



Noncommunicable Disease Risk Factors in the Americas: Considerations on the Strengthening of Regulatory Capacity

REGULA Technical Reference Document

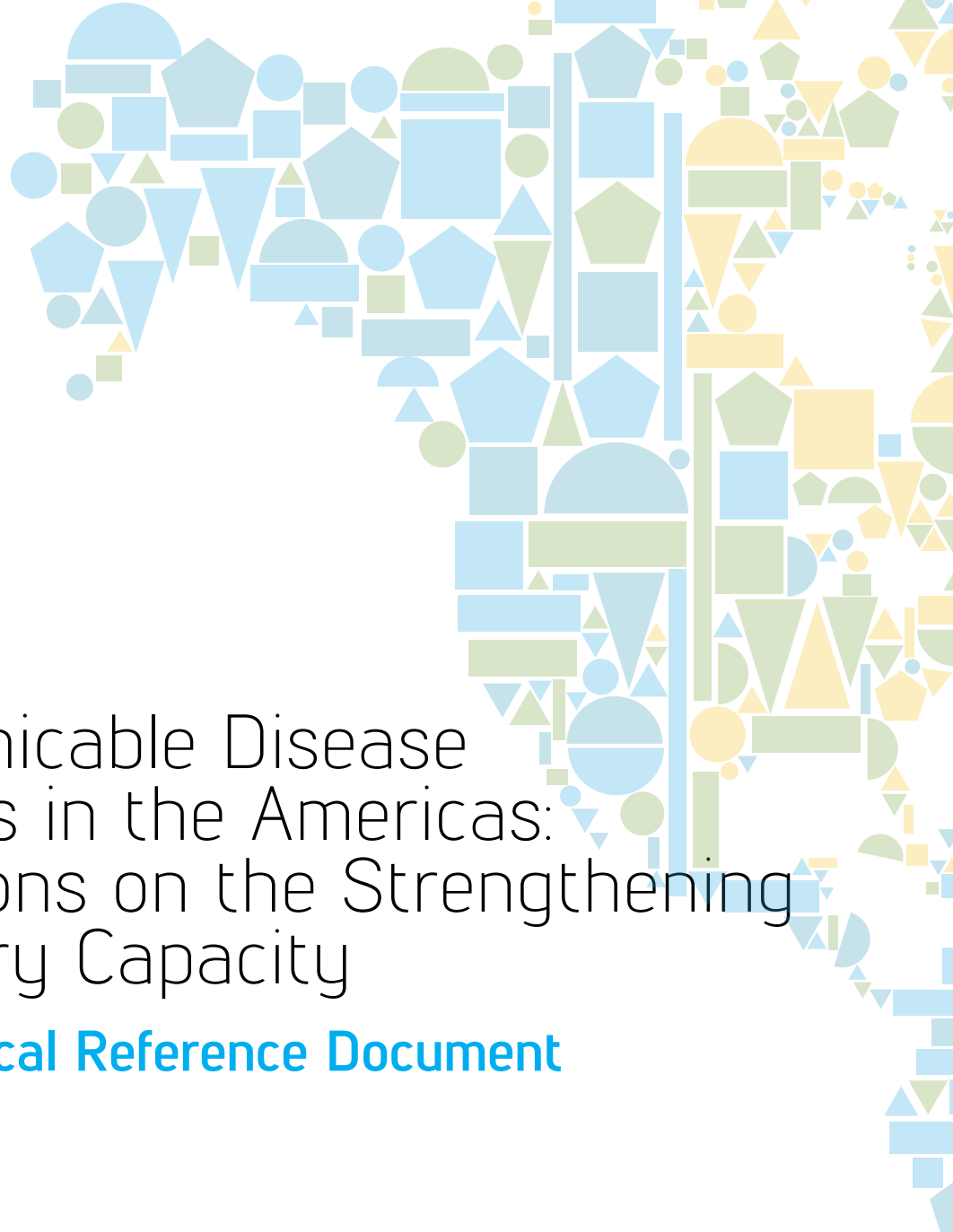


Pan American Health Organization



World Health Organization
REGIONAL OFFICE FOR THE Americas





Noncommunicable Disease Risk Factors in the Americas: Considerations on the Strengthening of Regulatory Capacity

REGULA Technical Reference Document



Department of Noncommunicable Diseases and Mental Health

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When Ministers of Health and heads of state
and government choose to take up the reins
of leadership,
they are unstoppable.

Foreword

In the Region of the Americas we are confronting a silent and devastating epidemic of non-communicable diseases (NCDs), leading to illness and premature deaths which significantly impact many persons during their most productive years of life. The extensive social and economic burdens of this epidemic are already adversely affecting the ability of our Member States to fully realize their social, economic and developmental potential. The NCD epidemic is largely driven by the consumption of commodities, such as tobacco, alcohol, and ultra-processed food, coupled with physical inactivity; with the poor and vulnerable being most affected. In 2011 the United Nations General Assembly recognized the high global burden of NCDs and their related risk factors and called for all sectors of society and government to work intersectorally.

There are public health tools that can be utilized to effectively tackle the NCD epidemic, and these include health promotion, risk reduction and protection from risks. Regulation is an essential public health function that can be used to reduce the burden of NCDs, yet to be effective it must be scientifically based, rigorously practiced, and effectively resourced. Regulating the main risk factors for NCDs can contribute to reducing the avoidable burden of disease, and promote advances towards universal access and universal health coverage by reducing health-care expenses associated with preventable NCDs. Furthermore, regulating risk factors for NCDs can improve the institutional and social infrastructure for stronger economic growth and development.

The Pan American Sanitary Bureau (PASB) is well positioned to significantly strengthen the capacity of our Member States to regulate NCD risk factors. While there will be huge challenges in ensuring changes in manufacturing and marketing aligned with public health priorities, there are examples of best practices in the Region which contribute to the public health. Examples of bold innovations include Mexico's taxation of sugar sweetened beverages to tackle childhood obesity, regional progress with tobacco taxation efforts and comprehensive legislation, or Ecuador's clear labeling of ultraprocessed foods. Our NCD Strategic Plan, many of our agreed resolutions, and binding treaties such as the Framework Convention for Tobacco Control, all call for regulatory action. We need our institutions to accept this challenge and use regulation as a public health tool. The REGULA Initiative aims to promote advances along this path. This Technical Reference Document is a first step and organizes basic knowledge and concepts about regulation of NCD risks, and proposes lines of action for the technical cooperation with and between countries. The next steps will involve work on the assessment, organizational development, technical improvement, and research into the legal frameworks of the regulatory institutions in each of our Member States.

Through strengthening regional regulatory capacity on NCD risk factors, we can play a key role in achieving the goal of risk reduction throughout the Americas by 2025, and we can fulfill the promise of health as an investment for development. PAHO makes this technical reference document available for your consideration, inviting you to participate in strengthening the regulation of NCD risk factors. When Heads of State and Governments, and Ministers of Health fully assume the mantle of leadership, they can bring tremendous benefit to the wellbeing of their communities. The evidence about the adverse impact of NCDs and related risk factors on our populations is irrefutable and now is the time to act.

Carissa Etienne, Director

Preface

The Global and Regional action plans on noncommunicable diseases (NCDs) include nine agreed voluntary targets, including a global target of a 25% reduction in premature mortality by 2025 adopted by WHO Member States. Public health strategies include a combination of health promotion, disease prevention and risk protection; with regulatory action on risk factors required for five of the specific targets. The WHO has identified 15 cost-effective interventions or “best-buys”, including ten which also call for regulatory action. Data available from country capacity surveys suggest that institutional regulatory capacity on NCDs needs to be strengthened significantly to increase its effectiveness.

Protecting the population from NCD risks is an essential public health function to be executed through the Ministries of Health. It is recognized that good regulation enhances economic welfare, provides the basis for risk reduction and disease prevention, promotes desired social behaviors, fosters political commitment, and provides administrative and social contexts. As such the institutional development of regulatory capacity enhances governance and influences the determinants of public health and economic performance. Just as public health interventions can guide, change, or limit choices, corporate and societal practices around which products are marketed and promoted can also influence the choices available to the public. The absence of regulation in the promotion and marketing of products can leave consumers exposed to harm as a result of choices designed primarily to optimize profitability.

This technical reference document (TRD) provides a comprehensive review of the situation of NCDs in the Americas and their main risk factors. It provides a review of the legal basis for international action, and explains the basic concepts around the regulatory process. This body of work and the recommended lines of action make the REGULA Initiative, an innovative product of the Department of Noncommunicable Diseases and Mental Health. This initiative seeks to assess and strengthen the institutional capacity for executing interventions aimed at NCD risk factors included in the different strategies and international agreements. This initiative has been inspired by the positive achievements of the Organization in strengthening the regulation of medical products. As a department-wide project, this initiative has benefitted from the involvement of the Office of the Legal Counsel, and the input of the Department of Health Systems and Services.

We believe that strengthening the regulatory capacity on NCD risk factors at the Ministries of Health in the Region of the Americas will significantly contribute to the achievement of national and global health goals. This TRD is a first step in fostering the strengthening of regulation as an essential public health function. PAHO will use its unique role of convening collaborative interaction between regulatory institutions of the Region and abroad, to foster and support Ministries of Health in their commitments to stewardship, by mapping regional institutional capacity, assessing progress, disseminating methods and tools, and developing standards of performance and legislation that can orient the reforms. This is the start of a long road that has the potential to make a difference in the battle to stop the devastating silent epidemic of NCDs.

Anselm Hennis, Director,
Department of Noncommunicable Diseases and Mental Health

Executive Summary

This document, prepared under the the Organization’s innovative initiative “Strengthening Regulatory Capacity in the Region of the Americas for NCD Risk Factors” (REGULA), provides an overview of the status of key noncommunicable disease (NCD) risk factors in the Americas and fulfillment of international agreements that support action by Ministries of Health to protect populations from the associated risks factors. It reviews the current regulatory situation in the Region, presents the key conceptual and operational elements of effective regulation, and proposes lines of action for technical cooperation to strengthen regulatory capacity for NCDs in the Americas. Its focus is on regulation, an approach that has been clearly recognized as an essential public health function and one in which capacity lags behind other fields of public health action. Strengthening regulatory capacity and action is by no means the only approach to reducing NCD risk factors, but it is an indispensable component of the suite of actions needed to prevent and control noncommunicable disease in the Region. Ten of the 15 “very cost-effective” interventions (also called “best-buys”) cited in the WHO Global Action Plan on NCDs and the WHO Global Status Report on NCDs (2014) involve the effective use of law or regulation. It has been estimated that these population-based interventions can be provided in low- and middle-income countries at a cost of US\$ 0.20 per capita and in upper middle-income countries for US\$ 0.50 per capita (WHO, 2011c).

The NCD Burden in the Americas

- Noncommunicable diseases are the leading cause of morbidity, mortality, and premature mortality in the Americas, associated with 75% of all deaths in 2012. WHO (2014f) estimates that as of 2012, 200 million people in the Region were living with one or more NCDs and that more than 5 million people died from one of these diseases. In the Region, the probability of dying from one of the four main NCDs for persons between 30 and 70 years old is 15%. Cancer, cardiovascular diseases, diabetes, and respiratory diseases were responsible for 82% of NCD deaths.
- Four risk factors account for the majority of preventable deaths and disability: unhealthy diet, tobacco use, harmful use of alcohol, and physical inactivity. These risks are created by humankind and can be reversed by humankind.
- Their rapid growth is caused by a combination of factors, including aging populations, continuing poverty, and widespread changes in human behavior, which in turn are related to the growing availability and intensive promotion of unhealthy products, the globalization of trade and consumer markets, the relatively high cost of healthy food or difficult access thereto, marginalization of traditional diets, rapid urbanization, automation of many activities, and lack of population awareness of the harmful effects of these risk factors.
- Providing care for premature and potentially preventable NCDs challenges the capacity and economic sustainability of health systems everywhere. The NCD epidemic will inflict a toll equivalent to US\$21.3 trillion in economic losses on low- and middle-income countries over the next two decades, a sum tantamount to the total gross domestic product (GDP) of these countries in 2013 (US\$24.5 trillion).
- According to experts, the costs of NCDs are so high that from an economic perspective it is “illogical and irresponsible to care about economic growth and simultaneously ignore NCDs. Interventions in this area will undeniably be costly. But inaction is likely to be far more costly” (Bloom et al., 2011).
- Two risk factors, unhealthy diet and physical inactivity, are the main causes of obesity, one of the great global epidemics of the late twentieth and early twenty-first century. More than 2.1 billion people—nearly 30% of the global population—are overweight or obese. Obesity, which is preventable, is now responsible for about 5% of all deaths worldwide. If its prevalence continues on its current trajectory, almost half the world’s adult population will be overweight or obese by 2030.

75% of all deaths
in 2012 associated
with NCDs

**Four risk
factors** unhealthy
diet, tobacco use, harmful
use of alcohol, and
physical inactivity

**US\$21.3
trillion**
in economic losses on
low- and middle-income
countries over the next
two decades

International Political Commitments to Regulatory Action

- Over the past decade, Member States in the United Nations system have progressively matured their understanding of the gravity of the effects of NCDs and their risk factors. That growing understanding has prompted the formulation of clear goals and evidence-based policies, leading in turn to a series of global and regional commitments to action, ranging from the legally binding provisions of the Framework Convention on Tobacco Control (FCTC) to the consensual recommendations adopted by Member States through global and regional governing bodies.
- In 2011, the United Nations General Assembly recognized that NCDs are highly preventable and committed to focusing on regulatory and legislative action to address their risk factors, in addition to improving access to health care.
- The Member States also committed to support the implementation of multisectoral, cost-effective, population-wide interventions in order to reduce the impact of common NCD risk factors invoking the relevant international agreements and strategies and applying educational, legislative, regulatory, and fiscal measures.
- In addition, Member States adopted a global target of a 25% reduction in premature mortality by 2025. The road to getting there includes a combination of primary prevention through reductions in risk factor exposure and improvements in NCD care. The targets include: a 10% relative reduction in the prevalence of insufficient physical activity and in the harmful use of alcohol; a 30% relative reduction in the mean population intake of salt/sodium; a 30% relative reduction in the prevalence of current tobacco use in persons 15+ years of age; a 25% relative reduction in the prevalence of raised blood pressure, and a halt in the rise of diabetes and obesity. Restrictions on the marketing of unhealthy foods to children, as well as trans fats and saturated fats, were also endorsed.

**It is
illogical and
irresponsible**
to care about economic
growth and simultaneously
ignore NCDs

**Committed
to support**
the implementation
of multisectoral,
cost-effective,
population-wide
interventions

A global target of a
25%
reduction
in premature mortality
by 2025

Examples of Successful Interventions

- While education and calls for personal responsibility are important to reduce NCDs and obesity, they are not enough. In order to change the environmental and social determinants of NCDs, interventions are needed that rely less on promoting healthy choices by individuals and more on “changing the defaults” to make healthy behaviors the easier choice.
- There are achievable, highly cost-effective measures that address these risk factors and have extraordinary potential to improve health and prevent premature death and suffering. Most of them require legislative and regulatory support, including regulation of price and availability, marketing restrictions, restrictions on or modification of products, labeling and other information for consumers, and/or restructuring of urban and educational environments to facilitate physical activity.
- Actions that have proven effective to address unhealthy diet include the promotion of breastfeeding, agricultural and economic incentives to increase the consumption of healthier food, disincentives to discourage consumption of unhealthy foods, reformulation of foods to reduce salt intake, regulation of the food served in schools, restriction of marketing of unhealthy food to children, use of front-of-package labels that provide simple visual messages, reduction of portion sizes, and elimination of trans fat.
- With regard to tobacco control, progress has been made in implementing the FCTC in the Americas thanks to initiatives by local and national governments, organized civil society, and international cooperation agencies. Tobacco is the risk factor with the clearest road map, and the only one with actions that are binding for the 30 of the 35 PAHO Member States that have ratified the Convention. However, not all the countries have progressed at the same rate in implementing the FCTC measures. The main measures include monitoring tobacco use and tobacco control policies; protecting people from secondhand smoke; offering cessation support; warning and educating the public about the dangers of tobacco; enforcing a comprehensive ban on tobacco advertising, promotion and sponsorship; raising prices through taxation; and reducing the supply by eliminating illicit trade and creating viable alternatives for farmers. Experience across the Region has demonstrated the need for a combination of different measures to maintain a downward trend in tobacco use. Interference from the tobacco industry and the emergence of alternatives such as e-cigarettes and flavored products will also need to be addressed in order to ensure that the downward trends continue.
- Regulatory policy options and interventions to reduce the harmful use of alcohol include limitation of its availability and hours of sale, bans or statutory regulations restricting marketing, use of pricing policy or excise taxes to reduce affordability and demand, countermeasures against drink driving, and reduction of the impact of illicit and informally produced alcohol.
- With regard to the promotion of physical activity, many of the approaches adopted in the countries can be summed up as “different ways of doing business”—for example, the way in which a street or a community is designed, the way a city’s transportation system is organized, or the way children spend their time at a daycare center or in school. While these changes do not necessarily involve regulation, the regulation of such processes as urban transportation and construction is increasingly used to facilitate change on a broader scale.

While **education** and calls for personal **responsibility** are essential to reduce NCDs and obesity, they are **not enough**

Interventions that make **healthy behaviors the easy choice** by “changing the defaults” are more needed

While regulation entails an expense, the cost of **preventing these risks** can be far less than the cost of regulatory inaction.

Regulatory Action

- In this document, regulation refers broadly to both legislative and executive action, whether at the national, state, or local level. Unlike the delivery of health services, many of these measures require the correction of market failures or the modification of widespread social practices—changes that can only be achieved through the effective use of legislation or regulation, often in areas outside the traditional scope of health systems. They involve working with other spheres of government (e.g., Ministries of Economy, Transportation, or Finance), adopting multisectoral approaches, developing capacity at the level of local governments as well as the national level, and building political will.
- Yet efforts to fulfill international agreements or resolutions have suffered from deficient implementation, enforcement, documentation, and/or evaluation. In many countries of the Region this capacity is still very limited. Like the effective delivery of universal health care, regulatory capacity must be built and nurtured as part of the institutional structure of health systems and governments. Thus, the health-related legal framework and regulatory capacity must also be strengthened at the national level. Government necessarily plays the lead implementation role in regulatory action. This role is strengthened when there is a clear legal framework and it is part of a political and technical process of governance that acts effectively to balance competing interests while protecting the greater good of society, including the health of the population.
- While regulation may set limits to industry activities, good regulation can also promote a market that is fairer and functions more effectively by creating a level playing field—one in which those producers who can and do act ethically to protect health are not at a disadvantage.
- Since three of the risk factors involve consumer products, there is significant overlap in the areas of regulation that can modify their impact on public health, particularly in the classic marketing areas of price formation, product design, product placement, and promotion. Regulation in these areas has frequently been hindered by intense lobbying, polarization, and legal challenges on the part of stakeholders with private economic interests.
- Effective regulation needs to follow a systematic process. It starts with an analysis of the risk and the identification of options for its mitigation. The next step is risk management, in which a decision is made and one or a mix of interventions are recommended for acting on the risk. This mix of interventions is likely to include a combination of regulation, health promotion, and clinical prevention. Next comes the actual rule-making, implementation, and enforcement, followed by the establishment of a monitoring and evaluation process.
- While regulation entails an expense, the cost of preventing these risks can be far less than the cost of regulatory inaction. Fiscal measures may have a dual function, both increasing revenue and at the same time decreasing consumption.
- The development of institutional capacity for providing regulatory support has been uneven in the Region and globally. Countries in the Region

Regulatory capacity must be **built and nurtured** as part of the institutional structure of health systems and governments.

It starts with an **analysis of the risk** and the identification of **options for its mitigation.**

Fiscal measures may have a dual function, both **increasing revenue** and at the same time **decreasing consumption**

have used a variety of models and approaches in developing their health regulatory capacity, ranging from a fully integrated model within the Ministry of Health to separate autonomous organizations. Still other countries have yet to create a regulatory institution.

- The regulatory process needs to have a mechanism for holding technical consultations, avenues for social participation, clear paths for the defense of health rights, and adequate support for communication, all of which should be embedded in the institution’s design, financing, and operation.
- Effective regulation requires the involvement and participation of society at large. Civil society plays five main roles: advocate, coalition builder, provider of evidence-based information, watchdog, and service provider.
- A well-established legislative and regulatory process for risk factors is central to reducing the potentially pernicious effects of uncontrolled regulatory processes that can be manipulated by vested political or private economic interests or other interference. Regulatory processes must be embedded in laws and in the institutional structure and culture of national governance.
- Prevention of corruption and conflicts of interest are concerns that must be tackled from the outset in any initiative to strengthen regulatory capacity. Concentration of power across the process can create opportunities for corruption—for example, if the same person or administrative unit controls the process from risk analysis to regulatory enforcement, grants the authorizations, conducts the inspections, and has the power to sanction.
- International trade and investment agreements have provisions to allow for the protection of

human health. Member States should seek to maintain or strengthen these provisions in international agreements in order to ensure their ability to address NCD and other health risks.

- PAHO Member States have proven the benefit of enhancing their regulatory capacity in the case of medicines and biologicals. The Organization, for its part, has promoted the adoption of quality standards in several areas, including good manufacturing practices or bioequivalence; it has created a network of reference centers, and it and helped to build a regional regulatory capacity system in the Caribbean. It has also certified seven institutions as regional reference centers focused on prioritizing the strengthening of legal regulatory frameworks, establishing structure, instituting quality management, defining core regulatory functions based on national policy priorities, building cooperation among partners regardless of their resource level, and seeking regulatory “convergence” more than “harmonization.”
- In short, the health sector, and the Member States as a whole, need not only to understand the science and solutions around implementing specific interventions to address the major risk factors of tobacco, unhealthy diet, alcohol and physical inactivity, but also to develop their capacity as effective legislators and regulators for NCD prevention. They must be able to identify and assess the risks for their countries, select the best strategies for mitigating those risks, follow up with implementation, document their reasoning and choices with unassailable competence, listen to their communities and stakeholders while not ceding to vested interests, implement and enforce their chosen measures effectively, and monitor and evaluate the results.

PAHO Member States have proven the **benefit** of **enhancing** their regulatory capacity in the case of medicines and biologicals.

Prevention of **corruption** and **conflicts of interest** are concerns that must be tackled

Implement and **enforce** their chosen **measures** effectively, and monitor and evaluate the results.

The Way Forward

- Based on the analysis presented, this document seeks to identify effective strategies for technical cooperation between Member States and to orient Pan American Sanitary Bureau (PASB) action to build regulatory capacity for NCD prevention. Three goals are envisioned: (1) to meet the global and regional targets for NCD risk factor reduction; (2) to strengthen the regulatory component of public health stewardship; and (3) to contribute to leveling the playing field between societal and economic actors while strengthening fair governance. To achieve these goals, five lines of action are proposed for technical cooperation initiatives by PASB and between countries: (i) organizational development of regulatory capacity; (ii) development of technical capacity for risk factor control; (iii) evaluation of regulatory processes once they are in place; (iv) advancement of the regulatory research agenda; and (v) enlistment of the unique role of the PASB for technical cooperation in these areas.
- Initial priorities for technical cooperation include: support for Member States in more clearly defining the functions of the national regulatory process, the organizational base, and the structure for regulatory action to address the NCD risk

factors; support for countries in structuring the financing needed to support effective regulatory processes; facilitation of working groups and creation of structures for the exchange of expertise and best practices around specific risk factors and regulatory practices; development (by the PASB) of model legislation for NCD risk factors and regulatory structures; implementation (by the PASB) of a global monitoring plan for NCDs to track fulfillment of global commitments on the regulation of NCD risk factors; support for impact assessment of the regulations implemented; identification of institutional practices that reduce corruption and facilitate a more level playing field between social and economic actors; and strengthening of fair governance.

- The Organization’s innovative initiative “Strengthening Regulatory Capacity in the Region of the Americas for NCD Risk Factors” (REGULA) will seek to support these efforts in the Region.

With implementation of the foregoing measures, we can greatly increase the likelihood of achieving the ambitious risk reduction goals, to which the parties have agreed, throughout the Americas by 2025.

With implementation of the foregoing measures, we can greatly increase the likelihood of achieving the ambitious risk reduction goals, to which the parties have agreed, **throughout the Americas by 2025.**



The health argument is irrefutable
and the need for action is
immediate

A. Introduction

In the Region of the Americas, 200 million people are living with one or more noncommunicable diseases (NCDs). NCDs are the leading cause of morbidity and mortality in the Americas and are associated with 75% of all deaths (WHO, 2014c). In 2012 the World Health Organization (WHO) estimated that 5.1 million people died from a NCD, and 2 million died prematurely (before the age of 70). This means that many people at the most productive time in their life are dealing with a disease that can last many years, at a huge cost to their family and to the health system. This can jeopardize their well-being, family assets, and stability and eventually incapacitate them and lead to their death. Hence there are many reasons why these illnesses are important to development. The disease burden attributable to NCDs in the Americas has increased enormously over the past two decades (Stucker, 2008). Globally, residents of low- and middle-income countries (LMICs) are 65% to 85% more likely to die from NCDs than those living in high-income countries (HICs), and in fact over 80% of cardiovascular and diabetes deaths and almost 90% of deaths from chronic obstructive pulmonary disease (COPD) occur in LMICs (Stuckler, 2008). The current and projected rapid increase in NCDs, if not addressed, stands to widen the health gap between rich and poor countries, slow economic growth in LMICs, and kill or disable individuals at the peak of their productivity (Stuckler, 2008).

The bulk of the NCD epidemic is man-made, resulting from four key risk factors: harmful use of alcohol, unhealthy diet, physical inactivity, and tobacco use. Their rapid growth is caused by a combination of aging populations, continuing poverty, and widespread changes in human behavior that are related in turn to the growing availability and intensive promotion of unhealthy products; the relentless and poorly regulated expansion of global trade and consumer markets; the

relatively high cost of healthy food, difficult access thereto, or marginalization of traditional diets; rapid urbanization; automation of many activities; and lack of population awareness of the harmful effects of the four main risk factors.

The growth of the burden of disease outpaces the capacity of any national or state-level health system. As a man-made epidemic, it can be modified by tackling its root causes. Ten of the 15 WHO “very cost-effective” interventions, or “best buys,” generally require the use of regulatory or legal authority for their implementation. Yet the Council on Foreign Relations notes: “These changes are outpacing the ability of developing-country governments to establish the health and regulatory systems necessary to adjust” (CFR, 2014). There are achievable, highly cost-effective measures (WHO, 2013a) that address these risk factors and that have an extraordinary potential to improve health, expand healthy life years, and prevent premature death and suffering, and some of them are included among the “best-buys.” However, most of these measures have not been widely implemented. Indeed, few countries have fully taken up the mantle as active stewards of this process. The State has an ethical responsibility to provide the conditions under which people can lead healthy lives if they choose to. “Doing nothing” is also an active decision by the State that will have an impact on people’s ability to lead a healthy life. The “stewardship State,” in addition to protecting its citizens from harm caused by others, sees itself as having the particular responsibility to protect the health of vulnerable groups, such as children, and to close the gap between the most and the least healthy in society (Nuffield Council of Bioethics, 2007).

For example, many people’s diets include food that has been prepared or processed by others, and therefore consumers’ choices are at least partly influenced by

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The PAHO Strategic Plan 2014–2019 cites “low regulatory capacity at the national level” as a risk for the control of NCDs, which in turn **“allows the tobacco, alcohol, processed food, and sugary beverage industries to interfere and hinder progress in countries”**

the products that are available and the way they are promoted, priced, and distributed. Businesses, including the food industry, have an ethical duty to help individuals make healthier choices. The food and drink industries should therefore review both the composition of the products they manufacture and the way they are marketed and sold. Where the market fails to uphold its responsibility—for instance, in failing to provide universal, readily understandable front-of-package nutrition labeling or to oversee the marketing of food more generally—regulation by the government is ethically justifiable (NCB, 2007).

In 2011, the United Nations General Assembly convened the High-Level Meeting on Noncommunicable Diseases and issued a Political Declaration on Prevention and Control of Noncommunicable Diseases. The Declaration, which recognized that NCDs are a threat to global development and highly preventable and committed the United Nations system to action, focuses on primary prevention through regulatory and legislative actions to address NCD risk factors, which it regards as particularly cost-effective population-wide interventions, or “best-buys” (United Nations, 2012).

Member States have committed to the WHO Global Action Plan for the Prevention and Control of NCDs 2013–2020 (WHO, 2013a) and to the global target of reducing premature mortality from NCDs (cardiovascular diseases, cancers, diabetes, and chronic respiratory diseases) by 25% by 2025. The following five targets are related to the control of NCD risk factors: halt in the rise in diabetes and obesity, 30% reduction in salt intake, 10% reduction in the harmful use of alcohol, 10% reduction in the prevalence of insufficient physical activity, and 30% reduction in tobacco use.

The regulation of NCD risk factors lowers their prevalence in the population, leading to primary prevention of disease. Furthermore, these strategies provide secondary and tertiary prevention of NCDs by reducing risk for the large population already

affected by NCDs, reducing relapses, and preventing the occurrence of additional NCDs in those already affected. Therefore, this approach acts both to keep healthy people healthy and to protect those already ill from further deterioration of their health.

Up to now, action has been insufficient to reverse the rising prevalence of these diseases (WHO, 2013a). Historically, many efforts to fulfill international agreements or resolutions have suffered from lack of implementation, enforcement, and/or deficient documentation or evaluation. The PAHO Strategic Plan 2014–2019 cites “low regulatory capacity at the national level” as a risk for the control of NCDs, which in turn “allows the tobacco, alcohol, processed food, and sugary beverage industries to interfere and hinder progress in countries” (PAHO, 2013c). This challenge is significant. Implementation of the groundbreaking WHO Framework Convention on Tobacco Control has encountered many obstacles, including institutional weakness to effectively address its mandates. Several Member States have attempted to tackle marketing practices related to alcohol, unhealthy food, and/or sugary drinks, only to be faced with challenges in the legislative or implementation processes, including politicization of the issue and pressure from vested interests, leading to the erosion of political will and the capacity of Ministries of Health. Some of these challenges have been overcome, while others have left the risks unabated, at great cost in terms of productivity and to national health systems. Execution of policies or laws and the enforcement thereof are often the weakest links.

With each of the four risk factors, consumer choice is a major element in the fight. In the case of food, all sectors, including academia, consumers, health professionals, and the industry, will need to continue to work toward effecting change in consumer patterns and involving other sectors (e.g., the financial and economic sectors) in developing engaged consumers, creating a level playing field for all, and implementing

well-thought-out regulations to create an environment that facilitates both producing healthier options and encouraging people to choose them (NCB, 2007).

In the Region, the scenario of poor regulatory capacity and performance reflects a deficit that can be explained, at least in part, by the low investment in this area. It can also be attributed to a limited understanding of the stewardship function of health systems. Ministries of Health must step up to the plate and take the lead in their primary role of protecting health as an essential public health function beyond and above the provision of health care coverage. Successful and sustainable policies rely on a combination of leadership and a strong, well-informed civil society mediated by a relationship of trust. The collaboration of industrial sectors, particularly the food sector, is also important.

Two overarching themes have emerged that need to be addressed in order to achieve effective regulatory action against the NCD risk factors. The first is strengthening institutional capacity for health regulation in general, and the second is building technical capacity in order to enact and implement specific targeted policies to reduce the risk factors for NCDs and thereby their prevalence. Clear recommendations for the regulation of NCD risk factors have been formulated globally (United Nations High Level Meeting), regionally (PAHO), and locally. Yet the effective enactment and implementation of these measures is far more likely to occur and be sustained in the presence of capacity for risk analysis and risk management. Without effective institutional capacity, the possibility of inaction or failure is far greater. Capacity-building is needed in both these areas.

