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Cost-benefit analyses in trade regulation: How to assess the health impacts of non-tariff measures?

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Abstract

Non-tariff measures (NTMs) have become an important element of international trade negotiations. Assessments of NTMs usually focus on economic impacts. However, by employing the concept of a cost-benefit framework, NTMs can be analysed beyond purely economic impacts to include social or environmental impacts. To compare these non-market impacts of an NTM with its economic impacts, all the costs and benefits of an NTM need to be expressed in one common metric. In the case of cost-benefit analyses, the common metric is achieved by monetising all costs and benefits. For this purpose, non-monetary and monetary methodologies can be combined to quantify and monetise non-economic impacts.

The impacts of technical regulations on health can be one example for non-market impacts of NTMs. This paper assesses how NTMs can be evaluated within a cost-benefit framework to provide a basis for policy decisions. The theoretical concepts of cost-benefit frameworks are analysed and compared with their practical application in the European Union. The paper also makes a critical assessment and evaluation of the cost-benefit framework and methodologies in order to value the impacts of NTMs on health in developing countries.

Declaration

This master paper has been written in partial fulfilment of the Master of International Law and Economics Programme at the World Trade Institute. The ideas and opinions expressed in this paper are made independently, represent my own views and are based on my own research. I confirm that this work is my own and has not been submitted for academic credit in any other subject or course. I have acknowledged all material and sources used in this paper. I understand that my paper may be made available in the World Trade Institute library.

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List of Abbreviations

AVE	ad-valorem equivalent
COI	cost of Illness
DALY	disability-adjusted life year
DG	Directorate-General
DG EMPL	Directorate-General for Employment, Social Affairs & Inclusion
DG ENV	Directorate-General for the Environment
DG SANCO	Directorate-General for Health and Consumers
DWL	deadweight loss
EC	European Commission
EFSA	European Food Safety Agency
EU	European Union
EUR	Euro
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Trade and Tariffs
GDP	gross domestic product
HIA	health impact assessment
HRQL	health-related quality of life
IMF	International Monetary Fund
ITC	Intentional Trade Center
MAST	Multi- Agency Support Team
NTB	non-tariff barrier
NTM	non-tariff measure
OECD	Organisation for Economic Cooperation and Development
QALY	quality-adjusted life year
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SPS	sanitary and phytosanitary
TBT	technical barriers to trade
TPD	Tobacco Products Directive
TSIA	Trade Sustainability Impact Assessment Guide
TTIP	Transatlantic Trade and Investment Partnership
UK	United Kingdom
UNCTAD	United Conference on Trade and Development
UNIDO	United Nations Industrial Development Organization
US	United States
USD	US Dollar
VSL/VOSL	value of a statistical life
VSLY/VOSLY	value of a statistical life year
WHO	World Health Organization
WTA	willingness-to-accept
WTO	World Trade Organization
WTP	willingness-to-pay

Introduction

Tariffs have progressively been reduced since the General Agreement on Trade and Tariffs (GATT) came into force in 1947.[1] In contrast, the proliferation and importance of non-tariff measures (NTMs) has increased significantly over the past decades.[2] As a consequence, the reduction of non-tariff barriers (NTBs) and the harmonization of NTMs has become an important factor of negotiation in multilateral, regional and bilateral trade agreements. A current example is the negotiation of the Transatlantic Trade and Investment Partnership (TTIP) between the European Union (EU) and the United States (US) which has led to significant public controversy over predicted reductions of NTBs and harmonisations of NTMs.[3]

During trade negotiations, governments must decide which NTMs they are willing to reduce and which NTMs they may want to maintain. Negotiations clarify which NTMs will be harmonized, converged or negotiated regarding mutual recognition agreements. The question remains how these decisions should be made? In order to make a thorough decision about which NTM could be eliminated and which NTM should be maintained, a government can, for example, compare the costs of an NTM with its benefits. This cost-benefit analysis can reveal if the benefits of the NTM outweigh its costs or vice versa. In order to make costs and benefits comparable, however, they need to be expressed in one common metric. Thus, costs and benefits both need to be quantified and monetised.

In particular NTMs in the form of technical regulations often provide non-economic benefits to the society as they aim to overcome market failures and pursue an underlying policy objective such as the protection of human health. These non-economic welfare benefits of an NTM are, however, difficult to quantify and monetise. As the share in international trade is steadily increasing for developing countries[4], there remains a need for an understanding of technical regulations by the governments of developing countries. On the one hand, trading partners often request the reduction of trade barriers, such as technical regulations, but on the other hand societies request that these technical regulations are maintained to protect the environment, public health or increase food safety. Thus, the question of how to assess the impacts of NTMs when deciding on their reduction (achieved by elimination, harmonization or recognition of equivalence) or maintenance is also highly relevant for developing countries. When taking into account that developing countries face different conditions for policy-making, the question remains whether the existing frameworks and methodologies are suitable in this context?

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[1] World Trade Organization (WTO), *World* Trade *Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century* (Geneva: World Trade Organization, 2012), 37.
[2] John C. Beghin, "Introduction and Main Findings," in *Non Tariff Measures with Market Imperfections: Welfare Implications*, ed. John C. Beghin, Frontiers of Economics and Globalization (Bingley, West Yorkshire: Emerald Group Publishing Limited, 2013), 3.
[3] "EU-US Trade Talks Resume amid Controversy," *Deutsche Welle (DW)*, accessed October 26, 2014, http://www.dw.de/eu-us-trade-talks-resume-amid-controversy/a-17485417.
[4] Olivier Cadot, Mariem Malouche, and Sebastian Saez, *Streamlining Non-Tariff Measures: A Toolkit for Policy Makers* (Washington, D.C.: International Bank for Reconstruction and Development/World Bank, 2012), 12.

At present many scholars discuss how the economic costs of NTMs can be analysed. Yet little has been written on how social impacts of NTMs beyond their economic costs can be determined, evaluated and quantified.[5] At the time of writing, there exists one main research paper which provides a detailed analysis of a cost-benefit framework specifically for NTMs: Beghin, J. & Marette S. & van Tongeren, F. "A Cost Benefit Framework for the Assessment of Non-Tariff Measures in Agro-Food Trade*", OECD Food, Agriculture and Fisheries Working Papers*, No. 21, OECD Publishing, 2009. This framework makes a comparison of the trade costs of NTMs with its non-trade benefits. Apart from this NTM specific cost-benefit framework, existing research concentrates on frameworks and methodologies for cost-benefit analyses of regulations in general. Such cost-benefit analyses are usually part of some form of regulatory impact assessment. As NTMs are policy measures with a potential impact on trade and are part of domestic regulations, this literature is used for this paper to assess how health benefits of regulations in general and thus also NTMs can be assessed.

The central research question of the paper asks how health impacts of NTMs can be assessed within a cost-benefit analysis. Impacts can consist of negative or positive impacts, i.e. costs or benefits. In order to answer this question the paper discusses the concept of cost-benefit analysis and presents methodologies to quantify and monetise health impacts for general regulations. Furthermore, it presents a concrete example of how the European Commission (EC) carries out cost-benefit analyses for regulatory impact assessments and how it has assessed the health impacts of three different regulations. For this purpose an online research was carried out on the EU impact assessment website and requests for examples were sent to staff of the Directorate-General (DG) for Trade, DG Health and Consumer Policy (DG SANCO) and DG Environment (DG ENV). Finally, the paper analyses whether these approaches and methodologies for the assessment of regulatory health benefits are also suitable for developing countries. As sanitary and phytosanitary (SPS) measures are one of the most frequently encountered types of NTM[6] and these measures address human, animal and plant life or health, the paper focuses on SPS measures on trade in goods and how to assess regulatory impacts for human health. Given the objective of SPS measures to protect human, animal and plant life or health, it is assumed that the impacts on health of such an NTM would usually be beneficial.

The monographic design and qualitative research approach of this paper deals with one specific research topic in depth, providing descriptive and analytical content. The research methodology consists of a single case study of the EU framework for cost-benefit analyses because the EU has developed a sophisticated cost-benefit framework and uses established methods to assess regulatory health benefits. This case study not only serves as a descriptive model but also provides a problem-solving purpose as the paper aims to draw conclusions about the transferability of this approach to developing countries.

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[5] Simon Schlueter et al., *Assesment of the Impacts of Non-Tariff Measures (NTM) on the Competitiveness of the EU and Selected Trade Partners: Analytical Framework for the NTM Impact Project*, NTM Impact Working Paper 09/02, (2009), 43, https://lirias.kuleuven.be/handle/123456789/284481.

[6] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 8.

The availability of publicly accessible information regarding the EU approach was expected to be a risk at the beginning of the research, but it turned out that the EU impact assessment procedures are well documented and very transparent. In contrast, it was a challenge to find well documented practical examples of EU impact assessments which quantify and monetise regulatory health benefits. When searching the online archive of European impact assessments, it became clear that few EU impact assessments quantify and monetise non-economic impacts and even less examples were found which specifically quantify and monetise regulatory health benefits.

Finally, the paper is structured as follows: the first chapter gives an overview of the most important concepts concerning NTMs. It defines an NTM, explains the classification as well as the trade effects of NTMs and presents a framework to determine whether an NTM is legitimate or whether a protectionist objective is pursued alongside it. The second chapter deals with the concept of cost-benefit analysis in detail. It includes a description of the parameters which must be taken into account, as well as of the methodologies which can be used to measure, i.e. quantify or monetise, health benefits of regulations. The third chapter analyses the EU impact assessment framework and describes three impact assessments which show how health benefits have been evaluated within that framework and which methodologies have been used for that purpose. In the last chapter, suggestions will be made about how developing countries can approach the assessment of regulatory health benefits.

1 The concept of non-tariff-measures

The following chapter will describe and clarify the most important concepts regarding NTMs. It will provide definitions as well as the Multi- Agency Support Team (MAST) classification of NTMs and explain why governments apply NTMs. The chapter shows what the possible effects of NTMs on trade and welfare can be. Finally, it analyses how NTMs can be evaluated in order to decide whether they are "good" or "bad", i.e. whether they have a legitimate or a protectionist objective.[7]

1.1 Definition and classification of NTMs

Definition of NTMs

The concept of NTMs is difficult to define as it can refer to a large variety of policy measures. Thus, the available definitions are very broad in their scope and quite similar.

The Organisation for Economic Cooperation and Development (OECD), in 2005, considered "all measures other than tariffs that restrict or otherwise distort trade flows" as relevant for its report on NTMs.[8] In the World Trade Report 2012 the World Trade Organization (WTO) defined NTMs in a similar way, describing them as policy measures other than tariffs which potentially affect trade.[9] Additionally, the World Trade Report has considered NTMs affecting services as "services measures" in its analysis. [10] Another recent and often used definition is the MAST definition provided by the United Conference on Trade and Development (UNCTAD) which describes NTMs as „policy measures, other than ordinary customs tariffs, that can potentially have an economic effect on international trade in goods, changing quantities traded, or prices or both".[11]

Overall the concept of NTMs generally refers to any policy measure at the border of a country or behind the border which can potentially impact international trade and which is not a tariff. Measures affecting trade in services have thereby been considered and analysed less often than measures affecting trade in goods. As NTMs constitute complex legal texts and regulations and rarely representation in figures, such as tariffs, they are difficult to compare and quantify.[12] Therefore, in 2005 the OECD suggested the future development of a widely accepted classification system for NTMs.[13]

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[7] Ibid., 50.
[8] Organisation for Economic Cooperation and Development (OECD), *Looking Beyond Tariffs: The Role of Non-Tariff Barriers in World Trade*, OECD Trade Policy Studies (Paris: OECD, 2005), 11.
[9] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 38.
[10] Ibid.
[11] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures: Evidence from Selected Developing Countries and Future Research Agende* (New York and Geneva: United Nations, 2010), xvi.
[12] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 9.
[13] Organisation for Economic Cooperation and Development (OECD), *Looking Beyond Tariffs: The Role of Non-Tariff Barriers in World Trade*, 11.

The MAST classification

In 2012 UNCTAD and the Group of Eminent Persons on Non-tariff Barriers supported by the Multi- Agency Support Team (MAST) established a comprehensive NTM classification to improve data collection and the analysis of NTMs.[14] This classification covers all measures considered to be relevant for international trade in goods and aims at a better distinction and identification of NTMs as well as the establishment of a system which allows data collection and monitoring in a database format.[15] Subsequently, it enables the provision of better and more transparent information for governments and exporters.[16] The MAST system classifies NTMs in two broad groups: import-related and export-related measures. Import-related NTMs are further sub-divided in chapters for technical (sanitary and phytosanitary (SPS) measures, technical barriers to trade (TBTs) and pre-shipment inspection and other formalities) and for non-technical more traditional policy measures (e.g. contingent trade-protective measures, non-automatic licensing, price-control measures, subsidies and rules of origin).[17] These chapters are sub-divided into groupings according to a tree structure with up to three further levels of subdivision.[18]

Table 1-1: Overview NTM classification[19]

NTM CLASSIFICATION BY CHAPTER		
IMPORTS	**TECHNICAL MEASURES**	A Sanitary and Phytosanitary Measures B Technical Barriers to Trade C Pre-Shipment Inspection and Other Formalities
	NON-TECHNICAL MEASURES	D Contingent Trade-Protective Measures E Non-Automatic Licensing, Quotas, Prohibitions and Quantity-Control Measures other than for SPS or TBT Reasons F Price-Control Measures, including Additional Taxes and Charges G Finance Measures H Measures Affecting Competition I Trade-Related Investment Measures J Distribution Restrictions K Restrictions on Post-Sales Services L Subsidies (Excluding Export Subsidies under P7) M Government Procurement Restrictions N Intellectual Property

[14] United Nations Conference on Trade and Development (UNCTAD), *Classification of Non-Tariff Measures: February 2012 Version* (New York and Geneva: United Nations, 2013), 1.
[15] Ibid.
[16] Ibid.
[17] Ibid., 3.
[18] Ibid., 2.
[19] Ibid., 3.

		O Rules of Origin
EXPORTS		P Export-Related Measures

The MAST classification system has three main advantages: Firstly, it provides an elaborate database format which facilitates NTM data collection, quantification and comparison. Secondly, the classification system has been agreed upon by the MAST group consisting of several international organizations (FAO, IMF, ITC, OECD, UNCTAD, UNIDO, World Bank, WTO) which ensures that a common classification system is accepted and used among different institutions.[20] Thirdly, UNCTAD delivers training courses on NTM data collection for trade experts from developing countries[21] based on the MAST classification system and coordinates these efforts with Intentional Trade Center (ITC) and World Bank data collection.[22] These joint efforts contribute to improving NTM data availability, which is an important challenge for NTM analysis.

SPS measures and TBTs

Scholars have found that technical regulations are the most prevalent and the most export impeding trade barriers.[23] SPS measures and TBTs generally occur in the same sectors across all countries as they refer primarily to product characteristics which are similar in all countries.[24] SPS measures are usually applied in the agricultural sector to food-related goods. TBTs, however, can be applied to a broader range of sectors and goods, and are often found related to textiles, footwear, processed food and chemicals.[25] The World Trade Report 2012 finds that technical regulations are more likely than other NTMs to have adverse trade effects and to create tension between producers and consumers as "essential policy aspirations, such as ensuring the health, safety and well-being of consumers, for example, may have adverse trade effects considered by some parties as indefensible on public policy grounds".[26] Taking into account the prevalence of SPS measures and TBTs as well as the controversy regarding their welfare benefits and trade costs, this paper will focus on SPS measures and TBTs concerning trade in goods.

