the food and beverage industry in enabling unhealthy eating at a profit was not forcefully pushed by the administration. Yet, the question of whether the new leadership under Mayor de Blasio, in office since 2014, would pursue innovative public health regulations in the same expert-driven, industry-confronting fashion as their predecessor [5] has been partially answered in the affirmative. In December 2015, a new sodium warning requirement came into effect in New York City chain restaurants to address the risk of cardiovascular disease and the National Restaurant Association promptly sued the health department before the New York State Supreme Court. [6]

Meanwhile, the academic examination of Denmark another high profile case shows the reverse side of contentious public discussion: the Danish fat tax faltered in the face of public and industry opposition and was quickly scrapped by the very government that had introduced it in the first place. Recent analysis suggests that political prioritisation rather than evidence of actual implementation success or health outcomes were instrumental in influencing decisions about policy continuation. [1,2] As described in chapter 5, the tax appears to have achieved some impact on consumption over the short period of its existence. Yet, political decision-makers did not wait for the results of meaningful early evaluations to become available. Rather, the political and public discourse shifted rapidly from addressing health concerns to a discussion of adverse economic impacts. [1,2] Moreover, the tax was part of a larger fiscal reform package that proceeded through financial rather than health decision-making structures. The political roll-out therefore suggests that it was intended primarily as a source of revenue. [2] Even if economic motives did not predominate at the outset, they became overwhelmingly relevant to the continuing debate after the legislation passed and the aftermath of the global financial crisis continued to impact on the EU. [1] The Danish taxation was met by forceful industry opposition that was similar to the experience in New York. [1,2] Although at odds with official government statistics, claims were made that the Danish economy had lost 1,300 jobs due to considerable implementation costs for businesses and a 10% increase in cross-border shopping, which resonated with the media and policy-makers. [2] Moreover, the design of the tax was

considered cumbersome and illogical, in part because certain rules did not seem to prioritize health effects: this included issues with meat taxation methods that did not differentiate between lean and fatty cuts and the absence of a provision that the tax needed to be passed on to consumers through price increases on the targeted products. [1] Both examinations of the Danish experience note that public health advocates did not come out forcefully in support of the tax [1,2] which contrasts with New York City's approach where subject matter experts in the health department designed interventions, actively sought out evidence, and enlisted advocates and experts to testify at Board of Health meetings. As outlined in this chapter, the example of New York City overall showed close and fruitful cooperation between government and external experts in policy design and the shepherding of proposals through the decision-making process. However, even there experts from academia, interest groups, and professional organisations were considerably underrepresented in media coverage compared to industry representatives and offered the most neutral policy assessments. [1] The recommendation from Denmark for health professionals to throw their weight behind similar future proposals [2] therefore also complements the lessons learned in New York City.

In the case of Denmark, its status of a geographically small EU member fully surrounded by the common internal market of the European Economic Area posed problems. Incongruence with EU law necessitated the revision of some details of the regulation that contributed to charges of ill design and lawsuits were threatened by opponents of the law who claimed further incompatibilities. [2] Moreover, the free flow of people and goods across borders put Danish food retailers at a (possibly mostly perceived) disadvantage compared to their European competitors. Similarly, New York's attempt to change local rules for the US food stamp program SNAP was pre-empted at federal level and its desire to implement a sugar-sweetened beverage tax was jurisdictionally limited to advocacy at state level.

In summary, the additional findings published in the academic literature support the key conclusions drawn in the research presented in this chapter. In particular, they further highlight the value of expert-driven policy-making and underline the need for government officials and public health experts to actively engage in public communication and more forcefully push arguments around public health protection to the forefront. Moreover, the example of Denmark as an EU member state re-

enforces the observation from New York City that the innovation potential in subsidiary jurisdictions does not come without with challenges in policy design and implementation due to higher-level law.

#### References

- [1] Vallgårda S, Holm L, Jensen JD. The Danish tax on saturated fat: why it did not survive. *European Journal of Clinical Nutrition*. 2015;69(2):223-226.
- [2] Bødker M, Pisinger C, Toft U, Jørgensen T. The rise and fall of the world's first fat tax. *Health Policy*. 2015;119(6):737-742.
- [3] Kelly P. Healthy eating initiatives in New York City, 2001-13. *ACT Population Health Bulletin*. 2015;4(3):4-7.
- [4] Donaldson EA, Cohen JE, Truant PL, Rutkow L, Kanarek NF, Barry CL. News Media Framing of New York City's Sugar-Sweetened Beverage Portion-Size Cap. *American Journal of Public Health*. 2015;105(11):2202-2209.
- [5] Mello MM, Studdert DM. Making the Case for Health-Enhancing Laws after Bloomberg. *Hastings Center Report*. 2014 Jan 1;44(1):8.
- [6] New York City Department of Health and Mental Hygiene. Health Commissioner Submits Affidavit in Support of Sodium Warning Rule. 2016. Available from: <a href="http://www.nyc.gov/html/doh/html/pr2016/pr001-16.shtml">http://www.nyc.gov/html/doh/html/pr2016/pr001-16.shtml</a> [last accessed 7 January 2016].

# 7. Translating innovative public health legislation into policy action: does the new South Australian Public Health Act offer a blueprint for systematic regional government engagement in obesity prevention?

The following manuscript takes a local perspective. It assesses the legal and political frameworks for regulatory action on food system determinants in the state of South Australia, drawing on many of the findings from previous chapters. In doing so, it offers an analysis of a concrete political and legal space in which some of the evidence collected in chapters 4-6 may be considered and translated into jurisdiction-specific action. The intention of this chapter is twofold: on the one hand, it aims to provide an account of South Australia's innovative 2011 Public Health Act for potential international application. On the other hand, it also seeks to communicate to policy-makers and advocates in this state, where the overarching *HealthyLaws* research project has taken place, some of the research results in the form of locally relevant considerations to support successful implementation of this significant new legislation.

# Statement of Authorship

Title of Paper	Translating innovative public health legislation into policy action: does the new South Australian Public Health Act offer a blueprint for systematic regional government engagement in obesity prevention?				
Publication Status	<ul><li>Published</li><li>✓ Submitted for Publication</li></ul>	Accepted for Publication  Publication Style			
Publication Details	Sisnowski J, Reynolds C, Handsley E, Broderick D, Translating innovative public health legislation into policy action: does the new South Australian Public Health Act offer a blueprint for systematic regional government engagement in obesity prevention?				

## **Principal Author**

Name of Principal Author (Candidate)	Jana Sisnowski	
Contribution to the Paper		writing of the manuscript, wrote outline and major parts s and comments from other authors, approved the final g as corresponding author.
Overall percentage (%)	70%	
Signature		Date 11/01/2016

#### **Co-Author Contributions**

By signing the Statement of Authorship, each author certifies that:

- ia the candidate's stated contribution to the publication is accurate (as detailed above);
- ii. permission is granted for the candidate in include the publication in the thesis; and
- iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Chris Reynolds
Contribution to the Paper	Drafted a section of the manuscript, provided comments on overall drafts of the manuscript reviewed and approved the final manuscript for journal submission.
Signature	Date 20116
Name of Co-Author	Elizabeth Handsley
Contribution to the Paper	Drafted parts of the manuscript, provided comments on overall drafts of the manuscript reviewed and approved the final manuscript for journal submission.
Signature	Date 22/01/2016
Name of Co-Author	Danny Broderick
Contribution to the Paper	Provided comments on overall draffs of the manuscript, reviewed and approved the final menuscript for journal submission.
Signature	Date 9

Translating innovative public health legislation into policy action: does the new South Australian Public Health Act offer a blueprint for systematic regional government engagement in obesity prevention?

This commentary considers how regional governments can best prepare their jurisdictions for systematic engagement in obesity prevention at the population level, in particular with regard to nutrition. Against the backdrop of still rising obesity prevalence in Australia and relative inaction by the federal government of this country, we describe the state-based 2011 South Australian Public Health Act as a new and innovative type of core public health law. The Act provides legal mechanisms to address the management and prevention of both communicable and noncommunicable diseases and conditions. We review its potential benefits and limitations in the area of obesity prevention by assessing which kinds of interventions South Australia could feasibly pursue under this new legislation to improve its food environment. In particular, we focus on Part 8 of the Act which allows for the establishment of codes aimed at preventing or containing chronic disease risks. We also relate the approach taken by South Australia to the recent Welsh Well-being of Future Generations Act 2015 as a complementary way of anchoring contemporary public health challenges in law. These two topical examples illustrate the need to provide a combination of, on the one hand, statutory whole-of-government agenda-setting and, on the other hand, concrete mechanisms for intervention in order to enable more effective prevention and management of key risk factors for chronic disease.

**Keywords**: Healthy public policy; law; population health; food environment; noncommunicable disease

#### Introduction

While varying widely across the developed world, obesity prevalence remains a pressing health concern for most industrialized, Western-style economies. On both measured and self-reported obesity, Australia ranks among the most obese nations, with a prevalence of 28.2% (21.3% self-reported) and 28.4% (20.3% self-reported) for men and women, respectively (OECD 2014). Most importantly, while adult obesity rates have stabilised in other 'leading' countries such the United Kingdom and the United States, Australian rates have continued to increase (OECD 2014).

Obesogenic environments (Egger and Swinburn 1997) and, in particular, dietary patterns shaped by unfavourable food environments have been identified as the major driver of these sustained increases in obesity prevalence (Swinburn *et al.* 2011, Vandevijvere *et al.* 2015). A broad consensus has emerged in the academic literature (e.g. Magnusson 2008a, Magnusson 2008b, Dietz et al. 2009, Pomeranz et al. 2009) that the law has a pivotal role to play in addressing chronic disease and its risk factors at the population level. Yet, across the developed Western world, tangible policy responses in the form of coordinated, multi-sectoral changes to the food environment have been few and far between (MacKay 2011, Capacci *et al.* 2012, Lankford *et al.* 2013, Lloyd-Williams *et al.* 2014, Sisnowski *et al.* 2015).

In this paper, we examine how public health and the law can be harnessed together in a systematic and comprehensive way, in particular by sub-national governments. We use the new South Australian Public Health Act as an example of regional action aiming to build a legal foundation for a re-orientation of public health towards addressing systemic risks to population health.

Host of the Second International Conference on Health Promotion in 1988 that adopted the Adelaide Recommendations on Healthy Public Policy (Kickbusch *et al.* 2008), South Australia is one of the less populous Australian states with a population of 1.7 million, 1.3

million of whom live in the metropolitan area of the state capital, Adelaide (Australian Bureau of Statistics). As a comparatively small and internationally low-impact state, South Australia represents one of the relatively protected political spaces close to the citizen that have, in other countries, been the drivers of paradigm shifts and bold action in contemporary public health (Reeve et al. 2015). This affords the state the possibility to become disproportionately influential by developing innovative approaches to chronic disease prevention on which other jurisdictions might build.

We begin by briefly outlining the national environment in which this state's new Public Health Act was enacted and has begun to be implemented. We then describe the key features that distinguish the South Australian approach from conventional public health legislation, and explore the range of policy options to which the Act's instruments might potentially be applied. In this context, we also consider its general limitations as a subsidiary law as well as the drawbacks of the concrete mechanisms it provides to address health risks. Finally, we discuss the South Australian Public Health Act's merits as an innovative public health approach by reference to Welsh efforts to anchor public health goals and responsibilities in regional cross-sectoral legislation. We conclude by making the case for the legal elevation of a broad definition of population health and relevant risk factors to a whole-of-government concern, accompanied by concrete mechanisms within public health law to achieve these goals.

#### The national policy framework and political environment

In Australia, obesity seemed to have successfully clawed its way to the top of the national public health agenda in 2009, when the National Preventative Health Taskforce (2009) issued a call for "urgent action" on preventive measures. In its response, the Commonwealth government, while reluctant to fully embrace regulatory recommendations in relation to nutritional risk factors, announced the establishment of the Australian National Preventive

Health Agency (ANPHA) and a commitment to a "learning by doing [approach]- taking promising approaches, and closely monitoring their results" (Government of Australia 2010). Five years later, political momentum appears lost: the 2014-15 federal budget dismantled ANPHA and the Commonwealth has yet to develop a legislative framework to systematically address the nutritional drivers of obesity. Although the Australia New Zealand Food Standards Code requires nutrition information panels on packaged food, attempts to institute comprehensive interpretative labelling fell short as the new national health star rating system came with softened language and an extended voluntary participation period in lieu of legislation. Similarly, food marketing is subject only to voluntary arrangements and instruments that are non-specific to health concerns and severely limited in reach and scope, such as the Children's Television Standards 2009.

The void left by inaction at federal level has not been filled by lower-level governments. At state level, regulatory obesity prevention has been limited to mandatory calorie labelling of standardised menu items at chain restaurants which was introduced in close succession in New South Wales, the Australian Capital Territory, and South Australia.

Meanwhile, some of the most high-profile pursuits of legal approaches to obesity prevention have taken place in countries that Australia traditionally looks to for comparison and inspiration such as certain jurisdictions in the United States (Gostin 2013) and the European Union (Lloyd-Williams *et al.* 2014, OECD 2014). These include junk food taxes in Hungary, Mexico, and the Navajo Nation in the United States; soda taxes in France and Berkeley, CA; and stringent standards for all foods purchased or served by municipal agencies in New York City. Nevertheless, while Australia at large has been lacking jurisdictional leadership reconsidering what is politically conceivable and practically feasible, in the state of South Australia there has been some progress towards legal foundations that could potentially underpin innovative regional approaches to chronic disease prevention.

#### The South Australian approach: redefining the remit of core public health law

The 2011 South Australian (SA) Public Health Act (Government of South Australia) represents a radical departure from conventional public health legislation, which has traditionally been fragmented: general sanitary and communicable disease controls are contained in longstanding public health acts, while issues such as food safety or tobacco control are covered separately. Moving away from a paradigm where communicable disease control was paramount, the SA Public Health Act established a general statutory duty to protect public health (section 56). This links back to a broad definition of public health as "the health of individuals in the context of the wider health of the community" and of public health action as "a combination of policies, programs and safeguards designed — (a) to protect, maintain or promote the health of the community at large, [and] (b) to prevent or reduce the incidence of disease, injury or disability within the community" (Section 3). Also highly relevant to whole-of-population approaches to obesity prevention is one of the chief objectives of the Act, namely "to ensure, so far as is reasonably practicable, a healthy environment for all South Australians" (Section 4).

Most importantly, the Act provides, for the first time in Australian public health law, two mechanisms that specifically address non-communicable conditions of significance to public health. It provides for formal regulation-making powers applying to all matters covered by the legislation, including specifically the management of noncommunicable conditions (Section 109). This paper focusses on the second provision which arises from Part 8, the section of the Act dedicated to noncommunicable diseases. It empowers the Health Minister to issue Codes of Practice relating to specified industries or activities implicated in any "noncommunicable condition of significance to public health" (Section 61). Overall, the possible scope of a Code is very wide and there are no significant limits imposed by the Act itself, which raises the possibility of addressing obesity. As to the actual declaration of public health

significance, the choice of the term "condition" suggests an expansive scope, covering a continuum from risk factors to health outcomes. A Code designed to address the underlying causes of obesity and related diseases could cover a wide range of matters, including advertisement or promotion of goods, their sale, and the provision of specified information to consumers. Once a Part 8 Code is finalised, the Minister can monitor its operation and publish reports, potentially 'naming and shaming' non-compliers. Failure to comply may also amount to a breach of the general duty to safeguard public health, prompting a notice specifying remedial action. Failure to comply could then result in prosecution and the provisions of the Code in effect would become mandatory.

Implementing a new legal mechanism: opportunities and limitations of Codes of Practice
Any action under state legislation is subject to limitations arising from the Commonwealth
Constitution and Australia's status as a federation. Under the Constitution, state law cannot be
inconsistent with any Commonwealth law. State laws also need to avoid imposing taxes on
goods and protecting local businesses by discriminating against interstate trade. Part 8 does not
allow for the imposition of taxes in any case, but Codes setting rules in areas such as marketing
and retail could be accused of discriminating against interstate traders. These restrictions might
extend to a Part 8 Code, which is a subordinate instrument made under a state act. However,
since compliance with Part 8 Codes is primarily voluntary, subject only to public shaming, in
the absence of a notice to comply with the general duty their application would not trigger the
opportunity for legal challenge. In addition, South Australia's ability to regulate the labelling,
packaging and content of goods sold within its jurisdiction is restricted due to mutual
recognition arrangements between the Australian states and territories. This means that, in
practice, higher South Australian standards may not dominate the market depending on the
respective market share. These limitations underline the fact that any future policy action in

South Australia would be entering into competition with higher-level law and conflicting policy goals. It is unlikely that the state government would draw up a Code that, in practice, ran counter to existing regulation and national agreement.

However, there is no reason why it could not supplement them or fill gaps, for example regarding the marketing or sale of particular foods and beverages. In particular, a Code could build on the aforementioned self-regulatory regimes, not just by including additional or stronger provisions, but by providing rigorous review from a public health perspective. If a Code reproduced any of the provisions in the existing industry Codes, this would allow an external review of potential breaches that previously have been adjudicated (and often dismissed) by the existing industry-established panels. Further, a Code might establish general nutritional principles for canteens in schools and other institutions, supplement the current requirements for point-of-sale information and labelling, or outline expectations for less junk food-promoting use of space in food retail. The built environment is another area that a Code may target through guidelines on fast food outlet density, average distances to supermarket/fresh produce retail, or on placement of new chain restaurants near educational institutions. As obesity prevention strategies develop, other areas where a Code could prove helpful will emerge.

#### Considerations for effective ways forward on chronic disease prevention

Through the SA Public Health Act's Code-making power, the State can employ a range of levers. The effectiveness of such an instrument may be questioned given that it would become legally binding only through individual court action against repeat offenders. Enforcement may therefore, in practice, be delayed or partial. In addition, regulated entities are granted the right to be consulted, an arrangement that may raise the likelihood of vested interests being preserved in the resulting guidelines. However, there is also an argument to be made that a more

compromise-oriented approach to regulation may yield greater benefits than proposals for heavy-handed government action that may be less likely to survive the decision-making process due to the threat they pose to the economic interests of the food industry and other large industries (Reeve and Magnusson 2013). The South Australian Part 8 approach closely aligns with the idea of legislative scaffolding (Reeve and Magnusson 2013) as a more realistic government approach to creating healthier environments: the Code mechanism provides the functions that Reeve and Magnusson (2013) consider essential to incremental, but politically feasible, action: it can prop up toothless self-regulatory arrangements by substituting declarations of intent with measurable indicators, provide independent oversight and, where applicable, different levels of adjudication, and negotiate more comprehensive and stringent standards in exchange for pursuing a co-regulatory approach. Nevertheless, whether even such collaborative proposals will gain enough traction within state government to prompt action is a crucial question that has not yet been resolved: in order for a Code to be developed and operationalised, decision-makers need to invest political capital. Simply having a mechanism available is potentially not enough of an incentive to commit a whole government to use it. Part of the problem is that the South Australian Public Health Act is a basic public health law. Therefore, Part 8 as a concrete instrument available to the executive remains within the confines of the health portfolio. This legal arrangement is therefore limited in its ability to overcome the "problem of policy cacophony" that occurs when decision-makers face competing policy goals, often from high-priority areas such as economic growth and employment, and lack "coherent directions on which they feel they can deliver" (Lang and Rayner 2007:166). While fluctuations in personal investment of decision-makers, political climate, and pre-dominating competing interests are features ingrained in governance and the policy formation process, they may weigh particularly heavily on chronic disease prevention which is inextricably linked to the predominant social and economic environments. Conversely, prevailing fiscal circumstances and general economic trends also have the potential to exert influence over the selection of tools for chronic disease prevention: it stands to reason that the level of political willingness to turn towards regulatory measures is linked, at least in part, to the organizational capacity of the government agency considering such approaches. In the case of SAHealth, the South Australian Department of Health, a decrease in organizational capacity following significant staff cuts in in recent years (Holderhead 2015) likely entailed a diminished capacity to deliver more labour-intensive, targeted health promotion activities. In the medium to long term, such developments within government may act as an incentive to consider applying less cost-intensive regulatory approaches such as Part 8 codes.

However, the Part 8 Code-making power is not the sole instrument available for South Australian government action on chronic disease prevention. As mentioned before, the Act also provides for full-scale regulation authorised by the Governor (Section 109). In addition, separate legislative initiatives pursued in parliament remain untouched by the legal and policy mechanisms available under the Act. Most importantly, the Act's provisions extend the Health-In-all-Policies framework that South Australia has been working to implement since 2007 (Kickbusch *et al.* 2008, Delany *et al.* 2014). In line with WHO and other jurisdictions worldwide, the state defines Health-In-all-Policies as a cross-portfolio approach to public health which seeks to realise health goals in collaboration with related sectors while contributing to the aims of these partners (Government of South Australia, 2011). This approach had previously been rooted mostly in policy pronouncements such as South Australia's Strategic Plan rather than anchored in public health law. In addition to the aforementioned general duty to protect public health, the Act codifies organisational aspects of a Health-In-all-Policies approach: for instance, the Minister for Health is assigned an advisory role to the rest of government on any issue with public health implications (Section 17) and

local governments are able to formally engage with partners to undertake public health planning or implementation (Section 51). These provisions aim at improved and sustained cross-government collaboration led by the public health sector.

At the same time, the required development of public health plans at state and regional levels (Sections 50-52) provides an example for public health as a whole-of-government task which incorporates statutory roles and responsibilities at both state and local government levels: while public health planning at state level remains within the health portfolio, local councils at large are designated the local health authority for their area and in charge of drawing up public health plans individually or in collaboration with neighbouring municipalities. Here, the new Act institutes cross-portfolio responsibility for health. An example of the possible use of these broad local council responsibilities for chronic disease prevention can be seen in the area of land-use regulations: perhaps most relevant to altering obesogenic environments. Specifically, local councils' generic responsibilities include the assessment of "activities and development, or proposed activities and development [...] to determine and respond to public health impacts" (Section 37). Through its land-use regulation powers, local government can exercise its statutory duty to influence health outcomes through aspects of urban design, including issues immediately relevant to obesity prevention such as the provision of open spaces and the regulation of commercial zoning. However, this example also illustrates how that the concrete scope and mechanisms of councils' responsibilities for chronic disease prevention can be curtailed overridden by broader state government policy: for instance, planning and development in South Australia is highly regulated by the state. As a result, the potential for councils to implement innovative local initiatives in zoning and building for health may be threatened by proposals currently being developed by the State government that favour establishing a single state-wide menu of planning rules (Government of South Australia 2015).