This document provides an overview of the status of the key noncommunicable disease risk factors in the Americas and the international agreements that support action by Ministries of Health to protect their populations against them. It reviews the current regulatory situation in the Region, outlines the main conceptual and operational elements of effective regulation, and proposes lines of action for technical

cooperation to strengthen regulatory capacity for NCDs in the Americas. Its focus is on regulation, a field that has been identified as an essential public health function and one in which capacity lags behind other areas of public health action. Strengthening regulatory capacity and action is by no means the only approach to reducing these risk factors, but it is an indispensable component of the suite of actions needed in order to prevent and control noncommunicable diseases in the Region. Ten of the 15 “very cost-effective” interventions (also called “best-buys”) cited in the WHO Global Action Plan on NCDs involve effective use of the regulatory function. These population-based interventions can be provided in low- and lower middle income countries for a median cost of less than US\$ 0.20 per person per year and for about US\$ 0.50 in upper middle-income countries (WHO, 2011d).

The present Technical Reference Document provides information in the status of NCDs in the Americas with a focus in regulation, since this area has received the least attention in the public health and NCD literature. It is intended to serve as a reference, providing an extensive review of the literature and links that can be used as a starting point for finding more information about the concepts, definitions, and current thinking by those who are starting to work in the field. Other documents with a more narrow scope will be developed by PAHO and Ministry of Health staff for specific audiences and issues. Potential audiences for this document are governments and their health authorities, nongovernmental organizations, and other civil society stakeholders. It has been greatly enriched by the thoughtful comments contributed by participants in the expert meeting on the regulation of the NCD risk factors held in Washington, D.C., on 17-18 November 17-18 2014 (PAHO, 2014g). This meeting was attended by leading experts from government offices, multilateral agencies, PAHO Country Offices and regional advisors, and academic experts from France and the United States, who provided extensive comments on the document and suggestions for lines of action. Most of their comments have been incorporated.

These population-based interventions can be provided in low- and lower middle income countries for a median cost of less than

**US\$ 0.20 per person per year and for about
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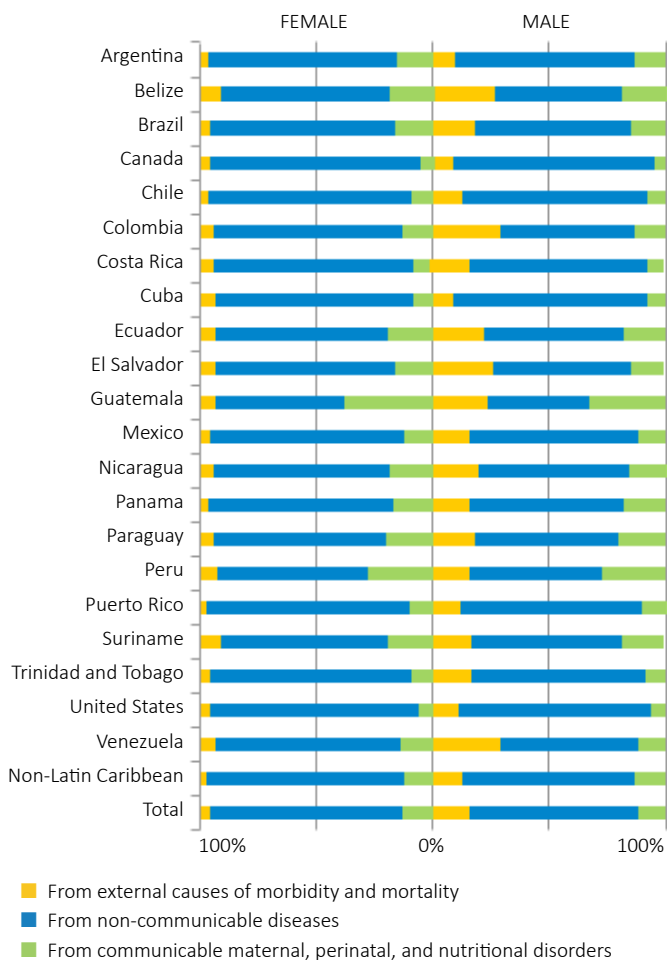
Regulation has been clearly recognized
as an essential public health function
but its capacity lags behind other
fields of public health action

B. A Problem Too Big to Ignore: The NCD Burden in the Americas

B.1. The Human Cost

Over the past 20 years, the incidence of infectious diseases has declined, while the prominence of noncommunicable disease and injuries has grown (Figure 1). Unfortunately, this is not merely a success story of vanquishing infectious disease; the burden of NCDs has grown rapidly (Figure 2) and strikes harder and earlier in life in low- and middle-income countries, due in part to poverty and the limited ability of health systems to respond. This situation imposes a great burden on individuals, families, the economy, health systems, and society. Provision of care for premature

FIGURE 1. Proportional mortality by country, sex, and group causes, 2007-2009
(proportion of total deaths for each sex)



Source: PAHO, Health in the Americas, 2012.

and potentially preventable NCDs challenges the capacity and economic sustainability of health systems everywhere.

A high proportion of these deaths occur early in life, with premature mortality in the Region representing 36% of all deaths from NCDs and 15% of all adult deaths (WHO, 2014f) (Figure 3). In other words, many die during their most productive years, leading these diseases to cause great social impact on the individuals and their families, their workplaces, and the broader economy (WHO, 2014c).

The main risk factors that underlie the occurrence of NCDs are well known and common across the Americas and throughout the world. Four of these risk factors underlie more than two-thirds of all new cases of NCDs: unhealthy diet (including salt, foods high in saturated and trans fats, and sugar, particularly sugary drinks), tobacco use, harmful use of alcohol, and physical inactivity. Each of these risks also leads

FIGURE 2. Diabetes mortality rates in selected countries of the Americas, 1998-2012
(age-standardized death rates per 100,000 population, both sexes, all ages)

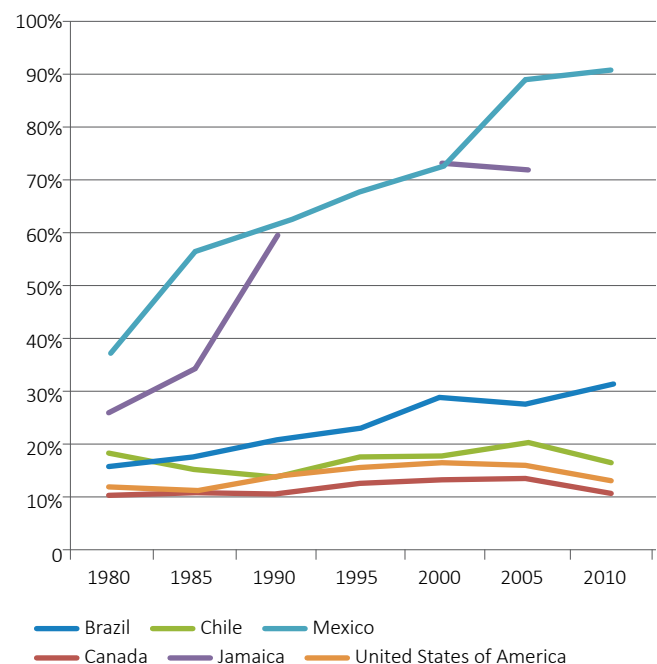
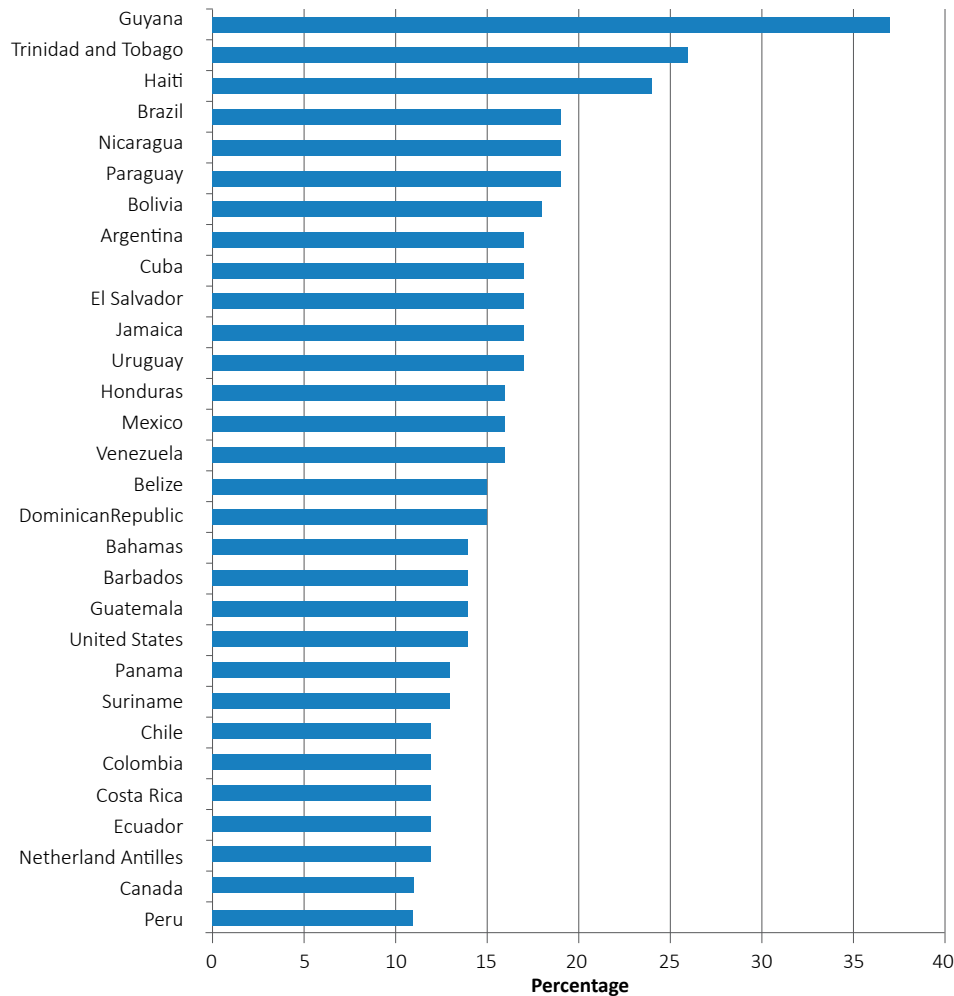


FIGURE 3. Dying too soon: Probability (%) of premature death from NCDs in adults age 30-70 years in the Americas, by country



Source: Data from PAHO Regional Health Observatory, Washington, D.C.: PAHO; 2014c.

to greater risk of complications in people who already have NCDs (Beaglehole et al., 2011).

Annual mortality due to the four leading risk factors is striking. Dietary risks as a whole are estimated to be the leading group of risk factors contributing to mortality. Globally, excessive sodium intake alone is estimated to be the cause of 1.7 million deaths annually from cardiovascular disease. Approximately 6 million people die annually from tobacco use, with over 600,000 deaths due to exposure to second-hand smoke. An estimated 5.9% (3.3 million) of all deaths worldwide and 5.1% of disability-adjusted life years (DALYs) were attributable to alcohol consumption in 2012 (WHO, 2014f). Lastly, insufficient physical activity contributes to 3.2 million deaths and 69.3 million DALYs each year (Lim, 2010). These risks arise from changing

patterns of consumption and behavior that result from transformations in our communities, urbanization, shifts from traditional to processed food and beverages, retail practices, urban design, transportation systems, commodity trade policies, marketing practices, and changes in work and daily life activities (NYC, 2010; Monteiro et al., 2013).

B.1.1. An Economic Burden that Threatens Development Progress

NCDs burden families with catastrophic health expenditures. The losses of breadwinners or reductions in family income due to these conditions are causes of family bankruptcy and impoverishment. At the national level, countries face increasing health expenditures and lost productivity (Table 1).

The economic burden of NCDs on families, governments, and society as a whole arises from a number of sources. The first is the direct costs related to medical and supportive care of ill individuals. The second source is the indirect costs related to loss of productivity. In 2010, direct costs associated with cardiovascular disease alone in the Region were estimated at US\$175.6 billion, while the indirect costs associated with lost productivity were approximately US\$127.5 billion (Bloom et al., 2011). These losses in productivity can arise from either “presenteeism” (when an employee goes to work despite a medical illness that prevents him or her from fully functioning on the job (Widera et al., 2010)) or absenteeism, both of which result in lowered productivity and economic output by the individual and reflect the poorer quality of life associated with NCDs. Since NCDs are chronic conditions, these costs may be incurred over long periods of time, creating compounded economic losses in terms of both productivity and health care expenditure. The costs of NCDs over time are projected to increase, with approximately 40% of the burden falling on low- and middle-income countries. Despite this investment, over three-fourths of the people with NCDs will die from them.

Table 2 shows the current and projected costs of five NCDs between 2011 and 2030. The global cost of these five NCDs alone through 2030 is estimated at US\$46.7 trillion (Bloom et al., 2011). The projected losses of US\$21.3 trillion in the world’s LMICs are nearly equal to their combined economic output in 2013 of US\$24.5 trillion (Council on Foreign Relations, 2014).

In addition to the affected individual, family members may be forced to cut back on their working hours to care for those with NCDs, thus decreasing income for the family, adding to stress, and pushing families into poverty. These costs are not well quantified and further research is needed. The national and international impact of NCDs includes the burden on health care systems to provide long-term services to NCD patients with chronic conditions. One economic analysis found that a 10% increase in the prevalence of NCDs is associated with a 0.5% lower rate of increase in the GDP (WHO, 2011b). The McKinsey Global Institute recently analyzed the global economic impact of obesity alone at roughly US\$2.0 trillion, or 2.8% of global GDP, roughly equivalent to the global impact from smoking or armed violence, war, and terrorism (Table 3).

TABLE 1. Effects of NCDs in low- and middle-income countries

Individuals and households	Health systems	National economics and governments
<ul style="list-style-type: none"> • Premature death and disability • Lost household income, potential impoverishment • Health expenditures including catastrophic expenses • Loss of savings and assets • Greater likelihood of children developing NCDs 	<ul style="list-style-type: none"> • Poor health outcomes • Diminished capacity to address other health needs • Resources to reboot health systems to chronic preventive care • Health labor force and training demands • Increase demand for high-cost medical interventions 	<ul style="list-style-type: none"> • Reduced labor supply • Lower productivity and competitiveness • Lower tax revenues • Increased health and social welfare expenditures • Lost demographic dividend • Political pressure from unmet population needs

Source: Adapted from Council on Foreign Relations, 2014.

TABLE 2. Current and projected global costs of five leading NCDs, 2011-2030 (trillions of US\$)

Country income group	Diabetes	Cardiovascular diseases	Chronic respiratory diseases	Cancer	Total
High	0.9	8.5	1.6	5.4	25.5
Low and middle	0.8	7.1	3.2	2.9	21.3
Upper middle	0.6	4.8	2.2	2.3	14.9
Lower middle	0.2	2.0	0.9	0.5	5.5
Low	0.0	0.3	0.1	0.1	0.9
World	1.7	15.6	4.8	8.3	46.7

Source: Bloom DE, et al., The global economic burden of noncommunicable diseases, Geneva: World Economic Forum; 2011

TABLE 3. Estimated annual global direct economic impact and investment to mitigate selected global social burdens, 2012

Burden	Cost (US\$ in trillions)	Percentage of GDP
Smoking	2.1	2.9
Armed violence, war, and terrorism (includes military budget)	2.1	2.8
Obesity	2.0	2.8
Alcoholism	1.4	2.0
Illiteracy	1.3	1.7
Climate change	1.0	1.3

Source: Adapted from Dobbs et al., 2014.

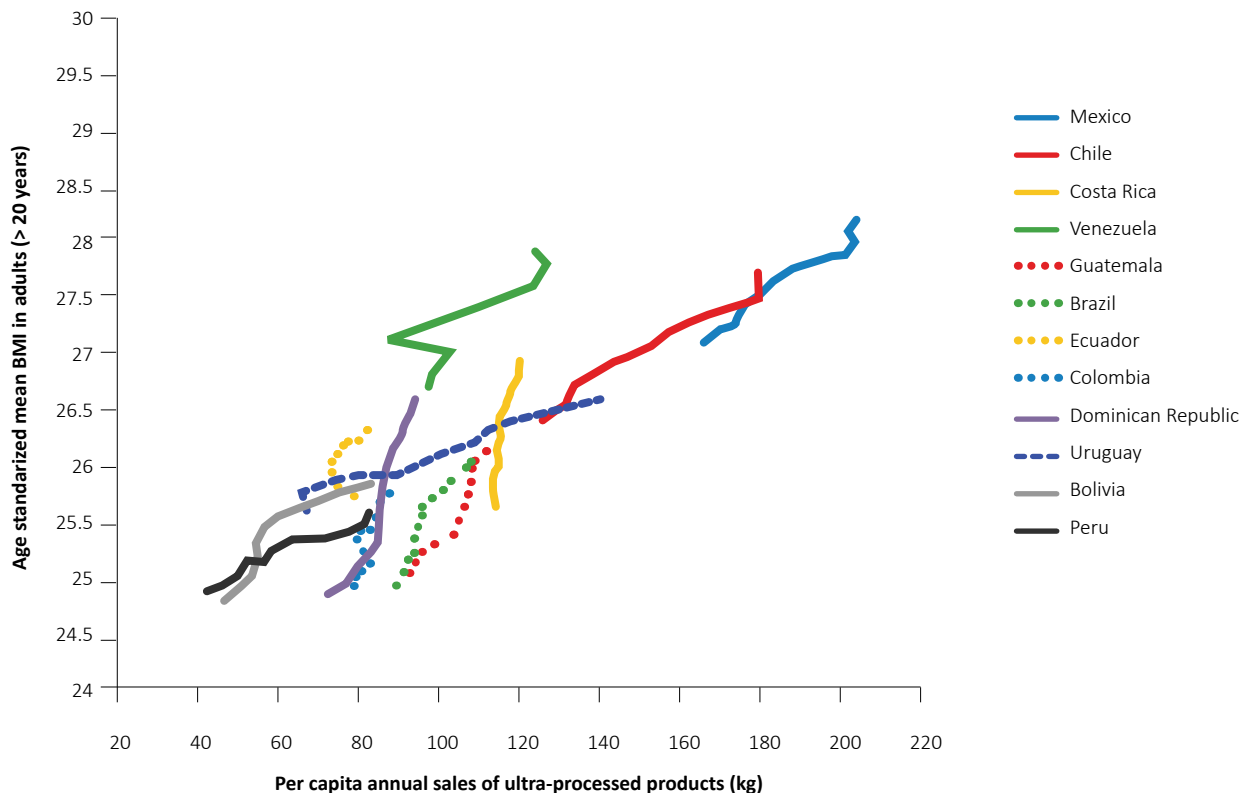
B.1.2. Dietary Risks: A Leading Risk Factor for Death and Disability

Over the past two decades, dietary risks have rapidly emerged as the leading underlying risk factor for death and disability both globally and in the Americas. Increases in dietary risks have emerged from a series of social changes, including urbanization, incorporation of women into the workforce, and increased consumption of food outside the home, all mediated by the substantial increase in the marketing and consumption of processed foods and beverages (PAHO, 2014a). These dietary risks have many sub-components, including decreased consumption of fruits, vegetables,

nuts, seeds, and omega-3 foods, along with excessive consumption of salt, trans fat, processed meats, and sugar-sweetened beverages (PAHO, 2014a). The increase in processed food consumption (Figure 4) is associated with increased body mass index.

Much, though not all, of this burden of dietary risk is associated with overweight and obesity, which in turns lead to metabolic changes and diabetes. Obesity nearly doubled globally between 1980 and 2008. Of all the WHO Regions, the Americas have the highest levels of overweight and obesity: 62% for overweight in both sexes and 26% for obesity in adults over 20 years of age (WHO, 2011b). In Chile, Mexico, and the United States,

FIGURE 4. Consumption of ultra-processed food and drink products, selected Latin American countries



obesity and overweight now affect 7 of every 10 adults (Rivera et al., 2014; Ministry of Health of Chile, 2010; NCHS, 2012). Among adolescent girls (15 to 20 years), overweight and obesity rates have risen steadily over the last two decades—for example, in Bolivia, from 21.1% to 42.7%; in Guatemala, from 19.6% to 29.4%; and in Peru, from 22% to 28.5%. Rivera et al. estimate that the national combined prevalence of overweight and obesity in Latin America ranges between 18.9% and 36.9% in school-age children (5-11 years) and between 16.6% and 35.8% in adolescents (12-19 years). Overall, between 42.5 and 51.8 million children under 19 years of age (20% of the total) are affected (Rivera et al., 2014).

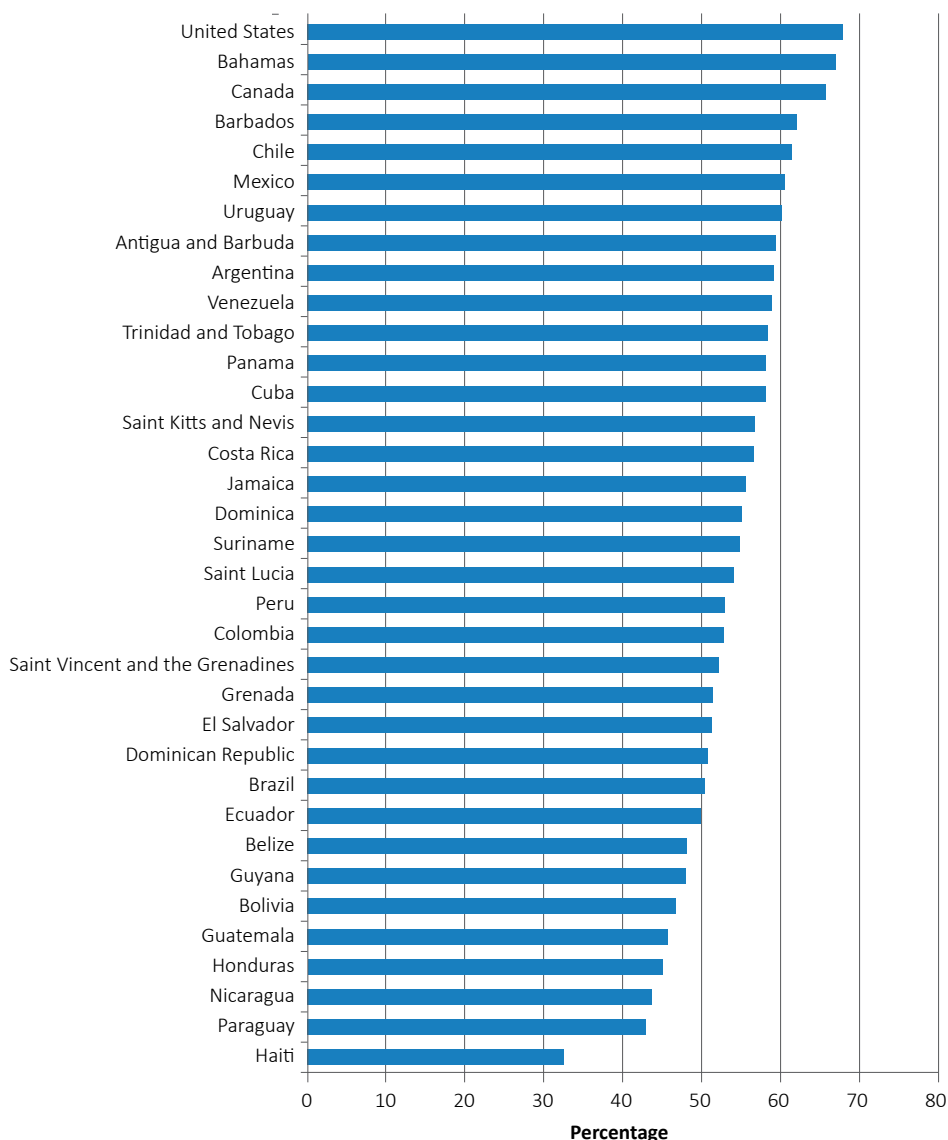
Obesity and socioeconomic disadvantage may be mutually reinforcing: children of all ages are twice as

likely to be obese in the most deprived areas compared with the least deprived areas (MGI, 2014). The prevalence of obesity is consistently higher in women than in men, with a gap of up to 24 percentage points .

B.1.3. Tobacco: A Continuing Presence

Tobacco use and exposure to secondhand smoke continue to be one of the main causes of preventable morbidity and mortality throughout the world. In the Region, tobacco-related deaths account for 16% of all adult deaths. There are 145 million smokers, and the smoking prevalence in adults is around 22%. Even though the prevalence continues to be higher in men, the Region has the smallest difference in prevalence rates between adult men and women. The rising trend

FIGURE 5. Prevalence of overweight and obesity (%) among adults in the Americas, 2010

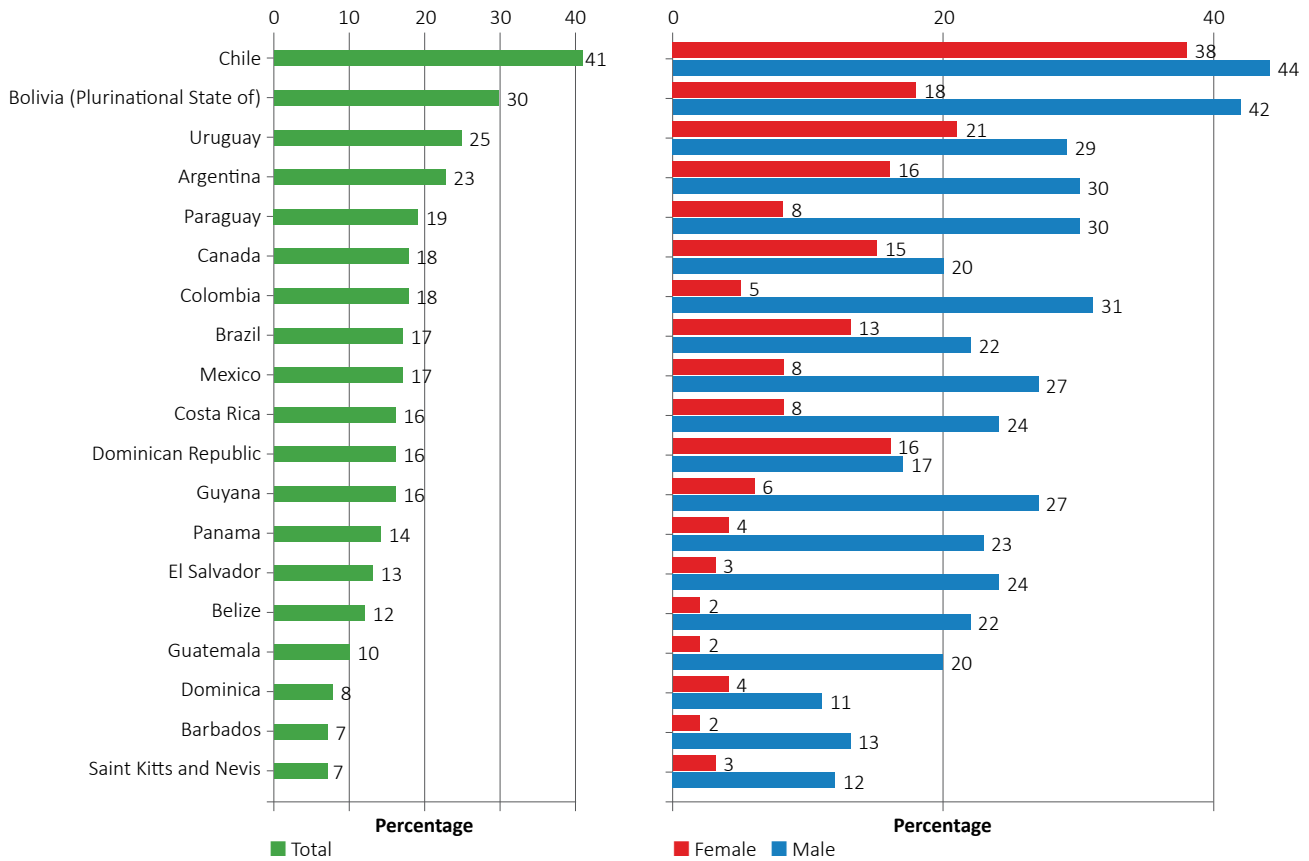


Source: WHO Global Infobase, 2010d.

in tobacco use among women is particularly notable in 13 to 15 year-olds. Among adults, the age-standardized prevalence of smoking varies widely between countries, from 41% in Chile to 7% in Barbados and Saint Kitts and Nevis (Figure 6). Despite the progress made in several countries as a consequence of implementing the FCTC mandates and the growing engagement of civil society

and Member States, a large proportion of the Region’s population is still not covered by even a single FCTC measure at the highest level of achievement. Finally, tobacco industry influence and interference has been and still is a severe obstacle to progress in tobacco control (PAHO, 2013d).

FIGURE 6. Estimated age-standardized prevalence of current use of smoked tobacco among adults ≥ 15 years old, selected countries of the Americas, 2011 (%)



Source: PAHO, Tobacco control report for the Region of the Americas, 2013d.

B.1.4. Harmful Use of Alcohol: Widespread and on the Rise

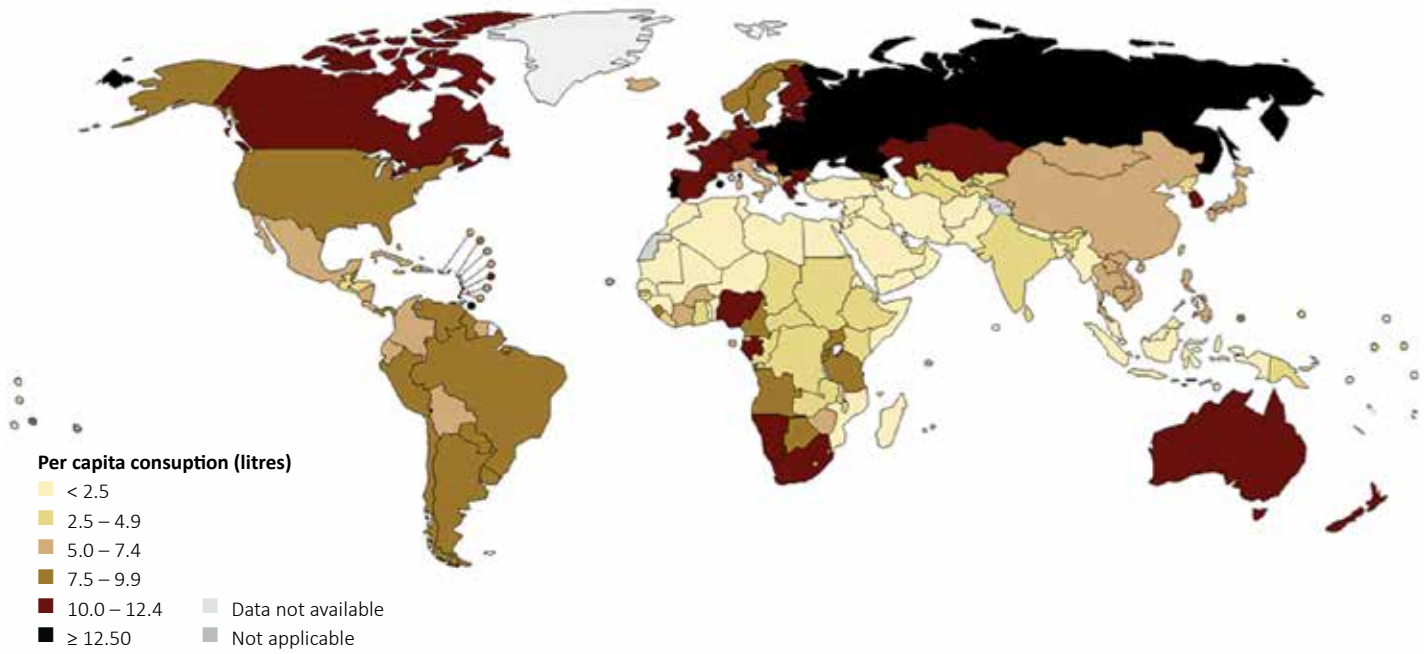
Both the numbers and rates of damages caused by alcohol are on the rise in Latin America and the Caribbean. Of the WHO Regions, the Americas have the second highest in percentage of drinkers and of heavy episodic drinking, behind the European Region (Figure 7).

