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Alberto Alemanno and Amandine Garde

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How to Prevent and Control Non-Communicable Diseases Associated with Tobacco, Alcohol and Unhealthy Diets?

Sieps
Swedish Institute for European Policy Studies

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Preface

During the last decade, the European Union has undertaken a range of measures aiming at prevention and control of Non-Communicable Diseases (NCDs). Regulation of the so called 'lifestyle risks' is, however, not uncontroversial. Henceforth, strategic consideration and careful policy planning are required at the EU and the Member States level, to successfully tackle the main NCD risk factors, namely alcohol, tobacco and unhealthy diets.

In this report, Associate Professor Alberto Alemanno and Professor Amandine Garde examine the courses of development of EU regulation targeting those three risk factors, and analyse the role of law in developing successful transnational NCD control and prevention strategies. In this highly sensitive area, law needs to be seen as a source of opportunity, but also as a potential source of problems. The authors of the report argue that multi-factorial nature of NCDs requires a multi-disciplinary and multi-level regulatory response. They review the complexities of lifestyle risk regulation and suggest possible methods of optimising regulatory intervention in promoting healthier lifestyles in the EU.

This report is a part of SIEPS´ research project *Social Europe*.

Anna Stellinger
Director

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Amandine Garde is Professor of Law at the University of Liverpool. Her current research focuses on the role that legal instruments can play in preventing non-communicable diseases. Her book 'EU Law and Obesity Prevention' is the first to offer a critical analysis of the EU's Obesity Prevention Strategy. She is currently working on a research project funded by the Economic and Social Research Council on the regulation of food marketing to children. As part of this project, she has spent five months at the World Health Organization and provided technical assistance to several states and regions worldwide on their implementation of the 2010 WHO Recommendations on the marketing of food to children. For more information: http://www.liv.ac.uk/law/staff/amandine-garde/

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List of abbreviations

AVMS	Audiovisual Media Services
CJEU	Court of Justice of the European Union
CAP	Common Agricultural Policy
CRC	Convention on the Rights of the Child
ECHR	European Convention of Human Rights and Fundamental Freedoms
EFTA	European Free Trade Area
EU	European Union
FCTC	Framework Convention on Tobacco Control
GATT	General Agreement on Tariffs and Trade
GMF	Global Monitoring Framework
HFSS	High in Fat, Sugar and Salt
ICAP	International Center for Alcohol Policies
ICESCR	International Covenant on Economic, Social and Cultural Rights
MERCOSUR	Mercado Común del Sur
NAFTA	North American Free Trade Area
NCD	Non-Communicable Disease
RTA	Regional Trade Agreement
SPS	Sanitary and Phytosanitary
TBT	Technical Barriers to Trade
TEU	Treaty on the European Union
TFEU	Treaty on the Functioning of the European Union
UN	United Nations
WHO	World Health Organization
WTO	World Trade Organization

Executive summary

In May 2013, the World Health Assembly unanimously adopted a Global Action Plan for the Prevention and Control of Non-Communicable Diseases for 2013–2020. This plan recognizes that NCDs such as cardiovascular diseases, cancers, chronic respiratory diseases and diabetes are largely preventable, and calls on all parties to take concrete steps to achieve specific targets to reverse current trends. As NCDs account for nearly 86% of deaths and 77% of the disease burden in the WHO European Region, the EU has started to reflect on the measures it could put in place to contribute to the NCD agenda.

In the last decade, the EU has adopted several strategies aimed at reducing the impact of the four main NCD risk factors: smoking, excessive alcohol consumption, unhealthy diets and physical inactivity. In line with WHO recommendations, these strategies recognize that NCDs can only be dealt with effectively if a broad range of sectors that impact on the different aspects of our daily lives are involved in the NCD agenda. However, these strategies differ significantly in nature: the EU tobacco control policy is characterized by a very strong command-and-control approach based on the adoption of legally binding rules to discourage smoking, whereas the EU Alcohol Strategy relies above all on the exchange of best practices between relevant actors and the adoption of self-regulatory standards by industry operators to prevent the harmful use – rather than preventing the consumption – of alcoholic beverages. The EU Obesity Prevention Strategy relies on an intermediate approach, mixing both the adoption of binding rules with calls on the food industry to regulate itself via the adoption of self-regulatory standards.

After briefly discussing the complexity and multifactorial nature of the causes of NCDs and highlighting the contested nature of any form of regulatory intervention aimed at changing individual behaviour, this report examines the different opportunities that 'lifestyle' regulation offers for the EU and its Member States to promote healthier lifestyles. A typology of the different categories of possible interventions (including disclosure requirements, marketing restrictions, the adoption of fiscal measures or the regulation of product composition) leads to the conclusion that the law provides significant and diverse opportunities for promoting healthier lifestyles and therefore reversing current NCD trends.

However, these opportunities will only be maximized if the constraints that the law imposes on policy-makers are understood and given due considera-

tion. Without framing the relevant issues in legal terms and on the basis of existing evidence, the public health community is unlikely to succeed in using the law effectively. This seems especially true in the light of the legal challenges that the tobacco, alcoholic beverages and food industries have systematically mounted against rules intended to regulate them. Three categories of rules must be given sufficient attention when regulating lifestyles. First, the EU can only act if it has the required powers to do so and it can only exercise them in conformity with the principles of subsidiarity and proportionality. Second, the EU must comply with international trade rules, and in particular uphold its obligations under WTO law. Finally, the EU legal order is founded on the rule of law and must, as such, respect the fundamental rights protected by the EU Charter, the European Convention on Human Rights and the general principles of EU law. If these principles are relatively straightforward to grasp, the case law of the CJEU shows that their application in practice has proven extremely difficult: they require that fine lines be drawn between legitimate and illegitimate EU intervention. The public health community in Europe must engage with this body of case law if the rules adopted by the EU and its Member States in order to promote healthier lifestyles are to withstand judicial review and thus effectively contribute to the NCD prevention and control agenda at global, regional and national levels.

1 Introduction

The UN General Assembly has declared that the global burden and threat of non-communicable diseases (NCDs) constitutes one of the major challenges for development in the twenty-first century: in 2008, 36 of the 57 million deaths globally (63%) were attributed to NCDs, including cardiovascular diseases, cancers, chronic respiratory diseases and diabetes.[1] The problem is particularly severe in Europe: according to data collected by the Regional Office for Europe of the World Health Organization (WHO), NCDs account for nearly 86% of deaths and 77% of the disease burden in Europe.[2] These alarming rates have led to a growing consensus that the EU should develop a policy 'to promote healthy lifestyle behaviours'.[3] In line with the thinking of the WHO, the EU has recognized that NCDs are largely preventable and that it can contribute to the action at global, regional and national levels by adopting a range of policies to prevent and control the surge of NCDs and reduce the impact of the four main NCD risk factors, namely tobacco use, the harmful use of alcohol, unhealthy diet and lack of physical activity. Yet the causes of NCDs are complex and the legality, design, legitimacy as well as the effectiveness of any regulatory intervention aimed at promoting healthier lifestyles remain highly contested. Therefore, whilst the international community places great faith in the power of law to change individual behaviour through regulatory intervention, achieving behavioural change is far from straightforward.

First, any regulatory attempt at changing consumption patterns tends to be dismissed, in the name of the principle of autonomy, as paternalistic. Thus, recent policy initiatives, such as the 'fat taxes' pioneered by Hungary and Denmark as well as New York's City plan to limit the serving size of sugary drinks, have immediately earned their proposers the nickname of 'nanny governments'. Second, the experimental nature and lack of solid empirical evidence of many of these policy interventions is an easy target for their critics. Third, the multifactorial nature of NCDs raises difficult questions not only for medicine and health policy but also for the community as a whole. In particular, social mobilization may play a crucial role in promoting the acceptance of these innovative and often experimental policies. However,

[1] Political Declaration of the UN High-Level Meeting on the Prevention and Control of Non-Communicable Diseases, 20 September 2011, Document A/66/L 1.

[2] WHO Regional Office for Europe, "Action Plan for Implementation of the European Strategy for the Prevention and Control of Non-Communicable Diseases 2012−2016", available at http://www.euro.who.int/__data/assets/pdf_file/0019/170155/e96638.pdf .

[3] European Commission, White Paper "Together for Health: Strategic Approach for the EU 2008–2013", 14689/07, COM(2007) 630 final.

unlike the area of communicable diseases, in which health activists typically have succeeded in rallying the support of society on *inter alia* access to anti-retroviral medicines to fight HIV/AIDS, NCD prevention strategies, which tend to be perceived as lacking similar urgency, have not (yet) succeeded in mobilizing society. Given the preventive nature of NCD action, the beneficiaries of these policies are largely 'statistical' by consisting in either the next generation or those who will be entering middle age decades from the present. Fourth, tackling NCDs involves a variety of short- and longer-term goals, including what may be challenging alterations to lifestyles, changes in how relevant industries formulate their products, revolutions in the way retail practices influence shopping behaviour or increases in the amount of physical exercise we engage in. Thus, it is of vital importance that behind any attempt at regulating lifestyle there is a holistic, yet realistic, understanding of the underlying phenomena when calling for action, and of the limits of intervention.[4]

A growing body of behavioural research shows that as people and their environment interact, the focus of intervention should not be exclusively focused on the critical product, but also on the context within which the individual evolves.[5] In other words, context matters and, as such, by contributing to determining behaviour, it carries the potential for behavioural change. Mounting evidence suggests that it is more difficult to make healthy choices in certain environments than in others.[6] These studies illustrate the considerable psychological effort needed to combat the temptations of an unhealthy lifestyle, as well as cultural norms, social and commercial pressures, and how freedom of choice can, perhaps counterintuitively, make it more difficult to resist temptation. Moreover, a key feature of behaviours that promote public health is that they will only deliver gains for the individual and for the population if maintained in the long term.[7] These research findings should lead societies to question their frequent portrayal of people leading unhealthy

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[4] Behavioural research offers promising avenues to increase our understanding of the lifestyle risk factors associated with NCDs. The literature is vast. For a popular treatment, see, e.g., D. Kahneman, *Thinking, Fast and Slow* (Farrar, Straus and Giroux, 2011); D. Ariely, *Predictably Irrational: The Hidden Forces that Shape Our Decisions* (HarperCollins, 2008); R. Thaler and C. Sunstein, *Nudge: Improving Decisions About Health, Wealth and Happiness* (Yale University Press, 2008).

[5] S. Planzer and A. Alemanno, "Lifestyle Risks: Conceptualizing an Emerging Category of Research", 1(4) *European Journal of Risk Regulation* (2010), 337.

[6] See, e.g., C. Sunstein, "The Storrs Lectures: Behavioral Economics and Paternalism", 122 *Yale Law Journal* (2013), 1826.

[7] Foresight Project Report, Tackling Obesities: Future Choices (London: Government Office for Science, October 2007), at 64. See also K. Brownell et al., "Personal Responsibility and Obesity: A Constructive Approach to a Controversial Issue", 29 *Health Affairs* (2010), 378.

lifestyles as lacking personal willpower. For example, it is often assumed that one gets fat because one keeps eating too much and fails to engage in enough physical activity. Nevertheless, weight gain and obesity is a much more complex phenomenon than this over-simplistic approach suggests. The role of genetic and epigenetic influences, and the crucial role of societal and environmental factors over which individuals have little control, support the view that obesity is not exclusively a question of personal responsibility. Responsibility is shared between, on the one hand, individuals, who must adopt an adequate lifestyle to protect their health and that of their children, and, on the other, policy makers and society, who must create environments that better suit human biology and support individuals in developing and sustaining healthy lifestyles, bearing in mind that the vast majority of human beings are predisposed to gaining weight.[8]

The adoption of behaviourally informed public measures raises a series of concerns related to both their legitimacy and their legality.[9] In particular, an objection commonly raised is that these measures could conflict with the principle of autonomy, i.e. the ability to order our lives according to our own decisions.[10] However, it is counter-argued that autonomy cannot be an end in itself but merely a means to an end. While it is true that people may know what their ends are, sometimes they go wrong when they choose how to attain them. According to this line of thought – which may be defined as new paternalism – if the benefits stemming from regulatory intervention justify the costs, society should be willing to eliminate freedom of choice, not to prevent people from obtaining their own goals but to ensure that they do so.[11] Interestingly, if we allow public authorities to make (certain) decisions for us, we gain not only in personal welfare but also in autonomy.[12] In sum, health should become 'the easier, default option rather than being agonizingly difficult'.[13] It is only by revealing the suffering of people and of the whole

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[8] D. King, Chief Scientific Adviser to the UK Government and Head of the Government Office for Science, Foreword, *Foresight Project Report, Tackling Obesities: Future Choices* (London: Government Office for Science, October 2007), at 1.

[9] A. Alemanno and A. Spina, *Nudging Legally – On the Checks and Balances of Behavioral Regulation*, Jean Monnet Working Paper, New York University School of Law, volume 6, 2013.

[10] See, e.g., R. Rebonato, *Taking Liberties – A Critical Examination of Libertarian Paternalism* (Palgrave Macmillan, 2012).

[11] See, e.g., S. Conly, *Against Autonomy – Justifying Coercive Paternalism* (CUP, 2013). More generally on legal paternalism, see A. Ogus and W. Van Boom (eds), *Juxtaposing Autonomy and Paternalism in Private Law* (Hart Publishing, 2011).

[12] *Ibid*.

[13] B. Thomas and L. Gostin, "Tackling the Global NCD Crisis: Innovations in Law & Governance", 41 *Journal of Law, Medicine & Ethics* (2013), 25.

society caused by the burden of NCDs that civil society will eventually mobilize and refuse to accept the growing health inequalities existing between rich and poor, uneducated and educated, the unfortunate and the privileged.

While the literature on the contribution that the law can make to this project is growing, it remains very insufficient given its importance to the debate. Most notably, it has not yet attracted the attention of a critical mass of legal scholars.[14] It is against this backdrop that this report surveys, systematizes and adds to the existing literature. By focusing on the European Union, it highlights the opportunities that legal instruments offer for the NCD prevention and control agenda, before turning to the constraints that the law imposes on policy-makers. It is only if one understands these constraints that opportunities can be maximized. While law is not a panacea for tackling the crushing burden of NCDs, legal interventions inspired by common sense and based on sound evidence could potentially make the difference and trace a new path in addressing self-destructive behaviours induced by market integration.

[14] See, however: A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010); R. Magnusson and D. Patterson, "Role of Law in Global Response to Non-communicable Diseases", 378(9794) *The Lancet* (2011), 859; G. Lien and K. Deland, "Translating the WHO Framework Convention on Tobacco Control (FCTC): Can We Use Tobacco Control as a Model for Other Non-communicable Disease Control?", *Public Health* (2011), 18; G. Alleyne, A. Binagwaho, A. Haines, et al., "Embedding Non-communicable Diseases in the Post-2015 Development Agenda", *The Lancet* (2013), 566; A. Alemanno and A. Garde, "The Prevention of Non-Communicable Diseases in the European Union", in T. Voon, A. Mitchell and J. Liberman (eds), *Regulating Tobacco, Alcohol and Unhealthy Foods: The Legal Issues* (Routledge, forthcoming).

2 Overview of lifestyle regulation and the law

2.1. Developments at global level: from the UN Political Declaration on NCDs to the NCD Global Action Plan

In September 2011, the UN General Assembly adopted a Political Declaration on the Prevention and Control of NCDs.[15] This was only the second time in UN history that the General Assembly had met to discuss a health issue (the previous occasion being a discussion on AIDS in 2001). The aim of the meeting was for countries to adopt a concise, action-oriented outcome document that would shape the NCD prevention and control agenda at global and national levels for years to come. To this end the declaration recommended the adoption of a 'regulatory mix' of cost-effective, population-wide interventions to reduce the impact of the four main NCD risk factors, namely tobacco use, the harmful use of alcohol, unhealthy diets and lack of physical activity.

The significance of the UN Political Declaration on NCDs should not be underestimated. It is only in recent years that the international community has started to think about NCDs more horizontally. Until it adopted its NCD Action Plan for 2008–2013,[16] the WHO had tended to focus on individual risk factors for NCDs, developing separate strategies on the four main ones: tobacco, which culminated in the adoption in 2003 of the first international health law treaty: the Framework Convention on Tobacco Control (FCTC);[17] unhealthy diets and physical inactivity, with the adoption of the global strategy on diet and physical activity in 2004[18] and the adoption of a set of recommendations on the marketing of food and non-alcoholic beverages to children in 2010;[19] and alcohol abuse, with the adoption of the global strategy to reduce the harmful use of alcohol also in 2010.[20] The UN Political Declaration has significantly increased the momentum initiated by the 2008–2013 WHO NCD Action Plan to try and identify common themes and adopt a more transversal approach covering all four major NCD risk factors. Thus, in preparation for the UN Summit, the WHO organized a conference on NCDs that led to the Moscow Declaration,[21] it gathered data on the burden of NCDs

[15] http://www.who.int/entity/nmh/events/un_ncd_summit2011/political_declaration_en.pdf.
[16] http://www.who.int/nmh/publications/9789241597418/en/.
[17] http://www.who.int/fctc/en/.
[18] http://www.who.int/dietphysicalactivity/en/.
[19] http://www.who.int/dietphysicalactivity/marketing-food-to-children/en/.
[20] http://www.who.int/substance_abuse/activities/gsrhua/en/.
[21] http://www.who.int/nmh/events/moscow_ncds_2011/conference_documents/en/.

worldwide[22] and it reflected on cost-effective interventions for NCD prevention and control.[23] Most recently, its efforts culminated in the development, in consultation with Member States, of a global action plan for the prevention and control of NCDs for 2013–2020, which the Sixty-sixth World Health Assembly unanimously approved in May 2013, including a Global Monitoring Framework with specific targets to be met by 2025.[24]

These documents, which together contribute to shape an emerging global policy for NCD prevention and control, share important features. First, as prevention is better than cure, they highlight the importance of prevention. This is particularly true not only for children but also in general in relation to all addictive habits (not least tobacco, alcohol and perhaps even sugar). A preventive approach is the only one that has the potential to influence the population's lifestyle through the creation of a supportive environment and to reverse existing NCD trends in the longer term. Second, NCD prevention and control policies must be based on sound, reliable evidence. Consequently, governments and other relevant stakeholders should continue to build on the foundations laid down by previous research findings and continue to finance research supporting intervention at all stages of the policy cycle from policy development and implementation to policy monitoring and evaluation. Third, emphasis is placed on the need to adopt multi-sectoral, multi-stakeholder, multi-level strategies. This vocabulary has become a common feature of the thinking on NCD prevention and control. The multi-sectoral component of NCD prevention and control strategies recognizes that tackling NCDs entails the integration of a broad range of policies across the entire policy spectrum, not only health, but also consumer, agricultural, food, trade, media, education, sport, employment and transport policies. There is no 'magic bullet': only a coordinated intervention from all the relevant governmental sectors may achieve the objectives laid down by the NCD Action Plan and its accompanying Global Monitoring Framework. Similarly, only a multi-level approach, with mechanisms ensuring the effective co-ordination between the different levels of intervention, may durably reverse the current surge of NCDs: the importance of local consumption habits and cultures requires intervention at local and national level, whilst the rapid globalization of tobacco, alcoholic beverages and food markets induced by trade liberalization requires a response at EU and international level. Furthermore, the multifactorial nature of NCDs and the consequent need for a multi-sectoral, multi-level regulatory approach calls for the involvement of a wide range of stake-

[22] http://www.who.int/nmh/publications/ncd_profiles2011/en/index.html.
[23] http://www.who.int/nmh/publications/cost_of_inaction/en/index.html.
[24] http://www.who.int/nmh/en/.

holders in the NCD debates, including public authorities at all levels, civil society representatives, not least consumer and public health associations, and private actors from the relevant industries. As will be discussed below, the involvement of industry operators must remain subject to the need to avoid undue influence and conflicts of interest.

These principles are all reflected in the three distinct policies that the EU has adopted on tobacco control, on the harmful use of alcohol and on nutrition and physical activity. The second section sketches the evolution of the EU's approach to NCD prevention and control and identifies the key features of its three main policies.

2.2 Towards the development of an EU NCD prevention and control strategy

The EU's awareness of the threat posed by the growing burden of NCDs to the EU economy and the well-being of its citizens is relatively recent.[25] This stems in particular from the powers the EU derives from the EU Treaties in the field of public health – the introduction of a chapter on public health in the early 1990s marking a turning point in the EU's approach to public health issues, together with the growing rates of NCDs and the rapid spread of their main risk factors more specifically.

From a few ad hoc measures…

Some measures were adopted in the early days of the European Community, before the Member States explicitly granted some competence to the EU in the field of public health. In particular, the first food labelling laws adopted at EU level may have had some (though a limited) impact on the burden of NCDs. In particular the Food Labelling Directive of 1979[26] and the Nutrition Labelling Directive of 1990[27] required that ingredients of foodstuffs be listed on most pre-packaged foodstuffs and regulated how nutrition information should appear on food labels. These measures have since been replaced by the Food Information Regulation discussed more specifically in the next section (see disclosure requirement).[28] However, at the time of their adoption, these two directives could only be characterized as by-products of the internal market: they were incremental rather than a systematic attempt to

[25] S. L. Greer and Kurzer, *European Union Public Health Policy. Regional and Global Trends* (Routledge, 2013).

[26] Directive 79/112, OJ 1979 L 33/1.

[27] Directive 90/496, OJ 1990 L 276/40.

[28] Directive 1169/2011, OJ 2011 L 304/18.

address the major NCD risk factors and therefore promote healthier lifestyles within the EU.

… to the introduction of a chapter on public health in the EU Treaties
The momentum to address the burden of NCDs at EU level gathered in the 1990s, as a result of both the pressing warnings of the international and the scientific communities and the express acknowledgment that the EU had an important role to play in public health matters.

Since the entry into force of the Maastricht Treaty in 1993, the EU Treaties have contained a specific chapter on public health which is now to be found in Article 168 TFEU. The first paragraph of this provision has imposed an obligation on the EU to ensure a high level of public health in all its policy areas. It is precisely with a view to implementing the Union's mainstreaming obligation that the Council emphasized, in its Conclusions of 8 June 1999, the necessity to integrate health protection requirements in all EU policies.[29]

Mainstreaming implies, at its core, that a high level of public health protection should not be pursued only via ear-marked, distinct policies, but must be incorporated in all policy areas. One could reason by analogy and rely on Olivier De Schutter's argument on the mainstreaming of fundamental rights: 'fundamental rights […] should be seen, as an integral part of all public policy making and implementation, not something that is separated off in a policy or institutional ghetto. Mainstreaming is transversal or horizontal.'[30] Assessing the impact of policies on public health requires, in turn, that a careful balancing exercise is carried out between competing interests at all stages of the policy-making process, from the first Commission proposal, to the adoption by the Council and the European Parliament of a given measure, to its application by all parties to which it is addressed, to its monitoring and evaluation. The practical difficulties involved in assessing how best a high level of public health protection could be ensured should not stop the EU from taking the mainstreaming obligation laid down in Article 168 TFEU seriously into account – the problem is to design an effective and transparent mechanism to ensure that this constitutional obligation is duly upheld.[31]

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[29] OJ 1999 C 195/4.

[30] O. De Schutter, "Mainstreaming Human Rights in the European Union", in Alston and O. De Schutter (eds), *Monitoring Fundamental Rights in the EU: The Contribution of the Fundamental Rights Agency* (Hart Publishing, 2005), at 44, citing C. McCrudden, *"Mainstreaming Equality in the Governance of Northern Ireland"*, Fordham International Law Journal (1999), 1696.

[31] A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010), at 74.

The EU's duty to mainstream health in all policies was further reinforced with the introduction, by the Lisbon Treaty, of Article 9 TFEU which confirms that

> in defining and implementing its policies and activities, the Union shall take into account requirements linked to the promotion of a high level of employment, the guarantee of adequate social protection, the fight against social exclusion, and a high level of education, training and protection of human health.

The introduction of EU powers in the field of public health has led to the adoption of two successive programmes of EU action in the field of public health for the periods of 2003–2008[32] and 2008–2013.[33] They both share the objective 'to promote health and prevent disease through addressing health determinants across all policies and activities',[34] not least 'by preparing and implementing strategies and measures, including those related to public awareness, on lifestyle related health determinants, such as nutrition, physical activity, tobacco, alcohol, drugs and other substances and on mental health'[35] and 'by tackling health determinants […], creating supportive environments for healthy lifestyles and preventing disease'.[36] The Lisbon Agenda on Growth and Competitiveness further strengthened the economic and social case for EU intervention by stressing that, in addition to good health being a valuable goal in itself, it also leads to better economic results and increased social cohesion, and consequently makes the European economy more competitive.[37] Moreover, the European Commission emphasized that tobacco, harmful use of alcohol, unhealthy diets and lack of physical activity result from differences in socioeconomic determinants giving rise to health gaps inconsistent with EU core values of solidarity, equity and universality.[38]

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[32] Decision 1786/2002 of the European Parliament and the Council, OJ 2002 L 271/1.

[33] Decision 1350/2007 of the European Parliament and the Council, OJ 2007 L 301/3.

[34] Article 2(2)(c) of Decision 1786/2002, OJ 2002 L 271/1.

[35] Para 3(1) of the Annex of Decision 1786/2002, OJ 2002 L 271/1.

[36] Article 2(2) and point 2.2 of the Annex of Decision 1350/2007, OJ 2007 L 301/3. See also the White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013', COM(2007) 630 final.

[37] European Council Conclusions, Lisbon, 23-24 March 2000.

[38] European Commission, White Paper "Together for Health: Strategic Approach for the EU 2008–2013", COM(2007) 630 final. The EU has also set up an Expert Group on Social Determinants and Health Inequalities to reflect its growing awareness of the need to tackle NCDs more comprehensively, see http://ec.europa.eu/health/social_determinants/policy/index_en.htm.

After several calls from the Council of the European Union for EU action on NCDs,[39] not only did the EU adopt a range of specific measures intended to curb the consumption of tobacco,[40] but it also adopted three strategies intended to tackle the major NCD risk factors more comprehensively and support its citizens in improving their lifestyles: the EU Alcohol Strategy (2006),[41] the Obesity Prevention White Paper (2007)[42] and a Council Recommendation on smoke-free environments (2009)[43] which complements the adoption of the 2001 Tobacco Products Directive[44] and 2003 Tobacco Advertising Directive.[45]

These three areas of EU intervention have several themes in common: they are intended to promote enabling environments more conducive to healthy lifestyles, and they recognize the imperatives of adopting a multi-sectoral, multi-level, multi-stakeholder approach to maximize their chances of influencing the lifestyles of EU citizens and contributing meaningfully to the global agenda on NCD prevention and control. However, these common features should not detract from the fact that EU intervention has varied in nature, scope and intensity depending on the risk factor under consideration. One does indeed observe a gradation of EU involvement, with a strong intervention in relation to tobacco control, a lesser intervention in relation to alcohol control, and the EU nutrition and obesity prevention policy somewhere between the two.

2.2.1 Tobacco

EU tobacco control efforts are marked by a strong regulatory involvement from the EU, coupled with recommendations to Member States and EU-wide anti-smoking campaigns. As a result, this field of EU policy has been at the forefront of a 'federal' experimentation, helping delineate the limits of EU competences and the relevance of the principles of subsidiarity and propor-

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[39] Some of these calls have focused specifically on one specific risk factor, whilst others have tended to be more horizontal in nature, targeting all risk factors. Examples of the latter type include: the Council Conclusions of December 2003 on Healthy Lifestyles; the Council Conclusions of June 2004 on Promoting Heart Health; and the Council Conclusions of June 2006 on the Promotion of Healthy Lifestyles and the Prevention of Type II Diabetes.

[40] See in particular Directive 2001/37 on tobacco products, OJ 2001 L 194/26 (currently under review), and Directive 2003/33 on tobacco advertising and sponsorship, OJ 2003 L 152/16.

[41] COM(2006) 625 final.

[42] COM(2007) 279 final. For an assessment of the EU's obesity prevention strategy, see A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010).

[43] OJ 2009 C 296/4.

[44] Directive 2001/37, OJ 2001 L 194/26.

[45] Directive 2003/33, OJ 2003 L 152/16.

tionality for EU law and policy-making, as discussed more fully below.[46] At this stage, suffice to say that the EU has not hesitated in this field to invoke its duty to mainstream public health into all EU policies to push the EU agenda, as illustrated by the on-going debates surrounding the revision of the Tobacco Products Directive.[47] The EU has also become a party to the Framework Convention on Tobacco Control (FCTC), the first international health treaty ever signed, thus becoming an actor alongside its 28 Member States on the public health scene at global level.