Wales offers another innovative approach to health legislation that illustrates how to further establish health and preventive action as a permanent feature of all regional government activity. The devolved government of the United Kingdom recently passed its Well-being of Future Generations Act that makes maintaining population well-being, including creating "a healthier Wales" (Welsh Government 2015), a whole-of-government objective. In codifying these provisions in a general purpose act rather than in public health law, the Welsh approach distinguishes itself from the South Australian preference for emphasising leadership from within the health portfolio. The Welsh Act requires "public bodies to do things in pursuit of the economic, social, environmental and cultural well-being of Wales", with the understanding that this means "a society [...] in which choices and behaviours [...] benefit future health" (Welsh Government 2015). While this approach lacks the concrete avenues for government action provided by the South Australian health law, it establishes a whole-of-government responsibility to deliver against health goals. This includes the collective setting of well-being objectives by the Welsh Ministers, the equivalent of a cabinet government, and detailed reporting on resource allocations and review activities (Welsh Government 2015). At subregional level, Welsh local authorities led by public services boards and community councils are required to establish well-being plans broadly similar to South Australian regional public health plans.

Overall, the Welsh precedent adds an important aspect to the scope of basic legislation that incorporates provisions aiming to facilitate systemic chronic disease prevention. The whole-of-government approach central to the Welsh Act offers opportunities for strengthening the policy and legal environment in which innovative public health legislation such as the SA Public Health Act operates. Specifically, a statutory duty to pursue health goals and to remain accountable as a collective regional government may break policy gridlock on chronic disease prevention where Health-In-all-Policies approaches with their emphasis on collaboration and

mutual attainment of policy goals fail to secure public health advances. In particular, it could counter-balance competing interests and priorities within the policy process and make it more compelling for policymakers in South Australia to use the innovative instruments provided by the Act.

#### Conclusion

The example of South Australia illustrates that there is potential for public health innovation, even at a time in Australia that is marked by scarce public health leadership at higher jurisdictional levels through Commonwealth laws or national agreement. South Australia has placed noncommunicable disease prevention at the core of its public health legislation, thereby taking a first step towards opening the way for an obesity prevention agenda. The challenge consists of mustering the political will to translate principles and instruments into concrete action, while navigating Commonwealth laws and prerogatives as well as competing interests at state level. While significant barriers remain in terms of political will, public perception, and an evidence base that is still taking shape, decision-makers here have laid the legal foundation for the State to become an Australian trailblazer in chronic disease prevention. They now have the opportunity to adapt and implement knowledge gained from a decade of increased international research and experiences in obesity prevention. Statutory anchoring of whole-of-government health goals and responsibilities, possibly synergistically integrated with other overarching goals of government as exemplified by the new Welsh well-being legislation, may offer a way forward on government action for chronic disease prevention.

#### References

- Australian Bureau of Statistics. (2015) Australian Bureau of Statistics data [online].

  Retrieved September 16, 2015, from

  <a href="http://www.abs.gov.au/ausstats/abs@.nsf/mf/3101.0">http://www.abs.gov.au/ausstats/abs@.nsf/mf/3101.0</a>.
- Capacci, S., Mazzocchi, M., Shankar, B., Brambila Macias, J., Verbeke, W., Pérez-Cueto, F.J.A., ... Traill, W.B. (2012). Policies to promote healthy eating in Europe: A structured review of policies and their effectiveness. *Nutrition Reviews*, 70 (3), 188-200.
- Delany, T., Harris, P., Williams, C., Harris, E., Baum, F., Lawless, A., ... Broderick, D. (2014). Health impact assessment in New South Wales & health in all policies in South Australia: Differences, similarities and connections. *BMC Public Health*, 14 (1), 699.
- Egger, G., Swinburn, B. (1997). An 'ecological' approach to the obesity pandemic. *BMJ*, 315, 477-480.
- Gostin, L.O. (2013). Bloomberg's health legacy: Urban innovator or meddling nanny? Hastings Center Report, 43 (5), 19-25.
- Government of Australia. (2010). Taking preventative action the government's response to the report of the national preventative health taskforce. Retrieved from <a href="http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Conte">http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Conte</a> nt/6B7B17659424FBE5CA25772000095458/\$File/tpa.pdf.
- Government of South Australia. (2011). The South Australian approach to Health in All

  Policies: background and practical guide, version 2. Adelaide: Government of South

  Australia.
- Government of South Australia, Department of Planning. (2015). *Transforming our planning system*. Retrieved from

- http://www.dpti.sa.gov.au/ data/assets/pdf\_file/0009/161298/Transforming\_our\_Pla\_nning\_System\_27\_March\_2015.pdf.
- Holderhead S. SA Health jobs to be cut, more than 400 staff moved out of city office.

  Adelaide Advertiser. February 27, 2015. Available from:

  <a href="http://www.adelaidenow.com.au/news/south-australia/sa-health-jobs-to-be-cut-more-than-400-staff-moved-out-of-city-office/news-story/6bc02ff1c41d40a4491734d5cca72fb2">http://www.adelaidenow.com.au/news/south-australia/sa-health-jobs-to-be-cut-more-than-400-staff-moved-out-of-city-office/news-story/6bc02ff1c41d40a4491734d5cca72fb2</a> [last accessed 26 April 2016].
- Kickbusch, I., Mccann, W. & Sherbon, T. (2008). Adelaide revisited: From healthy public policy to health in all policies. *Health Promotion International*, 23 (1), 1-4.
- Lang, T. & Rayner, G. (2007). Overcoming policy cacophony on obesity: An ecological public health framework for policymakers. *Obesity Reviews*, 8, 165-181.
- Lankford, T., Hardman, D., Dankmeyer, C. & Schmid, T. (2013). Analysis of state obesity legislation from 2001 to 2010. *Journal of Public Health Management and Practice*, 19, S114-S118.
- Lloyd-Williams, F., Bromley, H., Orton, L., Hawkes, C., Taylor-Robinson, D., Martin, O., ... Moonan, M. (2014). Smorgasbord or symphony? Assessing public health nutrition policies across 30 european countries using a novel framework. *BMC Public Health*, 14 (1), 1195.
- Mackay, S. (2011). Legislative solutions to unhealthy eating and obesity in Australia. Public *Health*, 125 (12), 896-904.
- National Preventative Health Taskforce. (2009). *Technical Paper 1: Obesity in Australia: A*\*Need for Urgent Action. Retrieved from

  <a href="http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Conte">http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Conte</a>

  \*nt/tech-obesity-toc~tech-obesity-1.

- OECD. (2014). *OECD Obesity Update 2014*. Retrieved from <a href="www.oecd.org/els/health-systems/Obesity-Update-2014.pdf">www.oecd.org/els/health-systems/Obesity-Update-2014.pdf</a>.
- Reeve, B., Ashe, M., Farias, R., Gostin, L. (2015). State and Municipal Innovations in Obesity Policy: Why Localities Remain a Necessary Laboratory for Innovation.

  \*American Journal of Public Health\*, 105(3), 442-450.
- Reeve, B. & Magnusson, R. (2013). 'Legislative scaffolding': A new approach to prevention.

  Australian and New Zealand Journal of Public Health, 37 (5), 494-496.
- Sisnowski, J., Handsley, E. & Street, J.M. (2015). Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States. *Health Policy*, 119 (6), 720-31.
- South Australian Public Health Act (2011).
- Swinburn, B.A., Sacks, G., Hall, K.D., Mcpherson, K., Finegood, D.T., Moodie, M.L. & Gortmaker, S.L. (2011). The global obesity pandemic: Shaped by global drivers and local environments. *The Lancet*, 378 (9793), 804-814.
- Vandevijvere, S., Chow, C.C., Hall, K.D., Umali, E. & Swinburn, B.A. (2015). Increased food energy supply as a major driver of the obesity epidemic: A global analysis.

  \*Bulletin og the World Health Organization, 93, 446-456.
- Well-being of Future Generations (Wales) Act (2015).

#### 8. Discussion and conclusion

The rationale for undertaking this research was to contribute to the evidence base that policy-makers will draw on when making decisions about strategies to address population nutrition and regulatory approaches to obesity prevention. The thesis therefore assessed the current prevalence of relevant regulatory measures across key OECD jurisdictions and analysed the evidence and experience from some of these approaches. The major finding is that current regulatory action has been limited in both prevalence and effectiveness in relation to health goals. At the same time, the thesis has also demonstrated that policy innovation is occurring and impacting on food environments. More innovative and widespread regulatory action can be facilitated by incorporating lessons learned by pioneering jurisdictions into policy processes as well as by adopting changes to general and health legislation. The rest of this chapter briefly summarises the findings from this thesis in more detail and formulates recommendations for both policy action and future research directions.

Chapters 2 and 3 set the stage for the subsequent original work: chapter 2 framed overweight and obesity as a significant health and socioeconomic concern driven by systemic barriers to healthy consumption barriers situated primarily in the food environment. Chapter 3 outlined the theoretical premise of privileging relevance to the policy-making process in collecting and appraising evidence.

The systematic overview in chapter 4 addressed the lack of basic data on obesity-related policies pursued by governments internationally. It demonstrated that, across jurisdictions, current regulatory approaches to obesity prevention are limited in reach and scope. No single jurisdiction has enacted a comprehensive suite of complementary actions that would address the breadth of components of the food environment. However, although consistent and widespread use of the law is lacking, governments have employed a range of regulatory measures in the name of obesity prevention, with a clear preference for setting-specific measures that aim to protect the health of vulnerable populations such as children. As the postscript illustrated, there is a growing interest in ascertaining which kind of regulatory approaches are being implemented across jurisdictions. At the same time, the complex, time-consuming search strategies

employed in this thesis and in the work by others emphasise the need for a central, comprehensive monitoring tool to track the evolving status quo. Attempts at creating such infrastructure for certain regions have certainly been made but, as the example of the NOPA database used in this study demonstrates, these have neither been administered sustainably nor collected the kind of information most relevant to exploring and weighting regulatory policy options.

Chapter 5 built on the previous study by extending the analysis from the prevalence of policy approaches to their effectiveness, to the extent that they have been assessed and the results been shared publicly. This work put into practice the theoretical approach outlined in chapter 3 by employing a realist approach that defines quality evidence pragmatically and with a view to its utility in policy-making processes. The results from this systematic review demonstrated that isolated regulatory interventions frequently result in some improvements in intermediate outcomes, particularly where very proximal process measures are evaluated. Despite their success in qualitatively improving minor aspects of the food environment, the thus far non-existent or minuscule effects on nutritional patterns may endanger their future acceptability with policy-makers. Consequently, a major conclusion of this study was the need to move beyond the assessment of short-term impacts towards a sustained monitoring and evaluation framework. Process and proximal outcome measures remain important, particularly where short terms of office demand a timely indication of policy success for political positioning and electoral leverage. However, the capacity to detect cumulative long-term effects and also to measure more distal outcomes (such as shifts in consumption patterns that are not directly attributable to any one intervention but result from shifts in social and political perceptions) is essential. Crucially, the latter necessitates a change in what is considered suitable evidence for successful policymaking. In particular, study designs such as the ones examined in this chapter that conflict with the traditional hierarchy of evidence in health sciences need to be accepted as the best available evidence for some policies.

Chapter 6 moved the level of analysis from a broad OECD-centred perspective to an indepth exploration of the food policy-making process in New York City. The chapter provided insights about the strategies and behaviours of policy-makers in one of the world's leading jurisdictions in nutrition-related disease prevention, with a view to making future food policy-making in other jurisdictions more successful. Policymakers there cited the demonstration of expansive municipal competencies in public health as one of the most important lessons to be learned from their efforts. As described in the postscript, the potentially transferrable finding of significant scope to redefine municipal responsibilities to include a major focus on the food environment has been confirmed by others and stands in contrast to the limited activity at national and supranational levels ascertained in chapter 4. Furthermore, the article offered procedural considerations for policy-making at all levels of government, including a clear indication that policy change in an emerging and contested field such as regulatory obesity prevention needs strong leadership to position problems on the political agenda and to elevate potential solutions to the decision agenda. Executivedriven nutrition policy can offer an expedient mechanism to protect expertly designed measures from the influence of competing interests. In this context, the brief comparison with the Danish experience in the postscript to this study further underlined the advantages of leadership from the health sector, even on cross-portfolio measures such as taxation, and of clear, consistent communication of an intervention's health goals by experts in the field. At the same time, the analysis also demonstrated that it is important to remain engaged in more deliberative democratic processes and to build community support, particularly with a view to future obesity prevention policy. Perhaps most importantly, in New York City it appears that controversial policies that made it to the implementation stage became the 'new normal' and stayed in place; even failed efforts may have changed social norms around nutrition and health eating.

The final manuscript shifted from retrospective examination to prospective analysis. The study described the policy environment in South Australia in an effort to outline the policy options available to the state. In doing so, it related the findings from the previous chapters back to policy-making opportunities in the state where this work and the wider research project of which it was a part have primarily taken place. The analysis placed a particular emphasis on the 2011 South Australian Public Health and its provision for executive-issued Codes of Practice with limited enforcement. In discussing whether such an approach- perhaps more so than more heavy-handed direct regulation- can gain enough traction within state government to prompt action, the

Welsh Well-being of Future Generations Act 2015 was introduced as an example of greater statutory whole-of-government responsibility for public health within a wider set of equity and sustainability goals. This commentary concluded by arguing that the two approaches exemplified by Wales and South Australia are highly complementary: by making noncommunicable disease prevention a whole-of-government agenda item and tapping into a wider advocacy network relevant to very upstream factors such as food production or international trade, population nutrition increases its chances of gaining traction within government. At the same time, instruments such as the provisions under the SA Public Health Act need to be in place in order to turn political willingness into more comprehensive and far-reaching action than is currently being taken by governments across the OECD.

In interpreting the results summarized above, some limitations of the research presented in this thesis must be taken into account. Most of these aspects have been described in the journal articles and manuscripts and therefore are only briefly addressed at this stage. With the international, food-system-wide outlook adopted, the geographical, jurisdictional, and subject matter scope that could be covered is necessarily limited. As a result, innovative endeavours at local and regional levels could not be captured in chapter 4. Similarly, the decision to limit the scope of the systematic review in chapter 5 to the major components of the food system that apply to the general population was motivated by considerations of feasibility and relevance across jurisdictional borders. Many jurisdictions at any level of government, notably also from non-Anglophone regions, would have made instructive case study subjects. However, the case of New York City, presented in chapter 6, was the most comprehensively accessible for research purposes and most applicable to the Australian context at which the lessons extracted are primarily directed.

Building on the findings of this thesis and the wider research and policy context, the following three key recommendations are put forward with a view to contributing to an academic, legal, and political infrastructure that enables successful nutrition policy-making for whole populations:

(1) Building an international infrastructure to collect and disseminate policy-relevant evidence:

With different types of interventions scattered across jurisdictions and with no systematic way of tracking their existence and effects, it is difficult to determine if particular approaches have been tried and which real-life effects can reasonably be expected from them. A centralised monitoring tool that allows all stakeholders to engage in an exchange of actual practices and their assessment at both policy and scholarly levels is sorely lacking. This becomes even more crucial when considering the potential for local and regional innovation exemplified by New York City and other lower-level jurisdictions of lesser international renown whose experiences are likely to be lost to a wider policy and academic audience. The collection and dissemination of policy-relevant evidence from all sources needs to be centralised and made more accessible to stakeholders outside of academia. In particular, policy-makers at all jurisdictional levels should both be diligent users of evidence and become themselves contributors to such a centralized effort to track both policy enactment and evaluation results.

Despite individual academic efforts and more concerted collaborations such as the NOURISHING initiative, reasonably comprehensive knowledge of the nature and long-term effects of policy innovations will only be accelerated through a global database administered by or promoted through internationally authoritative organizations such as the WHO, coupled with a reporting obligation at least for national governments. As the scope and purpose of the Global Coordination Mechanism on the Prevention and Control of Noncommunicable Diseases takes shape, there is a window of opportunity to introduce such a tool. The terms of reference for the Global Coordination Mechanism already envisage a website and virtual forum that are to include an inventory of country activities. [1] These new capabilities should be coupled with a normative obligation to report all relevant policies at national level, with facilities for sub-national jurisdictions to independently contribute evidence.

#### (2) Redefining evaluation frameworks and policy-academia relationships:

The assessment of population-level nutrition policy interventions needs to shift from conventional expectations steeped in evidence-based medicine towards a more nuanced program-based framework. Individual policies that measurably improve the food environment need to be afforded the longevity to achieve a gradual, concerted impact on consumer behaviour and, ultimately, health outcomes. More generally, the complexity of assessing food and obesity prevention policies calls into question the effectiveness of the current relationship between research and policy. Chapter 3 discussed differences in the mindsets and modus operandi of actors in the two spheres. The resulting implications for the generation and acceptance of different types of evidence has been well established, but the establishment of research priorities may need a more fundamental re-orientation in order to drive effective policy change. Researchers in fields that examine potential population-level approaches to nutrition should appreciate the particular challenges of translational and applied research: this includes a gradual change in culture towards the idea of researchers as advocates and providers of service for public policy.

A recent Lancet commentary [2] outlines a strategic science paradigm as a solution to the lack of policy impact. It suggests shifting the focus from dissemination to decision-makers at the end of the research process to involving policy-makers in the conception and planning of research. This proposal resembles a commissioning framework where needs assessment prompts the acquisition of tailored solutions. Rather than researchers independently identifying opportunities for research based on funding availability or being contracted by public entities to undertake policy evaluations, academic resources would ideally be matched systematically with public health policy research needs and be supported by sustained funding for policy-relevant research. Beyond the collaborative identification of research priorities, the communication of research results is essential even where policy and research priorities match up. In its suggestion to actively "identify agents for change" [2] within government, the Lancet commentary echoes the lessons from New York City where subject matter experts in the Bloomberg administration drove the policy agenda and actively enlisted academia to provide evidence and testimony. Conversely, researchers, advocates, and practitioners in the wider public health space have an obligation to engage with the political process: it is imperative that those in charge of evaluations or called upon for expert commentary clearly communicate to the sceptical public and nervous policy-makers the need for a longterm perspective and the inherent absence of neat cause-and-effect demonstrations in order to avoid disappointment and premature political U-turns.

(3) Combining international efforts with legal preparedness and capacity building in subsidiary jurisdictions:

Supranational and international organisations such as the European Union or the WHO are well positioned to become clearinghouses for information, drive policy development, and accelerate the convergence of policies and laws towards best practice through both formal rule-making and softer approaches. Concerted international action offers the advantage of accelerating and facilitating the uptake of evidence, and offers a measure of burden-sharing and blame-shifting when dealing with opposing industry interests or sceptical popular opinion. Collective rule-making also exerts a degree of coercion where individual negotiating parties might accept outcomes and commitments that they would not have pursued independently. The same considerations apply to benchmarking efforts such as the project undertaken by INFORMAS. Such non-governmental undertakings need to link into national and global processes in order to achieve the envisaged government accountability.

As with the systematic collection of evidence, the task of judging government performance at a level that is complex and technical appears a natural responsibility to assign to the OECD or the WHO. In addition, peer pressure from other governments and international organisations with recognized global reach seems a more realistic way of encouraging good government performance in food policy. These are considerations that may receive increased attention as the international health community approaches the review of the 2011 Political Declaration on the Prevention and Control of Non-communicable Diseases by the UN General Assembly, scheduled for 2018. With the International Health Regulations and the Framework Convention on Tobacco Control (FCTC), the WHO has set precedents in the use of international law or quasi-legal arrangements in other areas of public health. Although the direct applicability of the tobacco parallel has been rightly questioned, the FCTC's design as a framework convention with the option of appending binding protocols on specific subject matters, when politically feasible,

charts a way forward for tangible international policy efforts. In this context, it also needs to be noted that international cooperation in competing policy areas has the potential of limiting rather than enabling regulatory health and nutrition policy: With the Trans-Pacific Partnership Agreement and the Transatlantic Trade and Investment Partnership, two major international free trade agreement have recently been signed or are still being negotiated, respectively. There are concerns that these multilateral treaties curtail the opportunities for individual national governments to prioritise public health over trade and investment concerns by prescribing international regulatory coherence, limiting public health policies and laws as barriers to trade, and affording private companies greater power to contest government policy through investor–state dispute settlement arrangements. [3,4]

Clearly, the above proposals would require buy-in and commitment to participation and follow-up action from a large majority of individual governments, a feature that is still lacking at present. In recognition that the policy progress is incremental and health concerns compete with an evolving set of political priorities, there is value in ensuring preparedness for windows of opportunity tied to changes in the political landscape. Subsidiary jurisdictions, despite the constraints imposed by higher-level prerogatives, have a particularly valuable potential to generate innovation in law and policy. It seems that in smaller bureaucracies, lower-level policy-makers with the expertise and determination to effect policy change have a greater chance to push the agenda. These jurisdictions, in turn, are much less likely than national or supranational governments to endure scrutiny from other governments fearing a slippery slope and backlash from international corporations concerned for their profitability. The breadth of possible action is reflected by the small sample of subnational entities featured in this research: this includes legal preparedness in form of suitable public health legislation as demonstrated by South Australia, the anchoring of noncommunicable disease prevention goals alongside synergistic principles in general purpose legislation as done in Wales, and of course the trialling and judicious evaluation of new policy approaches observed in New York City. While the latter example arguably represents a rare confluence of enabling features, the former two elements constitute preparatory work that jurisdictions can

pursue even in the absence of political willingness to implement immediate policy action.

In conclusion, the research presented in this thesis describes the successes and shortcomings of current approaches as well as some of the key challenges within the policy-making process. It gives a nuanced picture of the current state of regulatory obesity prevention as it relates to nutrition policy and food environments and it provides concrete considerations for an international policy environment that is more favourable towards the use of innovative laws and regulations for food policy and obesity prevention. As part of the Australian National Preventive Health Agency (ANPHA) funded *HealthyLaws* research project, this work has informed evidencebased information put to a deliberative citizens' jury tasked with reaching consensus recommendations regarding the types of laws that should be enacted in Australia to address childhood obesity. With the results from the citizens' jury and other components of the *HealthyLaws* project, the findings from this research continue to be disseminated locally to policy-makers and other stakeholders in the state of South Australia. As academic and political interest in broad-based action against obesity and unhealthy eating patterns grows, this work joins an evolving body of research output aiming to contribute to an ambitious, but realistic, public health agenda that embraces regulatory policy options as pivotal levers to effect systematic qualitative improvements in food environments at local, regional, and national levels.

#### References

- [1] World Health Organization. Prevention and control of noncommunicable diseases. Terms of reference for the global coordination mechanism on the prevention and control of noncommunicable diseases. 2014. Available from: <a href="http://apps.who.int/gb/ebwha/pdf\_files/WHA67/A67\_14Add1-en.pdf?ua=1">http://apps.who.int/gb/ebwha/pdf\_files/WHA67/A67\_14Add1-en.pdf?ua=1</a> [last accessed December 6, 2015].
- [2] Brownell KD, Roberto C. Strategic science with policy impact. *Lancet*. 2015;385(9986):2445-2446.
- [3] Thow AM, Snowdon W, Labonté R, Gleeson D, Stuckler D, Hattersley L, Schram A, Kay A, Friel S. Will the next generation of preferential trade and

- investment agreements undermine prevention of noncommunicable diseases? A prospective policy analysis of the Trans Pacific Partnership Agreement. *Health Policy*. 2015;31;119(1):88-96.
- [4] Gleeson D, Friel S. Emerging threats to public health from regional trade agreements. *Lancet*. 2013;381(9876):1507-1509.