Alcohol is the most common underlying risk factor associated with death in young people. It contributes not only to common alcohol-related diseases like liver cirrhosis and traffic injuries but also to many other illnesses. For example, in the world as a whole it is responsible for 10% of DALYs from colorectal cancer,

8% from breast cancer, and 10% from hypertensive heart disease. Alcohol mortality strikes more men than women in every country, though the risk for negative consequences is higher among women for the same amount of alcohol consumed. Alcohol-specific mortality also varies widely by country (Gawryszewski and Monteiro, 2013). In addition to death and disability, harmful drinking has a host of other, often devastating, consequences for the drinker, the family, and the community (Casswell et al., 2011).

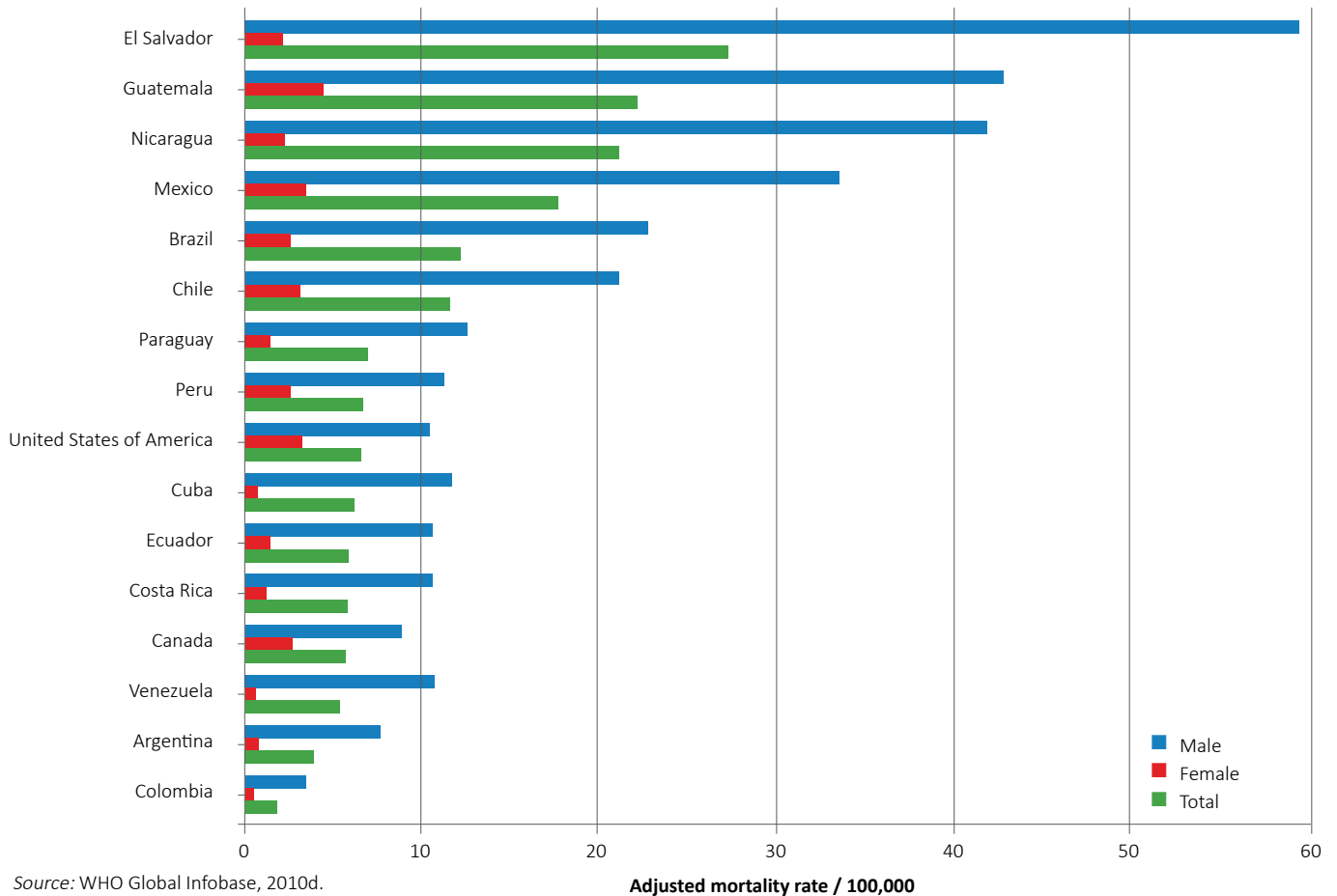
As can be seen in Figure 7 and Figure 8 , some countries with relatively low levels of consumption still have very high mortality rates (e.g., El Salvador and Guatemala),

FIGURE 7. Total annual alcohol consumption per capita (population 15+ years of age), in liters of pure alcohol, 2010



Source: WHO. Global Health Observatory. Geneva: 2010a.

FIGURE 8. Adjusted mortality rate per 100,000 population fully attributable to alcohol, 2007-2009, selected countries in the Americas



Source: WHO Global Infobase, 2010d.

illustrating the importance of the prevalence of heavy episodic drinkers and patterns of drinking, not just total annual average per capita consumption of alcohol. Patterns of consumption are highly significant in determining the effects of alcohol on crime and injuries (with acute heavy episodic drinking) and on chronic disease (with chronic heavy consumption or a mixed pattern of average low drinking levels alternating with episodes of heavy episodic drinking).

B.1.5. Physical Inactivity

Insufficient physical activity is the fourth NCD risk factor. WHO estimates that globally at least one in three individuals fail to get the WHO recommended amount of physical activity (150 minutes of moderate activity per week). However, in the Region of the Americas this ratio increases to one in two individuals, raising the risk of all-cause mortality by 20% to 30% (WHO, 2010b). Many factors contribute to decreasing physical activity, including automation of many work activities; rapidly increasing urbanization (usually without planning), with impediments to safe active transportation like walking, biking, or taking public transportation; shifts from active recreation to screen-time with computers and other devices; and fear of violence.

There is also a correlation between increased national income and insufficient physical activity (WHO, 2010b). While some of the health effects of physical inactivity are associated with obesity, physical activity exerts

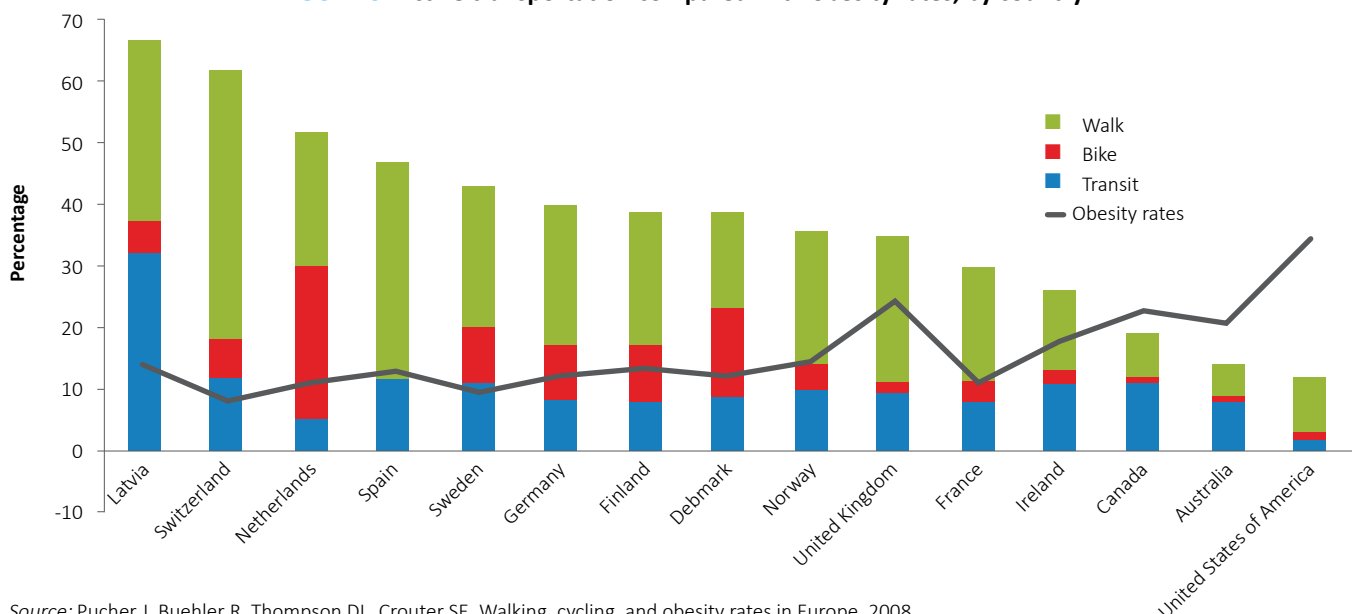
independent protective effects by reducing the risk for NCDs and their complications, irrespective of weight. Greater physical fitness is also associated with improved academic performance in children (Bezold, 2014). The design of communities and cities and the ability of people to move about safely on foot, by bicycle, or using public transit (called “active transportation”) also appear to have a major influence on levels of physical activity and obesity (Figure 9) (Bassett et al., 2008). These observations highlight an important role for local governments in the promotion of physical activity. The WHO Global Action Plan for the Prevention and Control of NCDs calls for a 10% reduction in insufficient physical activity by 2020, a target that is also endorsed by the PAHO Plan of Action for the Prevention and Control of NCDs in the Americas 2013-2019.

B.2. An Unequal Burden

The poor outcomes for individuals living with NCDs in lower- and middle-income countries are primarily a reflection of household poverty and underfunded health systems. In all nations, the burden falls more heavily on families in the lower income brackets. In addressing NCDs and their risk factors, specific attention should be paid to groups that experience differential burdens of illness or who may have special needs.

The poor are disproportionately exposed to NCD risk factors and are most likely to bear the dual burden

FIGURE 9. Active transportation compared with obesity rates, by country



Source: Pucher J, Buehler R, Thompson DL, Crouter SE. Walking, cycling, and obesity rates in Europe, 2008.

of disease, since they are affected by communicable diseases as well (PAHO, 2013b). For example, the highest rates of obesity and diabetes are seen in poor communities, exacerbated by the fact that poor-quality highly processed foods are frequently more affordable (Pagani, 2007). Furthermore, the poor have the scarcest resources to treat illnesses, often have high out-of-pocket costs, and are frequently excluded from insurance schemes or health systems (Etienne, 2014), leading to higher rates of hospitalization, disability, and mortality. Residents of low- and middle-income countries, and particularly of rural areas in those countries, are more likely to have a major cardiovascular event and to die from it if they have one (Yusuf, et al., 2014).

Certain racial and ethnic groups are more severely affected by diabetes. In the United States, for example, rates of diabetes are far higher among African Americans and Hispanics (CDC, 2014).

Women have higher rates of obesity in the Region than men, which can lead to increased rates of morbidity and mortality, as well as decreased productivity (WHO, 2010d). In addition, the rising trend in smoking prevalence among women is already leading to associated NCDs (PAHO, 2012).

There are many indigenous populations in the Region, but data on the impact of NCDs and the prevalence of risk factors is limited. However, studies indicate high rates of poor diet, diabetes, obesity, cardiovascular disease, asthma, arthritis, smoking, and binge drinking in some of the indigenous populations (NCD Alliance, 2012). Many other factors make NCD prevention and control difficult among indigenous populations—for example, low rates of formal education, geographic barriers, poor community health system infrastructure, and cultural aspects that may lead individuals to choose traditional treatments instead of seeking Western medical care (PAHO, 2012).

Children are now also showing increasing rates of NCDs. These rates are distributed differentially by social and ethnic group. A similar unequal distribution is also present in hypertension among children and adolescents (Din-Dzietham et al., 2007). This data demonstrates the early genesis of chronic disease risk and the need for a life-course approach in the prevention of noncommunicable disease. The increasing prevalence of NCDs in children is of particular relevance when considering the role and responsibility of the State in protecting children and youth.

An additional population of concern for NCDs is the group affected by mental illness. The mentally ill have far higher rates of smoking (Lasser et al., 2000), harmful use of alcohol, and poor diet. Higher comorbidity from diabetes, cancer, and cardiovascular disease may also be found in this population (McVeigh et al., 2006), and these conditions can be particularly challenging and expensive to treat. In addition, more recent medicines for schizophrenia elevate the risk for diabetes. NCDs, in turn, can also be a cause of depression.

Awareness and focus on these populations can help to identify unforeseen consequences of policies before they exacerbate the problems. Care must be taken to ensure that the regulations enacted to reduce the prevalence of NCD risk factors and the monitoring of disparities will effectively protect such groups and the impact on these populations, and also that subgroup-specific policies are in place. Attention should be given to monitoring and evaluating policies that specifically address populations with special needs. In some cases, population-specific policies or additional resources for high-risk groups may be needed.

An additional population of concern for NCDs is the group affected by mental illness.

The mentally ill have far higher rates of smoking, harmful use of alcohol, and poor diet.

A pair of hands, one on the left and one on the right, are shown in a dark blue, semi-transparent style. The hands are positioned as if holding something gently. In the center, between the palms, is a white silhouette of a family consisting of a woman on the left, a man on the right, and two children in the middle, all holding hands. The background is a solid, dark blue color.

Regulation has been identified as one of the main strategies for addressing NCD risk factors.

Strengthening this public health function is supported by international agreements that need to be fulfilled.

C. Time to Prevent: International Political Commitments to Regulatory Action

Regulation has been identified as one of the main strategies for addressing NCD risk factors. Strengthening this public health function is supported by international agreements that need to be fulfilled. At the highest policy level, broad coordinated effort has gone into achieving intergovernmental agreements, which now demonstrate international willingness and commitment to moving forward on a global health protection regulatory agenda. This framework of agreements has evolved over time, from the broad constitutive documents of the World Health Organization and the Universal Declaration of Human Rights in the 1940s to the more recent commitments on NCDs.

The key risk factors directly related to NCDs are “human-made,” which means that the NCD epidemic can also be reversed through effective interventions. In the 2011 Political Declaration of the High-Level Meeting of the General Assembly on the Prevention and Control of Noncommunicable Diseases (United Nations, 2012), the Member States assumed the commitment, among others, to **reduce their risk factors, create a health-promoting environment**, and strengthen national policies and health systems, as enshrined in the following paragraphs:

43. Advance the implementation of multisectoral, cost-effective, population-wide interventions in order to reduce the impact of the common non-communicable disease risk factors, namely tobacco use, unhealthy diet, physical inactivity, and harmful use of alcohol, through the implementation of relevant international agreements and strategies, and education, **legislative, regulatory, and fiscal measures...**

46. Strengthen international cooperation in support of national, regional, and global plans for the prevention and control of non-communicable diseases, inter alia, through the exchange of best practices in the areas of health promotion, **legislation, regulation**, and health systems strengthening...

The foregoing commitments are consistent with the founding principles of the Constitution of the World Health Organization (WHO, 1946), which are binding on its Member States:

THE STATES Parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:

... **Governments have a responsibility for the health of their peoples** which can be fulfilled only by the provision of adequate health and social measures.

Several articles further expand the functions of the Organization and its Member States:

Article 2(k) **To propose conventions, agreements and regulations, and make recommendations with respect to international health matters** and to perform such duties as may be assigned thereby to the Organization and are consistent with its objective;

Article 19. The Health Assembly shall have authority to adopt conventions or agreements with respect to any matter within the competence of the Organization. A two-thirds vote of the Health Assembly shall be required for the adoption of such conventions or agreements, which shall come into force for each Member when accepted by it in accordance with its constitutional processes.

Article 21. **The Health Assembly shall have authority to adopt regulations** concerning: ... (e) **Advertising and labeling** of biological, pharmaceutical and similar products moving in international commerce.

Article 62. **Each Member shall report annually** on the action taken with respect to recommendations made to it by the Organization and with respect

to conventions, agreements and regulations.

Article 63. Each Member shall communicate promptly to the Organization important **laws, regulations**, official reports and statistics pertaining to health which have been published in the State concerned.

The WHO Constitution supports the role of the State to promote the benefit of all, as well as the role of WHO and its Health Assembly to promote regulatory action and the accountability of Member States on regulatory issues, including annual communication of all health-related laws and regulations in the Americas, which in turn should be supported by the Pan American Sanitary Bureau (PASB).

The WHO Framework Convention on Tobacco Control was the first internationally binding treaty negotiated under the auspices of WHO, following Article 19 of its Constitution. Article 4 of the FCTC sets forth guiding principles, including the need to provide information on health consequences, political commitment, international cooperation, comprehensive intersectoral response, liabilities, technical and financial assistance, and the participation of civil society. Article 5(2) of the FCTC, under General Obligations, states that:

Toward this end, each Party shall, in accordance with its capabilities:

- (a) Establish or reinforce and finance a national coordinating mechanism or focal point for tobacco control; and
- (b) Adopt and implement effective **legislative, executive, administrative and/or other measures**

and cooperate, as appropriate, with other Parties in developing appropriate policies for preventing and reducing tobacco consumption, nicotine addiction and exposure to tobacco smoke.

In 2013, the 66th World Health Assembly adopted the Global Action Plan on Noncommunicable Diseases 2013-2020 (GAP for NCDs) (WHO, 2013a), its Global Monitoring Framework (WHO/WHA, 2014), and nine voluntary targets. In paragraph 24 it emphasizes:

As the ultimate guardians of a population’s health, governments have the lead have the lead responsibility for ensuring that appropriate institutional, legal, financial and service arrangements are provided for the prevention and control of noncommunicable diseases.

In endorsing the GAP for NCDs, the Member States agreed to the following six voluntary global targets, among others: a 10% relative reduction in the prevalence of insufficient physical activity; a 30% relative reduction in mean population intake of salt/sodium; a 30% relative reduction in the prevalence of current tobacco use in persons aged 15+ years; at least a 10% reduction in the harmful use of alcohol; a 25% relative reduction in the prevalence of raised blood pressure, or contain the prevalence of raised blood pressure, according to national circumstances; and a halt in the rise of diabetes and obesity. These global targets support an overall goal of a 25% reduction in premature mortality by 2025 (Figure 10). The WHO Global Strategy on Diet, Physical Activity, and Health (WHO, 2004) calls for the reduction of sugar consumption, an essential goal for meeting the WHO Global Action Plan target of a halt the rise of obesity and diabetes.

FIGURE 10. WHO Global Action Plan: Risk Factor targets



To achieve this purpose, Objective 2 of the GAP for NCDs issues a call to “**strengthen national capacity, leadership, governance, multisectoral action and partnerships to accelerate country response for the prevention and control of noncommunicable diseases**” (WHO, 2013a).

Among its policy options, the GAP for NCDs also emphasizes **strengthening institutional capacity and the workforce** and specifies the need to establish “**public health institutions to deal with the complexity of issues relating to noncommunicable diseases (including such factors as multisectoral action, advertising, human behavior, health economics, food and agricultural systems, law, business management, psychology, trade, commercial influence including advertising of unhealthy commodities to children and limitations of industry self-regulation ...**” WHO, 2013a).

Objective 3 of the GAP for NCDs (WHO, 2013a) focuses on reduction of the level of exposure to modifiable risk factors for noncommunicable diseases. Accordingly, paragraph 33 of the Plan states:

While deaths from noncommunicable diseases mainly occur in adulthood, exposure to risk factors begins in childhood and builds up throughout life, **underpinning the importance of legislative and regulatory measures, as appropriate ... to prevent tobacco use, physical inactivity, unhealthy diet, obesity and harmful use of alcohol and to protect children from adverse impacts of marketing.**

The GAP for NCDs builds on the FCTC and on preceding WHO Global Strategy documents on Diet, Physical Activity and Health (WHO, 2004), and on Harmful Use of Alcohol (WHO, 2010). This one calls for regulatory action in five of its 10 policy options including drink driving, availability, marketing, pricing and illicit alcohol.

Within the GAP for NCDs there is a mandate to adapt to regional conditions. In the Americas, the regional Plan of Action for the Prevention and Control of

Noncommunicable Diseases (PAHO, 2013b) explicitly states in its first line of action that the Member States should:

... mobilize efforts to address a risk factor or risk factors; and/or participate in coordinated and concerted actions that create healthy local environments, using incentives and disincentives, regulatory and fiscal measures, laws, and other policy options ...

... reduce the prevalence of the main NCD risk factors and strengthen protective factors, with emphasis on children and adolescents and on populations in vulnerable situations; use evidence-based health promotion strategies and policy instruments, including regulation, monitoring, and voluntary measures; and address the social, economic, and environmental determinants of health.

It further assigns to the Pan American Sanitary Bureau (PASB) the roles of prioritizing NCDs; furthering a settings-based approach; developing policies, plans, and programs; disseminating technical guidelines; mobilizing multisectoral engagement; and leading the dialogue with international agencies.

Objective 1.3 requests the PASB to:

Strengthen regional networks of national counterparts, ... expand the pool of expertise related to **whole-of-government and whole-of-society approaches**, including, as appropriate, evidence-based policy, legislation, regulation, training of professionals, and health system responses.

The same challenge is also put forth to the Member States. In addressing Strategic Line of Action 2, NCD Risk Factors and Protective Factors, the regional Plan of Action includes the following regulatory action:

There is momentum in the Region with regard to addressing key risk factors and protective

**Governments have a responsibility for the health of their peoples,
which can be fulfilled only by the provision
of adequate health and social measures**

factors through effective, evidence-based and cost-effective, population-based interventions and instruments, with attention to children and people living in vulnerable situations, and ... evidence-based initiatives to **reduce harmful use of alcohol use, and initiatives directed at overweight and obesity, particularly among children, such as food labeling specifications and regulations and policies on foods and drinks permitted in schools and public institutions.**

With regard to obesity, the recently approved regional Plan of Action on the Prevention of Obesity in Children and Adolescents (PAHO, 2014b) includes five strategic lines of action, one of which is directly related to regulation. It has a total of 18 indicators, seven of which are regulation-related.

In 2014, in fulfillment of commitments made under the Political Declaration from the United Nations High-Level Meeting on the Prevention and Control of Noncommunicable Diseases, the United Nations General Assembly (UNGA) reviewed an assessment of

progress to date. The UNGA review on NCDs (UNGA, 2014), paragraph 18, reaffirms the commitment to advance the implementation of “relevant international agreements, strategies, national policies, legislation and development priorities, including educational, regulatory and fiscal measures.”

Paragraph 30(h) calls for strengthening international cooperation “through the exchange of best practices in the areas of health promotion, legislation, regulation. ...”

These agreements establish the responsibility of the Member States to protect their population; describe the role of the Organization’s Secretariat in supporting and recommending regulations; call for policy, legislative, and regulatory interventions by Member States; and, at the same time, call for concerted cooperative action within the Region to move this agenda forward. The commitment is there. The challenge is to review the performance to date and move forward to full implementation.

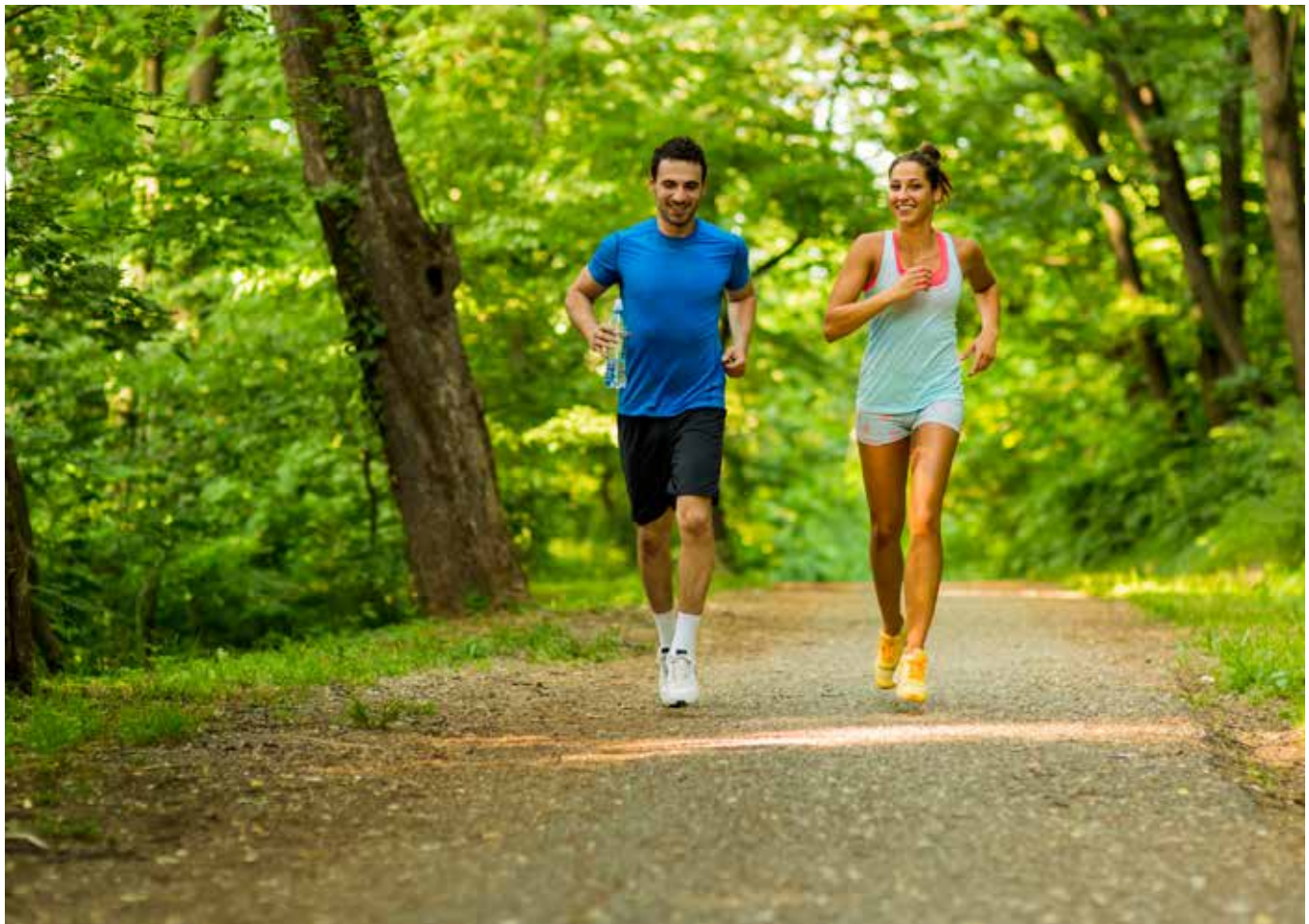


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D. NCD Risk Factors: The Toolbox to Put Global Commitments into Practice

The four NCD risk factors of unhealthy diet, tobacco use, harmful use of alcohol, and physical inactivity are unique in magnitude in terms of both their levels of population exposure and their preventable ill effects on health, which every year far surpass those of any side effect of medications, food-borne illness outbreak, or natural disaster in the Americas. These risks are too massive to leave them unaddressed. Furthermore, there is a strong and rapidly growing body of scientific knowledge and international regulatory experience, including a broad set of United Nations-endorsed measures, on how to do so effectively. While regulatory approaches are only a part of the needed suite of actions for NCDs, they are an important part and often a highly cost-effective one.

Three of these risk factors involve unhealthy consumer products that are massively and successfully marketed to the population. The extremely competent use of classic, highly effective marketing practices raises the consumption of these products to levels that cause widespread harm. As a result, there is significant overlap in the areas of regulation that can be enlisted to modify their impact on population health. These regulatory approaches may of necessity include strategies to address the classic “Ps” of marketing used to promote consumption: product design (including content, labeling, and packaging), placement and availability in the community, price formation, and promotion or marketing of unhealthy products to consumers, especially children and youth. The approaches might include, for example, reformulating content to reduce risk in the case of certain foods, labels that better inform consumers, plain packaging, taxes or minimum prices, subsidies, or restrictions on marketing or on locations or times of sale. Physical inactivity, the fourth

risk factor, is quite distinct. While it shares with the first three the need for the creation of healthy social norms, the policies and regulations that will increase physical activity generally address different types of determinants, such as urban design, transportation, or policies of institutions where people spend their time.

Taking into account Annex 3 of the Global Action Plan on NCDs (WHO, 2013a) and building on proven and cost-effective interventions, as well as practical experiences of local and national governments, Table 4 lists examples of a “toolbox” of risk protection practices for the first three of these risk factors. Many require regulatory support, generally to address issues that are often shared across risk factors, including regulation of retail practices, restriction of products, fiscal policy, dissemination of information to consumers, marketing restrictions, incentives, and measures that influence the social environment. The options for the regulatory mix are quite rich and provide health authorities with a broad spectrum of interventions that can be implemented and at times even coordinated across the risk factors. These broad strategy groups also help to identify the multisectoral partnerships needed. Among these measures, the World Economic Forum (WEF, 2011) and WHO (2015) have identified certain “best buys,” which include population-based measures on diet, tobacco use, alcohol, and physical activity, as well as clinical preventive measures related to cardiovascular disease, diabetes, and cancer (Table 5). The per capita cost of implementing the 2011 package of population-based “best buys” is quite low. In low- and middle-income countries it amounts to less than US\$ 0.20 a year, and for upper middle-income countries it is closer to US \$0.50. This minimal amount would come to less than 1% of total per capita spending on health (WHO, 2011b).

While regulatory approaches are only a part of the needed suite of actions for NCDs,

they are an important part and often a highly cost-effective one.

A broader set of feasible “good buys” is also available, most of which also have minimal cost implications for governments. Their implementation costs primarily involve inspection for compliance, while some of them, like taxation of unhealthy products, can even generate substantial revenue. Most have a strong evidence base, but some are still being evaluated. Table 4 lists a set of

TABLE 4. Toolbox of regulatory strategies in use or attempted for tobacco use, unhealthy diet, and harmful use of alcohol

Strategy group	Strategy
Retail practices	<ul style="list-style-type: none"> Assurance of availability of healthy products Retail license requirement for unhealthy products Restrictions on sales of unhealthy products near schools Restrictions on sales near schools Prohibition of self-serve sales Restrictions on product display settings
Restrictions on products	<ul style="list-style-type: none"> Product/portion size restrictions Product prohibition Content limits
Information	<ul style="list-style-type: none"> Warning labels Mandated information for consumers
Price	<ul style="list-style-type: none"> Excise taxes Sales taxes Minimum price Restrictions on discounting
Marketing	<ul style="list-style-type: none"> Prohibition on marketing to children Restrictions on time place and manner Broad prohibitions for all age groups Plain packaging
Social environment	<ul style="list-style-type: none"> Regulations on second-hand smoke Regulations on day care practices Regulations on school practices Regulations on workplace practices Regulations on public spaces
Other economic approaches	<ul style="list-style-type: none"> Agricultural subsidies (add or eliminate) Procurement policies (promote or restrict) Land use/agricultural use or urban zoning policies Incentives/subsidies for citizens

strategies that are being used for tackling NCDs risks, many of which reflect a common need to respond to marketing strategies across product types. This is an area of rapidly evolving science, as countries implement tested interventions and also experiment with innovation, like plain packaging of tobacco products and warning labels or taxes on sodas, and assess their impact.