2.2.2 Alcohol

Whilst the EU Alcohol Strategy entrusts Member States with the adoption of comprehensive multi-sectoral strategies, it also explicitly acknowledges that:

> studies carried out at national and EU level show that in some cases, where there is a cross border element, better coordination at, and synergies established with, the EU level *might* be needed. Examples include cross-border sales promotion of alcohol that could attract young drinkers, or cross-border TV advertising of alcoholic beverages that could conflict with national restrictions.[48]

However, very few EU harmonizing rules have been adopted to date to combat alcohol-related harm.[49] The Audiovisual Media Services Directive (AVMS Directive) constitutes an exception, in that it lays down rules on the content of alcohol promotions in AVMS.[50] These provisions are nonetheless extremely weak, and most Member States have relied on the minimum harmonization clause contained in the Directive to adopt stricter measures to protect the health of their citizens better – leading in turn to a high degree of fragmentation of the internal market.[51] Notwithstanding the fact that an effective multi-sectoral, multi-level strategy calls for EU intervention when policies have clear cross-border implications, the EU has responded to the calls for more robust intervention by reiterating that the primary responsibility for

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[46] This is discussed more fully below. See G. Howells, *The Tobacco Challenge* (Ashgate, 2011); A. Alemanno, "Out of Sight Out of Mind: Towards a New European Tobacco Products Directive", 18 *Columbia Journal of European Law* (2012), 197; A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010), chapter 3.

[47] The Commission published a proposal for a revised Tobacco Products Directive in December 2012: COM(2012) 788 final.

[48] At page 5. Emphasis added.

[49] J. Cisneros Örnberg, "Escaping Deadlock – Alcohol Policy-making in the EU", 16:5 *Journal of European Public Policy* (2009), 755.

[50] Articles 9(1)(e) and 22 of Directive 2010/13, OJ 2010 L 95/17.

[51] O. Bartlett and A. Garde, "Time to Seize the (Red) Bull by the Horns: the EU's Failure to Protect Children from Alcohol and Unhealthy Food Marketing", 4 *European Law Review* (2013), 498.

health matters lie with Member States – a response very much at odds with the approach the Commission has adopted in the field of tobacco control.[52]

If the EU has proven rather hostile to the adoption of harmonized rules to combat alcohol-related harm, it has been much more enthusiastic about facilitating the exchange of best practice and the adoption of self-regulatory standards.[53] In 2007, it set up the European Alcohol and Health Forum which gathers a broad range of members, from industry operators to consumer, youth and public health organizations. The innovative characteristic of the Forum is to require that every one of its now 71 members commits to the adoption of at least one specific, concrete commitment to help fight alcohol-related harm, which are then monitored and made publicly available on a dedicated database.[54]

2.2.3 Nutrition

For years, EU food law has been characterized by an emphasis on food safety rather than nutrition issues. This led MacMaolain to observe:

> The first element of quality is actually nutritional value, yet […] nutritional value has remained for the most part outside the factors that are taken into account in determining what qualifies as safe or high quality food[55] [...] As a consequence of this misinterpretation of the extent to which the [Union] is responsible for the protection of human health through the consumption of safe or quality food, the issue of nutrition has become side-lined,

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[52] In its First Implementation Report, published in September 2009, the Commission praised the EU Alcohol and Health Forum: http://ec.europa.eu/health/archive/ph_determinants/life_style/alcohol/documents/alcohol_progress.pdf. The second report, due for 2012, had not been published at the time of writing in 2013. See, however, COWI Consortium, "Assessment of the Added Value of the EU Strategy to Support Member States in Reducing Alcohol-related Harm", prepared for DG Sanco, EU Commission, December 2012 (but released in August 2013): http://ec.europa.eu/health/alcohol/docs/report_assessment_eu_alcohol_strategy_2012_en.pdf.

[53] On the differences between tobacco and alcohol control, see G. Lien and K. DeLand, "Translating the WHO Framework Convention on Tobacco Control (FCTC): Can We Use Tobacco Control as a Model for Other Non-communicable Disease Control?" 125 *Public Health* (2011) 847.

[54] http://ec.europa.eu/health/alcohol/forum/index_en.htm.

[55] In some cases, nutrition and food safety concerns may overlap. For instance, if food supplies are threatened with contamination – be it the potential risk of BSE in meat products or Salmonella in raw egg products – consumers may respond by altering their purchasing habits which may, in turn, alter the nutritional profile of their diet. See also the Aspartame assessment: http://www.efsa.europa.eu/en/press/news/120807a.htm http://www.efsa.europa.eu/en/topics/topic/aspartame.htm?wtrl=01. Nevertheless, this overlap tends to be the exception rather than the rule.

when in fact it should be the key component of any food quality programme.[56]

Over the last eight years, however, the growing burden of NCDs has contributed to a significant re-evaluation of the EU's initial position, and the EU has developed a nutrition strategy, culminating in the publication of the Obesity Prevention White Paper in 2007.[57]

Whilst EU tobacco control has preferred a traditional command-and-control approach and its Alcohol Strategy has embraced self-regulation, in the area of nutrition the EU has adopted a combination of both regulation and self-regulation. The Obesity Prevention White Paper set out an integrated EU approach to reduce ill health resulting from poor nutrition, overweight and obesity. Similarly to the EU Alcohol Strategy, it stresses that only an evidence-based, preventive, multi-stakeholder strategy may be effective in ensuring that individuals can improve their lifestyles. Nevertheless, it is much more forthcoming than the EU Alcohol Strategy in identifying the policies in which the EU has a clear role to play, including through the adoption of binding rules if necessary. In particular, it enumerates the EU policies relevant to obesity prevention: consumer policy and internal market law; audiovisual and media policy; food reformulation; agricultural policy; transport and sports policies; youth and social inclusion policies. This suggests that the Commission envisages a stronger EU involvement in relation to nutrition and physical activity than in relation to alcoholic beverages, as demonstrated in particular by the range of food information rules it has adopted over the years and which are discussed below.[58]

A significant part of EU activity in the field of nutrition has occurred via the EU Platform on Nutrition, Health and Physical Activity. The Platform, set up in 2005, served as a model for the EU Forum on Alcohol and Health. Its functioning is therefore identical: it is a multi-stakeholder forum which requires that each of its 34 members adopt at least one commitment to participate in the Platform's activities.[59] To facilitate the exchange of best practice between the EU and Member States the Commission also coordinates a High Level group on nutrition gathering representatives of the 28 EU Member States as

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[56] C. MacMaolain, *EU Food Law: Protecting Consumers and Health in a Common Market* (Hart Publishing, 2007), at 223 and 224.

[57] COM(2007) 279 final.

[58] See in particular Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18, and Regulation 1924/2006 on nutrition and health claims made on foods, [2006] OJ 2006 L 404/9, as amended.

[59] http://ec.europa.eu/health/nutrition_physical_activity/platform/index_en.

well as Norway and Switzerland.[60] The High Level group and the Platform meet together regularly to improve the coordination of their activities.[61]

2.2.4 What next?

The EU is in the process of agreeing its third public health programme. In November 2011 the Commission published a legislative proposal for a new 'Health for Growth' programme. The programme, which will run from 2014 to 2020, is intended to build on the achievements of the previous public health programmes.[62] In particular, its third objective is to identify, disseminate and promote the up-take of validated best practices for cost-effective prevention measures by addressing the key risk factors, namely smoking, alcohol abuse and obesity, as well as HIV/AIDS, with a focus on the cross-border dimension, in order to prevent diseases and promote good health.[63] Thus, the programme

> will support European cooperation and networking on preventing chronic diseases, including guidelines on quality cancer screening. Actions under this objective will also support measures which have as their direct objective the protection of public health regarding tobacco products and advertisement required by or contributing to the objectives of EU legislation in this field[64] [and] will focus on promoting good health and preventing diseases at EU level by helping and complementing Member States' efforts to increase their citizens' number of healthy life years.[65]

Finally, the proposed programme recognizes that promoting good health at EU level is an integral part of the 'Europe 2020: A European Strategy for

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[60] http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm.

[61] On the EU's nutrition policy, see PHEIAC, "Evaluation of the Implementation of the Strategy for Europe on Nutrition, Overweight and Obesity Related Health Issues", for DG Sanco, EU Commission, 29 April 2013 (but released in July 2013): http://ec.europa.eu/health/nutrition_physical_activity/key_documents/index_en.htm#anchor0

[62] COM(2011) 709 final.

[63] Point 2.3 of the Explanatory Memorandum (at 6), as reflected in Recital 10 of the Proposal: "Chronic diseases are responsible for over 80% of premature mortality in the EU. By identifying, disseminating and promoting the up-take of validated best practices for cost-effective prevention measures focused on the key risk factors, namely smoking, abuse of alcohol and obesity, as well as on HIV/AIDS, the Programme will contribute to prevent diseases and promote good health, also bearing in mind underlying factors of a social and environmental nature."

[64] Point 2.3 of the Explanatory Memorandum (at 7).

[65] Point 3.2 of the Explanatory Memorandum (at 8).

Smart, Sustainable and Inclusive Growth'[66,67], thus reinforcing the economic and social case for an EU intervention to prevent and control NCDs across the Member States.

[66] Communication from the Commission, COM(2010) 2020 final.
[67] Recital 2 of the Proposal.

3 The role of EU law in promoting healthier lifestyles

3.1 Law as a source of opportunities

Despite the proliferation of health rights in recent years – both at the international and domestic level – the role that law may play in promoting healthier lifestyles remains largely unexplored and often untested. The value of legal intervention and its inherent potential in stimulating progressive change either through the regulatory process or through litigation appears considerable, however. In particular, as illustrated by the faith shown in it by the UN Political Declaration on NCDs, law is expected to provide solutions to the most pressing global health challenges, such as those raised by the rapid growth of NCDs. While the law's ability to change those individual behaviours that lie behind the main risk factors of NCDs is questioned,[68] there remains great faith in its role as health promoter. At a time in which it is becoming clear that law's contribution to global health law cannot only be about the creation of individually enforceable rights and their enforcement through litigation before law courts,[69] public health regulation promises, through a set of innovative legal tools, to be capable of contributing to addressing the challenges posed by the rapid growth of NCDs at both individual and population levels.

3.1.1 Key strategies: a taxonomy and analysis of EU policies

The EU experience illustrates – in line with the WHO NCD strategies and UN Political Declaration – that different mechanisms could be used as a basis for the development of policies intended to promote healthier lifestyles and tackle the challenges raised by the most common risk factors. This part of our report aims to provide a taxonomy of the different types of strategies and interventions available to competent public authorities in both the prevention and control of NCDs. However, readers must bear in mind that their use must be contextualized within the multi-sectoral, multi-level and multi-stakeholder dimensions that characterize effective lifestyle policies. Moreover, some policy interventions may fall simultaneously under more than one of these categories.

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[68] See, e.g., W.A. Bogart, *Permit but Discourage – Regulating Excessive Consumption* (OUP, 2011); Sulkunen, *The Saturated Society – Governing Risk and Lifestyles in Consumer Culture* (Sage, 2009); and M. Valverde, *Diseases of the Will – Alcohol and the Dilemmas of Freedom* (CUP, 1998).

[69] B. Thomas and L. Gostin, "Tackling the Global NCD Crisis: Innovations in Law & Governance", 41 *Journal of Law, Medicine & Ethics* (2013), 16.

The tool-box that the EU has at its disposal to prevent and control NCDs consists of a set of policy interventions that broadly fall within eight main categories[70]:

a) disclosure requirements and information schemes
b) regulation of marketing
c) measures affecting product availability
d) economic instruments: subsidies and fiscal measures
e) fundamental rights
f) performance-based regulation
g) self-regulation
h) supportive policies: education campaigns, research and monitoring schemes

All these interventions share the common objective of promoting healthier lifestyles by reducing exposure to a given risk factor. However, each one of them is characterized by different features, responding to a different rationale and, inevitably, may produce a range of unintended consequences.[71] The following sections briefly present each category of lifestyle policy interventions; in particular, it illustrates their main features, rationales and unintended consequences, whilst discussing how EU institutions have used them to promote healthier lifestyles.

In the light of the above, we will discuss the different key strategies, from the least intrusive, such as information schemes, to more direct, 'command-and-control' interventions, such as the imposition of marketing restrictions and fiscal measures. We will then discuss alternative approaches such as the use of fundamental rights, performance-based regulations and self-regulation. Finally, we will stress that regulatory measures must co-exist with other types of intervention, not least education campaigns and research programmes, if their effectiveness is to be maximized, and that, to evaluate the implementation and effectiveness of each policy intervention there is a need for the establishment of monitoring schemes.

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[70] One may also include civil liability schemes (tort law) supporting the regulatory framework in place and its effective enforcement. On the role that tobacco litigation has played in the EU, see GHK, *Study on Liability and the Health Costs of Smoking,* first published in 2009 and updated in 2012: http://ec.europa.eu/health/tobacco/docs/tobacco_liability_final_en.pdf.

[71] This is all the more so as each category encompasses numerous policy options and institutional designs to achieve their declared objectives.

a) Disclosure requirements and information schemes

Due to the information asymmetries typical of credence goods, consumers often make poor product choices because they lack clear and comprehensible information. Disclosure requirements and information schemes are a very common method of regulation to address this concern. They provide consumers with information that industry operators would not otherwise have given them so that they can both protect themselves and police the market.[72] As regards lifestyle risks, these requirements generally boil down to information schemes, applying to labelling and other accompanying material, including modern technology tools, verbal or symbolic communication, that aim to convey information enabling consumers to make an informed choice about their consumption behaviour.

Policymakers perceive mandatory information disclosure as cheaper, easier to enforce, and overall less restrictive than many other regulatory interventions.[73] In the area of lifestyle regulation more specifically, information schemes purport to respect the basic autonomy of consumers by empowering them to make healthier choices, thus placing the ultimate decision on what to consume and what not to consume in their own hands. Moreover, disclosure requirements are more palatable to industry operators as they are less restrictive than many other conventional command-and-control tools: operators are not prevented from placing certain items on the market (provided they are safe); rather, they are merely requested to disclose certain of their properties. In the long term, they may lead to the establishment of a market where consumers reward companies for good practices and penalize them for bad ones, on the basis of the lifestyle information provided to them. This explains why the EU has historically favoured information disclosure over other forms of regulatory interventions, as illustrated by the emphasis it has placed on the 'information paradigm' and 'consumer empowerment' as a primary tool of consumer protection.[74]

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[72] See, e.g., O. Ben-Shahar and C.E. Schneider, "The Failure of Mandated Disclosure", 159 *University of Pennsylvania Law Review* (2011), 647.

[73] The fact that disclosure is a less restrictive alternative to other regulatory measures is a recurring theme in EU free movement law, as illustrated by the seminal decision *Cassis de Dijon* ruling of the Court: Case 120/78 *Rewe-Zentrale AG v Bundesmonopolverwaltung fur Brantwein*, [1979] ECR 649.

[74] S. Weatherill, *EU Consumer Law and Policy* (Edward Elgar, 2005), at 84, and M. Friant-Perrot and A. Garde, "From BSE to Obesity – EFSA's Growing Role in the EU's Nutrition Policy", in A. Alemanno and S. Gabbi, *New Perspectives in EU Food Law – Ten Years of European Food Safety Authority* (Ashgate, 2013, forthcoming). On consumer information, see also G. Howells, "The Potential and Limit of Consumer Empowerment by Information", 32 *Journal of Law and Society* (2005), 349.

Within the broad category of information disclosure requirements, one may distinguish two sub-categories. First, some information is intended to convey a neutral, objective message to make consumers aware of the properties of the goods they are about to purchase. For example, since 1979, the EU has required that a range of specified particulars be listed on food labels, including the ingredients, the use by date, any storage conditions etc.[75] More recently and after years of debate, the disclosure requirements have been extended to include a nutrition declaration informing consumers of the energy and nutrients content of foods. While falling short of requiring a 'front-of-the pack' display, the EU Food Information Regulation also requires that the information be legible and presented per 100 ml or per 100 g.[76] These changes are intended to ensure that the information provided to consumers is both sufficient and clearly presented and therefore better able to facilitate healthier diets.[77]

Second, other information conveys a negative message that is intended not only to create the relevant state of awareness of consumers but also to steer them away from a particular product or behaviour. Given the prominent role played by the appearance, imagery and general packaging of products, policymakers are increasingly determined to reduce the ability of manufacturers to market their products as they wish. In particular, as regulators have become belatedly aware of the power of marketing to induce consumer choices, they are ready to offset those marketing techniques, used since the 1960s, that are increasingly used to market not only tobacco and alcohol but also HFSS food. As will be discussed below, this may occur via multiple forms of intervention: mandatory information in the 'principal field of vision' (also called 'front of pack') to reach the average consumer, mandatory graphic and/or pictorial warnings, and other constraints imposed on the industry's ability to present its products. This is why, for example, the EU requires that health warnings are affixed to tobacco products, mandating not only the text of the warnings in question but also how they should appear on the packaging to ensure that they act as an effective deterrent for existing and potential

[75] Article 3 of Directive 79/112 on the labelling, presentation and advertising of foodstuffs for sale to consumers, OJ 1979 L 33/1, as subsequently amended.

[76] Articles 9(1)(l) and 29 to 35 of Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[77] Similarly, beverages containing more than 1.2% by volume of alcohol must clearly state their alcohol content: see Article 9(1)(k) of Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18, which repeals Commission Directive 87/250, OJ 1987 L 113/57. As far as tobacco products are concerned, they must indicate the tar, nicotine and carbon monoxide yields on their labels: see Article 5(1) of Directive 2001/37 on tobacco products, OJ 2001 L 194/26.

consumers.[78] Other jurisdictions are currently considering mandating similar graphic warnings, such as 'STOP' and 'high in…' labels, on other categories of products, such as HFSS food products. In the food sector, Chile recently proposed an amendment to its Food Health Regulation[79] which would place a 'skull-and-bones'-style label on the front-of-pack of any products considered as high in sugar, salt, calories and saturated fat.[80] Such labels, by conveying a negative message that is intended not only to create the relevant state of awareness of consumers but also to steer them away from the product, clearly falls under the second category of information schemes.

These two distinct categories of compulsory information schemes (positive and negative) tend to be both 'libertarian', in the sense that individuals are technically free to decide whether or not to engage in the kind of behaviour they are intended to warn against, and 'paternalistic', in the sense that they seek to steer the same individuals into a direction that it is deemed desirable by the policymaker (i.e. not smoking, not drinking in excess and eating healthily).

However, although both typologies of disclosure requirements are ubiquitous, they remain somewhat controversial. Many criticize information disclosure as ineffective in achieving its declared goal of making consumers capable of protecting themselves when making individual choices. To support their

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[78] Article 5(2) of Directive 2001/37 on tobacco products, OJ 2001 L 194/26. Each unit packet of tobacco products must carry both a general warning ('Smoking kills', 'Smoking can kill' or 'Smoking seriously harms you and others around you') and an additional warning taken from the list of 14 warnings set out in Annex I (e.g. 'Smoking causes fatal lung cancer', 'Smoking when pregnant harms your baby', 'Smoking is highly addictive, don't start'). Both general and additional warnings must rotate in order to guarantee their regular appearance and they must be printed in accordance with a range of harmonized size, legibility and positioning requirements (Article 5(5) and (6)).

[79] The Draft Amendment to the Sanitary Regulation on Food has been presented for an internal public consultation at the beginning of January 2013 with a deadline of 3 March 2013. In parallel, the authorities of Chile prepared a WTO notification that was circulated to the WTO members on 16 January 2013 (G/TBT/N/CHL/219). The Draft Amendment and other implementing measures are due to come into force within a year from the adoption of the Law, i.e. in less than six months from the time of writing. The text of the Draft Amendment is available at http://www.minsal.gob.cl/portal/url/page/minsalcl/ g_proteccion/g_alimentos/ prot_alim_y_nutr.html.

[80] The requirement applies to all food products that contain more sodium, total sugars or saturated fat per portion than the thresholds specified in the proposal. For products such as milk, cheese, fish and seafood, rice, pastas and stuffed pastas, meat products, dehydrated soups and broths, margarine and butter, breakfast cereals, confectionery, chocolate, biscuits, snacks and ice-cream, the Draft foresees specific, more stringent limits of those nutrients that will trigger the mandatory labelling by means of the STOP sign. The calculation whether the sign is mandatory for a given product will depend on the size of a portion, which needs to be defined in a separate implementing act.

claim, they rely on mounting evidence suggesting that few individuals read the information provided to them and even fewer actually process this information.[81] Others suggest that, even assuming that information schemes reach their addressees, there may be several factors explaining why they cannot effectively achieve their intended objective of promoting healthier lifestyles. First, as the public is made up of a heterogeneous group of individuals, there might be differences in understanding.[82] Second, the assumption that individuals are able to base their decisions on the information provided to them is increasingly being questioned today, due to cognitive limitations.[83]

It is against this backdrop that the EU is rapidly embracing the adoption of simplified information schemes, such as affixing pictorial warnings on tobacco products or front-of-pack labelling on foodstuffs.[84] In particular, the proposal for a new directive replacing the existing directive on tobacco products, which the Commission published on 19 December 2012,[85] combines a textual warning with a corresponding coloured photograph, thus making pictorial warnings on tobacco products compulsory (as opposed to optional as they have been since 2001) and the health message conveyed to consumers more effective.[86] Similarly, the Commission, as part of its proposed Food Information Regulation, that the front-of-pack labelling of packaged food should become mandatory in order to facilitate healthier choices 'at a glance', i.e. without requiring the consumer to engage in a thorough reading of the nutrition table on the back of the pack. However, this proposal did not make its way through the legislative process, and the Food Information Regulation as adopted in 2011 merely allows Member States to recommend a front-of-pack labelling scheme on a voluntary basis. This is what the UK has recently done with the agreement struck between the public health ministry and major

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[81] See, e.g., S. Schwarcz, "Rethinking the Disclosure Paradigm in a World of Complexity", *University of Illinois Law Review* (2004), 1.

[82] W.M. Sage, "Regulating through Information: Disclosure Laws and American Health Care", 9 *Columbia Law Review* (1999), 1701.

[83] See, e.g., C. Jolls and C. Sunstein, "Debiasing through Law", 35 *Journal of Legal Studies* (2006), 199; and D. Ariely, *Predictably Irrational* (Harper Perennial, 2009).

[84] See Article 34 of Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[85] The Commission published a proposal for a revised Tobacco Products Directive in December 2012: "Proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products", COM(2012) 788 final.

[86] Article 9 of the Commission's Proposal, COM(2012) 788 final. For more information on the revision of Directive 2001/37, including the impact assessment and relevant independent studies carried out for the Commission, see http://ec.europa.eu/health/tobacco/products/revision/index_en.htm. See also A. Alemanno, "Out of Sight, Out of Mind – Towards a New EU Tobacco Products Directive", *18 Columbia Journal of European Law* (2012), 197.

retailers that food labels should combine traffic-light labels with 'reference intakes'.[87] The idea behind the use of red, amber and green is 'to guide the traffic' towards healthier choices and increase accessibility to nutritional information of a wide range of consumers, and assist them in making healthier food choices 'at a glance'. Moreover, traffic-light labels may provide an incentive for manufacturers to develop healthier products – by reformulating their composition – thus avoiding the stigma which may be association with having four prominent red lights on the front of their packaging.

It is standardized packaging that emerges today as one of the most promising, yet controversial, forms of policy intervention aimed at tackling the growing consumption of unhealthy products by changing the environment (often defined as alcoholgenic, obesogenic or tobaccogenic) within which they are marketed. Contrary to conventional wisdom, standardized packaging does not necessarily equate to 'plain packaging', i.e. a pack stripped of all logos, colours, brand images, and promotional elements but rather maintaining the brand name displayed in a mandated size, font, and place.[88] Plain packaging (also referred to as 'generic') represents only one of the possible forms, yet the most orthodox, of package standardization currently in existence. Standardizing the pack is therefore a matter of degree. 'Plain packaging' represents the most extreme form of package standardization, as manufacturers are deprived of any freedom to decide how to present their products as to their shape, size and features related to the their presentation. Other less intrusive forms of standardization have also long been in existence. Thus, any attempt at limiting the freedom to design a package through the imposition of some presentation standards, e.g. given size, shape and provision of information, automatically translates into a form of pack standardization.

As previously illustrated, while information schemes have existed for a long time – as they aim to overcome the information asymmetries typical of credence products – the focus of these more recent forms of regulatory interventions focusing on the pack is now shifting to another policy goal: that of limiting the consumption of those products that – due to their constituents and effects – have been identified as unhealthy.

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[87] On the UK scheme, see http://www.nhs.uk/Livewell/Goodfood/Pages/food-labelling.aspx. On 19 June 2013, the Department of Public Health published guidance on front-of-pack labelling: https://www.gov.uk/government/publications/front-of-pack-nutrition-labelling-guidance.

[88] For an overview of the features of generic packaging see B. Freeman, S. Chapman and M. Rimmer, "The Case for the Plain Packaging of Tobacco Products", 103(4) *Addiction* (2007), 580; A. Alemanno and E. Bonadio, "The Case of Plain Packaging for Cigarettes", 1(3) *European Journal of Risk Regulation* (2010), 268.

The rationale underpinning all forms of package standardization is to reduce the attractiveness of the relevant products, first, by conveying negative information (e.g. quantity of critical nutrients, property of product constituents etc.) about the products available to consumers and, second, by reducing the ability of manufacturers to design and present them as they wish. These measures rely on the assumption that, given the proven association between marketing efforts and growing consumption, the introduction of standardized forms of packaging may somehow lower the prevalence of the consumption of the relevant product at either the population or individual level or both.[89]

Historically, while these forms of intervention were first introduced in tobacco control – and were enshrined in the FCTC – nowadays they are increasingly extended to alcohol and unhealthy products. The FCTC, read in conjunction with the Guidelines for Implementation of Article 11 and Article 13 of the FCTC,[90] presents plain packaging as well as mandatory health warnings as carrying the potential to eliminate the effect of advertising and promotion on packaging.[91] In essence, plain packaging aims at standardizing the appearance of all cigarette boxes in order to make them unappealing, especially for adolescents, thus reducing the prevalence and up-take of smoking.[92] Some evidence shows that this innovative way of marketing tobacco products is likely to reduce tobacco consumption.[93] In particular, studies show that plain packaging could attain such a result in two indirect, yet related, ways.[94] It not only contributes to make cigarettes look less attractive, but it also makes

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[89] See, e.g., D. Kenkel and L. Chen, "Consumer Information and Tobacco Use", in Jha and F. Chaloupka (eds), *Tobacco Control in Developing Countries, World Bank and World Health Organization* (OUP, 2000), 177-214; G. Ferris Wayne and G.N. Connolly, "How Cigarette Design Can Affect Youth Initiation into Smoking: Camel Cigarettes 1983–93", 11(1) *Tobacco Control* (2002), 32.

[90] WHO Framework Convention on Tobacco Control Working Group [hereinafter FCTC Working Group], *Guidelines for Implementation of Article 11 of the WHO Framework Convention on Tobacco Control,* 46 (Nov. 2008); WHO FCTC Working Group, *Guidelines for Implementation of Article 13 of the WHO Framework Convention on Tobacco Control,* 16 (November 2008).

[91] See M. Gershman, "Packaging: Positioning Tool of the 1980s", 76 *Management Review* (1987), 33 (on packaging as a form of advertisement); M. Wakefield et al., "The Cigarette Pack as Image: New Evidence from Tobacco Industry Documents", 11 *Tobacco Control* (2002), 73 (on tobacco packaging).

[92] B. McGrady, "TRIPS and Trademarks: The Case of Tobacco", 3 *World Trade Review* (2004), 57 and 66-67; B. Freeman, S. Chapman and M. Rimmer, "The Case for the Plain Packaging of Tobacco Products", 103(4) *Addiction* (2007), 587 (providing an overview of the features of generic packaging), at 581–82.

[93] *Ibid.,* at 583 (reporting that plain packaging would reduce tobacco consumption for non-smokers).

[94] *Ibid.,* at 582-83.

health warnings and information more visible.[95] These studies claim that generic packaging, by increasing the effectiveness of health warnings and reducing misconceptions about the risks of smoking, might carry the potential to reduce smoking up-take, especially among children and young people, and accordingly protect human health.[96] In particular, plain packaging is expected to play a valuable role in product perceptions and smoking initiation, effectively breaking the shift from experimentation to regular use.[97]

While 'plain packaging' has been adopted only by Australia in 2012 and mandatory warnings across dozens of countries in the words on cigarette products, several EU Member States, such as Belgium,[98] France,[99] the United Kingdom[100] and Ireland[101] are currently debating over the opportunity to introduce 'plain packaging', and other forms of standardized packaging, such as 'traffic light' nutritional labelling, in their own legal orders. In particular,

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[95] *Ibid.*

[96] *Ibid.* See TNS Opinion & Social, Directorate Gen. Communication, European Commission, "Eurobarometer Special", *Tobacco* 83 (May 2010), http://ec.europa.eu/health/tobacco/docs/ebs332_en.pdf (finding that smokers who believe some types of cigarettes are less risky for health focus on tar and nicotine levels, taste, terms in the brand's name and colour of the packs). See also G. Hastings, K. Gallopel-Morvan and J. Miguel Rey, "The Plain Truth about Tobacco Packaging", 17 *Tobacco Control* (2008), 361 (noting that tobacco is addictive and risky but, unlike drugs, does not provide any objective benefit).