## 9. Appendices

This chapter contains the methodological details associated with chapters 4-6. Some of this material has been published or submitted as supplementary online materials.

#### 9.1 Appendix 1 - Supplemental materials chapter 4

The following documents are associated with the article entitled "Regulatory approaches to obesity prevention: A systematic overview of current laws addressing diet-related risk factors in the European Union and the United States" (chapter 4, pp. 48-59):

Database: <a href="http://ec.europa.eu/enterprise/tris/public info/index en.htm">http://ec.europa.eu/enterprise/tris/public info/index en.htm</a>

Title	Country	Year	TRIS notification number	Accompanying comments related to obesity prevention/ reduction of caloric intake	Key related legislation reported
Act CIII of 2011 on the public health product tax [Neta tv]	Hungary	2013	622	By extension- amends 2011/340/HU.	"In accordance with the objective of taxation, the legislative proposal formulates more precise concepts for the taxable product group, specifically syrups."
Safety Act	Poland	2013	509	with a greater probability that they will be protected against the development of modernage diseases []. To meet these needs, this draft advocates restricting the sale, in educational institutions, of those categories of foods which contain excessive amounts of substances that could damage the development of children and adolescents, and introducing restrictions on their possible advertising particularly in places where advertising can most affect consumer groups such as children and adolescents i.e., among other places, in kindergartens, primary schools, secondary schools and other educational and care institutions. For these reasons, [] it is reasonable to introduce appropriate preventive	"Food and Nourishment Safety Act of 25 August 2006 (Journal of Laws of 2010, No 136(914)) as amended). The basic texts were submitted under an earlier notification: 2012/0637/PL This bill introduces amendments to the Food and Nourishment Safety Act of 25 August 2006 (Journal of Laws of 2010, No 136(914)) as amended)."
Regulations relating to the marketing of foods and beverages to children	Norway	2013	9005	Yes. "The purpose of these Regulations is to promote health by preventing obesity and dietrelated diseases in the population."	
The Healthy Eating in Schools (Nutritional Standards and Requirements) (Wales) Regulations	United Kingdom	2013	76	Yes. "The nutritional standards for school food are a key element of the Welsh Government's agenda to improve the quality of food and drink provided in schools. Better quality food in schools will make a major contribution to reducing the level of childhood obesity and improving the health and wellbeing of children and young persons."	"The Healthy Eating in Schools (Wales) Measure 2009 ('the Measure') was passed by the National Assembly for Wales in July 2009 and approved by Her Majesty in Council in October 2009. The Measure requires local authorities and school governing bodies to promote healthy eating and drinking by pupils in schools maintained by local authorities in Wales. Section 4 of the Measure gives the Welsh Ministers of the Welsh Government the power to make regulations about food and drink provided by local authorities or school governing bodies. These Regulations are made under this power."

Act on the amendment of the Food and Nourishment Safety Act	Poland	2012	637		This draft Act introduces amendments to the Food and Nourishment Safety Act of 25 August 2006 (Journal of Laws of 2010, No 136(914)) as amended). The purpose of the planned Regulation is to protect the health of school children by limiting access at schools and educational institutions to food products containing quantities of ingredients which are harmful to their childhood development. The ban on selling and serving in other forms includes: - synthetic sweeteners e.g. acesulfame K, aspartame, cyclamate, saccharin, sucralose, maltitol, glucose-fructose syrup (fructose corn syrup), - trans fats, - containing more than 1.25 g salt or 0.5 g sodium per 100 g, including crisps, salted peanuts, salty sticks, popcorn and salty snacks, - flavour enhancers e.g. E621 - monosodium glutamate, E627 - disodium guanylate, E631 - disodium inosinate, - sugars quantities greater than 10 g of simple sugars per 100 g of product.
Urgent measures to promote the country's development through a higher level of health protection: Article 8, point 16 of the Legislative Decree 158 of 2012.	Italy	2012	559	Yes. "The intention is to improve the nutritional quality of products that are particularly important for the entire population and specifically for young people. This is an important initiative that comes from the commitment of the Italian Ministry of Health to not only ensure food product safety by minimising possible biological, physical and chemical risks, but also ensure food products are healthy and of high nutritional quality. The proposed legislation also falls within a broader strategy, aimed at reducing inappropriate behaviour and promoting healthy eating, together with legislation aimed at providing incentives for the industry to produce food products with reduced fat and sugar content, regulate commercial promotion aimed at young children and ensure healthy food; specifically, the preventive role linked to eating fruit and vegetables regularly []. The reasons for the legislative initiative in question, as outlined above, are also based on directions at EU level aimed at increasing, within national policies, the consumption of fruit, in light of the increase in chronic non-contagious illnesses and of the fact that improper eating habits are a risk factor on which legislation can and must be enacted. [] The importance of fruit and vegetables is today known by everyone, not only due to their significant content of vitamins and minerals	

Decree approving the Blue Tick Mark as a food-choice logo and the conditions for its use (draft)	Netherlands	2012	414	Indirectly. "The new Article 11a of the aforementioned Commodities Act Decree defines the criteria subject to which the Minister for Public Health, Welfare and Sports will approve food-choice logos created by businesses, as well as the conditions for the use thereof. In the context of the aforementioned Article 11a, the "Ik Kies Bewust" (I choose consciously) Foundation has requested approval for the use of the "Blue Tick Mark" food-choice logo and associated product criteria, on behalf of a large group of food manufacturers and traders."	"On 4 February 2011, the Netherlands has notified a draft decree amending its Commodities Act Decree on Nutritional Value Information for Foodstuffs with respect to rules for a food-choice logo, mainly in compliance with Article 23 of Regulation (EC) 1924/2006 (notification no. 2011/0052/NL). Through its letter dated 11 August 2011 with reference C(2011) 5709 def., the European Commission has conditionally approved the aforementioned draft decree. The draft decree was subsequently adopted by decree of 8 November 2011, Official Journal [Staatsblad] 550, and has taken effect from 1 January 2012."
Notification of draft technical regulation entitled 'Circular concerning implementation of Articles 11 and 12 of Regulation (EC) No 1924/2006 on the wording of recommendations or endorsements by national professional associations in the medical sector and in the nutrition or dietetics sector and by health charities'	Greece	2012	446	No. "This document has been issued so that:  - it clarifies which professionals are covered by the term 'health professionals' who are prohibited from acting on their own in advertising products that bear health claims.  - it describes the criteria which must be met by professional associations so that they can make recommendations or endorsements about the health claims made on foods. "	Regulation (EC) No 1924/2006 on nutrition and health claims made on foods
Bill concerning the Bill Amending the Act on Various Excise Duties, the Fuel Excise Duty Act, the Tonnage Tax Act and Various Other Acts (Indexation of various excise duties and the current motor-vehicle taxes, adjustment to tonnage tax, increase in the countervailing charge, and extension of exemption from tax for hydrogen and electric cars) L 197	Denmark	2012	486	Bx extension- would have increased relevant excise taxes.	"The Bill means that a number of taxes will be adjusted by 1.8% per annum until 2020. The adjustment covers [among others] health-promotion taxes (wine, beer, alcopops, saturated fat, chocolate, ice cream, mineral water, etc.). The adjustment will be made by means of discretionary increases in 2013 (for health-promotion taxes only), 2015 and 2018."
Regulation on the use of the Keyhole label in the marketing of foodstuffs.	Iceland	2012	9008	"The aim of the Regulation is to make it easier for consumers to select healthy products. The Keyhole label has been used in Sweden, Norway and Denmark with good results."	
Tax payable on drinks and liquid preparations for drinks intended for human consumption	France	2011	597	Yes. "As part of the public health policy adopted by the Government, it is important to stop the spread of obesity, which adversely affects people's health and which represents a significant long-term social-security expense. To achieve this, it has been proposed to increase the price of sugary drinks, the uncontrolled consumption of which encourages weight gain, in order to encourage consumers to drink them less."	

Decree amending the Commodities Act Decree on nutritional value information for foodstuffs with respect to rules for a food choice logo, and of the Commodities Act Decree on Administrative Penalties (draft)	Netherlands	2011	52	Yes. "Ensuring a healthy composition of foodstuffs has attracted more and more attention in recent years, not only from governments but from consumers, producers and traders. This attention has resulted in the development of logos designed to indicate that a particular foodstuff has a healthier composition than other foods in a particular product group. These logos for foodstuffs will make it easier for consumers to make the "healthier choice". Some relevant characteristics in this respect are: energy content, saturated fats, trans fats, added sugar, dietary fibre and salt. [] The government's policy aims at stimulating healthy nutrition for the largest possible proportion of the Dutch population. In line with this policy is a broadly used logo facilitating the selection of healthier foods."	Regulation (EC) 1924/2006 harmonises the legal provisions of the Member States with respect to nutritional and health claims. A food choice logo as defined in the draft decree is within the scope of the concept of a nutritional claim as referred to in Article 2, second paragraph, 4°, of Regulation (EC) 1924/2006. Nutritional claims approved for the entire European Union as well as the relevant conditions are included in the Annex to Regulation (EC) 1924/2006. However, the rules applying to the use of the logo are valid only within the Netherlands. In light of this, the logo cannot be included in the Annex to Regulation (EC) 1924/2006. However, Article 23 of Regulation (EC) 1924/2006 accords Member States of the European Union the competence to adopt new legislation within the scope of that Regulation. The present draft decree exercises that competence.
Proposal for Law to change the chocolate duty law, the tobacco duty law, the beer and wine duty law and various other laws (Increases in duties on chocolate, sugar products, ice cream, soft drinks, tobacco, beer and wine)	Denmark	2011	651	Yes. "Unhealthy foodstuffs are today a major health risk for Danes and a primary reason for an excessive intake of fat and sugar in particular, not least among people with low income, who are already exposed to lifestyle illnesses."	
Amendment of Act 103 of 2011 on the public health product fee	Hungary	2011	599	By extension- amends 2011/340/HU.	"The primary goal of the amendment is to establish a precise definition of products subject to tax in the interest of preventing tax avoidance, and to extend the scope of the tax to products whose consumption presents a health risk, which is similar to products that are already subject to the tax."
Decree on the nutritional quality of meals served in university catering facilities as well as catering facilities in childcare establishments, healthcare establishments, social & socio-medical establishments and prisons	France	2011	564	Yes. "The measure aims to increase the nutritional quality of meals served in bulk catering facilities whilst ensuring that they suit the needs of the different types of consumers. For university establishments, this means facilitating students' access to varied and balanced meals. For childcare establishments, this means taking into account the particular needs of infant nutrition, which is also a factor in the prevention of obesity - something which has become a major public health issue in the majority of industrialised countries. Concerning social & socio-medical establishments, the provisions set out will notably permit the prevention or halting of malnutrition of the elderly living in institutions. In healthcare establishments, this will particularly mean limiting secondary anorexia due to illness, by stimulating patients' appetites. In prisons, the quality and variety of food proposed will be monitored."	"This regulatory text sets out the legislative provisions of article 1 of law No 2010-874 on the modernisation of agriculture and fisheries, codified in article L.230-5 of the rural and sea fisheries code."

Act No of 2011 on the public health product tax	Hungary	2011	340	Yes. "The bill sets out a gross single-stage value added tax in order to reduce the domestic consumption of products involving health risks, namely those with excessive sugar, salt, and caffeine content, and to provide the financing for health services, especially public health programs. [] The primary goal is to - indirectly - help improve the Hungarian population's state of health, therefore, it extends the effect of the public health product tax to food industry products whose consumption has been shown to be incompatible with a healthy lifestyle. It is common knowledge that excessive sugar and/or salt content, and the presence of additives that artificially increase the consumer's performance within a short time (for example caffeine), present a risk factor in this respect.  Creating a new budgetary resource for the financing of public health services, in particular public health programs, is a further goal."	
Executive Order on the use of the Keyhole Mark	Denmark	2011	314	Yes. "The draft Executive Order extends the scope of application of the Keyhole so that it also covers the labelling of foods at catering establishments that are not pre-packaged. In addition, the Executive Order also provides an opportunity to provide recipes with a Keyhole Mark. []The draft Executive Order has been prepared with a view to giving consumers better opportunities to make healthier choices when they eat out.	
Proposal for an Act on a tax on saturated fat in specific food (Fat Tax Act)	Denmark	2011	19	Yes. "The purpose of the Draft Act is to promote better diets and therefore improve the health of the population. This is achieved by reducing the intake of saturated fat through a tax of DKK 16 per kg of saturated fat in specific food, when the saturated fat content is more than 2.3 % by weight. Some food has a high saturated fat content while other food has a low saturated fat content. Dietary recommendations stipulate that fat should be a part of a daily diet and that it is healthier to consume fat consisting of unsaturated fatty acids than saturated fatty acids. Typical foods with a high saturated fat content are foods such as dairy products, meat products, fats and oils, while cereals, fruit, and vegetables have very low or no saturated fat. [] Tax increases alone do not solve the problem of increased prevalence of these widespread diseases. The individual Dane must also make choices and take responsibility for their own health. Tax which is appropriately structured can promote development in the right direction and support a healthy lifestyle."	
Order relating to the nutritional quality of meals served in schools	France	2010	758	Yes. "Child obesity is a major hazard to public health. Good food practices are gained at school where many young people obtain their meals. Straightforward recommendations have so far not proven effective. The adoption of these requirements will aid in standardising the implementation of food regulations in the composition of menus and in improving the quality of meals served in schools."	"This Order lays down the nutritional requirements for the daily composition of meals served in schools, the frequency of service of meals based on a minimum number of successive meals and the size of portions. The regulations defined aim to reduce the proportion of simple glucosides and lipids and to increase the proportion of fibres, vitamins, iron and calcium. It also lays down the requirements mentioned in a Decree relating to the same subject."

Decree on the nutritional quality of meals served by school catering services	France	2010	697	Yes. "Child obesity is a major public health issue. Good eating habits are notably acquired at school, where many children take meals. The recommendation-based actions taken to date have proven ineffective. The introduction of these requirements will enable the widespread implementation of nutritional rules for the composition of menus and an improvement in the quality of meals served in school canteens."	
Commodities Act [Warenwet] exemption regulation for jam with reduced sugar content	Netherlands	2010	310	Indirectly. Cf. below table on sugar content of jams, jellies, etc.	
Royal Decree approving quality regulations for candies, chewing gum, confits and confectionaries.	Spain	2010	187	Yes. "Meanwhile, current consumer trends, leaning towards the purchase of products that adhere to scientific nutritional recommendations, advise amendments to current definitions to allow for the production of products whose composition can be reformulated, allowing the industry to make changes to composition, such as the elimination of sugars, and the diversification of the products."	
Royal Decree approving quality regulations for confectionary, pastries, bakery and dessert products.	Spain	2009	589	Yes. "Meanwhile, current consumer trends, leaning towards the purchase of products that adhere to scientific nutritional recommendations, therefore the draft royal decree modifies the old defintions to allow for the production of products whose composition can be reformulated, allowwing for certain ingredients to be changed (fats instead of oils, elimination of sugars and salt, etc.)."	
Draft Cabinet of Ministers regulation "Requirements for the use of recommendations of and endorsements by associations of medical, nutrition and dietetic professionals and other health- related societies and foundations in the labelling and advertising of foods"	Latvia	2009	262	Indirectly. "The adoption of the regulation is necessary to protect consumers' health, the regulation will ensure the consumer's right to receive appropriate information about a product and will prevent recommendations and endorsements by associations of medical, nutrition and dietetic professionals and other health-related societies and foundations from being used inappropriately in food labelling and advertising. [] According to the health survey of the Latvian population carried out by the national Public Health Agency in 2006 (Health Behaviour among the Latvian Adult Population), 49.5% of the respondents admitted that recommendations or endorsements by associations of medical, nutrition and dietetic professionals have an impact on their choice of foods. "	Regulation (EC) No 1924/2006 of the European Parliament and of the Council on nutrition and health claims
Executive Order on the use of the Keyhole Label	Denmark	2008	440	Yes. "The Keyhole Label is a voluntary nutrition-labelling arrangement that highlights the better choices of foods within selected food groups with respect to the fat content and, where relevant, saturated fats, sugars, salt and dietary fibre. [] By supplementing the official dietary advice with a simple and credible marketing arrangement, consumers in a purchasing situation will be able to easily select healthier alternatives, which will contribute to better food habits. At the same time, the label will comprise an incentive for producers to develop additional, healthier alternatives."	
The Nutritional Requirements for Food and Drink in Schools (Scotland) Regulations 2008	United Kingdom	2008	32	Yes. "The Scottish Government is committed to improving the health of the nation and poor diet is a significant contributor to Scotland's poor health record. [] The Regulations will help to change eating habits and make an important contribution to improving the health of young people in Scotland."	

Administrative provisions amending the National Food Administration's administrative provisions (SLVFS 2005:9) on the use of a particular symbol	Sweden	2008	444	Yes. "The aim of the labelling is that, as an element in the work to promote public health, it should function as a simple and credible tool to make it easier for consumers to choose products which can contribute to good eating habits and good health. An unbalanced diet increases the risk of diet-related multifactorial diseases, such as obesity, type 2 diabetes, cardiovascular disease, brittle bones and certain forms of cancer."	
Draft Regulations on voluntary labelling of foodstuffs with the "Keyhole"	Norway	2008	9024	Yes. "Labelling of foodstuff with the Keyhole aims at guiding the consumers, in a simple and credible way toward healthier alternatives within specific food groups for a healthy diet. Such a labelling system will contribute toward changes based on the main challenges from the dietary recommendations. The dietary recommendations are mainly the same for the population in general, as it is for people with type 2-diabetes, or people with a high risk of developing diabetes, cardiovascular disease, or obesity. A labelling system that observes the dietary recommendations will therefore be helpful in preventing or treating persons with these types of health problems."	
Order amending regulations under foodstuffs law	Germany	2008	107	Yes. Cf. below table on sugar content of jams, jellies, etc.	
Draft Decree amending the amended Decree of 14 August 1985 implementing the Law of 1 August 1905 on fraud and falsification in the area of products and services with regard to fruit jams, jellies, marmalades and other similar products	France	2007	428	Yes. Cf. below table on sugar content of jams, jellies, etc.	
Education (Nutritional Standards for School Food) (England) Regulations 2007	United Kingdom	2007	226	Yes. "The nutritional standards for school food are a key element of the Government's programme to improve the quality of food and drink provided in schools. Better food in schools will make a major contribution to improving the health of children and young people. Healthier food in schools will also help stop the rise in obesity in children and young people which is a Government target (Public Service Agreement) shared between the Department for Education and Skills and the Department of Health. Heart disease, stroke, joint problems and type 2 diabetes are all direct effects of obesity which has increased in children aged 2 to 10 years from 9.6% in 1995 to 13.7% in 2003."	
Decree amending the Commodities Act Decree on meat, minced meat and meat products regarding the fat content of minced meat and lean minced meat.	Netherlands	2007	34	Yes. "Dutch legislation on the maximum permissible fat content of lean minced meat appears to be unclear. The draft Decree eliminates this confusion. The starting point for this is to choose the maximum permissible fat content in such a way that a contribution is made towards preventing excess weight and reducing the intake of saturated fats."	

Voluntary Front of Pack Signpost Nutrition Labelling System	United Kingdom	2006	38	Yes. "[] The scheme will present key nutritional information on certain foods in a prominent and easily understandable format and therefore help consumers to make healthier choices. The guidance will also provide a consistent basis for signposting and reduce potential confusion among consumers caused by the increasing use by retailers and manufacturers of different front of pack labelling systems. [] It is proposed that this signposting be introduced on foods where research has shown consumers have difficulty assessing nutritional quality, and which are eaten frequently or in large quantities. [] Consumers want to make healthier food choices, but many have difficulty using nutritional information as currently presented on food labels; consumers strongly support a standardised front of pack system, developed and controlled by an independent and authoritative body such as the Agency; and the proposed system is effective in helping consumers from a wide range of backgrounds to assess quickly and easily the nutrient content of foods, and therefore to make healthier choices."	"The UK Food Standards Agency (FSA) is currently conducting a public consultation exercise to gather stakeholders' views on two signposting formats. The results of this exercise will inform the FSA's decision as to which of the two to recommend for adoption. The UK has submitted a separate notification for each format. This notification is for the Multiple Traffic Light (MTL) format (which is the favoured of two proposed formats). The MTL indicates whether the product is high, medium or low in fat, saturated fat, sugar and salt, with a corresponding colour coding."
Nutritional Mark Order	Denmark	2006	540	Yes. "The Order establishes a voluntary nutritional marking in the form of a pictogram that can be used by those responsible for marketing foodstuffs with a view to providing an overview of the individual foodstuffs' nutritional characteristics. The mark illustrates whether a foodstuff should form a major, minor or minimum part of an overall diet. []It has been noted that there is a need to supplement official dietary advice and the rules on nutrition labelling by means of a simple instrument capable of giving shoppers a quick overview of individual foodstuffs' nutritional characteristics."	
Order laying down the conditions relating to the health message to accompany the messages advertising or promoting certain foods and drinks	France	2006	480	Yes. "It is a question of implementing a measure designed to educate people about nutrition, with the aim of increasing awareness among the general public, and particularly children, and of acquainting people with the key reference points in relation to nutrition. The measure also makes it possible to increase the funding granted to the National Institute for Prevention and Health Education for developing measures in relation to prevention and education in nutrition, particularly at a local level. This measure contributes to the fight against diseases associated with poor nutrition and helps prevent obesity. The health messages included in the draft order all correspond to nutritional items that have been recognised as particularly important health determinants. They originate from the recommendations of the National Nutrition and Health Programme developed by the Ministry for Health and Solidarity."	"The basic text is the draft decree implementing Article L. 2133-1 of the Public Health Code [2004/329/F]. The notification concerns this order, which defines the conditions under which the health messages must be displayed on promotional material relating to nutrition, the failure, on the part of advertisers, to display these messages being punishable by the payment, by the advertisers, of a tax representing 1.5% of the annual sum of the monies intended for the broadcasting and dissemination of promotional measures. The income from this tax will make it possible to increase the funding granted to the National Institute for Prevention and Health Education for undertaking measures in relation to education in nutrition."