TABLE 5. WHO “Best buy” interventions

Risk factor/ diseases	Interventions
Tobacco use	<ul style="list-style-type: none"> Reduce affordability of tobacco products by increasing tobacco excise taxes Create by law completely smoke-free environments in all indoor workplaces, public places, and public transport Warn people of the dangers of tobacco and tobacco smoke through effective health warnings and mass media campaigns Ban all forms of tobacco advertising, promotion, and sponsorship
Harmful alcohol use	<ul style="list-style-type: none"> Regulate commercial and public availability of alcohol Restrict or ban alcohol advertising and promotions Use pricing policies such as excise tax increases on alcoholic beverages
Diet and physical inactivity	<ul style="list-style-type: none"> Reduce salt intake Replace trans fats with unsaturated fats Implement public awareness programmes on diet and physical activity Promote and protect breastfeeding
Cardiovascular disease and diabetes	<ul style="list-style-type: none"> Drug therapy (including glycaemic control for diabetes mellitus and control of hypertension using a total risk approach) and counselling to individuals who have had a heart attack or stroke and to persons with high risk ($\geq 30\%$) of a fatal and nonfatal cardiovascular event in the next 10 years Acetylsalicylic acid (aspirin) for acute myocardial infarction
Cancer	<ul style="list-style-type: none"> Prevention of liver cancer through hepatitis B immunization Prevention of cervical cancer through screening (visual inspection with acetic acid (VIA) linked with timely treatment of pre-cancerous lesions)

Source: WHO, Global Status Report, 2015.

D.1. NCD Risk Factors: Key Recommendations and Experiences in the Americas

D.1.1. Building a Healthier Food Supply to Reduce Dietary Risk

Addressing unhealthy diet, the NCD risk factor with the largest impact on preventable death and disability from a wide range of illnesses, should be a top priority of governments. Reversing this trend is likely to take many years because food and physical activity habits are deeply ingrained in individual and social patterns of behavior and in production systems.

Effecting change will require a mix of strategies that recognizes the importance of individual choice, the role played by a rapidly growing and intensely marketed sector of unhealthy and highly processed foods and beverages, and the need to ensure universal access to fresh fruits and vegetables, traditional or minimally processed foods, and potable water. The financial constraints imposed on families in changing their dietary habits should also be taken into consideration (OECD, 2014). This area requires addressing both the dietary risk contributing to multiple illnesses through obesity, such as excess sugar and calories, and the factors contributing to cardiovascular disease primarily, such salt and trans and saturated fats. Unlike tobacco products, food is an essential resource for life. In order to reduce the risks of unhealthy diet, it is generally necessary to identify strategies that focus on curbing excessive intake of unhealthy elements such as salt, sugars, and unhealthy fats and increase access to healthy choices. Only rarely, as in the case of trans fat, are product bans appropriate.

A first important step in this area was the 1980 WHO International Code on Marketing of Breastmilk Substitutes, which sought to address the devastating contribution of infant formula, complementary foods, and reduced breastfeeding to infant mortality and illness. The Code was adopted as a recommendation to Member States to be incorporated into their national legislation. Twenty countries in Latin America have adopted all or parts of the Code; however, it continues to be poorly implemented in terms of monitoring and sanctioning violators (Lutter, 2013).

Both the 2011 United Nations Political Declaration on the Prevention and Control of Non-communicable Diseases and the subsequent WHO Global Action Plan and Monitoring Framework call for a halt in the rise of obesity and diabetes, and a 30% reduction in sodium intake. The Global Action Plan on NCDs lays out a detailed set of recommended policy interventions for a healthy diet, including:

- Promote and support exclusive breastfeeding for the first six months of life, continued breastfeeding until two years old and beyond, and adequate and timely complementary feeding.
- Implement the WHO recommendations on the marketing of foods and nonalcoholic beverages to children, including mechanisms for monitoring.
- Develop guidelines, recommendations or policy measures that engage different relevant sectors, such as food producers and processors, and other relevant commercial operators, as well as consumers, to:
 - Reduce the level of salt/sodium added to food (prepared or processed);
 - Increase availability, affordability and consumption of fruit and vegetables;
 - Reduce saturated fatty acids in food and replace them with unsaturated fatty acids;
 - Replace trans-fats with unsaturated fats;
 - Reduce the content of free and added sugars in food and nonalcoholic beverage;
 - Limit excess calorie intake and reduce the portion size and energy density of foods.
- Develop policy measures that engage food retailers and caterers in improving the availability, affordability, and acceptability of healthier food products.
- Promote the provision and availability of healthy foods in schools, other educational institutions, and the workplace.
- Consider the use of evidence-based economic tools, including the possibility of taxes and subsidies, that improve the affordability and encourage consumption of healthier food products and discourage the consumption of less healthy options.

- Cooperate with the agricultural sector in reinforcing measures directed toward food producers, retailers, caterers, and public institutions, and provide greater opportunities for the utilization of healthy agricultural products and foods.
- Conduct evidence-based public campaigns and social marketing initiatives to inform consumers and encourage them to adopt healthy dietary practices.
- Create health- and nutrition-promoting environments, including through nutrition education in schools, childcare centers, and other educational institutions, as well as workplaces, clinics and hospitals, and other public and private institutions.
- Promote nutrition labeling in compliance with, but not limited to, international standards.

A recent review on obesity prevention published by the McKinsey Global Institute analyzed the potential impact of 74 different strategies. The authors concluded that “no individual sectors in society, whether they are governments, retailers, consumer-goods companies, restaurants, employers, media organizations, educators, health-care providers, or individuals, can address obesity on their own. Capturing the full potential impact requires engagement from as many sectors as possible.... An ambitious, comprehensive, and sustained portfolio of initiatives is likely to be necessary to support broad behavioral change” (Dobbs, et al., 2014). Their analysis found that the interventions likely to have the greatest impact on obesity were reduction of portion size of packaged foods and fast food, reformulation of foods, and controls on the availability of high-calorie unhealthy food and beverages.

In September of 2014, the Member States of the Pan American Health Organization approved the Plan of Action for the Prevention of Obesity in Children and Adolescents (PAHO, 2014b), further strengthening the recommendations for addressing dietary risks based on the growing body of scientific evidence and evaluated interventions. The Plan states:

Identifying the drivers of the obesity epidemic is critical to informing and developing sound policies, actions, and health-related laws and regulations. From a dietary perspective. (...) it is now recognized that the individual’s food preferences, purchasing

decisions, and eating behaviors are shaped by price, marketing, availability, and affordability. These factors are in turn influenced by upstream policies and regulations on trade and agriculture (PAHO, 2014b).

The Plan calls for halting the obesity epidemic in children and adolescents through primary health care and promotion of breastfeeding and healthy eating, improvement of school food and physical activity environments, fiscal policies and regulation of food marketing and labeling, other multisectoral actions, surveillance, research, and evaluation.

As understanding of these dietary risks increases and more documentation becomes available, policies to address them have begun to be adopted. Innovative examples in the Americas include the following:

1. Legislation and national policies to promote breastfeeding have been introduced in many countries—for example, the Baby-Friendly Hospital Initiative, implementation and monitoring of the International Code, and protection of breastfeeding in the workplace (Lutter, 2013).
2. Mexico imposed a tax of 1 peso (US\$ 0.075) per liter on sugar-sweetened beverages and energy-dense nutrient-poor products in 2013 (Box 2) (Colchero, 2014), and a tax of US\$ 0.01 per ounce on sugar sweetened beverages was introduced in Berkeley, California, in 2014.
3. Limits on portion sizes of sugary drinks were attempted in New York City in 2012 but successfully blocked on a legal technicality (New York State Supreme Court, 2013).
4. Regulations on the marketing of food to children have been adopted in Brazil, Chile, and Peru (World Cancer Research Fund, 2014), and also in Quebec (Potvin, 2012).
5. Improvements have been introduced in national school food programs in Brazil, Chile, Colombia, Costa Rica, Ecuador, Mexico, Peru, the United States, and Uruguay. Brazil now requires that at least 70% of food provided to students be natural or minimally processed and that a minimum of 30% of the school budget be used to buy foods from local family farmers, while also prohibiting sugary drinks and setting limits on saturated and trans fats, sodium, and

added sugars (Brazil, Ministério da Educação, 2009) in keeping with new national dietary guidelines that emphasize a return to minimally processed foods (Brazil, Ministério da Saúde, 2014).

6. In the United States, public food procurement standards applying to all publicly financed foods have been adopted New York City, the State of Massachusetts, and other jurisdictions, while other initiatives seek to promote the consumption of water, prohibit sugary drinks, reduce sodium and added sugar, eliminate trans fat, and reduce saturated fats.
7. Labeling that provides simple visual “traffic light” messages to connote various food characteristics has been adopted in Ecuador (Figure 11) and is under consideration in Chile.

FIGURE 11. Example of “traffic light” in food label in Ecuador



8. Argentina and the United States recently banned trans fat (FDA, 2015). Trans fat labeling requirements are in place in Brazil, Chile, Paraguay, the United States, and Uruguay (World Cancer Research Fund International, 2014).

9. Thirteen countries in the Region have taken action to reduce salt. An example is the “Less Salt, More Life” [*Menos Sal, Mas Vida*] initiative in Argentina, which combines voluntary targets with mandatory maximum limits for breads and wheat-based products. A similar measure has been introduced in Paraguay, along with voluntary salt reduction initiatives in Brazil, Canada, Chile, and Mexico (World Cancer Research Fund, 2014). The work of PAHO in this area is described in Box 1.

FIGURE 12. Salt reduction campaign poster in Argentina



10. Also in the United States, mandatory calorie labeling was introduced in New York City chain restaurants in 2007 (Bollinger, 2010; Dumanovsky, 2011) and subsequently in other jurisdictions, as well as nationally in 2010 (U.S. Congress, 2010).

Box 1. PASB: Activating Salt Reduction in the Americas since 2009

The role played by the Pan American Sanitary Bureau (PASB) in its work on the regional initiative **cardiovascular disease prevention through population-wide dietary salt reduction** and its support of the Expert Group (2009–2011) and the subsequent Technical Advisory Group (2012–2015) has been an important model of technical cooperation and leadership. These initiatives have actively promoted voluntary and regulatory control of salt intake, which is an NCD dietary risk factor throughout the Region. Whereas only two countries in the Region had acted effectively to address salt reduction prior to 2009, today 13 Member States have programs under way, some of them quite comprehensive, ranging from regulation to voluntary initiatives and targets. Examples include evaluating population-based salt intake, raising awareness, promoting voluntary salt reduction, regulating salt use in manufacturing, improving food labeling, and promoting food science and health research.

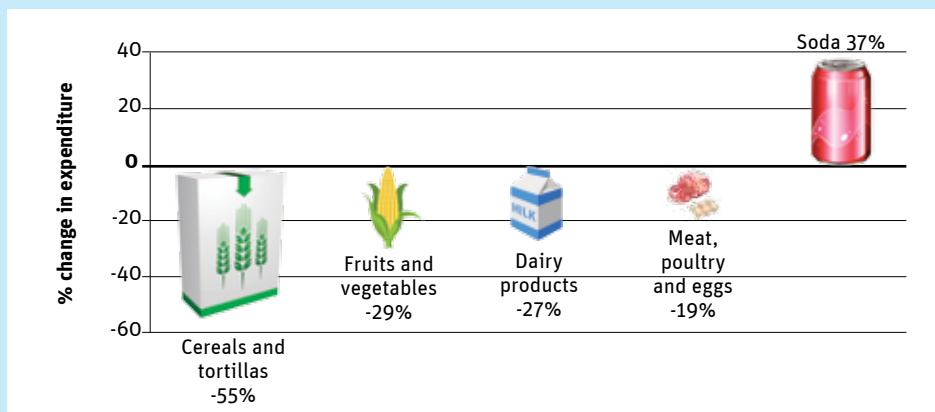
Since 2011, public health authorities in Argentina, Brazil, and Chile in the south and Canada, Mexico, and the United States in the north have promoted voluntary reformulation targets and timelines with the food industry. Most of these countries are focusing on salt reduction in packaged foods and bread, while Mexico has emphasized foods available in the school environment.

Argentina has reached voluntary salt-reduction agreements with more than 50 leading producers of processed foods and 9,000 bakeries in the country, which together have agreed to reduce sodium levels in 528 products over the coming years. The country has already achieved a 25% reduction in the salt content of bread and continues to work toward regulatory mandatory maximum levels for certain additional products. Paraguay has also created regulations. Keys to successful outcomes include the establishment of clear targets, engagement of national food producers, education, health promotion, stronger food labeling, regulation, ongoing monitoring, evaluation, reporting, and research (PAHO, 2013e).

Box 2. Experience with Taxation of Sugary Drinks, Mexico

Mexico provides a recent successful example of a government responding to the growing risk of obesity through the use of fiscal regulatory measures. WHO data identify Mexico as one of the most obese nations in the world (Figure 5). The total cost of 13 diseases related to body mass index in 2010 was estimated at US\$ 806 million (Rtveladze, 2014). At the same time, Mexican researchers have identified a massive shift in consumer spending away from healthier foods such as fruits and vegetables or dairy products toward sugar-sweetened beverages (Figure 13).

Figure 13. Trends in expenditure on soda and other food products, Mexico, 1984–1998



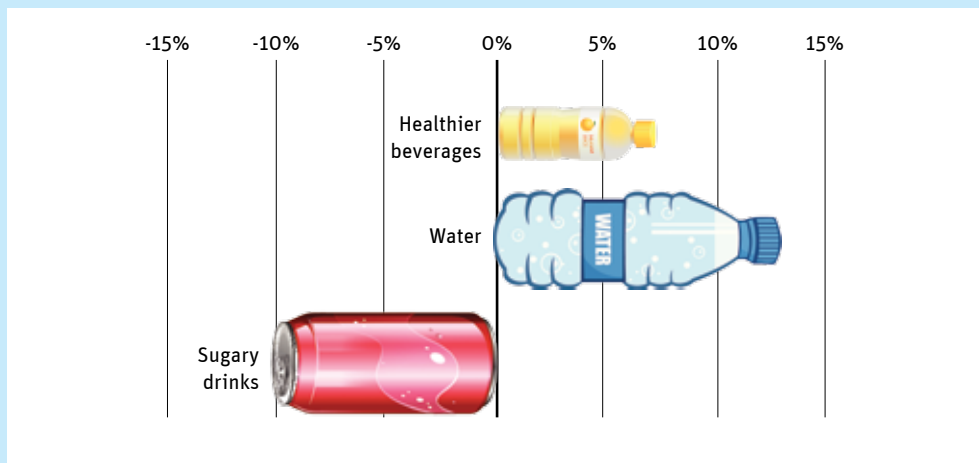
Source: Rivera et al., 2002 (based on data from the National Income and Expenditure Surveys 1984–1998).

In 2013, the Mexican government introduced two taxes, one on beverages with added sugar, and one that targeted junk foods. Based on estimates from two surveys, the National Institute of Public Health (INSP) predicted that a 10% increase in the price of sugary drinks would lead to a reduction of 10.1% to 12.9% in consumption, and that this result would be accompanied by an approximately 12% reduction in new cases of diabetes, leading to savings in direct medical costs alone of 4 billion to 21 billion pesos (US\$ 300 million to US\$ 1.57 billion). It also projected at least a 1% decrease in the national prevalence of overweight and obesity, leading to further savings in direct medical costs of 7 billion pesos (US\$ 52 million) (Colchero, 2014). These studies provided a key part of the evidence base for the 2013 tax on sodas of 1 peso (US\$ 0.075) per liter (Martin and Cattan, 2013).

Pre-tax projections were confirmed by the first preliminary analysis of the effectiveness of the sugary drink tax. The INSP and the University of North Carolina reported that there was a **10% decrease** in consumption of the taxed beverage products in the first quarter of 2014 compared with the same quarter in 2013 (Colchero and Rivera, 2014). There was also a 7% increase in untaxed products such as diet sodas, sparkling water, and still water, and a 13% increase in the bottled water category alone. These figures were obtained from urban centers with a population of at least 30,000 (Figure 14). Additional studies are under way to further understand the impact of this regulation. These results are similar to other studies on the price elasticity of sodas.

This case demonstrates the Mexican government's effective use of risk analysis to mitigate population-level risk through fiscal policy. The Mexican research community had worked over a number of years to document the worrisome rise in obesity (Barquera et al., 2009) and diabetes (Barquera et al., 2003). The government then created a fiscal strategy to address two key food groups that were known to be contributing to the epidemic. As with the proven FCTC-recommended strategies to control tobacco use, an excise tax was created with the goal of improving public health and at the same time gaining the added benefit of generating revenues. The risk reduction estimates appear to be on target.

Figure 14. Changes in beverage sales following introduction of a soda tax in 2013, Mexico



Source: Colchero, 2014.

Other areas for consideration include the development of agricultural policies that support greater priority for the production of fresh fruit and vegetables and other healthy crops and products.

Nevertheless, it appears clear that further education of political and social leaders and everyday citizens,

as well as advocacy by civil society, will be important in building social and political support for the needed measures and ensuring that future efforts to implement sustainable policies will be successful.

D.1.2. Regulation of Tobacco: A Spreading Success Story

The FCTC (WHO, 2003) was adopted unanimously by the 56th World Assembly in 2003, and entered into force in February 2005. It is the first treaty negotiated under the auspices of the World Health Organization. It represents a paradigm shift in developing regulatory strategies to address addictive substances, asserting the importance of demand reduction strategies as well as supply issues. It also underscores the importance of a strong political commitment and multisectoral approach to supporting and developing effective legislative, executive, administrative, and/or other measures for preventing and reducing tobacco consumption, nicotine addiction, and exposure to tobacco smoke.

The core demand reduction provisions are:

- Price and tax measures to reduce the demand for tobacco;
- Non-price measures such as:
 - Protection from exposure to tobacco smoke;
 - Regulation of the content of tobacco products;
 - Regulation of tobacco product disclosures;
 - Packaging and labeling of tobacco products;
 - Education, communication, training, and public awareness;
 - Tobacco advertising, promotion, and sponsorship;
 - Measures concerning tobacco dependence and cessation.

The core supply reduction provisions are related to:

- Elimination of illicit trade in tobacco products;
- Ban of sales to and by minors;
- Provision of support for economically viable alternative activities.

To support the Parties in implementing the main measures aimed at reducing the demand for tobacco products, the Conference of the Parties, which is the governing body of the FCTC, has approved guidelines for implementing these articles (WHO, 2013d). The guidelines are based on the strongest and most widely accepted scientific evidence and on the Parties' experiences. They set forth principles, definitions, and the key legislative elements needed in order to fulfill

the treaty's obligations (PAHO, 2013d).

Another important FCTC mandate is related to interference by the tobacco industry. Article 5.3 of the Convention states that "in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect those policies from commercial and other vested interests of the tobacco industry in accordance with national law." The guidelines for implementation of this article further elaborate in the topic.

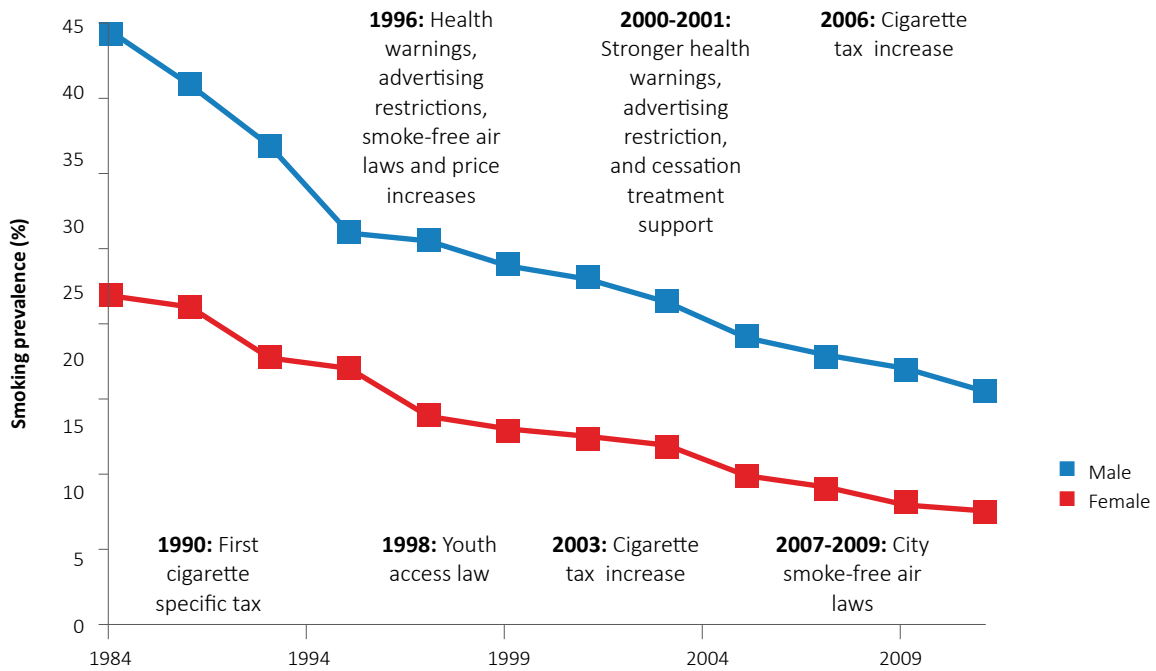
To help countries fully implement the FCTC, and as an entry point to its implementation, WHO has developed a technical tool known as MPOWER, an acronym for the following objectives:

- **M**onitor tobacco use and prevention policies;
- **P**rotect people from tobacco smoke;
- **O**ffer help to quit tobacco use;
- **W**arn about the dangers of tobacco;
- **E**nforce bans on tobacco advertising, promotion, and sponsorship;
- **R**aise taxes on tobacco.

The FCTC should be implemented as a whole; this does not mean that all measures should be implemented at the same time, but the ultimate goal is comprehensive implementation of the entire treaty. There is no single individual measure that can solve the tobacco epidemic alone. Experience supports this conclusion, as illustrated by the experience of Brazil (Figure 15), where prevalence rates have fallen by more than 50% over several decades (Levy, 2012). Similarly, in New York City (Figure 16), after a decade of stable rates, smoking began to fall with each new fiscal, regulatory, educational, or supportive measure.

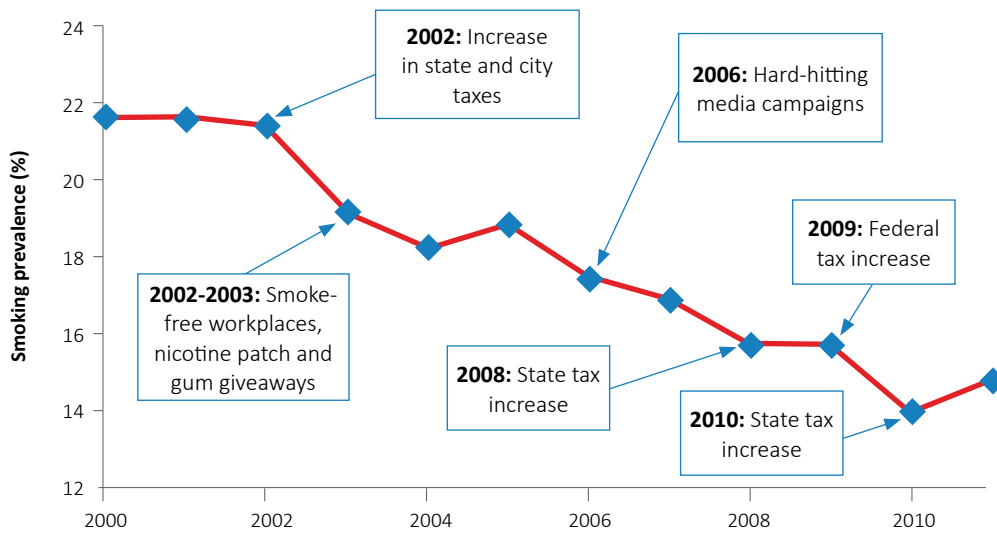
Analysis of the implementation and population reach of the MPOWER framework in the Americas (Figure 17) demonstrates both the extraordinary progress that has been made across the region, and the significant challenges that still lay ahead for full implementation. It is also the risk factor with the strongest monitoring system in place.

FIGURE 15. Changes in smoking prevalence in adults relative to tobacco policy changes, Brazil, 1989-2009



Source: SimSmoke predictions (Levy, 2012).

FIGURE 16. Smoking trend in adults relative to tobacco policy changes, New York City, 1993-2011



Source: Based on data from New York State Department of Health and New York City Department of Health and Mental Hygiene.

In setting and implementing their public health policies in tobacco control,
Parties shall act to protect them from commercial and other vested interests of the tobacco industry in accordance with national law

Box 3. Tobacco control leadership, Uruguay

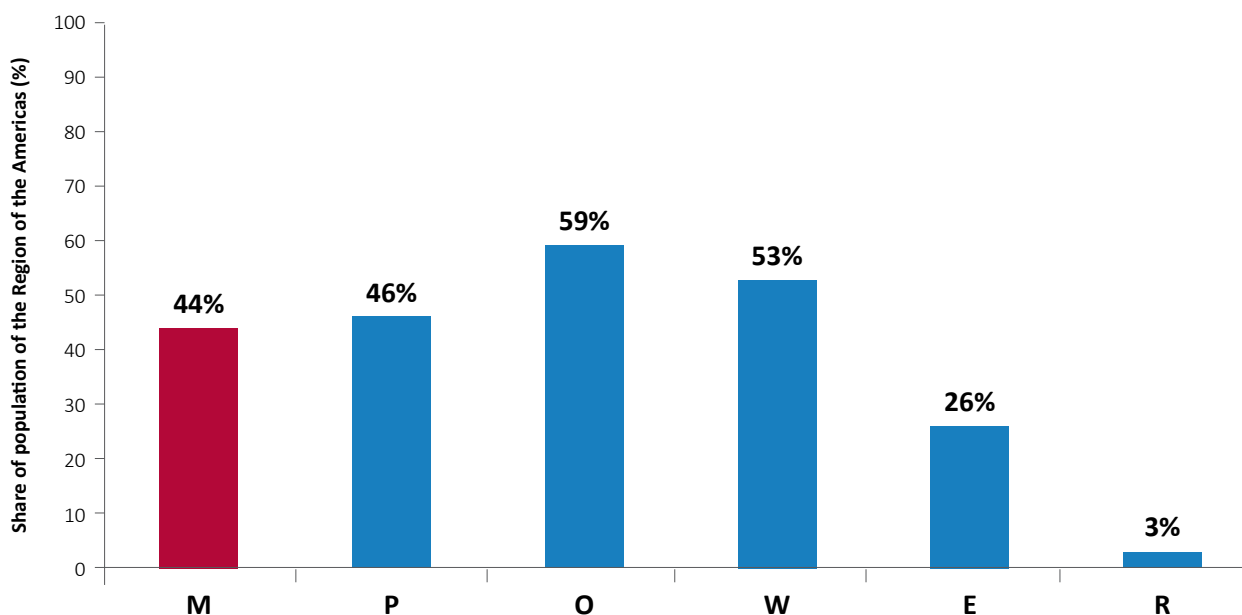
Uruguay was one of the first 40 countries to ratify the FCTC in 2004. Since then, the government has been implementing the mandates in an integrated and incremental manner, making the country one of the tobacco control leaders in the Region.

Currently Uruguay has implemented the following measures:

- Monitoring of tobacco use and prevention policies;
- Ban on tobacco use in all indoor public spaces, in indoor public and private workplaces, and on public transportation;
- Provision of free diagnosis and treatment for tobacco dependency at primary health care facilities;
- Imposing packaging and labeling requirements:
 - Graphic health warnings covering 80% of the main surfaces of the package;
 - Ban on misleading terms such as “light” or “low in tar”;
 - Inclusion of quantitative information of tobacco contents and/or emissions;
 - Restriction to single presentations (just one presentation per brand).
- Ban on all advertising, promotion, and sponsorship of tobacco products;
- Tax increases on tobacco;
- Ban on electronic cigarettes.

Uruguay’s comprehensive initiatives have been associated with unprecedented decreases in tobacco prevalence. During 2005-2011, the prevalence of current tobacco use in Uruguay decreased annually by an estimated 3.3%, a decline that significantly exceeded the pace in a nearby country with less intensive implementation of tobacco policies. Authors have concluded that if other low- and middle-income countries were to experience decreases in tobacco use of the magnitude seen in Uruguay, the result would have a substantial effect on the future global burden of tobacco-related diseases (Abascal et al., 2012).

FIGURE 17. Share of the population of the Region of the Americas covered, by selected tobacco control policies, 2012



Source: PAHO, 2013d.D.1.3.

D.1.3. Regulation of Alcohol Consumption

A growing body of scientific literature supports the implementation of evidence-based policy measures to reduce the harmful use of alcohol.

This body of evidence was recently reviewed by WHO and contributed to formulation of the Organization's 2010 *Global Strategy to Reduce the Harmful Use of Alcohol* (WHO, 2010c). The strategy's five objectives are:

- Raised global awareness of the magnitude and nature of the health, social, and economic problems caused by harmful use of alcohol, and increased commitment by governments to act to address the harmful use of alcohol;
- Strengthened knowledge base on the magnitude and determinants of alcohol-related harm and on effective interventions to reduce and prevent such harm;
- Increased technical support to, and enhanced capacity of, Member States for preventing the harmful use of alcohol and managing alcohol-use disorders and associated health conditions;
- Strengthened partnerships and better coordination among stakeholders and increased mobilization of resources required for appropriate and concerted action to prevent the harmful use of alcohol;
- Improved systems for monitoring and surveillance at different levels, and more effective dissemination and application of information for advocacy, policy development, and evaluation purposes.

Without the binging power of the FCTC, the Global Strategy recommends a series of ten policy options for addressing alcohol-related risks. Five of these options require regulatory action. These options are reflected in the following key areas for policy and regulatory action:

- Building of leadership, awareness, and commitment;
- Strengthening of the health services response;
- Reduction of the availability of alcohol;
- Restrictions on the marketing of alcoholic beverages;
- Pricing policies/excise taxes to reduce affordability and demand;

- Community action;
- Countermeasures against drunk driving;
- Reduction of the impact of illicit and informally produced alcohol;
- Reduction of the negative consequences of drinking;
- Monitoring and surveillance.

One key objective of the political commitment is to have an intersectoral approach to alcohol policy, including the establishment of an institution or agency to be responsible for formulating and following up on national policies, strategies, and plans, and for developing or strengthening existing comprehensive national and/or subnational plans of action and activities to reduce the harmful use of alcohol. Approaches that restrict physical availability, control alcohol marketing through regulatory mechanisms, and increase the price of alcoholic beverages (through taxation) have been identified as the most efficacious and cost-effective. In particular, public health strategies that seek to regulate the commercial or public availability of alcohol, such as effective licensing systems, controls on alcohol outlet density and hours of sale, and increase in the minimum drinking and purchasing age are among the most tried-and-true strategies for reducing consumption (Box 4) (Cook, 2014; Malaga et al., 2012).