[97] See G. Ferris Wayne and G.N. Connolly, "How Cigarette Design Can Affect Youth Initiation into Smoking: Camel Cigarettes 1983–93", 11(1) *Tobacco Control* (2002), 32 (discussing the paradigm which plain packaging may eventually change).

[98] On 19 January 2010, Belgium's Health Minister, in response to a question in the Belgian Parliament, expressed support for plain packaging, including at EU level. See 19-20 of the following (in French, and in Dutch): http://www.dekamer.be/doc/CCRA/pdf/53/ac096.pdf. See also the legislative proposal by MP Catherine Fonck (CDH) on standardized packaging, 3 May 2011, available (in French and Dutch) at http://www.lachambre.be/FLWB/PDF/53/1424/53K1424001.pdf. The debate is on-going in front of the Parliamentary Committee on Public Health.

[99] On 7 December 2010, Yves Bur, a member of France's National Assembly and a long-time tobacco control champion, introduced in the National Assembly Bill No. 3005, Bill aiming to establish plain and standardized packaging for cigarettes (Proposition de loi visant à l'instauration d'un paquet de cigarettes neutre et standardisé). The bill outlines some of the specifications of plain packaging, and the bill authorizes the Minister of Health to define remaining specifications. The bill and introductory statement from Yves Bur (in French) can be seen here: http://www.assemblee-nationale.fr/13/dossiers/paquet_cigarettes_neutre.asp.

[100] On 9 March 2011 the British Government released a new tobacco control plan "Healthy Lives, Healthy People: A Tobacco Control Plan for England". See: http://www.dh.gov.uk / en/MediaCentre/Pressreleases/DH_124966. Moreover, the UK has promoted the adoption of voluntary traffic light nutrition information labelling by issuing guidance to help businesses design front-of-pack labelling for their products. See http://www.food.gov.uk/multimedia/pdfs/frontofpackguidance2.pdf.

[101] On 28 May 2013 the Irish government announced its decision to follow Australia in introducing legislation requiring cigarettes to be in standardized packs, with a view to enforcement in 2014.

we witness today some early attempts at implementing standardized requirements on the packaging of alcohol and HFSS food. Although in the alcoholic beverages sector neither warning labels nor consumer-information measures are very common, some countries are considering adopting some forms of standardized packaging. Since the notification by Thailand to the TBT Committee of its proposal for combined graphic and pictorial warnings to be affixed on alcohol products,[102] it has appeared that imposing labelling requirement on alcoholic beverages may be more controversial than doing so on tobacco products.

These warnings, either mandated by governments or provided voluntarily by alcohol producers in a number of countries, tend to take the form of reminders about general health risks associated with alcohol consumption, the health risks associated with drinking during pregnancy, and the dangers of drinking whilst driving or operating machinery. Labels may also include additional information, such as reference to official drinking guidelines and information on alcohol units or standard drinks. According to the International Center for Alcohol Policies (ICAP),[103] while today there are around 20 countries mandating some forms of health warnings, only Thailand envisages to introduce mandatory warnings combining pictorial and textual warnings.

b) Regulation of marketing

The information paradigm extends beyond the regulation of compulsory information to cover the information that industry operators provide to consumers voluntarily as part of their marketing strategies. Thus, for instance, the Food Information to Consumers Regulation covers both mandatory and voluntary information[104].

If consumer information must be sufficient, it must also be trustworthy. The general principle of EU law that information should not be misleading is at the very heart of Directive 2005/29 on unfair business-to-consumer commercial practices.[105] The provisions of this framework directive, which applies in the absence of more specific provisions, have been tailored to tobacco control and food law. Thus, Directive 2001/37 on tobacco products prohibits the use of certain texts, such as 'low-tar', 'light', 'ultra-light', 'mild', names,

[102] *Thailand – Health Warnings for Alcoholic Beverages* – G/TBT/N/THA/332 and Add.1 – concern of US – 11.

[103] http://www.icap.org/table/HealthWarningLabels.

[104] See Article 36 of Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[105] OJ 2005 L 149/22. It was also underlying the provisions of its predecessor, Directive 84/450 on misleading advertising, OJ 1984 L 250/17.

pictures and figurative or other signs likely to mislead the consumer into the belief that such products are less harmful and give rise to changes in consumption.[106] Similarly, Regulation 178/2002 on food safety provides as a general principle of EU food law that food information shall not be misleading.[107] The scope of the notion of misleading food information has been further defined in Regulation 1924/2006 on nutrition and health claims made on foods[108] and in Regulation 1169/2011 on the provision of food information to consumers.[109]

Moreover, in light of the relationship between the marketing of a product and its increased consumption, certain measures have been adopted which go beyond the regulation of the information provided to consumers and restrict – sometimes even ban – the provision of commercial information to consumers. This is intended to limit the incentives that they may have to adopt unhealthy lifestyles. The FCTC, which is based on the best available evidence, identifies marketing restrictions as part of the package of measures required to reduce the demand for tobacco. Consequently, Article 13 provides that its Parties – including the EU and its 28 Member States – should 'recognize that a comprehensive ban on advertising, promotion and sponsorship would reduce the consumption of tobacco products' and 'in accordance with its constitution or constitutional principles, undertake a comprehensive ban of all tobacco advertising, promotion and sponsorship', including 'a comprehensive ban on cross-border advertising, promotion and sponsorship originating from its territory'.[110] This was further reiterated at the third session of the Conference of the Parties in November 2008 where it adopted guidelines for the implementation of Article 13.[111] Similarly, independent recent research findings have established that television advertising leads to an increase in consumption not only of the product of a given brand, but also of all the products of the category in question. In other words, not only will children prefer Coca-Cola to Pepsi if they see an advertisement for the former, but they will also increase their consumption of fizzy sugary drinks to the detriment of

[106] Article 7 and Recital 27 of the Preamble of Directive 2001/37, OJ 2001 L 194/26.

[107] Articles 8 and 16 of Regulation 178/2002, OJ 2002 L 31/1.

[108] OJ 2007 L 12/3. In particular, nutrition and health claims may only be made on food if they have been authorized and provided that the conditions for their use are duly respected.

[109] OJ 2011 L 304/18.

[110] Article 13 FCTC. Article 1(c) FCTC defines 'tobacco advertising and promotion' broadly to mean 'any form of commercial communication, recommendation or action with the aim, effect or likely effect of promoting a tobacco product or tobacco use either directly or indirectly'.

[111] Decision FCTC/COP3(12). An updated version was published in 2013: http://www.who.int/iris/bitstream/10665/80510/1/9789241505185_eng.pdf.

other categories of drinks such as water, milk or fruit juices.[112] This research constituted the basis for Resolution WHA63.14 of May 2010, in which the Sixty-third World Health Assembly approved a set of WHO recommendations on the marketing of food to children calling for a ban on all HFSS food marketing to children.[113] Similarly, the WHO Global strategy to reduce the harmful effects of alcohol, also endorsed by the Sixty-third World Health Assembly in May 2010, has recognized the growing evidence linking the marketing of alcoholic beverages with their excessive consumption and the increased probability of developing an NCD.[114] As the Science Group[115] of the European Alcohol and Health Forum noted, there is 'consistent evidence to demonstrate an impact of alcohol advertising on the uptake of drinking among non-drinking young people'.[116] These research findings, which establish that marketing for tobacco, alcoholic beverages and HFSS food negatively influences choices, preferences, consumption and behaviour, have led the EU to consider marketing restrictions as part of its regulatory 'tool-box'.

Marketing restrictions generally consist of limitations to the advertising and other forms of promotion (including sponsorship, merchandizing and product placement) of certain products. These restrictions generally translate into restrictions to the ability of economic operators to promote and market their

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[112] G. Hastings et al., "The Extent, Nature and Effects of Food Promotion to Children: A Review of the Evidence to December 2008", WHO, 2009, available at http://www.who.int/dietphysicalactivity/Evidence_Update_2009.pdf.

[113] The Recommendations, the Framework Implementation Report interpreting their provisions (2012) are available at http://www.who.int/dietphysicalactivity/marketing-food-to-children/en/index.html.

[114] Resolution WHA 63.13 notes that 'reducing the impact of marketing, particularly on young people and adolescents, is an important consideration in reducing harmful use of alcohol': WHO, "Global Strategy To Reduce the Harmful Use of Alcohol", 2010, http://www.who.int/substance_abuse/alcstratenglishfinal.pdf.

[115] An advisory group composed of independent experts on alcohol policy. The list of members is available at http://ec.europa.eu/health/alcohol/docs/science_list_2010_en.pdf.

[116] Science Group of the European Alcohol and Health Forum, "Does Marketing Communication Impact on the Volume and Patterns of Consumption of Alcoholic Beverages, Especially by Young People? – A Review of Longitudinal Studies", 2009, available at http://ec.europa.eu/health/ph_determinants/life_style/alcohol/Forum/docs/science_o01_en.pdf.
On the relationship between alcohol marketing and public health, see also: L. Smith and D. Foxcroft, "The Effect of Alcohol Advertising, Marketing and Portrayal on Drinking Behaviour in Young People: Systematic Review of Prospective Cohort Studies", 9 *BMC Public Health* (2009), 51; Meier, "Independent Review of the Effects of Alcohol Pricing and Promotion: Part A: Systematic Reviews", 2008, available at http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/documents/digitalasset/dh_091383.pdf; M. Morgenstern et al., "Exposure to Alcohol Advertising and Teen Drinking", 52 *Preventative Medicine* (2011), 146.

products either to the general public or to particularly vulnerable segments of the population, not least children.[117]

The EU first adopted marketing restrictions in Directive 89/552 on the free movement of broadcasting services which banned the advertising of tobacco products on television.[118] Directive 2003/33 on tobacco advertising and sponsorship subsequently extended this ban to all forms of tobacco advertising and sponsorship affecting the internal market.[119] As discussed below, this measure proved highly controversial and was (unsuccessfully) challenged before the CJEU as violating the principles of attributed power, subsidiarity and proportionality, as well as the freedom of (commercial) expression.[120] A few years later, as part of the discussions which led to the revision of Directive 89/552, Directive 2010/13 on AVMS completed the picture by banning all forms audiovisual commercial communications falling within its scope (including product placement).[121]

The AVMS Directive also contains provisions on the marketing of alcoholic beverages and HFSS food. However, these provisions are much less interventionist than the provisions on the marketing of tobacco products. First, they do not ban the marketing of either alcoholic beverages or HFSS food; rather, they identify certain specific practices which should not be permitted because of their effects. In particular, the AVMS Directive contains provisions specifically designed to protect children because they are more vulnerable to marketing than adults. Thus, Article 9(1)(e) requires that audiovisual media communications for alcoholic beverages 'shall not be aimed specifically at minors and shall not encourage immoderate consumption of such beverages'. This wording suggests that despite the mounting evidence on the relationship between alcohol marketing and children's drinking habits, Article 9(1)(e) does not prohibit audiovisual media commercial communications for alcoholic beverages from being shown to children.[122] The requirement is that they must not *specifically* be aimed at children. Thus, 'advertisements for such products could be broadcast right before, after or during children's

[117] A. Garde, "Advertising Regulation and the Protection of Children-Consumers in the European Union: In the Best Interest of… Commercial Operators?", 19 *International Journal of Children's Rights* (2011), 523.

[118] OJ 1989 L 298/23. See Article 13.

[119] OJ 2003 L 152/16.

[120] OJ 2003 L 152/16.

[121] OJ 2010 L 95/1. See in particular: Article 9(1)(d) on audiovisual commercial communications in general; Article 10(2) on sponsorship; and Article 11(4)(a) on product placement.

[122] We have referred to 'children', even though the AVMS Directive refers to 'minors' in relation to alcohol marketing and 'children' in relation to food marketing. Neither of these terms is defined in the Directive itself and the age of majority varies between Member States.

programmes without being considered as specifically aimed at minors', notwithstanding the fact that they would reach a large number of children.[123] More generally, Article 9(1)(g) requires that 'audiovisual commercial communications shall not cause physical or moral detriment to minors. Therefore they shall not directly exhort minors to buy or hire a product or service by exploiting their inexperience or credulity, directly encourage them to persuade their parents or others to purchase the goods or services being advertised, exploit the special trust minors place in parents, teachers or other persons, or unreasonably show minors in dangerous situations'. Here again, the wording of this provision leaves no scope for doubt: only 'direct' (as opposed to indirect) exhortations are caught.[124] However, as the Commission itself has acknowledged, 'it does appear that advertising techniques geared towards minors are frequently used in television advertising'.[125]

Second, the EU has stated on several occasions that the relevant industries have an important role to play in limiting the marketing of alcoholic beverages and HFSS food to children, thus expressing a preference for self-regulation of such marketing over the adoption of legally binding norms as in relation to tobacco products. Thus, Article 9(2), which was specifically adopted to respond to childhood obesity concerns, provides that 'Member States and the Commission shall encourage media service providers to develop codes of conduct regarding inappropriate audiovisual commercial communication, accompanying or included in children's programmes, of [HFSS food]'. Although it is welcome that Article 9(2) recognizes the negative influence of HFSS food marketing on children's dietary choices, its scope remains strictly circumscribed and one may doubt how effective this provision may ever be First, the wording of Article 9(2) is unclear, and the phrase 'inappropriate audiovisual commercial communication' seems to leave the food industry with an important margin of discretion. Second, Article 9(2) only requires Member States and the Commission to 'encourage' media service providers to develop codes of conduct on the marketing of HFSS food to children.[126] There is no duty to ensure either that such codes are adopted or that they are effective in limiting HFSS food marketing to children. Third, Article 9(2)

[123] O. Castendyk, E.J. Dommering and A. Scheuer, *European Media Law* (Kluwer Law International, 2008), 600.

[124] For a critical assessment of this provision, see A. Garde, "Advertising Regulation and the Protection of Children-Consumers in the European Union: In the Best Interest of… Commercial Operators?", 19 *International Journal of Children's Rights* (2011), 523.

[125] European Commission, "Audiovisual Media Services and Connected Devices: Past and Future Perspectives", COM(2012) 203 final, 8.

[126] For a review of the measures (regulatory and self-regulatory) adopted by different EU countries, see WHO Europe, *Marketing of Foods High in Fat, Salt and Sugar to Children: Update 2012-2013*, Copenhagen, 2013.

only requires that media service providers limit HFSS food marketing 'accompanying or included in children's programming'. As stated above, however, the AVMS Directive does not define what constitutes 'children's programming'. Consequently, the EU Pledge, the main self-regulatory initiative which several major food operators (not all of them) have adopted to comply with Article 9(2), only applies when at least 35% of the audience is made up of children aged under 12 years.[127] This percentage, which has been lowered from 50%, remains extremely high and will leave a range of programmes popular with children outside the scope of the food industry's commitment. Similarly, Article 9(2) does not define the group of children to be protected. The EU Pledge applies a threshold of 12 years of age. If it is generally accepted that children cannot fully grasp the commercial intent of advertising until the age of 11 or 12 and that children below 12 years of age must be protected, this does not mean that children who are 12 years or older are unaffected by HFSS food marketing. Older children also respond to the persuasive intent of advertising.[128] More needs to be done. The Commission itself has stated that it will 'support the development of stricter age and audience thresholds for advertising and marketing and more consistent nutritional benchmarks across companies'.[129] If this statement does not resolve the issue,[130] it goes some way towards acknowledging that the approach adopted to date has failed adequately to protect children from the harmful effects of HFSS food marketing on their health. Similar remarks apply to the commitments made by operators in the alcoholic beverages industry as part of their EU Forum on Alcohol and Health commitments.[131] More fundamentally, and as discussed below, self-regulation is unlikely to deliver the results expected from it in relation to

[127] http://www.eu-pledge.eu/.

[128] WHO, "A Framework for Implementing the Set of Recommendations on the Marketing of Foods and Non-Alcoholic Beverages to Children" (2012), available at http://www.who.int/dietphysicalactivity/framework_marketing_food_to_children/en/, 21.

[129] European Commission, "Audiovisual Media Services and Connected Devices: Past and Future Perspectives", COM(2012) 203 final, 9. The EU Pledge does not lay down uniform nutrition criteria, allowing food operators to promote certain items that should arguably fall within the category of HFSS food. However, a consultation on this issue is in progress: http://www.eu-pledge.eu/sites/eu-pledge.eu/files/releases/EU_Pledge_Nutrition_White_Paper_Nov_2012.pdf.

[130] Determining the age is absolutely key to the debate; however this question remains unresolved to date. It is argued that it can only be addressed effectively on the basis of a careful analysis of proportionality, with which stakeholders have largely failed to engage, to date.

[131] For a more thorough review of the inherently limited contribution which self-regulation can make to limit the impact on children of HFSS food and alcoholic beverages, see O. Bartlett and A. Garde, "Time to Seize the (Red) Bull by the Horns: The EU's Failure to Protect Children from Alcohol and Unhealthy Food Marketing", *4 European Law Review* (2013), 498.

marketing restrictions. This latter directive also lays down conditions on the marketing of alcoholic beverages and unhealthy food to children.[132]

Finally, marketing restrictions include other restrictions affecting the way in which the product is sold, which are often referred to as 'selling arrangements', such as visual display bans at points of sale[133] or prohibition on vending machines.

Given the importance of promotion and advertising in developed market economies characterized by free competition, any restriction on marketing may potentially affect fair competition and, in turn, reduce consumer choice. It is indeed through promotion and other forms of marketing that consumers become aware of new products or better conditions on the market. Restricting marketing, and in particular advertising, may therefore crystallize existing consumption patterns and ossify markets.[134] It is therefore imperative to engage in a thorough proportionality assessment to determine where the balance should lie in order to ensure the proper functioning of the internal market and a high level of consumer and public health protection. This is discussed more fully below.

c) Measures affecting product availability

Measures affecting the availability of products are probably the oldest form of regulatory intervention used to tackle lifestyle-related problems. Their rationale is to reduce the availability of a given product in order to reduce its overall consumption. The classic example of regulatory intervention aimed at controlling product availability is the creation of a (retail) monopoly, entrusted with the importation of, and trade in, tobacco, alcohol or food, or the licensing and the operation of specific activities, such as gambling services.[135] Another may be offered by age-limits, which – probably due to the EU's

[132] Audiovisual commercial communications for alcoholic beverages are covered in Articles 9(1)(e) and 22; audiovisual commercial communications for unhealthy food are covered in Article 9(2). The Directive also contains more general, non-product specific provisions relating to the content and the amount of marketing allowed in AVMS.

[133] A. Alemanno, "Out of Sight, Out of Mind – Towards a New EU Tobacco Products Directive", 18 *Columbia Journal of European Law* (2012), 197.

[134] See, for example, the Opinion of AG Jacobs in Case C-412/93 *Leclerc-Siplec v TF1 Publicité* [1995] ECR I-179.

[135] Several cases have involved the compatibility with the general provisions of the EU Treaties of national monopolies in the areas of tobacco, alcohol and gambling: on tobacco, see Case 59-75 *Manghera* [1976] ECR 91 and Case C-387/93 Banchero [1995] ECR I-4663; on alcohol, see Case C-189/95 Franzén [1997] ECR I-5909 and Case C-170/04 *Rosengren* [2007] ECR I-4071, as well as the decision of the EFTA Court in Case E-6/96 *Tore Wilhelmsen* [1997] EFTA Court Report 53; and on gambling, see e.g. Joined Cases C-338/04, C-359/04 and C-360/04 Placanica [2005] ECR 01891; Case C-243/01 Gambelli [2003] ECR I-13031.

limited competence in public health – currently differ between EU Member States. Another more recent example of measures affecting product availability is offered by product reformulation, which consists of changing the formula of a given product in order to reduce the presence of one or more of its constituents. The EU has trodden rather carefully and has not legislated much in this field. Nevertheless, it has promoted the exchange of best practice and has adopted the EU Salt Reduction Framework which sets a benchmark of a minimum of 16% salt reduction over four years for all food products, across the full range of food products from premium to economy items, so that all population groups could benefit and also encompassing salt consumed in restaurants and catering.[136] As salt reduction is only one element of the broader efforts on reformulation designed to improve the nutritional quality of food, such as reducing the content of total fat, saturated fatty acids, trans fatty acids or sugars, the Commission has fostered the exchange of best practice within the High Level Group and the EU Platform on Nutrition, Health and Physical Activity. Some Member States have chosen to go beyond the implementation of these examples of best practice and have implemented regulatory restrictions on the use of certain nutrients.[137] Denmark became the first country in the world to introduce laws strictly regulating the sale of many foods containing trans fats in March 2003, thus drastically limiting the use of partially hydrogenated oils in food to a maximum of 2% of fats and oils destined for human consumption. This restriction is on the *ingredients* used rather than the final products.

Another example of restrictions imposed on products is the limits imposed on portion sizes. This measure has given rise to vivid debates in New York, where the City's Board of Health voted in September 2012 in favour of limiting serving sizes of sugary drinks sold at restaurants and other food vendors it regulates to 16 ounces, as Mayor Bloomberg had proposed.[138] No such

[136] For information on the EU Salt Campaign, see http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/nutrition_salt_en.htm. On 7 December 2012, the Commission published a survey on the actions taken by Member States to reduce the excessive salt intake across the EU: http://ec.europa.eu/health/nutrition_physical_activity/docs/salt_report1_en.pdf.

[137] For an overview of restrictive measures adopted vis-à-vis trans-fats, see http://www.news-medical.net/health/Trans-Fat-Regulation.aspx.

[138] Notice of Adoption of an Amendment (81.08) to Article 81 of the New York City Health Code, New York City Department of Health and Mental Hygiene Board of Health Websites, available at http://www.nyc.gov/html/doh/downloads/pdf/public/notice-adoption-hc-art81-08.pdf.

proposal has been considered by the EU Commission, though the issue has been debated at the EU Platform on Nutrition, Health and Physical Activity.[139] Although these measures seem *prima facie* to vary in nature, they all affect the commercial availability of a product and pursue the common objective of limiting its overall consumption.

The major unintended consequences stemming from measures restricting product availability is the risk of development of alternative distribution channels providing the product or service free of output control, leading to smuggling, counterfeiting and other forms of illicit trade. For example, the illicit trade in cigarettes is estimated to cause annual financial losses of over EUR 10 billion in the budgets of the European Union and its Member States.[140] Furthermore, from a health perspective, illicit trade undermines policy initiatives aimed at reducing the consumption of tobacco products, particularly amongst vulnerable groups such as young people and low income groups. Illicit tobacco products tend not to be produced in accordance with the requirements of EU tobacco products legislation.[141] Enforcement of existing norms and international cooperation limit this risk very significantly. In effect, in the strategy it recently published on the illicit trade of tobacco, the Commission noted that existing measures to control tobacco supply chains, either by authorities or by economic operators themselves, were largely insufficient,[142] and it has undertaken to sign, ratify and implement the Protocol of the Framework Convention on Tobacco Control[143] at EU level, and ensure compliance with its provisions as far as matters falling within EU competences are concerned.[144] Furthermore, a risk also exists that a reformulated product will no longer appeal to consumers due to a change in taste or appearance – for example, reducing salt levels in a given food may render its taste unappealing to consumers.

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[139] See for example at paragraph 5.2.2 of the 2012 Monitoring Report of EU Platform Activities, 21 September 2012, available at http://ec.europa.eu/health/nutrition_physical_activity/docs/eu_platform_2012frep_en.pdf.

[140] This estimation of the European Anti-Fraud Office (OLAF) is based on seizures reported by the Member States which amounted to 4.5–4.6 billion cigarettes per annum between 2005 and 2011.

[141] Communication from the Commission to the Council and the European Parliament, *Stepping up the Fight against Cigarette Smuggling and other Forms of Illicit Trade in Tobacco Products – A Comprehensive EU Strategy*, COM(2013) 324 final, 4.

[142] *Ibid*., 10.

[143] The FCTC Protocol to Eliminate Illicit Trade in Tobacco Products was opened for signature on 10 January 2013 and is available at: http://www.who.int/fctc/protocol/about/en/.

[144] *Ibid.*, 15.

d) Economic instruments: subsidies and fiscal measures

Despite the sophistication of marketing campaigns aimed at highlighting quality and lifestyle choices behind consumer products, price remains one of the major drivers of consumption.[145] This explains why a variety of economic instruments has appeared on the NCD prevention and control agenda.[146] These instruments allow public authorities either to promote healthy lifestyles by lowering the price of healthy commodities, and in particular healthy food such as fruit and vegetables, or to discourage unhealthy lifestyles by increasing the price of goods and services which tend to be associated with unhealthy lifestyles, such as tobacco, alcoholic beverages or HFSS food. Taxation rates may be lowered and subsidies introduced on healthy foods to increase their consumption, for example, whereas taxation rates may be increased on unhealthy goods and services to decrease their consumption.

Subsidies

Subsidies used in lifestyle policy may be defined as financial aid given to certain goods (such as healthy foods) in order to lower their price (or even make them free) to facilitate their availability and therefore encourage their consumption.

The Common Agricultural Policy (CAP) has been strongly criticized for merely paying lip service to nutrition and health concerns,[147] on the ground that it has subsidized dairy products, red meat, sugar, tobacco and wine, and that it has resulted in the systematic destruction of large quantities of healthy food such as fruit and vegetables, with damaging consequences for diets and public health.[148] These findings have not, however, gathered unanimous

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[145] In a pan-European study of determinants of food choice, the four most important factors were 'quality or freshness', 'price', 'taste' and 'trying to eat healthily': M. Lennernas et al., "Influences on Food Choice Perceived To Be Important by Nationally-Representative Samples of Adults in the European Union", 51(2) *European Journal of Clinical Nutrition* (1997), 8.

[146] The theoretical prediction underpinning excise duties according to which the induced relative price effect actually works by decreasing consumption is supported by empirical evidence: see B.S. Frey, "Excise Taxes: Economics, Politics and Psychology", in S. Cnossen (ed) *Theory and Practice of Excise Taxation: Smoking, Drinking, Gambling, Polluting, and Driving* (OUP, 2005), 230-244.

[147] See in particular L. Elinder et al., Public Health Aspects of the EU Common Agricultural Policy: *Developments and Recommendations for Change in Four Sectors: Fruit and Vegetables, Dairy, Wine and Tobacco* (Finland: National Institute of Public Health, 2005); C. Birt et al., *A CAP on Health? The Impact of the EU Common Agricultural Policy on Public Health* (London: Faculty of Public Health, 2007).

[148] It has been estimated that since the creation of the CAP hundreds of thousands of premature deaths could be linked to the adverse effects of CAP subsidies: C. Birt et al., *A CAP on Health? The Impact of the EU Common Agricultural Policy on Public Health* (London: Faculty of Public Health, 2007), at 15.

approval and it has also been argued that the CAP has not resulted in poor nutrition standards being adopted by the European population.[149]

If health is not expressly mentioned as one of its objectives, the CAP can still play a potentially powerful role in increasing the availability and the affordability of healthy food and in promoting healthier lifestyles through a carefully designed use of subsidies. It is therefore not surprising that the Obesity Prevention White Paper has identified the CAP as an area of EU intervention for the prevention of overweight and obesity.[150]

Health has been an integral part of the reform of the common market for fruit and vegetables. In particular, Regulation 1182/2007 has made a budget of EUR 8 million available for the free distribution of fruit and vegetables to schools, hospitals and charitable bodies.[151] Furthermore, the EU has adopted a School Fruit Scheme, which entered into force in the school year of 2009-2010 and which subsidizes the free distribution of fruit and/or vegetables in schools.[152] It provides that European funds worth up to EUR 90 million per school year will pay for the purchase and distribution of fruit and vegetables to schools. Member States will have to establish the list of eligible products, bearing in mind that the School Fruit Scheme should not cover unhealthy products containing a high percentage of fat or added sugar. The aid is granted for supplying children in educational establishments, including nurseries, other preschool establishments, primary and secondary schools,[153] thus confirming that the core target group of the measure is children aged 6 to 10.[154] Participation in the Scheme is voluntary. If Member States decide to opt into the programme, they must match the money made available by the EU with national funds. The costs covered are 'the costs of supply and certain related costs of logistics, distribution, equipment, communication, monitoring and

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[149] Josef Schmidhuber has argued that 'there is no reason to suggest that the CAP has caused higher overall consumption levels nor that it has promoted the consumption of particularly unhealthy foods. On the contrary, if the CAP had any impact on EU food consumption patterns at all, it reduced overall consumption levels and particularly those of "unhealthy" foods (rich in sugar, saturated fats and cholesterol)': J. Schmidhuber, *The EU Diet: Evolution, Evaluation and Impacts of the CAP* (Food and Agriculture Organization, Rome, 2008).