Education (Nutritional Standards for School Lunches) (England) Regulations 2006	United Kingdom	2006	261	Yes. "The nutritional standards for school lunches are a key element of the Government's programme to improve the quality of food provided in schools. Better food in schools will make a major contribution to improving the health of children and young people. Healthier food in schools will also help stop the rise in obesity in children and young people which is a Government target (Public Service Agreement) shared between the Department for Education and Skills and the Department of Health. Heart disease, stroke, joint problems and type 2 diabetes are all direct effects of obesity which has increased in children aged 2 to 10 years from 9.6% in 1995 to 13.7% in 2003."	cf. 2007/226/UK
Regulation 11/1994. (VI. 8.) MKM on the operation of educational - training institutes	Hungary	2005	475	Yes. "The Draft regulates the procedure that must be developed to create a choice of food products that are sold in school canteens which is in line with the modern nutritional eating habits and complies with the "recommendations on healthy eating" in respect of the choice of food available in food outlets (buffets) and food dispensing machines operating in training and educational institutes."	
Draft regulation on claims on labels, advertisements and presentation of foodstuffs	Iceland	2005	9055	Indirectly. "When labelling, advertising and presenting foodstuffs to consumers it shall only be permissible to make those claims according to Article 6 in the regulation or claims that have been approved by other regulation on nutrition labeling (directive 90/496, directive 79/112 and directive 2003/120). Artical 6 sets forward criteria for labeling foodstuff as low fat, low calories, low sugar, sugar free, fiber-rich, salt, caffeine free, alcohol free. [] The objective of this Regulation is to ensure that claims on the nature and characteristics of foodstuffs as presented in the labelling, advertising and presentation of these foodstuffs shall be based on valid arguments and shall not mislead the consumers."	
Draft Law on Public Health Policy	Indirectly. "Art. L. 2133-1 Television or radio advertisements for drinks with added sugar, salt or synthetic sweeteners and for manufactured food products, broadcast from the French territory and received in this territory, must contain health information. The same information obligation is imposed on campaigns promoting these drinks and products.  Advertisers may be exempted from this obligation subject to payment of a contribution to		Cf. 2006/40/F		
The National Food Administration's administrative provisions on the use of a particular symbol	Sweden	2004	493	Yes. "The aim of the labelling is that, as an element in the work to promote public health, it should function as a simple and credible tool to make it easier for consumers to choose products which can contribute to good food habits and good health. An unbalanced diet increases the risk of diet-related multifactoral diseases, such as obesity, type 2 diabetes, cardiovascular disease, brittle bones and certain forms of cancer. The draft satisfies the wish of industry, consumers and experts in the field of nutrition for the scope to be extended. "	

Ancillary tables for comparative purposes (items highlighted in grey do not meet inclusion criteria and are not included in main results)

Sugar content of jams, jellies etc.					Council Directive 2001/113/EC of 20 December 2001 relating to fruit jams, jellies, marmalades and sweetened chestnut purée intended for human consumption
The draft Jam and Similar Products (England) Regulations 2014 The draft Jam and Similar Products (Scotland) Regulations 2014 The draft Jam and Similar Products (Wales) Regulations 2014 The draft Jam and Similar Products (Northern Ireland) Regulations 2014	United Kingdom	2013	649	No. "The proposed amendment is being made to take account of innovation in the type of jam products now available on the UK market. Over recent years, a wider variety of products have been developed using different mixtures of fruits that have a soluble dry matter content that is below the 60% minimum both in the UK and in other Member States, resulting in some other Member States taking advantage of the derogation to reduce the minimum soluble dry matter content of such products. In order to provide manufacturers with the freedom and flexibility and to avoid stifling innovation we are proposing to lower the minimum soluble dry matter content to 50% to reflect these recent developments."	
Draft Regulation of the Minister of Agriculture and Rural Development amending the Regulation on the labelling of foodstuffs	Poland	2012	246	No, mere reference to labelling of low-sugar jams and jellies.	
Commodities Act [Warenwet] exemption regulation for jam with reduced sugar content	Netherlands	2010	310	Indirectly. "The 2002 Commodities Act Decree on Preserved Fruit Products implements Directive 2001/113/EC and contains rules for the designation and composition of various preserved fruit products such as jam and marmelade. Article 13 of the aforementioned Decree prescribes that the content in soluble dry matter of preserved fruit products should be at least 60%. Such content is determined mainly by the amount of sugar. One producer of preserved fruit products has indicated a wish to market jam with a reduced sugar content (from 50% to 33%). For this producer, it is important to continue using the word jam" to designate the product. However, due to the reduced sugar content, the amount of soluble dry matter in this product is lower than required under Article 13 of the 2002 Commodities Act Decree on Preserved Fruit Products. The producer has therefore filed a request for exemption from that requirement. As the Netherlands does not consider it necessary to maintain obstacles to a reduction in the sugar content of jam, the Netherlands is prepared to comply with this request."	
"Amendments to the Cabinet of Ministers Regulation No 378 of 8 July 2003 "Requirements for the quality, classification and labelling of fruit jams, jellies, marmalades and sweetened chestnut purée""	Latvia	2010	133	No. "In order to prevent consumers from being misled, separate requirements for the quality, classification and labelling of jams and preserves and reduced sugar preserves are established."	

Draft Decree implementing Article L. 214-1 of the Consumer Code regarding certain sugar confectionary products.	France	2008	218	Yes. "The soluble dry matter content is set at 60% minimum by Community Directive 2001/113/EC of 20 December 2001. However, part II of Annex 1 to this Directive gives the Member States the option, for the purpose of responding to certain specific cases, to authorise designations reserved for products defined in part I of this text, for these products of which the soluble dry matter is less than 60%. Article 1 of the Draft Decree increases the soluble dry matter content to a minimum value of between 55% and 60% for fruit jams, jellies, marmalades and marmalade-jellies. At national level, the reduction in the sugar content of fruit jams is in line with the objectives of the health and nutrition plans (PNNS), which recommend a reduction in the consumption of sugar, with market trends, which are offering a growing number of fruit preparations containing less sugar and with the desire expressed by the majority of consumers during consumption studies. This amendment is also in line with the guidelines laid down in the Green Paper of 8 December 2005 by the European Commission, as part of the fight against obesity. At Community level, several countries market products with a soluble dry matter content of less than 60% under the	
Order amending regulations under foodstuffs law	Germany	2008	107	Yes. "Reducing the minimum content of soluble dry matter in jams, marmalades and jellies is intended to take account of the fact that it has also been customary for many years in Germany to manufacture these products on a 50% fruit/50% sugar basis. In addition, the reduction is intended to contribute to measures to prevent malnutrition and obesity by promoting healthy eating."	
Draft Decree amending the amended Decree of 14 August 1985 implementing the Law of 1 August 1905 on fraud and falsification in the area of products and services with regard to fruit jams, jellies, marmalades and other similar products	France	2007	428	Yes. "At national level, the reduction in the sugar content of fruit jams is in line with the objectives of the health and nutrition plans (PNNS), which recommend a reduction in the consumption of sugar, with market trends, which are offering a growing number of fruit preparations containing less sugar and with the desire expressed by the majority of consumers during consumption studies. This amendment is also in line with the guidelines laid down in the Green Paper of 8 December 2005 by the European Commission, as part of the fight against obesity."	
Sugar content of fruit juices and other beve	erages that incl	ude juice p	reparations		
Urgent measures to promote the country's development through a higher level of health protection: Article 8, point 16 of the Legislative Decree 158 of 2012.	Italy	2012	559	Yes. "The intention is to improve the nutritional quality of products that are particularly important for the entire population and specifically for young people. This is an important initiative that comes from the commitment of the Italian Ministry of Health to not only ensure food product safety by minimising possible biological, physical and chemical risks, but also ensure food products are healthy and of high nutritional quality. The proposed legislation also falls within a broader strategy, aimed at reducing inappropriate behaviour and promoting healthy eating, together with legislation aimed at providing incentives for the industry to produce food products with reduced fat and sugar content, regulate commercial promotion aimed at young children and ensure healthy food; specifically, the preventive role linked to eating fruit and vegetables regularly []. The reasons for the legislative initiative in question, as outlined above, are also based on directions at EU level aimed at increasing, within national policies, the consumption of fruit, in light of the increase in chronic non-contagious illnesses and of the fact that improper eating habits are a risk factor on which legislation can and must be enacted. [] The importance of fruit and vegetables is today known by everyone, not only due to their significant content of vitamins and minerals	

Technical regulation for description, production and placing for sale of non-alcoholic beverages and kvass	Latvia	2008	269	No. "The Regulation lays down definitions of non-alcoholic beverages, requirements for safety and quality of raw materials and other materials used in production of beverages, general technological requirements, requirements for safety and quality of finished products and general requirements for placing for sale. []The technical regulation draft was drawn up to ensure equal conditions for all economic entities, to classify beverages, lay down production, quality and presentation requirements for their groups and categories. []"	
Draft Royal Decree laying down the minimum quality parameters of fruit juices and the applicable methods of analysis.	Spain	2007	173	No. "The draft Royal Decree lays down certain analytical parameters of authenticity and quality as well as the official methods of analysis to assess the composition, in order to ensure commercial quality control and to prevent fraud to the consumer and unfair competition. [] The current national standard (Royal Decree No 1050 of 1 August 2003) includes the legislation of Council Directive 2001/112/EC of 20 December 2001, without laying down the analytical parameters that facilitate the quality control of fruit juices and other similar products intended for human consumption."	
Slovak Ministry of Agriculture and Ministry of Health Decree implementing the chapter of the Slovak Republic Foodstuffs Code governing fruit juices and certain similar products intended for human consumption	Slovakia	2005	259	No. Limits maximum permissable use of of sugars and requires labelling indicating sugar content and the disclosure of minimum fruit content.	
Decree of the Ministry of Trade and Industry on juices and certain similar products	Finland	2004	207	No. "Juice is intended to be used as such or diluted. The undiluted juice content is at least 35 % of the weight. Vegetable juices, pure juices and juices do not come within the scope of the Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption. However, there are plenty of these products on the market. It is necessary to regulate the composition and brand names of the products to ensure that consumers are not misled in respect of the composition of the products."	

## Relevant European Union Member State submissions to NOPA not captured by TRIS 2004-2013

Submissions by countries that are members of the European Free Trade Association (EFTA), but not EU Member States, are italicized Database: <a href="http://data.euro.who.int/nopa/">http://data.euro.who.int/nopa/</a>

English Title	Country	Year adopted	WHO Content Analysis	Original title + electronic source (if given and valid)
Law on School Nutrition	Slovenia		Summary: The Law on School Nutrition details the ban on vending machines for primary schools in Slovenia which is based on guidelines for school nutrition	NA
Edw on School Nathtion	Sieverna		Policy actions addressed in the document: Pre-school and school nutrition; Commercial provision of food in line with food-based dietary guidelines	

Media Law	Iceland	2011	Summary: In April 2011, the national Parliament passed a new Media law. Advertisements are thereby not permitted to air adjacent to programmes intended for children under the age of 12. Furthermore, it is prohibited in commercial communications and teleshopping to encourage minors to consume foods and beverages that may be considered as unhealthy.  Policy actions addressed in the document: Ensure appropriate marketing practices	http://eng.menntamalaraduneyti.is/media/MRN- pdf/Media-Act-38-English-translation-nov-2011.pdf (English translation)
Regulation on health protection requirements for catering facilities in preschool institutions, schools	Estonia	2008	Summary: In 2008, Ministry of Social Affairs adopted updated regulation on health protection requirements for catering facilities in pre-school institutions, schools. By that regulation a school lunch covers 30-35% of the daily energy and nutrient needs and in kindergartens 85-90% of the daily energy and nutrient needs.  Policy actions addressed in the document: Pre-school and school nutrition	Tervisekaitsenõuded toitlustamisele koolieelses lasteasutuses ja koolis https://www.riigiteataja.ee/akt/12912436
Ministerial Order No. 1563 for approval, the list of foods not recommended to preschoolers and school and the principles underlying healthy diets for children and adolescents]	Romania	2008	Summary: This Order approves the recommended food list for pre-school and schoolchildren, provided in Appendix of this Order. Schools are prohibited from marketing these products which fall within the criteria and limits listed in the Appendix of this Order. The principles that underpin a healthy diet for children and adolescents are provided in the Appendix of this Order.  Policy actions addressed in the document: Food-based dietary guidelines; Ensure appropriate marketing practices	ORDIN Nr. 1563 din 12 septembrie 2008 pentru aprobarea Listei alimentelor nerecomandate preșcolarilor și școlarilor și a principiilor care stau la baza unei alimentații sănătoase pentru copii și adolescenți
Decree of the Flemish Government to complete the code for advertising and sponsorship on radio and television with specific provisions on advertising and sponsorship aimed at children and young people	Belgium/Flanders Province	2007	NA	Besluit van de Vlaamse Regering houdende de aanvulling van de code voor reclame en sponsoring op radio en televisie met specifieke bepalingen over reclame en sponsoring, gericht op kinderen en jongeren

Basic acts and other framework laws are indicated in bold and listed chronologically; implementing or amending subsidiary laws are indicated in italics and listed under the reference law where it also falls within the time period under review; basic acts repealed and/or incoporated into a later basic act are indicated in bold and italics under the most recent basic act

Database: <a href="http://eur-lex.europa.eu/homepage.html">http://eur-lex.europa.eu/homepage.html</a>

CELEX number	Title	Publication Reference	Comment
02013R1308	Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007	OLI 347 20 12 2013 n 671	Current basic act providing for the School Milk, School Fruit, and Food distribution programs.
32007R1234	Council Regulation (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation)	OJ L 299, 16.11.2007, p. 1	Repealed by Regulation (EU) No 1308/2013.
32012R0121	Regulation (EU) No 121/2012 of the European Parliament and of the Council of 15 February 2012 amending Council Regulations (EC) No 1290/2005 and (EC) No 1234/2007 as regards distribution of food products to the most deprived persons in the Union	OJ L 44, 16/02/2012, p. 1	
32009R0966	Commission Regulation (EC) No 966/2009 of 15 October 2009 amending Regulation (EC) No 657/2008 laying down rules for applying Council Regulation (EC) No 1234/2007 as regards Community aid for supplying milk and certain milk products to pupils in educational establishments	OJ L 271, 16/10/2009, p. 10	
32009R0288	Commission Regulation (EC) No 288/2009 of 7 April 2009 laying down detailed rules for applying Council Regulation (EC) No 1234/2007 as regards Community aid for supplying fruit and vegetables, processed fruit and vegetables and banana products to children in educational establishments, in the framework of a School Fruit Scheme	OJ L 94, 08/04/2009, p. 38	
32009R0013	Council Regulation (EC) No 13/2009 of 18 December 2008 amending Regulations (EC) No 1290/2005 on the financing of the common agricultural policy and (EC) No 1234/2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) in order to set up a School Fruit Scheme	OJ L 5, 09/01/2009, p. 1	
32008R0657	Commission Regulation (EC) No 657/2008 of 10 July 2008 laying down detailed rules for applying Council Regulation (EC) No 1234/2007 as regards Community aid for supplying milk and certain milk products to pupils in educational establishments	OJ L 183, 11/07/2008, p. 17	
32007R1544	Commission Regulation (EC) No 1544/2007 of 20 December 2007 amending Regulation (EC) No 2707/2000 laying down rules for applying Council Regulation (EC) No 1255/1999 as regards Community aid for supplying milk and certain milk products to pupils in educational establishments	OJ L 337, 21/12/2007, p. 64	Repealed with Commission Regulation (EC) No 2707/2000 by Commission Regulation (EC) No 657/2008.

32013R0609	Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009	OJ L 181, 29/06/2013, p. 35	
32009L0039	Directive 2009/39/EC of the European Parliament and of the Council of 6 May 2009 on foodstuffs intended for particular nutritional uses	OJ L 124, 20/05/2009, p. 21	Repealed by Regulation (EU) No 609/2013.
32007L0029	Commission Directive 2007/29/EC of 30 May 2007 amending Directive 96/8/EC as regards labelling, advertising or presenting foods intended for use in energy-restricted diets for weight reduction	OJ L 139, 31/05/2007, p. 22	
32012L0012	Directive 2012/12/EU of the European Parliament and of the Council of 19 April 2012 amending Council Directive 2001/112/EC relating to fruit juices and certain similar products intended for human consumption	OJ L 115, 27/04/2012, p. 1	Corrigendum: 32012L0012R(01), OJ L 31, 31/01/2013, p. 83
32011R1169	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004	OJ L 304, 22/11/2011, p. 18	
32008R0109	Regulation (EC) No 109/2008 of the European Parliament and of the Council of 15 January 2008 amending Regulation (EC) No 1924/2006 on nutrition and health claims made on foods	OJ L 39, 13/02/2008, p. 14	
32006R1924	Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods	OJ L 404, 30/12/2006, p. 9	
32013R1018	Commission Regulation (EU) No 1018/2013 of 23 October 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health	OJ L 282, 24/10/2013, p. 43	Allows the claim 'Carbohydrates contribute to the maintenance of normal brain function' under restricted conditions in response to MS concerns over sending a " conflicting and confusing message to consumers, particularly in light of national dietary advice to reduce sugars consumption".
32013D0063	Commission Implementing Decision (EU) No 2013/63 of 24 January 2013 adopting guidelines for the implementation of specific conditions for health claims laid down in Article 10 of Regulation (EC) No 1924/2006 of the European Parliament and of the Council	OJ L 22, 25/01/2013, p. 25	

32013R0536	Commission Regulation (EU) No 536/2013 of 11 June 2013 amending Regulation (EU) No 432/2012 establishing a list of permitted health claims made on foods other than those referring to the reduction of disease risk and to children's development and health	OJ L 160, 12/06/2013, p. 4	Allows, among others, for health claim related to substitution of sucrose or glucose by fructose.
32012R1047	Commission Regulation (EU) No 1047/2012 of 8 November 2012 amending Regulation (EC) No 1924/2006 with regard to the list of nutrition claims	OJ L 310, 09/11/2012, p. 36	Specifies conditions for use of claims "reduced saturated fat" and "reduced sugars" to prevent reformulation that would increase total energy content.
32012R0432	Commission Regulation (EU) No 432/2012 of 16 May 2012 establishing a list of permitted health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health	OJ L 136, 25/05/2012, p. 1	
32011R0432	Commission Regulation (EU) No 432/2011 of 4 May 2011 refusing to authorise certain health claims made on foods, other than those referring to the reduction of disease risk and to children's development and health	OJ L 115, 05/05/2011, p. 1	Refuses, among others, health claims related to the reduction of waist circumference as a "beneficial physiological effect as defined by the Authority, namely,[] an improvement in adverse health effects associated with an excess abdominal fat"; the reduction of body fat; the reducation of body weight; reduced caloric intake; and decreased hunger.
32010R0383	Commission Regulation (EU) No 383/2010 of 5 May 2010 refusing to authorise a health claim made on foods, other than those referring to the reduction of disease risk and to children's development and health	OJ L 113, 06/05/2010, p. 4	Rejects claim related to a decreased sense of hunger as not meeting the requirement a cause-and-effect relationship that is "nutritionally or physiologically beneficial in terms of effect on food energy intake".
32010R0116	Commission Regulation (EU) No 116/2010 of 9 February 2010 amending Regulation (EC) No 1924/2006 of the European Parliament and of the Council with regard to the list of nutrition claims	OJ L 37, 10/02/2010, p. 16	Regulates claims related to unsaturated fat and omega-3 fatty acid content.
32009R0984	Commission Regulation (EC) No 984/2009 of 21 October 2009 refusing to authorise certain health claims made on food, other than those referring to the reduction of disease risk and to children's development and health	OJ L 277, 22/10/2009, p. 13	Rejects claim related to the effect of consumption of Elancyl Global Silhouette® on the regulation of body composition in people with light to moderate overweight: 'Clinically tested as of 14 days. Your silhouette is apparently and globally redrawn, resculpted and refined at 28 days'.
32009R0983	Commission Regulation (EC) No 983/2009 of 21 October 2009 on the authorisation and refusal of authorisation of certain health claims made on food and referring to the reduction of disease risk and to children's development and health	OJ L 277, 22/10/2009, p. 3	Rejects claim that "three portions of dairy food everyday, as part of a balanced diet, may help promote a healthy body weight during childhood and adolescence".

32006R1925	Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods	OJ L 404, 30/12/2006, p. 26
32008R1333	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives	OJ L 354, 31/12/2008, p. 16
32013R0913	Commission Regulation (EU) No 913/2013 of 23 September 2013 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in certain fruit or vegetable spreads	OJ L 252, 24/09/2013, p. 11
32013R0723	Commission Regulation (EU) No 723/2013 of 26 July 2013 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of extracts of rosemary (E 392) in certain low fat meat and fish products	OJ L 202, 27/07/2013, p. 8
32012R1049	Commission Regulation (EU) No 1049/2012 of 8 November 2012 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of polyglycitol syrup in several food categories	OJ L 310, 09/11/2012, p. 41
32011R1129	Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives	OJ L 295, 12/11/2011, p. 1
32011R1130	Commission Regulation (EU) No 1130/2011 of 11 November 2011 amending Annex III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives by establishing a Union list of food additives approved for use in food additives, food enzymes, food flavourings and nutrients	OJ L 295, 12/11/2011, p. 178
32011R1131	Commission Regulation (EU) No 1131/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council with regard to steviol glycosides	OJ L 295, 12/11/2011, p. 205
32008R1334	Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC	OJ L 354, 31/12/2008, p. 34
32012R0793	Commission Implementing Regulation (EU) No 793/2012 of 5 September 2012 adopting the list of flavouring substances provided for by Regulation (EC) No 2232/96 of the European Parliament and of the Council, introducing it in Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council and repealing Commission Regulation (EC) No 1565/2000 and Commission Decision 1999/217/EC	OJ L 243, 07/09/2012, p. 1
32008L0005	Commission Directive 2008/5/EC of 30 January 2008 concerning the compulsory indication on the labelling of certain foodstuffs of particulars other than those provided for in Directive 2000/13/EC of the European Parliament and of the Council	OJ L 27, 31/01/2008, p. 12

# Relevant US statutory and regulatory laws 2004-2013

Databases: <a href="http://thomas.loc.gov/home/thomas.php">http://thomas.loc.gov/home/thomas.php</a> (congressional legislation), <a href="http://www.qpo.gov/fdsys/search/home.action">http://www.qpo.gov/fdsys/search/home.action</a> (federal regulation)

Legislation and respective implementing regulations	Signed by President/Publication	Congress/Rule status
S. 3307 Healthy, Hunger-Free Kids Act of 2010	December 13, 2010	111th
78 FR 39068 National School Lunch Program and School Breakfast Program: Nutrition Standards for All Foods Sold in School as Required by the Healthy, Hunger- Free Kids Act of 2010	Vol. 78, No. 125 (June 28, 2013)	Interim Final Rule
78 FR 13443 Child Nutrition Programs: Nondiscretionary Amendments Related to the Healthy, Hunger-Free Kids Act of 2010	Vol. 78, No. 40 (February 28, 2013)	Final Rule
77 FR 4088 Nutrition Standards in the National School Lunch and School Breakfast Programs	Vol. 77, No. 17 (January 26, 2012)	Final Rule
77 FR 25024 Certification of Compliance With Meal Requirements for the National School Lunch Program Under the Healthy, Hunger-Free Kids Act of 2010	Vol. 77, No. 82 (April 27, 2012)	Interim Final Rule
H.R. 3590 Patient Protection and Affordable Care Act	March 23, 2010	111th
H.R. 6124 Food, Conservation, and Energy Act of 2008	Veto overridden June 18, 2008	110th
74 FR 48373 Senior Farmers' Market Nutrition Program Regulations, Nondiscretionary Provisions of Public Law 110–246, the Food, Conservation, and Energy Act of 2008	Vol. 74, No. 183 (September 23, 2009)	Final Rule
H.R. 6197 Older Americans Act Amendments of 2006	October 17, 2006	109th
S. 2507 Child Nutrition and WIC Reauthorization Act of 2004	Jun 30, 2004	108th
74 FR 69243 Special Supplemental Nutrition Program for Women, Infants and Children (WIC) Revisions in the WIC Food Packages Rule To Increase Cash Value Vouchers for Women	Vol. 74, No. 250 (December 31, 2009)	Interim Rule
74 FR 38889 Marketing and Sale of Fluid Milk in Schools	Vol. 74, No. 149 (August 5, 2009)	Final Rule
73 FR 52903 Fluid Milk Substitutions in the School Nutrition Programs	Vol. 73, No. 178 (September 12, 2008)	Final Rule
72 FR 68966 Special Supplemental Nutrition Program for Women, Infants and Children (WIC): Revisions in the WIC Food Packages	Vol. 72, No. 234 (December 6, 2007)	Interim Rule
69 FR 70871 National School Lunch Program: Requirement for Variety of Fluid Milk in Reimbursable Meals	Vol. 69, No. 235 (December 8, 2004)	Final Rule
Regulations without enabling legislation enacted during search period		
75 FR 82148 Nutrition Labeling of Single-Ingredient Products and Ground or Chopped Meat and Poultry Products	Vol. 75, No. 249 (December 29, 2010)	Final Rule

75 FR 16325 Child and Adult Care Food Program: At-Risk Afterschool Meals in Eligible States	Vol. 75, No. 62 (April 1, 2010)	Final Rule
72 FR 41591 Afterschool Snacks in the Child and Adult Care Food Program	Vol. 72, No. 146 (July 31, 2007)	Final Rule
71 FR 74618 Senior Farmers' Market Nutrition Program Regulations	Vol. 71, No. 238 (December 12, 2006)	Final Rule
70 FR 33804 Food Standards: Requirements for Substitute Standardized Meat and Poultry Products Named by Use of an Expressed Nutrient Content Claim and a Standardized Term	Vol. 70, No. 111 (June 10, 2005)	Final Rule
69 FR 58799 Nutrition Labeling: Nutrient Content Claims on Multi-Serve, Meal-Type Meat and Poultry Products	Vol. 69, No. 190 (October 1, 2004)	Final Rule

# 9.2 Appendix 2 - Supplemental materials chapter 5

The following documents are associated with the manuscript entitled "Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition" (chapter 5, pp. 65-85).