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[20] Ibid., 1.
[21] United Nations Conference on Trade and Development (UNCTAD), "New Online Training Course on Non-Tariff Measures to Be Launched by UNCTAD," accessed October 26, 2014, http://unctad.org/en/pages/newsdetails.aspx?OriginalVersionID=787.
[22] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 7.
[23] Julien Gourdon and Alessandro Nicita, "Non-Tariff Measures: Evidence from Recent Data Collection," in *Non-Tariff Measures - A Fresh Look at Trade Policy's New Frontier*, ed. Olivier Cadot and Mariem Malouche (Washington, D.C.: International Bank for Reconstruction and Development/World Bank, 2012), 66.
[24] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 17.
[25] Ibid.
[26] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 37.

1.2 Government motives for NTM application

Governments have different motives to apply NTMs. The trade literature generally divides NTMs according to the underlying intentions into two main groups: NTMs motivated by the aim to increase national welfare and NTMs motivated by political economy motives.[27]

NTMs intended to increase national welfare

The first set of NTMs, which aim at increasing national welfare (for an explanation of the welfare concept see subchapter 2.3.3), is motivated by legitimate public policy objectives such as the protection of public health, safety, the environment, infant industries or the regulation of imperfect competition in the domestic market.[28] In order to pursue these objectives, governments apply NTMs to address market failures. Market failures are situations where the market does not provide the desired outcome.[29] This can be the case when following the individual interest of an economic subject leads to a sub-optimal outcome from a collective perspective.[30] The most common market failures discussed in relation to NTMs are information asymmetries, production and consumption externalities and global common issues.[31]

The first type of market failure which can be addressed by NTMs are information asymmetries.[32] In this case some parties to an economic transaction have an informational advantage over other parties - leading to an inefficient market outcome.[33] This occurs, for example, if producers from different countries market the same product with different safety or quality standards. Uninformed consumers with different preferences for high- and low-quality products do not possess enough information about these product differences and are unwilling to pay more for the higher-quality products.[34] Hence, the average product quality and welfare in the higher-quality producing country will decrease as a result of trade with a low-quality producing country.[35] The optimum policy option in this case would be a labelling requirement which allows consumers to distinguish between the qualities of different product.[36]

The second type of market failure which can be addressed by NTMs are negative externalities.[37] A negative externality describes a situation where an economic agent does not fully internalize all the costs of its activity, creating additional costs for agents or the

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[27] Ibid., 50.
[28] Ibid., 53–56.
[29] John C. Beghin et al., *Measuring Costs and Benefits of Non-Tariff Measures in Agri-Food Trade*, Working Paper No. 11001 (Ames, Iowa: Iowa State University, Department of Economics, 2011), 2; Horst Hanusch, *Nutzen-Kosten-Analyse*, 3rd ed. (München: Franz Vahlen, 2011), 3.
[30] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 41.
[31] Beghin et al., *Measuring Costs and Benefits of Non-Tariff Measures in Agri-Food Trade*, 6–10.
[32] Beghin, "Introduction and Main Findings," 3.
[33] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 53.
[34] Ibid., 54.
[35] Ibid.
[36] Ibid.
[37] Beghin, "Introduction and Main Findings," 3.

environment which are not involved in the activity.[38] As a consequence, the scale of the agent's activity exceeds the social optimum.[39] Negative externalities can arise in the context of environmental pollution. In this case, a government could intervene by applying performance standards, emission quotas, or requiring mandated technologies.[40]

Other market failures which justify government interventions and the application of NTMs are positive externalities (e.g. infant industry protection which enables the spill-over of dynamic learning effects to other sectors of the economy)[41], network effects and imperfect competition (e.g. monopoly power).[42]

NTMs aiming at increasing national welfare can also be motivated by beggar-thy-neighbour policies.[43] These policies aim at increasing national welfare at the expense of other countries' welfare by either improving the home country's terms of trade, or by increasing a home firm's profits.[44] A country with sufficient international market power can, for example, use NTMs to improve its terms of trade, i.e. to improve the ratio of its export to import prices, and thereby increase its national welfare.[45] Furthermore, a country can use NTMs as TBT or SPS measures which are adapted to the home firm's production processes and thus weigh more heavily on foreign firms.[46] As a result these NTMs would provide production cost advantages and increase market shares for the home country firm.

Further less obvious government motives to use NTMs are trade competitiveness concerns or policy substitution motives.[47] Both motives aim at improving the home countries' position in international trade. The latter motive specifically intends to use certain NTMs when tariffs or the use of other NTMs is restricted by international trade agreements.[48] Assuming the underlying government rational for these motives rather is to increase overall national welfare than to satisfy the political economy concerns of specific interest groups, these types of NTMs are also described here within the group of welfare increasing NTMs.

NTMs motivated by political economy goals

The second set of NTMs is motivated by political economy goals corresponding to concerns of special interest groups.[49] Rather than increasing social welfare, governments may use NTMs as a response to pressures from specific interest groups which depend on government

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[38] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 54.
[39] Ibid.
[40] Ibid.
[41] Ibid., 55.
[42] Ibid., 56.
[43] Ibid.
[44] Alan V. Deardorff and Robert Mitchell Stern, *Measurement of Nontariff Barriers* (Michigan: University of Michigan Press, 1998), 1.
[45] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 56.
[46] Ibid., 58.
[47] Ibid., 50.
[48] Ibid.
[49] Avinash Dixit, Gene M. Grossman, and Elhanan Helpman, "Common Agency and Coordination: General Theory and Application to Government Policy Making," *Journal of Political Economy* 105, no. 4 (August 1997): 762.

support or financial contributions.[50] These interest groups can be domestic producers, domestic importers, domestic consumer groups or foreign exporters whose interests may differ significantly.[51] Domestic producers, for example, will favour import restrictions in the form of import tariffs or quotas. Moreover, they will favour SPS measures and TBTs which drive foreign firms out of the domestic market and allow domestic producers to increase their market shares and profits.[52] The concerns of domestic consumer groups are mainly reflected in public policy objectives regarding the protection of public health and safety.[53]

In sum, the World Trade Report 2012 distinguishes NTMs according to where the pressure to take regulatory action comes from and divides NTMs and the underlying government motives into two groups: interventions intended to increase national welfare due to public interests and interventions motivated by political economy concerns to satisfy pressure from specific producer or consumer groups.[54]

NTMs could also be classified regarding their "legitimate" or "protectionist" use which would lead to a distinction between two sets of NTMs. One set of NTMs aims at legitimate non-trade-related public policy objectives and another set of NTMs aims at trade-related protectionist objectives such as satisfying political economy concerns of certain interest groups or pursuing NTMs as an instrument of policy substitution for tariffs. In practice, however, the detection of government motives and a distinction between legitimate and protectionist NTMs is very difficult. The challenges of today's trading environment, such as increased global production networks and increased consumer concerns regarding food and product safety, contribute to an increased pressure on governments to apply NTMs.[55] As a consequence, it becomes more and more difficult to distinguish the underlying objectives of NTMs and to decide whether a specific NTM is legitimate or whether it is misused for protectionist purposes. NTMs applied due to public policy objectives are generally not aimed at impacting trade or trade policy, but due to their increase they are becoming an important trade policy tool, even though their original objective might be a different one.[56] Irrespective of the underlying motives and irrespective of whether trade effects are the primary goal or a by-product of the NTM, in the end all NTMs have trade effects.[57]

1.3 Trade and welfare effects of NTMs

Trade effects of NTMs

Non-tariff measures can have trade-restrictive effects as they can increase the costs for foreign exporters as well as for domestic companies and domestic consumers. Specifically, technical

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[50] Ibid.
[51] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 50, 59.
[52] Ibid., 59, 60.
[53] Beghin, "Introduction and Main Findings," 3.
[54] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 50.
[55] Ibid., 37.
[56] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 13.
[57] *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 51.

regulations like SPS measures and TBTs can increase the fixed costs for foreign producers as they are required to adapt the products and/or production process to the specific product requirements in the export market.[58] Furthermore, conformity assessment procedures may lead to additional costs.[59] The effect is that the additional trade-related costs will make exporters' products less competitive in the export market.[60] The impacts of technical regulations are thereby more difficult to measure than those of quantity and price control measures as the former have more diverse and complex effects than simply price-raising and quantity-reducing effects as will be shown below.[61]

A simple partial equilibrium model showing the supply and demand for a certain good demonstrates the price and quantity changes and thus the trade-restrictive effects of NTMs.[62] The theoretical framework developed by Disdier and Marrette[63] below describes a domestic market with one homogeneous good which is only differentiated by one characteristic that is potentially dangerous for consumers' health. Furthermore, three assumptions are made for reasons of simplicity: [64] firstly, it is assumed that consumers have internalized the damage in consuming the good in their demand curve. Secondly, the good with the dangerous characteristic is produced only by foreign producers. Thirdly, the additional costs to comply with the standard are variable costs per unit of the good and not fixed costs as the latter would lead to a non-linear supply curve.

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[58] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 18.
[59] Ibid.
[60] Ibid.
[61] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries* (New York and Geneva: United Nations, 2013), 17, 18.
[62] Ibid., 18.
[63] A. C. Disdier and S. Marette, "The Combination of Gravity and Welfare Approaches for Evaluating Nontariff Measures," *American Journal of Agricultural Economics* 92, no. 3 (April 1, 2010): 713–26.
[64] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 19, 20.

Figure 1-1: Trade effects of a public SPS standard[65]

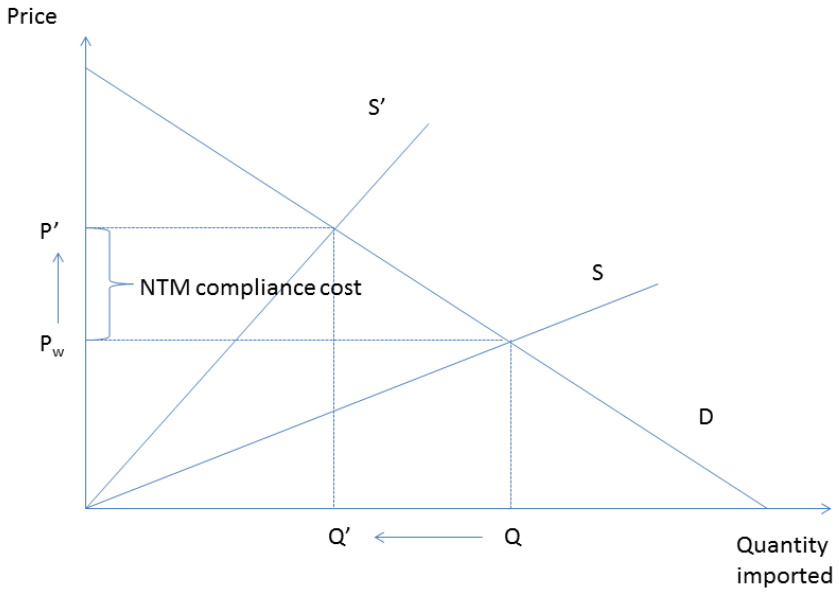

Figure 1-1 shows the effect of a public standard applied to this good to avoid negative health effects for consumers. The standard creates compliance costs for the foreign firms which increases its production costs and shifts its supply curve to the left (S -> S'). As a result of the increased costs and the decrease in supply, the price for consumers will increase above the world price (P_w -> P') and the imported quantity will decrease (Q -> Q'). This demonstrates in a simplified framework how an SPS measure such as a public product standard to protect human health can have a trade-restrictive effect.

Technical regulations can also have a demand-enhancing effect, if the standard increases consumer information about the safety of the product and signals higher product quality.[66] This would lead to an upwards shift of the demand curve and could counteract a former decrease in demand due to internalization of the damages. [67]

Various methodologies exist to quantify the trade effects of NTMs. The main objective of quantification is thereby to estimate the price effects of NTMs and calculate ad-valorem equivalents (AVEs).[68] AVEs express the trade-restrictiveness of NTMs in a percentage change of the price of the good which can then be compared with tariff rates. One methodology to calculate AVEs of NTMs is the analysis of price gaps/price wedges of

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[65] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 54; United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 20.
[66] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 20.
[67] Ibid.
[68] Michael Ferrantino, *Quantifying the Trade and Economic Effects of Non-Tariff Measures*, OECD Trade Policy Working Papers, No. 28 (Paris: OECD Publishing, 2006), 9.

products with and without or before and after the application of an NTM.[69] Other methodologies to quantify the effects of NTMs focus on the incidence rather than on the price effects of NTMs - like the coverage ratio and frequency index. [70] Furthermore, the impact of NTMs on traded quantities and values (gravity models) or on the overall economy (computable general equilibrium models) can be calculated.[71]

Welfare effects of NTMs

The focus of academic discussion has so far been on trade effects of NTMs (trade enhancing and trade reducing effects), but technical regulations such as SPS measures and TBTs can also have welfare effects because they address market failures. Overcoming these market failures eventually leads to achieving public policy objectives and an increase in national welfare.[72] An analysis of the effects of SPS measures and TBTs must, therefore, not only consider their trade-effects, but also their effects on national welfare. Welfare benefits can, for example, consist of the reduction of negative health impacts of a potentially dangerous product characteristic.[73] Disdier and Marrette[74] show that "despite a reduction in trade, welfare improves when the application of a SPS measure/TBT corrects an existing market imperfection".[75]

Welfare effects can be analysed with the same single market linear demand-supply framework as for the analysis of the trade effects in figure 1-1. Figure 1-2 shows that, on the one hand, economic welfare losses can be created as the trade-restrictive effects of the technical regulation leads to a reduction of the consumer and/or producer surplus and produces a deadweight loss (DWL). Thus the NTM leads to an inefficient outcome from an allocative or Pareto efficiency point of view. On the other hand, the technical regulation creates social welfare benefits due to the reduction of negative health impacts. These welfare effects will be determined economic and social welfare effects as the former refers to increased economic costs and the latter to social impacts on society.