[150] Obesity Prevention White Paper, at 6.

[151] Regulation 1182/2007, OJ 2007 L 273/1.

[152] Council Regulation 13/2009, OJ 2009 L 5/1.

[153] Article 2.

[154] Recital 11: 'this age group has been selected because of budgetary reasons, but also because eating habits are formed at a young age.' One could argue that eating habits are formed at a much younger age than six. On the other hand, nurseries and pre-educational establishments are included within the definition of 'educational establishments' and Member States may extend the participation in the Scheme to younger children.

evaluation'.[155] The co-financing envisaged is on a 50-50 basis, except in the so-called 'Convergence Regions' where gross domestic product per capita is lower and where the EU finances 75% of the scheme and national authorities the remaining 25%.[156]

However, subsidies may only be effective if they are both sufficiently high and sustainable in time to ensure long-term, population-wide shifts in consumption patterns – an outcome the measures outlined above are unlikely to achieve alone.

Fiscal measures

Fiscal measures used in lifestyle policy may be defined as taxes that are levied upon given substances (such as tobacco, alcohol and unhealthy food or beverages) or services in order to dissuade potential consumers from their consumption. The imposition of taxes on specific consumption goods and services is generally defined as 'excise taxation'. It found its origin in the theories of Arthur Pigou, a twentieth-century English economist, who presented the arguments for imposing special taxes on goods and services whose prices did not reflect the true social cost of their consumption.[157] The theoretical prediction underpinning excise duties according to which the induced relative price effect actually works by decreasing consumption is supported by empirical evidence.[158]

Classic examples of Pigouvian taxes are duties on cigarettes, alcohol, gambling and environmental emissions. The EU has adopted minimum rates of excise duties on cigarettes, alcoholic beverages and environmental emissions. However, these measures were not necessarily adopted with public health protection in mind but rather to raise revenues.[159] Moreover, they have

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[155] Article 2(1).

[156] Article 2.

[157] A.C. Pigou, *The Economics of Welfare* (Macmillan, 1920), Chapter IX: Divergences between Marginal Social Net Product and Marginal Private Net Product.

[158] B.S. Frey, "Excise Taxes: Economics, Politics and Psychology", in S. Cnossen (ed.), *Theory and Practice of Excise: Smoking, Drinking, Gambling, Polluting, and Driving* (OUP, 2005), 230-244.

[159] The rates and structures of the minimum excise duties applicable are set in sectoral directives. For alcoholic beverages, see Directive 92/83, OJ 1992 L 316/21, and Directive 92/84, OJ 1992 L 316/29. For manufactured tobacco products, see Directive 92/79, OJ 1992 L 316/8, Directive 92/80, OJ 1992 L 316/10, and Directive 95/59, OJ 1995 L 291/40 – these three directives have been more recently amended by Directive 2010/12, OJ 2010 L 50/1; in the interest of clarity and rationality, these directives on tobacco excise duties have been codified by Directive 2011/64, OJ 2011 L 176/24. For carbon emissions, see Council Directive 2003/96, OJ 2003 L 283/51. Common provisions have also been adopted on the control, holding and movement of duty-suspended products in Directive 92/12, OJ 1992 L 76/1, and Directive 2008/118, OJ 2009 L 9/12.

tended to be measures of minimum harmonization only: hence the continuing diversity of prices across the EU – though the scope of variation has been somewhat reduced by the amendment of tobacco taxation directive.[160] More recently, the idea has emerged of extending fiscal measures to food whose consumption is linked to obesity and other health-related risks.[161] Here again, the stated aim of a 'fat tax' or a 'soda tax' is not only to offset the price imbalance between healthier and unhealthier food – the latter tending to be much cheaper – but also to raise revenue, either general revenue or resources to be invested more specifically in nutrition or physical activity programmes.[162]

Although the WHO Global Strategy on Diet, Physical Activity and Health makes reference to fiscal measures,[163] it does not 'prescribe any specific tax or subsidy, but it notes that several countries have adopted fiscal measures to promote availability of and access to various foods, and to increase or decrease consumption of certain types of food'.[164] The Strategy notes that public policies can influence prices through several measures including tax policies and subsidies. The text of the Strategy acknowledges that decisions on such policy options are the responsibility of individual Member States, depending upon their particular circumstances. Due to the inherently regressive nature of these fiscal measures, it also states that 'evaluation of such measures should include the risk of unintentional effects on vulnerable populations'. A similar caution in endorsing 'fat taxes' can be found in the EU.

If the EU has not adopted any harmonizing legislation on food taxes, some Member States have started to experiment with them.[165] In the absence of common EU rules on indirect taxation, they retain the freedom to adopt such

[160] Council Directive 2011/64/EU of 21 June 2011 on the structure and rates of excise duty applied to manufactured tobacco.

[161] See e.g. H. Rosin, "The Fat Tax: Is It Really Such a Crazy Idea?", *The New Republic,* May 18, 1998.

[162] See e.g. K. Brownell et al., "The Public Health and Economic Benefits of Taxing Sugar-Sweetened Beverages", 361 T*he New England Journal of Medicine* (2009), 1599; A. Leceister and F. Windmeijer, "The 'Fat Taxes': Economic Incentives to Reduce Obesity", Institute for Fiscal Studies, Briefing note, n. 49, 2005.

[163] Section 41(2).

[164] Frequently Asked Questions About the WHO Strategy on Diet, Physical Activity and Health, point 5, http://www.who.int/dietphysicalactivity/faq/en/.

[165] See, e.g., in Denmark, Lov om afgift af mættet fedt i visse fødevarer (Act on a tax on saturated fat in specificfood), LOV nr 247 af 30/03/2011 Gældende (Fedtafgiftsloven), adopted on 31 March 2011 and withdrawn in November 2012; in Hungary, 2011. évi CIII. Törvény a népegészségügyi termékadóról, Date of publication: 19 July 2011. Magyarközlöny (Hungarian Gazette) 2011. évi 85. Szám, 25125.

taxes, provided that they are not discriminatory and do not protect the home market to the detriment of the markets of other Member States.[166]

Two main unintended consequences of increased taxation have been identified. First, due to their regressive nature, the introduction of fiscal measures aimed at promoting healthier behaviours raises questions of moral and distributive justice. This is all the more so as taxes may only be effective in shifting consumption patterns towards healthier products if they are sufficiently high.[167] One way to offset this problem may be to ensure that the revenues raised through taxation are earmarked specifically for supporting the more disadvantaged group, either through education campaigns or through the introduction of subsidies promoting healthier lifestyles. Second, in relation to their use in promoting healthy diets, food taxes also raise issues of effectiveness and may serve to legitimize an emerging fat-thin dichotomy according to which thin is good and fat is bad,[168] whilst the classification of food is necessarily far more complex than this simplistic dichotomy suggests, requiring the adoption of nutrition profiling models.[169]

e) Fundamental rights

Another approach that offers a promising avenue for regulatory intervention in the area of NCD prevention and control is the reliance on fundamental rights arguments. Legal systems can promote the right to health and several other fundamental rights protected by the EU legal order. However, to date, this approach has been neglected by policymakers, and by the EU more specifically. This can be explained by the fact that industry operators have hijacked the fundamental rights discourse. As illustrated below, the industry, not the policymakers, has systematically invoked fundamental rights when opposing the adoption of specific regulatory measures. However, policy makers in charge of developing effective NCD control and prevention strategies could also rely on those rights to underpin their policies. Thus, we propose to distinguish, on the one hand, the use of human rights as a 'shield' by industry operators when defending their economic interests before courts of law and, on the other hand, their use as a 'sword' by policy makers as an integral part

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[166] A. Alemanno and I. Carreno, "Fat Taxes in the European Union between Fiscal Austerity and the Fight Against Obesity", 4(2) *European Journal of Risk Regulation* (2011), 571; and A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010), at chapter 7.

[167] O. Mytton, D. Clarke and M. Rayner, "Taxing Unhealthy Food and Drink to Improve Health", *British Medical Journal* (2012), 344.

[168] J.E. Oliver, *Fat Politics: The Real Story Behind America's Obesity Epidemic* (OUP, 2006), 76.

[169] M. Friant-Perrot and A. Garde, "From BSE to Obesity – EFSA's Growing Role in the EU's Nutrition Policy", in A. Alemanno and S. Gabbi (eds), *Foundations of EU Food Law and Policy: 10 Years of European Food Safety Authority* (Ashgate, 2013, forthcoming).

of their health strategies. As fundamental rights may become a constraint which policy makers have a duty to consider, we have discussed this aspect of the role of fundamental rights in NCD prevention and control policies in the next section of this report. For the time being, we will focus on the use policymakers could make of fundamental rights as a sword, i.e. as a vehicle for better health. We argue that the NCD and the fundamental rights agendas can be mutually reinforcing.

Before discussing the role of fundamental rights in the NCD debate, it is worth bearing in mind that the EU is 'founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights'.[170] More specifically, Article 6 TEU identifies three main sources of EU fundamental rights: the EU Charter of Fundamental Rights (EU Charter), the European Convention on Human Rights and Fundamental Freedoms (ECHR), and the general principles of EU law resulting from the constitutional traditions common to the Member States.

If the ECHR does not contain specific provisions on health, the EU Charter does: its Article 35 provides that 'a high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities'. Furthermore, the right to health can be considered as falling within the general principles of EU law, in light of the fact that all Member States have ratified the two UN Treaties offering its most comprehensive expression, namely: Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) and Article 24 of the Convention on the Rights of the Child (CRC).[171] Therefore, the question is not so much whether the right to health is protected by the EU legal order, but what this right entails and how it can be operationalized to promote healthier lifestyles and thus contribute to the prevention and control of NCDs in Europe.

The concept of health is defined very broadly as 'a state of complete physical, mental and social well-being, rather than merely the absence of disease

[170] Article 2(1) TEU. See also Case C-294/83 *Parti Ecologiste 'Les Verts'* [1986] ECR 1339.

[171] One should note that before the adoption of the ICESCR and the CRC, Article 25 of the Universal Declaration of Human Rights already provided: "everyone has the right to a standard of living adequate for the health and the well-being of himself and of his family". The right to health has also been expressed in a range of other UN Treaties, including the Convention on the Elimination of All Forms of Racial Discrimination, the Convention on the Elimination of All Forms of Discrimination against Women, the International Convention on the Protection of the Rights of All Migant Workers and Members of their Families, and the Convention on the Rights of Persons with Disabilities. For a comprehensive discussion of the right to health in international law, see J. Tobin, *The Right to Health in International Law* (OUP, 2012).

or infirmity'.[172] As such, this definition, which was explicitly endorsed by the CJEU in its *Working Time Directive* judgment,[173] extends the right to health beyond the provision of medical care to encompass the right to prevention, treatment and control of diseases. This is not to say, however, that the right to health is a right to be healthy; rather, it is 'a right to the highest attainable standard of health',[174] subject both to an individual's biological, social, cultural and economic preconditions and the State's available resources. In particular, the right to health requires that States ensure 'the prevention, treatment and control of epidemic, endemic, occupational and other diseases',[175] that they 'develop preventive health care'[176] and that they 'combat disease and malnutrition, including within the framework of primary health care, through, *inter alia* […] the provision of adequate nutritious foods […]'.[177]

In recent years, a growing number of international law documents have confirmed that states can invoke the right to health in order to promote healthier lifestyles and support their NCD prevention and control policies. Thus, the FCTC refers explicitly to Article 12 of the ICESCR in its Preamble. This supports the argument which several scholars have put forward that tobacco control is an integral component in the protection of the right to health.[178] Not only is the burden of the tobacco pandemic not fairly distributed – tobacco consumption rates being much higher among poor communities both within and among states – but also exposure to tobacco prevents the fulfilment of the right to health, as well as several health-related rights, including the right to life, the right to a clean environment and the right to information. Tobacco

[172] Constitution of the WHO: http://apps.who.int/gb/bd/PDF/bd47/EN/constitution-en.pdf. See also the Declaration of Alma-Ata, International Conference on Primary Health Care, 6-12 September 1978: http://www.who.int/publications/almaata_declaration_en.pdf.

[173] Case C-84/94 *UK v. Council* [1996] ECR I-5755.

[174] See Article 12 of the ICESCR, as interpreted by General Comment N° 14 (2000) on the right to health, adopted by the Committee on Economic, Social and Cultural Rights, and Article 24 of the CRC as most recently interpreted by the Committee on the Rights of the Child in General Comment N° 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health.

[175] Article 12(2)(c).

[176] Article 24(2)(f).

[177] Article 24(2)(c).

[178] O. Cabrera and L. Gostin, "Human Rights and the Framework Convention on Tobacco Control: Mutually Reinforcing Systems", 7 *International Journal of Law in Context* (2011), 285. On the relationship between tobacco control and fundamental rights, see also C. Dresler and S. Marks, "The Emerging Human Right to Tobacco Control", 28 *Human Rights Quarterly* (2006), 599; and M. Crow, "Smokescreen and State Responsibility: Using Human Rights Strategies to Promote Global Tobacco Control", 29 *Yale Journal of International Law* (2004), 209.

control measures are therefore intended to implement the commitments of public authorities to respect, protect and fulfil these rights.[179]

Given the growing burden of mortality, morbidity and disability associated with NCDs and their risk factors, this argument could be extended to cover other risk factors such as alcoholic beverages and HFSS food. Thus, the Committee on the Rights of the Child recently called on States to address not only tobacco consumption, but also alcohol consumption and obesity. In particular, it noted that

> children's exposure to 'fast foods' that are high in fat, sugar or salt, energy-dense and micronutrient-poor, and drinks containing high levels of caffeine or other potentially harmful substances should be limited. The marketing of these substances – especially when such marketing is focused on children – should be regulated and their availability in schools and other places controlled.[180]

These calls are echoed by the UN High Commissioner for Human Rights who recently stressed that 'obesity […] and substance use' were among 'the areas requiring sustained and immediate attention'.[181] States – and indirectly the EU as a federation of States – should therefore 'prioritize issues that have received little attention to date […] They should ensure adequate attention to the underlying determinants of child health, including, *inter alia*, access to minimum safe and nutritionally adequate food, basic shelter, housing, sanitation, safe and potable water and a healthy and safe environment.'[182]

In light of the interdependence and indivisibility of international human rights, the realization of the right to health is indispensable for the enjoyment of all the other rights, and achieving the right to health is dependent on the realization of many other human rights. The other rights which could be in-

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[179] *Ibid*.

[180] At paragraph 47 of the General Comment N° 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health. The Committee on the Rights of the Child has also expressed its concerns relating to growing childhood obesity in General Comment N° 17 (2013) interpreting Article 31 of the CRC on the right of the child to rest, leisure, play, recreational activities, cultural life and the arts: "Growing dependence on screen-related activities is thought to be associated with reduced levels of physical activity among children, poor sleep patterns, growing levels of obesity and other related illnesses" (at paragraph 46).

[181] Annual Report of the United Nations High Commissioner for Human Rights, 29 April 2013, A/HRC/23/59, at para 6.

[182] UN Human Rights Office of the High Commission, The Right of the Child to the Enjoyment of the Highest Standard of Health, March 2013, at para 99.

voked in the NCD debate include the right to life, the right to a clean environment, the right to information,[183] the right to education, the right to adequate food, and the umbrella principle requiring that all actions concerning children shall be taken in their best interest.[184] In particular, the need to address NCDs, and obesity more specifically, has been at the heart of the work carried out by the UN Special Rapporteur on the Right to Food who has interpreted the right to adequate food as including the right to *nutritious* food. This, in turn, has led him to argue forcefully in favour of the adoption of regulatory (as opposed to self-regulatory) measures restricting the marketing of HFSS food to children.[185]

Embracing a fundamental rights approach to NCD prevention would not only strengthen the basis for the adoption of effective NCD prevention and control measures, but it would also be in line with the recognition that non-state actors, including private industry operators, have an obligation to 'avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur' and should 'seek to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if

[183] For a discussion on these rights and their relevance to the tobacco control agenda, see O. Cabrera and L. Gostin, "Human Rights and the Framework Convention on Tobacco Control: Mutually Reinforcing Systems", 7 *International Journal of Law in Context* (2011), 285.

[184] In its General Comment N° 14 (2013) on the right of the child to have his or her best interests taken as a primary consideration, the Committee on the Rights of the Child stated: "one needs to bear in mind that the purpose of assessing and determining the best interests of the child is to ensure the full and effective enjoyment of the rights recognized in the Convention and its Optional Protocols, and the holistic development of the child" (at para 82). On the EU Children's Rights Strategy, see H. Stalford, *Children and the European Union – Rights, Welfare and Accountability* (Hart Publishing, 2012). On the failure of the EU to uphold the best interest of the child in its consumer and public health policies more specifically, see A. Garde, "Advertising Regulation and the Protection of Children-Consumers in the European Union: In the Best Interest of… Commercial Operators?", 19 *International Journal of Children's Rights* (2011), 523.

[185] O. de Schutter, *The Right to an Adequate Diet: the Agriculture-Food-Health Nexus*, Report presented at the 19th Session of the United Nations Human Rights Council, 26 December 2011, A/HRC/1/9/59.

they have not contributed to those impacts'.[186] Furthermore, a rights-based approach to NCD prevention would highlight the need to reduce social disparities in health between different population groups, providing equality of opportunity for all to enjoy the highest attainable standard of health.[187] This is all the more important if the relationship between NCDs and social exclusion is to be addressed effectively.

While virtually all attempts made by the relevant industries to challenge the legality of EU action against their products have been accompanied by the invocation of a breach of fundamental rights, as discussed below, this does not imply that the law cannot be used as a tool to promote the right to health and several other fundamental rights protected by the EU legal order. Some encouraging signs can be found in the most recent case law of the EU Courts. Thus, in its recent *Deutsches Weintor* decision,[188] the CJEU specifically relied on Article 35 of the EU Charter to dismiss the claims of alcoholic beverages industry operators that the EU legislature had exceeded the limits on its margin of discretion by banning the use of health claims on all beverages containing more than 1.2% by volume of alcohol.[189] This decision goes some way towards supporting the argument that fundamental rights may be invoked not only as a shield by industry operators to protect their private economic interests, but also as a sword by the EU legislature when regulating, in the general public interest, the activities of these very operators.[190] In so doing, it continues a long line of case law (discussed below) in which the CJEU has upheld

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[186] Guiding Principles on Business and Human Rights, April 2011: http://www.business-human-rights.org/UNGuidingPrinciplesPortal/Home. See also the Report of the Special Representative of the Secretary-General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework, 21 March 2011, A/HRC/17/31, at paras 13(a) and 13(b): http://www.ohchr.org/Documents/Publications/GuidingPrinciplesBusinessHR_EN.pdf. On the accountability of industry operators for human rights violations, see R. McCorquodale, "Pluralism, Global Law and Human Rights: Strengthening Corporate Accountability for Human Rights Violations", 2 *Global Constitutionalism* (2013), 287.

[187] See in particular at paras. 7, 11 and 24 of General Comment N° 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health.

[188] Case C-544/10 *Deutsches Weintor eG v Land Rheinland-Pfalz* (nyr), hereafter *Deutsches Weintor*.

[189] Art. 4(3) of Regulation 1924/2006 on nutrition and health claims made on foods, OJ 2006 L 404/9, as last amended by Commission Regulation 116/2010, OJ 2010 L 37/16.

[190] It is noteworthy that the wording of Art. 35 of the EU Charter is less prescriptive than Art. 12 of the International Covenant on Economic, Social and Cultural Rights (as broadly interpreted by General Comment 14 (2000)) and Art. 24 of the UN Convention on the Rights of the Child, the two main sources of the right to health in international law. Nevertheless, Art. 35 should be interpreted in their light for coherence purposes.

the restrictions imposed by the EU legislature on the economic freedom of private operators in order to ensure a high level of public health protection.[191]

f) Performance-based regulation

The terminology 'performance-based regulation' might appear redundant, since all regulatory interventions aim to improve society in ways that reduce social harms, whether by increasing the safety of the food supply chain, by improving industry's environmental performance, or by reducing workplace risk. Yet regulators may steer those they govern to improve their performance in at least two simple ways. They can prescribe exactly what actions regulated entities must take to improve their performance – what is often defined as 'command-and-control' regulation; or they can incorporate the regulation's goal into the language of the rule. In this way the regulation determines the desired level of performance but allows that outcome up to the discretion of the regulated entity which has to choose how to achieve it.[192] In sum, every time a regulatory instrument sets performance goals and allows individuals and firms to choose how to meet them, it may be called a performance-based regulation or, alternatively, outcomes-based regulation.

While incorporating performance goals into regulatory standards is by no means a new idea, in recent years there has been renewed interest in expanding the use of performance standards in a variety of areas, not least environmental regulation,[193] as well as health and safety.[194]

Under such an approach, public authorities first decide which companies are to be regulated and set a public health goal for each regulated company (e.g. salt reduction or obesity decrease by 10% in five years). Then, the government measures whether each company has met its target. If it has, then the company is praised and benefits from the good publicity. If not, substantial fees are imposed on the enterprise, which may also be 'named and shamed'.

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[191] As the Explanations relating to the complete text of the EU Charter published in December 2000 state, "the second sentence of Article 35 is based on Article [168(1) of the TFEU]" (http://www.eucharter.org/home.php?page_id=67, 52). Could one perhaps suggest that the EU Charter's explicit reference to the EU health mainstreaming provision reinforces the EU's obligation by making it an issue of fundamental rights and linking it to the right to health?

[192] See, e.g., C. Coglianese, J. Nash and T. Olmstead, "Performance-Based Regulation: Prospects and Limitations in Health, Safety, and Environmental Protection," Regulatory Policy Program Report No. RPP-03 (2002).

[193] S. Sugarman, "Performance-Based Regulation: Enterprise Responsibility for Reducing Death, Injury and Disease Caused by Consumer Products", 34 *Journal of Health Policy, Politics and Law* (2009), 1035.

[194] O. Lobel, "Interlocking Regulatory and Industrial Relations: The Governance of Workplace Safety", 57 *Administrative Law Review* (2005), 1072.

The financial charges must be significant in order to internalize the negative social costs that flow from the products the company puts onto the market.[195]

The immediate advantage of such an approach is to avoid the concern that public authorities engineer healthy lifestyles through a set of *ad hoc* interventions. The responsibility here lies with the relevant companies in the tobacco, alcohol or food sector to figure out a way to meet these targets or face a penalty. The idea is to exploit the industry's well-known ability to innovate and to steer it towards the public interest. What is the role, then, for performance-based standards in the regulator's tool-box? Once it is determined that some form of government regulation is needed to solve a particular problem, what are the conditions under which a performance-based standard is the appropriate regulatory instrument to use? What particular challenges can be expected to arise in implementing performance-based regulation? Despite its intriguing character, this form of regulatory intervention seems to open a Pandora's box of questions relating to their institutional designs. Thus, for instance, the implementation of any form of performance-based regulation as applied to the food sector presupposes the ability to pinpoint those products whose manufacture and consumption should be discouraged. While this is the role that nutrition profiles are called upon to play, the current controversy on how to draw them suggests the inherent difficulty existing in implementing this form of regulatory intervention[196].

In any event, we are not aware of any examples of attempts at integrating this approach into the NCD prevention and control tool-box. However, in its attempt to strike a balance between paternalism and autonomy, performance-based regulation may offer an interesting avenue for future research into its potential as a form of NCD prevention and control tool box.

g) Self-regulation

Whilst all the forms of intervention described above find their origin in binding legal rules, self-regulation emerges as a possible approach to NCD prevention that may exist autonomously from the law.[197] Self-regulation means

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[195] S. Sugarman, "Salt, High Blood Pressure, and Performance-based Regulation", 3 *Regulation and Governance* (2009), 84.

[196] P. Scarborough, C. Arambepola, A. Kaur, Bhatnagar and M. Rayner, "Should nutrient profile models be 'category specific' or 'across-the-board'? A comparison of the two systems using diets of British adults", 64(6) *European Journal of Clinical Nutrition* (2010), 553-60.

[197] However, whenever it is a legislative act that mandates self-regulation, this process is referred to as co-regulation. As a result of the legislative framing, the parties concerned are then able to conclude voluntary agreements between themselves in order to achieve the objectives set by the legislative act.

the possibility for economic operators, non-governmental organizations or associations to adopt amongst themselves and for themselves common guidelines at European level.[198] These guidelines may take the form of a code of conduct or a sectoral agreement, for example. They do not generally imply that the European institutions have adopted any particular stance. However, the latter reserve the right to adopt a legislative act when it concerns an area for which the EU has competence.

Due to its flexible nature and lack of enforcement mechanisms, this approach is favoured by the industry and often by the Member States, who perceive self-regulation as a cheaper alternative over traditional government regulation of food and alcoholic beverages.[199] As stated above, the EU has adopted, in the area of nutrition, a combination of both regulation and self-regulation via the EU Platform on Nutrition, Diet and Physical Activity. The EU Alcohol Strategy has clearly self-regulation the privileged and near-exclusive approach of the EU Alcohol Strategy made – at least, to date. Nevertheless, the EU experience shows severe limits in the ability of the EU Platform and the EU Forum to deliver tangible results in terms of health gains.[200]

Self-regulation raises the broader public policy question of whether the relevant industries should play some role in the attempts at preventing and controlling NCDs. While it is well-established, especially after the entry into force of the FCTC, that the tobacco industry has no role to play as a partner in the governmental efforts to limit tobacco consumption, the question of determining whether the alcohol and food industries should be involved is much more complex. Given the choice made by the 2011 Political Declaration to develop a multi-stakeholder approach towards NCDs, the question is not *whether* these industries should be involved at all, but *how* they could be. This has been recently confirmed by the 2013 Action Plan that recommends that 'multiple actors, both State and non-State actors including civil society, academia, industry, non-governmental and professional organizations […] be engaged for [NCDs] to be tackled effectively'[201]. Yet due to the serious risk of 'regulatory capture' and 'conflict of interest', the Action Plan also warns that

[198] For a definition in EU law, see the Inter-Institutional Agreement (IIA) on Better Lawmaking between the European Parliament, the Council and the Commission, OJ 2003 C 321.

[199] L. Sharma, S.P. Teret, and K.D. Brownell, "The Food Industry and Self-Regulation: Standards to Promote Success and to Avoid Public Health Failures", 100(2) *American Journal of Public Health* (2010), 240.

[200] See in particular O. Bartlett and A. Garde, "Time to Seize the (Red) Bull by the Horns: the EU's Failure to Protect Children from Alcohol and Unhealthy Food Marketing", 4 *European Law Review* (2013), 498.

[201] Section 18, Overarching principles and approaches.

'public health policies, strategies and multisectoral action for the prevention and control of [NCDs] must be protected from undue influence by any form of vested interest'. In particular, it requires that 'real, perceived or potential conflicts of interest must be acknowledged and managed'.

The extent to which the EU has promoted the use of self-regulation to restrict the marketing of HFSS food and alcoholic beverages to children offers an interesting case study. A range of independent studies support the view that self-regulation is not a suitable regulatory mechanism to protect children effectively from the harmful consequences that the marketing of HFSS food and alcoholic beverages has on their health.[202] This should not come as a surprise. Self-regulation has such inherent and arguably insurmountable weaknesses that it will rarely act as an effective replacement for legislation. Clearly, 'to defend the right to market alcohol [and HFSS foods] is essential business activity for the vested interests involved',[203] and consequently any self-regulatory commitments will always be compromised. An inherent conflict of interest does arise when commercial operators are asked voluntarily to stop marketing to children that works whilst they have a primary responsibility towards their shareholders to increase their profits. Marketing is one of the most effective tools available to them to reach this objective and thus for both the food and the alcoholic beverages industries it has been an established commercial objective actively to target children as key marketing audiences.[204]

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[202] For a criticism of the use of self-regulation to limit the marketing of HFSS food and alcoholic beverages to children, see in particular: C. Hawkes, "Self-regulation of Food Advertising: What it Can, Could and Cannot Do to Discourage Unhealthy Eating Habits Among Children", 30 *Nutrition Bulletin* (2005), 374; D. Ludwig and M. Nestle, "Can the Food Industry play a Constructive Role in the Obesity Epidemic?", 300(15) *Journal of the American Medical Association* (2008), 1808; K Brownell and K Warner, "The Perils of Ignoring History: Big Tobacco Played Dirty and Million Died. How similar is Big Food?", 87 *Milbank Quarterly* (2009), 259; T. Babor, "Alcohol Research and the Alcoholic Beverage Industry: Issues, Concerns and Conflicts of Interest", 104 *Addiction* (2009), 34; L. Sharma, S. Teret and K. Brownell, "The Food Industry and Self-regulation: Standards to Promote Success and to Avoid Public Health Failures", 100 *American Journal of Public Health* (2010), 240; A. Gilmore, "Public Health, Corporations and the New Responsibility Deal: Promoting Partnerships with Vectors of Disease?", 33 *Journal of Public Health* (2011), 2; L. Dorfman, et al., "Soda and Tobacco Industry Corporate Social Responsibility Campaigns: How do they Compare?", 9 PLoS Medicine (2012), 1241; R. Moodie et al., "Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-processed Food and Drink Industries", 381 *Lancet* (2013), 670.