## PROSPERO International prospective register of systematic reviews

# Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition

Jana Sisnowski, Jackie Street, Tracy Merlin

#### Citation

Jana Sisnowski, Jackie Street, Tracy Merlin. Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition. PROSPERO 2015:CRD42015025276 Available from

http://www.crd.york.ac.uk/PROSPERO\_REBRANDING/display\_record.asp?ID=CRD42015025276

#### **Review question(s)**

What is the effect on calorie intake of statutory provisions of a regulatory nature that aim to reduce the consumption of energy-dense foods and beverages in the general population?

#### **Searches**

We will systematically search 17 databases that span academic research and research undertaken by public agencies and public or private organizations. In addition, we will hand-search the reference lists of all articles that met the inclusion criteria detailed below.

Restrictions: articles published January 1, 2004 to October 31, 2015 involving humans.

#### Types of study to be included

We include all studies that evaluate real-life, fully implemented regulatory policy intervention with at least one comparison measure.

#### Condition or domain being studied

The condition of interest is population nutrition (measured variable) with the aim of reducing the prevalence and/or incidence of overweight and obesity (unmeasured variables).

#### Participants/ population

Any sample of the general population in a jurisdiction covered by the regulatory intervention in question who came into contact with a setting/subject/activity subject to the new rules. Data pertaining to sub-groups will be included only where these are studied as part of a regulatory intervention that targets the general population; this excludes particular settings such as schools or workplaces.

#### Intervention(s), exposure(s)

Inclusion criteria:

Included are studies of interventions that were rolled out as part of a legislative or regulatory change in health policy, with the aim of improving population nutrition, and are targeted at the general population.

Exclusion criteria:

Excluded are studies that do not examine an intervention meeting the above criteria, that were published prior to 2004, and studies that do not include a comparator.

#### Comparator(s)/ control

The comparator will be either a non-exposed comparison group drawn from another jurisdiction or pre/post-implementation data.





#### Outcome(s)

**Primary outcomes** 

Average BMI or weight; calorie intake and related proxy measures.

#### **Secondary outcomes**

Indicators measuring parameters on the assumed causal pathway to changed consumption patterns, including measures of the degree of program implementation and non-behavioral consumer responses such as usage, awareness, and knowledge.

#### Data extraction, (selection and coding)

Each title/abstract will initially be assessed by the first reviewer. A subset of 10% of the initially excluded items will then again be reviewed for eligibility by a second reviewer. Where reviewer assessment differs, a consensus decision will be reached by the co-authors.

Data will be extracted using a pre-established template covering study design, study population, measured outcomes, comparators, and results.

#### Risk of bias (quality) assessment

Quality assessment will be conducted on the basis of the NIH/National Heart, Lung, and Blood Institute Study Quality Assessment Tools which include specific tools for Observational Cohort and Cross-Sectional Studies and Pre-Post Studies without a control group. Two authors will independently grade all eligible studies as high, medium, and low quality. Highly variable quality will result in a narrative synthesis.

#### Strategy for data synthesis

Data will be aggregate, but may be limited to particular subgroups of the general population depending on study focus. Anticipating heterogeneous study designs and study quality, we plan to perform a narrative synthesis of reported results grouped by intervention.

#### Analysis of subgroups or subsets

Data on subgroups of the population will be extracted and synthesized if such data is reported in aggregated form in the original studies.

#### Contact details for further information

Jana Sisnowski

178 North Tce

5005 Adelaide, South Australia

Australia

jana.sisnowski@adelaide.edu.au

#### Organisational affiliation of the review

University of Adelaide

http://www.adelaide.edu.au/

#### **Review team**

Ms Jana Sisnowski, University of Adelaide Dr Jackie Street, University of Adelaide Professor Tracy Merlin, University of Adelaide

#### Anticipated or actual start date

30 November 2015





## Anticipated completion date

31 January 2016

#### **Funding sources/sponsors**

This project was conducted as part of the study Healthy-Laws – Public Perspectives in Public Health Law, funded by the Australian National Preventive Health Agency (ANPHA), project ID: 182BRA2011. ANPHA has no role in the study design; the collection, analysis, and interpretation of data; or the writing of the manuscript.

#### **Conflicts of interest**

None known

#### Language

English

#### **Country**

Australia

#### Subject index terms status

Subject indexing assigned by CRD

#### **Subject index terms**

Diet; Diet, Reducing; Food; Health Policy; Humans; Nutritional Status; Nutrition Policy; Obesity; Overweight; Public Policy

#### Stage of review

Ongoing

#### **Date of registration in PROSPERO**

07 December 2015

## Date of publication of this revision

07 December 2015

#### DOI

10.15124/CRD42015025276

Stage of review at time of this submission	Started	Completed
Preliminary searches	No	Yes
Piloting of the study selection process	Yes	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

#### **PROSPERO**

#### International prospective register of systematic reviews

The information in this record has been provided by the named contact for this review. CRD has accepted this information in good faith and registered the review in PROSPERO. CRD bears no responsibility or liability for the content of this registration record, any associated files or external websites.

Improving food environments and tackling obesity: a realist systematic review of the policy success of regulatory interventions targeting population nutrition - Overview of database search strategies

# 1. **PubMed** (n=8,995)

January 1, 2004 – O	ctober 31, 2015; humans; string:(A AND (B OR C OR D OR E)) NOT E
A	(Policy[tiab] OR policies[tiab] OR regulation[tiab] OR regulations[tiab] OR regulatory[tiab] OR Government
Policy/intervention	Regulation[MH] OR prevention & control[MH] OR Risk Reduction Behavior[MH:noexp] OR Policy[MH:noexp] OR
	Public Policy[MH:noexp] OR Health Policy[MH:noexp] OR Nutrition policy[MH] OR intervention[tiab] OR
	interventions[tiab] OR law[tiab] OR laws[tiab] OR legislation[tiab] OR legislative[tiab] OR legal[tiab] OR health
	promotion[tiab])
В	(obesity[tiab] OR obese[tiab] OR adiposity[tiab] OR adipose[tiab] OR overweight[tiab] OR weight[tiab] OR
Obesity	bodyweight[tiab] OR Overnutrition[MeSH Terms] OR Body Weights and Measures[MeSH Terms] OR Body
	Weight[MeSH Terms] OR BMI[tiab] OR body mass index[tiab] OR Overweight[MeSH Terms]
С	nutrition[tiab] OR nutritional[tiab]OR diet[tiab]OR dietary [tiab] OR diets [tiab] OR food[tiab] OR foods[tiab] OR calorie
Nutrition	[tiab] OR calories [tiab] OR calorie-dense[tiab] OR calorie dense[tiab] OR caloric [tiab]) OR energy [tiab] OR energy-
	dense[tiab] OR energy dense[tiab] OR intake [tiab] Or Energy Intake[MH] OR consumption [tiab] OR eating[tiab] OR
	Food Habits[MH] OR Food Preferences[MH] OR Nutritional Status[MH]
D	vegetable[tiab] OR vegetables[tiab]OR fruit[tiab] OR fruits[tiab] OR sugar[tiab] OR sugars[tiab] OR sugary[tiab] OR
Foods/food	fat[tiab]) OR fats[tiab] OR fatty [tiab] OR fast food[tiab] OR junk food[tiab] OR drink[tiab] OR drinks[tiab] OR
components	beverage[tiab] OR beverages[tiab] OR Food and Beverages[MH]
Е	menu[tiab] OR menus[tiab] OR label[tiab] OR labels[tiab] or labeling[tiab] OR labelling[tiab] OR restaurant[tiab] OR
Infrastructure and	restaurants[tiab] OR grocery[tiab] OR groceries[tiab] OR store[tiab] OR stores[tiab] OR bodega*[tiab] OR
settings	supermarket*[tiab] OR market[tiab] OR markets[tiab] OR greenmarket[tiab] OR greenmarkets[tiab] OR tax[tiab] OR
	taxes[tiab] OR taxation[tiab] OR Taxes[MH:noexp] OR subsidy[tiab] OR subsidies[tiab] OR subsidization[tiab] OR
	subsidisation[tiab] OR zoning[tiab] OR density[tiab] OR procurement[tiab]
F	Clinical Trial [Publication Type] OR Controlled Clinical Trial [Publication Type] OR Randomized Controlled Trial
Publication Type	[Publication Type] OR randomized[tiab] OR randomised[tiab] OR Comment [Publication Type] OR Editorial
	[Publication Type] OR Letter [Publication Type] OR News [Publication Type] OR Newspaper Article [Publication Type]

# 2. **Embase** (n= 6,254)

Search string: (#1 A)	ND (#2 OR #3 OR 4 OR #5) AND ([article]/lim OR [article in press]/lim OR [review]/lim) AND [humans]/lim AND	
[embase]/lim AND [	2004-2015]/py) NOT #6	
#1	'policy'/syn OR policy:ab,ti OR policies:ab,ti OR 'public policy'/mj OR 'public policy':ab,ti OR 'health policy'/mj OR	
Policy/intervention	'health policy':ab,ti OR 'nutrition policy'/mj OR 'nutrition policy':ab,ti OR 'law'/mj OR law:ab,ti OR laws:ab,ti OR	
	'legislation'/mj OR legislation:ab,ti OR legislative:ab,ti OR legal:ab,ti	
#2	'obesity'/syn OR obesity:ab,ti OR obese:ab,ti OR overweight:ab,ti OR bodyweight:ab,ti OR 'body weight'/syn OR 'body	
Obesity	weight':ab,ti OR bmi:ab,ti OR 'body mass index'/mj OR 'body mass index':ab,ti	
#3	'nutrition'/syn OR nutrition:ab,ti OR nutritional:ab,ti OR diet:ab,ti OR diet:ab,ti OR diet:ab,ti OR food:ab,ti OR	
Nutrition	foods:ab,ti OR calories:ab,ti OR 'calorie dense':ab,ti OR 'calorie'/mj OR calorie:ab,ti OR caloric:ab,ti OR 'energy	
	dense':ab,ti OR intake:ab,ti OR energy:ab,ti OR consumption:ab,ti OR 'feeding behavior'/exp OR eating:ab,ti OR 'dietary	
	intake'/exp	
#4	'vegetable'/mj OR vegetable:ab,ti OR 'vegetables'/mj OR vegetables:ab,ti OR 'fruit'/mj OR fruit:ab,ti OR fruits:ab,ti OR	
Foods/food	'sugar'/mj OR sugar:ab,ti OR sugary:ab,ti OR 'sugar sweetened':ab,ti OR 'fat/mj OR fat:ab,ti OR 'fast food'/mj OR 'fast	
components	food':ab,ti OR 'junk food':ab,ti OR drink:ab,ti OR drinks:ab,ti OR 'beverage'/mj OR beverage:ab,ti OR 'beverages'/mj OR	
	beverages:ab,ti	
#5	menu:ab,ti OR menus:ab,ti OR label:ab,ti OR labels:ab,ti OR labelling:ab,ti OR labelling:ab,ti OR restaurant:ab,ti OR	
Infrastructure and	'restaurants'/mj OR restaurants:ab,ti OR grocery:ab,ti OR groceries:ab,ti OR store:ab,ti OR stores:ab,ti OR bodega*:ab,ti	
settings	OR supermarket*:ab,ti OR 'market':ab,ti OR markets:ab,ti OR greenmarket:ab,ti OR greenmarkets:ab,ti OR 'tax':ab,ti OR	
	'tax'/mj OR taxation:ab,ti OR 'taxes':ab,ti OR 'taxes'/mj OR subsidy:ab,ti OR subsidies:ab,ti OR subsidisation:ab,ti OR	
	subsidization:ab,ti OR zoning:ab,ti OR 'density':ab,ti OR procurement:ab,ti OR 'food assistance'/mj OR 'food	
	packaging'/syn OR 'food availability'/syn	
#6	'clinical trial':ab,ti OR rct:ab,ti OR 'gene' OR 'gene'/de OR gene OR 'genes' OR 'genes'/de OR genes OR gene:ab,ti OR	
Exclusions	genetic:ab,ti OR 'cell' OR 'cell'/de OR cell OR 'cells' OR 'cells'/de OR cells OR 'absorption' OR 'absorption'/de OR	
	absorption OR 'mutation' OR 'mutation'/de OR mutation OR hormone:ab,ti OR hormonal:ab,ti OR 'physical activity':ab,ti	
	OR 'physical activity'/exp OR 'physical activity'/de OR 'physical activity' OR 'exercise' OR 'exercise'/de OR exercise OR	
	chemistry:ab,ti OR 'surgery'/exp OR 'surgery'/de OR 'surgery' OR organ* OR 'alcohol' OR 'alcohol'/de OR alcohol OR	
	'drinking' OR 'drinking'/de OR drinking OR 'transplantation' OR 'transplantation'/de OR transplantation OR medicine:ab,ti	
	OR medicines:ab,ti OR 'drug' OR 'drug'/de OR drug OR 'drugs' OR 'drugs'/de OR drugs OR 'addiction' OR 'addiction'/de	
	OR addiction OR hospital:ab,ti OR hospitals:ab,ti OR 'malnutrition' OR 'malnutrition'/de OR malnutrition OR	
	'undernutrition' OR 'undernutrition'/de OR undernutrition OR 'cancer' OR 'cancer'/de OR cancer	

# 3. **CINAHL** (n=8,160)

(S1 AND ((S2 OR	S3 OR S4 OR S5) ) ) NOT S6		
, ,	Date: 20040101-20151031; Publication Type: Doctoral Dissertation, Journal Article, Meta Analysis, Meta Synthesis,		
Research, Review, S	Research, Review, Systematic Review; Search modes - Boolean/Phrase; Source types- Academic Journals, Dissertations		
S1	(MM "Health Policy+") OR (MM "Policy Studies+") OR (MM "Policy Making") OR (MM "Health Policy Studies") OR		
Policy/intervention	(MM "Nutrition Policy+") OR (MM "Public Policy+") OR "policy" OR "policies" OR (MM "Legislation") OR		
	"legislation" OR "legislative" OR "law" OR "laws" OR "legal" OR (MH "Public Health Nutrition")		
S2	(MH "Obesity/LJ/EV/PC/RF") OR "obesity" OR "obese" OR "overweight" OR (MH "Body Weight/EC/EV/LJ/ST/TD")		
Obesity	OR (MH "Weight Control/EC/EV/LJ/ST") OR "bodyweight" OR "weight"		
S3	(MH "Nutrition") OR "nutrition" OR "nutritional" OR "diet" OR "dietary" OR "food" OR "foods" OR "calorie" OR		
Nutrition	"calories" OR "caloric" OR "calorie-dense OR "energy-dense" OR "intake" OR "consumption" OR "eating" OR (MH		
	"Food Preferences/EV/PC/LJ") OR (MH "Food Intake") OR (MH "Energy Intake") OR (MH "Energy Density") OR (MH		
	"Portion Size") OR (MH "Food and Beverages")		
S4	(MH "Fruit/EC/LJ/ST/SD/UT") OR "fruit" OR "fruits" OR (MH "Vegetables/EC/LJ/ST/UT") "vegetable" OR		
Foods/food	"vegetables" OR "sugar" OR "sugary" OR "sugar-sweetened" OR "fat" OR (MH "Fast Foods/EC/LJ/ST/SD/UT") OR "fast		
components	food" OR junk food" (MH "Fruit/EC/LJ/SD/ST") OR "junk food" OR "drink" OR "drinks" OR "soda" OR "beverage" OR		
	"beverages"		
S5	"menu" OR "menus" OR (MH "Food Labeling/EC/EV/LJ/ST/SN/UT") OR "label" OR "labels" OR "labelling" OR		
Infrastructure and	"labeling" OR "restaurant" OR "restaurants" OR "grocery" OR "groceries" OR "store" OR "stores" OR "bodega" OR		
settings	"supermarket" OR "market" OR "markets" OR "greenmarkets" OR "greenmarkets" OR (MH "Taxes") OR "tax" OR		
	"taxation" OR "taxes" OR (MH "Food Assistance/AM/EC/EV/LJ/PC/ST/TD") OR "subsidy" OR "subsidies" OR		
C.C	"subsidisation" OR "subsidization" OR "zoning" OR "density" OR "procurement"  ONLY "Give a Tailed III" OR ONLY "Brandon in a Controlled Trials" OR "latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "Latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "Latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "Latinization" OR "DCT" OR ONLY "Brandon in a Controlled Trials" OR "DCT"		
S6	(MH "Clinical Trials+") OR (MH "Randomized Controlled Trials") OR "clinical trial" OR "RCT" OR (MH "Physical Activity") OR (MH "Physical Fitness +") OR (MH "Francisca" OR (MH "Francisca") OR (MH "Francisca") OR (MH "Francisca")		
Exclusions	Activity") OR (MH "Physical Fitness+") OR (MH "Exercise+") OR (MH "Sports+") OR "physical activity" OR "exercise"		
	OR (MH "Genes+") OR (MH "Genetic Research+") OR "gene" OR "genes" OR "genetic" OR (MH "Cells+") OR "cell" OR "cells" OR "absorption" OR "mutation" OR (MH "Hormones+") OR "hormone" OR "hormonal" OR "chemistry" OR		
	"surgery" OR "organ" OR "organs" OR "organic" OR "alcohol" OR (MH "Alcohol-Related Disorders+") OR (MH		
	"Alcohol Drinking+") OR (MH "Surgery, Operative+") OR "transplantation" OR "medicine" OR "medicines" OR (MH		
	"Drugs+") OR (MH "Therapeutics+") OR (MH "Diagnosis+") OR "drug" OR "drugs" OR "addiction" OR (MH "Health		
	Facilities+") OR "school" OR "schools" OR "hospital" OR "hospitals" OR "malnutrition" OR "undernutrition" OR		
	"cancer"		

## 4. **PsycINFO** (n=2,074)

(#1 and (#2 or #3 or	#4 or #5)) and #6	
#1	(exp Policy Making/ or exp Health Care Policy/ or exp Government Policy Making/ or exp Legislative Processes/ or	
Policy/intervention	Laws/) or	
	(policy or policies or legislation or legislative or law or legal).ti,ab.	
#2	(Obesity/ or Overweight/ or Body Weight/ or Body Mass Index/) or	
Obesity	(obesity or obese or overweight or bodyweight or weight or BMI or body mass index).ti,ab.	
#3	(exp Nutrition/ or Food Intake/ or Food/ or Food Preferences/ or calories/ or exp Eating Behavior) or	
Nutrition	(nutrition or nutritional or diet or dietary or food or foods or calorie or calories or calorie-dense or caloric or energy-dense	
	or consumption or eating).ti,ab.	
#4	(exp "Beverages (Nonalcoholic)"/) or	
Foods/food	(vegetable or vegetables or fruit or fruits or sugar or sugary or sugar-sweetened or fat or fast food or junk food or soda or	
components	drink or drinks or beverage or beverages).ti,ab.	
#5	(labeling/ or exp Taxation/ or exp "Welfare Services (Government)"/) or	
Infrastructure and	(menu or menus or label or labels or labelling or labeling or restaurant or restaurants or grocery or groceries or store or	
settings	stores or bodega or supermarket or market or markets or greenmarkets or greenmarkets or tax or taxation or taxes or	
	subsidy or subsidies or subsidization or subsidization or zoning or density or procurement).ti,ab.	
#6	limit 17 to (("0400 empirical study" or "0450 longitudinal study" or "0453 retrospective study" or "0830 systematic	
Limitations	review" or 1200 meta analysis or 1800 quantitative study) and ("0100 journal" or "0110 peer-reviewed journal" or "0130	
	peer-reviewed status unknown") and (dissertation or journal article) and human and yr="2004 - 2015")	

# 5. Campbell Library database (n=30)

All text search, publication year 2004-2015, coordination groups 'nutrition', 'social welfare', and 'Knowledge Translation and Implementation': obesity AND policy (n=6) and nutrition AND policy (n=24)

# 6. Cochrane Library databases of Abstracts of Reviews of Effects (DARE), of Systematic Reviews (CDSR), and Health Technology Assessment (HTA) (n=20)

Search in: Cochrane Reviews (Reviews only), Other Reviews, Technology Assessments and Economic Evaluations

#1 AND #2

#1: policy:ti,ab,kw or regulation:ti,ab,kw or law:ti,ab,kw or legislation:ti,ab,kw Publication Year from 2004 to 2015, in Other Reviews and Technology Assessments (Word variations have been searched)

#2: obesity:ti,ab,kw or overweight:ti,ab,kw or nutrition:ti,ab,kw or calorie:ti,ab,kw (Word variations have been searched)

#### 7. **DoPHER** (n=149)

Combined Freetext (All but Authors) search for (A AND B) NOT C

A: "policy" OR "policies" OR "regulation" OR "regulations" OR "regulatory" OR "intervention" OR "interventions" OR "laws" OR "legislative" OR "legislative" OR "legal"

B: "obesity" OR "obese" OR "overweight" OR "weight" OR "bodyweight"

C: "activity" OR "exercise" OR "RCT" OR "randomized" OR "randomised"

### 8. Google Scholar (n=100)

First 20 pages of results for the following searches:

a) With all of the words: tax; with at least one of the words: "food junk", food, beverages, "sugar-sweetened beverage", soda, fat, sugar; anywhere in the article; 2004-2015

- b) With all of the words: healthy; with at least one of the words: store, bodega, retail, cart, vendor anywhere in the article; 2004-2015
- c) With all of the words: labling; tax; with at least one of the words: calorie, menu, interpretative, "front of pack" anywhere in the article; 2004-2015
- d) With all of the words: fruit, vegetable; with at least one of the words: voucher, subsidy, discount, incentive anywhere in the article; without the words: WIC; 2004-2015
- e) With all of the words: healthy; with at least one of the words: procurement, "food standards"; 2004-2015

## 9. **Grey Literature Report in Public Health** (n=288)

Full-text search, publication year 2004-2015: obesity AND policy

## 10. **MedNar** (n=1,311 non-patent top results from 166,096 found in all sources)

Full Record: (((obesity OR overweight) AND ((policy OR policies OR legislation OR law OR laws OR legislation OR regulation OR regulations OR regulatory) AND (effectiveness OR impact OR effect OR effects OR evaluation))) NOT (exercise OR activity OR RCT OR clinical OR randomized OR randomized))

## 11. NICE Evidence Search (n=390)

Full text search: obesity and policy and nutrition and effectiveness; types of information: evidence summaries, policy and service development

## 12. **OpenGrey.eu** (n=91)

2004-2015 (policy OR policies OR law OR legislation OR legislative) AND (obesity OR overweight Or nutrition OR calorie OR food OR drinks OR food OR foods)

## 13. WHOLIS (n=427)

Advanced search, word or phrase (obesity Or overweight Or nutrition Or weight Or bodyweight), 2004-2015

## 14. US National Technical Information Service Public NTRL database (n=0)

The website hosting this database continued to be unreachable during the research period and was therefore not included despite the original plan specified in the review protocol.