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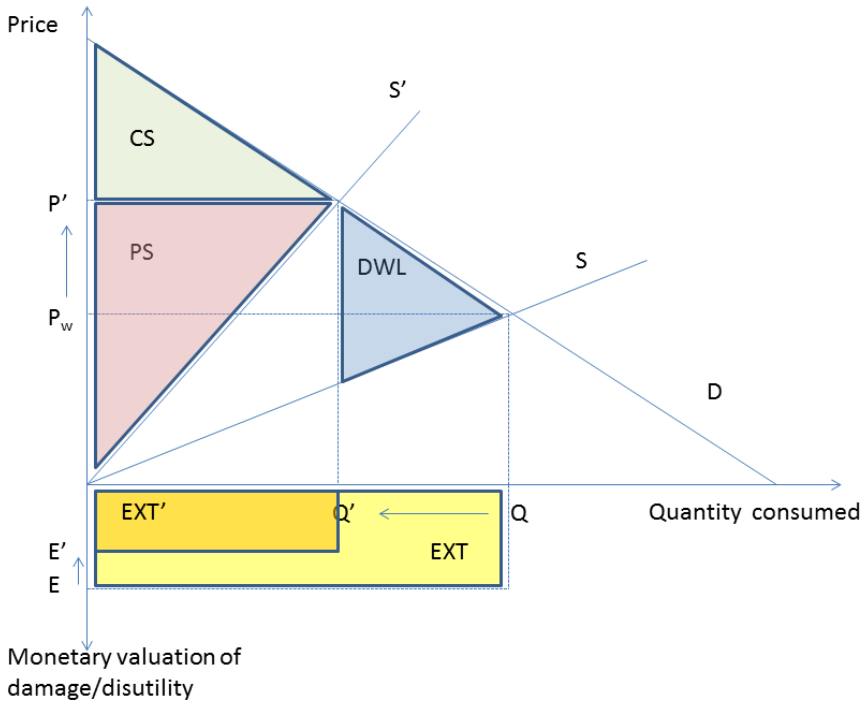
[69] Ibid.
[70] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 22.
[71] Ibid., 24, 25.
[72] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 50.
[73] United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 21.
[74] Disdier and Marette, "The Combination of Gravity and Welfare Approaches for Evaluating Nontariff Measures."
[75] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 62.

Figure 1-2: Welfare effects of a public SPS standard[76]



Looking at figure 1-2 the areas CS and PS reflect the producer (PS) and consumer surplus (CS) in the presence of a public product standard to protect consumers' health. DWL represents the corresponding deadweight loss due to the allocative inefficiency created by the NTM. Deadweight losses reflect reductions on social surplus (=consumer + producer surplus) relative to an economically efficient result in a perfectly competitive market.[77] In the lower part of figure 1-2 the valuation of the market failure that leads to dangerous health effects of the product is calculated as E. With a product quantity of Q this leads to a negative societal welfare impact of EXT. The NTM in the form of the public product standard reduces this health risk from E to E' and thus reduces the negative welfare impact to EXT'. The welfare net impact of the NTM will depend on whether the reduction of the negative health impact from EXT to EXT' outweighs the DWL created by the trade-restrictiveness of the NTM.

A difficulty of this analysis consists of determining the monetary value for the negative societal impact described as E. One possibility to measure the overall net national welfare impacts of NTMs is the use of cost-benefit frameworks which include not just an evaluation of the economic impacts, but also an evaluation of other societal impacts such as impacts on health. The basic framework for cost-benefit analyses as well as possible methodologies to value health impacts and determine the monetary value for E will be described in chapter 2.

Another important point to keep in mind when discussing effects of NTMs is that despite the fact that the regulations constituting NTMs are located in the destination market, the

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[76] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 54; United Nations Conference on Trade and Development (UNCTAD), *Non-Tariff Measures to Trade: Economic and Policy Issues for Developing Countries*, 20.
[77] Anthony Boardman et al., *Cost-Benefit Analysis*, 4 edition (Boston: Prentice Hall, 2010), 60.

challenges creating the additional costs to comply with the technical regulations often lie in the home market.[78] Domestic companies face high trade-related compliance costs or may not be capable of complying with the requirements in the destination market if the necessary quality infrastructure facilities and capacities as well as appropriate customs and administrative procedures do not exist in their home country. [79]

1.4 Evaluation and streamlining of NTMs

Whether NTMs are "good" or "bad" can be evaluated from two perspectives: Firstly, WTO law can be taken into account to determine whether an NTMs is legitimate and secondly a cost-benefit analysis can determine whether an NTM is justified from a national welfare perspective because its welfare benefits outweigh its welfare costs.

The WTO rules (as well as rules of regional and bilateral trade agreements) provide a legal framework to determine which NTMs are legal and which are not.[80] The WTO disciplines can therefore be used to differentiate between NTBs and NTMs. The former are policy measures which are perceived as protectionist and illegitimate regarding WTO rules and should therefore be eliminated. The latter are legitimate policy measures which can be maintained but sometimes need to be improved in their design and implementation.

In the multilateral trading regime the General Exceptions Clause (Art.XX) of the GATT Agreement allows for regulations which are necessary to achieve one of the listed policy objectives like protecting human, animal and plant life as long as they do not constitute a disguised restriction to trade or an arbitrary or unjustifiable discrimination.[81] The WTO SPS[82] and TBT[83] Agreements set more specific rules to evaluate the legitimacy of technical regulations. The former regulates measures aiming at the protection of human, animal and plant life whereas the latter regulates all other product standards, technical regulations and conformity assessments procedures.[84] According to the SPS Agreement, technical regulations are allowed only to the extent necessary (i.e. they are the least-protective measure for the chosen level of protection) to protect human, animal and plant life or health, if they are based on scientific evidence and if they do not constitute a disguised restriction on international trade or an arbitrary and unjustifiable discrimination (SPS Agreement Arts.2.1-2.3). The TBT

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[78] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 21.
[79] Ibid.
[80] Ibid., 22, 23.
[81] *General Agreement on Tariffs and Trade 1994, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A*, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (1999), 1867 U.N.T.S. 187, 33 I.L.M. 1153 (1994) [hereinafter GATT 1994], (n.d.).
[82] *Agreement on Sanitary and Phytosanitary Measures, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A*, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 33 (1999), 1867 U.N.T.S. 410. [hereinafter SPS Agreement], (n.d.).
[83] *Agreement on Technical Barriers to Trade, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A*, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 33 (1999), 1867 U.N.T.S. 410. [hereinafter TBT Agreement], (n.d.).
[84] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 26.

Agreement similarly allows technical regulations as long as they are non-discriminatory and do not constitute an unnecessary obstacle to trade and are not more trade restrictive as necessary to achieve a "legitimate objective" (TBT Agreement Arts.2.1-2.2).

Based on the WTO disciplines Cadot, Malouche and Saez have established a framework for an NTM review which can be used to assess and streamline government regulations and also to differentiate between NTMs and NTBs.[85] The framework analyses three main issues: (1) the necessity to address a market failure, (2) the proportionality of the NTM regarding the problem addressed, and (3) the non-discriminatory character of the regulation. Regarding these issues, the following questions need to be analysed: For (1), is there a market failure which requires government intervention? If not, the regulation is an NTB and should be eliminated. Regarding (2), does the NTM target and correctly address the market failure? If not, it needs to be redesigned. Furthermore, do the welfare benefits of the NTM outweigh its costs? If not, the justification of the regulation should be debated. Concerning (3), the non-discriminatory nature of the NTM, is the measure designed in a non-discriminatory manner? If the measure is an SPS measure, is it of a scientific basis? In order to analyse the proportionality of an NTM, a cost-benefit analyses can be carried out to analyse the benefits of the regulation (reducing negative effects) and costs created by the trade restrictive effects.

Apart from the question of whether an NTM is WTO consistent and perceived as legitimate from a WTO perspective, a government also needs to consider whether an NTM is legitimate from a national welfare perspective. When determining whether an NTM is "good" or "bad", looking at trade costs alone can therefore be very misleading.[86] From an allocative efficiency perspective, a government should aim at maximizing national welfare and choose the NTM where the wedge between national welfare benefits and costs of the NTMs is the widest.[87] In order to assess these choices a cost-benefit framework can be used which will be described in the following chapter.

1.5 Conclusion

The concept of NTMs covers a broad range of policy measures which affect trade in goods by changing the quantities traded or the prices of the affected goods. NTMs are categorized according to the MAST classification and the most prevalent types of NTMs are technical regulations, in particular SPS measures and TBTs. Governments have different motives for applying NTMs. These can be divided into two broad categories: the motive to increase national welfare and political economy motives. NTMs which are applied to increase national welfare often address market failures to pursue public policy objectives. This is the case for SPS measures or TBTs which aim to overcome a market failure to protect public health. Therefore, technical regulations like SPS measures and TBTs do not only have impacts on trade, but they also have further welfare impacts for the society. The legitimacy of NTMs can be evaluated from the perspective of compliance with WTO law and from a national welfare

[85] Ibid., 42.
[86] Ibid., 56.
[87] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff Measures in the 21st Century*, 53.

perspective if their welfare benefits outweigh its welfare costs. In order to assess the latter perspective a cost-benefit analysis can be used which will be described in the next chapter.

2 Cost-benefit analyses for the assessment of regulatory health impacts

As mentioned in the introduction and in subchapter 1.3. most research about the effects of NTMs has focused on the question how to assess the trade effects, i.e. the economic costs of NTMs. Little research has been published on how to assess social benefits of NTMs. Social benefits of technical regulations like TBTs or SPS measures can, for example, consist of the reduction of risks of negative health impacts as shown in figure 1-2 in subchapter 1.3. The question is therefore how can these health benefits from reduced health risks be measured? One approach to measure these benefits is to carry out cost-benefit analyses. Cost-benefit analyses have been used in public policy for a long time to assess regulations[88], but their application to trade policy and NTMs is rather new.[89] NTMs are policy measures with a potential impact on trade which are part of a regulation. The regulation can thereby consist of different policy measures or NTMs. As the NTM is part of the regulation a cost-benefit framework can also be used to assess the impacts of an NTM. Therefore, the general concept of cost-benefit analyses will be described as a possible approach to assessing health benefits of NTMs. The following chapter will explain what the purpose of a cost-benefit analysis is, which main steps need to be conducted and which parameters need to be defined. Furthermore, different methodologies to quantify and monetise the non-market impacts of regulations will be analysed.

2.1 Purpose and objective of cost-benefit analyses

A cost benefit analysis is an assessment method which is often used for regulatory impact assessments.[90] It calculates the overall net impact of a public policy on national welfare by monetising all the negative and positive impacts of a policy on society as a whole.[91] The net impact is calculated by subtracting the total costs from the total benefits.[92] The objective of a cost-benefit analysis is to determine if a policy is worthwhile from a national welfare point of view and should be implemented or not.[93] If the value of the benefits exceeds that of the costs, a policy should be implemented or a project should be executed.[94] Moreover, the cost-benefit analysis enables policy-makers to rank policy options according to their net negative or

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[88] Alan Diener, Bernie O'Brien, and Amiram Gafni, "Health Care Contingent Valuation Studies: A Review and Classification of the Literature," *Health Economics* 7, no. 4 (June 1998): 314.
[89] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 53.
[90] Sílvia Helena G de Miranda, "Regulatory Impact and Cost-Benefit Analyses – Tools to EvaluateRegulatory Quality and Improve Transparency among Countries," in *Non-Tariff Measures - A Fresh Look at Trade Policy's New Frontier*, ed. Olivier Cadot and Mariem Malouche (Washington, D.C.: International Bank for Reconstruction and Development/World Bank, 2012), 271.
[91] Boardman et al., *Cost-Benefit Analysis*, 2.
[92] Stephanie Riegg Cellini and James Edwin Kee, "Cost-Effectiveness and Cost-Benefit Analysis," in *Handbook of Practical Program Evaluation*, ed. Joseph S. Wholey, Harry P. Hatry, and Kathryn E. Newcomer, 3rd ed. (San Francisco: John Wiley & Sons, 2010), 494.
[93] Richard O. Zerbe Jr. and Allen S. Bellas, *A Primer for Benefit-Cost Analysis* (Cheltenham/Northampton: Edward Elgar Publishing, 2006), 2.
[94] Ibid.

positive effects on national welfare.[95] Thereby a cost-benefit analysis aims to contribute to more rational decision-making[96] and improve the quality of public policies.[97] Quality in this context means that public policies are chosen and designed in a manner to increase national welfare as much as possible.[98] The cost-benefit analysis does not substitute political decision-making, but it contributes to more informed decision-making.[99]

A cost-benefit analysis can not only be applied to public policies, but also to projects, regulations, programs and other government interventions.[100] Boardman et al. classify cost-benefit analyses into two main types: *ex ante* and *ex post* cost-benefit analyses.[101] The former type is carried out before a policy is implemented and provides guidance on the question of whether it should be implemented or not.[102] The latter type is conducted after a policy or project has been implemented and provides general conclusions regarding the question whether such classes or types of policies or projects are worthwhile and should be implemented again in the future.[103] Further types of cost-benefit analyses are cost-benefit analyses *in media res*, i.e. a cost-benefit analysis carried out during a policy implementation to gather information about the current policy as well as for future policies, and comparative cost-benefit analyses, i.e. comparing ex ante and ex post cost-benefit analyses of the same policy or project.[104]

Cost-benefit analyses have been criticised with regard to different aspects. One major point of critique is the measurement of goods such as human life or wilderness which are seen by some as "priceless goods".[105] The monetisation in such sensitive areas has been criticised as unethical[106] because these priceless goods should be beyond economic measurement.[107] Another important point of critique is that most cost-benefit analyses fail to account for distributional effects. A cost-benefit analysis aims to measure the net impacts of a regulation on overall social welfare.[108] Social welfare is considered to be the aggregate welfare value of the individual welfare of all members of a society and no one's welfare weighs more in the aggregated value than others.[109] This means if a regulation has a negative impact on the

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[95] Raymond J. Kopp, Alan J. Krupnick, and Michael Toman, *Cost-Benefit Analysis and Regulatory Reform: An Assessement of the Science and the Art*, Discussion Paper 97-19 (Washington, D.C.: Resources for the Future, 1997), 2.
[96] Anthony Boardman et al., *Cost-Benefit Analysis*, 4 edition (Boston: Prentice Hall, 2010), 2.
[97] Kopp, Krupnick, and Toman, *Cost-Benefit Analysis and Regulatory Reform: An Assessement of the Science and the Art*, 2.
[98] Ibid.
[99] Claudio M. Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," *European Journal of Political Research* 43, no. 5 (2004): 723.
[100] Boardman et al., *Cost-Benefit Analysis*, 2.
[101] Ibid., 3.
[102] Ibid.
[103] Ibid.
[104] Ibid.
[105] Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," 724.
[106] S. Virani and S. Graham, *Economic Evaluation of Environmental Policies and Legislation*, Final Report Prepared for European Commission Directorate General III (Industrial Affairs) (Loddon: Risk & Policy Analysts Limited, 1998), 61.
[107] Leslie Paul Thiele, "Limiting Risks: Environmental Ethics as a Policy Primer," *Policy Studies Journal* 28, no. 3 (2000): 553.
[108] Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," 5,6.
[109] Ibid.

welfare of a certain group (e.g. on the poor) which is outweighed by a positive welfare impact on another group (e.g. the rich), the overall net impact of the regulation is positive and the regulation will still be considered to have social welfare benefits, independent of the negative effects on the first group.[110] As distributional effects are, however, relatively hard to assess in impact assessments, this is rarely done in practice.[111]

Responding generally to the critique of cost-benefit analyses, it is often argued that without regulatory impact assessments and cost-benefit analyses, the same challenges for decision-making remain. As Radaelli puts it: The "problems of distribution, fairness, equity, and threats to the environment and biodiversity would still be there, but the decision-maker would have to address these problems with less empirical information".[112] Therefore, it can be counter argued that a cost-benefit analysis at least provides more transparency to a decision-making processes and makes the decision more explicit and decision-makers more accountable.