As with tobacco, addressing the issue of marketing, particularly marketing directed toward young adults and adolescents, is key to reducing the harmful use of alcohol. Alcohol marketing repeats much of the tobacco playbook—that is, linking alcohol brands to sports and cultural activities, sponsorships, and product placements, and enlisting the use of new media, including social media and other communication channels. The increasing globalization of communications leads to the transmission of alcohol-related and other marketing messages across national borders and jurisdictions via satellite television, the Internet, and other means, as well as through the sponsorship of sports and cultural events, emerging as a serious concern in some countries, where it undermines efforts to reduce promotion. In the United States alone, between 2001 and 2005 the alcoholic industry spent US\$ 4.7 billion to place 1.4 million advertisements for alcoholic beverages on television. An analysis of the advertisements found that in the wake of a 32% increase in spending on televised

Box 4. Reducing access to alcohol in Brazilian cities

In Brazil, restrictions on alcohol sales have been implemented effectively at the municipal level with public support. The mayor of Diadema, an industrial city with a population of almost 400,000 in the state of São Paulo, passed a law in 2002 obligating the city's 4,800 bars and restaurants to stop selling alcohol between 11 p.m. and 6 a.m. Since the law was passed, the number of homicides has fallen by 47.4%, the number of road accidents, by 30%; the number of assaults against women, by 55%; and the number of alcohol-related hospital admissions, by 80% (Duailibi et al., 2014). Contrary to popular belief, business improved after the measure was introduced, with more investment in the town and an increase in jobs created. At least 120 other municipalities have followed Diadema's lead, and the whole state of Pernambuco recently passed a similar law.

Paulínia, another municipality in Brazil, stepped up efforts to enforce laws regarding the sale of alcohol beverages to minors and intoxicated people and increased the regulation of bar permits and infractions against those who drink and drive. During Carnival in 2003 and 2004, purchasing spirits near the Sambodrome was prohibited, as was the sale of alcohol to minors. In addition, the price of beer was raised 100%. The result of these measures was staggering: police and medical incidents fell by nearly 70%. Currently, the program "Paulínia Legal" is mobilizing to increase awareness of alcohol policy among corporations, public organizations, local commerce, and the community. The law prohibiting sales to minors continues to be enforced and the program is working side-by-side with other public organizations to regulate the operation and functioning of bars and other establishments (PAHO, 2007).

alcohol ads and a 34% increase in the number of alcohol ads on television from 2001 to 2005, exposure to these ads increased 41% for youth (ages 12 to 20), 39% for young adults (ages 21 to 34), and 48% for adults (ages 21+) (CAMY, 2005).

Price elasticity, or a drop in purchases in response to rising prices, has been clearly demonstrated in the case of alcohol consumers, including young people and heavy drinkers, lending further support the argument for fiscal policies. The policy options and interventions for this area include: (a) establishing a system of specific domestic taxation on alcohol accompanied by an effective enforcement system that takes into account the alcoholic content of the beverage; (b) regularly reviewing prices in relation to the level of inflation and income; (c) banning or restricting the use of direct and indirect price promotions, discount sales, sales below cost, and flat rates for unlimited drinking or other types of volume sales; (d) establishing minimum prices for alcoholic beverages; (e) providing price incentives for non-alcoholic beverages; and (f) reducing or ending

subsidies to economic operators in the area of alcohol (WHO, 2010c).

Civil society initiatives can also have a tremendous impact in changing policies and norms. In the United States, the NGO Mothers Against Drunk Driving (MADD) was created to pressure for the regulation of alcohol availability and drinking and driving, among other measures. Its efforts have led to an increase in the legal drinking age from 18 to 21 in all states, preventing an estimated 17,000 deaths a year (NHTSA, 1997).

Control of the leading NCD risk factors can also have positive externalities for other public health efforts. Two important examples are the relationship between reduced alcohol consumption and a reduction in road traffic injuries or improvement in mental health. Road traffic injuries are the leading cause of death among 4-15-year-olds and the second leading cause of death in the population aged 15-44. These deaths are almost entirely preventable. In order to see progress, a combination of different methods must be employed to improve outcomes and prevent injuries. A reduction in

Alcohol marketing repeats much of the tobacco playbook:

linking alcohol brands to sports and cultural activities, sponsorships, and product placements, and enlisting the use of new media.

the harmful use of alcohol can have important benefits both for reducing road traffic injuries and improving mental health outcomes.

D.1.4. Physical Inactivity

Evidence-based policies to increase physical activity have centered on changing the environments in which people live, work, study, or play to promote the reincorporation of physical activity into daily life. Increasing physical activity and the strategies to do so can have many ancillary benefits, including improved educational achievement, better social and mental health, cleaner air, and more sustainable development. The WHO Global Action Plan for NCDs (WHO, 2013a) set a target of a 10% reduction in the prevalence of insufficient physical activity by 2025. This target supports the broader goals of reducing the rise in overweight and obesity and the prevalence of elevated blood pressure.

The Global Action Plan recommended the following policy interventions:

- Adoption and implementation of national guidelines on physical activity for health;
- Establishment of a multisectoral committee or similar body to provide strategic leadership and coordination;
- Development of appropriate partnerships and engagement of all stakeholders, including government, NGOs, civil society, and economic operators in actively and appropriately implementing actions aimed at increasing physical activity across all ages.
- Development of policy measures in cooperation with relevant sectors to promote physical activity through activities of daily living, including “active transport,” recreation, leisure, and sports—for example:
 - National and subnational urban planning and transport policies to improve the accessibility, acceptability and safety of, and supportive infrastructure for, walking and cycling;
 - Improved provision of quality physical education in educational settings (from infant years to the tertiary level), including opportunities for physical activity before, during, and after the formal school day;

- Actions to support and encourage “physical activity for all” initiatives for all ages
- Creation and preservation of built and natural environments that support physical activity in schools, universities, workplaces, clinics and hospitals, and the wider community, with a particular focus on providing infrastructure to support active transport, i.e. walking and cycling, active recreation and play, and participation in sports;
- Promotion of community involvement in implementing local actions aimed at increasing physical activity.

The Plan of Action for the Prevention of Obesity in Children and Adolescents, approved by the PAHO Directing Council in 2014, includes recommendations on physical activity in two areas. The first area focuses on promoting and strengthening school and early learning policies and programs that increase physical activity. The indicator that will be assessed is the number of countries in which at least 70% of the schools have implemented a program that includes at least 30 minutes a day of moderate to intense (aerobic) physical activity. The second area calls for multisectoral action to develop a variety of new urban recreational spaces, such as Bogota’s Ciclovías [Cycling Events] or Brasília’s Sunday Eixão [Big Route] (PAHO, 2014b).

Many of the approaches adopted in the countries can be summed up as “different ways of doing business”—for example, the way a street or a community is designed, the way a city’s transportation system is organized, or the way children spend their time in a daycare center or school. While these changes do not necessarily involve changes in legislation, the regulation of such processes as transportation and construction is increasingly used to facilitate change on a broader scale. In a growing trend, jurisdictions are adopting rules or guidelines to better guide these decisions, both to promote physical activity and to reduce greenhouse gas emissions.

With regard to educational settings, many countries and subnational jurisdictions are regulating physical activity requirements for the school environment. Such regulation, accompanied by enforcement and support to school systems for its implementation, is a critically important component of childhood obesity prevention. Physical activity interventions and greater student fitness have also been associated with improved

student academic performance (Martin et al., 2014; Egger et al., 2009).

Other regulatory approaches have included the use of “complete streets” policies to ensure that urban planning and construction allow people to walk, cycle, or take public transport as safely and conveniently as using cars. Specific standards for “age-friendly” streets and parks, which allow the elderly to walk safely, are also a growing component of this movement. Zoning and general planning policies that promote more compact community development, proximity to mass transportation, and mixed land use (residential and commercial) also assist in increasing both physical activity and sustainability. In general, experts have concluded that in order for a complete streets policy to be truly effective, it must be accompanied by other policies and enabling programs as well as adequate funding (International Technology Scanning Program, 2010).

Notably, one area of real potential lies in finding synergies between the promotion of active transportation and the efforts to protect against climate change (Figure 18). In the United States, for example, the state of California is using funds raised by cap and trade policies to support the implementation of active transportation programs and the design of more sustainable communities.

Multisectoral Action to Promote Physical Activity: The Ciclovía Epidemic

One important example of the use of regulatory approaches is provided by the healthy epidemic of open streets events in the Americas, such as Bogotá’s *ciclovías*, where policies are used to shut down major thoroughfares at specific times for bicycling, walking, and community recreation. The advent and recurrence of *ciclovías*—over 350 programs with at least two events a year—are an innovation that is spreading in the Region to improve the availability of physical activity for city residents. In Bogotá, the first *ciclovía*

FIGURE 18. Active transportation: Health and sustainability co-benefits



initiative dates back to 1974. Currently, the city holds approximately 70 events a year, more than one a week (Torres et al., 2013), and has greatly expanded its network of bicycle lanes. Alongside these events, there is a citywide bus network, called the *TransMilênio*, that carries passengers throughout the city of Bogotá. The network functions like rapid public transit, since there are designated lanes for the buses to use, thus cutting down on commuter traffic. These interventions have not only been well attended, involving nearly 3 million participants (El Espectador, 2014), they have also contributed to an increase in adequate physical activity for the population. Of those who have attended the *ciclovías*, 59.5% reported meeting their physical activity recommendation, and those who used the *ciclorutas*,

or permanent bike lanes, 70.5% reported fulfilling their physical activity requirement (Torres et al., 2013). Around 30% of all trips in Bogotá are made using public transportation, approximately 9% on the *TransMilenio* bus system. Residents who have one or two *TransMilênio* stations in their neighborhood have a higher likelihood of meeting their physical activity requirements than those without the stations (Sarmiento et al., 2010). These results are mirrored in different places around the Region, with cities accelerating their uptake of the programs at a rapid rate.

Other examples of policies to promote physical activity are described in Box 5 and Box 6.

Box 5. Multisectoral action: Active Design Guidelines and Street Design Manual, New York City

When New York City was beginning its efforts to reverse the obesity epidemic, it was clear to public health leaders that it would be necessary to involve urban planners, the transportation sector, architects, and designers. The process started with collaboration between the Department of Health and Mental Hygiene and the American Institute of Architects (AIA), with a jointly sponsored “Fit City Conference” to explore the connection between environmental design and physical activity. The unspoken goal was to bring people from these different sectors together and forge a multisectoral partnership. Leading architects and researchers described their findings and their physical activity-promoting designs ranging from affordable housing to Apple stores. This annual conference gradually began to draw leading professionals and public officials in a wide range of areas to the table. A few years into the process, with nine city commissioners in the hall, the Commissioner of Design and Construction announced his commitment to create “Active Design Guidelines.” This undertaking became a two-year collaborative effort across the departments of design, construction, health, planning, and transportation, together with the AIA, to pull together the best scientific evidence with leading designers and planners, eventually producing the city’s award-winning “Active Design Guidelines.” Initially, with a voluntary set of guidelines, the city government then began to explore how to incorporate these criteria into building contracts, zoning, building codes, and other regulatory processes, and this effort continues (NYC, 2010).

Box 6. Financial incentives for fitness, Canada

Canada’s Children’s Fitness Tax Credit offers a unique example of the use of fiscal regulatory approaches in this area. Building on positive experiences with financial incentives for physical activity through workplace wellness, the government created this national tax credit for children’s physical activity. It allows parents to reduce their taxable income by CAD 500 for a child enrolled in physical activity, leading to a rebate on the order of CAD 75 (CAD 150 for a disabled child). While some parents report that the intervention made them increase their child’s physical activity, others have questioned whether it has been the most effective use of resources, or if the money would be better used in direct funding programs. Others are interested in expanding the credit to adults (Spence et al., 2012).



Health should become the easier, default option,
rather than being agonizingly difficult.



E. Regulation

E.1. Why regulation?

Thomas and Gostin (2013) eloquently captured the overarching rationale for regulating NCD risk factors when they said: “Health should become the easier, default option, rather than being agonizingly difficult.” Achieving this goal, however, represents a significant challenge to the ability of nations to govern over economic interests and may at times constrain individual choice.

When is it fitting for governments to intervene to protect health so that safeguarding it becomes easier? Historically, many of the major advances in public health over the last 200 years were achieved not only through medicine but through changes in the environment, which often required the use of law and regulation and not infrequently were the subject of great social controversy.

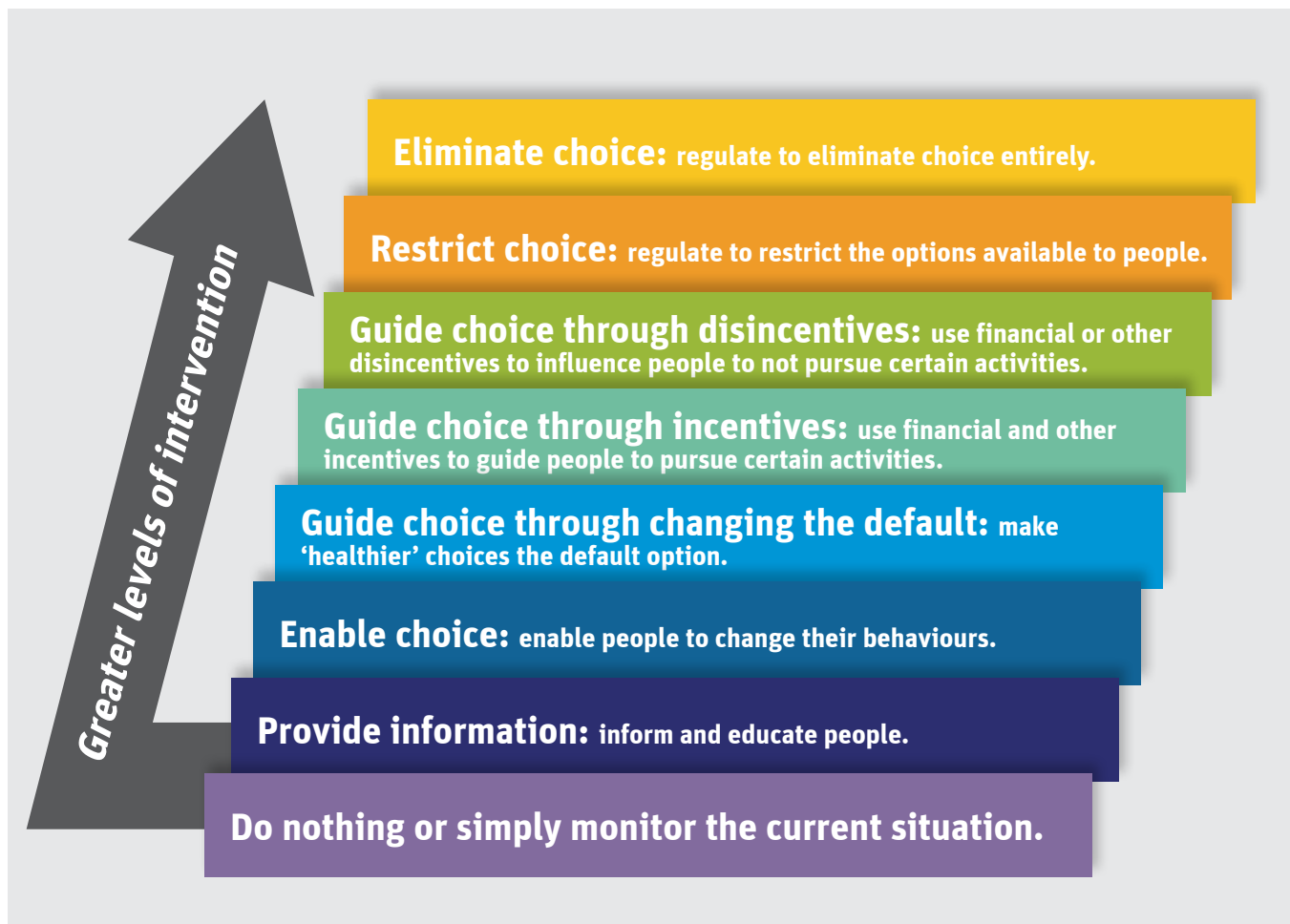
As we face the new challenges of the twenty-first century, it is once again fitting to ask: What is the proper level of government intervention? In reviewing this issue, the Nuffield Council on Bioethics (2007) cited John Stuart Mill’s classic “harm principle,” which holds that state intervention is primarily warranted where an individual’s actions affect others. In the case of public health policy, the decision may entail a crucial ethical analysis. The requirement for state intervention may also arise from the need to remedy health inequalities and limitations on the possibilities of individual consent. Mill also noted with regard to children and other vulnerable groups that “those who are still in a state to require being taken care of by others, must be protected against their own actions as well as against external injury” (Mill, 1859).

The Nuffield Council argues that interventions to reduce health inequality should focus on strategies that aim to improve health opportunities and outcomes in the most disadvantaged groups. They emphasize that the process of elaborating any measures needs to be “transparent, fair, and inclusive” and propose a “stewardship” model of government action that aims to “reduce the risks of ill health that people might impose upon each other;

pay special attention to the health of children and other vulnerable people; reduce ill health by regulations that ensure environmental conditions that sustain good health, such as the provision of clean air and water, safe food, and decent housing; and make it easy for people to lead healthy lives,” while not coercing those who are not vulnerable to do so. However, just as public health interventions can guide, change, or restrict choice, corporate and societal practices around which products should be marketed and how to promote them can also shape or restrict the choices available to the public. The absence of regulation can leave consumers exposed to harm as a result of choices designed primarily to optimize profitability.

The Nuffield Intervention Ladder (Figure 19) describes different types of interventions open to government and policymakers, with progressive steps from individual freedom and responsibility to state intervention as one moves up the ladder. The benefits to individuals and society should be weighed against the erosion of personal freedom, while economic costs and benefits should be considered along with health and societal benefits (Nuffield Council, 2007). In some cases, the elimination of choice may be very reasonable and little missed (as in banning lead paint or trans fat), but if it is applied too broadly, public indignation might reasonably ensue.

Thomas and Gostin (2013) note that “the anti-paternalism objection rests on a perverse assumption—namely, that the status quo, with its rising NCD rates, is itself the product of individual choices freely made. The reality, of course, is that myriad collective decisions—made by governments and private interests—shape the menu of options available to individuals, determining the price and availability of nutritious foods, the accessibility of places to exercise, ways to commute to and from work, and so on. There is no avoiding government influence over risk behaviors. The question is only whether that influence will advance or detract from the ability to lead a healthy lifestyle.”

FIGURE 19. Nuffield Intervention Ladder

Source: Adapted from Nuffield Council, 2007

E.2. Regulation as Part of Effective Governance

Protecting the population from certain risks is a core role of the State. For millennia, societies have needed and desired rules with which to order their affairs. While the problems and the risks that societies identify as their priorities have changed over time, the basic concept that it is legitimate to use rules to address risks, whether to govern economic stability, health, or safety, has long been accepted. It is recognized that regulation enhances economic welfare, provides the basis for the prevention and resolution of legal conflict, solidifies social behavior, fosters political commitment, and provides administrative and social order. Key arguments for government intervention in social affairs can include redistribution of resources, provision of

social goods, or reparation of market failures (including externalities, asymmetric information, and market power imbalances). A central aim for regulation is to address externalities of economic processes—in this case, the impact of economic processes on population health (Alemanno et al., 2011). The cost of addressing such externalities through repair or prevention is often far more efficient (smaller) than the cost of regulatory inaction.

Effective regulation is an essential part of governance. Governance has been defined as “the traditions and institutions by which authority in a country is exercised. This includes (a) the process by which governments are selected, monitored, and replaced; (b) the capacity of the government to effectively formulate and implement sound policies; and (c) the respect of citizens and the state for the institutions that govern economic and

social interactions among them” (Kaufmann, Kray, and Mastruzzi, 2010).

The OECD defines regulation as “any instrument by which governments, their subsidiary bodies, and supranational bodies (such as the EU or the WTO) set requirements on citizens and businesses that have legal force. The term may thus encompass a wide range of instruments: from primary laws and secondary regulations to implement primary laws, subordinate rules, administrative formalities and decisions that give effect to higher-level regulations (for example, the allocation of permits), and standards” (OECD, 2010). Regulation is not limited to restrictive measures; it also encompasses policies to promote healthy practices and products. Like the OECD definition, the present document refers to regulation and regulatory capacity in the broader sense, encompassing both action by legislative bodies and regulatory action by government agencies or bodies.

While law and regulation have been widely used to establish health rights, they have been less consistently applied to the prevention of NCDs. Yet these approaches have the ability to impact the underlying determinants, help shape new social norms, and ensure effectiveness through enforcement. Government necessarily plays the lead implementation role in regulatory action that is based on laws, as this role cannot be delegated. This point is especially relevant in the case of NCDs in which government has a dual role—i.e., responsibility both for protecting against the underlying risks and for compensating/protecting against medical and financial catastrophe from the impact of NCDs should the risk materialize. However, historically there has been a tendency toward privatizing the gains and socializing the losses from risks, as in the case of risks for disease and disability from NCDs (den Butter et al., 2009), and this imbalance must be righted. Furthermore, governments are already overwhelmed by global pressure from shared commercial and economic processes and risks, such as commerce in tobacco and processed foods. These processes and risks often

require concerted action by countries, with increased demand for international coordination of health regulation and other legal frameworks.

To ensure that regulations are actually implemented, it is also important to make certain that they have a firm legal basis and that the capacity to enforce the provision exists, or that the institutional development needed to enforce it will be built (PAHO, 2011). Since regulation and its enforcement are responsibilities that cannot be abdicated by government, building capacity for regulatory action is an important part of overall institutional development in the countries. It is most effective when it is part of a political and technical process of governance that acts effectively to balance competing interests while protecting the greater good of society, including the health of the population.

Among the indicators of governance used by the World Bank’s Worldwide Governance Indicators Project (Kaufman, Kraay, and Mastruzzi, 2010), the following are relevant to the regulation of NCDs:

- Government effectiveness: Perceptions of the quality of public services, the quality of the civil service and degree of its independence from political pressures, the quality of policy formulation and implementation, and the credibility of the government’s commitment to such policies;
- Control of corruption: Perceptions of the extent to which public power is exercised for private gain, including both petty and grand forms of corruption, as well as “capture” of the state by elites and private interests;
- Regulatory quality: Perceptions of the ability of the government to formulate and implement sound policies and regulations that permit and promote private sector development.

Some of the essential characteristics of regulatory processes that will support effective governance include transparency, ability for the public to comment

While law and regulation have been widely used to establish health rights, they have been less consistently applied to the prevention of NCDs.

and be heard, control of potential conflicts of interest, and avoidance of regulatory capture while still allowing affected commercial parties a voice in the process. They all require trust, effectiveness, quality, compliance, and accountability. In the Region, there is great heterogeneity in the assessment of governance. The broader issues of governance affect the ability to effectively govern NCD risk factors. Recommended regulatory actions often require intersectoral action beyond the Ministry of Health and its agencies by authorities in sectors such as finance, agriculture, industry, and communications, requiring coordinated and independent exercise of public power in defense of health.

E.2.1. Regulation as an Essential Public Health Function

Health risk regulation saw a period of strong development during the second and third quarters of the twentieth century, bringing great societal benefit. In the 1980s and 1990s, some parties were voicing their advocacy for a reduced role of government in areas that included health protection. It was argued that less government would lead to greater economic growth and hence better capacity to address people's needs. This philosophy permeated many fields, including public health, and limited the growth of health risk regulation. In some countries, the period of retrocession in regulatory capacity, or of not investing in improvement, produced a growing imbalance in society's capacity to address the root causes of public health problems (Van Paridon, 2013).

In fact, empirical research has demonstrated that less regulation has not been beneficial for economic development, nor has it made countries more resilient (Table 6) (Van Paridon, 2013). This outcome has been especially notable in the context of globalization of trade. Having regulatory policies of limited quality clearly did not translate into positive economic development. Today, the OECD and other organizations promote quality regulations, laws, trust, organizational development of regulatory agencies, and better management. In a profound reform process, the OECD recommends a policy cycle that closes the loop of intervention, design, and evaluation of outcomes with policy coherence, using evidence-based approaches to support decisions and better assessment of the benefits of interventions.

TABLE 6. Correlation between Gross Domestic Product growth and regulation decline, 2003-2009

Country grouping	Correlation
OECD	-0.42
Middle & Eastern Europe	-0.29
<i>Latin America and the Caribbean</i>	0.07
Africa	-0.05
Middle East	0.17
Asia	-0.54
Pacific	-0.36

Source: Adapted from Van Paridon, 2013.

These shifting policies and trends have created a challenge for national health authorities to follow the process, ensure their effective stewardship of regulatory functions, and understand their relationship to the law.

The need to include regulatory functions as part of the stewardship of public health was reaffirmed in the conceptual framework of the Essential Public Health Functions (EPHFs) (PAHO, 2011), which sought to identify the building blocks for public health work:

1. Monitoring, evaluation, and analysis of health status;
2. Surveillance, research, and control of the risks and threats to public health;
3. Health promotion;
4. Social participation in health;
5. Development of policies and institutional capacity for public health planning and management;
6. **Strengthening of public health regulation and enforcement capacity;**
7. Evaluation and promotion of equitable access to necessary health services;
8. Human resources development and training in public health;
9. Quality assurance in personal and population-based health services;
10. Research in public health;
11. Reduction of the impact of emergencies and disasters on health.

EPHF 6 focuses on strengthening institutional capacity to develop the regulatory framework and create new laws and regulations, to protect citizens within the health care system, and to execute these activities effectively.

Implementing these essential public health functions for the effective prevention of NCDs requires a sustainable source of funding, human resources, engagement of society, clear and effective mechanisms for inclusion and accountability, multisectoral participation, unambiguous dialogue, consensus-building among different social actors, and a firm, long-term political commitment on the part of the various authorities responsible for formulating policies, legislation, and regulations and for implementing the necessary strategies (PAHO, 2014d). This capacity must exist at the national level, but a great deal of regulation of NCD risks may also occur at the state/province or local level, where capacity also needs to be strengthened.

A regional survey was conducted in 2002 to assess capacity for implementing the PAHO Essential Public Health Functions (PAHO, 2002). The responses reflected a significant lag, particularly in certain functions related to stewardship (regulation and public health population-based services).

The survey has not been repeated and the detailed database is not available. Information is limited on the institutional and human capacity available and on the quality and effectiveness of action in these areas. There seems to be a systematic gap in the analysis of health law and regulations as they apply to the health systems. During the development of this initiative, it became clear that even in some of the PAHO Country Representative Offices knowledge about the regulatory actions and branches within the Ministries of Health was sketchy.

E.2.2. Transparency and Quality

Certain principles can be applied to improve regulatory quality and, in particular, to ensure credibility. They must take into account key factors that could distort the regulatory process and make it prone to corruption (Box 7). Prevention of corruption and conflict of interest is a concern that must be tackled from the outset in any initiative to strengthen regulatory capacity. Concentration of economic power in a limited number of corporations can generate enormous pressure

on staff and managers, especially in poorly financed institutions (Gray, 1998) and countries in economic distress. While there is no silver bullet for corruption, certain principles of organizational design can help make it less easy to happen.

Concentration of power throughout the process is another element that creates opportunities for corruption: if the same person or administrative unit controls the process from risk analysis to regulatory enforcement, grants authorizations, conducts inspections, and has the power to sanction, it creates

Box 7. Elements to consider in reducing corruption

- Rule-making
 - Quality and precision of the rule
 - Stakeholder participation
- Managing monopoly
 - Clarity in communication
 - Elimination of differential information
 - Decreased concentration of power
 - Shared control over the process
- Eliminating discretion
 - Increased transparency
 - Decreased transaction costs
 - Reduced opportunity costs
 - Limited direct contact with the regulated entity
 - Control over conflict of interest
 - Reasonable but clearly specified response times
- Ensuring accountability
 - Established structures for accountability
 - Reduced space for discretionary action
 - Staff professional meritocracy system
 - Adequate staff salaries
 - Control systems

Source: Based on Shah, 2007.

opportunities for corruption. Designing separate but interlinked processes between different units may reduce this concentration and diminish these opportunities. Uncertain or excessive time and requirements for businesses to carry out procedures—for example, authorization of a food label or certification of a site—also make the process prone to corruption (Hamilton, 2013).

E.2.2.1. Conflict of Interest

An important element to consider is the interaction between the regulator and the regulated entity, whether in the private or the public sector.. In some cases, producers may be able to contribute valuable information for understanding their product, identify opportunities for improvement, and in making the regulatory intervention feasible. At the same time, their interests are often diametrically opposed to the health protection interests at stake, particularly when health protection requires reductions in sales, and they may act to sabotage regulatory efforts. To protect their public health mission, regulatory institutions must consider these conflicts in the design of their administrative procedures and act accordingly. The WHO reform process has involved extensive discussions on the establishment of rules for interaction with so-called Non-State Actors (WHA, 2014), having as a central concern the protection of public health from real or perceived influence by private interests, as stated in the GAP for NCDs (WHO, 2013a). Similarly, the OECD (2003) has enacted a set of guidelines for managing conflict of interest.

Dealing with industrial interests is at the core of the action of regulatory agencies. Industry is in many cases the regulated entity or its producer. Transparency in all interactions is key to be defined by government, including establishing clear rules for consultation, receipt of information, public comment, public hearings, and other opportunities for input. Some agencies have developed specific sets of practices to help optimize interactions and constrain inappropriate or illicit relations between the regulators and the regulated entities. For example, within Brazil's regulatory agency, the National Agency for Health Surveillance (ANVISA), appointments with regulated entities as well as citizens are scheduled through the *Parlatório* system, where all encounters are recorded. The agency is also subject to Brazil's 2011 freedom of information law and is required to have procedures for public consultation (Brazil, ANVISA, 2014).

In the case of tobacco, there is a long history of deceptive strategies by the tobacco industry seeking to undermine regulatory action, much of it confirmed by the industry's own internal documents, which were made public and clearly exposed as a consequence of tobacco litigation in Minnesota (Box 8). As mentioned in the previous chapter, Article 5.3 of the FCTC states that "in setting and implementing their public health policies with respect to tobacco control, Parties shall act to protect these policies from commercial and other vested interests of the tobacco industry in accordance with national law." The guidelines for implementation of this article elaborate how countries should interact with the tobacco industry. This concept was reaffirmed in the 2011 Political Declaration of the High-level Meeting of the United Nations General Assembly on the Prevention and Control of Noncommunicable Diseases (paragraph 38), which notes "the fundamental conflict of interest between the tobacco industry and public health" (United Nations, 2011). Researchers are now observing similar strategies to undermine regulatory action being employed by the food industry as well (Brownell, 2009; Moodie, 2013).

Given the history of attempts at corrupting or derailing regulatory processes, one of the key challenges for health authorities and regulatory agencies is developing appropriate ways to interact with the regulated sectors. For example, Brazilian health regulations on the marketing of unhealthy food to children were challenged and blocked by the food industry through the courts, although a strong resolution that addresses all marketing to children in general was later passed in 2014 (CONANDA, 2014). The alcohol and food industries should not be involved in a government's assessment of risk from their products. In the case of tobacco, as noted earlier under the FCTC mandates, polices and regulation must protect against the industry acting in its vested interest. Therefore, interactions between the government and the tobacco industry must be strictly limited to those that are necessary for effective regulation of the tobacco industry or tobacco products,

Dealing with industrial interests is at the core to the action of regulatory agencies.