[203] S. Casswell, "Current Status of Alcohol Marketing Policy – an Urgent Challenge for Global Governance", 107 *Addiction* (2012), 478, 481.

[204] G. Hastings, "'They'll Drink Bucket Loads of the Stuff': An Analysis of Internal Alcohol Industry Advertising Documents" (Alcohol Education and Research Council, 2009).

The overall assessment is clear: if the Commission has been very vocal in promoting the use of self-regulation as an alternative to the adoption of legally binding rules to restrict HFSS food and alcohol marketing to children,[205] this belief in the virtues of self-regulation is based on assumptions rather than existing evidence. The major loopholes contained in the provisions of the AVMS Directive are even more glaring in light of the latest WHO strategic documents. Apart from calling on Member States to implement the FCTC and introduce a ban on all forms of tobacco advertising, sponsorship and other forms of promotion, the WHO Global NCD Action Plan also urges them to implement the WHO Recommendation on the marketing of food and non-alcoholic beverages to children. The Recommendations clearly emphasize that the key policy parameters should be set by the competent regulatory authorities, rather than industry operators, in such a way as to avoid conflicts of interest.[206] Finally, the WHO Global NCD Action Plan calls on Member States to restrict the marketing of alcoholic beverages to children. The introduction of marketing restrictions on tobacco and alcoholic beverages is even recognized as a 'best buy', namely a cost effective form of intervention to reduce the burden of NCDs.[207] If the EU has acted on the evidence supporting restrictions on tobacco advertising, it has failed – to date – to seize the opportunities offered by the EU Treaties to regulate effectively marketing practices which promote the harmful use of alcohol and unhealthy diets.

Therefore, while one should be cautious before assuming that all self-regulatory schemes are animated by the aim to counter the public interest and delay regulation, one should not exclude either that this is indeed true of several of these schemes. Thus, public authorities should determine the parameters of any given self-regulatory scheme and its effectiveness should be thoroughly scrutinized by independent parties and at regular intervals. It is only then that conflicts of interest can be avoided.

h) Supportive policies

Education campaigns

Despite the potential of all regulatory instruments discussed above to tackle NCDs, law is not, and cannot be, a panacea. It is only when accompanied by

[205] See, e.g., the speech of John Dalli, then Commissioner for Health and Consumer Protection, on the regulatory challenges and solutions for responsible advertising at the Conference "Advertising We Care", 28 March 2012: http://www.aereurope.org/content/view/1039/68/lang,en_GB/.

[206] Recommendations 4 and 6.

[207] WHO and World Economic Forum, "From Burden to 'Best Buys': Reducing the Economic Impact of Non-Communicable Diseases in Low- and Middle-Income Countries", 2011, www.who.int/nmh/publications/best_buys_summary.pdf, Table 2, page 7.

education campaigns that its effects can be maximized. Education campaigns are a softer form of lifestyle intervention that typically relies on persuasion rather than on coercion to attain the objective. Research programmes aim to promote a better understanding of the underlying risk factors of NCDs by scientifically exploring the implications stemming from overconsumption and overexposure to certain products. The EU has supported several education campaigns and research projects as part of its developing lifestyle policy.[208] This is arguably very much in line with and supportive of the EU's consumer information paradigm discussed above.

The EU also considers that the provision of voluntary information by the relevant industries, such as nutritional guidelines, may be considered as belonging to a set of policies whose objective is to educate consumers about what they choose to buy and consume. However, as voluntary information is often provided to the detriment of the clarity of mandatory information, the EU legislature has increasingly felt the need to frame the provision of voluntary information by helping the relevant industries 'to strike a balance between the provision of mandatory and voluntary information'.[209]

Research programmes

Research programmes constitute another essential component of NCD prevention. Given the important role played by evidence in the design and implementation of NCD policies, it is crucial that public authorities commit significant resources to developing policy-relevant research programmes.

NCD monitoring and evaluation schemes

Any successful policy is conditional upon its effective implementation, monitoring and evaluation. NCD prevention is no exception. To this purpose it is imperative to establish a monitoring system capable, first, of determining a baseline and, second, of providing a systematic check over the implementation of any given policy. However, in contrast to infectious disease surveillance, the monitoring of chronic diseases is not yet systematically embedded in health systems and raises more controversy.[210] This is often due to the fact that while infectious diseases are perceived as a legitimate concern for public health systems, NCDs are still seen as falling within the confidentiality/privacy remit of the patient/doctor relationship.

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[208] For example, see the EU Ex-Smokers are Unstoppable Campaign: http//www.exsmokers.eu.

[209] See, e.g., Article 36 of Regulation 1169/2011 on the provision of food information to consumers, OJ 2011 L 304/18.

[210] For a perspective, R.A. Epstein, "What (Not) To Do About Obesity: A Modern Aristotelian Answer", 93 *Georgetown Law Journal* (2005), 1361.

European Member States have in place different systems to monitor NCD prevalence; however, the EU has yet not envisaged the creation of an EU-wide monitoring system. This being said, following the process initiated by the UN Political Declaration to develop a global monitoring framework for NCDs, including a set of indicators and global voluntary targets,[211] the EU together with its Member States is supposed to implement a monitoring system. As mentioned above, this global monitoring framework (GMF) comes after nearly a year of inclusive consultations led by the WHO, and is one of three critical parts of the Global NCD Framework (the GMF, the Global Action Plan for NCDs 2013–2020, and a global coordinating mechanism for NCDs). It goes without saying that monitoring of NCD rates is a pre-condition for holding governments accountable for health outcomes among their populations and, eventually, to verify compliance with the voluntary targets. Monitoring emerges as a key strategy that all EU Member States should implement in order to take seriously their commitment to promote healthier lifestyles.

3.1.2 Conclusions on law as a source of opportunities

As illustrated by our systematization of possible interventions, a broad range of strategies exists to prevent and control NCDs. These different strategies have different natures, involve different actors and vary in scope, yet as they all require some form of legal intervention, they illustrate how the law may offer opportunities for the prevention and control of NCDs. Moreover, as previously illustrated, all the categories of intervention we have identified are highly dependent in both their conception and implementation on a strong evidence base, effective monitoring schemes and convincing education campaigns.

It is clear that the EU is fully aware not only of the need to address the growing burden of NCDs affecting its Member States, but also of the potential of the legal system to help it achieve this objective. Therefore addressing NCDs at EU level does not only require political will; it also requires that legislators choose from within the 'NCD tool-box' those instruments that are most appropriate.

3.2 Law as a source of constraint

Our previous discussion about the many opportunities the law offers to tackle NCDs suffices to show that the question is not so much ***whether*** the law can play an important role in promoting healthier lifestyles. Rather, the question

[211] At paras 61 and 62.

is ***how*** the law can be validly designed to support effective NCD prevention and control policies.

The importance of this question cannot be understated: good laws concerning NCDs must be able to withstand legal challenges as much as can possibly be anticipated. Without framing the relevant issues in legal terms, on the basis of existing evidence, the public health community is unlikely to succeed in using the law effectively. History has shown that the tobacco,[212] alcohol[213] and food industries[214] systematically challenge laws adopted as part of the NCD prevention and control agenda. These industries will be far more likely to succeed if the laws they challenge have been adopted without sufficient concern for a range of legal principles derived from the following three sets of domestic, EU and international provisions:

– constitutional law (3.2.1)
– international (and intra-Community) trade law (3.2.2)
– human rights law (3.2.3)

Each one of these three categories must be considered in turn in order to grasp how the law may act as a source of constraint to the advancement of the NCD prevention and control agenda in Europe.

3.2.1 Constitutional law

There is a clear consensus that effective NCD prevention and control strategies must be 'multi-level': the global operation of the major players of the food, tobacco and alcohol industries calls for a response at global and regional levels, whilst local cultures, circumstances and consumption patterns

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[212] See, among the most recent disputes litigated internationally: Panel report, *United States – Measures affecting the production and sale of clove cigarettes*, wt/ds406/r.; Request for Consultations by Ukraine, *Australia – Certain Measures Concerning Trademarks and other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, wt/ds434/1, ip/d/30, g/tbt/d/39, g/l/985; FTR Holdings SA (Switzerland), Philip Morris Products SA (Switzerland) and Abal Hermanos SA (Uruguay) v. Oriental Republic of Uruguay, request for arbitration (ICSID Case no. arb/10/7, 19 February 2010); Notice of arbitration, Australia/Hong Kong agreement for the promotion and protection of investments, Philip Morris Asia limited, 21 November 2011.

[213] See, e.g., C-405/98 *Konsumentombudsmannen v Gourmet International Products AB* (*Gourmet*) [2001] ECR I-1795, para 21; Case E-2/12, *HOB-vín ehf. ./. The State Alcohol and Tobacco Company of Iceland (ÁTVR) (HOB-vin)*, EFTA Court, judgment of 11 December 2012, nyr; see Case C-189/95 *Criminal Proceedings against Harry Franzén* [1997] ECR I-5909 and Case C-170/04 *Rosengren and Others v. Riksåklagaren* [2007] ECR I-4071, as well as the decision of the EFTA Court in Case E-6/96 *Tore Wilhelmsen* [1997] EFTA Court Report 53.

[214] See, e.g., Joined Cases C-154 and 155/04 *Alliance for Natural Health* [2005] ECR I-6451; Case C-544/10 *Deutsches Weintor*, nyr.

call for a response at national and local levels. It is therefore necessary to enquire not only about which regulatory intervention should be adopted to reverse current NCD trends, but also about the most appropriate level for such intervention. This enquiry adds a layer of complexity to lifestyle regulatory intervention, in that it raises the controversial question of allocation of powers between different levels of governance. The question becomes more difficult for quasi-federal legal systems such as the one established by the EU Treaties, which require an enquiry as to where competence lies between the different levels of governance and how these powers should be exercised by the competent level or levels when competence is shared.

Article 5(1) of the Treaty on the European Union (TEU) provides: 'The limits of Union competences are governed by the principle of conferral. The use of Union competences is governed by the principles of subsidiarity and proportionality.'

The principle of conferral reflects the seminal judgment of the CJEU in *Van Gend en Loos*, where it held that 'the [EU] constitutes a new legal order of international law for the benefit of which the States have limited their sovereign rights, albeit within limited fields, and the subjects of which comprise not only Member States but also their nationals'.[215] In other words, if the EU Treaties[216] do not provide a legal basis, i.e. a specific Treaty article allowing the EU to intervene in a certain area, then action may only be taken by Member States. As regards NCD control and prevention more specifically, the principle of conferral means that the EU cannot adopt all the measures necessary to prevent NCDs which are multi-factorial in nature: some measures will originate from the EU, whereas some others will have to be adopted by the Member States, at national or at local level, due to a lack of EU competence. As the case law of the CJEU demonstrates, putting flesh on the bones of these general statements has proven rather difficult.

As Article 5(1) makes clear, the difficulties do not stop at this first stage. Once it has been established that the EU has the competence to act, it becomes necessary to determine whether, and if so how, it should exercise its powers. The principles of subsidiarity and proportionality constrain EU action, by requiring, first, that the EU should act only when the objectives of a pro-

[215] Case 26/62 *Van Gend en Loos* [1963] ECR 3. Art. 1(1) TEU reiterates and emphasizes this principle: 'By this Treaty, the High Contracting Parties establish among themselves a European Union, hereinafter called "the Union" on which the Member States *confer competences* to attain objectives they have in common.' Emphasis added.

[216] The 'EU Treaties' refer to the Treaty on European Union (TEU) and the Treaty on the Functioning of the European Union (TFEU).

posed intervention can be better achieved by the EU than by Member States and, second, that EU intervention should not go beyond what is necessary to achieve the objectives.

This section, by discussing one of the sources of constraints for lifestyle regulatory intervention, demonstrates how the principles of conferral, subsidiarity and proportionality come into play in relation to the EU's developing NCD prevention and control policy, and highlights the difficulties these principles raise for the EU legislature.

The principle of conferral

The *Tobacco Advertising* litigation has been foundational in reminding the EU legislature that, because of the principle of conferral, there are limits to the EU's regulatory intervention. It also has the obvious advantage of focusing specifically on the regulation of tobacco advertising and is therefore of direct relevance to the EU's NCD prevention and control policy. Before assessing the lessons that can be learnt from the CJEU case law, we will briefly recap on its background.

In July 1998, the European Parliament and the Council adopted, on the 'internal market' legal basis – what is now Article 114 TFEU – a directive laying down a general prohibition on the advertising and sponsorship of tobacco products.[217] Germany opposed this directive but was outvoted by the other Member States following a qualified majority vote in favour of its adoption. Germany subsequently challenged its validity, arguing *inter alia* that the EU did not have the required competence to adopt such a measure. More specifically, it contended that the 1998 directive was in reality a disguised public health measure whose effects on the internal market, if any, were purely incidental, thus preventing Article 114 TFEU from providing a proper legal basis. The CJEU accepted Germany's argument and annulled the 1998 directive. It held that Article 114 TFEU was intended to improve the conditions for the establishment and functioning of the internal market, as opposed to vesting in the EU legislature a general power to regulate the internal market, thus confirming that the scope of Article 114 TFEU is not unlimited. It is only if a measure genuinely seeks to improve the conditions for the establishment and functioning of the internal market that this legal basis can be invoked.[218]

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[217] Directive 98/43, OJ 1998 L 213/9.

[218] Case C-376/98 *Germany v Council and the European Parliament (Tobacco Advertising I)* [2000] ECR I-8419.

In May 2003, the European Parliament and the Council adopted a second directive on the advertising and sponsorship of tobacco products by narrowing down its scope. It prohibits the advertising of tobacco products in the press and other printed publications, in information society services and in radio broadcasts; and the sponsorship by tobacco companies of radio programmes and events or activities with cross-border effects.[219] Germany again challenged the validity of this directive on the ground (among others) that it did not contribute to the establishment or the functioning of the internal market. This time, however, the CJEU dismissed the action as unfounded and held that the conditions required for recourse to Article 114 TFEU as a suitable legal basis were in fact met.[220]

The *Tobacco Advertising* litigation raises the key question of the extent to which the EU may adopt harmonizing legislation with the objective of protecting public health. In particular, it addresses the argument invoked by Germany and the tobacco industry that Article 114 TFEU cannot provide a valid legal basis if health is a decisive factor in the adoption of a given legislative act – here a directive. The same argument was made when tobacco manufacturers challenged the validity of the Tobacco Products Directive a few years later.[221]

While it is true that the Tobacco Advertising and the Tobacco Products Directives are more about restricting tobacco use[222] than promoting the free movement of tobacco products to increase their consumption, health considerations have constituted a decisive factor in their adoption.[223] This situation unavoidably creates serious tensions around the legitimacy of EU regulatory intervention, as Article 168(5) explicitly excludes the possibility for the EU to adopt public health harmonizing measures based on its provisions, despite its reference to the fight against major cross-border health scourges, in particular tobacco and the abuse of alcohol, as an EU priority:

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[219] Directive 2033/33, OJ 2003 L 152/16, Articles 3 and 4 more specifically. Only publications intended for professionals in the tobacco trade and publications from non-EU countries which are not principally intended for the EU market are exempt.

[220] Case C-380/03 *Germany v Council and the European Parliament (Tobacco Advertising II)* [2006] ECR I-11573.

[221] Case C-491/01 *British American Tobacco* [2002] ECR I-11453.

[222] One will note that the Tobacco Products Directive does not go as far as prohibiting the placement of tobacco products on the EU market, as it is not politically feasible to ban tobacco products altogether: see in particular G. Howells, *The Tobacco Challenge* (Ashgate, 2011).

[223] This stems not only from the Preambles of these Directives and clear statements from the Commission to this effect, but also from the fact that they were proposed by DG SANCO and that they were negotiated by health ministers.

> The European Parliament and the Council […] may also adopt incentive measures designed to protect and improve human health and in particular to combat the major cross-border health scourges, measures concerning monitoring, early warning of and combating serious cross-border threats to health, and measures which have as their direct objective the protection of public health regarding tobacco and the abuse of alcohol, excluding any harmonization of the laws and regulations of the Member States.

However, reading Article 168(5) TFEU in isolation conveys a misleading impression of EU powers in relation to public health matters, and NCD prevention and control more specifically. As discussed above, Articles 9 and 168(1) TFEU mandate that a high level of human health protection should be ensured in the definition and implementation of all EU policies and activities – hence the reliance placed by the EU on Article 114 TFEU as a primary tool for the development of its NCD prevention and control policy. The question therefore is how far public health may constitute a driving factor for the adoption of EU harmonizing rules relating to NCDs.

That health is a decisive factor is not a problem *per se*. The internal market has always paid consideration to health concerns: e.g., general free movement provisions (Article 36 TFEU); harmonization measures adopted on the basis of Article 114 (see Article 114(3)[224]). However, as the CJEU clearly stated in its first *Tobacco Advertising* judgment, Article 114 should not be relied on to 'circumvent the express exclusion of harmonization' under Article 168(5) TFEU.[225] Nevertheless, the Court has also pointed out that such exclusion does not mean that harmonizing measures based on other Treaty provisions could not have an impact on public health, since the latter had to form a constituent part of other EU policies, as confirmed by the third paragraph of Article 114 TFEU.[226] If the conditions for recourse to this article had been fulfilled, as they were in the second *Tobacco Advertising* case, it would have constituted an adequate legal basis. As the Court observed in *Alliance for Natural Health*, 'provided that the conditions for recourse to [Article 114 TFEU] as a legal basis are fulfilled, the [EU] legislature cannot be prevented

[224] 'The Commission […] will take as a base a high level of protection, taking account in particular of any new development based on scientific facts. Within the respective powers, the European Parliament and the Council will also seek to achieve this objective.'
[225] *Tobacco Advertising I*, para 79.
[226] *Tobacco Advertising I*, para 78.

from relying on that legal basis on the ground that public health protection is a decisive factor in the choices to be made.'[227]

The question thus remains to determine when Article 114 provides a suitable legal basis for the adoption of harmonizing rules contributing to the NCD prevention and control agenda, i.e. when Treaty provisions, and Article 168(5) more specifically, are not circumvented. In its more recent *Vodafone* judgment, which upholds the establishment of maximum roaming charges within the EU, the Court restated the conditions to be fulfilled for a measure to be validly adopted on the basis of Article 114 TFEU. To rely on this provision:

– there must exist an 'internal market barrier' resulting from the disparities in the legal systems of the Member States measures;
– this market barrier must not consist of an 'abstract risk of obstacles', but should be 'such as to obstruct the fundamental freedoms' or create 'distortions of competition' within the internal market;
– the intended harmonization should 'genuinely have as its object the improvement of the conditions for the establishment and functioning of the internal market'.[228]

The existence of barriers to trade depends on the overall level of EU harmonization in a given area. The less an aspect is regulated, the higher the potential for the existence of obstacles to trade. In the absence of harmonization, Member States remain competent to adopt national measures regulating, for instance, information schemes, sales conditions, and product requirements in the light of public health objectives.[229] Thus, the rules governing the information, sale conditions and product requirements of tobacco, alcohol and food products may differ from one Member State to another. For instance, some Member States have introduced rules banning the display of tobacco at points of sale,[230] whilst others have not. However, it is settled case law that 'a mere

[227] Joined Cases C-154 and 155/04 *Alliance for Natural Health* [2005] ECR I-6451, at para 30. See also B. De Witte, "Non-Market Values in Internal Market Legislation", in N. Shuibhne (ed), *Regulating the Internal Market* (Edward Elgar Publishing, 2006), 61. See also Case C-491/01 *British American Tobacco* [2002] ECR I-11453, at para 62, and by analogy, Case C-58/08 *Vodafone* [2010] ECR I-4999: 'provided that the conditions for recourse to [Article 114 TFEU] as a legal basis are fulfilled, the [EU] legislature cannot be prevented from relying on that legal basis on the ground that consumer protection is a decisive factor in the choices to be made' (at para 36).

[228] See in Case C-58/08 *Vodafone* [2010] ECR I-4999, para 32.

[229] For an overview of Member States' regulatory autonomy in the EU, see I. Maletic, *The Law and Policy of Harmonisation in Europe's Internal Market* (Edward Elgar Publishing, 2013).

[230] This is the case in Ireland, Finland and the UK.

finding of disparities between national rules is not sufficient to have recourse' to this provision.[231] One must consider the effects of such disparities: the differences must be 'such as to obstruct the fundamental freedoms or to create distortions of competition' and thus have a direct effect on the functioning of the internal market.[232] While 'national rules laying down the requirements to be met by products, in particular those relating to their designation, composition or packaging, are in themselves liable, in the absence of harmonization throughout the Community, to constitute obstacles to the free movement of goods',[233] it is disputable that other regulations, such as those dealing with the way in which products are sold, may be considered *per se* as barriers to trade. The *Philip Morris* judgment[234] delivered in September 2011 by the EFTA Court provides some guidance on this point.[235] The Court held that 'by its nature' a ban on the visual display of tobacco products is not only liable to favour domestic products over imported ones – as consumers tend to be more familiar with the former – [236] but also that such a discriminatory effect would be particularly significant with regard to market penetration of new products.[237] It follows that one approach for finding a basis under Article 114 TFEU for an EU-wide lifestyle regulatory intervention would be to establish that, due to the progressive emergence of national restrictions, there exists a risk of obstacles to trade such as obstruction of the free movement of goods or distortions of competition on the relevant market, especially *vis-à-vis* new products.[238]

This interpretation is further supported by the interpretation given to the other requirements justifying reliance on Article 114: even though an identified obstacle to trade is merely prospective it could still be adopted under this provision insofar as: (i) the emergence of such obstacles is 'likely'; and (ii) the measure in question is 'designed to prevent them'.[239] As stated by the CJEU:

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[231] See, lastly, Case C-301/06 *Ireland v Parliament and Council* [2009] ECR I-0593, paras 63-64.

[232] See, e.g., *Tobacco Advertising II,* paras 37 and 51; *Tobacco Advertising I,* para 90.

[233] Para 64. See also Joined Cases C-267/91 & C-268/91 *Criminal Proceedings against Bernard Keck and Daniel Mithouard* (Keck), para 15 and *Tobacco Advertising I*, para 64.

[234] Case E-16/10, *Philip Morris Norway AS ./. Staten v/Helse- og omsorgsdepartementet* (*Philip Morris*), [2011] EFTA Court, judgment of 12 September 2011.

[235] A. Alemanno, "The Legality, Rationale and Science of Tobacco Display Bans after the Philip Morris Judgment", 4(2) *European Journal of Risk Regulation* (2011), 591.

[236] *Philip Morris*, para 48 referring to C-405/98 *Konsumentombudsmannen v Gourmet International Products AB* [2001] ECR I-1795, para 21.

[237] *Philip Morris,* para 49.

[238] See, e.g., *Tobacco Advertising II*, para 37 and 51; *Tobacco Advertising I*, para 90.

[239] See *Tobacco Advertising I*, para 86 and Case C-491/01 *British American Tobacco* [2002] ECR I-11453, para 61; *Tobacco Advertising II*, para 38: and more recently Case C-58/08 Vodafone [2010] ECR I-4999, para 33.

> In that context, having regard to the fact that the public is increasingly conscious of the dangers to health posed by consuming tobacco products, it is likely that obstacles to the free movement of those products would arise by reason of the adoption by the Member States of new rules reflecting that development and intended more effectively to discourage consumption of those products by means of warnings and information appearing on their packaging or to reduce the harmful effects of tobacco products by introducing new rules governing their composition.[240]

It is therefore conceivable that a competence to harmonize which did not exist in the past may come into being where public pressure for national regulation increases.[241] As was astutely observed, this mounting public pressure 'pushes the prospect of such regulation beyond the constitutionally crucial threshold of "likelihood"'.[242] This illustrates how the CJEU, by interpreting the notion of 'likelihood' in those terms, has transformed the competence to harmonize pursuant to Article 114 TFEU from a static mechanism to a dynamic one.[243] In the same judgment, it also stated that 'progress in scientific knowledge is not […] the only ground on which the EU legislature can decide to adapt EU legislation since it must, in exercising the discretion it possesses in this area, also take into account other considerations, such as the increased importance given to the social and political aspects of the anti-smoking campaign'.[244] This statement clearly suggests that the case law developed thus far may be extended by analogy beyond tobacco to justify EU actions in areas such as the fight against harmful use of alcohol and unhealthy diets.[245]

If we return to marketing restrictions, fine lines must be drawn between forms of marketing that can be regulated at EU level and forms of marketing that

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[240] *British American Tobacco*, para 67.

[241] See Case C-210/03, *Swedish Match AB and Swedish Match UK Ltd v Secretary of State for Health (Swedish Match)* [2004] ECR I-11893, para 38.

[242] P. Oliver, *Oliver on Free Movement of Goods in the European Union,* 5th edition (Hart Publishing, 2010), 438.

[243] For a critique of the excesses deriving from such a dynamic interpretation, see, e.g. Editorial comments: "The Court of Justice in the limelight – again", 45 *Common Market Law Review* (2008), 1574; M. Dougan, "Legal Developments", 48 *Journal of Common Market Studies* (2010), 171.

[244] *British American Tobacco,* para 80.

[245] The Court's overstretching of the internal market legal basis has attracted concern from several commentators who are alarmed by its possible negative consequences on both Member States' regulatory autonomy and individual legal protection: see, e.g., M. Seidel, "Präventive Rechtsangleichung im Bereich des gemeinsamen Marktes", *Europarecht* (2006), 26; M. Kumm "Constitutionalizing Subsidiarity in Integrated Markets: The Case of Tobacco Regulation in the European Union", 12 *European Law Journal* (2006), 503; D. Wyatt, "Community Competence to Regulate the Internal Market", in M. Dougan and S. Currie (eds), *50 Years of the European Treaties: Looking Back and Thinking Forward* (Hart Publishing, 2009), 93-136.

cannot. Within the former category, one will find television, internet, radio and other forms of marketing which are cross-border in nature and therefore affect the functioning of the internal market. On this basis, the provisions of the AVMS Directive on the marketing of HFSS food or alcoholic beverages could be strengthened in line with existing evidence on the relationship between health and consumption patterns. This would in turn help Member States to fulfil their global commitments to curb the rising tide of NCDs by 2025. By contrast, other marketing restrictions cannot be validly adopted by relying on Article 114 TFEU or any other current provisions of the EU Treaties, insofar as they neither affect trade between Member States nor lead to appreciable distortions of competition. In particular, the *Tobacco Advertising* litigation has identified that this would be the case for the following forms of marketing:

– static forms of food advertising (advertisements in hotels, on billboards, umbrellas, ashtrays and similar items);
– advertisements screened in cinemas; and
– the sponsorship of events that do not have any cross-border appeal.

In these cases, the EU does not have the required powers to adopt common EU rules and it is for each Member State to regulate such forms of marketing, if they wish to do so.[246] It remains that determining the exact scope of EU powers may be extremely controversial. Would the EU be competent to regulate in-school marketing? Or to restrict product displays at points of sale? Or to ban vending machines selling tobacco, alcoholic beverages or HFSS food? Some of these questions have been evoked, in particular as part of the debates surrounding the revision of the Tobacco Products Directive. However, they have not given rise to any proposal from the Commission.[247] Likewise, it appears that the Commission's reticence in embracing plain packaging within the same proposal has also to do with doubts about its competence to act.[248] In particular, in the absence of national measures enacting plain packaging, it appears that a EU-wide standardized pack would provide a modest contribution to market integration. This appears all the more true as the "object"

[246] As discussed below, the freedom of Member States is subject to the general Treaty provisions preventing them from hindering the free movement of goods and the free movement of services.

[247] COM(2012) 788 final: http://ec.europa.eu/health/tobacco/products/revision/. On regulating displays at points of sale, see A. Alemanno, "Out of Sight Out of Mind: Towards a New European Tobacco Products Directive", 18 *Columbia Journal of European Law* (2012), 197; on regulating in-school marketing, see A. Garde, *EU Law and Obesity Prevention* (Kluwer Law International, 2010), at 84.