In the case of an NTM a cost-benefit analysis can serve different purposes. The cost-benefit analysis can be used to determine whether the NTM should be implemented at all, whether an NTM that is already in place should be removed within a trade agreement or whether it should be maintained because national welfare benefits dominate. The most suitable type of cost-benefit analysis would be a cost-benefit analysis *in media res* which draws on impact information from the existing NTM or an *ex ante* impact analysis. If an NTM is assessed during a trade negotiation it is usually already in place, but an *ex ante* analysis can still be suitable if not enough information is available regarding the actual impacts of the NTM. In such a situation an existing NTM can be analysed like a newly planned regulation regarding the question if the NTM is worthwhile to maintain.

2.2 General steps of a cost-benefit analysis

The main steps of a cost-benefit analysis are described very similarly, for example in Boardman[113], Cellini[114], or Zerbe and Bellas[115]. The box provides a brief overview of the eight steps which will be described in more detail.

[110] Ibid., 6.
[111] Randall Lutter, *Study on Economic Analysis of Regulation in the U.S.: What Lessons for the European Commission?*, Report to the Enterprise Directorate General, European Commission (Brussels, 2001), 11, Brussels.
[112] Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," 724.
[113] Boardman et al., *Cost-Benefit Analysis*, 6 ff.
[114] Cellini and Kee, "Cost-Effectiveness and Cost-Benefit Analysis," 495 ff.
[115] Zerbe Jr. and Bellas, *A Primer for Benefit-Cost Analysis*, 3 ff.

Box 2-1: Main steps of a cost-benefit analysis

1. Framework setting: definition of policy at issue and type of analysis
2. Definition of affected groups
3. Identification and categorization of costs and benefits
4. Calculation of time horizon for policy impacts
5. Quantification and monetization of costs and benefits
6. Discounting of costs and benefits to obtain a net present value
7. Sensitivity analysis
8. Recommendations

Firstly, the framework for the analysis needs to be set. It has to be determined which kind of analysis shall be conducted (*ex ante, in media res* or *ex post*) and what needs to be analysed or compared (one policy or programme or alternative policies or programmes).[116] Secondly, it has to be decided whose costs and benefits should be included and counted in the assessment. As explained above in subchapter 2.1. the goal of a cost-benefit analysis is to analyse the impacts on society. This makes it necessary to define the boundaries of the society which is usually done in terms of a national state. Yet when analysing NTMs theoretically also impacts outside the national boundaries would need to be taken into account as will be discussed in the next subchapter 2.3.1. Thirdly, the actual costs and benefits have to be identified and categorized as completely as possible. Thereby it is common to categorize the negative impacts as costs and the positive impacts as benefits, but it is also possible to categorize them as inputs and outputs.[117] Fourthly, the time horizon for the effects of the policy has to be predicted to calculate the costs and benefits which will occur over that period. Fifthly, an appropriate measurement needs to be chosen to quantify all impacts. For a cost-benefit analysis it is important that costs and benefits are expressed in the same value unit and that a monetary value is attached to each of the impacts as far as possible. This enables a comparison between different costs and benefits. Sixthly, a social discount rate has to be applied to the impacts to obtain their present values and the net present value has to be computed. In this step prospective costs and benefits are discounted to estimate their present value for the calculation.[118] This is necessary because the resources spent on a policy have opportunity costs and because most people prefer to consume now rather than later and thus value future benefits less.[119] The social discount rate which is applied includes the preferences of future generations.[120] The net present value of a policy option or programme is calculated by subtracting the costs from the benefits and if the net value is positive the policy or programme is worthwhile. If different policy options were to be compared, the policy with the highest net value would be the best policy option. As second last step, a sensitivity analysis needs to be performed, which tries to take account for the uncertainties related to the predicted impacts. Finally, a recommendation for a policy option has to be made. Regarding

[116] Boardman et al., *Cost-Benefit Analysis*, 5.
[117] Cellini and Kee, "Cost-Effectiveness and Cost-Benefit Analysis," 499.
[118] Boardman et al., *Cost-Benefit Analysis*, 12.
[119] Ibid.
[120] Robert J. Brent, *Applied Cost-Benefit Analysis* (Cheltenham/Lyne: Edward Elgar, 1996), 4.

this final step, it is important to reiterate that a cost-benefit analysis is one factor of many which feeds into a political decision-making process and it is not a substitute for the latter.[121]

As the scope of this paper is limited, the paper will focus in the following on the most important steps that help to answer the research question how to analyse health impacts of NTMs. These steps are (2) the definition of affected groups, (3) the identification and categorization of impacts and (5) the quantification and monetisation of the impacts of a regulation. The paper will not discuss further challenges that may arise concerning the estimation of the discounting rate, the sensitivity analysis or other steps of the analysis.

2.3 Selected parameters and underlying concepts of a cost-benefit analysis

As has been explained in the foregoing subchapter 2.2., the main steps of a cost-benefit analysis include (2) the definition of the affected groups and (3) of the impacts which have to be assessed. These steps analyse who is affected by a regulation and how this group is affected and will determine significantly the outcome of the analysis. Therefore, the following three subchapters will describe which affected groups and which potential impacts could be considered when analysing the costs and benefits of a regulation, or more specifically of an NTM. Furthermore, the chapter will briefly explain the role of risk assessments and define the concept of welfare as these are important underlying concepts for a cost-benefit analysis.

2.3.1 Potentially affected groups

A governmental policy or regulation can have impacts on different groups. The policy can create costs and benefits for consumers as well as for producers, but also for the whole society and the government itself. When looking specifically at NTMs it is, furthermore, important to also take account of the impacts not only on domestic groups, but also on foreign producers, consumers and governments. Yet it is probably unrealistic that the latter impacts are taken into account if the regulation is assessed from a domestic policy improvement perspective.

The first group whose costs and benefits of an NTM need to be considered for a cost-benefit analysis are the producers.[122] Costs for producers are usually created by increased production costs due to specific product or production requirements. Benefits can be experienced in the form of a reduction of the risk to be affected by harmful effects of an input or intermediate product which can contaminate the production process.[123] These potential impacts will be described further in the next subchapter. For the purpose of a more detailed analysis the group of producers can also be further differentiated into the different actors of the supply chain (e.g. producers of the main resources and inputs, processors or manufacturers and retail sale agents).[124]

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[121] Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," 723.
[122] John Beghin, Frank van Tongeren, and Stéphane Marette, *A Cost-Benefit Framework for the Assessment of Non-Tariff Measures in Agro-Food Trade*, OECD Food, Agriculture and Fisheries Papers 21 (Paris: OECD Publishing, 2009), 9, 10.
[123] Beghin et al., *Measuring Costs and Benefits of Non-Tariff Measures in Agri-Food Trade*, 11.
[124] Ibid.

The second group which might be affected by impacts of NTMs are consumers.[125] On the one hand, consumers can be negatively affected by increased consumer prices caused by increased production costs. On the other hand, consumers can benefit from an NTM if it addresses market failures and overcomes information asymmetries[126] or if it reduces or eliminates harmful product characteristics. Thus, the benefits of NTMs for consumers can be of different types which will be described in the following subchapter.

Furthermore, society as a whole or citizens can be considered as third group which is potentially affected by a regulation or an NTM.[127] Society as a whole is different from consumers such that they do not have to be participants of a given market and purchase and consume a certain good. An NTM applied to a good can have costs or benefits for the whole society if it regulates market failures concerning a public good or an externality. For example, an NTM can have positive effects on health or the environment if it reduces air or water pollution.

The fourth group that can be affected by a regulation or NTM is the government or its administrative authorities as they can have costs of administrative implementation of the regulation or costs resulting from conformity assessment procedures that need to be carried out to secure compliance with the regulation.

Moreover, if the regulation at issue is an NTM that affects tradable products, the NTM can also affect imported goods and thus foreign producers, consumers, societies and governments. From a global welfare perspective the costs and benefits for foreign consumers can be taken into account, if a technical regulation leads to a change of the production process and a reduction of harmful product characteristic. If these products are not only exported to the country applying the NTM, but also exported to other third countries and consumed by foreign consumers in these third countries, foreign consumers will also be affected. As pointed out by Beghin et al. with increasing international integration, trade can become an important vector for external effects.[128] However, as this paper assumes that a cost-benefit analysis of a regulation is carried out with the purpose of increasing domestic welfare, it is unlikely that costs and benefits to foreign stakeholders are taken into account in such a cost-benefit analysis. A domestic government would only analyse effects on the domestic producers, consumers and the government to determine the national welfare effects and decide whether a regulation or NTM is worthwhile or not. Impacts on foreign producers such as increased production costs are, however, still reflected in the calculation of increased prices and decreased quantities of the traded products in the home market.

In sum, for a cost-benefit analysis of an NTM it is important to consider which of the four groups are affected by the regulation at issue as this will determine the further analysis and its outcome. An NTM would actually affect foreign producers, consumers, societies and

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[125] Beghin, van Tongeren, and Marette, *A Cost-Benefit Framework for the Assessment of Non-Tariff Measures in Agro-Food Trade*, 9.
[126] Schlueter et al., *Analytical Framework for the NTM Impact Project*, 35.
[127] Andrea Renda et al., *Assessing the Costs and Benefits of Regulation*, Study for the European Commission, Secretariat General (Brussels: CEPS and Economisti Associati, 2013), 40 ff.
[128] Beghin et al., *Measuring Costs and Benefits of Non-Tariff Measures in Agri-Food Trade*, 2.

governments, but due to the underlying motivation of the cost-benefit analysis in this paper, to decide for or against an NTM based on its effects on national welfare, the foreign groups will not be taken into account further.

2.3.2 Types of regulatory impacts

Following on from the steps of a cost-benefit analysis in subchapter 2.2., after determining who is affected by the NTM it has to be assessed how these groups are affected. This analysis includes assessing which kind of impacts the NTM has on whom and which kinds of costs and benefits are caused by these impacts. Positive impacts create benefits and negative impacts create costs. In general, impacts can be classified as economic, environmental and social impacts which can create different types of costs and benefits for the affected groups. These different types of impacts and costs and benefits will be described in the following.

Economic impacts of an NTM can create economic costs and benefits. Economic costs for producers created by an NTM are often administrative compliance costs because businesses have to comply with the regulation. Economic costs for consumers resulting from the NTM are increased product prices which the consumers may face as a result of increased production costs and restricted trade. Economic benefits for producers can result from an NTM if a technical regulation prevents producers from buying harmful inputs such as disease-affected seeds which create a production loss.[129] Alternatively, economic benefits can result if the NTM overcomes information asymmetries for consumers about a good or contributes to a better product quality, which then leads to an increase in the demand for the good and increases trade.[130] The harmonization of product standards and shared standards can also have a trade enhancing effect resulting in economic benefits for consumers and foreign producers.[131]

Social impacts generally refer to impacts which are intangible and which typically (but not exclusively) affect consumers or society as a whole. Social benefits can, for example, be experienced in the form of improvements in health conditions whereas social costs can consist in the deterioration of conditions on the labour market (in this case producers might also be affected), or regarding the access to social security and education.[132] The above example of an NTM which overcomes imperfect information related to food safety can also have social impacts, if the NTM reduces risks arising from harmful ingredients in the food product and creates health benefits for consumers.

Environmental impacts refer to costs or benefits of regulations which often occur to global common goods such as the environment or the climate.[133] As the environment also affects the life of people, an environmental benefit often also leads to health benefits.

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[129] Ibid., 8.
[130] Ibid., 3.
[131] John C. Beghin, *Non Tariff Measures with Market Imperfections: Trade and Welfare Implications* (Emerald Group Publishing, 2013), 4.
[132] European Commission, Impact Assessment Guidelines (Brussels: European Commission, 2009), 36, 37.
[133] Ibid., 38, 39.

Within these generic classifications of types of impacts the costs and benefits that occur in these fields can be further categorized. Brent, for example, divides costs into private and social, intangible and tangible, direct and indirect costs.[134] Renda et al. distinguish between direct (compliance and hassle costs), indirect and enforcement costs. On the benefit side they differentiate between direct (additional citizen's welfare, utility or satisfaction and improved market efficiency) and indirect benefits (indirect compliance benefits, wider macroeconomic benefits and other non-monetisable benefits).[135]

These classifications of impacts and types of costs and benefits can help policy makers to analyse the impacts of a regulation. It is important to include at least all the main costs and benefits of a regulation or policy to obtain a credible result of a cost-benefit analysis. Thereby it is more difficult to assess the social and environmental impacts than the economic impacts and to quantify and monetise the former in order to make them comparable within a cost-benefit framework. Economic impacts are usually easier to quantify and monetize because they can more easily be linked to market prices. The economic impact of an NTM that addresses an externality affecting production can, for example, be directly related to the value of the avoided production loss.[136] Similarly, benefits are more difficult to measure than costs. Renda et al. found that "costs are more evident, measurable, concentrated on one group and immediate in term[s] of time" than benefits which are normally more difficult to measure as they tend to be more disperse and long-term.[137]

As described, regulations can have different types of impacts. Taking into account the prevalence of SPS measures and TBTs in international trade which often address health issues, the paper focuses on the question how to assess health benefits of NTMs. Subchapter 2.4 will therefore describe methodologies to quantify and monetise these health benefits of regulations.

2.3.3 Understanding of welfare

Before turning to methodologies which can be used to quantify and monetise health impacts, it is necessary to briefly clarify the term 'welfare' because a cost-benefit analysis aims to determine net welfare impacts of regulations. Without further discussing the extensive and disputed literature on the definition of the term 'welfare' the following general distinction is drawn between an economic and social understanding of this term.

The existing research which analyses the impacts of NTMs usually determines welfare effects in terms of trade effects. Welfare gains are described as the gains in efficiency and trade resulting from a reduction of NTMs.[138] This understanding of welfare is described by Greve as an economic perspective on welfare which is mainly concerned with the utility of the use

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[134] Brent, *Applied Cost-Benefit Analysis*, 4.
[135] Renda et al., *Assessing the Costs and Benefits of Regulation*, 22–39.
[136] Beghin et al., *Measuring Costs and Benefits of Non-Tariff Measures in Agri-Food Trade*, 5.
[137] Renda et al., *Assessing the Costs and Benefits of Regulation*, 19,20.
[138] Marco Fugazza and Jean-Christophe Maur, "Non-Tariff Barriers in CGE Models: How Useful for Policy?," *Journal of Policy Modeling* 30, no. 3 (May 2008): 482.

of income and individuals perceptions.[139] Van Praag and Frijerts describe a similar understanding when defining welfare as "the evaluation assigned by the individual to income or, more generally, to the contribution to our well-being from those goods and services that we can buy with money".[140]

If an NTM is applied to reduce negative effects of harmful product characteristics on human health, it creates welfare gains for the society's health. These welfare effects capture a different meaning of the term welfare which can be described as social welfare. Social welfare in this context refers to a measurement "that captures as many as possible of the important features of well-being that might be affected by a policy".[141] What is seen as an important feature of well-being is then a normative question which theoretically has to be defined for each case because "the underlying 'social welfare function' in a cost-benefit analysis is one of an arbitrarily large number of such functions on which consensus is unlikely to be achieved"[142]. In this paper the understanding of welfare impacts which are assessed in cost-benefit analyses refers to the idea of social welfare.