Industry is in many cases directly responsible for the regulated object.

and they must be conducted in an accountable and transparent manner. On the other hand, food manufacturers, while they are part of the problem, are also more likely to become part of the solution and their input may be needed for certain regulatory measures. Manufacturers may have indispensable knowledge and expertise on issues such as food technology, ingredient availability, and the food safety implications of modifying products to reduce NCD risks. Several countries have been successful with interactions of this

Box 8. Tobacco industry tactics that interfere with control efforts

Several tactics used by the tobacco industry interfere with tobacco control efforts:

- **Influencing the political and legislative process.** The industry has been highly resourceful in undermining governments' efforts to protect health by creating and exploiting legal loopholes and hiring lobbyists to influence decision-makers and weaken normative texts.
- **Exaggerating the economic importance of the industry.** The industry often uses economic arguments to suggest that effective tobacco control would nullify the alleged economic benefits of its business to local communities and national economies, but the data exaggerate its economic importance.
- **Manipulating public opinion to improve the industry image.** The industry uses a wide range of public relations tactics to manipulate public opinion and improve its image, including so-called "social responsibility" initiatives.
- **Fabricating support through front groups.** The industry uses affiliated businesses in its own and other industries to create seemingly independent grassroots groups that support its interest but that commonly receive direct tobacco industry funding.
- **Discrediting proven science.** In order to weaken tobacco control efforts, the industry creates false controversy about the scientific evidence on the harm of tobacco by manipulating standards of scientific proof and distorting evidence.
- **Intimidating governments with litigation.** Legal action or even the threat of action is a popular industry tactic to intimidate governments and dissuade them from introducing effective tobacco control policies.

Source: WHO, 2013c.

kind around the reduction of salt. While interaction with manufacturers can be valuable, it should not be allowed to "capture" the process.

Ways to strengthen the health authority include the existence of a clear legal mandate, adherence to well-designed and well-defined regulatory or legislative processes to reduce risks, mobilization of civil society support, and high-quality communication with the public. While not a guarantee, these conditions can help to reduce the likelihood of successful political or judicial challenges by the industry or regulatory "rollercoaster" effects resulting from industry tactics.

E.2.3. Building High-Quality Regulatory Processes

Regulatory processes have a natural flow of phases that need to be carried out to ensure a high quality end result. They must start with *risk identification* and analysis to identify the problem (scoping). Problem identification may come from different sources: social demand, scientific inquiry, political sources, international requirements for information, or the identification of a need by the country's own health system. In the *risk assessment* process, hazard identification and dose-response assessment are widely employed, with data coming from available research and local knowledge based on surveillance. Data may come from regular surveys of behavioral risk factors, environmental scans, or information about product sales, prices, marketing, or distribution. Risk assessment includes identifying the hazard inherent in the agent and the dose-response relationship; analyzing risk distribution in the population; characterizing the impact in different social, economic, and minority groups; and identifying levels of action and uncertainty (National Risk Council, 2009). Maintaining an eye on social disparities, perception, and culture is key.

Characterizing risk from NCD risk factors at the population level in each country must also be based on its particular social, economic, demographic, and cultural conditions. If the evidence demonstrates, for example, that a certain amount of sugar in the diet is a causal factor contributing to type 2 diabetes (WHO, 2014e), then the risk characterization might identify the country's specific patterns of carbohydrate consumption, general conditions, and demographics that make it possible to estimate the magnitude of the risk and identify populations with higher exposure to risk (WHO, 2014e). Most important, in this phase, characterization

of the risk can help to estimate the predicted benefit of an action in the population. A recommendation is then formulated based on the achievable or desirable level of risk exposure reduction (Figure 20). One common challenge is that research and data are often insufficient to assess how exposure may differ by subgroup—for example, by dietary patterns, different income, age, or ethnicity, however this should not impede action based on population wide data.

The next stage, *risk management*, considers the development of management options, identifying the levels at which they would be implemented, their potential cost and benefits, and the combination of interventions that could be most effective. Finally, the decision-making process is the last step, when one or a mix of interventions may be recommended to mitigate the risk. It can include combinations of legal, regulatory, health promotion, and clinical prevention measures, which are often needed for optimal effectiveness. From here, the specific regulatory action can be launched.

Some of the key characteristics that help to achieve effective regulation are evidence-based data, cost-effectiveness, population-wide reach, presence of legal support, and affordability. Using the best possible evidence at all stages is essential in order to ensure credibility and provide a rigorous basis for decision-making. In many cases multisectoral and multi-stakeholder approaches will be needed, although some decisions may be fully within the scope of the health sector authority. The legal scope of regulation and global legal frameworks should also be assessed as a part of the risk regulation process. Regulation should address public and private interests, at a low implementation cost whenever possible, to maximize support and avoid distortions (Nijsen, 2013). Though the cost of implementing regulation is generally modest, it is rarely free. However, it should not always be viewed as a negative, as it must be weighed against the often larger social and economic cost of failing to regulate.

To make significant progress in the field of NCD risk factor prevention, feasible measures that can achieve substantial, population-wide risk reduction must be prioritized. Only in some cases, like trans fat or flavored tobacco products, will full risk elimination be feasible. In other cases, risks are more likely to be reduced but not eliminated, as in the case of physical inactivity or alcohol consumption. When risks are under-regulated or the regulations are poorly developed or enforced,

the risks are less likely to be reduced or eliminated. Deficits in this process, or in the organizational design to support it, can lead to loss of opportunities or of public trust.

The *risk regulation* process includes several further steps: the actual rule-making, the implementation, and the enforcement. Communicating proposals to stakeholders and the public and involving them in the process are also essential components. Thorough discussion of draft rules from multiple viewpoints, including the perspective of those who will enforce them, is useful in ensuring that final measures will be enforceable. Furthermore, clear plans, preparation, and operational support for enforcement are as essential as writing a good rule. Enforcement is an area that is typically deficient in many settings, reducing the effectiveness of measures in which significant technical effort and political capital had been invested.

Key considerations for transparency and legitimacy of the *regulatory process* include the means for obtaining technical consultation, avenues for social participation, clear paths for the defense of health rights, and adequate support for communication, all of which should be clearly embedded in the institutional design and operation.

Typically, opportunities for public input occur at three points in the process: identification of the problem, consultation on the development of rules and analysis of the regulatory impact, and accountability during implementation. Open and transparent processes should be established (Coglianese et al., 2008) that allow for both participation of less economically powerful stakeholders and the protection of public health from real or perceived conflicts of interest (WHA, 2014). Channels for input from the scientific community, the regulated sector, civil society, and other consultative bodies must be established and openly and strictly managed.

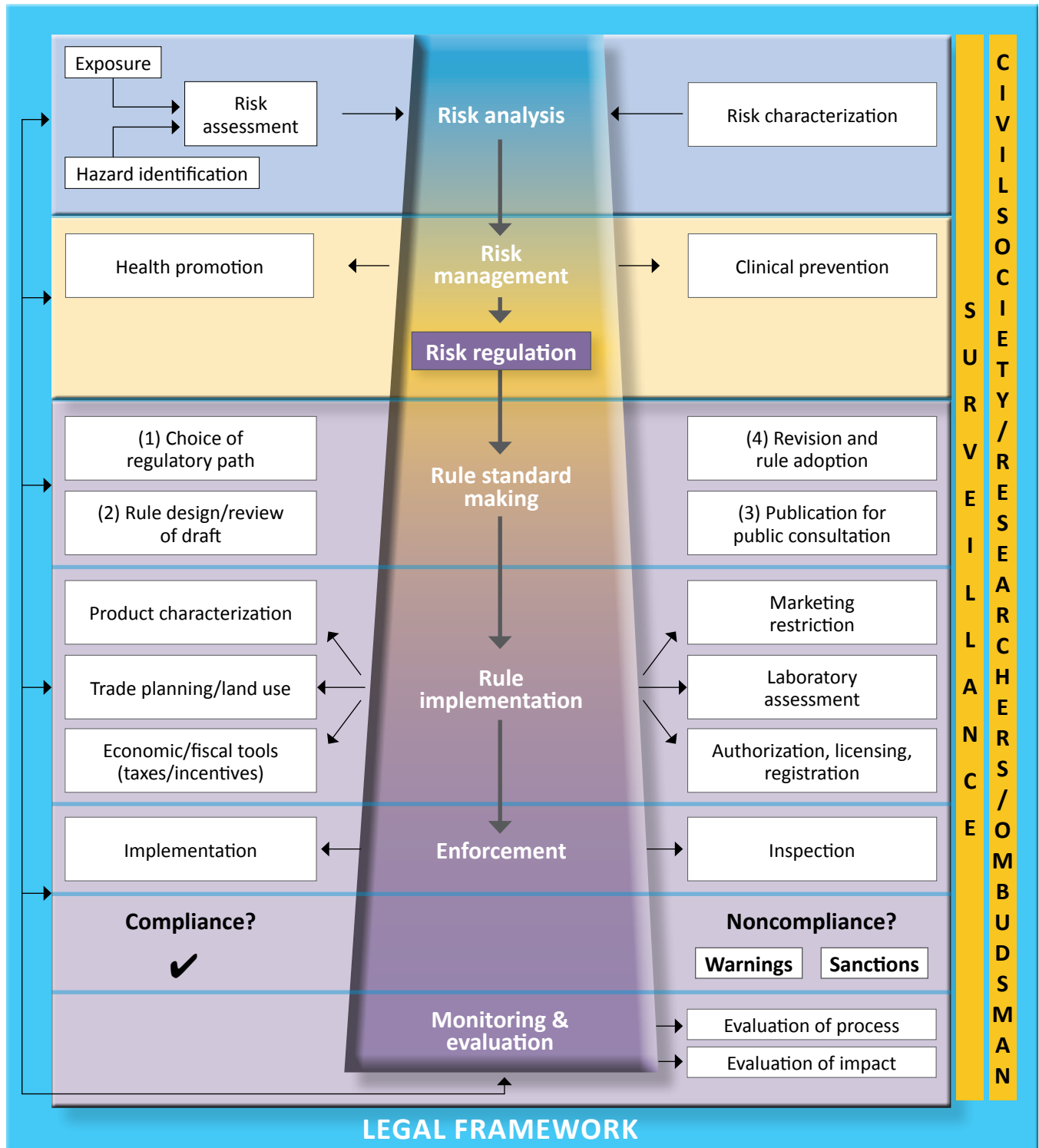
Depending on the organization of a county's resources and capacities, regulatory authority may be distributed between different spheres of government (central/federal, state/province, and local/municipal). In some cases, the national governments may provide implementation and enforcement support at the local levels, while in others that responsibility may devolve to the local level. Clarity in the identification of enforcement responsibilities is essential, as can be seen today, for example, in countries trying to

implement their laws on smoke-free air. In many spheres, particularly areas related to local commerce and physical activity, much regulation may be done at the local level. Many countries have found it useful to create networks of regulatory authorities.

health impact of legislation and regulations on NCDs will be important for keeping them consistent and up to date.

Finally, regular assessment of the implementation and

FIGURE 20. The Regulatory Process, from Risk Analysis to Regulation and Enforcement



E.2.4. Governance of Risk Management

A well-established regulatory process for NCD risk factors is central to reducing the potentially pernicious effects of uncontrolled regulatory processes that can be manipulated by vested political or private economic interests or other interference. Regulatory processes must be embedded in the institutional structure and culture of national governance. One framework that has been developed by an independent think tank is the International Risk Governance Council (IRGC) Framework. This framework addresses three challenges that result from differential knowledge and claims about an NCD risk: complexity, scientific uncertainty, and sociopolitical ambiguity (IRGC, 2008).

Bouder et al. (2007) have observed that the “concept of risk governance comprises a broad picture of risk: not only does it include what has been termed ‘risk management’ or ‘risk analysis’, it also looks at how risk-related decision-making unfolds when a range of actors are involved, requiring coordination and possibly reconciliation between a profusion of roles, perspectives, goals and activities. ... Finally, risk governance also illuminates a risk’s context by taking into account such factors as the historical and legal background, guiding principles, value systems and perceptions, and organizational imperatives.”

An important part of this approach is that it is a cycle. There is no assumption that, once a strategy to manage a risk is created and carried out, the risk will be completely neutralized. Rather, there is the clear knowledge that evaluation is key and that there will always be ways to mitigate new risks and improve the systems created. For this purpose, it is necessary not only to build the capacity to create risk management strategies, such as regulation, but also to conduct thorough risk assessment and evaluations of the regulatory processes. At times, archaic or ineffective regulations must also be dispensed with to ensure that the time and effort invested in regulatory action are focused on today’s risks and effective in achieving the relevant goals. For example, part of New York City’s innovative chronic disease prevention regulations grew out of an effort to update the entire New York City Health Code for the twenty-first century, both eliminating archaic provisions and bringing in new ones to address current challenges (Merrill and Lynn Silver, personal communication, 2014).

E.2.5. Trade as a Major Challenge

As emphasized by United Nations Secretary-General Ban Ki-moon at the 2011 High-Level Meeting on Noncommunicable Diseases, “addressing NCDs is critical for global public health, but it will also be good for the economy; for the environment; for the global public good in the broadest sense. If we come together to tackle NCDs, we can do more than heal individuals—we can safeguard our very future.” To deliver on this aspiration for policy coherence (as cited in WHA59.26 on International Trade), it is critically important to design trade policies and trade agreements that support health (United Nations, 2012). Trade agreements generally have provisions that are concerned with protecting human health. Member States must remain vigilant to ensure that these provisions are maintained and respected and that they are not allowed to create barriers to health protection.

Three of the NCD risk factors discussed here are well known commodities (alcohol, unhealthy foods and beverages, and tobacco,) that are frequently imported and exported between countries. Most trade agreements (bilateral, regional, and global) and global trade instruments address the issues related to the commerce of commodities. Trade agreements compel states to lower barriers to trade such as tariffs. A second relevant area is foreign investment agreements. Investment contracts between the state and an investor provide legal protection for the investor, including aspects related to taxation and regulation. Investment treaties between states protect the property rights of foreign investors and are increasingly used to challenge regulation through international arbitration rather than domestic courts.

A concern that is often encountered is whether the adoption of legislation or regulation to address the risks arising from tobacco, food, or alcohol will be considered a violation of agreements under the World Trade Organization (WTO).

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement) clearly establishes that “members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health” (WTO, 1995, Art. 2.1). It also calls upon Members to follow international standards, recommendations, or guidelines where they exist. The recommendations,

standards, or guidelines adopted by WHO and cited in this technical reference document relating to the reduction of risks from alcohol, food and tobacco are potential examples of such guidelines.

Trade agreements are relevant to NCDs in several policy contexts, in particular: (1) the design of regulations and compliance with existing agreements; (2) the development of international standards; and (3) other trade negotiations. It is important to ensure that future agreements do not constrain domestic regulatory autonomy to the extent that it impedes good regulation or goes against policies aimed at preventing and controlling NCDs more broadly.

The SPS Agreement also calls on States to use scientifically documented risk assessment procedures such as those discussed here. “Members shall ensure that their sanitary or phytosanitary measures are based on an assessment, as appropriate to the circumstance, of the risks to human, animal or plant life or health, taking into account risk assessment techniques developed by the relevant international organizations” (WTO, 1995, Art. 5.1). Countries must establish SPS measures on the basis of an appropriate assessment of the actual risks involved, and, if requested, make known which factors they took into consideration, the assessment procedures they used, and the level of risk they determined to be acceptable. Although many governments already use risk assessment in their management of food safety and animal and plant health, the SPS Agreement encourages wider use of systematic risk assessment. Measures must be likely to be effective and not more trade-restrictive than necessary to address the health risk.

In light of these requirements, it is increasingly important for States to carry out and document their risk assessment and risk mitigation procedures and decisions, and to support such decisions based on scientific evidence and on international guidelines and recommendations, in order to strengthen their ability to withstand challenges under trade and investment rules.

This careful preparation is necessary because, even with a well-founded and well-documented process, industry, the tobacco industry in particular, has used legal challenges, even spurious ones, as a tool for intimidation and harassment of national governments seeking to protect the public health. For example, a leading tobacco company initiated litigation over tobacco packaging regulations in Australia and in Uruguay based on investment agreements. Similar efforts can be expected as measures to address dietary risk multiply. After the 2011 United Nations High-Level Meeting on Noncommunicable Diseases, at the 2014 Technical Barriers to Trade (TBT) Committee, almost one-third of the 46 specific trade concerns raised had to do with health protection, including labeling and restrictions on unhealthy foods and drinks (WTO, 2014). For example, rules on flavored tobacco, food labeling, and alcohol labeling have been questioned in meetings of the WTO TBT Committee. Recognizing the tension between the protection of health and the protection of commercial interests in international trade, some have advocated for a global framework convention on healthy diet, similar to the FCTC, to more clearly lay out a required international standard for ensuring a safe and healthy food supply and diet (Consumers International and World Obesity Federation, 2014). WHO has also worked with partners to provide training and technical assistance to Member States on how to address trade issues in relation to tobacco control.

The public health perspective should be further strengthened in trade agreements (as proposed in UNDP, 2013), with regard to access not only to medication but also to the sovereign right of the countries to protect the health of their population from risks derived from traded commodities. This issue is critical for the Region of the Americas, given the existence of several economic blocs: the Andean Community (CAN), the Caribbean Community and Common Market (CARICOM) the North American Free Trade Agreement (NAFTA) (currently under review), and the Southern Common Market (MERCOSUR), as well as the free trade agreements

Although many governments already use risk assessment in their management of food safety and animal and plant health,
the SPS Agreement encourages wider use of systematic risk assessment.

currently in development: the Trans-Pacific Partnership (TPP) and the Trans-Atlantic Trade and Investment Partnership (TTIP). All these pacts require concerted action between countries to enhance public health and ensure effective protection of the population against health risks. Some of these regional blocs also have their own standardization processes, and these processes may be either important avenues for reducing NCD risks or potential sources for their exacerbation. Two recent examples from the Mercosur bloc represent positive precedents for action by common markets to address NCD risk factors. Agreements were reached in 2015 prioritizing goals for salt reduction in the food supply and principles for addressing the obesity epidemic amongst those nations (Mercosur, 2015a and Mercosur, 2015b).

E.2.6. Complementing Regulation: Education Essential, But No Substitute for Regulation

For the State to fulfill its role of health risk protection, regulation at the population level must be complemented with health promotion and the treatment and prevention of clinical disease. The three approaches—health risk regulation, health promotion, and disease prevention—are interrelated. Without good policy and regulatory frameworks, communities typically face far greater challenges to eating healthfully and getting enough exercise, and it is more difficult to institute health-promoting policies and effect changes in setting based practices. While health risk regulation includes risk analysis and risk management instruments that can “shield” the population from exposure to the risks or set it “on track” to avoid unnecessary risks, a broader health promotion framework includes multiple approaches to generating coherent action toward modifying health determinants and risks. An example would be the following functions, patterned after the Ottawa Charter (WHO, 1986): (1) build healthy public policy; (2) create supportive environments; (3) strengthen community action; (4) develop personal skills through health education; and (5) reorient health services toward prevention. Effective regulation routinely uses complementary health promotion strategies to communicate and raise public awareness and understanding of issues.

In disease prevention, the action focuses mainly on the community and the individual, enlisting individually targeted interventions to reduce their exposure.

Individuals can act to reduce their risk, but often only at great cost, either through resistance to the cues in their environment or through response to clinical preventive interventions. Complementary educational strategies should usually be included in policy design, and they are extremely important in implementation. In England, for example, a recent reform focused on public health action at the local level and called for a commitment to action on alcohol, tobacco, and healthy diets through the District Action Network on Public Health: “All local authorities are expected to use their existing regulatory powers, as well as local proximity and wide-range of services, to act as community leaders in behavioral change techniques.” (District Councils’ Network, 2013).

Health education to change lifestyle behaviors has been the main pillar of government and health system prevention activities for decades. However, its limitations must be understood. Merely educating the public about risks or creating education programs to reduce them is insufficient, especially when risks are widespread and community settings discourage behavioral changes or reflect strong economic interests. Health promotion effectiveness is low if it is restricted to education alone. Some of the limiting factors are:

- Insufficient financing to match the scale of corporate marketing;
- Imperfect, biased, and unbalanced information provided to consumers;
- Difficult access to all social groups;
- The long-term nature of NCD-associated risks, which often means that individuals do not take them seriously enough;
- Cost constraints. While health promotion is targeted toward those at greatest risk, a large percentage of those who develop a condition are not reached; and
- Difficulty scaling up health education activities to reach the entire population at risk and sustaining educational interventions over time.

A good example of these limitations can be seen in the levels of fruit and vegetable consumption in the United States, which have remained relatively constant for decades, far below the recommended amounts,

despite widespread efforts to educate the population. Between 1988 and 2002, only 11% of the population met the recommended guidelines for fruit and vegetable consumption, with no change except for a fall in vegetable consumption even after a massive national “Five a Day” health promotion effort (Casagrande et al., 2007).

Geoffrey Rose (1981), a leader in the thinking on how to prevent disease, laid out the strongest arguments for population-based approaches to reducing risks. In his seminal 1981 article in the *British Medical Journal*, Rose writes: “The preventive strategy that concentrates on high-risk individuals may be appropriate for those individuals, as well as being a wise and efficient use of limited medical resources; but its ability to reduce the burden of disease in the whole community tends to be disappointingly small. Potentially far more effective, and ultimately the only acceptable answer, is the mass strategy, whose aim is to shift the whole population’s distribution of the risk variable” (Rose, 1981). Rose argues strongly for the use of policy, environmental, and regulatory measures to shift population risk. Policy and regulatory approaches complement education for several reasons: if they are implemented effectively, they can reach all citizens; they can address barriers to change and create supportive environments; and they have far lower implementation costs.

The more recent Bangkok Charter for Health Promotion argues that “to make further advances in implementing these strategies, all sectors and settings must act to: **advocate** for health based on human rights and solidarity; **invest** in sustainable policies, actions, and infrastructure to address the determinants of health; **build capacity** for policy development, leadership, health promotion practice, knowledge transfer and research, and health literacy; **regulate and legislate** to ensure a high level of protection from harm and enable equal opportunity for health and well-being for all people; and **partner and build alliances** with public, private, nongovernmental, and international organizations and civil society to create sustainable actions” (WHO, 2005).

E.2.6.1. Is self-regulation useful?

One question that arises is whether these changes in the environment aimed to facilitate healthier practices must be imposed by government or whether self-regulatory processes by the producing industries are

effective alternatives. Existing evidence and reviews from a variety of fields suggest that, while self-regulatory efforts can at times contribute to the solution, they are a poor substitute for government leadership and regulation. Indeed, their purpose can often be precisely to delay or disarm efforts for effective policies. Proposals for self-regulation multiply as the threat or reality of government intervention draws closer, as seen today in the case of food. It should be noted that even *failure* to regulate by government imposes a series of environmental determinants on individual choice, since it yields the field to market failures and profit-driven practices. In some cases the challenge is finding the “sweet spot” where the good will and efforts of at least some industrial producers can be harnessed as part of a strong national process of change. It would appear that this positive engagement of industry is most likely to occur when it is clear that government is willing to use its considerable power for change (Castro, 2011). The threat of regulatory action can also be useful as a “backstop” to strongly encourage industry to make effective change. Neither regulatory nor self-regulatory measures are easy to implement, and both require monitoring and enforcement in order to be effective. Where dramatic reductions in the sales of harmful products is needed, as is the case of tobacco or sugary drinks, self-regulation is unlikely to be effective.

According to Sassi (2010), “governments are often reluctant to use regulation because of the complexity of the regulatory process, the enforcement costs involved, and the desire to avoid confrontation with the food industry. They may prefer to cooperate with the food industry in developing guidelines to reformulate food by lowering sugar, salt, and fats in processed foods, and develop consistent nutritional advice on food labels. ... Neither party may have a choice. Every alternative to cooperation would likely bring heavy losses to both, including financial losses. But realizing an effective and transparent cooperation is a daunting task because the potential for conflict, given the scale of the interests at stake, is vast.”

In the area of tobacco control, voluntary codes or agreements have time and again proven to be ineffective. These voluntary codes, usually initiated by the tobacco industry itself, are inherently weak, and they are often violated by the industry itself (PAHO, 2013d). Similarly, Babor et al. (2013), studying beer ads in the United States, found that the alcohol industry’s

current self-regulatory framework was ineffective in preventing violations.

The food industry generally recognizes that trans fats can be eliminated from industrialized food products. In the Americas, a voluntary commitment was reached for their reduction to negligible levels through the Declaration of Rio de Janeiro (PAHO, 2008), signed by several government and industry representatives. Nevertheless, in a study of trans fat reduction in New York City, it was found that extensive efforts to seek voluntary changes had not achieved the desired results, whereas a mandatory ban was highly successful (Angell et al., 2012). A recent international review of the different approaches found that trans fat bans were the most effective, followed by mandatory labeling or mandatory labeling combined with voluntary efforts, and that voluntary efforts alone had some effect but it was more modest (Downs et al., 2013). The US just moved to a mandatory approach in 2015 (FDA, 2015).

On the other hand, in the United Kingdom the Food Standards Agency has led a strong and coordinated effort to reduce salt in processed foods since 2003, combining voluntary participation with clear target-setting and monitoring by government, and the initiative has succeeded in achieving sizable reductions. Salt levels in many foods have fallen significantly—some by at least 40% to 50%—and more than 11,000 tons of salt have been removed from foods. Between 2003 and 2011, average salt consumption per person per day in Britain dropped by about 15%. Coincidentally, during the same period average blood pressure fell by 3.0/1.4 mm Hg, even among those not on medication; stroke mortality decreased by 42%; and ischemic heart disease, by 40%. Researchers attribute most of these changes to the reduction in population salt intake (He et al., 2014). In contrast in the UK, the public private partnership to reduce harmful use of alcohol, which unlike salt reduction would clearly have reduced sales, has been less successful (Faculty of Public Health UK, 2008).

In the Americas, Argentina used a mix of voluntary and regulatory measures with strong government leadership to obtain significant reductions under its “Less Salt, More Life” program. Salt in artisanal bread fell 25% in tandem with a strategy that reached 8,000 bakeries with the collaboration of the federation of bakers. The Argentine Government then developed

a combination of voluntary targets and partnerships for salt reduction for a wide range of products, supplemented with regulatory requirements for certain sectors and for those failing to join the voluntary effort (Argentina, 2013).

In the United States, major soda producers recently pledged to reduce calories from sodas by 20% by 2025. However it is not clear to what extent this target involves taking credit for existing trends versus truly driving those trends. Nestle notes: “Since the late 1990s, U.S. per capita consumption of soft drinks has dropped by about 20 percent. If current trends continue, the soda industry should have no trouble meeting its promise of another 20 percent reduction by 2025” (Nestle, 2014).

Sharma et al. (2010) proposed four aims and eight standards that should be met before self-regulatory efforts by the food industry can be considered in good faith, potentially impactful, or a possible substitute for government regulation (Box 9). The process will not be easy, and in some cases it may risk derailing effective government action.

E.2.6.2. A Multisectoral Challenge

The effective prevention of NCDs requires the concurrence of other sectors, branches, and spheres of government, multilateral agencies, civil society, and other non-State actors (PAHO, 2013b; United Nations, 2012; WHO, 2013a). Key government sectors include the fiscal authority, agriculture, trade, transportation, education, and land-use planning. At times regulation must be a cooperative effort, done jointly and synchronously with the health sector, and at other times it is sequential. Work has often been done in collaboration with Ministries of Finance or Economy on setting prices and taxes (on alcohol, foods, beverages and tobacco); with Ministries of Education and Labor on the implementation of rules on healthy diets in schools and workplaces; and with consumer protection agencies or agencies that regulate marketing. Multisectoral collaboration may also reach outside the government more broadly to involve civil society and business without conflict of interest (except for the tobacco industry, which is a separate case). For example when businesses or hospitals adopt healthy food standards and smoke free campuses.

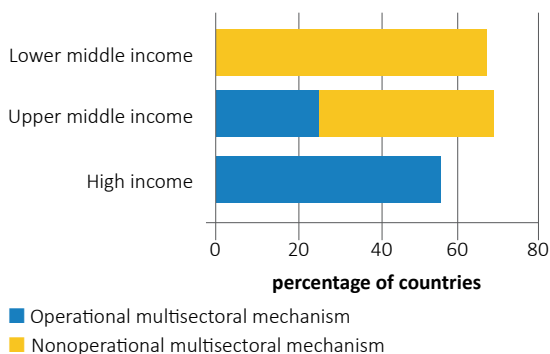
A survey conducted by PAHO (2013a) identified a scarcity of operational mechanisms for multisectoral actions in

Box 9. Proposed Standards for Food Industry Self-regulatory Activities

Transparency	Transparent self-regulatory standards created by a combination of scientists (not paid by industry) and representatives of leading nongovernmental organizations, parties involved in global governance (e.g., WHO, FAO), and the industry No single party given disproportional power or voting authority
Meaningful objectives and benchmarks	Specific codes of acceptable behaviors based on scientifically justified criteria Predefined benchmarks to ensure the success of self-regulation
Accountability and objective evaluation	Mandatory public reporting of adherence to codes, including progress toward achievement of full compliance with pledges and attainment of key benchmarks Built-in and transparent procedures for outside parties to register objections to self-regulatory standards or their enforcement Objective evaluation of self-regulatory benchmarks by credible outside groups not funded by industry to assess health, economic, and social outcomes Periodic assessments/audits to determinate compliance and outcomes
Oversight	Possible oversight by an appropriate global regulatory or health body (e.g., WHO)

Source: Adapted from Sharma et al., (2010).

FIGURE 21. Reported capacity for multisectoral public health action in the Americas



Source: PAHO/WHO, Country capacity survey, 2013a.

all countries of the Region, and the scarcity was greatest in lower middle-income countries (Figure 21).

E.2.7. Civil Society and Social Participation

Civil society is generally considered to comprise the full range of voluntary civic and social organizations and institutions. It is a key component of a democratic society. While government exercises State power, it is constrained by the political environment and its

priorities may change as the latter shifts. Civil society, on the other hand, has greater independence and often provides the long-term commitment to specific issues that is needed in order to sustain action. It typically plays five main roles: advocate, coalition builder, provider of evidence-based information, watchdog, and service provider (WHO, 2014a; WHO EB 136/5 Framework for Engagement with Non-State Actors).

As an advocate, civil society can enlist public opinion in support of (or against) regulatory action, promote government actions if it favors the cause, identify legislative priorities, and help to develop legislative measures. As a builder of networks, alliances, and coalitions, civil society can mobilize organizations from many different backgrounds behind a common cause or objective. Examples of this role are smoke-free alliances, general tobacco control leagues, coalitions on diet and health, and other networks typically organized around adherence to a common platform. Civil society may act to inform policy decisions, and it often translates science for use by policy makers, media, and the public. As a watchdog, civil society monitors and reports on the progress of governments and

other institutions in meeting their commitments and achieving their goals through independent monitoring and evaluation, sometimes producing “report cards” or “shadow reports.”

Over decades, civil society has played a critically important role in supporting the progress of Member States in tobacco control and counterbalancing the political influence of the industry, becoming increasingly professionalized and effective over the course of time (Champagne et al., 2010). Its importance is also recognized in Article 4.7 of the FCTC, which states that “the participation of civil society is essential in achieving the objective of the Convention and its protocols.” It is likely that the control of NCD risk factors will arise from shared civil society and government leadership in the coming years.

Civil society is subject to similar pressures and influences as governments. Bias or conflicts of interest may be present if these organizations are responding to specific interests, influenced by industry or governments, or under financial pressure that might make them less than an objective player. Ensuring transparency in relation to input from civil society can be a challenge, especially in light of the experience with tobacco, alcohol and food industries use of industry-financed “front groups” to lobby government and campaign against regulatory measures (Clark, 1995). To ensure a healthy role for civil society, a number of good governance factors are relevant, including government transparency and accountability, existence of a legal framework for the identification of conflicts of interest, unambiguous rules governing relationships with nongovernmental organizations and collaboration between the private sector and the State, and clear official support for input from civil society.