[248] See A. Alemanno, "Out of Sight Out of Mind: Towards a New European Tobacco Products Directive", 18 *Columbia Journal of European Law* (2012), 197.

of the "overall legislative framework" of EU tobacco discipline is not "the establishment and functioning of the internal market", but rather the pursuit of public health objectives.

Overall, the EU cannot adopt the comprehensive set of measures required to promote healthier lifestyles and change the environment in which we live to make it more conducive to healthier lifestyles. The example of the *Tobacco Advertising* litigation shows that all forms of marketing which cannot be regulated at EU level will require the intervention of individual Member States. This leads to an unavoidable degree of fragmentation. If fragmentation is not problematic in itself – it is an inherent feature of the EU legal order – it must however be managed efficiently: as discussed below, it is on this condition that the EU and its Member States will be able to develop an effective multi-level strategy for the prevention and control of NCDs in Europe.

The limits set to the exercise of EU powers by the principles of subsidiarity and proportionality

Once it is established that the EU has the required powers to adopt harmonizing legislation, it is necessary to determine whether the EU has exercised its powers in conformity with the principles of subsidiarity and proportionality. It clearly derives from a consistent line of case law that these two principles are subject to judicial review before the CJEU under Article 263 TFEU or indirectly before national courts. However, assessing whether they have been complied with raises inherently political questions, relating to the level of action and the intensity of an EU intervention. This explains why the CJEU has been reluctant to review in any detail the decisions made by the EU legislature as to how it should exercise its powers. It is only if the EU legislature manifestly exceeds the margin on its discretion by adopting a measure which should have been adopted at national rather than EU level and/or which is not legitimate nor adequately tailored to the objectives pursued, that the CJEU will annul it on the grounds of subsidiarity and/or proportionality.[249]

Subsidiarity

The principle of subsidiarity constrains EU action by requiring that EU intervention be triggered only where it adds value to action at national or local level.[250] For each measure envisaged as part of the developing EU NCD prevention and control policy under Article 114 TFEU (or other legal bases in areas of shared competence), the question thus arises whether the EU can achieve the objectives of a proposed measure better than the Member States can.

[249] See, e.g., Case C-120/97 *Upjohn Ltd* [1999] ECR 223, para 34
[250] Art. 5(3) TEU.

Traditionally, EU institutions have tended to pay lip service to the principle of subsidiarity, due probably to 'its lack of conceptual contours'.[251] In particular, the CJEU has often been criticized for failing to engage meaningfully with the question of whether the EU legislature has complied with its requirements.[252] One may wonder whether the *Vodafone* decision heralds a change in the approach of the CJEU.[253] On the one hand, it referred explicitly and for the first time to the Protocol on Subsidiarity and Proportionality which requires that the EU should legislate only to the extent necessary and that EU measures should leave as much scope for national decisions as possible, consistent however with securing the aim of the measure and observing the requirements of the Treaty.[254] On the other hand, the Court's reference to the Protocol did not trigger a thorough subsidiarity review of EU action.[255] It did not engage in any depth with the substantive aspects of subsidiarity to conclude that the EU legislature had not infringed the principle of subsidiarity.[256] Rather, it simply recognized the existence of economic interdependence between retail and wholesale charges for roaming services.[257] This is perhaps all the more surprising, as Advocate General Maduro had explicitly invited the Court to carry out a more thorough subsidiarity review: in light of the inherently cross-border nature of roaming services, he concluded that the EU would be both more willing to address the problem of high prices than Member States individually and in a better position to balance the costs and benefits of the intended action for the internal market and that the Roaming Regulation therefore complied with the principle of subsidiarity.[258]

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[251] R. Schütze, *European Constitutional Law* (CUP, 2012), 178.

[252] See in particular A. Dashwood, "The Relationship between the Member States and the European Union/European Community", 41 *Common Market Law Review* (2004), 2. This is not to suggest, however, that if the Court had reviewed the EU's compliance with the principle of subsidiarity that it would necessarily have concluded that the measures under review did not comply with this principle: P. Craig, "Subsidiarity: A Political and Legal Analysis", 50 *Journal of Common Market Studies* (2012), at 81.

[253] Case C-58/08 *Vodafone* [2010] ECR I-4999.

[254] *Protocol (No. 2) on the Application of the Principles of Subsidiarity and Proportionality* OJ 2010 C 83/206.

[255] Paras. 77-79. One could also note that the Court did not refer to paragraph 5 of the Protocol which requires that 'draft legislative acts shall be justified with regard to the principles of subsidiarity and proportionality. Any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality. […] The reasons for concluding that a Union objective can be better achieved at Union level shall be substantiated by qualitative and, wherever possible, quantitative indicators.'.

[256] M. Brenncke, "Case Law", 47 *Common Market Law Review* (2010), 1812. In a similar vein, see A. Biondi, "Subsidiarity in the Courtroom", in A. Biondi and Eeckhout (eds), *EU Law after Lisbon* (OUP, 2012) 213-227.

[257] Paras 78 and 79.

[258] Opinion of AG Maduro, at paras 30–34.

By analogy with the *Vodafone* decision, one can argue that services with significant cross-border implications (for example, internet advertising) are such that EU action provides by nature a far more effective intervention than action by Member States at national level.[259] Similarly, the EU tends to be in a better position than Member States to regulate the composition, labelling and presentation of products such as tobacco, food and alcoholic beverages that are traded extensively across borders within the EU (and beyond). The EU has therefore adopted a wide range of measures on the content, labelling or packaging of tobacco and food products. The EU could envisage the adoption, on the basis of Article 114 TFEU, of further harmonizing measures to regulate the labelling of alcoholic beverages, to mandate the plain packaging of tobacco products[260] or to ban the use of trans-fats in foods.[261]

One expression of the principle of subsidiarity has arguably been the reliance by the EU on a range of harmonization techniques which allow for the accommodation of national diversity in areas, such as the promotion of healthier lifestyles, where specific national circumstances may have an important role to play in determining consumption patterns and cultural preferences. Thus, to balance the need for free movement with the need for national regulatory autonomy, the AVMS Directive has relied on a range of harmonization techniques. In particular, it has combined a clause of minimum harmonization with the Transmitting State Principle.[262]

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[259] The role of advertising in EU market integration has been most vividly described by AG Jacobs in his Opinion in Case C-412/93 *Société d'Importation Edouard Leclerc-Siplec v TF1 Publicité SA and M6 Publicité SA* [1995] ECR I-179, at para 21: 'Without advertising it would be extremely difficult for a manufacturer located in one Member State to penetrate the market in another Member State where his products have not previously been sold and so enjoy no reputation among consumers.'

[260] A. Alemanno, "Out of Sight Out of Mind: Towards a New European Tobacco Products Directive", 18 *Columbia Journal of European Law* (2012), 197.

[261] However, in the absence of legislative harmonizing measures on these issues, Member States retain their freedom to regulate these areas, on the condition that they comply with the general Treaty provisions, not least those on the free movement of goods and services.

[262] It is regrettably not possible to be exhaustive, in this short case study, of all the mechanisms the EU has used to try and accommodate national diversity with the demands of the EU internal market. However, it is worth pointing out that the EU has relied on the mechanism of partial harmonization (e.g. it does not define what a children's programme is and leaves the definition to each Member State) and the mechanism of optional harmonization (e.g. Article 11 of the AVMS Directive allows Member States to derogate from the prohibition of product placement, provided that they respect certain conditions relating to the type of programme the product placed, the integrity of the programme and the information of consumers). On the regulation of product placement, see L. Woods, "The Consumer and Advertising Regulation in the Television without Frontiers and Audiovisual Media Services Directives", 31 *Journal of Consumer Policy* (2008) 63; C. Angelopoulos, "Product Placement in European Audiovisual Productions", in *Product Placement* (European Audiovisual Observatory, 2010), 11; A. Garde, "Towards the Liberalisation of Product Placement on UK Television?", 16 *Communications Law* (2011), 92.

Under Article 4 of the AVMS Directive, Member States are 'free to require media service providers under their jurisdiction to comply with more detailed or stricter rules'. In light of the EU's failure to act on the basis of existing evidence concerning the relationship between HFSS food and alcohol marketing and children's health, several Member States have relied on this provision to exceed the minimum level of protection that the AVMS Directive provides. Some Member States have decided to ban advertising to children entirely for all goods and services, as Sweden has done since 1991,[263] whereas other Member States have restricted the marketing of alcoholic beverages[264] or HFSS food.[265]

However, the discretion which Member States derive from the clause of minimum harmonization is limited by the Transmitting State principle which requires that 'Member States shall ensure freedom of reception and shall not restrict retransmissions on their territory of [AVMS] from other Member States for reasons which fall within the fields coordinated by this Directive'.[266] In other words, Member States may only impose standards exceeding the minimum level of protection provided in the AVMS Directive on providers established in their jurisdiction.[267] They cannot impose standards on providers established in other Member States, as these providers only have to comply with the law of the State from which they transmit, not the law(s) of the other State(s) into which they transmit.[268]

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[263] Section 7 of the Swedish Radio and Television Act states that commercial advertising in television broadcasts, teletext and on-demand television may not be designed to attract the attention of children of less than 12 years of age.

[264] For an overview of Member States' regulatory intervention, see the Contact Committee document attached to minutes of 35th meeting of the Contact Committee established by Article 29 of the AVMS Directive, http://ec.europa.eu/avpolicy/docs/reg/tvwf/contact_comm/35_table_1.pdf.

[265] For example, the UK bans HFSS food advertising in or around programmes aimed at children (including pre-school children), or in or around programmes likely to be of particular appeal to children aged 4 to 15: see http://www.ofcom.org.uk/consult/condocs/foodads_new/. Similarly, the Irish Children's Advertising Code prohibits the use of celebrities or sport stars to promote HFSS food to children up to 18 years of age: see http://www.bci.ie/codes/childrens_code.html.

[266] Article 3(1).

[267] On the state of establishment principle, see A. Herold, "Country of Origin Principle in the EU Market for Audiovisual Media Services: Consumer's Friend or Foe?", 31 *Journal of Consumer Policy* (2008), 5; and O. Castendyk, E.J. Dommering and A. Scheuer, *European Media Law* (Kluwer Law International, 2008), 847.

[268] This was most vividly illustrated by the decision of the CJEU in the De Agostini case in which it ruled on the compatibility of the Swedish ban on advertising to children and distinguished the extent to which it could apply depending on whether the service providers were broadcasting from Swedish territory or from another EU Member State: Case C-34/95 *Konsumentombudsmannen (KO) v De Agostini (Svenska) Forlag AB* [1997] ECR I-3875.

Furthermore, if Member States exercise the discretion that they retain under the AVMS Directive to adopt stricter standards applicable to the AVMS providers transmitting to other Member States from their territories, then they must do so in conformity with the general Treaty provisions, and in particular Article 34 TFEU on the free movement of goods and Article 56 TFEU on the free movement of services. The case law of the CJEU on these two provisions has tended to leave a relatively broad margin of discretion when Member State had imposed restrictions on the marketing of certain goods and services on public health grounds. Thus, in *Bacardi*, the *Loi Evin* imposing a near total ban on alcohol advertising in France was challenged.[269] After accepting that restrictions on the advertising of alcoholic beverages reflected public health concerns, the Court stated:

> [R]ules on television advertising such as those at issue in the main proceedings are appropriate to ensure their aim of protecting public health. Furthermore, they do not go beyond what is necessary to achieve such an objective. They limit the situations in which hoardings advertising alcoholic beverages may be seen on television and are therefore likely to restrict the broadcasting of such advertising, thus reducing the occasions on which television viewers might be encouraged to consume alcoholic beverages.[270]

Thus, in this decision, the Court hardly discussed the proportionality of the measure, leaving a particularly broad, largely unfettered discretion to Member States.[271] Similarly, when requested to assess the compatibility of the Norwegian ban on the visual display of tobacco products, the EFTA Court ruled that review of proportionality and of the effectiveness of the measures taken relied on findings of fact which the national court was in a better position to make.[272] It concluded 'that it was for the national court to identify the aims which the legislation at issue actually intended to pursue and to decide

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[269] Case C-429/02 *Bacardi France* [2004] ECR I-6613. See also the judgment delivered on the same day in Case C-262/02 *Commission v France* [2004] ECR I-6569.

[270] Case C-429/02 *Bacardi France* [2004] ECR I-6613, para 38.

[271] As Tridimas has noted, the Court paid lip service to the argument that indirect television advertising was allowed in multinational sporting events where the French audience was very high but not in bi-national events which tended to attract lower audience numbers. The Court confined itself to pointing out that bi-national events targeted specifically a French audience and therefore the restriction of the prohibition to such events made it proportionate. The Court was preoccupied not so much with upholding a consistent health policy but with national choice: T. Tridimas, *The General Principles of EU Law*, 2nd edition (OUP, 2006), 222.

[272] Case E-16/10 *Philip Morris*, 12 September 2011, para 86, annotated by A. Alemanno, "The Legality, Rationale and Science of Tobacco Display Bans after the Philip Morris Judgment", 4(2) *European Journal of Risk Regulation*, (2011), 591.

whether the public health objective of reducing tobacco use by the public in general can be achieved by measures less restrictive than a visual display ban on tobacco products.'[273] Even though the EFTA Court stated that the national authorities needed to demonstrate that they had complied with the principle of proportionality,[274] it did not check whether the Norwegian authorities had done so when adopting the contested measures.

However, the assessment of the proportionality of measures restricting the marketing of HFSS food – as opposed to tobacco products or alcoholic beverages – may prove much more difficult. In effect, there is no dispute that it is only HFSS food, as opposed to food in general, that should be subjected to a marketing ban. This distinction therefore calls for the establishment of nutrition profiling schemes.[275] To date, however, the EU has not proposed an EU-wide scheme allowing for the classification of food into HFSS or non-HFSS categories.[276]

The question of the age of the child also raises difficult questions. The EU has not defined what a child is for the purposes of the implementation of the rules of the AVMS Directive, including those on the marketing of alcoholic beverages and HFSS food. It leaves the decision to Member States, as do the WHO Recommendations. Thus, the UK has – on the basis of a detailed impact assessment – decided to ban all HFSS food marketing in and around television programmes for children younger than 16 years of age. Norway

[273] At para 88.

[274] At para 85.

[275] This probably explains why the WHO calls on States to implement the WHO Recommendations on the marketing of food and non-alcoholic beverages to children without however listing this type of intervention as one of the 'best buys'. On the establishment of nutrition profiles and their relevance to the EU's nutrition policy, see M. Friant-Perrot and A. Garde, "From BSE to Obesity – EFSA's Growing Role in the EU's Nutrition Policy", in A. Alemanno and S. Gabbi (eds), *Foundations of EU Food Law and Policy – Ten Years of European Food Safety Authority* (Ashgate, 2013, forthcoming).

[276] In the first report on the application of the AVMS Directive, which it published in May 2012, the Commission nonetheless stated that it would 'support the development of […] more consistent nutritional benchmarks across companies' that there was a European Commission, *First Report on the Application of the Audiovisual Media Services Directive* (2012), 9. The EU Pledge does not lay down uniform nutritional criteria, allowing food operators to promote certain items that should arguably fall within the category of HFSS food. However, a consultation on this issue has been launched: http://www.eu-pledge.eu/sites/eu-pledge.eu/files/releases/EU_Pledge_Nutrition_White_Paper_Nov_2012.pdf. See also the discussions which took place at the EU Platform meeting on 19 June 2013 and which focused on food marketing to children: http://ec.europa.eu/health/nutrition_physical_activity/docs/ev20130619_ccl_en.pdf.

is currently reflecting on new rules on HFSS food marketing to children.[277] The age originally proposed was 18; it was then lowered to 15. As stated above, policies should be based on evidence rather than mere assumptions, and this is true irrespective of whether the legislator has a higher or a lower threshold in mind. A comprehensive approach is not an arbitrary approach. The burden of proof rests on the legislature to establish that the rules it has adopted are suitable and necessary, and that it has drawn the lines adequately: if less restrictive rules can attain the same objectives, then the lesser rules should be preferred. It is argued that Member States must tread with caution: it is better to ensure a broad coverage of all relevant media and promotional techniques popular with children, even if this means that – on the basis of existing evidence – an age threshold of 15 is chosen, rather than imposing a higher threshold of 18, which is not necessarily supported by evidence, and losing the battle in court on the grounds of proportionality.[278] Any lost case – by giving rise to a 'regulatory chill' – may lead to a domino effect whereby other public authorities may feel deterred from taking the risk of having their rules successfully challenged on proportionality grounds.

The scheme set up by the AVMS Directive contrasts sharply with the scheme set up by the 2003 Tobacco Advertising Directive which lays down uniform EU standards and therefore prevents Member States from derogating from its provisions. The decision to adopt provisions of maximum harmonization therefore puts a heavy burden on the EU to evaluate the consequences of its regulatory intervention carefully, both for the EU and for its 28 Member States. In relation to the cross-border advertising of tobacco products, evidence does call for the highest standard, and it is arguable that this standard is more effectively achieved collectively at EU level than by the unilateral action of Member States. However, it is also true that if the EU does not adequately regulate the marketing of alcoholic beverages and HFSS food, as is the case in the AVMS Directive, then the clause of minimum harmonization only provides a temporary respite to Member States. The more protective standards they may adopt to compensate for the EU's failure to act in line with existing evidence will only apply to providers established in their

[277] M. Vaale-Hallberg, "Fighting Non-Communicable Diseases: Possible Comprehensive Ban on the Marketing of Unhealthy Food and Beverages to Children", *European Food and Feed Law Review* (2012), 213.

[278] This is even more so in light of WTO obligations that require that rules that also require that any marketing restrictions will only be upheld if they are necessary. On the relationship between WTO rules and the NCD agenda, see B. McGrady, *Trade and Public Health – The WTO, Tobacco, Alcohol and Diet* (CUP, 2011), especially chapters 3 and 4 dealing with marketing restrictions.

territories, not to providers transmitting from other Member States if these Member States do not have similar standards in place.

Differentiated harmonization may offer several advantages. First, it may help secure an agreement between Member States on the need for harmonization, whilst still promoting the objectives of the internal market by limiting the scope of their discretion through minimum standards. This is all the more so as a minimum standard does not necessarily constitute a minimal standard[279] and as the provisions on the marketing of tobacco products clearly illustrate.[280] Second, differentiated harmonization allows for a degree of caution in areas where the necessary evidence has not yet been gathered to determine with certainty what constitutes the most appropriate standard. In any event and as discussed in the second section of this report, once scientific evidence accumulates in favour of a stricter standard, it is always open to the EU and its Member States to reopen the debate and review existing provisions in order to take the evidence in question on board. Minimum harmonization can therefore be envisaged as a laboratory for EU integration. The flexibility it offers may allow the EU to tread with caution in a policy area such as NCD prevention where the need for multi-sectoral, multi-level strategies renders the negotiating process between all relevant stakeholders all the more complex.

Nevertheless, differentiated integration also entails certain risks which the EU should take great care to avert. First, the harmonized standard should not be set at a level so low that it becomes meaningless both from an internal market point of view and from a public health perspective. The provisions of the AVMS Directive on the marketing of alcoholic beverages and HFSS food perfectly illustrate the point, since the standards that they lay down are so low that they cannot provide the basis for any meaningful harmonization at EU level. Second, differentiated integration may accentuate the fragmentation of the EU legal order. While a certain degree of fragmentation is unavoidable, it is paramount to ensure as much coherence as possible within this setting. This is why it is important to ensure that EU policies are based on evidence rather than mere assumptions. This leads to a third risk, namely the risk that different actors may rely on the subsidiarity rhetoric to reach specific, predetermined outcomes. For example, one cannot help but notice that the European Commission has invoked its duty to comply with the principle of subsidiarity to justify its refusal to regulate the alcohol industry – the few,

[279] See in particular Case C-84/94 *UK v Council (Working Time Directive)* [1996] ECR I-5755.

[280] The relevant provisions impose a ban on all commercial communications covered by the Directive: see Article 9(1)(d) on audiovisual commercial communications in general; Article 10(2) on sponsorship; and Article 11(4)(a) on product placement.

largely ineffective, provisions discussed above aside. The fact that drinking patterns vary from one Member State to another should not necessarily mean that regulating the marketing of alcoholic beverages is more effectively done at national rather than at EU level. The Commission has – to date – failed to explain why the market for alcoholic beverages should be treated so distinctly from the market for tobacco products and why the cross-border marketing of alcoholic beverages should not be regulated at EU level. Subsidiarity can cut both ways.[281]

Proportionality

Any EU measure must also comply with the principle of proportionality which requires that the content and form of EU action shall not exceed what is necessary to achieve the objectives of the EU Treaties.[282] According to settled case law, an EU act is proportionate when it is suitable and necessary to achieve its declared goal.[283] In particular, the principle of proportionality requires that (1) measures adopted by EU institutions should not exceed the limits of what is suitable or appropriate in order to attain the legitimate objective pursued by the legislation in question (suitability); and (2) where there is a choice between several appropriate measures, the least onerous method should be used (necessity). [284]

Under the suitability limb of the proportionality test, it is necessary to determine whether a given lifestyle regulatory intervention is capable of attaining its internal market and public health objectives. As previously discussed, any EU-wide scheme harmonizing domestic rules should be capable of overcoming the disparities between national schemes. Yet the question remains whether the chosen EU-wide scheme is appropriate to contribute to the attainment of its other declared objective: ensuring a high level of public health protection. This inquiry shifts the focus of the suitability analysis from the harmonization to the public health objective of the measure. It inevitably requires the Court to open the Pandora's box of the effectiveness of the measure in achieving a high level of human health protection through the reduction of

[281] See, on this point, G. Lyon-Caen, "Subsidiarity", in Davies, A. Lyon-Caen, S. Sciarra and S. Simitis (eds), *European Community Labour Law: Principles and Perspectives. Liber Amicorum Lord Wedderburn of Charlto*n (Oxford Clarendon Press, 1996), at 49.

[282] Art. 5(4) TFEU.

[283] Case C-11/70 *Internationale Handelsgesellschaft* [1970] ECR 1125.

[284] See, to that effect, joined cases C-96/03 and C-97/03 Tempelman and van Schaijk [2005] ECR I-1895 [48]; Case C-86/03 *Greece v Commission* [2005] ECR I-10979, para 96; Case C-504/04 *Agrarproduktion Staebelow* [2006] ECR I-679, para 37; Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, para 411, as well as the parallel Case T-70/99 *Alpharma v Council* [2002] ECR II-3495. See more recently, Case C-58/08 Vodafone [2010] ECR I-4999, para 53.

the morbidity and mortality induced by the consumption of tobacco products, alcoholic beverages and unhealthy diets.

Scrutinizing the suitability of a lifestyle measure in attaining a high level of public health protection raises several difficulties which largely derive from the inherent scientific uncertainty surrounding the adoption of regulatory measures as part of the NCD prevention and control agenda and from the difficulty in establishing a causal link between these measures and their expected outcome. The difficulties are further compounded by the fact that lifestyles cannot be improved by individual measures taken in isolation. There is no 'magic bullet'; only a multi-sectoral policy will lead to healthier lifestyles, which makes the effectiveness of a specific intervention all the more difficult – if not impossible – to quantify.[285] Moreover, it is well known that the effect of any form of lifestyle intervention tends to appear gradually and over time. More critically, the specific effects of lifestyle control policy are difficult to discern from those stemming from the overall policy. In these circumstances, it is to be welcomed that the Court is prepared to grant a broad margin of discretion to the EU legislature to determine which policy tools are likely to achieve a public health objective.[286]

The necessity limb requires verification of whether a less restrictive measure could achieve the declared goal of ensuring a high level of public health protection.[287] In the presence of alternative, equally effective policy options, the EU legislature is bound to choose the least intrusive one of them. Such an assessment inevitably requires a comparative analysis between the measure under review and other policy options. In an area such as NCD prevention and control, this analysis is extremely difficult to carry out as a result of the multi-sectoral approach required from competent authorities. Which policy options should be considered? How should they be measured and compared, and with reference to what benchmark?

Plain packaging provides an interesting case study to test the challenges raised by the application of the proportionality test to a lifestyle measure. The question is whether plain packaging is necessary to achieve the internal market objective (Article 114 TFEU is the legal basis) and whether this could

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[285] A. Garde, "Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance", in L. Gormley and N. Shuibhne (eds), *From Single Market to Economic Union – Essays in Honour of John Usher* (OUP, 2012), 117.

[286] E-16/10 *Philip Morris Norway AS ./. Staten v/Helse- og omsorgsdepartementet* [2011] EFTA Court, judgment of 12 September 2011.

[287] See, e.g., Case C-137/85 *Maizena* [1987] ECR 4587, para 15; Case C-339/92 *ADM Ölmühlen* [1993] ECR I-6473, para 15; and Case C-210/00 C Käserei [2002] ECR I-6453, para 59.

be achieved by a less onerous method. If we assume that the trade barrier targeted by the EU packaging requirement is represented by the adoption in one, or more, Member States of a national standardized pack regime, then it is difficult – not to say impossible – to think about a different measure to overcome this regulatory obstacle. Due to the health protection goal pursued by standardized packaging requirements, one should also verify whether this policy tool is necessary to achieve this objective. As mentioned above, this examination inevitably leads to a debate about the effectiveness of plain packaging, as compared with other tobacco control tools, which may possibly score better in terms of impact on trade. Given the ancillary character of the public health objective inherent in the choice of the legal basis supporting an EU-wide packaging scheme, one might expect that the CJEU would limit its assessment of the necessity test *vis-à-vis* the harmonization objective. However, when recently called upon to examine the proportionality of an EU measure pursuing both objectives (namely, a prohibition on marketing certain tobacco products for oral use), the CJEU did not connect that analysis with the internal market objective underpinning the Tobacco Products Directive.[288] Instead, the Court carried out the proportionality analysis by reference to the public health objective alone and concluded that 'it was the only measure that appeared appropriate to cope with the real danger that those new products would be used by young people, thus leading to nicotine addiction'.[289]

As Advocate General Fennelly suggested in his opinion in *Tobacco Advertising I*,

> health protection cannot function independently as an objective. Therefore, however great may be the health benefits of restricting most forms of advertising, even in exclusively domestic contexts, this will only satisfy the first condition of proportionality if [… the measure] contributes to achieving internal market objectives; otherwise it must be condemned for failing to meet an essential objective which is also a condition of the exercise of competence in the first place.[290]

This shows the inherent link existing between competence and proportionality analysis: a policy option that fails to satisfy the legal competence test under Article 114 TFEU is also likely to fail the suitability test under proportionality. It is therefore necessary that the EU legislature proves the suitability of any proposed lifestyle measures, such as an EU-wide standardized

[288] Case C-210/03, Swedish Match [2004] ECR I-11893.
[289] *Ibid.*, para 49.
[290] *Tobacco Advertising I*, para 149.

packaging requirement, vis-à-vis the internal market objective, its ability to overcome trade barriers, and distortions of competition stemming from the actual disparities in product sales regulations. Yet this does not address the issue of determining whether other less onerous policy options may achieve the same policy goal.

The current practice of carrying out an impact assessment for all major Commission initiatives may lead EU courts to refer to such preparatory works before reaching their conclusions. Thus, as the Impact Assessment guidelines require the Commission to establish 'which policy options and delivery mechanisms are most likely to achieve' the objectives pursued by the underlying initiative,[291] they may take this assessment into account when determining whether the final measure is necessary and therefore compatible with the principle of proportionality.[292]

Concluding remarks on the constraints imposed by EU constitutional law
In practice, and as the *Tobacco Advertising* litigation clearly illustrates, industry operators tend to challenge NCD prevention and control measures by invoking simultaneously the principles of conferral, subsidiarity and proportionality. This is intended not only to increase their chances of seeing a measure annulled, but also to ensure that defending such challenges is costly for regulators, hoping that this will, in turn, discourage them from adopting further regulatory measures as part of the NCD agenda.[293] This 'regulatory chill effect'[294] could also lead them to privilege self-regulation as a cheaper alternative over traditional regulation of food and alcohol products.[295]

The principles of conferral, subsidiarity and proportionality unavoidably lead to a certain degree of fragmentation of the EU legal order. Even though comprehensive strategies must be developed to minimize the harm resulting from smoking, alcohol abuse and unhealthy diets, the EU alone cannot adopt such strategies, as is clearly illustrated by the *Tobacco Advertising* litigation. It is

[291] Impact Assessment Guidelines, 2009, 28.

[292] A. Alemanno, "The Better Regulation Initiative at the Judicial Gate: A Trojan Horse within the Commission's Walls or the Way Forward?", 15(3) *European Law Journal* (2009), 382; A. Alemanno, "A Meeting of Minds on Impact Assessment: When Ex Ante Evaluation Meets Ex Post Judicial Control", 17(3) *European Public Law* (2011), 485.