2.3.4 The role of risk assessments

Another issue which needs to be discussed briefly is the role of risk assessments which are normally not necessarily part of a cost-benefit analysis. When assessing health impacts risk assessments, however, play an important role in analysing the level of impacts of a regulation or an NTM. Health impacts are mainly impacts which reduce or increase the risk of morbidity or mortality for humans. A regulation or an NTM has positive health impacts if it reduces the risk of illness or the risk to die prematurely. Contrary, a regulation has negative health impacts or creates costs for public health if it increases these risks. A risk assessment comprises the analysis of four main components: hazard identification, dose-response evaluation, human exposure evaluation and risk characterization.[143] The first step analyses the presence of a hazard which can potentially have adverse effects on human health.[144] The second step assesses the quantitative relationship between the amount of exposure to the hazard and the extent of illness.[145] The third step determines the actual exposure to the hazard and the final component determines the likelihood of the health impacts.[146]

A risk assessment has to be carried out before the quantification and monetisation of impacts, because only after specifying the effects of a regulation these effects can be quantified and

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[139] Bent Greve, "What Is Welfare?," *Central European Journal of Public Policy*, no. 1 (2008): 53.
[140] B.M.S. Van Praag and P. Frijters, "The Measurement of Welfare and Well-Being: The Leyden Approach," in *Well-Being: Foundations of Hedonic Psychology*, ed. Daniel Kahneman, Edward Diener, and Norbert Schwarz (New York: Russell Sage Foundation, 1999), 427.
[141] Kopp, Krupnick, and Toman, *Cost-Benefit Analysis and Regulatory Reform: An Assessement of the Science and the Art*, 3.
[142] David W Pearce, Giles Atkinson, and Susana Mourato, Organisation for Economic Co-operation and Development, *Cost-Benefit Analysis and the Environment: Recent Developments* (Paris: Organisation for Economic Co-operation and Development, 2006), 17.
[143] Kofi Asante-Duah, *Public Health Risk Assessment for Human Exposure to Chemicals* (Dordrecht: Kluwer Academic Publishers, 2002), 74–76.
[144] Ibid.
[145] Ibid.
[146] Ibid.

monetised.[147] This estimation of initial effects of a regulation can be more difficult and complex than the actual process of quantification and monetisation and often case specific methods have to be sought.[148] However, if the regulation to be assessed is a SPS measure a risk assessment should already exist. The SPS Agreement requires that SPS measures are based on scientific risk assessment if they are not based on an international standard.[149] The risk assessment can be executed by the country applying the SPS measure itself or the country can base the measure on an "appropriate" risk assessment.[150]

For NTMs with health impacts risk assessments can be an important part of a cost-benefit analysis to determine the reduction of risk levels. Due to time and space limitations the paper will focus on the quantification and monetisation of health benefits which will be described in the next subchapter.

2.4 Methodologies to assess health impacts of regulations/NTMs

As described in subchapter 2.2. a cost-benefit analysis used to assess health impacts of an NTM requires different steps including the identification and categorization of possible health impacts, the prediction of the level of impacts and the monetisation of the latter. Obtaining accurate estimates for the costs and benefits of a regulation can, however, be very difficult.[151] Often a lot of resources and efforts of a cost-benefit analysis need to be invested in the prediction of the level of impacts and their monetisation.[152] The difficulty for the last step arises particularly from the fact that cost-benefit analyses require all impacts to be expressed in one common metric in order to make them comparable.[153] This means that all costs and benefits need to be monetised, i.e. measured in monetary terms. Monetised costs can then be subtracted from the monetised benefits and the net value will show whether a government intervention is worthwhile for society or not.[154] Looking at the partial equilibrium graph in subchapter 1.3., the reduction of consumer surplus, the deadweight loss, as well as the reduction of the negative societal impact caused by the NTM need to be put in monetary values. The first element could be measured by the price increase and the second element would be reflected in the trade restrictive effects. These two impacts of the regulation can be monetized with market prices. For example, to measure the change in the consumer surplus the market price can be taken to evaluate the change in the quantity consumed.[155]

The third element, the reduction of negative societal impacts in the form of health risks, is, however, more difficult to monetise, because health impacts usually do not have a market price. In a perfect market the market price reflects the marginal social costs and benefits of an

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[147] European Commission, *Impact Assessment Guidelines*, 25.
[148] Jan Thiessen et al., *Quantifying the Benefits of Regulatory Proposals: International Practice* (Basel: prognos, 2013), 6.
[149] SPS Agreement Art.5.1
[150] SPS Agreement Art.5.1
[151] Cellini and Kee, "Cost-Effectiveness and Cost-Benefit Analysis," 494.
[152] Boardman et al., *Cost-Benefit Analysis*, 274.
[153] Australian Government Productivity Commission, *Identifying and Evaluating Regulation Reforms: Productivity Commission Research Report.* (Melbourne: Australian Government, 2011), 114.
[154] Boardman et al., *Cost-Benefit Analysis*, 78.
[155] Ibid., 282.

additional unit of a good or service.[156] When a market failure leads to a difference between market price and the actual social cost or a market does not exist at all, a shadow price can be estimated.[157] A shadow price is an estimate of what the market price would be if the good was traded in a perfect market.[158] For non-market goods such as health there are two main approaches that can be used to estimate a shadow price: cost-based and preference-based calculations. A cost-based approach is, for example, the human capital approach where the value of the foregone earnings of a dead person is calculated.[159] Preference based approaches refer to people's behaviour and their preferences regarding the non-market good. Different preference based methodologies exist to estimate shadow prices for non-market goods. As preference based approaches are the most consolidated approaches for the valuation of risk reductions in the field of health impacts, the paper will focus on these approaches.[160]

The general preference-based metric to measure non-market impacts is the willingness-to-pay (WTP) approach which can be used to measure a broad range of impacts. The following subchapter will describe the WTP concept as well as revealed and stated preference methods which can be used to estimate the WTP. Health impacts in particular are measured regarding their impact on mortality and morbidity risks. Mortality refers to the risk of death whereas morbidity refers to non-fatal health risks which can range from experiencing light illnesses like a cold to severe illnesses like cancer. Mortality risks are mainly measured by the value of a statistical life (VSL or VOSL) and value of a statistical life year (VSLY or VOSLY) approaches which are based on the WTP metric. They will be described in subchapter 2.4.1. Morbidity risks are mainly evaluated by non-monetary approaches like the disability-adjusted life years (DALY) and quality-adjusted life years (QALY) metrics which will be described in subchapter 2.4.2. This selection of methodologies is also in line with an analysis of 21 selected regulatory impact assessments from Australia, United States, United Kingdom and the EU that found a certain convergence of these methods being used to quantify and monetise non-market impacts in these countries.[161]

2.4.1 Monetary valuation methods: WTP, WTA, VSL, VSLY

When assessing environmental or social impacts of a regulation often no market exists which would show which monetary value this impact has for the society. Labelling is one of few cases where the monetary value of a non-market good like the environment can be assessed based on a market price. In this case the prices of a labelled good, i.e. produced under environmentally friendly conditions, can be compared to that of a non-labelled good and the price difference would be an estimate for the value of the environmental protection. However, when market prices do not exist or the observed market prices do not reflect the true value of a good to society, shadow prices can be used to measure these non-market impacts.[162] The most common concept to estimate shadow prices for non-market goods is the WTP concept

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[156] Ibid., 341.
[157] Ibid.
[158] Ibid.
[159] Renda et al., *Assessing the Costs and Benefits of Regulation*, 132.
[160] Ibid., 221.
[161] Thiessen et al., *Quantifying the Benefits of Regulatory Proposals: International Practice*, 47.
[162] Boardman et al., *Cost-Benefit Analysis*, 80.

which will be described in this subchapter as well as the more specific concepts of value of a statistical life (VSL) and value of a statistical life-year (VSLY).

The concept of willingness-to-pay (WTP)

The concept of WTP shows how much an individual is willing to pay for not being affected by or reducing a risk, an externality or the poor quality of a product.[163] There are two major methods to estimate shadow prices based on the WTP for a non-market good: revealed and stated preference methods. Firstly, indirect market methods based on revealed preference methods can be used. Revealed preference approaches assume that the value of the non-market good which is assessed is reflected indirectly in the prices of a related market where people's real-life behaviour can be examined.[164] Revealed preference methods analyse what people do and pay to avoid a risk and try to use market information related to other goods which allows drawing conclusions about the demand curve or value of the good at issue. Secondly, contingent valuation methods based on stated preference methods can be used to estimate shadow prices for impacts which cannot be linked to any changes in observable behaviour in a market.[165] Stated preference methods ask people directly what they think they would pay to reduce the risk of premature death or how they would rank different risk options. Revealed preference methods are expected to be more accurate than stated preference methods, but it is difficult to obtain the necessary market data.[166]

Revealed preference and indirect market methods:

Quite a wide range of different techniques are described in the literature to establish the WTP based on revealed preferences. The market analogy method, for example, uses market information from a good provided by private actors to value similar goods provided by the government.[167] Another method establishes shadow prices based on trade-offs. In this case opportunity costs are used to estimate shadow prices, i.e. the price for what people give up to obtain something else determines the shadow price.[168] The intermediate good method estimates the value of a project based on the value added to a good which is then used as an intermediate good in a downstream activity.[169]

Revealed preference methods assessing health risks aim to analyse how individuals chose between alternatives which have different health risks and monetary consequences.[170] For the evaluation of health impacts particularly three revealed preference methods are important: the hedonic pricing method, the averting behaviour or defensive expenditure method and the cost of illness (COI). The hedonic pricing method has mostly been used with data from the

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[163] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 45.
[164] Daniel Fujiwara and Ross Campbell, *Valuation Techniques for Social Cost-Benefit Analysis Stated Preference, Revealed Preference and Subjective Well-Being Approaches: A Discussion of the Current Issues* (London: HM Treasury, Department for Work and Pensions, 2011), 10.
[165] Boardman et al., *Cost-Benefit Analysis*, 341.
[166] Jayson L. Lusk, Jutta Roosen, and Jason F. Shogren, *The Oxford Handbook of the Economics of Food Consumption and Policy* (Oxford University Press, 2011), 870.
[167] Boardman et al., *Cost-Benefit Analysis*, 342.
[168] Ibid., 344.
[169] Ibid., 349.
[170] James K. Hammitt, "QALYs versus WTP," *Risk Analysis* 22, no. 5 (2002): 997.

housing and the labour market.[171] It estimates the relationship between the price for a good and the characteristics that determine the value of the good, which enables to determine the marginal effect of one characteristic on the value of the good.[172] Hedonic wage methods focusing on the labour market are based on wage differentials which need to be paid to individuals for accepting job characteristics such health or safety risks.[173] The averting behaviour method is based on the idea that individuals and households can avoid a bad non-market impact by choosing more costly types of behaviour.[174] Costly can thereby mean more time-consuming or entailing restrictions on what the individual would normally chose to do.[175] Alternatively, the individual can avoid the bad non-market impact by purchasing a market good, for example a protective equipment like seatbelts, which reduces its mortality risk.[176] This purchase is called a defensive expenditure and represents an implicit price for the avoided negative impact.[177] The cost (benefit) of a regulation can then be measured by the increase (decrease) of the defensive expenditure.[178] The OECD describes two main complications which arise in the practical application of the defensive expenditure and the averting behaviour method.[179] Firstly, it is explained that the defensive expenditure usually represents only a partial or lower bound estimate of the actual value of the non-market good or bad. Secondly, often averting behaviour or defensive expenditure create joint products, i.e. they have more than one effect. Therefore, the net cost of the changed behaviour or expenditure should be calculated by subtracting the secondary effects. Determining the part of behaviour that is of interest and attaching a cost to the different effects might, however, be difficult in practice. When determining the value of a health impact it might, furthermore, be appropriate to add some components of COI measures to the willingness-to-pay estimates to achieve a more comprehensive measurement of the social welfare impact.[180] The COI is similar to the defensive expenditure method, because it measures the value of the non-market good by looking at the expenditure made e.g. on medicines in order to avoid illness.[181] It differs from defensive expenditure in such that the decision of purchase is not made by the individual alone but also by social administrators and thus the expenditure does not necessarily measure the individuals' preferences to avoid negative health impacts.[182]

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[171] Fujiwara and Campbell, *Valuation Techniques for Social Cost-Benefit Analysis Stated Preference, Revealed Preference and Subjective Well-Being Approaches*, 13.
[172] Boardman et al., *Cost-Benefit Analysis*, 353.
[173] Fujiwara and Campbell, *Valuation Techniques for Social Cost-Benefit Analysis Stated Preference, Revealed Preference and Subjective Well-Being Approaches*, 13.
[174] David W Pearce, Giles Atkinson, and Susana Mourato, *Cost-Benefit Analysis and the Environment: Recent Developments* (Paris: OECD Publishing, 2006), 98, 99.
[175] Ibid.
[176] W. Kip Viscusi and Joni Hersch, "Cigarette Smoking, Seatbelt Use, and Differences in Wage-Risk Tradeoffs," *The Journal of Human Resources* 25, no. 2 (1990): 202–27.
[177] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 99.
[178] Boardman et al., *Cost-Benefit Analysis*, 365.
[179] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 99.
[180] Wilhelmine Miller, Lisa A Robinson, and Robert S Lawrence, eds., *Valuing Health for Regulatory Cost-Effectiveness Analysis*, Committee to Evaluate Measures of Health Benefits for Environmental, Health, and Safety Regulation (Washington, D.C.: National Academies Press, 2006), 30.
[181] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 99.
[182] Ibid., 99, 100.