E.3. Where do we stand in country capacity to regulate NCD risk factors?

In 2013, WHO conducted its periodic global country capacity survey (WHO, 2013e) to gain insight into the current status of NCD response capacity in the Region. This survey collected responses from Ministries of Health through WHO Country Offices worldwide to a set of standardized questions. A total of 36 countries responded in the Region of the Americas. The results reveal significant strength in the Region for tobacco

control legislation, as well as ample opportunity to improve action on regulating other risk factors such as alcohol and unhealthy diets (PAHO, 2013a).

The survey found that the capacity of Ministries of Health and related institutions to effectively deliver protection to the population from the leading health risks factors for these diseases is limited. Programs to address these factors are neither well documented nor structured in the form of action plans and strategies. This situation is clearly reflected in the pattern of implementation of international commitments. Experience has shown limited effectiveness and organizational development over the years. One notable exception is tobacco control: development and implementation of the WHO Framework Convention on Tobacco Control has led to significant advances in the Region.

The survey also showed that, overall, 97% of the countries in the Region had plans for NCDs, but this number decreased on closer examination of each country’s focus on specific risk factors. While a large portion of the countries in the Region had an operational plan for tobacco control, only 31% had an operational plan for alcohol, only 22%, for dietary risks; 42%, for physical activity; and 31%, for addressing overweight. Many key risks lacked regulatory policies, and even where these were present, a large number were not actively enforced. While many countries had plans under development, some had no risk factor specific plans at all. Another important aspect considered in the survey was whether a country conducted surveillance for all the NCD risk factors. Data was often totally lacking, outdated, or incomplete. Without effective surveillance systems, countries will have difficulty monitoring and addressing NCD risks.

With regard to taxation on NCD risk factors, the survey found widespread taxation on alcohol and tobacco in the Region. However, it should be noted that these products have been taxed for centuries and not necessarily with the goal of reducing their consumption and improving people’s health. Moreover, in the case of tobacco, most countries have not reached the level recommended by WHO as a percentage of the final retail price. As for the taxation of sugary drinks and unhealthy foods, at the time of the survey measures of this kind were nearly absent; no healthy food subsidies were noted (although some exist); and no subsidy for physical activity was reported. These findings show

both the potential in the Region for using taxation on alcohol, unhealthy food, and tobacco as an intervention to achieve public health goals and the challenges that lie ahead in using these very effective measures.

An analysis of policy output in selected countries of the world, including 20 countries in the Americas (Stein, 2006), revealed that the Region had deficiencies in the quality of policy output. Furthermore, the author identified lack of enforcement and implementation, difficulty in intersectoral coordination, and deficient coordination between different levels of government. The underlying problem was deemed to be issues of governance. Weakness of Ministries of Health in effectively implementing risk protection policies can be related to more general challenges to governance, as well as to the low priority traditionally given to preventive interventions, especially those related to health promotion and regulation.

No studies were found that analyze or compare the health regulatory structures for addressing NCD risks within the Ministries of Health. Empirical observation suggests a frequent lack of clear definition of location of the authority and the specific roles and responsibilities, especially at the extremes of the regulatory process (risk assessment and enforcement). The PAHO Country Representative Offices have observed the impact of lack of professionalization in public health regulatory actions; improvisation of organizational processes, with consequent impact on the quality and effectiveness of service; and internal competition for financial resources.

E.3.1. How is regulatory capacity built? Dedicated Regulatory Institutions and Other Models

Institutional development for providing regulatory support has been heterogeneous both in the Region and globally. Countries have typically developed their regulatory capacity in three different modalities: integrated within their Ministries of Health, integrated within their health systems, or as separate autonomous organizations. In some cases, the regulation of key risk factors is carried out by governmental agencies outside the health sector. A review of the mission statements of some of the regulatory agencies in the Region shows only one that clearly states its linkage to the health system. In other respects, most of the statements are similar.

The regulatory design can take a variety of forms.

- Some countries have maintained responsibility and authority for regulatory action within their Ministries of Health. Given the complexity of NCD risk factors and the interrelationship between areas, regulatory functions in the Ministries of Health may be integrated within a division wholly devoted to NCD issues as part of an integrated NCD plan that also addresses clinical or programmatic efforts (integrated and centralized).
- Some countries keep the regulation of each risk factor in a separate area or combine only a couple of risk factors together.
- Alternatively, a Ministry may have a central regulatory unit providing support and working across divisions or departments, as with a General Directorate of Epidemiology or Health Statistics. In other words, enforcement is central, while the assessment of risk is split up among different areas.
- Regulatory responsibility may also be split: central departments or divisions may have standards setting responsibility while specialized regulatory structures conduct the rule-making process as well as implementation and enforcement of the rules. In this case, the normative function is centralized and enforcement is specialized.
- On the other hand, some countries might prefer to have a “normative role” within the Ministry of Health and give other institutions responsibility for enforcement their rules in a collaborative manner. In other words, both the normative and the enforcement functions are split.
- Another approach has been to create semiautonomous or autonomous regulatory agencies to professionalize these functions in order to be more specialized, at least theoretically, in building “shields” against conflicts of interest. This approach was used, for example, in Brazil, with creation of the National Health Surveillance Agency (ANVISA) in 1999 (Law 9,782 of that year); in Mexico, with creation of the Federal Commission for Protection against Health Risks (COFEPRIS) (Mexico, Diario Oficial, 2001); in Colombia, with creation of the National Food and Drug Surveillance Institute (INVIMA) in 2007 (Congressional Law 1,122); and the United States, with creation of the Food

and Drug Administration in 1905 (Pure Food and Drug Act, 1906). In the Region of the Americas, 13 countries have medical product regulatory entities (PAHO, 2012), several of which also address NCD risk factors. Such arrangements would correspond to the specialized integrated health regulatory agency model.

Regardless of the organizational structure adopted, the processes related to the normative or regulatory role and those related to enforcement and surveillance should be split in order to stimulate transparency and avoid conflicts of interest and corruption.

Box 10 spotlights five regulatory authorities in the Region and outlines the different areas they cover.

Box 10. Mission statements of national regulatory agencies

Brazil: National Health Surveillance Agency

(Agência Nacional de Vigilância Sanitária – ANVISA)

To protect and promote public health and intervene in the risks caused by the production and use of products regulated by health surveillance. This mission is to be carried out in coordination with states, municipalities, and the Federal District, in accordance with the principles of the Brazilian Unified Health System. It is aimed at improving the quality of life of the population.

Canada: Health Products and Food Branch (HPFB)

To take an integrated approach to managing the health-related risks and benefits of health products and food by minimizing health risk factors to Canadians while maximizing the safety provided by the regulatory system for health products and food, and (by) promoting conditions that enable Canadians to make healthy choices and providing information so that they can make informed decisions about their health.

Colombia: National Food and Drug Surveillance Institute

(Instituto Nacional de Vigilancia de Medicamentos y Alimentos – INVIMA)

To protect and promote the health of the population through risk management associated with the consumption and use of food, drugs, medical devices, and other products subject to sanitary surveillance.

Mexico: Federal Commission for Protection against Health Risks

(Comisión Federal para la Protección contra Riesgos Sanitarios – COFEPRIS)

To protect people from health risks caused by the use and consumption of goods, services, and health products, environmental and occupational exposures to risks, and the occurrence of health emergencies, and to oversee the provision of health services through the regulation, control, and prevention of health risks.

United States: Food and Drug Administration (FDA)

FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our nation's food supply, cosmetics, and products that emit radiation.

FDA is also responsible for advancing the public health by helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

FDA also plays a significant role in the Nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

While pharmaceuticals and food have traditionally been health regulatory areas, food is less likely to be addressed than pharmaceuticals, and tobacco and alcohol even less so. Furthermore, within food regulation, the health sector has traditionally focused on foodborne infectious disease and contaminants rather than the prevention of diet-related noncommunicable diseases, although NCDs now generate a far greater disease burden. All these agencies have attributions at the central or national level but share responsibility with local authorities at the local level.

Figure 22 shows the limited coverage of food, beverages, and tobacco among the product groups regulated by national health regulatory authorities, although these products may be regulated by other governmental bodies (based on the current data from National Regulatory Authorities of Regional Reference process, presented by James Fitzgerald, Director, Health Systems and Services, personal communication during expert meeting in 2014).

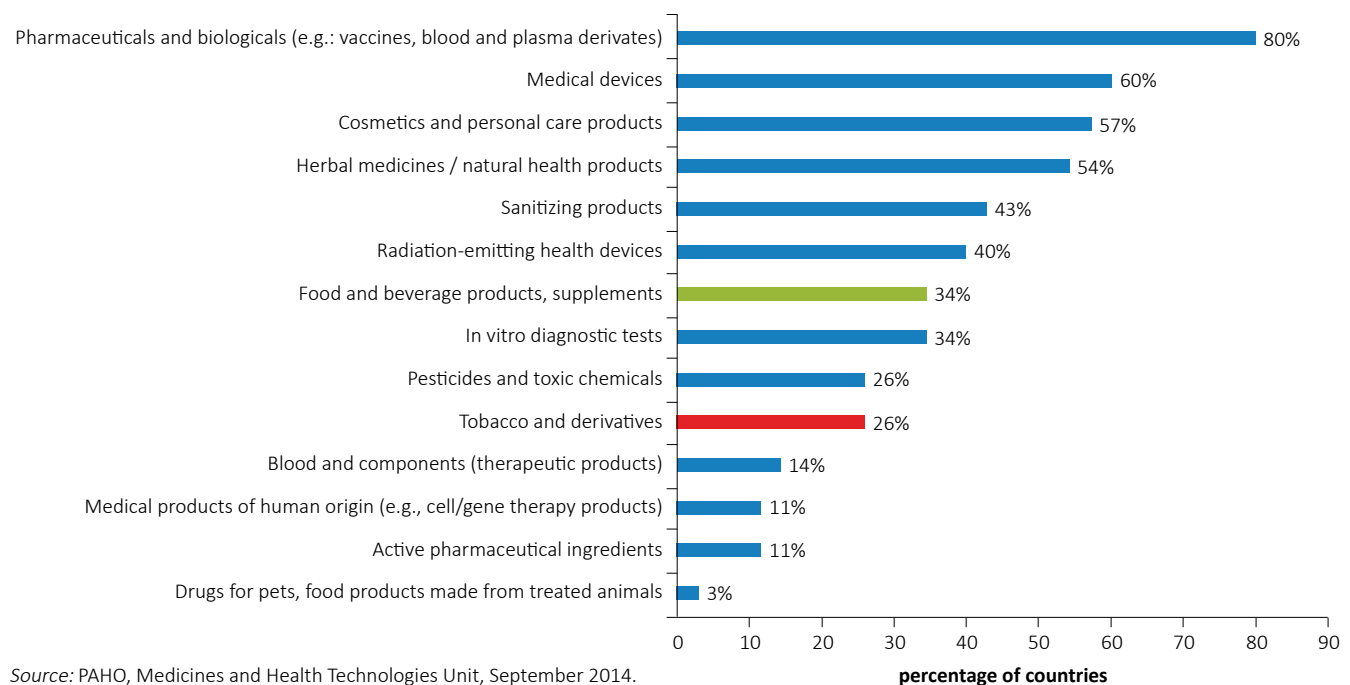
E.3.2. Lessons Learned from the Regulation of Medical Products

There can be clear benefits from strengthening national regulatory agencies (NRAs). The Pan American Network for Drug Regulatory Harmonization (PANDRH), established in 1999 (PAHO, 2009), supports

harmonization processes by examining specific areas and issuing recommendations on priority matters as well as harmonized guidelines proposed by the working groups of the regularly convened PANDRH Conference. The PANDRH process offers useful lessons and a model for building regulatory capacity and increasing collaboration on NCD risk factors. Specifically, the mission of PANDRH is to promote drug regulatory harmonization for all aspects of quality, safety, and efficacy of pharmaceutical products as a contribution to the quality of life and health care of the citizens of the Member States of the Americas. PAHO serves as its secretariat and supports it in achieving its four strategic objectives: (1) promote effective governance of the Network and active participation of NRAs toward regulatory convergence and harmonization; (2) define priorities, strategies, and mechanisms for regulatory convergence and harmonization and support their dissemination, adoption, and implementation by NRAs; (3) promote the strengthening of competency in good regulatory practices and regulatory science; and (4) promote the exchange of experiences and regulatory knowledge among NRAs both within and outside PANDRH.

In 2006, as part of an effort to strengthen regulatory agencies, PAHO developed a system to evaluate and qualify NRAs. It is starting to facilitate and improve

FIGURE 22. Some products under regulation by the health sector, 35 PAHO member countries, September 2014 (percentage of countries)



Source: PAHO, Medicines and Health Technologies Unit, September 2014.

cooperation mechanisms across NRAs in the Region. While harmonization was a key goal, priority has been given to the adoption of quality standards in several defined areas, such as good manufacturing practices and bioequivalence. In addition, a network of reference centers has been created, and PAHO helped to build a regional regulatory capacity system in the Caribbean. Today the priority is strengthening legal regulatory frameworks, structure, and quality management; defining core regulatory functions based on national policy priorities; building cooperation across partners regardless of resource level; and seeking regulatory “convergence” more than “harmonization.”

Regulatory capacity is assessed periodically in 25 countries using 20 indicators; in addition, specific standards are surveyed in greater detail. Currently seven institutions have been certified as PAHO regional reference institutions for medicines and biological products. A number of these institutions are also involved in the regulation of NCD risk factors, although current collaboration with them does not include these areas. These leading institutions could potentially act as “reference” collaborators with other countries by sharing their expertise. The foregoing activities are in line with practices being promoted in PAHO for technical cooperation among countries. They may help to improve national regulatory capacity in other countries and facilitate harmonization in some cases. The agencies involved include ANVISA (Brazil), Health Canada, INVIMA (Colombia), COFEPRIS (Mexico) and the FDA (United States). An international comparative analysis of the NCD regulatory capacity of Ministries of Health could provide valuable information to enrich technical cooperation.

This process has succeeded in developing standards for the Region of the Americas on the improvement of regulatory agencies and in creating a network of reference institutions on which Member States can rely. While medicines, biologicals, and medical technologies represent a specific interest sector for which it is desirable to have expedited market exchange within the Region, there is an urgent need for effective high-

quality regulation of other products as well, particularly those associated with NCDs.

E.3.3. Legislative Action in the Region to Support the NCD Health Risk Regulatory Authority

Most of the ten greatest public health achievements of the twentieth century relied on the development and enforcement of legislation and regulations (Kopakka, 2011). Nevertheless, a recent expert consultation on legislation and health (PAHO, 2014e) identified the following challenges: inadequate frameworks and regulations for implementing the right to health, a lack of clarity regarding governmental powers, a need to review national laws with regard to the promotion and protection of health throughout the life course, and the need to enact national health laws pertaining to NCDs and their risk factors. The tools available to the public health sector were reviewed during the consultation (PAHO, 2014e), including taxation, subsidies, dissemination of information, changes in the built environment, and direct and indirect regulation and self-regulation.

A number of PAHO Member States have enshrined the right to the enjoyment of the highest attainable standard of health in their national constitutions. Many Member States have enacted laws that control and regulate tobacco use in accordance with the WHO Framework Convention on Tobacco Control (FCTC). At the same time, the Pan American Sanitary Bureau has seen a growing demand from national health authorities, legislatures, courts, and national human rights institutions for technical cooperation on formulating, reforming, or interpreting health-related laws and regulations, as well as on the development of best practices.

Despite these positive trends, some Member States still face significant challenges in the formulation, implementation, review, and/or reform of health-related laws and regulations. For example, some of them need to promote broader dissemination of health-related technical standards and guidelines to Ministries of Health and the legislative and judicial branches.

A number of PAHO Member States have enshrined

the right to the enjoyment of the highest attainable standard of health in their national constitutions.

Others should promote better coordination between the legislative branch (e.g., health commissions) and the health authority (e.g., governance and stewardship units), while still others should consider taking better advantage of their tax-related legislative and regulatory powers in protecting and promoting the health of their populations. In addition, some Member States still need to bring their domestic laws and regulations into alignment with international agreements such as the FCTC and human rights covenants that they may have ratified.

E.3.4. Financing the Institutions in the Region

Financing is an essential element for effective regulation and enforcement. Risk identification and analysis of risks are fundamentally a stewardship responsibility of the State that generates a public good and should generally be funded through the regular public budget. The same applies to basic support functions. However, when it comes to the implementation and enforcement of risk regulation, including the registration process, authorizations, rights, licenses, sanctions, and taxes, it may be more appropriate for the regulated entities or industries to carry the burden and even finance the other regulatory functions.

Today many regulatory bodies have become at least partially self-sustaining by levying assessments, fees, or fines that help to cover their operating costs (Table 7). These approaches are used, for example, by health regulatory agencies in Brazil, Mexico, and the United States to fund part of their regulatory activities. Financial design is a key component of the organizational development of regulatory capacity.

Four main approaches are generally used for funding the regulatory function.

- One common approach is specific fees for services/activities. While fees can have the advantage of best reflecting the cost and can be protective of agency independence, the methodology has higher transaction costs and may not be a stable or reliable revenue stream. Fees, however, can be a very useful mechanism for providing supplemental funds for agencies when they are required for specific purposes (Brown and Ashley, n.d.).
- A second common method is appropriation from general tax revenues. This approach has the advantage of simplicity and potentially of independence from regulated entities. However, it also has the potential to facilitate political interference in agency operations through the budgeting process; it may not be as reliable or stable as the alternatives. Also, it does not impose a cost on the regulated sector.
- A third approach is to assess the regulated industry for the cost of regulation, after which the companies may pass on the costs to consumers. The advantages of this approach are that regulatory costs are imposed on the regulated sector; assessments are fees for services rather than taxes; revenue is stable and reliable; and funding is consistent and has transparency. States must be aware, however, that in some countries all production costs, including fees of this kind, are tax-deductible, so the approach could turn into a hidden subsidy to industry.
- A fourth approach would be a combination of these different streams to meet the needs of a given system.

TABLE 7. Potential sources and typical uses of revenue for entities that regulate NCD risks

General taxpayer revenue	Regulated entity fees and fines
<ul style="list-style-type: none"> • Establishment and organization • Basic science for risk assessment • Development of norms and standards • Laboratory development • Evaluation of regulation • All other activities 	<ul style="list-style-type: none"> • Registration • Registration renewal • Licenses • License renewal • Authorizations and certificates • Laboratory analyses and verifications • Inspection and monitoring • Sanctions

Source: Own elaboration.

While it has not been widely used, taxation of NCD risk factors such as tobacco, alcohol, and sugary drinks could also be used to cover certain costs of regulatory capacity or to support a broader range of public health promotion activities. Examples of the use of taxation for health promotion activities include the case of the Solidarity Health Fund (*Fondo Solidario para la Salud – FOSALUD*) in El Salvador, financed by taxes on unhealthy products (FOSALUD, 2015) and the case of Panama, where revenue from a 2009 increase in taxes (Panama, 2009) was used to finance key tobacco control measures both nationally and regionally. In Thailand, the Thai Health Promotion Foundation is financed by a 2% surcharge tax on tobacco and alcohol (Thai Health Promotion Foundation, 2015).

The WHO Global Health Expenditure Database (WHO, 2014b) provides data for 126 of the WHO Member States. In 2012, the percentages represented by prevention and public health expenditures were available for only three countries in the Region of the Americas: for Canada, the proportion was 7% of national health expenditure; for Mexico, 2%; and for the United States, 3%. The data available is inconsistent, but it tends to show a dramatically low investment in prevention and even an absence of information on prevention investments, including regulation. What is clear is that levels of investment in prevention, which includes regulatory action, are low and inconsistent. The need for better documentation of health sector spending in this area is also evident.



F. Looking Forward: Building Regulatory Capacity in the Americas

This technical reference document has provided an initial glimpse into the issues around regulatory capacity to address NCD risks in the Region. The various mandates from our global and regional bodies have been reviewed, highlighting regulation as an essential public health intervention. The potential contribution of regulatory action to the reduction of harm from these risk factors and to meeting NCD global targets is clear.

The PAHO Expert Meeting to Discuss the Initiative to Strengthen the Regulatory Capacity in the Region of the Americas for Noncommunicable Disease (NCD) Risk Factors, held on 17-18 November 2014, reviewed the draft document and drafted the recommendations included in this section.

Where do we go from here? If we start from the premise, established above, that the State is responsible for enabling individuals to lead healthy lives, and then it must act as a public health “steward”. The role of the Pan American Sanitary Bureau (PASB) is to support the Member States and work with them to develop this stewardship function. The PASB, working with the Ministries of Health, should seek a path forward for the Region following three main lines of action:

- Meeting the global and regional targets for NCD risk factor reduction;
- Strengthening the public health function of stewardship in its regulatory component;
- Leveling the playing field between social and economic actors and strengthening fair governance.

Strengthening regulatory capacity in the Region requires a clear vision, flexibility with regard to models, and recognition both of the power and limitations of regulation and of the need for synergy with other public

health approaches. It is essential to build capability for the medium and long term while still providing tools to create progress in the short term. Furthermore, building capacity will mean using a diversity of models: one size doesn’t fit all. Nations will vary in their priorities, the social inequities they need to address, and the structures that will work best for them. Regulatory capacity building will need to occur in concert with strengthening other essential public health functions, particularly surveillance (EPHF 2), health promotion (EPHF 3), and social participation (EPHF 4).

To address these considerations, five lines of action are envisioned as part of an initiative to strengthen regulatory capacity. In the first four lines of action, the PASB would support the Ministries of Health in: (i) organizational development of regulatory capacity; (ii) development of technical capacity for control of specific risk factors; (iii) evaluation of the regulatory processes; (iv) advancement of the regulatory research agenda; and (v) use of the unique role of the PASB (Figure 23). This section considers each of these lines of action as part of a plan of work for technical cooperation between Member States and the PASB.

The following sections provide more detailed descriptions of the potential lines of work. Among these, some of the highest priorities for immediate technical cooperation in the Americas include:

- Support for Member States enabling them to more clearly define the organizational base and the structure for regulatory action to address the NCD risk factors (in the countries);
- Support for Member States in structuring the financing needed to support an effective regulatory process (in the countries);

The various mandates from our global and regional bodies have been reviewed, **highlighting regulation as an essential public health intervention.**

FIGURE 23. Lines of action for regulatory strengthening



Source: Own elaboration.



The **REGULA** initiative logo portrays the protective effects of regulation of noncommunicable disease risk factors.

The green circle represents the protection of people, in particular vulnerable groups such as children.

The colored bands represent the risk factors of physical inactivity, unhealthy diet, alcohol, and tobacco.

The green wavy lines evoke a road for developing capacity, as well as the image of road safety.

- Formation of working groups and creation of structures for the exchange of expertise and best practices around specific risk factors and regulatory practices;
- Development of model legislation to address NCD risk factors and create regulatory structures (by the PASB);
- Implementation of a global monitoring plan for NCDs to track implementation of global commitments on the regulation of NCD risk factors (by the PASB);
- Support for assessing the impact of the implemented regulations;
- Identification of institutional practices that reduce corruption and facilitate a more level playing field between social and economic actors, and strengthen fair governance.

F.1. Lines of Work

F.1.1. Organizational Development of Regulatory Capacity

Member States may wish to consider efforts to strengthen their organizational base for the regulation of NCD risk factors, including its structure, design, processes, legal framework, financial support, and available human capital. The PASB can work with them to better inform these decisions and assist in mobilizing cooperation between countries to share experiences in this area.

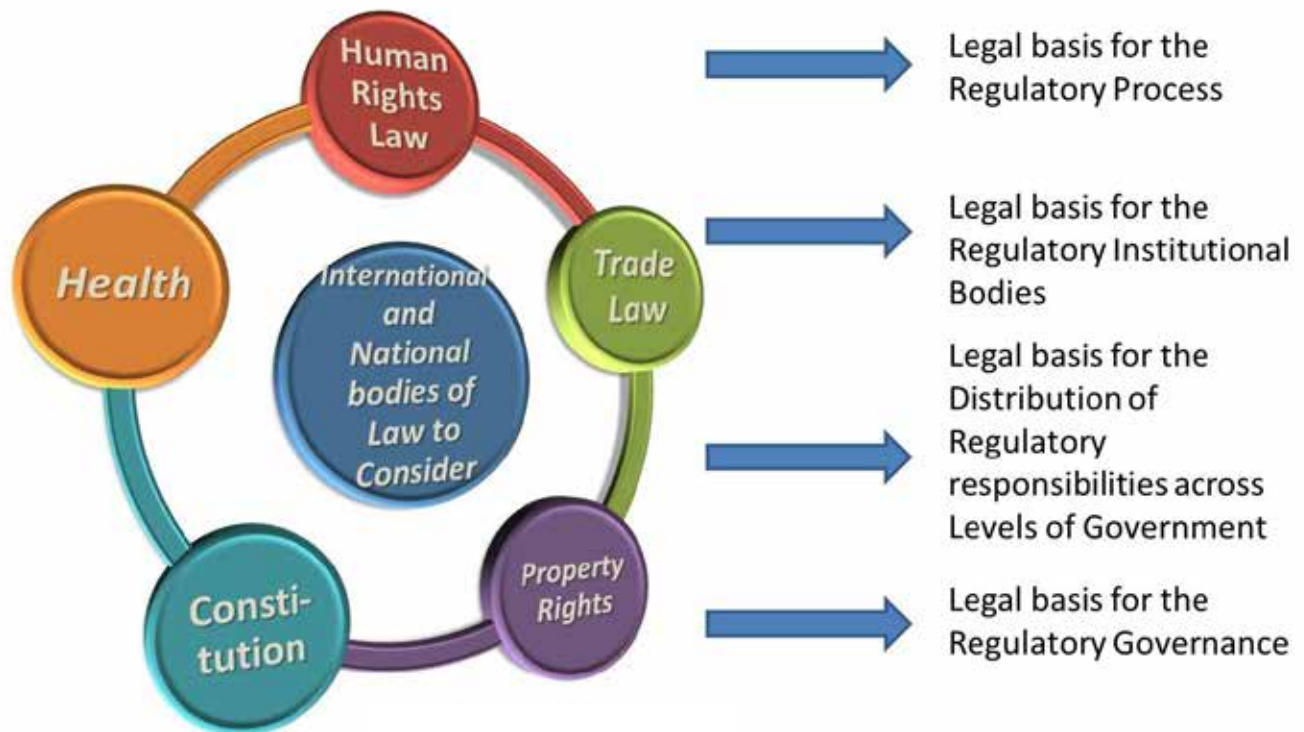
(a) Organizational structure design alternatives. No one formula is appropriate for all the countries. Effective regulation requires vision, explicit principles, and clarity on the core regulatory functions. It calls for commitment, clear legal authority, a well-structured regulatory process, trained staff, sustainable funding, and enforcement mechanisms. Explicit principles that should be followed by any health regulatory authority are transparency, participation, diversity, equity, and distribution of responsibility—all of these with health stewardship. This last principle implies that if the regulatory authority is shared with other government sectors or levels, the health authority should maintain responsibility for risk assessment and for defining the level of protection from risks

that should be pursued. Technical cooperation may include sharing models for the organization of health regulatory activities and consideration of their benefits and drawbacks.

(b) Comprehensive regulatory processes. Regardless of the organizational structure that a country may adopt, for optimal effectiveness all regulatory processes need to be carried out successfully from beginning to end, and from risk assessment to enforcement and risk communication. The necessary structure to support each phase of the process should be identified and assigned and the professional, legal, and financial resources ensured. Again, technical cooperation between countries can help to identify and share lessons learned and the most successful experiences.

(c) Funding of regulatory capacity. Funding constraints are key limitations for the development of regulatory capacity. It is essential to identify institutional mechanisms for sustainably funding the regulatory structures. Also, it is important to expand the tracking of budgetary support for prevention in general and for regulation in particular in order to understand how effectively the health resources are being spent. Technical cooperation can focus on sharing experiences and best practices in financing regulation among the regulatory authorities in the Region.

(d) Legal framework. The legal framework for regulatory entities is as important to their effectiveness as their financing. It is necessarily based on the national constitution and its health laws, but it also has to be consistent with law on property rights, trade and investments, and human rights, as well as codes on procedure. At the same time, it should also relate to the international bodies of law in these fields (Voon et al., 2014) (Figure 24). Careful crafting of this legal framework is key to ensuring that Ministries of Health and/or their specialized agencies have the necessary authority to carry out their regulatory functions, including the enactment and enforcement of regulations. The framework should consider the distribution of regulatory functions within the Ministry of Health, across other government agencies, and at other levels of government (e.g., state, provincial, or municipal). Ideally, the space

FIGURE 24. Legal framework for all risks

Modified from Voon T, Michell AD, Liberman J. *Regulating Tobacco, Alcohol & Unhealthy Foods*. Routledge, NY, 2014

for local innovation should be protected while still ensuring that the central government has authority to act. It also has to consider key governance aspects such as transparency, social participation, and relationship to other regulated sectors. Legal initiatives for specific risk factors (e.g., tobacco, alcohol, diet, or nonalcoholic beverages) may have common aspects and requirements in the basic design of the model legislation, which are then adapted to the national or local legal, social, and political situation. Technical cooperation and sharing of lessons learned and best models for legal frameworks for health regulation is another area for technical cooperation, as in the case of the Manual for Developing Tobacco Control Legislation in the Region of the Americas, published by the PASB in 2013 (PAHO, 2013f).

(e) Qualified human resources. Regulatory institutions require qualified professionals for their legal work and health specialists with an understanding of the specifics of NCD risk factors to conduct a high-quality risk assessment and management process. Therefore, it will be important to develop precise profiles of the needed expertise, as well as training capacity, since these issues are not typically taught

to legal or health professionals. Both groups, regulatory professionals and technical personnel, will benefit greatly from training in risk assessment, risk management, risk communication, and public health ethics. Regulatory personnel require the skills needed to draft rules, shepherd them through approval, implement them, and enforce effective regulation. Appropriately trained personnel will be needed in many spheres of government, from local inspectors to national leaders.

- Training will be required on risk regulatory functions and on specific risk factors.
- Training should also be available to civil society and the public in general to promote understanding of and participation in the regulatory processes.

For these reasons, human resources development is a critical challenge. Linkage with academic research and teaching institutions at the national and international level will be important. There are now a number of experiences with human resources development in the Region that can and should be shared. For example, Brazil has invested in the training of personnel for regulatory and surveillance functions as part of

implementing its national health reform. FDA includes capacity building in their international programs (FDA, 2015b). Development of highly specialized capabilities such as risk analysis and surveillance requires both medium- and long-term professional development, as well as good staff management and retention policies, to avoid loss of the expertise once it has been acquired.

(f) Governance structure and processes. Special consideration needs to be given to the structure and processes for good governance of regulatory systems. In these fields, which involve financial interests that represent a large portion of each country's GDP, it is essential to develop mechanisms for preventing and addressing conflict of interest and corruption in regulatory agencies. Such measures should be built into agency structure and practices while still ensuring the smooth flow of work and avoiding bottlenecks. Key measures may include:

- Establish, adopt, and implement an appropriate framework for working with different sectors of the regulated industries. All regulatory bodies face the challenge of developing transparent mechanisms for interacting with the private sector that allow for appropriate input and yet at the same time avoid regulatory capture and undue influence (Voon et al., 2014).
- Define the role and support of academia along the different stages of the process, especially in terms of the involvement of investigators in risk assessment, risk characterization, and analysis of options.
- Define the role and support for civil society and for its equitable participation (bearing in mind that its members have been important allies in advancing and monitoring progress on a number of NCD risk factors, tobacco in particular). It is essential to redress the balance of power in this area, giving greater voice to those who suffer the consequences of inaction.
- Define how the structure will be institutionalized for long-term sustainability.
- Define how local governments will be involved and empowered so that policy changes at the national level will become reality at the local level, and so that local governments can also act independently

and synergistically to control NCD risks.