[293] D. Stuckler and M. Nestle, "Big Food, Food Systems, and Global Health", 9(6) *PLoS Medicine* (2012).

[294] C. Callard, H. Chitanondh and R. Weissman, "Why Trade and Investment Liberalization May Threaten Effective Tobacco Control Efforts", 10 *Tobacco Control* (2001), 68.

[295] L. Sharma, S.P. Teret, and K.D. Brownell, "The Food Industry and Self-Regulation: Standards to Promote Success and to Avoid Public Health Failures", 100(2) *American Journal of Public Health* (2010), 240.

not suggested that fragmentation is problematic in itself; nevertheless, to be effectively managed it requires that the key constitutional principles of EU action apply with sufficient certainty.

3.2.2 EU and international trade law

As virtually all NCD policies previously discussed aim to reduce the consumption of goods that are freely traded across the world, their implementation inevitably encroaches, at least potentially, upon international trade rules. As a result, the trade regime, due to its vocation towards the liberalization of trade, comes into play and emerges as one of the most immediate obstacles to the development of an effective NCD prevention and control strategy. At the same time, trade liberalization efforts, as fostered by Regional Trade Agreements (RTAs) like the EU, NAFTA or MERCOSUR as well by the multilateral trade regime enshrined in the WTO Agreements, by stimulating demand for tobacco,[296] alcohol[297] and HFSS products,[298] translate into negative health consequences. This phenomenon, which has been empirically proven, is often referred to as 'coca-colonization' as it results from the spread of Western cultural and dietary models through investments in marketing and other communication techniques.[299] Therefore trade agreements do not only constrain the regulatory autonomy of states, by questioning the legality of their attempts at protecting public health, but they also contribute, by stimulating the demand for the relevant goods, to worsening public health.

This is not to suggest, however, that international trade law is totally unresponsive and detrimental towards domestic attempts aimed at tackling the rise in NCDs through the adoption of policies aimed at reducing consumption.

Each trade regime, be it the EU or the WTO, attempts to strike a balance between trade liberalization and public health protection. The question there-

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[296] See, e.g., A. Taylor, F. Chaloupka, E. Guindon, and M. Corbett, "The Impact of Trade Liberalization on Tobacco Consumption", in J. Prabhat and F. Chaloupka (eds), *Tobacco Control in Developing Countries* (OUP, 2000), 343-364.

[297] See, e.g., M. Kuo, J.L. Hee, G. Gmel et al., "Does Price Matter? The Effect of Decreased Price on Spirits Consumption in Switzerland", 27 *Alcoholism: Clinical and Experimental Research* (2003), 720.

[298] R.E. van der Hoeven, C. Blouin and M. Chopra, "Trade and the Social Determinants of Health" *The Lancet* (2009) 502; C. Hawkes, C. Blouin, S. Henson, N. Drager and L. Dubé (eds) 373 *Trade, Food, Diet and Health: Perspectives and Policy Options* (Wiley Blackwell, 2010).

[299] See, e.g., T. Lobstein, "Tackling Childhood Obesity in an Era of Trade Liberalisation", in C. Hawkes, C. Blouin, S. Henson, N. Drager and L. Dubé (eds) *Trade, Food, Diet and Health: Perspectives and Policy Options* (Wiley Blackwell, 2010).

fore from both a legal and policy perspective is whether the domestic regulatory autonomy left to the states reflects an appropriate balance between these two conflicting interests.

The constraints of international trade provisions to the implementation of a NCD policy are roughly similar at European Union (EU) and World Trade Organization (WTO) levels.[300] As both EU and WTO law start from the premise that trade liberalization, by allocating resources in the most efficient manner, will maximize opportunities for states, consumers and businesses alike, they impose a set of market-access commitments.[301] However, while Member States are prohibited from distorting free trade by adopting protectionist measures discriminating against imports, international trade rules also recognize that Member States should be able to invoke public interest objectives, including public health protection, to justify exceptions to the general principle that goods and services should move freely.[302] They nonetheless limit the discretion that Member States have to impose trade restrictions on public health grounds by requiring that these restrictions be proportionate, i.e. legitimate and no more restrictive than necessary to protect public health.[303]

The notion of discrimination is key to the enquiry: a State should not, as a rule, favour goods or services originating from its territory to the disadvantage of imported goods and services.[304] This notion has been construed widely to cover both direct and indirect discrimination. In cases of direct discrimination, Member States adopt measures which explicitly invoke nationality to treat imports less favourably than the goods or services coming from other Member States: these measures are therefore said to discriminate both in law and in fact. For example, a tax imposed on imported alcoholic products, such as beer, but not applicable to domestic products would breach the principle of non-discrimination. Also indirectly discriminatory measures,

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[300] For a detailed analysis of the relationship (commonalities and divergences) between EU and WTO rules, see F. Ortino, *Basic Legal Instruments for the Liberalisation of Trade: a Comparative Analysis of EC and WTO Law* (Hart Publishing, 2004).

[301] In the EU context, see, e.g., Article 34 TFEU and Article 56 TFEU and in the WTO context see, e.g., Article III(4) GATT.

[302] In the EU context, see, e.g., Article 36 and Article 52 TFEU; and in the WTO context Article XX GATT and Article XIV GATS.

[303] In the EU, in the absence of a detailed set of principles against which to test the proportionality of EU action, the scope of this principle has largely been defined by the CJEU.

[304] For a comprehensive account of the relationship between WTO law and the global NCD agenda, see B. McGrady, *Trade and Public Health: The WTO, Tobacco, Alcohol, and Diet* (CUP, 2011) and T.S. Voon, 'WTO Law and Risk Factors for Non-Communicable Diseases: A Complex Relationship', *Research Handbook on Environment, Health and the WTO*, G. van Calster and D. Prévost (eds) (Edward Elgar, 2013), 390-408.

while they are origin-neutral, may have the effect of putting imported goods or services at a disadvantage: these measures are therefore said to discriminate in fact but not in law. For example, a tax imposed on all beers, regardless of their origin (domestic or imported), may amount to an indirect discrimination if applied by a wine-producing country. Given the substitution effect between beer and wine, such a measure may indeed protect the domestic industry of wine against the production and importation of beers. This might be relevant in the case of a 'fat tax': the application of differential taxes to food or alcoholic products, by altering the conditions of competition between goods based on the relative health risks they pose, may afford protection to domestic products and, as a result, violates Article III(2) GATT.

Both directly and indirectly discriminatory measures fall within the scope of trade rules, except if they can be justified on public health protection or other grounds of public interest. However, even though these measures may validly be inspired by one of these legitimate objectives, they remain subject to some policy-balancing mechanisms aimed at scrutinizing their regulatory legitimacy.

Regardless of the applicable mechanism (be it 'necessity' in the WTO[305] or 'proportionality' in the EU), the regulatory legitimacy of the measure will generally be determined by reference to its suitability to protect health and depending on whether that health goal could be achieved by less trade-restrictive means. This means that one should not crack a nut with a sledge hammer. In other words, the means used to achieve a specific objective, such as public health, must be tailored to the objective in question. As a result, 'the adequacy of policy space found in the relevant tests turns ultimately on a case-by-case analysis of what is and what is not permitted and how this may affect public health as a value in and of itself'.[306]

Admittedly, the line between what constitutes a legitimate restriction on trade and what does not may be extremely difficult to draw – as in most disciplines, the devil lies in the detail. In this context, one may therefore wonder whether the judiciary is well-placed and epistemically capable of conducting such an assessment. Yet there is a vast amount of case law on the relationship between free trade and public health protection in both the EU and WTO contexts.[307]

[305] B. McGrady, "Necessity Exceptions in WTO Law: Retreaded Tyres, Regulatory Purpose and Cumulative Regulatory Measures", 12 *Journal of International Economic Law* (2009), 153.

[306] See B. McGrady, *Trade and Public Health: The WTO, Tobacco, Alcohol, and Diet* (CUP, 2011), 27.

[307] See, Alemanno, *Trade in Food – Regulatory and Judicial Approaches in the EU and the WTO* (Cameron May, 2007); B. McGrady, *Trade and Public Health: The WTO, Tobacco, Alcohol, and Diet* (CUP, 2011).

The policy-balancing tests devised vary from one case to another, depending in particular on whether the rules considered are EU or WTO rules, and in the latter case, which WTO Agreements do apply (e.g. GATT,[308] Technical Barriers to Trade (TBT),[309] Sanitary and Phytosanitary (SPS)[310]). The difficulties facing the public health community are further compounded by the fact that the burden of proof largely rests on the parties invoking the need to restrict trade to protect public health.[311] In other words, it is the party arguing that public health concerns justify a derogation from the principle of free trade that must gather and present the evidence necessary to establish, first, that the restriction pursues the legitimate objective of public health protection and, second, that it is proportionate to the objective pursued. Existing evidence must therefore be framed in such a way as to satisfy the legal tests applicable in each specific case.[312] However, given the epistemic unease with which most legal interpreters approach scientific evidence, the required scrutiny over the legality of the contested measure is likely to be difficult to exercise.

Advocate General Maduro summed up this difficulty in his opinion in the *Dutch Vitamin case* as follows:

> must the Community judicature's review be restricted to addressing the various stages of the decision-making process, or should it assess the quality of the scientific analysis conducted or even review the latitude attributed to policy as opposed to science?[313]

As is often the case, the answer to this question depends on the circumstances of the case as well as on the formulation of the invalidity grounds by the parties. As a result, there exist several difficulties in scrutinizing the suitability of a lifestyle measure in attaining its declared objective. These range from some broader issues, such as the multifactorial nature of the phenomena that are regulated, to more specific ones, such as the difficulty in pinpointing

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[308] Article III(4) GATT.

[309] Article 2.2 TBT ('technical regulations *shall not be more trade restrictive* than necessary to fulfil a legitimate objective').

[310] Article 2.2 SPS ('any sanitary or phytosanitary measure is applied only *to the extent necessary* to protect human, animal or plant life or health').

[311] B. von Tigerstrom, "How Do International Trade Obligations Affect Policy Options for Obesity Prevention? Lessons from Recent Developments in Trade and Tobacco Control", 37(3) *Canadian Journal of Diabetes* (2013), 182.

[312] However, under the WTO SPS and TBT Agreements, necessity serves as positive obligation rather than an exception.

[313] See on this point, A.G. Poiares Maduro in Case C-41/02 *Commission v Netherlands* [2004] ECR I-11375, para 32.

the exact contribution of every individual policy intervention. In particular, within a suitability analysis of any lifestyle intervention, the interpreter faces three major difficulties in determining the ability of a given measure to attain its declared purpose. The first is due to the inherent scientific uncertainty surrounding these forms of intervention. This encompasses the uncertainty related to the dynamics associated with the phenomenon (e.g. obesity) that the regulation aims to regulate as well as the uncertainty related to the ability of a given policy option to tackle one or more of those dynamics. The second, which derives from the first, relates to the difficulty of establishing a causal link, or at least a correlation, between these measures and their expected outcome. These difficulties are further compounded by a third one: the fact that lifestyles cannot be improved by individual measures taken in isolation. In lifestyle intervention there is indeed no 'silver bullet'. Rather consensus has emerged that only a multi-sectoral policy may help facilitate healthier lifestyles, which makes the effectiveness of a specific intervention all the more difficult – if not impossible – to quantify.[314] As a result of this multi-sectoral, multi-level approach, the EU's emerging lifestyle policy is the result of a combination of both regulatory and self-regulatory measures adopted at both EU and national levels. Given the resulting complexity of the regulatory landscape, all efforts to determine the suitability of any particular lifestyle policy intervention appear particularly arduous and call for a more holistic analysis. Nevertheless, an approach that favours an overall assessment of the suitability of an individual measure to achieve its declared objective within its broader policy framework is not yet well-established in the case law of the CJEU nor in that of the WTO. There are, however, some encouraging signs in a few cases in which the CJEU examined the proportionality, and in particular the suitability, of a given measure by referring to the broader policy context within which the contested measure was adopted and called upon to operate.[315] It is predicted that the examination of lifestyle measures will require that the courts systematically embrace such an approach.

Recently the EFTA Court was called upon in *Philip Morris* to assess the suitability of the ban on visual display of tobacco products at point of sale, and held that

[314] A. Garde, "Freedom of Commercial Expression and Public Health Protection: The Principle of Proportionality as a Tool to Strike the Balance" in L. Gormley and N. Nic Shuibhne (eds), *From Single Market to Economic Union – Essays in Honour of John Usher* (OUP, 2012), at 117.

[315] See, e.g., Franzen, para 64; Opinion of AG Jacobs, Gourmet, para 25: 'In general, I consider, advertising restrictions cannot but contribute to the effect to a non-negligible degree, alongside high excise duties and State control of retail sales for home consumption'.

> where the […] State concerned legitimately aims for a very high level of protection, it must be sufficient for the authorities to demonstrate that, even though there may be *some scientific uncertainty as regards the suitability and necessity of the disputed measure*, it was reasonable to assume that the measure would be able to contribute to the protection of human health.[316]

The Court continued: 'in the absence of convincing proof to the contrary, a measure of this kind may be considered suitable for the protection of public health'.[317]

Traditionally EU courts tend to adopt a quite deferential approach when called upon to review science-based measures. Thus, according to an established principle in the case law 'where a Community authority is required to make complex assessments in the performance of its duties, its discretion also applies, to some extent, to the establishment of the factual basis of its action'.[318]

This deferential approach to judicial review of EU measures has been further elaborated in the *Upjohn* judgment, dealing with medicinal products, where the CJEU declared

> where a Community authority is called upon, in the performance of its duties, to make complex assessments, it enjoys a wide measure of discretion, the exercise of which is subject to a limited judicial review in the course of which *the EC judicature may not substitute its assessment of the facts for the assessment made by the authority concerned*. Thus, in such cases, the EC judicature must restrict itself *to examining the accuracy of the findings of fact and law* made by the authority concerned and to verifying, in particular, that the action taken by that

[316] Case E-16/10 *Philip Morris Norway AS ./. Staten v/Helse- og omsorgsdepartementet* (*Philip Morris*), EFTA Court, judgment of 12 September 2011. Emphasis added.

[317] Para 84.

[318] Case 138/79 *Roquette Frères v Council* [1980] ECR 3333, para 25; Joined Cases 197/80 to 200/80, 243/80, 245/80 and 247/80 *Ludwigshafener Walzmühle v Council and Commission* [1981] ECR 3211, para 37; Case C-27/95 *Bakers of Nailsea* [1997] ECR I-1847, para 32; Case C-4/96 *Nifpo and Northern Ireland Fishermen's Federation* [1998] ECR I-681, paras 41 and 42; Case C-120/97 *Upjohn* [1999] ECR I-223, para 34; and Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, para 168.

authority is not vitiated by a manifest error or a misuse of powers and that it did not clearly exceed the bounds of its discretion.[319]

Over time, this deferential standard of review has been specifically extended by the General Court of the EU to those situations where EU institutions are 'required to undertake a scientific risk assessment and to evaluate highly complex scientific and technical facts'.[320]

However, this 'reductionist approach' following the traditional limited court control in complex technical matters such the control of '*erreur manifeste d'appréciation*' has progressively come under attack.[321] Given the growing quantity of data required to justify regulatory action, courts are somehow expected – in order to satisfactorily discharge their duty – to merge procedural judicial review with substantive judicial review. As a result, today EU Courts often recall that, whilst the Commission must be allowed a wide discretion while exercising 'complex scientific assessments', that discretion is not excluded from review.[322] We might therefore expect the courts to engage more with the scientific evidence underpinning those measures that will come under their scrutiny. The recent judgment of the General Court in *Laboratoires CTRS* epitomizes such a trend.[323] In this judgment the General Court annulled a Commission decision refusing to grant marketing authorization for an orphan drug, Orphacol. To do so, it reassessed both the procedural requirements established by the EU pharmaceutical regulatory framework as well as their substantive application, thus *de facto* substituting its judgment for that of the Commission.

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[319] See Case C-120/97 *Upjohn Ltd* [1999] ECR 223, para 34. See, also, Case C-405/92 *Mondiet* [1993] ECR 6133. See, for a similar statement, in the competition law field, Joined Cases 56/64 and 58/64 *Consten and Grundig v Commission* [1966] ECR 299, at 347. See, in particular, the most recent interpretation of this judgment in Case C-168/01 *GlaxoSmithKline Services Unlimited v Commission* [2006] ECR 9291, at para 241 where it is said that: 'the Court dealing with an application for annulment of a decision applying Article 81(3) EC carries out, in so far as it is faced with complex economic assessments, a review confined, as regards the merits, to verifying whether the facts have been accurately stated, whether there has been any manifest error of appraisal and whether the legal consequences deduced from those facts were accurate'.

[320] See Case T-13/99 *Pfizer Animal Health v Council* [2002] ECR II-3305, paras 168-69 and 323.

[321] K-H. Ladeur, "The Introduction of the Precautionary Principle into EU Law: A Pyrrhic Victory for Environmental and Public Health Law? Decision-making under Conditions of Complexity in Multi-Level Political Systems", 40 *Common Market Law Review* (2003), 1465; A. Alemanno, "Annotation of European Court of Justice, Case C-79/09, Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute", 48(4) *Common Market Law Review* (2011), 1329.

[322] See, e.g., Case C-79/09 *Gowan Comércio Internacional e Serviços Lda v. Ministero Della Salute* [2010] ECR I-13533, para 55.

[323] Case T-301/12, *Laboratoires CTRS v European Commission* (nyr).

Finally, one should highlight the different contexts in which the EU and WTO trade regimes apply. While the EU systematically engages in positive harmonization, the WTO has no general authority to directly set health (or any other) policies for its Members. However, by referring the Member States to the existing international standards, the WTO encourages harmonization in order to minimize the obstacles to market-access stemming from regulatory diversity. International instruments, even if non-binding such as FCTC guidelines, may benefit from a presumption of conformity with WTO rules and therefore penetrate the WTO legal system.

To conclude, international trade rules as they emerge from the growing number of RTAs and the WTO constitute a source of constraint for the development of lifestyle policies based on the adoption of legally binding rules. This is not to suggest that NCD prevention policies cannot pass muster of those rules. However, their legality is set to be decided by the application of policy-balancing mechanisms whose case-by case application renders their outcome rather unpredictable and may give rise to 'regulatory chill', not least if it is coupled with the intimidating lobbying carried out by the industries primarily affected by the developing NCD prevention and control agenda.

The public health community, assisted by qualified lawyers, must thoroughly engage with existing trade rules as interpreted by the competent courts, tribunals and dispute settlement bodies. This requires that public health experts liaise with trade experts to ensure that they understand the relevant rules and can develop an effective, litigation-proof strategy from the moment they start to envisage the adoption of regulatory measures as part of their NCD prevention and control agenda. The more robust the rules, the less likely industry operators can successfully challenge them. Such engagement will also help address the problem of discipline fragmentation: international trade expertise must become aware of the NCD prevention and control agenda, and *vice versa*. It is only if the current gap is bridged that the public health community will participate as effectively as possible in the debate and dispel the fears that health has been sacrificed on the altar of the globalization agenda.

3.2.3 Fundamental rights

As discussed above, fundamental rights offer significant opportunities to policy makers willing to promote healthier lifestyles. However, the fact remains that when fundamental rights have been invoked in the context of NCD prevention and control, it has largely been because industry operators have included them in their vigorous and creative litigation strategies to protect their economic interests. Consequently, if the right to health and other

related rights have been largely absent from the debate to date, other rights have featured in it rather prominently. In particular, industry operators have argued, when challenging NCD policies, that EU measures regulating the content, presentation (including the labelling), advertising or promotion of their products infringe several of the fundamental rights they derive from EU law: the freedom of expression and information, the freedom to choose an occupation and the right to engage in work, the freedom to conduct a business and the right to property.[324] All these rights are protected by the EU legal order. Nevertheless, none of them are absolute: they may be restricted on grounds of public health protection.[325] The CJEU has granted a particularly broad margin of discretion to the EU legislature in deciding which measures should be put in place as part of the EU's developing NCD prevention and control strategy. In fact, the Court has never annulled any EU 'lifestyle' measures on the ground that they violated EU fundamental rights. This, coupled with the fact that the fundamental rights narrative developed by industry operators is incomplete, confirms that the use of fundamental rights should be seen as constituting a potentially powerful sword for policy makers – and the international health community – as part of their NCD prevention and control strategies, rather than merely a shield for the protection of private operators' economic interests. This is not to suggest, however, that policy makers can dispense with the proportionality assessment involved in balancing competing rights against each other.

The right to property and the freedom to conduct a business

The right to property and the freedom to conduct a business are often invoked *in tandem*. In a consistent line of decisions delivered before the EU Charter became legally binding, the Court highlighted that neither of those rights constitutes an unfettered prerogative but should be viewed in light of their social function. They could therefore be restricted provided that the restrictions imposed corresponded to objectives of general interest pursued by the EU and that they did not constitute, as regards the aim pursued, a disproportionate and intolerable interference with the very substance of the rights thus

[324] See, e.g., Case C-376/98 *Tobacco Advertising I* [2000] ECR 1-8419; Case C-491/01 *British American Tobacco* [2002] ECR I-11453; Case C-131/03 P, R.J. Reynolds Tobacco and Others v Commission [2006] ECR I-7795; Case C-380/03 Tobacco Advertising II [2006] ECR I-11573; Case C-301/06 Ireland v European Parliament and Council of the European Union [2009] ECR I-0593.

[325] Human rights are 'far from constituting unfettered prerogatives'. See in this respect Case 4-73 *J. Nold, Kohlen- und Baustoffgroßhandlung v Commission of the European Communities* [1974] ECR I-491, para 14.

guaranteed.[326] The Court unequivocally applied these principles in the *British American Tobacco* judgment where it rejected any suggestion that the EU had unlawfully interfered with the right to property of tobacco manufacturers and their freedom to pursue a trade or profession by adopting the Tobacco Products Directive:

> As regards the validity of the Directive in respect of the right to property […] the only effect produced by Article 5 of the Directive is to restrict the right of manufacturers of tobacco products to use the space on some sides of cigarette packets to show their trademarks without prejudicing the substance of their trade mark rights, the purpose being to ensure a high level of health protection when the obstacles created by national laws on labelling are eliminated.[327]

The Court also emphasized that imposing a limitation on the freedom to trade and pursue a profession was no more than the consequence of the restriction upon the exercise of the right to property, so that the two restrictions merged. Thus, the reasons justifying the restriction upon the manufacture and distribution of tobacco products were the same as those justifying the restrictions placed upon the use of property. Moreover, as EU institutions enjoy a margin of discretion in the choice of the means needed to achieve their policies, traders are unable to claim that they have a legitimate expectation that an existing situation which is capable of being altered by decisions taken by those institutions within the limits of their discretionary power will be maintained. In particular, no informed trader was entitled to expect that patterns of trade would be respected.[328] Finally, by virtue of the principle of proportionality, measures imposing financial charges on economic operators are lawful provided that the measures are appropriate and necessary for meeting the objectives legitimately pursued by the legislation in question.[329]

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[326] See in particular Case 44/79 Liselotte Hauer v Land Rheinland-Pfalz [1979] ECR 3727; Case 52/81 *Offene Handelsgesellschaft in Firma Werner Faust v Commission of the European Communities* (Werner Faust [1982] ECR 3745; Case 265/87 Hermann Schräder HS Kraftfutter GmbH & Co. KG v Hauptzollamt Gronau (Hermann Schraeder) [1989] ECR 2237; Case 5/88 *Hubert Wachauf v Bundesamt für Ernährung und Forstwirtschaft* (Wachauf) [1989] ECR 2609; Case C-280/93 Germany v Council [1994] ECR I-4973; Case C-293/97 The Queen v Secretary of State for the Environment and Ministry of Agriculture, Fisheries and Food, ex parte H.A. Standley and Others and D.G.D. Metson and Others (Standley and Others) [1999] ECR I-2603.

[327] *British Amercian Tobacco*, paras 149 and 150.

[328] See also *Werner Faust*, para 27.

[329] See also *Hermann Schraeder*, para 21.

Following the entry into force of the Lisbon Treaty, the Court has maintained this approach, except that it relies directly on the EU Charter rather than on the unwritten general principles of EU law.

The recent judgment in *Sky Österreich* illustrates how the Court balances competing interests when invoking the EU Charter, and in particular Article 16 (freedom to conduct a business) and Article 17 (right to property).[330] In this case, Sky Österreich invoked both those rights to challenge the validity of Article 15(6) of the AVMS Directive. This requires that any broadcaster established in the EU shall have access to events of high interest to the public which are transmitted on an exclusive basis by a broadcaster established under their jurisdiction. Its objective is to ensure that any broadcaster can choose short extracts to be used in general news programmes without being charged more than the additional costs directly incurred in providing access. In its judgment, the Grand Chamber confirmed that the EU legislature was entitled to give priority, in the necessary balancing of the rights and interests at issue, to overriding requirements of public interest over private economic interests, on the condition that the restriction was proportionate, i.e. that a fair balance had been struck between several rights and fundamental freedoms protected by the EU legal order with a view to reconciling them.[331] On the facts of the case, the Court concluded that the EU legislature could limit the freedom to conduct a business and the right to property 'to give priority, in the necessary balancing of the rights and interests at issue, to public access to information over contractual freedom'.[332]

In the light of the Court's case law, manufacturers affected by lifestyle measures are unlikely to succeed in their claims if they submit that their fundamental right to property, including intellectual property, and fundamental freedom to pursue their business are infringed because they have to bear some of the economic burden of EU lifestyle intervention. Therefore, even if the EU was to go further and impose drastic measures such as standardized packaging of tobacco products across the EU, preventing the use of brands on tobacco (or other products) packs – a step that it has not yet proposed to take[333] – then it

[330] Case C-283/11 *Sky Österreich v Österreichischer Rundfunk* (*Sky Österreich*), 22 January 2013, nyr.

[331] *Sky Österreich*, para 60. See also Case C-275/06 *Productores de Música de España v Telefónica de España SAU* (*Promusicae*) [2008] ECR I-271, paras 65 and 66 and Case C-544/10, *Deutsches Weintor*, para 47.

[332] *Sky Österreich*, para 66.

[333] While the EU Commission's proposal for a revised tobacco products directive stopped short of proposing the first 'plain packaging' scheme in the EU, the same proposal expressly foresees that this policy may be adopted by some EU Member States unilaterally. See Recital (41) of the Commission's proposal.

is arguable that the very substance of the right to property and the freedom to trade would not be affected.[334] Not only would industry operators benefit from transition periods to adapt to the new regulatory environment, but they would also continue to benefit from the protection that intellectual property law offers traders from the unauthorized use of their trademarks.[335]

Freedom of expression

Industry operators have also argued that restrictions on tobacco or alcohol advertising and sponsorship violate their right to free commercial expression.[336] Freedom of expression is of a different nature, as it does not pertain to the products, the services or the brands manufacturers place on the market, but to the commercial discourse they develop in order to promote their consumption.

Under Article 10 of the ECHR, 'everyone has the right to freedom of expression',[337] and this provision has been held to apply not only to artistic and political but also to commercial expression,[338] on the ground that consumers have the right to receive information on the goods and services available to them in a given market: 'for the citizen, advertising is a means of discovering the characteristics of goods and services offered to him'.[339] Nevertheless, freedom of expression may also be restricted on public health

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[334] Art. 52(1) of the EU Charter requires that 'any limitation on the exercise of the rights and freedoms recognized by this Charter must be provided for by law and respect the essence of those rights and freedoms', thus recognizing that there are 'limitations on limitations' to fundamental rights and freedoms under the 'essential core' doctrine: any limitation on fundamental rights – even proportionate ones – must never undermine the 'very substance' of a fundamental right. This sets an absolute limit to all governmental power by identifying an 'untouchable' core within a right. However, the role of this doctrine remains unclear in EU law: R. Schütze, *EU Constitutional Law* (CUP, 2012), at 419.

[335] The Commission has not offered any compensation for the changes it hopes to introduce in the EU to further restrict the tobacco industry. This is most unlikely to infringe EU law if one considers, by analogy, the Court's decision in Joined Cases C-20/00 and C-64/00 *Booker Aquaculture and Hydro Seafood* [2003] ECR I-7411 para 85. See on this point E. Bonadio, "Plain Packaging of Tobacco Products under EU Intellectual Property Law", 34(9) *European Intellectual Property Review* (2012), 599.

[336] See Case C-376/98 *Tobacco Advertising I* [2000] ECR 1-8419; Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573; Case C-544/10, *Deutsches Weintor*.

[337] See also Art. 11(1) of the EU Charter: 'Everyone has the right to freedom of expression…'.