# 9.3 Appendix 3 - Supplemental materials chapter 6

The following documents are associated with the article entitled "Targeting population nutrition through municipal health and food policy: Implications of New York City's experiences in regulatory obesity prevention" (chapter 6, pp. 88-99).

### Online Appendix: additional methodological information

The following two tables provide additional details regarding the results of the document review and the interview coding process.

#### 1. Overview of results included in the document review

This table lists by category the results from the document search. The documents included here are not identical to the reference list of the main article: not every document was useful to the analysis and additional sources were used in the research. As explained in the main text, we conducted systematic searches of PubMed, the New York Academy of Medicine's grey literature repository GreyLit, and the New York City Health Department (DOHMH) website for research articles, reports, and policy documents. Relevance was established based on title and abstract, and occasional full-text screening where no abstract was provided. To meet inclusion criteria, documents had to pertain to NYC-specific regulatory obesity prevention efforts and, except for policy documents, contain an analytical component. Hence, news-style articles and editorials, opinion pieces, and articles focusing purely on methodological approaches were excluded.

	Policy documents	Commentary/ procedural research	Evaluatory research
General chronic disease prevention policy	Summers C, Cohen L, Havusha, A, Sliger F, Farley T. Take Care New York 2012: a policy for a healthier New York City. <i>City Health Information (CHI)</i> . 2009; 28(suppl 5).  New York City Department of Health and Mental Hygiene. <i>Take Care New York</i> 2004. New York City, NY: New York City	Alcorn T. Redefining public health in New York City. <i>Lancet</i> . 2012;379(9831):2037-8.  Borden DP. Innovative policies under Bloomberg's 'New' Public Health. <i>Hastings Cent Rep</i> . 2014;44(1):6-7.  Colgrove, J. <i>Endemic City. The Politics of Public Health in New York</i> . New York, NY:	Centers for Disease Control and Prevention. Obesity in K-8 students-New York City, 2006-07 to 2010-11 school years. MMWR Morb Mortal Wkly Rep. 2011;60(49):1673- 1678.* Centers for Disease Control and Prevention. Obesity prevalence among low-income, preschool-aged children- New York City and
	Department of Health and Mental Hygiene; 2004. http://webcache. googleusercontent.com/search?q=cache:BG axH5pLetQJ:www.nyc.gov/html/doh/downl oads/pdf/tcny/tcny-policy.pdf. Acessed December 2, 2014.  New York City Department of Health and Mental Hygiene. Preventing non- communicable diseases and injuries: innovative solutions from New York City. New York City, NY: New York City	Russell Sage Foundation; 2011.  Dowell D, Farley TA. Prevention of non-communicable diseases in New York City.  Lancet. 2012;380(9855):1787-9.  Farley TA. The role of government in preventing excess calorie consumption: the example of New York City. JAMA. 2012;308(11):1093-4.  Farley TA, Dowell D. Preventing childhood obesity: what are we doing right? Am J Public	Los Angeles County, 2003-2011. MMWR Morb Mortal Wkly Rep. 2013;62(2):17-22.*  Day SE, Konty KJ, Leventer-Roberts M, Nonas C, Harris TG. Severe obesity among children in New York City public elementary and middle schools, school years 2006-07 through 2010-11. Prev Chronic Dis. 2014;11:E118. *  Li W, Maduro G, Begier EM. Increased Life Expectancy in New York City: What

Department of Health and Mental Hygiene; 2011. <a href="http://www.nyc.gov/html/doh/html/ncd/nyc-solutions.shtml">http://www.nyc.gov/html/doh/html/ncd/nyc-solutions.shtml</a> . Accessed September 16, 2014.	Health. 2014;104(9):1579-83.  Freudenberg N, Libman K, O'Keefe E. A tale of two obesCities: the role of municipal governance in reducing childhood obesity in New York City and London. J Urban Health. 2010;87(5):755-70.	Accounts for the Gains? New York City Department of Health and Mental Hygiene: Epi Research Report, 2013; 1-12.
	Freudenberg N, McDonough J, Tsui E. Can a food justice movement improve nutrition and health? A case study of the emerging food movement in New York City. <i>J Urban Health</i> . 2011;88(4):623-36.	
	Frieden TR. Take Care New York: a focused health policy. <i>J Urban Health</i> . 2004;81(3):314-6.	
	Frieden TR. Asleep at the Switch: Local Public Health and Chronic Disease. <i>Am J Public Health</i> . 2004; 94(12): 2059–2061.	
	Frieden TR, Bassett MT, Thorpe LE, Farley TA. Public health in New York City, 2002-2007: confronting epidemics of the modern era. <i>Int J Epidemiol</i> . 2008;37(5):966-77.	
	Gostin LO. Bloomberg's Health Legacy: urban innovator or meddling nanny? <i>Hastings Cent Rep.</i> 2013;43(5):19-25.	
	Jacobson PD, Parmet WE. Defending public health regulations: the message is the medium. <i>Hastings Cent Rep.</i> 2014;44(1):4-6.	
	Laugesen MJ, Isett KR. Evidence Use in New York City Public Health Policymaking. Frontiers in Public Health Services and Systems Research 2013;2(7).	
	Pomeranz JL. The Unique Authority of State	

	Obesity 97.  Magnus	al Health Departments to Address . Am J Public Health. 2011;101:1192- son R. Bloomberg, Hitchens, and the an critique. Hastings Cent Rep. (1):3-4.
	health-e	MM, Studdert DM. Making the case for nhancing laws after Bloomberg. s Cent Rep. 2014;44(1):8.
	need fo	EW. The Affordable Care Act and the public health leadership. <i>Hastings</i> p. 2014;44(1):7.
Problem definition	Comparenviron	T, Dannefer R, Sacks R, Van Wye G. ing sugary drinks in the food retail ment in six NYC neighborhoods. <i>J</i> nity Health. 2014;39(2):327-35.
	Bedell .  Nutritic  York, N	P, Hadi E, Cespedes A, Grimshaw V,  . Farmers' Markets- Bringing Fresh, us Food to the South Bronx. New Y: New York City Department of and Mental Hygiene, 2008.
	Do We the Bro Public York C Hygien doh/dov	P, Noyes P. Sugary Drinks: How Much Consume? A Neighborhood Report by ax, Brooklyn and Harlem District Health Offices. New York, NY. New ty Department of Health andMental e, 2011. http://www.nyc.gov/html/ vnloads/pdf/dpho/dpho-sugary-drinks- df. Accessed September 9, 2014.
	Weiss G GS, Ne	MD, Schwartz-Soicher O, Jack D, CC, Richards CA, Quinn JW, Lovasi ckerman KM, Rundle AG More rhood retail associated with lower

obesity among New York City public high school students. *Health Place*. 2013;23:104-10.

Basch CH, Ethan D, Rajan S. Price, promotion, and availability of nutrition information: a descriptive study of a popular fast food chain in New York City. *Glob J Health Sci.* 2013 Aug 25;5(6):73-80.

Black JL, Macinko J. The changing distribution and determinants of obesity in the neighborhoods of New York City, 2003-2007. *Am J Epidemiol.* 2010;171(7):765-75.

Black JL, Macinko J, Dixon LB, Fryer GE Jr. Neighborhoods and obesity in New York City. *Health Place*. 2010;16(3):489-99.

Dannefer R, Adjoian T, Van Wye G. Retail Audit of Sugary Drinks in Six New York City Neighborhoods. *EPI Data Brief*. 2012;17.

Day S, Lim S, Olson C, Konty K, Kerker B. Child Obesity Risk: Nutrition & Physical Activity. *NYC Vital Signs*. 2011;10(4):1-4.

Dumanovsky T, Nonas CA, Huang CY, Silver LD, Bassett MT. What people buy from fast-food restaurants: caloric content and menu item selection, New York City 2007. Obesity (Silver Spring). 2009;17(7):1369-74.

Elfassy T, Yi S, Nonas C. Perceived Access to Fresh Fruits and Vegetables in New York City. *EPI Data Brief.* 2014;49.

Erinosho T, Dixon LB, Young C, Brotman LM, Hayman LL. Nutrition practices and children's dietary intakes at 40 child-care centers in New York City. *J Am Diet Assoc*.

2011;111(9):1391-7.

Galvez MP, Hong L, Choi E, Liao L, Godbold
J, Brenner B. Childhood obesity and
neighborhood food-store availability in an

inner-city community. *Acad Pediatr*. 2009;9(5):339-43.

Gordon C, Purciel-Hill M, Ghai NR, Kaufman L, Graham R, Van Wye G. Measuring food deserts in New York City's low-income neighborhoods. *Health Place*. 2011;17(2):696-700.

Gupta L, Hinterland K, Myers C, Kerker B. Overweight and Obesity among Public High School Students in New York City. *NYC Vital Signs*. 2012;11(2):1-4.

Huang C, Dumanovsky T, Silver LD, Nonas C, Bassett MT. Calories from beverages purchased at 2 major coffee chains in New York City, 2007. *Prev Chronic Dis*. 2009;6(4):A118.

Janevic T, Borrell LN, Savitz DA, Herring AH, Rundle A. Neighbourhood food environment and gestational diabetes in New York City. *Paediatr Perinat Epidemiol*. 2010;24(3):249-54.

Jordan HT, Tabaei BP, Nash D, Angell SY, Chamany S, Kerker B. Metabolic syndrome among adults in New York City, 2004 New York City Health and Nutrition Examination Survey. *Prev Chronic Dis.* 2012;9:E04.

Karnik A, Foster BA, Mayer V, Pratomo V, McKee D, Maher S, Campos G, Anderson M. Food insecurity and obesity in New York City

primary care clinics. *Med Care*. 2011;49(7):658-61.

Kwate NO, Yau CY, Loh JM, Williams D. Inequality in obesigenic environments: fast food density in New York City. *Health Place*. 2009;15(1):364-73.

Neckerman KM, Bader MD, Richards CA, Purciel M, Quinn JW, Thomas JS, Warbelow C, Weiss CC, Lovasi GS, Rundle A. Disparities in the food environments of New York City public schools. *Am J Prev Med*. 2010;39(3):195-202.

Nelson JA, Chiasson MA, Ford V. Childhood overweight in a New York City WIC population. *Am J Public Health*. 2004;94(3):458-62.

New York City Department of Health and Mental Hygiene. *One in 6 New York City adults is obese*. New York, NY: New York City Department of Health and Mental Hygiene; 2003. <a href="http://www.nyc.gov/html/doh/downloads/pdf/survey/survey-2003obesity.pdf">http://www.nyc.gov/html/doh/downloads/pdf/survey/survey-2003obesity.pdf</a>. Accessed September 9, 2014.

New York City Department of Health and Mental Hygiene. Consumption of Sugar Sweetened Beverages (SSBs) in New York City. *EPI Data Brief*. 2011;4.

New York City Department of Health and Mental Hygiene. Describing the Food Environment in the South Bronx Neighborhood of Crotona-Tremont. *EPI Data Brief.* 2014;44.

Park Y, Quinn J, Florez K, Jacobson J,

Neckerman K, Rundle A. Hispanic immigrant women's perspective on healthy foods and the New York City retail food environment: A mixed-method study. *Soc Sci Med.* 2011;73(1):13-21.

Rehm CD, Matte TD, Van Wye G, Young C, Frieden TR. Demographic and behavioral factors associated with daily sugar-sweetened soda consumption in New York City adults. *J Urban Health*. 2008;85(3):375-85.

Sealy YM. Parents' perceptions of food availability: implications for childhood obesity. *Soc Work Health Care*. 2010;49(6):565-80.

Stark JH, Neckerman K, Lovasi GS, Konty K, Quinn J, Arno P, Viola D, Harris TG, Weiss CC, Bader MD, Rundle A. Neighbourhood food environments and body mass index among New York City adults. *J Epidemiol Community Health*. 2013;67(9):736-42.

Thorpe LE, List DG, Marx T, May L, Helgerson SD, Frieden TR. Childhood obesity in New York City elementary school students. *Am J Public Health*. 2004;94(9):1496-500.

Viola D, Arno PS, Maroko AR, Schechter CB, Sohler N, Rundle A, Neckerman KM, Maantay J. Overweight and obesity: can we reconcile evidence about supermarkets and fast food retailers for public health policy? *J Public Health Policy*. 2013;34(3):424-38.

Van Wye G, Kerker BD, Matte T, Chamany S, Eisenhower D, Frieden TR, Thorpe L. Obesity and diabetes in New York City, 2002 and

		2004. <i>Prev Chronic Dis.</i> 2008;5(2):A48.  Wallach JB, Rey MJ. A socioeconomic analysis of obesity and diabetes in New York City. <i>Prev Chronic Dis.</i> 2009;6(3):A108.  Yaemsiri S, Olson EC, He K, Kerker BD. Food concern and its associations with obesity and diabetes among lower-income New Yorkers. <i>Public Health Nutr.</i> 2012;15(1):39-47.	
Calorie posting	New York City Department of Health and Mental Hygiene, Board of Health. Notice of adoption of an amendment (§81.50) to Article 81 of the New York City Health Code. 2006.  http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50.pdf. Accessed August 27, 2014.  New York City Department of Health and Mental Hygiene, Board of Health. Notice of adoption of a resolution to repeal and reenact §81.50 of the New York City Health Code. 2008.  www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-50-0108.pdf. Accessed August 27, 2014.	Bernell B. The history and impact of the New York City menu labeling law. Food Drug Law J. 2010;65(4):839-72.  Farley TA, Caffarelli A, Bassett MT, Silver L, Frieden TR. New York City's fight over calorie labeling. Health Aff (Millwood). 2009;28(6):w1098-109.	Bassett MT, Dumanovsky T, Huang C, Silver LD, Young C, Nonas C, Matte TD, Chideya S, Frieden TR. Purchasing behavior and calorie information at fast-food chains in New York City, 2007. Am J Public Health. 2008;98(8):1457-9.*  Cohn EG, Larson EL, Araujo C, Sawyer V, Williams O. Calorie postings in chain restaurants in a low-income urban neighborhood: measuring practical utility and policy compliance. J Urban Health. 2012;89(4):587-97.  Downs JS, Wisdom J, Wansink B, Loewenstein G. Supplementing menu labeling with calorie recommendations to test for facilitation effects. Am J Public Health. 2013;103(9):1604-9.*  Dumanovsky T, Huang CY, Bassett MT, Silver LD. Consumer awareness of fast-food calorie information in New York City after implementation of a menu labeling regulation. Am J Public Health. 2010;100(12):2520-5.  Dumanovsky T, Huang CY, Nonas CA,

Trans-fat restriction	New York City Department of Health and Mental Hygiene, Board of Health. Notice of	Angell SY, Silver LD, Goldstein GP et al. Cholesterol control beyond the clinic: New	Angell SY, Cobb LK, Curtis CJ, Konty KJ, Silver LD. Change in trans fatty acid content
			Vadiveloo MK, Dixon LB, Elbel B. Consumer purchasing patterns in response to calorie labeling legislation in New York City. <i>Int J Behav Nutr Phys Act</i> . 2011;8:51.
			Schindler J, Kiszko K, Abrams C, Islam N, Elbel B. Environmental and individual factors affecting menu labeling utilization: a qualitative research study. J <i>Acad Nutr Diet</i> . 2013;113(5):667-72.
			Gordon C, Hayes R. Counting calories: resident perspectives on calorie labeling in New York City. <i>J Nutr Educ Behav</i> . 2012;44(5):454-8.
			Elbel B, Gyamfi J, Kersh R. Child and adolescent fast-food choice and the influence of calorie labeling: a natural experiment. Int J <i>Obes (Lond)</i> . 2011;35(4):493-500.
			Elbel B. Consumer estimation of recommended and actual calories at fast food restaurants. <i>Obesity (Silver Spring)</i> . 2011;19(10):1971-8.
			Elbel B, Kersh R, Brescoll VL, Dixon LB. Calorie labeling and food choices: a first look at the effects on low-income people in New York City. <i>Health Aff (Millwood)</i> . 2009;28(6):w1110-21.
			Matte TD, Bassett MT, Silver LD. Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labelling: cross sectional customer surveys. <i>BMJ</i> . 2011;343:d4464.

	Adoption of an Amendment (§81.08) to Article 81 of the New York City Health Code. 2006. <a href="www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf">www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf</a> . Accessed August 27, 2014.	York City's trans fat restriction. <i>Ann Intern Med</i> . 2009;151(2):129-34.  Lichtenstein AH. New York City trans fat ban: improving the default option when purchasing foods prepared outside of the home. <i>Ann Intern Med</i> . 2012;17;157(2):144-5.  Mello MM. New York City's war on fat. <i>N Engl J Med</i> . 2009;360(19):2015-20.  Tan AS. A case study of the New York City trans-fat story for international application. <i>J Public Health Policy</i> . 2009;30(1):3-16.	of fast-food purchases associated with New York City's restaurant regulation: a pre-post study. <i>Ann Intern Med.</i> 2012;157(2):81-6.
Green Carts			Fuchs ER, Holloway SM, Bayer K, Feathers A. Innovative Partnership for Public Health: An Evaluation of the New York City Green Cart Initiative to Expand Access to Healthy Produce in Low-Income Neighborhoods. Columbia University School of International and Public Affairs Case Study Series in Global Public Policy: 2014;2(22014). https://sipa.columbia.edu/system/files/Green Carts Final June16.pdf. Accessed November 2, 2014.
			Kerker P, Farley S, Johns M, Leggat P, Nonas C, Parton H. Green Cart Evaluation, 2008-2011. <i>EPI Data Brief</i> . 2014;48.  Li KY, Cromley EK, Fox AM, Horowitz CR. Evaluation of the placement of mobile fruit and vegetable vendors to alleviate food deserts in New York City. <i>Prev Chronic Dis</i> . 2014;11:E158.
			Lucan SC, Maroko A, Shanker R, Jordan WB. Green Carts (mobile produce vendors) in the Bronxoptimally positioned to meet

Schools/ Childcare	New York City Department of Health and Mental Hygiene, Board of Health. Notice of Adoption of Amendments to Article 47 of the New York City Health Code. 2006. http://www.nyc.gov/html/doh/down loads/pdf/public/notice-hc-20060615-art47.pdf. Accessed August 27, 2014.  New York City Department of Health and Mental Hygiene, Board of Health. Notice of Adoption of Amendments of Nutritional Requirements for Children's Camps (Health Code Article 48). 2012. http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article48.pdf. Accessed August 27, 2014.	Golub M, Charlop M, Groisman-Perelstein AE, Ruddock C, Calman N. Got low-fat milk? How a community-based coalition changed school milk policy in New York City. Fam Community Health. 2011;34 Suppl 1:S44-53.  Nonas C, Silver LD, Kettel Khan L, Leviton L. Rationale for New York City's Regulations on Nutrition, Physical Activity, and Screen Time in Early Child Care Centers. Prev Chronic Dis. 2014;11:130435  Perlman SE, Nonas C, Lindstrom LL, Choe-Castillo J, McKie H, Alberti PM. A menu for health: changes to New York City school food, 2001 to 2011. J Sch Health. 2012;82(10):484-91.	neighborhood fruit-and-vegetable needs? <i>J Urban Health</i> . 2011;88(5):977-81.  Centers for Disease Control and Prevention. Effects of switching from whole to low-fat/fat-free milk in public schools - New York city, 2004-2009. <i>MMWR Morb Mortal Wkly Rep</i> . 2010;59(3):70-3.  Nonas C, Silver LD, Kettel Khan L. Insights and Implications for Health Departments From the Evaluation of New York City's Regulations on Nutrition, Physical Activity, and Screen Time in Child Care Centers. <i>Prev Chronic Dis</i> . 2014;11:130429.  Sekhobo JP, Edmunds LS, Dalenius K, Jernigan J, Davis CF, Giddings M, Lesesne C, Kettel Khan L. Neighborhood disparities in prevalence of childhood obesity among low-income children before and after implementation of New York City child care regulations. <i>Prev Chronic Dis</i> . 2014;11:E181.  Van Wye G, Seoh H, Adjoian T, Dowell D. Evaluation of the New York City breakfast in
			the classroom program. <i>Am J Public Health</i> . 2013;103(10):e59-64.
City Food Standards	City of New York, Office of the Mayor.  Executive Order 122: Food Policy Coordinator for the City of New York and City Agency Food Standards. 2008.  http://www.nyc.gov/html/doh/downloads/p df/cardio/food-executive-order-122.pdf. Accessed August 27, 2014.	Lederer A, Curtis CJ, Silver LD, Angell SY. Toward a healthier city: nutrition standards for New York City government. <i>Am J Prev Med</i> . 2014 Apr;46(4):423-8.	
	City of New York. New York City Food Standards: Meals/Snacks Purchased and		

	Served. Posted August 1, 2013.  www.nyc.gov/html/doh/downloads/pdf/car dio/cardio-meals-snacks-standards.pdf. Accessed September 9, 2014.  City of New York. New York City Food Standards: Food Vending Machines Implementation Guide. Posted August 1, 2013. http://www.nyc.gov/html/doh /downloads/pdf/cardio/food-standards- guide.pdf. Accessed September 9, 2014.		
Food access			Baronberg S, Dunn L, Nonas C, Dannefer R, Sacks R. The impact of New York City's Health Bucks Program on electronic benefit transfer spending at farmers markets, 2006-2009. <i>Prev Chronic Dis.</i> 2013;10:E163.  Dannefer R, Williams DA, Baronberg S, Silver L. Healthy bodegas: increasing and promoting healthy foods at corner stores in New York City. <i>Am J Public Health</i> . 2012;102(10):e27-31.
			New York City Department of Health and Mental Hygiene. New York City Healthy Bodegas Initiative: 2010 Report. New York, NY: NYC Department of Health and Mental Hygiene; 2010. <a href="https://www.nyc.gov/html/doh/downloads/pdf/cdp/healthy-bodegas-rpt2010.pdf">www.nyc.gov/html/doh/downloads/pdf/cdp/healthy-bodegas-rpt2010.pdf</a> . Accessed September 9, 2014.
SNAP	United States Department of Agriculture. Letter to the New York State Office of Temporary and Disability Assistance. Food Politics website. <a href="http://www.foodpolitics.com/wp-content/uploads/SNAP-Waiver-Request-Decision.pdf">http://www.foodpolitics.com/wp-content/uploads/SNAP-Waiver-Request-Decision.pdf</a> . Dated August 19, 2011. Accessed January 21, 2015.	Brownell KD, Ludwig DS. The Supplemental Nutrition Assistance Program, soda, and USDA policy: who benefits? <i>JAMA</i> . 2011;306(12):1370-1.  Farley TA, Van Wye G. Reversing the obesity epidemic: the importance of policy and policy research. <i>Am J Prev Med</i> . 2012;43(3 Suppl	Payne GH, Wethington H, Olsho L, Jernigan J, Farris R, Walker DK. Implementing a farmers' market incentive program: perspectives on the New York City Health Bucks Program. <i>Prev Chronic Dis.</i> 2013;10:E145.