Stated preference methods and contingent valuation studies:

The most common stated preference method is a contingent valuation study.[183] Contingent valuation studies are carried out with questionnaires which are designed to elicit individual's preferences and their WTP for changes in quantities or qualities of goods.[184] The studies ask consumers to evaluate a hypothetical market context and ascertain their preferences contingent upon this hypothetical scenario.[185] In general the contingent valuation method can be used to monetize almost everything.[186] Most often it has been used for transportation risks, but it is also applied to health risks related to food, medical technologies or hazardous waste.[187] In general, economists prefer revealed preference methods because the market observations reveal actual market behaviour and preferences.[188] Stated preference methods, in contrast, use surveys which provide statements about hypothetical market preferences.[189] Albeit these controversies, the contingent valuation method is used widely for the valuation of non-market goods and the number of studies about health impacts using contingent valuation is increasing.[190]

The main steps of a contingent valuation study are the identification of a sample group, asking questions about their valuation of the good at issue, the extraction of the WTP results and the extrapolation of the results to the rest of the population.[191] As contingent valuation studies are expensive and time-consuming, the extrapolation of survey results is an appealing approach. However, the extrapolated survey results have to be controlled for the differences between the surveyed population and the population at issue (e.g. differences in income or access to alternative goods).[192]

There are four main techniques to carry out contingent valuation surveys. The first two techniques are the open-ended (the individual is asked to state its maximum payment) and closed-ended iterative bidding method (the individual is asked about willingness to pay certain amounts) whereby the closed-ended approach of data collection is generally preferred over the open-ended approach.[193] The second and fourth technique are the contingent ranking method (the individual is asked to rank different sets of qualities of goods with a corresponding payment) and the dichotomous choice, binary choice or referendum method (the individual is asked about its consent to different prices).[194] The dichotomous choice approach is a popular approach used in contingent valuation studies.[195] The first three methods are direct elicitation or non-referendum methods as they intend to directly elicit

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[183] Hammitt, "QALYs versus WTP," 997.
[184] Boardman et al., *Cost-Benefit Analysis*, 372.
[185] W. Kip Viscusi, "The Value of Risks to Life and Health," *Journal of Economic Literature*, 1993, 1939.
[186] Renda et al., *Assessing the Costs and Benefits of Regulation*, 122.
[187] Hammitt, "QALYs versus WTP," 997.
[188] Boardman et al., *Cost-Benefit Analysis*, 372.
[189] Ibid.
[190] Diener, O'Brien, and Gafni, "Health Care Contingent Valuation Studies: A Review and Classification of the Literature," 313.
[191] Boardman et al., *Cost-Benefit Analysis*, 373.
[192] Ibid.
[193] Ulla Slothuus, *Economic Evaluation: Theory, Methods & Application*, Health Economics Papers (Odense: Faculty of Social Sciences, University of Southern Denmark, 2000), 34, 35.
[194] Boardman et al., *Cost-Benefit Analysis*, 375.
[195] Slothuus, *Economic Evaluation: Theory, Methods & Application*, 35.

willingness-to-pay values or preference profiles for each respondent over a set of alternatives.[196] The fourth method applies indirectly as it elicits patterns of responses over a large number of respondents to correspond the preferences with different characteristics of the respondents.[197] There is no consensus about which survey method to prefer as the choice depends mainly on which type of survey will provide the most reliable statement of preferences.[198]

Apart from criticism about surveys in general (e.g. that they are not exact science) the following specific points of critique about contingent valuation can be made. First of all Viscusi describes the concern that results will only be reliable to the extent that the respondents understand, grasp and accurately evaluate the tasks they are responding to. [199] Furthermore, the neutrality regarding the presentation of the information as well as judgmental biases by the respondents have been criticized.[200]

The concept of willingness-to-accept (WTA)

When talking about the willingness-to-pay, it is important to briefly mention a closely related concept: the willingness-to-accept. The willingness-to-accept approach measures the minimum willingness to accept compensation for a loss, i.e. for tolerating higher than "normal" risks.[201] Which of the two concepts should be used depends on the property rights related to the benefits: if there is a right to the benefit, the WTA is chosen; without property rights related to the benefit, the WTP is the correct approach.[202] Evidence suggests that the results of WTA and WTP differ considerably because individuals are willing to pay less to acquire a good they do not yet possess (in the case of WTP) than they need to be compensated for giving up on a good which they already own ('loss aversion' in behavioural economics in the case of WTA).[203] Evidence from experimental economics shows that the two alternative estimates differ significantly.[204] As the estimates for WTA are often regarded as being implausibly high, the WTP approach has been used more even if the WTA might suit a certain situation better.[205]

Overall, the willingness-to-pay is an approach to value non-market goods which has a very wide range of applicability. It can also be applied to measure the monetary value of health impacts of NTMs. When analysing the impacts of an NTM the WTP approach enables to take the demand side into account and to evaluate and monetise impacts on consumers, not only on producers.[206] Another advantage of the WTP approach is that it does not simply reflect the negative impacts on health or productivity, but it also includes a utilitarian evaluation, an

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[196] Boardman et al., *Cost-Benefit Analysis*, 373.
[197] Ibid.
[198] Viscusi, "The Value of Risks to Life and Health," 1939.
[199] Ibid.
[200] Boardman et al., *Cost-Benefit Analysis*, 382.
[201] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 156, 194.
[202] Ibid., 155.
[203] Boardman et al., *Cost-Benefit Analysis*, 391.
[204] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 280.
[205] Hammitt, "QALYs versus WTP," 990.
[206] Schlueter et al., *Analytical Framework for the NTM Impact Project*, 35.

evaluation of the disutility of being exposed to negative effects.[207] Considering the different available techniques to estimate these values, revealed preference methods seem to be preferred over stated preference methods, because they are expected be influenced less by biases and insecurities.

The concepts of the value of a statistical life (VSL) and a statistical life year (VSLY)

The concept of willingness-to-pay can also be used to estimate the value of a statistical life (VSL or VOSL) or the value of a statistical life year (VSLY or VOSLY). As these two concepts are important when assessing health benefits of a regulation they will be explained more in detail. The VSL tries to determine the value people give to the marginal change in their likelihood of death.[208] It measures the WTP for little reductions in the risk to die prematurely.[209] It is important to point out that this measurement does not suggest that an individual's life can be valued, but it refers to a "statistical" life and is neither applied to an identifiable individual nor a very large individual risk.[210] A safety improvement leading to a reduction of the risk of death for all users saves a statistical life as opposed to saving ex ante the life of an identifiable individual.[211] Another closely related concept is the concept of VSLY which estimates the discounted annual value of a person's remaining life.[212] This is another method to estimate reductions in fatality risks which is sometimes called the life expectancy method as it accounts towards the remaining life years of the affected person.[213] The VSL is an appropriate approach for acute and "latent" deaths, whereas the VSLY is more relevant for chronic health impacts.[214] The VSL estimate remains constant over a life whereas VSLY declines with increasing age.[215]

People's WTP for the reduction of the risk of fatality can also be estimated by using revealed preference methods which observe market behaviour (indirect market methods) or by using stated preference methods (mainly contingent valuation methods). The most widely accepted revealed preference market methods is the labour market approach which analyses the risk premium for occupational hazards and averting behaviour/defensive expenditure approaches based on consumer product purchase and use decisions.[216] Consumer purchase studies have, for example, been applied to the purchase of safety-enhancing devices like airbags, smoke detectors or safer cars. Boardman et al. explain their underlying concept to measure the value of a statistical life as follows:[217] Based on a decision tree the following equations can be derived for the example of buying an airbag: The probability of surviving without an airbag is p, and the probability to survive with airbag is p+w as w determines the probability to save a statistical life by using an airbag (w=1/10 000, i.e. an airbag saves one statistical life of 10

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[207] Cadot, Malouche, and Saez, *Streamlining Non-Tariff Measures*, 45.
[208] Hammitt, "QALYs versus WTP," 992.
[209] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 294.
[210] Ibid.
[211] Boardman et al., *Cost-Benefit Analysis*, 346.
[212] Ibid., 412.
[213] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 295.
[214] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 204.
[215] Peter Abelson, *Establishing a Monetary Value for Lives Saved: Issues and Controversies* (Canberra, 2008), 4, Canberra, http://www.dpmc.gov.au/deregulation/obpr/docs/Working-paper-2-Peter-Abelson.pdf.
[216] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 294.
[217] Boardman et al., *Cost-Benefit Analysis*, 346, 347.

000 people having an airbag). Furthermore, it is assumed that consumers are indifferent between buying the 300 USD airbag. This leads to the following options to determine the VSL: 1) buying an airbag: (p+w)*VSL - 300USD and 2) not buying an airbag: p*VSL. As consumers are assumed to be indifferent, the two options can be equated and resolved to find a value for VSL, in this case 3 million USD. Labour market studies assess the additional wage premium which people have to be offered as compensation to assume increased risk of death on the job.[218] One problem about these two approaches to value a statistical life is, however, that it is assumed that people dispose of full information regarding the risk faced and that they act in a fully rational way.[219]

The VSLY can be estimated by three main approaches:[220] The value of a statistical life year can, for example, be derived from VSL estimates with a "rule of thumb". In this case the VSLY estimate is divided by the discounted remaining life years of a person. This approach is appealing due to its simplicity but also has drawbacks (deficits of the underlying life time consumption model and sensitivity regarding the discount rate). Moreover, the value of a statistical life year can be estimated by either direct estimations using the contingent valuation method or by indirect estimations based on the VSL estimates which are extended with further WTP estimates for given risk changes.

As various studies have been carried out over the years to estimate VSLs and VSLYs, analysts can draw on these results. Around 1990 various studies have been published estimating VSL values between 1.4 million USD and 4 million USD.[221] More recent studies have found higher values even though controlling for inflation.[222] Miller et al. find that the majority of VSL estimates vary from 1 to 10 million USD per statistical life.[223] Boardman et al. review four different meta-analyses and provide a table with their own VSL and VSLY estimates based on the results of the review:[224] Their estimate for the VSL is 5 million USD (with sensitivity analysis at around 3-7 million USD per life saved) and for the VSLY around 235.000 USD per person per year (based on a 40 year life expectancy). Pearce et al. also provide a table with an overview of recent VSL studies and their estimated values.[225]

Various countries have adopted one single VSL value for their policy assessments, but recent research has started to investigate in how fare values can be transferred between different contexts.[226] Based on empirical evidence four factors have been determined which influence the valuation of life risks and might make it necessary to adjust a VSL value to specific situations:[227] income, risk levels, latency in the occurrence of the negative health impacts and the age of the affected people. The evidence of the influence of the latter factor is mixed. In

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[218] Ibid., 347.
[219] Ibid., 348.
[220] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 204–207.
[221] Boardman et al., *Cost-Benefit Analysis*, 408.
[222] Ibid.
[223] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 294.
[224] Boardman et al., *Cost-Benefit Analysis*, 408–411.
[225] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 199.
[226] Ibid.
[227] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 295; Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 193.

contrast, it is widely acknowledged that income and absolute risk are the two determining factors for the validity of VSL estimates.[228] Viscusi and Aldy found an income elasticity of the WTP for mortality risk reduction of about 0.5 to 0.6.[229] According to Hammit, in practice the effects of individual differences in wealth or health quality are, however, generally ignored.[230] He explains that "it is possible to ignore the effects of individual differences in wealth or other factors that are considered ethically inappropriate by replacing individual VSLs with a value that is obtained by averaging over the objectionable characteristics".[231]

As various studies to estimate the VSL and VSLY have been carried out the question is not only in how far the values can be transferred between different contexts of policy assessments, but also in how far these usually country-specific results can be used for other countries. Boardman et al. establish the following four sets of criteria which can be considered to adjust values when transferring these estimates from one country to another or using them for a non-representative region.[232] The first set of criteria includes socio-economic factors and personal characteristics of a population which can differ in income, taste, age etc. The most important factor is thereby the difference in income as described above in 2.4.1. The VSL rises with increasing income and the estimate therefore has to be adapted by converting it to the domestic currency of the target country and by adjusting the estimate for differences in income. The second set of criteria refers to physical and other regional characteristics such as population densities, climate or topographies. Depending on the regulation or policy which is being assessed these factors might also affect the transferability of estimates. The third set of criteria accounts for the differences in the project criteria. The policy at issue should be as comparable as possible to the policy assessed by the study in terms of the availability and quality of alternatives of choices. Finally, the third set of criteria accounts for temporal changes as valuations may change over time with changing framework conditions.

2.4.2 Non-monetary valuation methods: QALY, DALY

Apart from the various methods described above to estimate the WTP for a non-market good also two non-monetary methods exist which are important in the health policy field: quality-adjusted life years (QALY) and disability-adjusted life years (DALY). QALYs have been used for almost four decades in the assessment of health impacts and DALYs for about two decades.[233] These two methods are the most common alternatives to WTP-based approaches when valuing morbidity impacts.[234] QALY and DALY values quantify health impacts and are often used in the evaluation of health policies in cost-utility analyses.[235] A cost-utility analysis is similar to a cost-effectiveness analysis as the costs of alternative policies are compared to

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[228] Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 198.
[229] W. Kip Viscusi and Joseph Aldy, "The Value of a Statistical Life: A Critical Review of Market Estimates throughout the World," *Harvard Law and Economics Discussion Paper*, no. 392 (2002): 4.
[230] Hammitt, "QALYs versus WTP," 994.
[231] Ibid.
[232] Boardman et al., *Cost-Benefit Analysis*, 433–436.
[233] F. Sassi, "Calculating QALYs, Comparing QALY and DALY Calculations," Health Policy and Planning 21, no. 5 (July 28, 2006): 402.
[234] Renda et al., *Assessing the Costs and Benefits of Regulation*, 137.
[235] Boardman et al., *Cost-Benefit Analysis*, 475.

quantified, but not monetised health outcomes.[236] In order to be used for a cost-benefit analysis the quantified QALY or DALY outcomes have to be monetised using further monetary approaches like the WTP and VSLY. QALYs can, for example, be directly monetized using estimated shadow prices for life years.[237] Various studies have been carried out to estimate the value of a QALY, but there is no clear consensus about the value.[238]

A QALY comprises two dimensions of health effects: the number of life years gained and the quality of life during these years.[239] The different options of health effects on those two dimensions are put into the common metric, the QALY. If a regulation reduces morbidity risks and provides health benefits it leads to an increase in QALYs. The estimation of QALYs is carried out in three steps: (i) the description of health states or disease conditions and the estimation of their duration; (ii) the valuation of these health states compared to other health states; (iii) the multiplication of the values given to these states by the estimated length of each health state.[240] The second step, the valuation of each health state, is analysed based on a health-related quality of life (HRQL) index. This index ranges from 1 which equals perfect health to 0 which represents death. In between different health states are possible when the individual suffers from illnesses of different severity like bronchitis or lung cancer.[241] Patients who have suffered from these diseases, medicals who are familiar with them or persons from the average population value each given health state.[242] In the third step these health quality weights are then multiplied by the duration of the corresponding health state to obtain the QALY values as described by Robinson and Hammit in the following summary box:

Box 2-2: Example for the use of QALYs[243]

(1) Status Quo: Without the regulation an individual would live for 10 more years with a HRQL of life of 0.7 which equals 7 QALYs.
(2) Implementation of regulation: With the regulation the average affected individual would live for 15 more years with a HRQL of 0.9 which equals 13.5 QALYs.
(3) QALYs gained: The QALY gain resulting from the regulation is therefore the difference between 13.5 QALYS and 7 QALYs which results in 6.5 QALYs gained. The QALY gain consists of two components: The increase in life expectancy from 10 to 15 years and an improvement of morbidity measured in HRQL from 0.7 to 0.9.

[236] Ibid.
[237] Ibid.
[238] Richard A. Hirth et al., "Willingness to Pay for a Quality-Adjusted Life Year In Search of a Standard," *Medical Decision Making* 20, no. 3 (July 1, 2000): 332.
[239] Renda et al., Assessing the Costs and Benefits of Regulation, 137.
[240] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 5.
[241] Matthew D. Adler, "QALY's and Policy Evaluation: A New Perspective," *Yale J. Health Pol'y L. & Ethics* 6 (2006): 2.
[242] Ibid.
[243] Lisa A. Robinson and James K. Hammitt, "Skills of the Trade: Valuing Health Risk Reductions in Benefit-Cost Analysis," *Journal of Benefit-Cost Analysis* 4, no. 1 (January 28, 2013): 120, http://www.degruyter.com/view/j/jbca.2013.4.issue-1/jbca-2012-0006/jbca-2012-0006.xml.