- Sharing experiences among countries on how to do this can be of great value.

F.1.2. Development of Technical Capacity for Risk Control

Regardless of the organizational design, Member States will need trained personnel with an understanding of the issues around specific risk factors and up-to-date knowledge of current practices in order to produce quality risk assessment and offer a selection of options. There are a number of key building blocks that can support action on specific risk factors, Activities undertaken by the PASB and exchanges between countries can support these efforts.

(a) High-quality legislation or regulation. Well-drafted evidence-based legislation, regulation, or other policies on specific risk factors should be enacted by each Member State to support the control of risk factors. Model legislation can be developed and provided by the PASB to guide the Member States using comparative analysis of current experiences and policies developed in the Region or globally. PASB can also assist in sharing experiences with national legislation, an approach that was used in developing the Manual on Tobacco Legislation mentioned earlier (PAHO, 2013f). International and regional agreements represent a special situation in which having legislative guidance for implementation is useful, providing governments with positive elements they can use to defend their public health action. Since governments taking action on NCD risk factors are usually strongly pressured by economic interests, the existence of model regional legislation may help to lend additional support and credibility to their efforts.

(b) Strengthening the regulatory process. The regulatory process has technically specialized components that require strong and capable performance: risk assessment, rule-making/standards-setting, authorization and operations, enforcement, design and implementation of economic instruments, legislative support, risk communication, consultation with transparency, and social participation. Applying these tools to each risk, such as unhealthy diet, tobacco, alcohol,

or physical activity, has its own specificities that need to be understood and considered. Good models are already being developed, such as marketing restrictions, taxation, and front-of-package food labeling. Risk assessment and impact estimation models that have been developed in specific countries are already being widely shared. One example is methods for estimating the impact of tobacco taxation. In another example, models developed in the United States for estimating the health impact of soda taxes were adapted for use in Mexico, and the Mexican experience, in turn, provided input for improving the approach used in the United States. Academic institutions may be able to play an important complementary role. To ensure effectiveness, Member States will need to consolidate a strong technical basis for their regulatory processes. This specialized technical capacity for risk assessment is a starting point for defining the quality of the remaining process.

(c) Working groups and forums for exchange.

Development of capacity around the control of a specific risk factor may be fostered by convening or facilitating forums for exchange and collaboration at the regional or sub-regional levels. This approach can apply to policies for specific NCD risk factors or to building blocks for the overall regulatory process. Such forums could bring the relevant parties together from the pertinent sectors—for example: fiscal and health authorities to discuss taxation models; transportation, planning, and health authorities to address physical activity; food regulators to address labeling, sodium reduction, or trans fat; or communicators to discuss communication strategies for sharing their experiences and moving forward in coordination. The work that PAHO has done on salt reduction over the past decade has been one successful example of regional collaboration. In many cases, Member States may be dealing with the same companies, products, or issues, and communication between regulators may help to make the regional response more coordinated and effective. These efforts should include, and seek to facilitate, the contributions of academia and civil society. In some cases, under transparent and explicit rules, they might include representatives of the regulated entities.

F.1.3. Evaluation of the Regulatory Processes

- Member States should invest a portion of their resources to evaluate the effectiveness of the regulatory process and of specific regulatory measures and their impact. The PASB is well positioned to accompany these processes and provide advice and external support to evaluation efforts.

(a) Monitoring plan/program implementation. A scientifically sound, transparent, and participatory evaluation of regulatory processes (including the different stages of the process, such as risk assessment, risk management, risk communication, and implementation and enforcement, as well as use of multisectoral approaches) will strengthen the credibility of regulatory bodies and contribute to their ongoing improvement efforts. This evaluation process should be accompanied by assessment of the ability of regulatory processes to address the specific needs of populations in vulnerable situations. These types of evaluations will help to identify areas requiring improvement and development. Valuable experience has already been gained with the strengthening of regulatory agencies for medical products, built on the assessment of functions included in specific drug regulatory guidelines, using a standardized survey that measures progress toward a benchmark through the Regional Platform on Access and Innovation for Health Technologies (PRAIS). A standard survey tool on the regulation of NCD risks could serve similar purposes.

(b) Surveillance of risk factors. As part of the stewardship function of every Ministry of Health, up to date information on the distribution of risk factors within different groups at the national and regional level is essential for monitoring progress, carrying out risk assessment and impact estimates, and adjusting the NCD programs and policies. Just as national NCD plans and budgets provide for the surveillance of disease, they should also set aside resources for the periodic surveillance of NCD risk factors. This surveillance should examine the distribution of risk in order to monitor equity and identify how best to reduce inequities in the NCD burden. It also should monitor policy implementation. Tobacco surveillance has done well in collecting data on prevalence and

monitoring policies, but for alcohol, diet (including salt and sugary drinks), and physical activity there is need for more systematic collection of a minimum core database. To support this effort, the regional Plan of Action on NCDs also calls for the adoption of surveillance methods that are standardized and allow for comparisons.

(c) Member State assessment of progress. It is essential to have a strong monitoring and evaluation framework in place to track implementation of the commitments agreed to by the Member States. This process is currently most advanced for tobacco control under the FCTC (PAHO, 2013d), but it needs to exist for all of the areas identified in the Global Monitoring Framework for NCDs and for the risk factors. Member States should conduct a periodic review of existing regulations and policies that target NCD risk factors in terms of the commitments they have made in various strategies and plans of action, both nationally and in coordination with regional agreements.

(d) Assessment of implemented regulations. Evaluation of the implementation, effectiveness, and impact of specific measures can support their maintenance, revision, renewal, spread, or withdrawal and provide input for other countries. But many questions are still unanswered. How often should be adjusted? How high do they have to be? What kind of food labels change behavior? Where and when should the sale of alcohol be prohibited to optimize impact while minimizing restrictions? What factors go into effective risk assessment? To what extent are measures self-enforcing? What investments are needed for enforcement? Which organizational approaches are most successful for constraining corruption and balancing societal input and participation in regulatory processes? Effective indicators for short-, medium-, and long-term impact need to be identified. This requirement applies both to isolated measures and to determination of the best and most cost-effective mix for achieving an impact. Through evaluation it may be possible to estimate return on investment (ROI). The inclusion of ROI, or economic and fiscal impact in general, can be a powerful tool for Ministries of Health in their budget and policy negotiations. Evaluation research is another area for which funding is a challenge.

- It is also important to look for the unintended effects of regulations, both during the processes of regulatory assessment/risk management and afterwards. Of particular importance are any positive or negative impacts on other sectors, such as tourism, education, or transportation.

F.1.4. Advancement of the Regulatory Research Agenda

- A research agenda is needed in order to better orient future development of the risk regulation and regulatory processes and continue to build the evidence base. Research on specific approaches to risk management and other regulatory process improvements is scarce and much needed. The agenda should be based on knowledge of what is currently being regulated. It should convene funders of research, regulatory bodies, and investigators. A research agenda can be implemented in collaboration with regional research and academic institutions, especially those that are well positioned for implementation. The PASB can foster connections between the countries and between researchers and funders, and it can promote the discussion and dissemination of results. Some promising areas for research include:

(a) Comparative institutional design. A comparative analysis of institutional design between different countries can improve understanding of the current situation, the common principles, and the best practices to be adapted to specific national structures. Historically, comparative health system analysis has proven useful in studying health reform processes, and it can also be applied to the sphere of public health and regulatory action. To assess regulatory capacity for current NCD risks, it is important to ask the question: What legal attributes does the Ministry of Health or the regulatory agency need in order to regulate effectively? Starting from a basic descriptive understanding of how the processes currently work, the next questions are: What works best in risk assessment and risk management? Who does the job best? Who implements the processes? Who enforces the measures? What factors are needed for effective risk assessment? Why have some countries developed specialized agencies in the past? What are the pros and cons of the different organizational models? Are autonomous

agencies more effective than simpler structures integrated into the ministries? Are they more expensive? What organizational approaches are most successful in constraining corruption and balancing societal input and participation in regulatory processes? These analyses can only be made through international comparisons.

- (b) Process effectiveness.** An essential part of the work is to develop a research agenda to better understand how public health can most effectively deliver real risk reduction. Better understanding of the performance of the different regulatory components (risk assessment, rule-making/standards-setting, authorization and operations, design and implementation of economic instruments, enforcement, risk communication, consultation with transparency, and social participation) will provide helpful guidance to improve regulatory institutions.
- (c) Intervention effectiveness/redesign.** Identifying the optimal regulatory mix for each of the risk factor models could help to improve regulatory effectiveness and reduce cost.
- (d) Translational risk analysis methods.** Methodological approaches can be identified to simplify risk analysis for countries with less capacity, emphasizing translational research to apply basic risk analysis done internationally while making the necessary adjustments to each country's specific population characteristics.
- (e) Identify institutional practices that prevent corruption.** Research on regulatory governance, considering the specific sociopolitical history and conditions of each country, can assess the quality of rule-making, the degree of transparency, the effectiveness of check-and-balance mechanisms for eliminating excessive concentration of regulatory discretion, the need for measures to correct information asymmetry, and progress in efforts to establish accountability and meritocracy. Also, research on undue interference by the regulated sectors in regulatory policy- and decision-making is a critical factor in enhancing the public health effectiveness of these functions.
- (f) Comparative legislation.** Along with comparative institutional analysis, comparative legislative

analysis should help to identify best practices, better understand interactions between countries, determine the needed scope of regional agreements, and recognize ways in which to improve current practices.

- (g) Information needs.** Research to fill the information gaps both on NCD risks and on institutional development in the Region should be fostered and funded. Some of the areas that have been identified include: (i) information on current financial support systems for the regulation of NCD risk factors in the Region; (ii) more precise knowledge about the legislative authority behind regulatory action on NCD risk factors across the Region; (iii) a better map of subnational initiatives for NCD risk factor control; (iv) improved understanding of the economic and social impacts of regulation on other sectors; and (v) basic independent and reliable data sources in some countries or in the case of certain products—for example, much of the data on alcohol consumption comes from the alcohol industry. The first four subjects are appropriate for evaluation studies or literature/legal reviews; the last requires the creation or use of independent data sources. It is important to generate evidence that allows for an even dialog with the industries and supports informed decision-making in each country.

F.1.5. The Unique Role of the Pan American Sanitary Bureau

The PASB can work to support the Member States in the first four lines of action. Given the nature of the Bureau and its technical cooperation, there are unique functions that position it to add value:

- (a) Capacity to create and convene collaborative interaction.** The PASB can act as a convener, facilitator and coordinator of technical cooperation and research on these issues:
 - Recent experiences in promoting universal health coverage and reducing salt in food have shown the usefulness of working groups for situation analysis, identification of strategic priorities, and capacity-building at the country level.
 - The Bureau's structure, credibility, and previous experience in building networks of regulatory authorities and laboratories, developing model

legislation, and monitoring NCD risk factors position it to be a uniquely effective catalyst for progress. To enhance capabilities within the Region and eventually achieve a level playing field for all, the best strategy is for countries to seek continuous improvement and learning from one other. Those with more advanced institutional development are best equipped to help others enhance their capabilities or to serve as a reference for certain processes.

(b) Fostering stewardship, advocating for NCD risk regulation within the health sector and across government, and attracting high-level interest in other multilateral institutions are also key roles for the PASB. Given the cumulative weight of the existing foundational documents, political declarations, strategies, plans, and resolutions, it is evident that global political will to tackle the causes of the NCD epidemic has arrived.

- The PASB is well positioned to assist Ministries of Health in strengthening their stewardship role through organizational and financial innovation as well as in supporting their NCD risk regulatory entities and activities.
- The PASB is also well positioned to work with other multilateral organizations, including United Nations agencies and global, regional, and sub-regional development banks, to use their financing mechanisms to strengthen State regulatory capacity.

(c) Regional assessment of progress is already being done as part of implementation of the FCTC and needs to be expanded to cover the remaining risk factor measurements, as recommended in the global and regional action plans. The PASB should conduct a periodic review, perhaps every two years, of Member State efforts across the Region to fulfill the international commitments and recommendations targeting the four key NCD risk factors and seek to identify the factors that facilitate success or create obstacles.

(d) Development of standards of performance. The evaluation tool used with the System for Evaluation of National Regulatory Authorities of Regional Reference for Drugs and Biological Products (PAHO, 2014f) has provided countries with a standard for assessing the work of their regulatory entities and setting their own development agenda. Similar standards for the regulation process itself, together with best practices for specific NCD risks, can also serve as guides for Member States as they move forward.

(e) Development of model legislation. Model legislation can be generated to support each of the regulatory functions as well as the specific characteristics of each of the risk factors. PAHO/WHO has worked with Member States on the preparation or exchange of model legislation, regulations, and policies in a variety of areas. Examples include food hygiene (WHO/FAO, 1977), drug regulation, and model tobacco legislation (PAHO 2013d). The preparation of model legislation to implement the priority regulatory actions identified in the Global Action Plan and other WHO regulatory recommendations for the four key risk factors has been another area of technical collaboration. While models for tobacco regulation are reasonably well established, models for alcohol, food-related NCD risks, and physical activity have been emerging more recently. Resources include the World Cancer Research Fund, which is tracking legislative and regulatory action on diet through its NOURISHING framework (World Cancer Research Fund International, 2014), and the Campaign for Tobacco-Free Kids Legal Consortium, which provides an extensive database on international tobacco control legislation (Campaign for Tobacco-Free Kids. 2014).

(f) Identification and dissemination of methodological approaches and tools. Methodologies and best practices have been identified for NCD risk assessment and characterization, rule-making, enforce-

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ment, risk communication, monitoring and surveillance, interaction with the regulated parties, and social participation, and these could be usefully shared and improved. A repository and sharing of the methods best applicable to the Region could serve as guidance for the Member States in building their technical capacity.

(g) Mapping of regional institutional capacity.

Development of a tool to regularly update the status of regulatory capacity to control NCD risk factors and actions to implement recommendations will help to orient the prioritization of work with areas, countries, or collaborative partnerships.

(h) Building synergy with interrelated initiatives (road safety).

The regulation of road safety risk factors can provide real reductions in preventable

deaths and injuries. By building regulatory capacity for NCD risk factors, particularly physical inactivity and harmful use of alcohol, there is an opportunity to create synergy with the regulation of road safety risk factors. In fact, much of the capacity needed for the control of road safety is similar to that used for the control of NCD risk factors. For example, there are overlaps in legal frameworks, qualified human resources, governance structures, model legislation, risk assessment, implementation of guidelines, and multisectoral action.

G. Discussion and Conclusions

As this document has shown, Member States in the United Nations system have progressively matured their understanding of the gravity of the effects of NCDs and its risk factors over the past decade. From this growing understanding, clear goals have been formulated and a series of global and regional commitments to action have been assumed, taking the form of evidence-based policies and programmatic endeavors. These commitments range from legally binding provisions, such as the Framework Convention on Tobacco Control, to consensual recommendations adopted by the Member States through global and regional governing bodies. The body of scientific evidence on the problems and their solutions has been growing as well. While the learning process continues, a great deal is known about what needs to be done. Taking these measures will clearly have an extraordinary benefit in reducing premature mortality and suffering, as well as in freeing up resources currently spent on preventable NCDs and redirecting them toward meeting other health and societal goals. These measures should work in concert to make healthy choices the easy and natural choices in the Americas. The first successes are in: the implementation of comprehensive tobacco control policies has resulted in reductions in tobacco consumption in countries like Brazil, Canada, Panama, the United States, and Uruguay, with early benefits for cardiovascular health and the reduction of cancer. In addition, restrictions on alcohol sales in Brazilian and Peruvian cities have led to major benefits. However, unlike the delivery of health care services, many of these measures require different ways of doing business, the correction of market failures around certain products, or the planning of urban spaces, which can only be achieved through the effective use of legislation or regulation in areas where health systems have not traditionally been active. They may

involve other spheres of government, multisectoral approaches that involve taxation, economic incentives, changes in transportation systems, the engagement of agriculture or other sectors, or neighborhood planning that reaches into local government. They require education and building political will. The new sustainable development goals and the international mandates that have been agreed upon (the global and regional action plans on NCDs and the regional Plan of Action for the Prevention of Obesity in Children and Adolescents) will not be met without robust use of regulatory measures alongside education and supportive programs.

This document has addressed regulation, a field that has traditionally been dominated by legal and economic perspectives, from the standpoint of public health. It recognizes the role of regulation, which for years has been ignored or treated only as a peripheral component of the health system, and not as an essential public health function. The present technical reference document seeks to bring the role of regulation back to center stage in the discussion on building effective public health systems.

Many limitations and challenges were encountered in the preparation of this document. We acknowledge that not all the regulatory institutions nor all the countries were included, as this is part of our current incomplete knowledge of the region. There is a lack of detailed information on institutional design and capacity for the regulation of NCD risk factors in the Americas. The information available permitted only a superficial examination of conditions in the Region. Monitoring of the implementation of existing policies and regulations is limited. Despite the WHO constitutional mandate to report on the enactment of health laws and legislation, this practice fell into disuse several decades ago and the

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database on health-related legislation and regulation in the Region is far from complete. Nor is there a clear legislative framework to offer to Member States for their action. Information is also lacking on the human resources available, their training, and the technology to support their actions. Similarly, there is a shortage of detailed information on best practices for enhancing and modernizing the governance processes, for tackling corruption, and for increasing public trust in the role of the State.

Future work will need to address the issue of equity in greater depth. How can regulation be used most effectively to target and benefit the populations that are particularly vulnerable to the burden of NCDs? There was not enough information to explore this issue, but it should be clear from the present document that Member States, in addition to protecting their citizens from the harm caused by NCD risk factors, should see themselves as having a particular responsibility to close the gap between the most and the least healthy in society.

The institutional systems to support this work are still somewhat weak in most of the countries. Capacity-building is needed at the political, institutional, and technical levels, ranging from the ability to assess a problem to being able to choose solutions and enforce their implementation.

In short, the health sector and the Member States as a whole need not only to understand the science and solutions around implementing specific interventions to address the major risk factors of tobacco, dietary risks, alcohol, and physical inactivity, but also to develop their capacity as effective legislators and regulators. This capacity includes the ability to identify and assess the risks for their countries, select the best strategies to mitigate those risks and the sequence of implementation, document their reasoning and their choices with unassailable competence, listen to their communities and stakeholders while not yielding to vested interests, implement and enforce their chosen measures effectively, and monitor and evaluate their results. In many countries of the Region this capacity is still very limited, and like the capacity to effectively deliver universal health care, it must be built and nurtured as part of the institutional structure of health systems and governments.

We have shown in this document that the costs from NCDs challenge the viability and universality of health systems, as well as the economic development of communities and countries. Clearly, the magnitude of the impact of NCDs on health and on economic security creates an ethical responsibility to act. People's choices, and their health, are deeply influenced by the products on the market and the way they are promoted, priced, and distributed. Many unhealthy products are poorly regulated. **Where the market fails to uphold its responsibility, regulation by government is ethically justified, and failure to act comes at a high price.** Successful and sustainable policies will be best produced through a combination of public leadership and a strong, well-informed civil society, mediated by a relationship of trust.

Ten of the 15 WHO “best buys,” or “very cost-effective” interventions, for reaching the global NCD goals require regulatory action. Appropriate use of regulation will help to eliminate risks through primary prevention and to diminish them through secondary prevention, by improving the survival and quality of life of patients already living with NCDs. **Good regulation can also promote a market that is fairer and functions more effectively by creating a level playing field**—one in which producers who act ethically to protect health are not at a disadvantage.

The Organization's innovative **REGULA initiative** seeks to support countries in improving their capacity to regulate the risk factors for NCDs. It will advance technical cooperation between countries in building their capacity for stewardship. The proposed five lines of action—organizational development, technical capacity, evaluation, research, and the role of the Pan American Sanitary Bureau—provide a broad menu of actions for countries to choose from, and the Bureau stands ready to support them in their work. Through these efforts, we can play a key role in achieving the goals for risk reduction throughout the Americas by 2025.

When Ministers of Health and Heads of State and Government choose to take up the reins of leadership, they are unstoppable. The health argument is irrefutable and the need for action is immediate. ■

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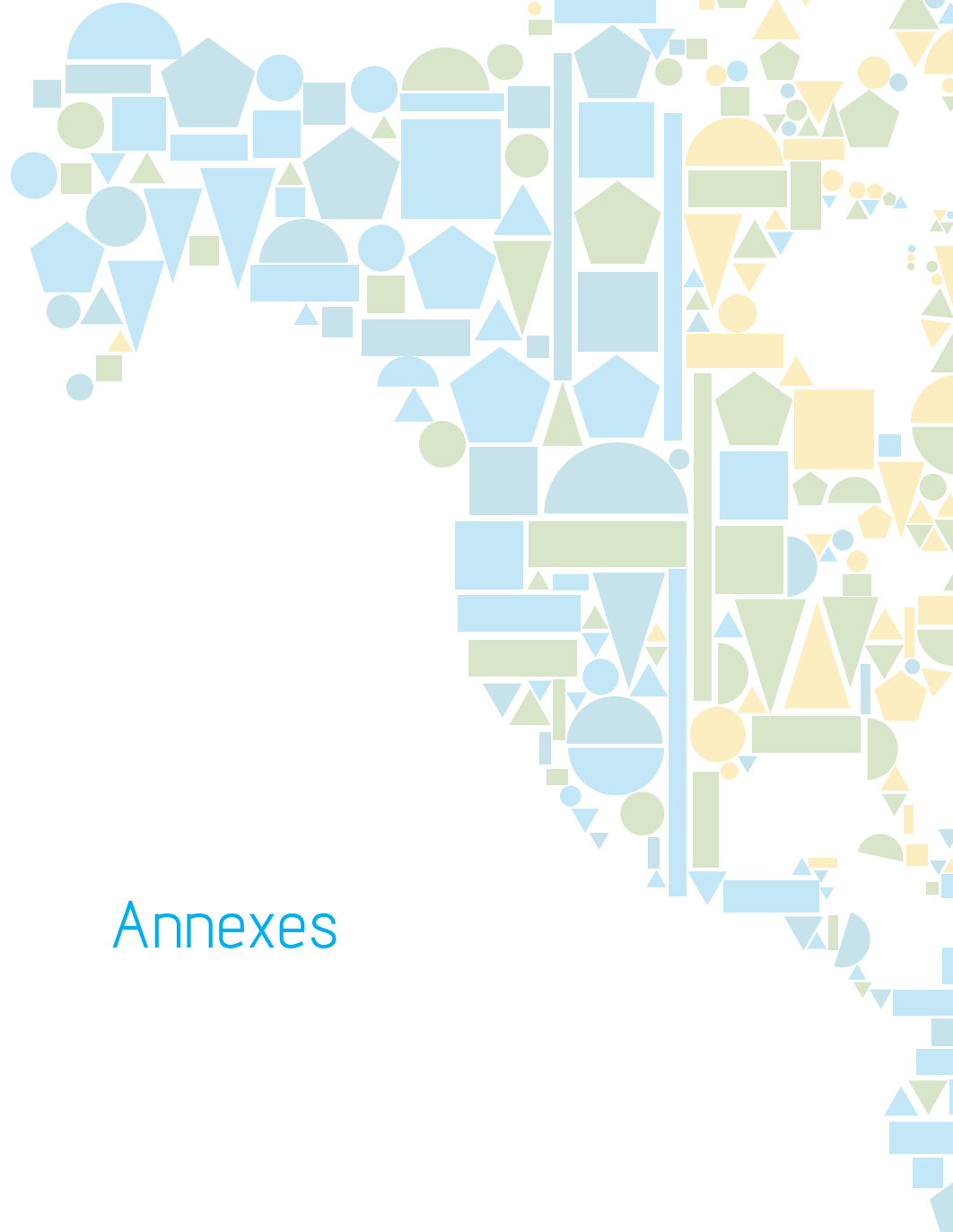
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Annexes

Annex 1: Country Capacity Survey — Results for NCD Risk Factor Plans (2013)

Country	Alcohol		Diet		Physical activity		Tobacco		Overweight	
	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented
Northern America										
Canada	no		operational	2010	operational	2005	operational	2001	operational	2010
United States	operational	2010	operational	2010	operational	2010	operational	2010	operational	2010
Mexico, Central America, and Latin Caribbean										
Costa Rica	under development		operational	2012	operational	2012	operational	2012	under development	
Cuba	operational	2002	under development		operational	2000	operational	2002	operational	2008
Dominican Republic	no		no		no		no		no	
El Salvador	operational	2012	under development		under development		operational	2006	under development	
Guatemala	no		no		under development		operational	2008	under development	
Honduras	no		no		no		operational	2010	no	
Mexico	don't know		operational	2010	under development		don't know		under development	
Nicaragua	no		no		no		operational	2010	under development	
Panama	operational	2008	operational	2007	operational	2010	operational	2008	operational	2009
Puerto Rico	operational	1972	operational	2013	operational	2005	operational	2008	operational	2007
South America										
Argentina	operational	2011	operational	2008	operational	2011	operational	2004	operational	2012
Bolivia	operational	2007	no		no		operational	2007	no	
Brazil	no		operational	1999	operational	2011	operational	1997	under development	
Chile	operational	2010	operational	2005	operational	2011	operational	2005	operational	2011
Colombia	operational	2011	operational	2011	operational	2011	operational	2011	under development	211

Country	Alcohol		Diet		Physical activity		Tobacco		Overweight	
	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented	Status of Plan	Implemented
South America (continues)										
Ecuador	operational	2012	no		no		operational	2011	no	
Paraguay	not in effect		under development		operational	2013	operational	2005	no	
Peru	operational	2012	under development		under development		under development		under development	
Uruguay	no		under development		operational	2009	operational	2005	no	
Venezuela	under development		don't know		under development		operational	1984	under development	
Non-Latin Caribbean										
Anguilla	no		no		operational	2012	no		operational	2012
Barbados	no		operational	2010	operational	2012	operational	2010	operational	2009
Belize	under development		no		no		no		no	
British Virgin Islands	no		no		operational	2006	operational	2006	no	
Dominica	no		under development		no		operational	2006	no	
Grenada	no		no		no		no		no	
Jamaica	no		no		no		under development		no	
Montserrat	not in effect		operational	2012	under development		no		operational	2012
Saint Kitts and Nevis	no		no		no		no		no	
Saint Lucia	no		no		no		no		no	
Suriname	no		no		no		under development		no	
Trinidad and Tobago	no		under development		operational	2012	operational	2012	operational	2012
Percentage with operational plans	31%		33%		42%		61%		31%	

Annex 2: Country Capacity Survey — Results for Surveillance (2013)

Country	Alcohol			Fruits and vegetables			Salt			Physical inactivity			Tobacco			
	Adolescent	Year	Adult	Year	Adult	Year	ANY	Year	Adolescent	Year	Adult	Year	Adolescent	Year	Adult	Year
Northern America																
Canada	yes	2012	yes	2012	yes	2012	yes	2004	yes	2012	yes	2012	yes	2012	yes	2012
United States	yes	2012	yes	2012	yes	2011	yes	2004	yes	2012	yes	2011	yes	2012	yes	2012
Mexico, Central America, and Latin Caribbean																
Costa Rica	yes	2009	yes	2010	yes	2010	no		yes	2010	yes	2009	yes	2010	yes	2010
Cuba	yes	2010	yes	2010	no		no		no	2010	yes		no	2010	yes	2010
Dominican Republic	yes	2009	yes	2011	no		no		no		no		no		yes	2008
El Salvador	no		yes	2004	no		yes	2004	no	2004	yes		yes	2004	yes	2004
Guatemala	yes	2009	yes	2010	yes	2009	no		yes	2011	yes	2009	yes	2010	yes	2010
Honduras	yes	2012	yes	2012	yes	2012	no		yes		no	2012	yes		no	
Mexico	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012
Nicaragua	no		no	2010	no		yes		no		no		no		no	
Panama	no		yes	2010	no		no		no		yes		yes	2012	yes	2013
Puerto Rico	yes	2011	yes	2012	yes	2011	no		yes	2011	yes	2011	yes	2012	yes	2012
South America																
Argentina	yes	2012	yes	2011	yes	2012	yes	2012	yes	2009	yes	2012	yes	2009	yes	2012
Bolivia	yes	2012	no		yes	2012	no		yes		no	2012	yes		no	
Brazil	yes	2012	yes	2008	yes	2012	yes	2009	yes	2008	yes	2012	yes	2008	yes	2008
Chile	yes	2010	yes	2010	no		yes	2010	no		yes		yes	2010	yes	2010
Colombia	yes	2011	yes	2008	yes	2011	yes	2011	yes	2011	yes	2007	yes	2007	yes	2007
Ecuador	yes	2010	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012	yes	2012
South America (continues)																

Country	Alcohol			Fruits and vegetables			Salt		Physical inactivity			Tobacco			
	Adolescent	Year	Adult	Adolescent	Year	Adult	ANY	Year	Adolescent	Year	Adult	Adolescent	Year	Adult	Year
Paraguay	no		yes	no		yes	yes	2011	no		no	no		yes	2011
Peru	yes	2010	yes	yes	2010	no	no		yes	2010	yes	yes	2010	yes	2009
Uruguay	yes	2012	yes	yes	2012	yes	yes	2006	yes	2012	yes	yes	2012	yes	2006
Venezuela	yes	2009	no	yes	2008	dk	no		yes	2008	dk	yes	2010	yes	2011
Non-Latin Caribbean															
Anguilla	yes	2009	no	yes	2009	no	no		no		no	yes	2009	no	
Antigua and Barbuda	yes	2009	no	yes	2009	no	no		yes	2009	no	yes	2009	no	
Bahamas	no		yes	no		yes	yes	2011	no		yes	yes	2009	yes	2011
Barbados	yes	2011	yes	yes	2011	yes	yes	2013	yes	2011	yes	yes	2011	yes	2013
Belize	yes	2011	yes	yes	2011	yes	no		yes	2011	yes	yes	2008	yes	2006
British Virgin Islands	yes	2009	yes	yes	2009	yes	no		yes	2009	yes	yes	2009	yes	2009
Dominica	yes	2009	yes	yes	2009	yes	no		yes	2009	yes	yes	2009	yes	2008
Grenada	yes	2008	yes	yes	2008	yes	no		yes	2008	yes	yes	2008	yes	2011
Jamaica	yes	2010	yes	yes	2010	yes	no		yes	2006	yes	yes	2010	yes	2007
Montserrat	yes	2008	yes	yes	2011	no	no		yes	2011	no	yes	2011	no	
Saint Kitts and Nevis	yes	2006	yes	yes	2011	yes	no		yes	2011	yes	yes	2010	yes	2008
Saint Lucia	yes	2007	yes	yes	2012	yes	yes	2012	yes	2007	yes	yes	2011	yes	2012
Suriname	yes	2009	yes	yes	2009	no	no		yes	2009	no	yes	2009	no	
Trinidad and Tobago	yes	2011	yes	yes	2011	yes	yes	2011	yes	2011	yes	yes	2011	yes	2011
Percentage with survey	86%		86%	78%		69%	42%		75%		69%	92%		81%	



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