Soda tax		2):S93-4.  Barnhill A, King KF.Evaluating equity critiques in food policy: the case of sugar-sweetened beverages. <i>J Law Med Ethics</i> . 2013 Spring;41(1):301-9.	Brownell KD, Frieden TR. Ounces of prevention- the public policy case for taxes on sugared beverages. <i>N Engl J Med</i> . 2009;360(18):1805-8.**
Soda portion size cap	New York City Department of Health and Mental Hygiene, Board of Health. Proposed resolution to amend Serving Sizes in Food Service Establishments (Health Code Article 81). 2012.  www.nyc.gov/html/doh/downloads/pdf/notice/2012/amend-food-establishments.pdf. Accessed August 27, 2014.  New York City Department of Health and Mental Hygiene, Board of Health. Notice of Adoption of Amendment of Serving Sizes in Food Service Establishments (Health Code Article 81). 2012.  http://www.nyc.gov/html/doh/downloads/pdf/notice/2012/notice-adoption-amend-article81.pdf. Accessed August 27, 2014.  New York City Department of Health and Mental Hygiene. Summary and Response to Public Hearing and Comments Received Regarding Amendment of Article 81 of the New York City Heath Code to Establish Maximum Sizes for Beverages Offered and Sold in Food Service Establishments. 2012. http://www.nyc.	Fairchild AL. Half empty or half full? New York's soda rule in historical perspective. <i>N Engl J Med</i> . 2013;368(19):1765-7.  Min HM. Large-sized soda ban as an alternative to soda tax. <i>Cornell J Law Public Policy</i> . 2013;23(1):187-232.  Shelley D, Ogedegbe G, Elbel B. Same strategy different industry: corporate influence on public policy. <i>Am J Public Health</i> . 2014;104(4):e9-e11.	Elbel B, Cantor J, Mijanovich T. Potential effect of the New York City policy regarding sugared beverages. <i>N Engl J Med</i> . 2012;367(7):680-1.**

gov/html/doh/downloads/pdf/boh/article8	<u>L</u>	
response-to-comments.pdfAccessed		
October 23, 2014.		

<sup>\*</sup>Also a problem statement, but the evaluatory component represents the novel aspect of the research. \*\* Prospective evaluation/modeling

### 2. Main themes and codes

This table provides an overview of the final list of codes and overarching themes that emerged from the thematic analysis of the document review and interview data. As outlined in the main text, data analysis primarily followed an inductive process, with only a small number of codes pre-specified based on the conceptual frameworks proposed by John W. Kingdon and the International Obesity Task Force.

Themes and dependent codes	Sources	
Policy rationales	Equivalent to Kingdon's problem stream (theoretical framework)	
Problem severity	Kingdon's streams framework	
Government responsibility	Kingdon's streams framework	
Availability of solutions	Kingdon's streams framework	
Precedent in tobacco prevention	International Obesity Task Force (IOTF) decision-making framework	
Feasibility	Document review/interviews	
Isolation of substance/product	Document review/interviews	
Economic impact/business response	Document review/interviews	
Rule-making authority	Document review/interviews	
Policy design	Equivalent to Kingdon's solution stream (theoretical framework)	
Evidence	Adapted from International Obesity Task Force (IOTF) decision-making framework	
Research evidence	International Obesity Task Force (IOTF) decision-making framework	
Monitoring and surveillance data	International Obesity Task Force (IOTF) decision-making framework	
Observational and experimental studies	Adapted from International Obesity Task Force (IOTF) decision-making framework	
Modelling/theory and program logic	Adapted from International Obesity Task Force (IOTF) decision-making framework	
Evaluation of precedents	Adapted from International Obesity Task Force (IOTF) decision-making framework	

Parallel evidence (e.g. tobacco control)	Adapted from International Obesity Task Force (IOTF) decision-making framework
Expert opinion	Adapted from International Obesity Task Force (IOTF) decision-making framework
Policy tools	Document review/interviews
Internal rules	Document review/interviews
Regulation	Document review/interviews
Legislation	Document review/interviews
Programming	Document review/interviews
Political advocacy	Document review/interviews
Policy targets	Document review/interviews
Trans fats	Document review/interviews
Sugar-sweetened beverages (soda)	Document review/interviews
Institutional nutrition standards	Document review/interviews
Consumer information	Document review/interviews
Nutrition assistance rules	Document review/interviews
Food access	Document review/interviews
Policy settings	Document review/interviews
Schools/Childcare	Document review/interviews
City procurement	Document review/interviews
"Food Service Establishments"	Document review/interviews
Convenience stores /bodegas	Document review/interviews
Chain restaurants	Document review/interviews
Food carts	Document review/interviews
Greenmarkets	Document review/interviews
Policy aims	Document review/interviews
Providing public education	Document review/interviews
Force industry transparency	Interviews
Improving obesity prevalence	Document review/interviews

Testing effectiveness/generating evidence	Interviews
Policy outcomes	Document review/interviews
Legal challenges	Document review/interviews
Evaluation	Document review/interviews
Enforcement	Document review/interviews
Consumption changes	Document review/interviews
Health impact	Document review/interviews
Public awareness and health education	Document review/interviews
Changing social norms	Interviews
Setting precedents	Interviews
Actors and stakeholders	Document review/interviews
Industry opposition	Document review/interviews
Civil society opposition	Document review/interviews
Institutional seclusion	Interviews
Community outreach	Interviews
Jurisdictional authority	Document review/interviews
Relationship with City Council	Document review/interviews
Relationship with state level	Document review/interviews
Relationship with federal level	Document review/interviews
Unique features	Document review/interviews
Executive leadership	Document review/interviews
Institutional expertise	Interviews
Population diversity	Document review/interviews
Size of jurisdiction	Document review/interviews
Media landscape	Interviews
Public health agenda	Document review/interviews
Food access	Document review/interviews

Punitive/unequitable	Document review/interviews
Recommendations	Interviews
Innovate at local level/redefine mayoral purview	Interviews
Harness authority of executive and legislature	Interviews
Community engagement, regard for lay opinions	Interviews
Leverage opportunities for public education	Interviews
Enlist experts and multipliers	Interviews



RESEARCH BRANCH OFFICE OF RESEARCH ETHICS, COMPLIANCE AND INTEGRITY

LEVEL 7, 115 GRENFELL STREET THE UNIVERSITY OF ADELAIDE SA 5005 AUSTRALIA

TELEPHONE +61 8 8313 5137 EMAIL

FACSIMILE +61 8 8313 3700 hrec@adelaide.edu.au

CRICOS Provider Number 00123M

26 June 2014

Dr J Street

School: School of Population Health

Dear Dr Street

ETHICS APPROVAL No:

H-2014-122

PROJECT TITLE:

International experiences in regulatory approaches to obesity

prevention: targeting population level nutritional intake

The ethics application for the above project has been reviewed by the Low Risk Human Research Ethics Review Group (Faculty of Health Sciences) and is deemed to meet the requirements of the National Statement on Ethical Conduct in Human Research (2007) involving no more than low risk for research participants. You are authorised to commence your research on 26 Jun 2014.

Ethics approval is granted for three years and is subject to satisfactory annual reporting. The form titled *Project* Status Report is to be used when reporting annual progress and project completion and can be downloaded at http://www.adelaide.edu.au/ethics/human/guidelines/reporting. Prior to expiry, ethics approval may be extended for a further period.

Participants in the study are to be given a copy of the Information Sheet and the signed Consent Form to retain. It is also a condition of approval that you immediately report anything which might warrant review of ethical approval including:

- serious or unexpected adverse effects on participants,
- previously unforeseen events which might affect continued ethical acceptability of the project,
- proposed changes to the protocol; and
- the project is discontinued before the expected date of completion.

Please refer to the following ethics approval document for any additional conditions that may apply to this project.

Yours sincerely,

Sabine Schreiber Secretary, Human Research Ethics Committee Office of Research Ethics, Compliance and Integrity



RESEARCH BRANCH

OFFICE OF RESEARCH ETHICS, COMPLIANCE AND INTEGRITY

LEVEL 7, 115 GRENFELL STREET THE UNIVERSITY OF ADELAIDE SA 5005 AUSTRALIA

TELEPHONE +61 8 8313 5137 **EMAIL** 

FACSIMILE +61 8 8313 3700 hrec@adelaide.edu.au

CRICOS Provider Number 00123M

Applicant:

**Dr J Street** 

School:

**School of Population Health** 

**Project Title:** 

International experiences in regulatory approaches to

obesity prevention: targeting population level

nutritional intake

The University of Adelaide Human Research Ethics Committee Low Risk Human Research Ethics Review Group (Faculty of Health Sciences)

**ETHICS APPROVAL No:** 

H-2014-122

App. No.: 0000019003

APPROVED for the period:

26 Jun 2014 to 30 Jun 2017

It is noted that this project will be conducted by Ms Jana Sisnowski PhD candidate.

Sabine Schreiber Secretary, Human Research Ethics Committee Office of Research Ethics, Compliance and Integrity



# Human Research Ethics Committee (HREC) 2014 Application for ethics approval

Office use only	
Received:	
RM No. & Date Record Created	
Ethics Approval No:	

### **LEVEL OF ETHICAL REVIEW:**

Indicat	e the <u>level of ethical review</u> that is being sought for this application:
	Full HREC review (applies to all research involving more than "low risk research" as defined in the National Statement on Ethical Conduct in Human Research)
$\boxtimes$	Low risk review (applies to "low risk research" as defined in the National Statement on Ethical Conduct in Human Research (2007). Research timetables should allow for the possibility that a project submitted as a low risk application may be deemed to involve more than low risk, or to raise other issues, therefore requiring full review. Researchers may be requested to provide additional information.

# SECTION 1: APPLICANT, PROJECT SUMMARY AND OTHER RESEARCHERS' DETAILS

If the project is to be undertaken by a research student the student's primary or other supervisor at the University of Adelaide is the 'applicant'.

Applicant's name, title and position:	Dr. Jackie Street		
Phone:	+61 8 8313 6498	EMPLID:	a1094732
School or Department:	School of Population Health	Campus and Institution address:	University of Adelaide School of Population Health 178 North Terrace Mail Drop DX 650 205 SA 5005 Australia
Email:	jackie.street@adelaide.edu.au		
Qualifications and research experience relevant to the project	Dr Jackie Street, PhD, BSc (Hons), Grad. Dip. Primary Health Care, is an internationally recognized expert in community engagement in health technology assessment and an experienced qualitative researcher. Over the past six years she has personally conducted more than 36 interviews, 6 focus groups and three deliberative forums and overseen the conduct of many other qualitative projects. Amongst other things, she was a program manager on the ARC Linkage qualitative research project, FluViews, a Chief Investigator on the Siren project (a qualitative and quantitative study on community responses to public health interventions during the pandemic), worked on the ASTUTE project (an NHMRC funded project looking at policy-decision for disinvestment), has supervised honours and masters students engaged in qualitative research and is a consultant on community engagement for health technology assessment to Adelaide Health Technology Assessment (AHTA). She has published in peer reviewed journals and presented at International conferences, on methods for collecting community and stakeholder perspectives for health technology assessment and policy development.		

### Project title:

International experiences in regulatory approaches to obesity prevention: targeting population-level nutritional intake

**Proposed commencement date of activities that require human ethics approval**: Note: research must not commence without the prior written approval of the HREC as retrospective approval cannot be provided.

August 2014

### Estimated completion date of the project:

January 2015

Student Researcher(s):

Student's name, title:	Jana Sisnowski	Student ID:	a1639046
Program Level:	PhD	School or Department (if not same as Principal Researcher's)	Population Health
Email:	jana.sisnowski@adelaide. edu.au	Phone/Mobile:	+61 481 318 214
Qualifications and relevant research experience	Jana Sisnowski is a PhD student with previous degrees (BA, MA) in Political Science and International Affairs with a focus on health policy. As part of her PhD she is currently auditing a Qualitative Research Methods course intended to provide an overview of methods and issues in qualitative research. Having worked for the Council of the European Union and in public health advocacy for nonprofit organizations in the European Union and the United States, she has experience interacting with elected and non-elected officials of all levels a well as other stakeholders in the policy-making process. She will have supervision and guidance from her supervisor, Dr. Jackie Street, at all stages of the project.		

Other Researcher(s) (add extra rows to table as required):

Name(s), title(s) and position(s) (for all co-supervisors & researchers external to the University of Adelaide)	EMPLID(s) (if applicable)	Other researcher(s)' qualifications and experience relevant to the project

Source of any project funding:

Australian National Preventive Health Agency (ANPHA) grant #182BRA2011 University of Adelaide Graduate Centre Research Abroad Scholarship 2014

Location of the research. Include details of all sites where the project will be undertaken:

New York City and surrounding areas in New York State, USA Copenhagen, Denmark

Has or will this project be submitted for approval to other HRECs? Include the HREC's name and current status of the application (i.e. submitted, approved, deferred or rejected) and attach this documentation.

No.

### **SECTION 2: NATURE OF THE PROJECT**

Aims of the project: (discuss in lay terms; include the research hypothesis to be investigated, outline the values and benefits to participants)

This project is part of the study HealthyLaws- Public Perspectives in Public Health Law, funded by the Australian National Preventive Health Agency (ANPHA). The overarching aim is to examine the role and use of regulatory measures to address the high prevalence of obesity and overweight in Australia and other highly industrialized nations. Within this framework, this study component seeks to understand and assess the policy environment and context that have influenced the initiation, decision-making, and implementation processes in the jurisdictions of New York City and Denmark which have set international precedents by considering and

enacting far-reaching regulatory measures with varying degrees of success. To this end, in depth interviews with policy-makers and stakeholders engaged in the processes surrounding the consideration and/or adoption of such measures will be conducted with the intention to produce a detailed analysis of policy formulation, decision-making and implementation processes that have taken place. Results will highlight lessons learned and the potential application of these findings to other jurisdictions interested in exploring similar regulatory approaches.

Rationale of the project: (explain in plain language the research methodology and its appropriateness to achieving the aims. Provide evidence of an adequate sample size to establish a valid result)

Little has been published about how and why regulatory measures targeting the dietary risk factors for obesity have started to emerge in certain jurisdictions and what can be learned from the experiences of these trailblazers. In order to explore these questions, we will employ case study methodology. These methods are well suited to "retain the holistic and meaningful characteristics of real-life events" (Yin 2009, p. 4) while utilizing a range of evidence (Yin 2009), in this case, key informant interviews and a review of documentary evidence from case-specific research articles, relevant news media coverage and policy documents.

The two case studies will be conducted as separate, single case studies and will initially be analyzed as such. However, a subsequent cross-case analysis is anticipated.

Both the selection of New York City and Denmark as our case studies and the subsequent selection of interviewees follow a nonprobability, purposive sampling approach (Given 2008). New York City and Demark were selected in accordance with the idea of extreme case sampling (Given 2008) as both jurisdictions have been exceptional compared to fellow OECD countries in terms of the timing, content and reach of the regulatory measures considered and implemented. Data collection in the field will consist of interviews with 10-20 key informants at each of the two case study sites. Individuals will be selected based on their role as representatives of stakeholder organizations, not as private individuals, following the logic of stakeholder sampling (Given 2008). This approach is further elaborated in subsequent sections covering study plan and design and participant selection.

Internal validity is therefore constructed by identifying a maximally complete set of stakeholders relevant to each site. In the absence of probability sampling, external validity in case study research is achieved not through sample size and valid inferences about the underlying population, but thorough qualitative analysis leading to potentially generalizable theoretical propositions (Yin, 2009).

Data analysis will follow a qualitative, inductive research process through thematic analysis: the development of theoretical strands from the data will be based on the three stages of free line-by-line coding, organization of these codes into descriptive themes, and the subsequent development of analytical themes as described by Thomas and Harden (2008). This approach mirrors the coding process along a developmental path from open coding to selective coding detailed in greater depth by Liamputtong and Ezzy (2005). The extended stays at both sites will make possible concurrent initial coding of completed interviews to adjust the general direction of questioning if necessary as well as to inform specific questions in subsequent interviews.

**Background to the project:** (briefly discuss any previous research of relevance and cite no more than 4 key references, if applicable)

Overweight and obesity is a major preventable public health challenge in Australia that affects individuals, families, and the community at large. From a socioeconomic point of view, overweight, obesity and resulting ill health generate considerable costs that are borne at both individual and societal levels. Laws and regulations can be powerful tools for changing health behaviors and protecting vulnerable population groups but may also impact on business profits and viability and can limit individual freedoms.

The importance of the wider societal and economic environment in shaping nutrition at the population level implies a role for governments to intervene through laws and regulations aimed at creating a positive health impact (Mello et al. 2006). Possible regulatory interventions addressing the dietary causes of obesity have been extensively explored in experimental and modeling studies (e.g. Thow et al. 2010, Epstein et al. 2012, Eyles et al. 2012, Elbel et al. 2013).

However, the most prominent real life examples of current regulatory approaches have mostly been reported anecdotally in the academic literature (e.g. Mytton et al. 2012). Where large scale regulatory interventions have been analyzed, the focus has been on the short term effectiveness of single interventions such as menu labeling at local level (e.g. Bassett et. al 2008, Elbel et. al 2009, Dumanovsky at al. 2011) rather than on the processes and factors that shaped, enabled or precluded the development of multi-pronged regulatory obesity prevention regimes in the jurisdictions concerned.

We aim to address this research gap by providing a contextualized in depth analysis of policy development in two case studies, New York City and Denmark. It is our intention to generate insights into the substance and implications of these approaches as well as an assessment of the conditions that produced the specific policies in place and discarded or discontinued other options. Our findings, while specific to New York City and Demark, may inform political discussions pertaining to the feasibility and acceptability of different regulatory options, and guide future policy development in other jurisdictions.

Have there been any preliminary studies, if Yes, provide the project title and HREC approval number(s):

No.

Outline the study plan and design, giving a detailed description of all planned interactions between researchers and participants. Attach copies of surveys, interview or focus group schedules, questions, and topics to be covered. Outline details of interventions or drugs to be administered (complete the Drugs to be Administered Form at http://www.adelaide.edu.au/ethics/human/guidelines/applications/).

This project consists of two case studies set in New York City and Denmark. At each site, 10-20 key informants will be recruited to participate in semi-structured interviews. Field visits are scheduled for the second half of 2014; with 10 weeks (August 25<sup>th</sup> – October 31<sup>st</sup>, 2014) to be spent in New York City and surrounding regions and another up to ten weeks to be spent in Copenhagen, Denmark (November 3<sup>rd</sup>, 2014 – January 9<sup>th</sup>, 2015). An overview of interview topics is attached to this application (please see attachment #4). The interviews will ask about policy development and decision-making processes related to regulatory measures addressing dietrelated risk factors for obesity based on precedents set in the respective jurisdiction. More abstract inquiries intended to uncover possible lessons-learned and participants' views regarding their transferability will feature towards the end of the interviews.

If research is to be conducted with or about participants living outside Australia; outline any local legislation, regulations, permissions or customs that need to be addressed before the research can commence. Outline the steps taken to ensure that this has been adequately considered and addressed.

Attach authorizing correspondence, approval documentation to the application.

While the case study sites are located outside of Australia, the United States and Denmark are not fundamentally different from Australia in terms of general culture and politico-legal systems. No separate ethics application is required as all researchers involved in more than a consulting role are based at the University of Adelaide. Informal cooperation with local researchers in the United States and Denmark has been established to provide additional local guidance where needed. Once prospective interviewees have been approached and their willingness to participate has been established in principal, we will confirm with them whether overseas institutions such as the New York City and Denmark departments of health might possibly require separate institutional ethics approval.

### **SECTION 3: PARTICIPANTS AND RECRUITMENT**

Who will be the participants in this project. Participants also includes data about people or human tissue samples. Include the source and other variables of all participants.

Participants will be professionals involved in relevant rule making processes in their capacity as elected officials, government officials, and as representatives of interest groups.

What is the number of participants? Outline how this sample will allow the aims of the project to be achieved.

10-20 interviewees at each of the two sites.

Age range of participants?

Professionals, age 21+.

Outline the participant selection and exclusion criteria:

As outlined above, participant selection follows a nonprobability, purposive sampling approach. Rather than selecting participants from a defined study population, we established a list of relevant stakeholder categories based on generic as well obesity prevention-specific stakeholder groups identified in the literature. We matched site-specific organizations to this pre-established list and added stakeholders to each case study list by working backwards from the major regulatory measures enacted or considered and the associated expressions of opinion given in press releases, interviews or statements appearing in major newspapers, and official consultation processes.

How will initial contact be made? How and by whom will any personal information including names, and contact details (including email addresses) be accessed? Researchers must ensure that personal information is not accessed without the consent of the individual.

Initial contact will be established by e-mail based on information that is available in the public domain, including organizational charts and staff profiles, contact details on legislative or regulatory proposals and public notices or procedures. Once contact with an initial set of potential interviewees has been established, additional or more appropriate informants will be sought via referral.

What materials will be used to recruit participants? (attach advertisements, flyers, letters/emails of introduction, copy of Facebook event pages etc)

E-mails based on the Information Sheet will be send electronically to recruit participants and obtain preliminary consent (please see attachment #1).