Four main methods of direct measurement exist to obtain the weights of health states: the health rating method, the time-trade-off method, the standard gamble method and the health index method.[244] For the health rating method QALYs are estimated by questionnaires in which the respondents have to assign a value between 0 (death) and 1 (perfect health) to different health states like "seriously disabled", "moderately disabled" or "minimally disabled".[245] For the time trade-off method respondents have to compare different health status with different time and quality of life characteristics and numbers can then be calculated from indifferences between different combinations of quality and length of life.[246] The standard gamble method is based on a decision tree that makes respondents chose between a certain health outcome and an uncertain treatment outcome with the possibility of a better or worse outcome.[247] The choice of these methods to determine the HRQL weights is important as it may influence the outcome of the assessment of the health impacts and might therefore influence priority decisions.[248]

As described above, QALYs can be used to evaluate different health states and risks of premature death of different individuals. The results from the different health conditions of the affected individuals can be summed to determine the overall QALYs which are lost or gained by a regulation.[249] In order to monetise the QALYs the QALY estimates can be used to qualify an estimated VSLY by applying the QALY weights (w) (0-1) to the VSLY: $QALY_t = w_t$*VSLY.[250] Hammit, however, argues that this combination is not advisable because firstly the QALY system and the cost-benefit analysis framework are not completely compatible. Secondly, he argues that the qualitatively different effects of factors such as the baseline risk or health states "imply that individuals cannot be expected to have a constant rate of substitution between QALYs and wealth" and therefore the monetary value of a QALY is not constant.[251] The relative value of mortality risk changes under WTP approaches and the QALY measurement is dependent upon the life expectancy, competing mortality risks and the individual's health as well as on the severity and the longevity of health effects.[252] WTP approaches additionally consider economic factors. The VSL, for example, reflects the marginal rate of substitution between mortality risks and income and is therefore clearly related to a person's wealth.[253] In contrast, the QALY metric is normally considered to be unrelated to the individual's economic situation.[254]

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[244] Boardman et al., *Cost-Benefit Analysis*, 477; Magnus Johannesson, *Theory and Methods of Economic Evaluation of Health Care* (Dordrecht: Kluwer Academic Publishers, 1996), 175.
[245] Boardman et al., *Cost-Benefit Analysis*, 477.
[246] Paul Dolan, "The Measurement of Health-Related Quality of Life for Use in Resource Allocation Decisions in Health Care," *Handbook of Health Economics* 1 (2000): 1733.
[247] Ibid.
[248] Bjarne Robberstad, "QALYs vs DALYs vs LYs Gained: What Are the Differences, and What Difference Do They Make for Health Care Priority Setting?," *Norsk Epidemiologi* 15, no. 2 (2005): 186.
[249] Renda et al., *Assessing the Costs and Benefits of Regulation*, 137.
[250] Boardman et al., *Cost-Benefit Analysis*, 412.
[251] Hammitt, "QALYs versus WTP," 998.
[252] Ibid., 992.
[253] Ibid.
[254] Ibid., 991.

The DALY metric is closely related to the QALY concept as it was developed in the 1990s broadly with the same framework as the QALY metric.[255] It was developed as a summary measurement for the health of a population in preparation of the World Health Organisation (WHO) Global Burden of Disease study.[256] The motivation behind this project was to develop a metric which would account for nonfatal health impacts and which would allow estimating relative health impacts across different diseases to improve allocative efficiency.[257] Instead of measuring the life years gained like the QALY the concept of a DALY measures the life years lost to premature death including the loss of healthy life years due to poor health.[258] This means that DALYs estimate an optimal life expectancy and then subtract the life years which are lost due to premature death and due to "any mental or physical disability caused by disease or injury".[259] The DALY scale is therefore inverted from the QALY measure as it measures perfect health with 0 and death with 1. DALYs include a weighting factor which is age-related and they measure the loss in mortality or morbidity in relation to an idealized optimal life expectancy whereas QALYs measure the latter in relation to immediate death.[260] In the DALY metric the age where people provide support to others is weighted more than the life of children and old people because their social value is higher.[261] Apart from age and sex DALYs are constructed as well as QALYs to not consider any other non-health characteristics such as income, education or ethnicity because people should be treated as equal as possible.[262]

Although the QALY and DALY metrics are widely used, their underlying assumptions are controversial and debated. QALYs and DALYs both adjust for life expectancy of the affected people, but only DALY adjusts for age as has been described above. The age-weighting factor in DALYs includes a controversial judgement that life years at a younger age are worth more for society than life years at an older age.[263] Another critique about the use of QALYs is that that their construction implies that the utility of a particular health status is proportional to the time this status prevails.[264] Furthermore, some scholars criticize that QALYs and DALYs combine two very different dimensions, i.e. mortality and morbidity, in one common metric. Other scholars, however, argue that this is necessary to make different health states comparable for resource allocation/comparison of different policy options.[265] It is also questioned if DALYs and QALYs (which are more subtle measurements as they account also for morbidity effects) provide more information than crude measurements like the VSL.[266]

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[255] Sassi, "Calculating QALYs, Comparing QALY and DALY Calculations," 402.
[256] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 89.
[257] Ibid.
[258] Ibid., 88.
[259] Ibid., 89.
[260] Hammitt, "QALYs versus WTP," 988.
[261] Robberstad, "QALYs vs DALYs vs LYs Gained," 186.
[262] Ibid., 185.
[263] Hammitt, "QALYs versus WTP," 988.
[264] Boardman et al., *Cost-Benefit Analysis*, 481.
[265] Hammitt, "QALYs versus WTP," 183.
[266] Robberstad, "QALYs vs DALYs vs LYs Gained," 190.

Another critique is that at the international level the QALY and DALY metrics discriminate developing countries.[267] This is partially due to the fact that different diseases are weighted differently and communicable diseases which are more prevalent in developing countries are weighted higher.

2.4.3 Cost-benefit versus cost-effectiveness frameworks

Apart from cost-benefit analyses also other instruments for decision-making exist such as the cost-effectiveness analysis. As the concept of cost-effectiveness analysis is an alternative approach to cost-benefit analyses, especially in the area of health policy,[268] the former is described briefly to distinguish between the two concepts. A cost-effectiveness analysis compares policy alternatives based on their costs to a quantified but not monetized benefit, e.g. it compares the costs of different measures per lives saved.[269] Therefore, a cost-effectiveness analysis can only recommend which measures is the most cost-efficient to achieve a determined goal, but it cannot determine whether "something is worth doing".[270] The cost-effectiveness analysis is, however, useful when a desired outcome is designed and a set of alternative regulatory options need to be compared in terms of their cost-effectiveness.[271]

In order to differentiate between cost-benefit analyses and cost-effectiveness analyses it can be said that the two concepts address different steps of analysis. A government can carry out a cost-benefit analysis to determine if an NTM at issue is worthwhile because the welfare benefits outweigh the economic costs (“Should a regulation be implemented?”). Additionally, a government could carry out a cost-effectiveness analysis to find the most cost-effective policy design achieving a desired result (“How should the regulation be implemented?”). The latter analysis could help to determine if the NTM is to be maintained, whether the NTM could be converged or harmonized with main trading partners or international standards or if mutual recognition agreements should be negotiated. However, it should be taken into account that the concepts of cost-benefit analysis and cost-effectiveness analysis are interlinked, because the design of a regulation will determine the costs and benefits of a regulation. Thus, the design of the regulation has an impact on the outcome of the cost-benefit analysis.

2.4.4 Other methods, approaches, concepts

Apart from the frameworks and methodologies which are presented above, there are also further approaches to assess regulatory impacts which are discussed in literature. Therefore, three concepts which may be encountered frequently in discussions about impact analyses are explained briefly in the following subchapter.

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[267] Ibid., 188.
[268] Boardman et al., *Cost-Benefit Analysis*, 464.
[269] Beghin, van Tongeren, and Marette, *A Cost-Benefit Framework for the Assessment of Non-Tariff Measures in Agro-Food Trade*, 17.
[270] Boardman et al., *Cost-Benefit Analysis*, 484.
[271] Cellini and Kee, “Cost-Effectiveness and Cost-Benefit Analysis,” 496.

Partial equilibrium and computable general equilibrium models

Partial equilibrium and computable general equilibrium models provide economic frameworks which can model the effects of a policy, but they are not specifically designed to establish a monetary value for a non-market impact. These models rather generally analyse the impacts of a regulation on the economy and predict e.g. an increase or decrease of demand for a market good. Partial equilibrium models show direct impacts on the economic agents in the same sector whereby computable general equilibrium models show effects on the whole economy including other sectors or markets. Partial equilibrium models can be used when the impact of the regulation on other markets is expected to be *de minimis* and can be considered irrelevant or estimated without employing a model which represents the whole economy.[272] This can be the case, for example, if the direct impacts of the regulation are likely to be more significant than the indirect impacts on other markets.[273] When the indirect effects are expected to be large it is more suitable to apply a general equilibrium model. [274]

The life satisfaction approach

The life satisfaction approach is a new approach which has gained attention over the past decade. It is based on the idea that the final goal of public policy should "be to promote people's happiness or satisfaction".[275] The life satisfaction approach therefore "estimates the value of non-market goods by looking at how they impact on people's reported well-being".[276] It is a new approach to evaluation techniques that aims to adress some of the defaults associated with stated and revealed preference methodologies by focusing on the measurement of well-being rather than the satisfaction of preferences. This is assumed to better represent an individual's utility.[277] The "approach uses econometric methods to estimate the life satisfaction provided by non-market goods, and this is then converted into a monetary figure by also estimating the effect of income on life satisfaction."[278] The OCED has developed a Better Life Index and has developed a new set of guidelines on the measurement of subjective well-being which use the life satisfaction approach for cost-benefit analyses and particularly for the valuation of non-market goods.[279]

2.5 Conclusion

For the assessment of health benefits of NTMs cost-benefit analyses can be used as one possible framework. The purpose, the general steps to be followed and the main parameters and concepts of a cost-benefit analysis have been explained. This has shown that a cost-benefit analysis is quite complex, time- and resource-intensive. A major challenge is thereby

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[272] Kopp, Krupnick, and Toman, *Cost-Benefit Analysis and Regulatory Reform: An Assessement of the Science and the Art*, 27.
[273] Renda et al., *Assessing the Costs and Benefits of Regulation*, 51.
[274] Kopp, Krupnick, and Toman, *Cost-Benefit Analysis and Regulatory Reform: An Assessement of the Science and the Art*, 27.
[275] Renda et al., *Assessing the Costs and Benefits of Regulation*, 224.
[276] Fujiwara and Campbell, Valuation Techniques for Social Cost-Benefit Analysis Stated Preference, Revealed Preference and Subjective Well-Being Approaches, 13.
[277] Ibid.
[278] Ibid., 7.
[279] Renda et al., Assessing the Costs and Benefits of Regulation, 145.

the definition of indirect non-market impacts of the regulation such as impacts on health and particularly its quantification and monetisation. Selected monetary and non-monetary methodologies have been presented as possible methodologies which can be used to measure health benefits of regulations. In this regard the concept of WTP has been explained including revealed and stated preference methods to estimate WTP values and the specific WTP concepts VSL and VSLY. The QALY and DALY metrics have been added because these non-monetary metrics are often used in the public health field. The described concepts of measurements differ in terms of their theoretical foundations, underlying assumptions, their units of measurement and their results i.e. the values they assign to changes in health risks.[280] Hammit, moreover, adds that "[t]he effects of individual characteristics including age, health, competing mortality risk, and income, on the value of reducing mortality risk differ systematically between QALY and WTP approaches."[281] As a consequence, the method for an assessment of health benefits should be selected on a case-by–case basis. The choice between WTP and QALY or DALY measures will depend on the specific case at issue, the data, time and resources available and judgments about which assumptions and individual characteristics need to be taken into account.

The underlying assumptions as well as the effects of individual characteristics on these methodologies have been criticised by various scholars. However, it also has to be taken into account that extending the metrics to account for all the different characteristics which might determine the outcome of the measurements would make their application even more complex and resource intensive. Furthermore, it can be argued that the measurement of health impacts in cost-benefit analyses is not meant to substitute a political decision-making process. Such a cost-benefit analysis of health impacts including the quantification and monetisation of impacts is rather intended to improve information about a subject-matter and enable the decision-maker to make more informed decisions. Therefore, it is argued that it is better to have a result which is as accurate as possible than no result at all.

The concept of cost-benefit analysis can also be applied to analyse NTMs and specifically technical regulations like SPS measures. NTMs in the form of technical regulations are regulations with the particularity that they have an effect on traded goods and change their quantities or prices. A cost-benefit analysis can be particularly useful to assess the impacts of NTMs which address market failures related to product quality and therefore do not directly translate into clearly identifiable short-term illness.[282] However, a cost-benefit analysis is technically complex and data-intensive. Therefore, the framework might be suitable above all to assess selected NTMs only which might have a particular importance in a trade negotiation either for the trading partner or for society. Moreover, the analyst can try to rely as far as possible on existing studies and data concerning the health impacts at issue to reduce the resource intensity of the assessment. Beghin et al. agree that the WTP and QALY measures can in principle be used to analyse NTMs.[283] However, they also point out that the application

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[280] Hammitt, "QALYs versus WTP," 998.
[281] Ibid., 990.
[282] Beghin, van Tongeren, and Marette, *A Cost-Benefit Framework for the Assessment of Non-Tariff Measures in Agro-Food Trade*, 18.
[283] Ibid., 17.

of the cost-benefit framework to NTMs has one drawback: A cost-benefit analysis takes into account non-market impacts on consumers and the society, but it does not account for consumer's responses in demand. Therefore, "[t]he costs estimated through QALYs methods are not mapped into demand adjustments linked to reactions of consumers. Consequently, they cannot take into account market price reactions and their concomitant impact on producers and consumers".[284] Despite this drawback a cost-benefit analysis can be a useful tool to assess health benefits of technical regulations.

[284] Ibid.

3 Cost-benefit analyses of health impacts in practice: Impact assessments by the European Commission

The objective of the following chapter is to provide practical examples how the EU uses cost-benefit analyses to assess health benefits of NTMs. Answers are provided to the questions whether and how the methodologies described above for the quantification and monetisation of these benefits are used. The European framework for cost-benefit analyses has been selected, because it is expected that having the largest shares of world exports and imports.[285] Given its political importance[286] the EU has developed a sophisticated impact assessment and cost-benefit framework and uses established methods to assess regulatory health benefits. Together with the UK system the EU's impact assessment system has been considered as one of the most advanced compared to the other EU member states' approaches.[287] As will be explained in subchapter 3.2.2. the European Commission (EC), however, does not assess health impacts of NTMs. Therefore, three alternative standard regulatory impact assessments have been selected which assess potential health impacts of tradable goods. These standard impact assessments could theoretically also be applied to assess an NTM, because, as explained in the foregoing chapters, an NTM *de facto* is a regulation affecting trade in goods. The following chapter will show how the cost-benefit framework and the methodologies highlighted in the last chapter are applied in practice by the EC. The chapter will first outline the challenges to find an example of a regulatory cost-benefit analysis of health impacts in which a methodology for quantification or monetisation has been used. Furthermore, it will describe the general impact assessment framework used in the EU, the types of impacts which are analysed in EU impact assessments and the methodologies which are recommended to be used within a cost-benefit analysis to quantify and monetise impacts. Based on the theoretical approach laid down in the EU guidelines the chapter surveys three practical examples of realised impact assessments.