[338] See in particular the European Court of Human Rights decisions in *Markt Intern v Germany*, Appl. No. 10572/83, judgment of 20 November 1989; *Groppera Radio AG and Others v Switzerland*, Appl. No. 10890/84, judgment of 28 March 1990; *Casado Coca v Spain*, Appl. No. 15450/89, judgment of 24 February 1994; and *Krone Verlag GmbH & Co. KG v Austria*, Appl. No. 9605/03, judgment of 14 November 2008.

[339] *Casado Coca v Spain*, para 51; see also *Krone Verlag GmbH & Co. KG v Austria*, para 31. This statement is all the more relevant in light of the role which advertising has been granted in EU internal market law.

and other public interest grounds provided that the restriction in question is proportionate.[340] Thus, in the *Tobacco Advertising II* judgment, the Court rejected the argument put forward by tobacco manufacturers that the contested Directive constituted an unlawful interference with their right to free commercial expression. After recalling its settled case law that the EU legislature should be granted a broad margin of discretion in areas entailing political, economic and social choices on its part, and in which it was called upon to undertake complex assessments,[341] the Court concluded that even assuming that the measures laid down in Articles 3 and 4 of the Directive prohibiting advertising and sponsorship had the effect of weakening freedom of expression indirectly, the measures they imposed were not disproportionate.

The Court has tended to grant an extremely broad margin of discretion to the EU legislature in determining how far it would restrict fundamental rights to ensure a high level of public health protection. It is highly commendable that the Court has not substituted its assessment for that of the legislature.[342] Lifestyle risk regulation does involve complex assessments which result not only from the scientific understanding of specific health risks but also from the social and political evaluation of those risks.[343] EU political institutions are better equipped than the Court to determine how competing interests should be balanced against each other. This does not mean, however, that the EU legislature has a *carte blanche*: it bears the burden of proving that the measures it has adopted are suitable and necessary to achieve their objective of reducing the burden of NCDs in Europe. Discretion does not mean arbitrariness.[344] If the Court's decision in *Tobacco Advertising II* may be criticized for its failure to engage effectively with existing evidence demonstrating the proportionality of the advertising ban, the outcome of the case is nonetheless compelling.[345] The FCTC has called on its Parties to introduce comprehensive bans

[340] Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573. Art. 10(2) of the ECHR, which explicitly provides for the possibility to restrict the freedom of expression, differs from Art. 11 of the EU Charter, which is more similar to the US First Amendment in its formulation than it is to the ECHR. For a comparison of the European and the US approaches to the doctrine of free commercial speech, see A. Garde, "Freedom of Commercial Expression and the Protection of Public Health in Europe", 12 *Cambridge Yearbook of European Legal Studies* (2010), 225.

[341] Case C-380/03 *Tobacco Advertising II* [2006] ECR I-11573, para 155.

[342] The respective role of judges and administrators are fundamentally distinct and should remain so: J. Jowell, "Beyond the Rule of Law: Towards Constitutional Judicial Review", *Public Law* (2000) 681.

[343] See the Opinion of AG Geelhoed in *British American Tobacco*, para 120.

[344] UK courts have expressed this point elegantly: 'The protection of public health is a very important counter-balance to unrestricted commercial expression. It is not a factor affording to a decision maker an unfettered discretion.' McCombe J. in *The Queen v BAT UK et al*. [2004] EWHC 2493 (Admin), at para 32.

[345] A. Garde, "Freedom of Commercial Expression and the Protection of Public Health in Europe", 12 *Cambridge Yearbook of European Legal Studies* (2010), 225.

on tobacco advertising, promotion and sponsorship so that the consumption of tobacco products is reduced.[346] Thus, it is legitimate for the EU and its Member States as parties to the FCTC to limit the freedom of industry operators to promote cigarettes and other tobacco products whose consumption is inherently harmful to health. Advertising bans are therefore intended to support the creation of a 'passive market' for tobacco products: if such products can still lawfully be placed on the EU market, the EU and its Member States nonetheless have a duty to regulate this market to steer existing and potential consumers away from smoking given the costs of smoking and the evidence linking marketing and consumption patterns. The legality of a measure such as the ban on tobacco advertising and sponsorship can be affected only if the measure is manifestly inappropriate having regard to the objective which the competent institutions seek to pursue.[347] That the judiciary grants a broad margin of discretion to the legislature is all the more necessary 'in a field as complex and fluctuating as advertising'.[348]

In any event, the shortcomings of the discourse of industry operators, where fundamental rights are invoked as a 'shield', are even more glaring if assessed in light of the arguments supporting the use of fundamental rights as a 'sword'. Several UN bodies have called for a rights-based approach towards marketing restrictions, on the basis that fundamental rights should enhance, rather than undermine, the NCD prevention and control agenda. As the UN Special Rapporteur on the Right to Food has argued,

> it is unacceptable that when lives are at stake, we go no further than soft, promotional measures that ultimately rely on consumer choice, without addressing the supply side of the food chain. Food advertising is *proven* to have a strong impact on children, and must be strictly regulated in order to avoid the development of bad eating habits early in life. [… There is] no reason why the promotion of foods that are known to have detrimental health impacts should be allowed to continue unimpeded.[349]

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[346] Art. 13 of the FCTC.

[347] At para 155. See also Case C-84/94 *United Kingdom v. Council* [1996] ECR I-5755, para 58; Case C-233/94 *Germany v. Parliament and Council* [1997] ECR I-2405, paras 55 and 56; Case C-491/01 *British American Tobacco* [2002] ECR I-11453, para 123.

[348] Case C-71/02 *Karner* [2004] ECR I-3025, para 51.

[349] "The Right to an Adequate Diet: the Agriculture-Food-Health Nexus", Report presented at the 19th Session of the United Nations Human Rights Council, 26 December 2011, A/HRC/1/9/59, http://www.srfood.org/images/stories/pdf/officialreports/20120306_nutrition_en.pdf.

The same argument supports the imposition of restrictions on the marketing of alcoholic beverages. More recently, the UN Committee on the Rights of the Child called on States to address not only tobacco consumption, but also alcohol consumption and obesity. In particular, it noted that

> children's exposure to 'fast foods' that are high in fat, sugar or salt, energy-dense and micronutrient-poor, and drinks containing high levels of caffeine or other potentially harmful substances should be limited. The marketing of these substances – especially when such marketing is focused on children – should be regulated and their availability in schools and other places controlled.[350]

The UN High Commissioner for Human Rights also stressed that 'obesity […] and substance use' were among 'the areas requiring sustained and immediate attention'.[351] States – and indirectly the EU as a Union of 28 States – should therefore 'prioritize issues that have received little attention to date […] They should ensure adequate attention to the underlying determinants of child health, including, *inter alia*, access to minimum safe and nutritionally adequate food, basic shelter, housing, sanitation, safe and potable water and a healthy and safe environment.'[352] The principle that all actions by public authorities should be undertaken in the best interests of the child calls for the imposition of tougher restrictions on the marketing of HFSS food and alcoholic beverages to children. The right to health, the right to adequate food, the right to education, and the right of the child to be free from economic exploitation, all support the argument that the EU should ban the marketing of HFSS food and alcoholic beverages to children, alongside the comprehensive ban it has imposed on all forms of tobacco marketing affecting the functioning of the internal market.

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[350] At paragraph 47 of the General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health. The Committee on the Rights of the Child has also expressed its concerns relating to growing childhood obesity in General Comment No. 17 (2013) interpreting Article 31 of the CRC on the right of the child to rest, leisure, play, recreational activities, cultural life and the arts: 'Growing dependence on screen-related activities is thought to be associated with reduced levels of physical activity among children, poor sleep patterns, growing levels of obesity and other related illnesses' (at paragraph 46). The General Comments of the Committee on the Rights of the Child are available at http://www2.ohchr.org/english/bodies/crc/comments.htm.

[351] Annual Report of the United Nations High Commissioner for Human Rights, 29 April 2013, A/HRC/23/59, at para 6.

[352] UN Human Rights Office of the High Commission, The Right of the Child to the Enjoyment of the Highest Standard of Health, March 2013, at para 99.

Towards the increased human rights accountability of private actors

While international human rights law binds states rather than non-state actors, this does not mean that non-state actors do not have an active role to play in ensuring that rights are adequately respected, protected and fulfilled. Given the role of 'disease vector' played by the tobacco, alcohol and HFSS-food industries, this should be even more so.[353] This is why one could invoke the Guiding Principles on Business and Human Rights[354] which form part of the 'Protect, Respect and Remedy' Framework which the UN Human Rights Council adopted in 2011.[355] In particular, the Guiding Principles require that 'business enterprises should respect human rights', i.e. 'they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved'.[356] This responsibility is a global standard of expected conduct for all business enterprises wherever they operate and it applies 'to all enterprises, regardless of their size, sector, operational context, ownership and structure'.[357] The interpretive guide produced by the Office of the UN Human Rights Commissioner lists as one example of business impact on human rights targeting high-sugar foods and drinks at children, with an impact on child obesity.[358] The guide further states that 'If an enterprise is at risk of causing or contributing to an adverse human rights impact through its own activities, it should cease or change the activity that is responsible, in order to prevent or mitigate the chance of the impact occurring or recurring.'[359] More recently, the Commission of the Child reinforced the calls on private companies to promote healthier lifestyles:

> Among other responsibilities and in all contexts, private companies should: […] comply with the International Code of Marketing of Breast-milk Substitutes and the relevant subsequent World Health Assembly resolutions; limit advertisement of energy-dense, micro-

[353] R. Jahiel and T. Babor, "Industrial Epidemics, Public Health Advocacy and the Alcohol Industry: Lessons from other Fields", 102 *Addiction* (2007), 1335; and A. Gilmore, "Public Health, Corporations and The New Responsibility Deal: Promoting Partnerships with Vectors of Disease?", 33(1) *Journal of Public Health* (2011), 2. Among the large body of literature criticizing these industries for making vast profits by promoting unhealthy lifestyles and thus NCDs, see also R. Moodie et al., "Profits and Pandemics: Prevention of Harmful Effects of Tobacco, Alcohol, and Ultra-processed Food and Drink Industries", 381 *The Lancet* (2013), 670.

[354] The Guiding Principles are available with a wealth of other information on a dedicated portal: http://www.business-humanrights.org/UNGuidingPrinciplesPortal/Home.

[355] http://www.business-humanrights.org/SpecialRepPortal/Home/Protect-Respect-Remedy-Framework/GuidingPrinciples. Since their unanimous adoption in 2011, the Guiding Principles they have been taken up by the EU, ASEAN, the African Union, the OECD and the IFC.

[356] *Ibid.,* Principle 11.

[357] *Ibid.,* Principle 14.

[358] *Ibid.,* at page 17.

[359] *Ibid.*, at page 18.

nutrient-poor foods, and drinks containing high levels of caffeine or other substances potentially harmful to children; and refrain from the advertisement, marketing and sale to children of tobacco, alcohol and other toxic substances.[360]

Some recent developments illustrate their potential, suggesting that they will be more than mere rhetoric. It is by relying on them that, in May 2013, McDonald's shareholders adopted a resolution requesting that the company identify and publicly report its human rights impacts.[361] In particular, this resolution requests McDonald's to go further than merely producing CEO-signed statements saying that it will avoid negative human rights impacts; it also requires that McDonald's examine what those impacts are by conducting human rights due diligence, in line with the UN Guiding Principles (Principle 17).[362] Admittedly, this resolution focuses on the assessment of forced labour and human trafficking in the supply chain. However, there is no reason to believe that the food, tobacco and alcoholic beverage industries could not be called to account for their adverse impacts on the right to health and other related fundamental rights. In particular, several UN bodies have called on States to take preventive measures to ensure that the right to health and the right to (adequate) food are effectively protected. On this basis, it is not far-fetched to suggest that a company which extensively targets children with the marketing of tobacco, HFSS food or alcoholic beverages to children, whilst children lack the cognitive abilities required to take a critical stance towards advertising, would fall foul of their commitments under the Guiding Principles.[363]

3.2.4 Conclusions on law as a source of constraints

This section has illustrated that the opportunities offered by a legal approach to NCD prevention may only be maximized if the constraints that the law imposes on policy-makers are understood and given sufficient consideration. Without framing the relevant issues in legal terms and on the basis of existing evidence, public authorities are unlikely to succeed in using the law effectively. This seems especially true in the light of the legal challenges that the tobacco, alcoholic beverage and the food industries have systematically mounted against virtually all attempts made at regulating them. Three cat-

[360] General Comment No. 15 (2013) on the right of the child to the enjoyment of the highest attainable standard of health, paragraph 81.

[361] http://www.business-humanrights.org/Links/Repository/1019332.

[362] Principle 17.

[363] On the relevance of the right to health and related rights to the NCD prevention and control agenda, see the discussion above on the use of fundamental rights as an opportunity in section 3.1 of this report.

egories of rules must be given sufficient attention when regulating lifestyles. First, the EU can only act if it has the required powers to do so and it can only exercise them in conformity with the principles of subsidiarity and proportionality. Second, the EU must comply with international (and intra-EU) trade rules, and in particular uphold its obligations under WTO law. Thus, although the EU Commission eventually decided not to propose an EU-wide plain packaging standard, its published proposal for a revised tobacco products directive expressly allows Member States to introduce a similar scheme at the domestic level.[364] This will offer a test case to examine the legality of one of the most extreme forms of standardized packaging scheme under both EU and WTO law. It is within the framework of our examination above that its fate will be determined. Given the higher intensity of the judicial review of national measures, as compared to that which is exercised upon EU measures, a plain packaging standard would be less likely to survive under EU law than an EU-wide scheme. However, although the burden of proof is borne by the acting Member State, which has to adduce evidence or data in support of the contested measure, the national authorities cannot – in principle – 'be deprived of the possibility of establishing that an internal restrictive measure satisfies those requirements, solely on the ground that that Member State is not able to produce studies serving as the basis for the adoption of the legislation at issue'.[365] This would seem to suggest that, despite a more intrusive standard of judicial review, national measures might still survive, at least in principle, the proportionality scrutiny, even in the absence of hard evidence showing their effectiveness. It is on this fine balance between procedural and substantive review that the future of domestic and EU-wide standardized packaging requirements will be decided.

Finally, the EU legal order is founded on the rule of law and must, as such, respect the fundamental rights protected by the EU Charter, the European Convention on Human Rights and the general principles of EU law. If these principles are relatively straightforward to grasp, the case law of the CJEU shows that their application in practice has proven extremely difficult: they require that fine lines be drawn between legitimate and illegitimate EU interventions. The trend is described above, whereby both public authorities and the public health community are slowly realizing the potential that arguments based on the protection of fundamental can offer to the NCD agenda. The

[364] See Recital (41) of the proposal for a Directive on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products.

[365] Joined Cases C-316/07, C-358/07, C-360/07, C-409/07 & C-410/07, *Markus Stoß v Wetteraukreis,* [2010] ECR I-08069, para 72.

balancing exercises that courts of law will be called upon to perform as more lifestyle-related measures are adopted and the Global Action Plan is implemented in Europe and beyond will consequently become more refined. This in turn should help the public health community develop the skills it both lacks and urgently needs to oppose the audacious legal arguments industry operators have relied upon to challenge in court the development of NCD agendas at global, regional, national and local levels. The more the public health community can deal with the legal constraints that the law imposes on public authorities, the more it can maximize the opportunities that the law offers to the NCD prevention and control agenda.

4 Conclusions

After discussing the frequency, complexity and multifactorial nature of NCDs and their projected growth at exponential rates, this report introduces the current debate revolving around the legitimacy and design, as well as the effectiveness of any regulatory intervention aimed at promoting healthier lifestyles. In particular, the introductory part of the report briefly highlighted the contested nature of any form of regulatory intervention aimed at changing individual behaviour. While all forms of lifestyle intervention tend to raise moral, ethical and philosophical reservations, this report has established that an EU lifestyle policy is emerging within the broader framework set by the WHO.

Despite its limited competence in public health, the EU has progressively recognized the impact of NCDs on the EU's economy and the well-being of its citizens. In particular, the significant population differences in life expectancy,[366] premature mortality, morbidity and disability between and within Member States,[367] by translating into health gaps inconsistent with some of its core values, such as solidarity, equity and universality, have led the EU to start developing a form of lifestyle policy.[368] As discussed, the EU has intervened to different degrees depending on the risk factor at stake, preferring at times to promote the exchange of best practice and the adoption of commitments by industry operators over the adoption of legally binding rules. In particular, we have observed a gradation of EU involvement, with stronger intervention in relation to tobacco control, lesser intervention in relation to alcohol control, and the EU nutrition and obesity prevention policy somewhere in between the two.

As a result, it is not surprising that it is in the field of tobacco control that the validity of EU rules has systematically been challenged before courts in judicial review actions: in no other field has the EU adopted measures intended to restrict so significantly the ability of commercial operators to expand their market shares. If these challenges led to the annulment of the first tobacco

[366] For example, in 2002, the difference in male life expectancy at age 20 years between the fifteen countries that had been members before 2004 (the EU15) and the Baltic States (Estonia, Latvia and Lithuania) was 9.8 years.

[367] WHO Regional Office for Europe, "Action Plan for implementation of the European Strategy for the Prevention and Control of Non-Communicable Diseases 2012−2016", available at <http://www.euro.who.int/__data/assets/pdf_file/0019/170155/e96638.pdf >.

[368] European Commission, White Paper "Together for Health: Strategic Approach for the EU 2008–2013", 14689/07, COM(2007) 630 final.

advertising directive, this has also contributed to a clarification (albeit limited) of the scope of EU powers in the field of lifestyle risk regulation.

Indeed, as our analysis has shown, a broad range of strategies exists to prevent and control NCDs. These different strategies have different natures, involve different actors and vary in scope, yet as they all require some forms of legal intervention, they illustrate how the law may offer opportunities for the prevention and control of NCDs as well as constraints.

It is against this backdrop that, in part 3 of this report, we have illustrated the opportunities arising out of a smart use of the law to promote healthier lifestyles through a careful selection of policies conducive to effective behavioural change. Thus, we have demonstrated how addressing NCDs at EU level does not only require political will, but also requires that legislators choose those instruments from the 'NCD tool-box' that are the most appropriate. Indeed, our discussion about the many opportunities the law offers to tackle NCDs has shown that the question is not so much *whether* the law can play an important role in promoting healthier lifestyles. Rather, the question is *how* the law can be validly designed to support effective NCD prevention and control policies.

It is in the light of the above that, while keeping its focus on the role that law may play in addressing the challenges raised by NCDs, the second section of part 3 discussed the constraints set by the EU legal order itself.

First, as there is a clear consensus that effective NCD prevention strategies must be 'multi-level', the legal system must determine the most appropriate level – EU or national – for this intervention. Thus, under EU law, it is necessary to enquire whether the EU has the required competence to adopt lifestyle measures and how it should exercise its powers in light of the principles of proportionality and subsidiarity. Although pursuing a public health goal by promoting – rather than restricting – the free movement of cigarettes, alcohol and food products in Europe might appear somehow contradictory, this is the legal logic that has dominated the EU's NCD regulatory approach. Hence perhaps the need felt by the EU to experiment also with other forms of policy interventions, such as the exchange of best practice and self-regulation. As a result of these dynamics, the emerging NCD prevention and control policy in Europe is a combination of both regulatory and self-regulatory measures adopted at either EU or national levels. The resulting regulatory landscape is therefore particularly complex and unavoidably fragmented.

Second, as virtually all NCD policies aim to reduce the consumption of goods that are freely traded across the world, their implementation inevitably encroaches, at least potentially, upon international (and intra-EU) trade rules. As a result, we have discussed how the EU and international trade regimes, due to their vocation towards the liberalization of trade, emerge as one of the most immediate obstacles to the development of an effective NCD prevention and control strategy.

Third, we have analysed how, despite their potential for promoting healthier lifestyles, fundamental rights have tended to be invoked by the relevant industries in order to limit governmental action aimed at the prevention and control of NCDs. Nevertheless, as illustrated above, the law can be used as a tool to promote the right to health and several other fundamental rights protected by the EU legal order, via the EU Charter, the ECHR or the general principles of EU law. In other words, if fundamental rights have been invoked as a shield by industry operators, they could also be invoked as a sword by public health actors.

The constitutional structure of the EU as a union of Member States with a diverse mix of cultural, social, political and economic structures presents both challenges and opportunities for the development of an EU-wide NCD prevention and control policy. Beyond the constraints that we have highlighted hides an unresolved tension regarding the role and right of individual Member States to develop and implement national policies and legislation as well as their obligations under both EU law and global health law. All these factors add a further level of complexity to the already difficult process of translating research into policy and effective action.

The difficulties stemming from the attempt at elaborating a comprehensive lifestyle policy are compounded by the fact that policymakers and lawyers often specialize in sub-disciplines, somewhat like doctors do (except that medicine does not have the same geographical frontiers as law does). Thus, if one is to counter effectively the attacks mounted at national, regional and global levels by the tobacco, alcohol and food industries, the public health community, under the leadership of the WHO, must establish a multi-disciplinary, multi-national and multi-lingual network of lawyers able to operate in different jurisdictions and to navigate different legal specializations. In light of the multi-factorial nature of NCDs, it goes without saying that these lawyers would not work in isolation; they would need to cooperate closely with other disciplines to ensure that the relevant policies are evidence-based and acceptable. By providing some common objectives and identifying prior-

ity areas for action, the Global Action Plan provides a unique opportunity to gather the momentum required to ensure that it is successfully implemented.

By illustrating that the value of legal intervention and its inherent potential in stimulating progressive change appears considerable, this report has attempted to place EU lifestyle risk regulation more firmly on the agenda of both the EU and its Member States. Even though law is not a panacea, it has an important role to play in ensuring that healthy choices are facilitated and could soon become 'the easier, default option rather than being agonizingly difficult'.[369] As governmental action against NCDs has become a strategic priority worldwide at national, regional and global levels, the EU has no option but to embrace – in light of both its constitutional principles and international legal obligations – the challenges that it poses. As we hope we have demonstrated, the EU seems ready – on the basis of the competence and tools it has been granted by the EU Treaties – to play a meaningful role in NCD prevention and control. This may signal to the world that the EU may become a stronger ally in the fight against the NCD epidemic – assuming, of course, that it has the required political will to do so.

[369] B. Thomas and L. Gostin, "Tackling the Global NCD Crisis: Innovations in Law & Governance", 41 *Journal of Law, Medicine & Ethics* (2013), 25.

Sammanfattning på svenska

I maj 2013 antog Världshälsoorganisationen (WHO) enhälligt en global handlingsplan för bekämpande av icke-smittsamma sjukdomar (NCD)* under perioden 2013-2020. I planen konstateras att NCD – som hjärt- och kärlsjukdomar, cancer, kroniska lungsjukdomar och diabetes – är i huvudsak möjliga att förebygga och man uppmanar alla parter att vidta konkreta åtgärder för att uppnå specifika mål och vända den nuvarande trenden. Eftersom NCD svarar för närmare 86 procent av dödsfallen och 77 procent av sjukdomsfallen i WHO:s europeiska medlemsländer, har man också från EU:s sida börjat diskutera vilka åtgärder man kan vidta för att bidra till handlingsplanen.

Det senaste decenniet har EU antagit ett flertal strategier i syfte att minska effekterna av de fyra främsta riskfaktorerna när det gäller NCD: rökning, hög alkoholkonsumtion, dåliga matvanor och fysisk inaktivitet. I linje med WHO:s rekommendationer slås i strategierna fast att NCD bara kan hanteras på ett effektivt sätt om man kopplar in ett flertal av de områden som påverkar vårt dagliga liv. Det finns dock stora skillnader mellan strategierna. EU:s politik för tobakskontroll kännetecknas exempelvis av kraftfulla åtgärder baserade på juridiskt bindande regler för att motverka rökning, medan EU:s alkoholstrategi främst vilar på god branschsed och regler som industrin själv har satt upp för att motverka skadlig användning – snarare än konsumtion – av alkoholhaltiga drycker. EU:s strategi för att motverka övervikt och fetma blandar dessa båda förhållningssätt, med bindande regler som ålägger livsmedelsindustrin att anta och följa regler man själv kommit överens om.

Efter en kort, inledande beskrivning av de komplexa orsakerna bakom NCD och de inbyggda konflikter som finns när det gäller varje form av reglerande ingripanden avsedda att påverka individuella beteenden, granskas i den här rapporten de olika möjligheter till livsstilsreglering som EU och dess medlemsstater har när det gäller att främja en hälsosam livsstil. En genomgång av de olika formerna av möjliga åtgärder (inklusive informationskrav, marknadsföringsrestriktioner, införande av skatter eller regler för vad en produkt får innehålla) leder oss till slutsatsen att lagen medger betydande möjligheter att främja en hälsosammare livsstil och därmed vända den nuvarande utvecklingen vad gäller NCD.

De möjligheterna kan dock bara utnyttjas fullt ut om man beaktar de restriktioner lagen ålägger beslutsfattarna. Om inte de relevanta frågorna formuleras i juridiska termer – med hänsyn till vetenskapliga fakta – kommer de som är verksamma inom folkhälsosektorn knappast att ha framgång när det

gäller att använda lagen på ett effektivt sätt. Det visas inte minst av de juridiska motåtgärder som tobaks-, alkohol- och livsmedelsindustrin systematiskt har vidtagit för att motverka de åtgärder som är avsedda att reglera dem. Tre regelverk måste ges tillräcklig uppmärksamhet när det gäller livsstilsreglering. För det första: EU aldrig kan agera om man inte har de nödvändiga befogenheterna och man kan bara utöva befogenheterna i enlighet med principerna om subsidiaritet och proportionalitet. För det andra: EU måste följa internationella handelsregler, framför allt de skyldigheter man har gentemot Världshandelsorganisationens (WTO) regelverk. För det tredje och slutligen: EU är en rättsordning och måste respektera de grundläggande rättigheter som skyddas av EU:s stadga om de grundläggande rättigheterna, Europakonventionen om de mänskliga rättigheterna och de allmänna bestämmelserna i EU-rätten.

Men även om principerna är relativt enkla att begripa visar Europeiska domstolens (CJEU) rättspraxis att deras praktiska tillämpning är utomordentligt svår, de kräver nämligen att man till fullo förstår var gränsen går mellan tillåtna och otillåtna åtgärder. Alla som är engagerade i hälsofrågor i Europa måste därför sätta sig in i den samlade rättspraxis som finns angående de regler som har antagits av EU och dess medlemsländer i syfte att främja en hälsosammare livsstil. Det är nödvändigt för att insatserna ska kunna tåla en juridisk granskning och därmed effektivt bidra till arbetet med att motverka NCD på global, regional och nationell nivå.

* *Den engelska beteckningen för icke-smittsamma sjukdomar är Non-Communicable Diseases och förkortas NCD. Någon motsvarande svensk förkortning finns inte. Också i Sverige används därför vanligen förkortningen NCD.*

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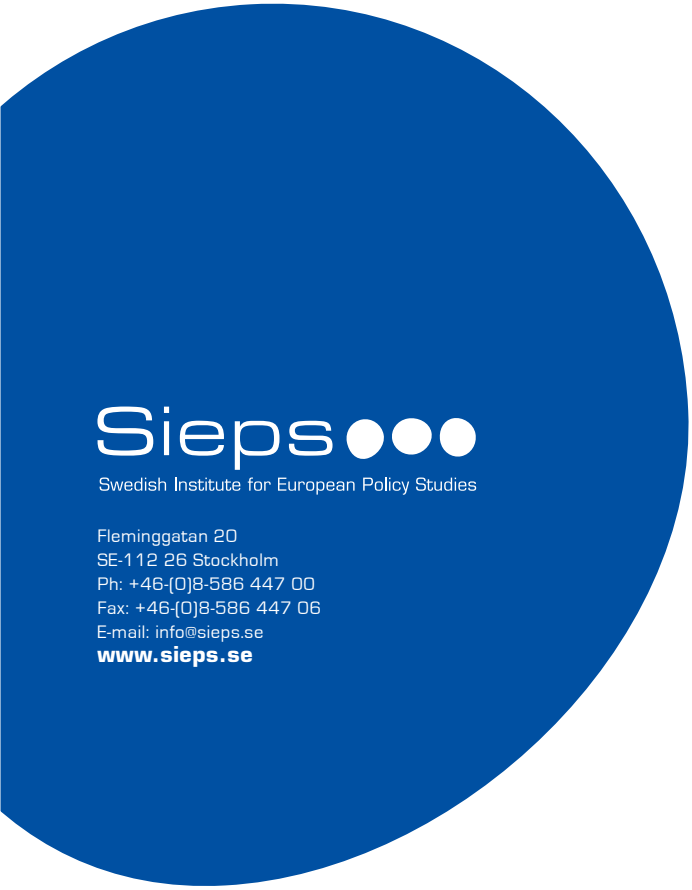

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