Outline the specific tasks that participants will be asked to undertake including approximate time involved? (include these details on the Participant Information Sheet)

Participants will be asked to participate in a semi-structured interview of 30-60mins in duration. Additionally, they may be asked for help in identifying additional interviewees and relevant documentation through e-mail correspondence prior to the interview. In their own interest, they will be asked to review any draft publications including direct quotes to ensure that they are comfortable with potentially identifiable sections of the results.

If recruitment is to be conducted by a third party or another organisation, outline how this will be done?

NA

Describe any possible risks to the participant(s) when undertaking the research including emotional, social, legal or physical (in health research this would also take into consideration exposure to radiation e.g. X-rays, toxicity, etc.).

Considering that all participants are adults who are taking part in this project as part of their professional role and during their regular working hours, risks in relation to the proposed research are minimal. However, we recognize potential risks to confidentiality associated with our small sample size and, in particular, the risk that some of the participants may be identifiable due their public association with the regulatory measures in question. Participants will be assured that the information that they provide will be treated in strict confidence and, as far as possible, participants will not be individually identifiable in the resulting publications arising from this study. In reporting the findings, we will ensure that no information which could readily identify individuals such as gender, age and job description of participants will be provided.

We will, however, seek permission to identify the organization participants represent. If participants object, we will revert to a generic stakeholder category such as "government body", "interest group", "elected official".

Participants will be given the opportunity to discontinue participation at any time, to decline to answer any of the questions posed and to decline the inclusion of specific quotes taken from their transcripts in any publications arising from the study.

Participants will be informed of the above strategies in the information sheet as well as verbally immediately before the beginning of the interview.

### How will these risks be addressed?

As outlined above, all participants are free to withdraw from the research project at any time before, after, and during their interview. They will be at liberty to refuse to answer any questions during the interview. Participants will be informed about this through the consent form and information sheet which will be send by e-mail for information purposes before the interview and will be provided in hard copy format at the time of the interview. Additionally, participants will be verbally reminded of their rights immediately before the interview. A contacts and complaints section will be included in the information sheet. Participants will be consulted prior to the publication of any research article with regard to the inclusion of any direct quotes or close paraphrasing.

Describe any possible risks to the health or safety of the researcher(s) when undertaking the research? Note: where interviews are to be held in participants' homes as opposed to public places provide a rationale other than convenience for why this is necessary (and outline the personal safety protocol for the researchers involved)

NA

#### **SECTION 4: ETHICAL CONSIDERATIONS**

The University templates for participant information sheets, consent forms and independent contacts and complaints procedures are at <a href="http://www.adelaide.edu.au/ethics/human/guidelines/applications/">http://www.adelaide.edu.au/ethics/human/guidelines/applications/</a> Attach the relevant document(s) to the application.

Describe how the likely benefits of the research will justify any risks of harm, discomfort or burden to participants.

As described above, risks identified are minimal and mostly related to confidentiality and non-identifiability of any information that participants might consider harmful to their careers if publicly disclosed. These risks will be addressed and remedied to the fullest extent possible given the nature of the project.

The overarching aim of this project is to contribute to the knowledge base needed to guide policy-making in Australia and particularly in South Australia. In this context, understanding of international experiences in the consideration and implementation of legislation and regulation for obesity prevention will be invaluable for development of local policy and has the potential to contribute to the development of a politically feasible, comprehensive and effective obesity prevention regime. The overall ANPHA project will culminate in a guidance document outlining recommendations and advice on the potential impediments and facilitators to the implementation of regulatory obesity prevention measures for the attention of policy-makers and politicians in South Australia and elsewhere.

These potentially far-reaching benefits justify the demands on participants' time and the potential need to adjust final publications in order to exclude any risk to their careers. This is even more true considering that all participants are professionally engaged in policy-making and are likely to have a personal and professional interest in sharing the lessons-learned from their work.

Outline the protocol that will be followed in the event of any adverse events? Note: an adverse event can include situations where participants may decide to withdraw themselves or their information during/after an interview or focus group.

Considering that all participants are mature age working professionals, taking part in this project within the realm of their professional role, we do not consider it necessary or appropriate to establish a protocol beyond the freedom of every participant to withdraw at any stage of the project and to review results prior to publication. However, additional impartial follow-up can be provided upon request using the contacts and complaints details included in the information sheet.

Will participants receive any reimbursement of out of pocket expenses, or financial or other rewards as a result of participation? What is the amount or nature of the reimbursement/reward and the justification for this?

No, participation is considered to be within the remit of participants' professional role.

How and when will a written Participant Information Sheet (in plain language) be provided to potential participants? For online surveys, the information sheet may be incorporated into the survey preamble. Attach this document or provide a copy of the online survey information to the application.

The information sheet will be provided by e-mail and again immediately before the beginning of the interview.

### How will written consent be obtained from participants and any third parties?

The consent form will be send by e-mail for information purposes and written consent will be obtained immediately before the beginning of the interview.

How and when will you give the Contacts for the Project and Independent Complaints Procedure Sheet. For some projects, including online surveys, a summary of this information may be added to the survey preamble. Attach this document to the application.

The contacts and complaints sheet is part of the information sheet which will be provided by e-mail and again immediately before the beginning of the interview.

For participants not fluent in English or who have difficulty understanding English, what arrangements will be made to ensure comprehension of the Information Sheet and Consent Form?

All participants are professionals with English as their native and/or working language.

### SECTION 5: PROTECTION OF PRIVACY AND CONFIDENTIALITY OF INFORMATION

Which of the following statements apply to the research:

	<b>Complete anonymity of participants?</b> (e.g. researchers will not know the identity of participants as the participants are part of a random sample and are required to return responses with no form of personal identification)
	<b>Non-identified samples or data?</b> (e.g. the personal identifiers have been removed from the data and replaced by a code, there is no link between the original identifiers and the code so that it is impossible to identify the individual to whom the sample of information relates)
	<b>Re-identifiable samples or data?</b> (e.g. the personal identifiers are removed and replaced by a code. Those handling the data subsequently do so using the code. If necessary, it is possible to link the code to the original identifiers and re-identify the individual to whom the sample or information relates)
	Participants have the option of being identified in any publication arising from the research?
	Participants are referred to by a pseudonym in any publication arising from the research?
$\boxtimes$	Other methods of protecting the privacy of participants? (please describe below)
	ipants will be identified by organizational affiliation if they consent to this option, otherwise a generic holder category will be used.

Will researchers be taking photographs or recordings of participants using audio tape, film/video, or other electronic medium and how are these to be used?

All interviews will be digitally recorded and transcribed.

How will the confidentiality of the data collected/disseminated, including the identity of participants, be assured? Where the sample size is very small, it may be impossible to guarantee anonymity/confidentiality of participant identity. Participants involved in such projects need to be clearly advised of this limitation in the Participant Information Sheet.

We recognize the risk of participants being identified even in the absence of any individual information. We will seek permission from participants to identify the organization they represent only, and will, where permission is declined, revert to generic stakeholder categories. To further protect participants from being identified against their wishes through clues related to their professional role, participants will be given the opportunity to discontinue participation at any time, to decline to answer any of the questions posed and to decline the inclusion of specific quotes and paraphrasing taken from their transcripts in any publications arising from the study. This is clearly spelt out in the participant information sheet (see attachment #1) and consent form (see attachment #2).

#### **SECTION 6: DATA ANALYSIS AND STORAGE**

How is the information (data) to be analysed, and who will have access?

The interviews will be transcribed and analyzed inductively to uncover themes, building theory through an iterative and reflective analytical process. The analysis of the data will focus on decision making processes rather than the particular role or position that interviewees had. This will help to protect participant confidentiality even where organizational affiliation is revealed with the consent of the participants concerned.

Only members of the research team will have access to the research data. The data will be de-identified at the transcription stage although the professional role of the participant will be retained for the purposes of the research analysis. This level of detail will not be included in the publication as described above.

Will participants receive feedback of findings prior to any publication (including access to transcripts of interviews or drafts of reports)?

Yes, participants will receive drafts of research articles and their consent will be sought with regard to the presentation of results. Any concerns raised with regard to anonymity and potential identifiability will be

addressed prior to publication. All participants will also be provided with an electronic copy of the research article(s) arising from this project. For any subsequent related publication or presentation involving the same results, consent will be presumed.

Will the project outcomes be made publicly accessible at the end of the project and in what forms (e.g. journal article, book, conference paper, the Media)?

Project outcomes will be published in peer-reviewed journals and these research articles will be incorporated into a PhD thesis in a combined conventional/by publication format. The findings of the studies will be presented at relevant scientific conferences and a public presentation.

Outline the methods to be used for the storage, location, and access to, all records and materials (written or electronic) that have been used/collected during and after completion of the project.

All data will be stored as digital audio files and transcripts on a password protected computer or a USB held in a locked storage facility. All data will initially be stored on a password protected laptop computer and will be transferred via remote access onto a password protected server at the School of Population Health, University of Adelaide. USB and laptop computer will be held in a locked facility whenever not in use. Only research staff directly connected with the project will have access to the files. The interview recordings on the recording device will be destroyed after the transcription. The location of data will be recorded using the University of Adelaide's DataConnect service.

Outline the length of time that the records and materials will be retained by the University. (Note that the minimum period for retention of research data is 5 years from the date of any publication and varies depending on the specific type of research. For more information refer to Section 2.1 of the Australian Code for the Responsible Conduct of Research at http://www.nhmrc.gov.au/guidelines/publications/r39)

Data will be stored for five years after any publication arising from the research in compliance with the Australian Code for the Responsible Conduct of Research requirements. At the end of this period all documents will be shredded and computerized data will be erased from servers, workstations, and USBs.

### SECTION 7: CONFLICT OF INTEREST OR OTHER ETHICAL ISSUES

Outline any 'conflict of interest' issues that may arise during the project?

No conflicts of interest have been identified prior to the beginning of the project and none are anticipated to arise during the project.

Do the researchers expect to obtain any direct or indirect financial or other benefits from conducting this research? (Note that such benefits must be declared to the HREC and included in the *Information Sheet*.)

No.

Outline any other ethical or relevant issues not discussed in this application:

N/A

#### References:

Bassett MT, Dumanovsky T, Huang C, Silver LD, Young C, Nonas C, Matte TD, Chideya S, Frieden TR 2008, Purchasing behavior and calorie information at fast-food chains in New York City, *American Journal of Public Health*, Vol. 98, No. 8, pp. 1457-1459.

Dumanovsky T, Huang CY, Nonas CA, Matte TD, Bassett MT, Silver LD 2011, Changes in energy content of lunchtime purchases from fast food restaurants after introduction of calorie labelling: cross sectional customer surveys, *British Medical Journal*, Vol. 26, No. 343, d4464.

Elbel B, Kersh R, Brescoll VL, Dixon LB 2009, Calorie labeling and food choices: a first look at the effects on low-income people in New York City, *Health Affairs (Millwood)*, Vol. 28, No. 6, w1110-1121.

Elbel B, Taksler GB, Mijanovich T, Abrams CB, Dixon LB 2013, Promotion of healthy eating through public policy: a controlled experiment, *American Journal of Preventive Medicine*, Vol. 45, No. 1, pp. 49-55.

Epstein L, Jankowiak N, Nederkoorn C, et al 2012, Experimental research on the relation between food price changes and food-purchasing patterns: a targeted review. *American Journal of Clinical Nutrition*, Vol. 95, No. 4, pp. 789–809.

Eyles H, Ni Mhurchu C, Nghiem N, Blakely T 2012, Food pricing strategies, population diets, and non-communicable disease: a systematic review of simulation studies, *PLoS Medicine*, Vol. 9, No. 12, e1001353.

Given, LM (ed.) 2008, The Sage encyclopedia of qualitative research methods, vol. 2, Sage: Thousand Oaks, CA.

Liamputtong P, Ezzy D 2005, Qualitative research methods, 2nd edn, Melbourne: Oxford University Press.

Mello M, Studdert D, Brennan T (2006) Obesity - the new frontier of public health law. *New England Journal of Medicine*, no. 354, pp. 2601 - 2610.

Mytton OT, Clarke D, Rayner M 2012, Taxing unhealthy food and drinks to improve health. *British Medical Journal*, no. 344, e2931.

Thomas J, Harden A 2008, Methods for the thematic synthesis of qualitative research in systematic reviews, *BMC Medical Research Methodology*, vol. 8, pp.45-55.

Thow AM, Jan S, Leeder S, Swinburn B 2010, The effect of fiscal policy on diet, obesity and chronic disease: a systematic review, Bulletin of the World Health Organization, Vol. 88, No. 8, pp. 609-614.

Yin, RK 2009, Case study research: design and methods, 4th edn, Sage: Thousand Oaks, CA.

#### **SECTION 8: DECLARATION BY THE RESEARCHERS**

Declaration by the researcher(s)

I/we have read the National Statement on Ethical Conduct in Human Research (2007).

#### I/we, the researcher(s) agree to:

- start this research project only after obtaining final approval from the Human Research Ethics Committee (HREC)
- only carry out this research project where adequate funding and personnel is available to enable the project to be carried out according to good research practice and in an ethical manner
- notify the HREC in writing in the event of any adverse or unforeseen events; amendments;
   completion; discontinuation of the project or changes to research personnel
- provide an annual progress report to the HREC for the duration of the research project;
- provide the HREC with a final report
- agree to participate in an audit if requested by the HREC.

#### In addition, as the applicant, I:

- accept responsibility for the conduct of this research project according to the National Statement on Ethical Conduct in Human Research (2007)
- certify that all researchers and other personnel involved in this project are appropriately qualified and experienced or will undergo appropriate training and supervision to fulfil their role in this project
- will take responsibility for the confidential maintenance of the data as per the <u>University's</u>
   Responsible Conduct of Research Policy and as required by legislation.

Signatures are required from/all persons named in section 1 of this application: Applicant's Date: April 16, 2014 Jackie Street Name: signature: Researcher's Jana Sisnowski Date: April 16, 2014 Name: signature: Researcher's Date: Name: signature: Researcher's Date: Name: signature:

Researcher's signature:	Name:	Date:
Researcher's signature:	Name:	Date:
Researcher's signature:	Name:	Date:

#### **SECTION 9: CHECKLIST**

The following documents are attached to this application:

Yes	No	N/A*	
$\boxtimes$			Participant Information Sheet (required for all projects including on-line surveys)
$\boxtimes$			Standard Consent Form for a participant in a research project (written consent is required for the majority of projects)
		$\boxtimes$	Third Party to Participation Form required where participants are children under 18 years or a dependent adult
$\boxtimes$			Contacts and Independent Complaints Procedure information or sheet (required for all projects, including on-line surveys)
			(Note: included in Participant Information Sheet)
		$\boxtimes$	Survey instrument/Questionnaire (include a printed copy of on-line survey)
$\boxtimes$			Procedure/protocol for interviews or focus groups including topics and questions
			Recruitment advertisement, flyers, recruitment letters, social media event sites
$\boxtimes$			(Note: an abridged form of the participant information sheet, therefore not submitted in duplication)
		$\boxtimes$	Adverse event procedure/interview protocol (if required)
			Evidence of approval/rejection by other HRECs, including comments and requested alterations to the application
			Research with people outside Australia: Evidence of permissions, approvals from overseas authorities etc
			Administration of Drugs Form

<sup>\*</sup>Not applicable

### SECTION 10: HOW TO SUBMIT THIS APPLICATION

- 1. Print the completed form and get all signatures.
- 2. Scan the signed form including all attachments as **one pdf file** and email to <a href="mailto:hrec@adelaide.edu.au">hrec@adelaide.edu.au</a>.
- 3. <u>Submission deadlines</u> apply to applications requiring full HREC review. Applications submitted for low risk review can be submitted at any time. Research timetables should allow for the possibility that a project submitted as a low risk application may be deemed to involve more than low risk, or to raise other issues, therefore requiring full review. Researchers may be requested to provide additional information.



## INFORMATION SHEET

Research project: International experiences in regulatory approaches to obesity prevention: targeting population-level nutritional intake

Principal Investigator: Dr. Jackie Street Student Researcher: Jana Sisnowski Student's Degree: PhD in Public Health

We would like to invite you to participate in the research project: "International experiences in regulatory approaches to obesity prevention: targeting population-level nutritional intake".

#### What is the project about?

This project will study the initiation, decision-making, and implementation processes of regulatory approaches to obesity prevention in New York City and Denmark. The objective is to understand the drivers of and enablers and barriers to the policy-making process and ultimate policy success. Results will highlight lessons learned and the potential application of these findings to other jurisdictions interested in exploring similar approaches.

This research is part of the study *HealthyLaws- Public Perspectives in Public Health Law*, funded by the Australian National Preventive Health Agency. Project outcomes will be published in peer-reviewed journals and incorporated into a PhD thesis at the University of Adelaide.

#### What are the benefits of the research project?

The overarching aim of this project is to guide policy-making in Australia and particularly in South Australia. In this context, understanding of international experiences in the consideration and implementation of legislation and regulation for obesity prevention will be invaluable for development of local policy. The overall ANPHA project will culminate in a guidance document outlining recommendations and advice on the potential impediments and facilitators to the implementation of regulatory obesity prevention measures for the attention of policy-makers and politicians in South Australia and elsewhere. We will take all the necessary steps to make the recommendations reach the relevant governmental agencies; however, there is no guarantee that suggestions will be taken up.

### What will participation involve?

If you accept the invitation to participate in this project, you will need to sign a consent form and will be asked to participate in an interview of approximately one hour. The interviews will be audio recorded and transcribed. You might also be asked to help us identify additional interviewees and relevant documentation in the public domain prior to the interview. At the end of the project, findings will be shared with you and all participants included in this study.

#### How will confidentiality be ensured?

The information we obtain from you will be dealt with confidentially, only the research team will have access to the data. The audio files and transcriptions will be stored temporarily on a USB key and

password protected laptop, both of which will be held in secure locations when not in use. All data will be transferred to password protected servers at the University of Adelaide as soon as possible. The interview recordings will be destroyed after the transcription. Data will be stored for five years after any publication arising from the research in compliance with the Australian Code for the Responsible Conduct of Research. At the end of this period, all documents will be shredded and computerized data will be erased from servers, workstations, and USBs.

We recognize potential risks to confidentiality associated with our small sample size and, in particular, the risk that some participants may be identifiable due their public association with the policies in question. We assure you that the information you provide will be treated in strict confidence and that, as far as possible, participants will not be individually identifiable in publications arising from this study. In reporting the findings, we will ensure that no information which could readily identify individuals such as gender, age, and job description of participants will be provided. We would like to identify the organization you represent and ask your permission to do so on the consent form. If you object, we will revert to generic stakeholder categories such as "government body", "interest group", "elected official" to further protect your anonymity. In addition, we will ask you for your permission prior to the inclusion of any direct quotes or close paraphrasing in publications for public view.

### Can I with withdraw from the project?

Participation in this project is completely voluntary. You have the right to discontinue participation at any time leading up to and during your interview. You are also free to refuse to answer any of the questions posed and to decline the inclusion of specific quotes taken from your transcript in any publications arising from the study.

### Who do I contact if I have questions about the project?

If you have any questions about this project, please contact Dr. Jackie Street or Jana Sisnowski by e-mail or phone.

Dr. Jackie Street: <a href="mailto:jackie.street@adelaide.edu.au">jackie.street@adelaide.edu.au</a>, + 61 8 8313 6498 Jana Sisnowski: <a href="jackie.street@adelaide.edu.au">jana.sisnowski@adelaide.edu.au</a>, + 61 8 8313 1689 The University of Adelaide

178 North Terrace, Australia 5005

Mail Drop DX650 550

#### What if I have a complaint or any concerns?

The study has been approved by the Human Research Ethics Committee at the University of Adelaide (approval number H-2014-TBD). If you have questions or problems associated with the practical aspects of your participation in the project, or wish to raise a concern or complaint about the project, then you should consult the Principal Investigator. Please contact the Human Research Ethics Committee's Secretariat at +61 8 8313 6028 or by email to <a href="mailto:hrec@adelaide.edu.au">hrec@adelaide.edu.au</a> if you wish to speak with an independent person regarding concerns or a complaint, the University's policy on research involving human participants, or your rights as a participant. Any complaint or concern will be treated in confidence and fully investigated. You will be informed of the outcome.



## **Human Research Ethics Committee (HREC)**

and in my opinion she/he understood the explanation.

### **CONSENT FORM**

	Title:	International experiences in regular prevention: targeting population-le	
	Ethics Approval Number:	TBD	
2.	I have had the project, so far a My consent is given freely.	as it affects me, fully explained to my s	atisfaction by the research worker.
3.	consideration and implement	e of this research project is to understa ation of legislation and regulation for o d policy considerations in South Austra	bbesity prevention with a view to
4.	have been informed that, while information gained during the study may be published, I will not be dentified and my personal views will not be divulged. I also understand that if particular quotes from my interview are included in a paper for public view that I will have the opportunity to review these and provide or withdraw consent for use.		
	I agree to be identified by professional role.	organizational affiliation, without any	reference to my person or
	Yes No In this c	ase a generic stakeholder category suc c. will be used.	ch as government body, interest
5.	I understand that I am free to	withdraw from the project at any time	2.
5.	I agree to the interview being	digitally audio recorded. Yes	No 🗌
	I am aware that I should keep a copy of this Consent Form, when completed, and the attached Information Sheet.		
7.	Information Sheet.		
	Information Sheet. ticipant to complete:		
Par	ticipant to complete:	Signature:	Date:

(print name of participant)

Signature: \_\_\_\_\_\_ Position: \_\_\_\_\_ Date: \_\_\_\_\_

### **Interview topics**

Information will we provided at the beginning of the interview about the consent process, digital audio recording of the interview, the publication process and measures in place at all stages to ensure confidentiality.

### Topics to be covered:

- 1) General discussion of the role of government in chronic disease prevention, lifestyle risk factors, and diet-related risk factors in particular
- 2) Types of regulatory measures considered and/or implemented to date in respective jurisdiction:
  - a. Settings and target groups
  - b. Cost and resources
  - c. Sequence in considering/proposing/enacting measures
- 3) Policy-making process
  - a. Policy initiation process: who, what, when, and why?
    - i. Motivating factors: problem severity etc.
    - ii. Role of evidence
    - iii. Role of political views, ideology
  - b. Policy development:
    - i. Stakeholder engagement: timing, contributions, possible changes to original policy proposal
    - ii. Conflicting views and goals
  - c. Policy implementation:
    - i. Anticipated obstacles vs. unexpected complications
    - ii. Public reactions
    - iii. New stakeholders
    - iv. Unexpected outcomes or side effects
- 4) Evaluation of measures:
  - a. Perceived successes and failures
  - b. Formal post-implementation evaluation:
    - i. What are the criteria/end points for evaluation (e.g. reduced demand, reduction in BMI, reduction in diet-related chronic disease incidences or prevalence)
  - c. Unique factors in jurisdictions that have acted as barriers or enablers
- 5) Overarching topic: interaction between different areas and levels of government (EU and EU Member States for Denmark; city, state, and federal levels for New York City): role, impediments etc.
- 6) Outlook and reflection:
  - a. Gaps in the current regime, outlook
  - b. Lessons learned, advice to other jurisdictions