3.1 The practice: General use of cost-benefit analyses, quantification and monetisation approaches and selection of examples

The following subchapter describes the general use of cost-benefit analyses in EU impact assessments and shows that only a small number of impact assessments quantify and monetise social benefits. Furthermore, it explains the resulting challenges to find a suitable practical example of an impact assessment which monetises health benefits in the EU.

In the beginning of the 1990s only a few OECD countries were using regulatory impact assessments, but by the mid-1990s more than half of them had adopted some kind of

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[285] European Commission, "EU Position in World Trade," *European Commission, Trade*, accessed October 26, 2014, http://ec.europa.eu/trade/policy/eu-position-in-world-trade/.
[286] "Exploring Europe's Significance in a Globalized World," *International Policy Digest*, accessed October 26, 2014, http://www.internationalpolicydigest.org/2014/02/09/exploring-europes-significance-globalized-world/.
[287] European Court of Auditors, *Impact Assessments in the EU Institutions: Do They Support Decision-Making?*, Special Report No 3 (Luxembourg: European Court of Auditors, 2010), 9.

framework on regulatory impact assessments.[288] At the beginning of 2000 already half of the OECD countries used regulatory impact assessment comprehensively and a few countries applied them selectively for some types of regulations.[289] Today regulatory impact assessments are widely used and almost all OECD countries have some kind framework for regulatory impact assessment or impact assessments in place (they have different names in different countries).[290]

Nonetheless, not all governments make use of cost-benefit analyses as part of impact assessments for their decision making.[291] As cost-benefit analyses are technically challenging and information-intensive, resource constraints and lack of available information may be some of the reasons why governments do not apply them.[292] Looking at the quantification and monetisation of regulatory impacts prognos found that the extent of quantification and monetization in practice is lower than the official commitment to using cost-benefit analyses and the available guidance on methodologies let assume.[293] Furthermore, they found that in the impact assessments analysed often more weight was put on the analysis of costs than on the analysis of benefits. According to them this is mainly due to two reasons: Firstly, it is usually more difficult from a methodological point of view to quantify costs than benefits. Secondly, methodological challenges arise particularly when assessing other than economic impacts, e.g. "societal" impacts in the form of social and environmental impacts. The latter is said to be due to the lack of market value for public goods and methodological complexity for the estimation of the latter. These results are in accordance with the results of the foregoing chapter describing the cost-benefit analysis framework and possible methodologies for the assessment of health impacts which have been perceived to be very complex and resource-intensive.

This conclusion is confirmed when looking at the practice of impact assessment in the EU. Until 2005 only few of the impact assessments carried out in the EU had included quantified or monetized cost-benefit-analyses.[294] In 2010 the European Court of Auditors evaluated impact assessments in the EU and found that in 84% of the evaluated impact assessments (based on sample assessments from 2003-2008) social benefits were analysed.[295] Yet in all the impact assessments 23% of the social benefits and 12% of the social costs were quantified or monetized whereas 53% of the economic costs and 41% of the economic benefits were monetised.[296] Insufficient quantification of costs and benefits was also identified by the Impact Assessment Board as a deficiency of EU impact assessments.[297] According to the

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[288] Radaelli, "The Diffusion of Regulatory Impact Analysis – Best Practice or Lesson-Drawing?," 723.
[289] Ibid.
[290] Thiessen et al., *Quantifying the Benefits of Regulatory Proposals: International Practice*, 5.
[291] World Trade Organization (WTO), *World Trade Report 2012: Trade and Public Policies: A Closer Look at Non-Tariff* Measures *in the 21st Century*, 53.
[292] Ibid.
[293] Thiessen et al., *Quantifying the Benefits of Regulatory Proposals: International Practice*, 64.
[294] Renda et al., *Assessing the Costs and Benefits of Regulation*, 2.
[295] European Court of Auditors, *Impact Assessments in the EU Institutions: Do They Support Decision-Making?*, 37.
[296] Ibid., 38.
[297] Impact Assessment Board, *Impact Assessment Board Report for 2012* (Brussels: European Commission, 2012), 26.

European Court of Auditors one of the main impediments to increased quantification and monetization of costs and benefits is the timely collection of comparable data. Challenges regarding the availability of data are though partially owed to difference in data quality and reliability among member states.[298]

This background makes it difficult to find practical examples of impact assessments which show how the EU applies cost-benefit frameworks and uses the described methodologies to quantify and monetise regulatory health benefits. In the search for such an example the first objective was to find an impact assessment of NTMs including a cost-benefit analysis of NTMs which also quantifies and monetises health benefits. As will be explained further down in subchapter 3.2.3., however, impact assessments for trade agreements assessing the effects of NTM only quantify or monetise economic effects, but not health impacts.

Thus, the second objective was to find an impact assessment of a general EU regulation which, from a trade perspective, could constitute an NTM and which included the monetisation of health benefits of the regulation. The assumption is that even if social impacts of NTMs might not be quantified for the purpose of trade analyses, the regulation which includes measures affecting trade, i.e. NTMs, would be analysed for national or in the case of the EU for community policy-making. In the search for such an impact assessment the online archive of the EU impact assessments was screened for assessments in selected policy areas which might assess regulations with health effects, i.e. DG Health and Consumer Policies, Agriculture and Rural Development, Maritime Affairs and Fisheries. The aim was to find an impact assessment of a regulation which potentially constitutes an SPS measure and in which health impacts have been monetised to show how these types of impacts are currently analysed by the EC. Following these criteria three impact assessments have been selected which monetise at least to some extent potential health benefits of the regulation at issue. These are described in subchapter 3.3.

3.2 Impact assessments and cost-benefit analyses in the EU

Taking the EU as practical example for the assessment of health impacts the following subchapter aims to provide an overview over the approach to impact assessments and cost-benefit analyses in the EU. It describes the existing guidelines for selected types of impact assessment, explains which are the main institutions involved in such an impact assessment and lays out the main steps that need to be undertaken in the course of the impact assessment. Furthermore, it discusses which types of benefits are assessed in EU impact assessments and which methodologies for the quantification and monetisation of health impacts are recommended. Finally, the main strengths and weakness of the EU impact assessment are summarised.

[298] European Court of Auditors, *Impact Assessments in the EU Institutions: Do They Support Decision-Making?*, 39.

3.2.1 EU impact assessment guidelines, steps and institutions

This subchapter provides an overview of the general framework for impact assessments in the EU. It describes the relevant guidelines for an assessment of health impacts of NTMs and what information these provide about methodologies to assess social impacts. Moreover, it gives an overview of the main institutions involved and the main steps of an impact assessment.

Selected EU impact assessment guidelines

Impact assessments in the EU have to be carried out for all legislative proposals, non-legislative initiatives such as action plans or negotiating guidelines which will define future policies as well as implementing measures and delegated acts with clearly significant impacts.[299] These impact assessments have to follow the respective guidelines provided by the EC. The key guidelines in the EU impact assessment system which may be relevant for the assessment of health impacts will be described in the following.[300] Currently the main impact assessment framework for the EC is provided in the Impact Assessment Guidelines 2009. These guidelines provide quality standards and compulsory procedures to be followed when carrying out an impact assessment.[301] The methodologies which can be used to quantify and monetise regulatory impacts are provided in the Annexes to the Guidelines, particularly in Annex 9 on the assessment of non-market impacts on environment and health.[302] The guidance on methodologies to be used in Annex 9 is further complemented by an external review of different methods for assessing costs and benefits of regulation which was carried out by the Centre for European Policy Studies in preparation for a revision of the EU Impact Assessment Guidelines.[303]

Apart from the general Impact Assessment Guidelines some DGs have prepared additional guidance documents for their specific thematic fields. Those which may be relevant for the assessment of health benefits of NTMs and where more information can be found regarding the assessment of these benefits are listed and briefly described in the following:

On the one hand, there are various guidelines which describe approaches and methodologies for the assessment of different social and health impacts. The DG for Employment, Social Affairs & Inclusion (DG EMPL) and DG SANCO have, for example, prepared a specific Guide for Assessing Social Impacts which shall help to assess the social impacts of a specific policy by providing questions and sources six different policy domains (among others public health, social protection, health, social security and educational systems).[304] DG SANCO provides a European Policy Health Impact Assessment Guide which has been elaborated to

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[299] European Commission, *Impact Assessment Guidelines*, 6.
[300] An overview of key documents for EU impact assessments is provided here: http://ec.europa.eu/smart-regulation/impact/key_docs/key_docs_en.htm
[301] European Commission, *Impact Assessment Guidelines*.
[302] European Commission, *Part III: Annexes to Impact Assessment Guidelines* (Brussels: European Commission, 2009).
[303] Renda et al., *Assessing the Costs and Benefits of Regulation*.
[304] European Commission, *Guidance for Assessing Social Impacts within the Commission Impact Assessment System* (Brussels: European Commission, 2009), http://ec.europa.eu/smart-regulation/impact/key_docs/docs/guidance_for_assessing_social_impacts.pdf.

provide a specific guide to assessing health impacts of Community actions and policies and a standard generic methodology for health impact assessments.[305] However, this guide is from 2004 and does not provide much in-depth information about approaches to quantify health impacts; it rather describes a general impact analysis framework.

On the other hand, the EC provides guidance for impact assessments in the field of trade policy. The Trade Sustainability Impact Assessment Guide (TSIA) of 2006 is a framework provided by DG Trade to specifically assess impacts of trade agreements.[306] The objective is to integrate sustainability into trade policy making and trade negotiations and to pursue a commercial policy that achieves the biggest gains in welfare not just in trade terms.[307] Therefore, TSIAs shall help to "measure both the economic and the non-trade impacts potentially arising from trade agreements" to provide guidance on how to design the trade agreement itself as well as possible accompanying measures.[308] These objectives as laid out in the TSIA Guidelines give the impression that TSIAs also account for social non-market impacts of trade policies which could as well include the assessment of NTMs and their health impacts. This is not the case. The general impact assessment is carried out before a proposal for a negotiation mandate. It identifies the main expected economic, social and environmental impacts and provides general guidance on whether action should be taken or not, i.e. whether the Commission should receive a mandate to negotiate a trade agreement.[309] TSIAs are, in contrast, an ongoing process carried out during the negotiation as well as after the negotiation when the trade agreement is implemented. The TSIA therefore provides information on how action should be taken, i.e. how the trade agreement should be designed.[310]

Main institutions involved in EU impact assessments

The main institution responsible for an impact assessment is the specific DG that is responsible for the policy proposal.[311] Each DG disposes of an impact assessment unit as the main source of support.[312] The unit C.2 for Regulatory Policy and Impact Assessment at the Secretariat General is responsible for the general layout of the guidelines and general questions. An Impact Assessment Board examines the quality of each impact assessment and makes recommendations on improvements if necessary and approves the quality of the impact assessment.[313] Both of these institutions as well as other EU services can also provide internal expertise through impact assessment steering groups and inter-service consultation.[314] Furthermore, the Commission also involves external expertise from stakeholders and works with experts from academia, governments or consultancies in order to better understand and

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[305] Debbie Abrahams et al., *European Policy Health Impact Assessment (EPHIA) - A Guide* (International Health Impact Assessment Consortium, 2004), 2, 3, http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf.
[306] European Commission, External Trade, *Handbook for Trade Sustainability Impact Assessment* (Brussels: European Commission, 2006).
[307] Ibid., 7.
[308] Ibid.
[309] Ibid., 11.
[310] Ibid.
[311] European Commission, *Impact Assessment Guidelines*, 6.
[312] Ibid., 3.
[313] Ibid., 6.
[314] European Commission, External Trade, *Handbook for Trade Sustainability Impact Assessment*, 6.

assess the impacts of a particular policy.[315] Apparently the EC relies quite heavily on external expertise for their impact assessments, more than the US, Australia or the UK.[316]

Main steps of EU impact assessments

The main steps of the procedure to carry out an impact assessment can be summarized as follows: At the beginning a roadmap for the impact assessment is drafted and published and an impact assessment steering group is set up involving all relevant commission services.[317] For the collection of expertise and information the guidelines point out that an impact assessment can draw on external expertise and consultants, but it must be drafted by the fully responsible Comisssion service itself.[318] Furthermore, the guidelines state that the primary source of advice should be the expert groups set up by the EC and its agencies.[319] Furthermore, the obligatory involvement of interested stakeholders which are consulted regarding key issues of the impact assessment forms an integral part of the impact assessment process.[320] After the analysis has been carried out, the draft impact assessment report is presented to the Impact Assessment Board for recommendations and revised before it goes into inter-service consultation, to the College of Commissioners and to EU institutions. Lastly, the final report is published online for the public where it is categorized according to policy areas and years.[321]

3.2.2 Analysis of health impacts in the EU

As the EU has been selected as a practical example for the assessment of health impacts of NTMs, in the following subchapter it will be described which type of impacts are suggested to be analysed within a Trade Sustainability Impact Assessment (TSIA) for trade agreements and how impacts of NTMs are assessed by the EC. The result is that health impacts of NTMs are not assessed in the context of trade policy analyses in the EU. Therefore, the main EU Impact Assessment Guidelines will be taken into account to see in how far health benefits are analysed in the context of regular impact assessments of EU policy proposals.

Health impacts in the trade policy context

Looking at the guidelines for Trade and Sustainability Impact Assessments these have been designed in order to provide information during ongoing trade negotiations or thereafter on how action should be taken, i.e. how a trade agreement which is under negotiation or accompanying measures should be designed.[322] Furthermore, as described above the objective of TSIAs is to also measure non-trade impacts of trade agreements.[323]

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[315] European Commission, *Impact Assessment Guidelines*, 18, 19.
[316] Thiessen et al., *Quantifying the Benefits of Regulatory Proposals: International Practice*, 48.
[317] European Commission, *Impact Assessment Guidelines*, 7.
[318] Ibid., 18.
[319] Ibid.
[320] Ibid., 19.
[321] Online archive for EU impact assessments: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2014_en.htm
[322] European Commission, External Trade, *Handbook for Trade Sustainability Impact Assessment*, 11.
[323] Ibid., 7.

In particular, the TSIA Guidelines provide the following nine key themes for impact areas which clearly include social impacts such as impacts on health and education:[324]

Table 3-1: Key impact areas TSIAs

Pillar	**Economic**	**Social**	**Environment**
Themes	Real income Fixed capital formation Employment	Poverty Health and education Equity	Biodiversity Environmental quality Natural resource stocks

Therefore, it could be expected that during a trade negotiation such as the TTIP negotiation between the EU and the US an assessment of NTMs was undertaken which includes the analysis not only of economic impacts, but also of social impacts such as health effects. Commissioned by DG Trade Ecorys has carried out an economic analysis on NTMs in EU-US trade and investment in 2009.[325] In 2014 DG Trade has furthermore published an inception report for a Trade Sustainability Impact Assessment for the TTIP negotiations which is also authored by Ecorys.[326] The first study identified and selected the most important NTMs in 23 sectors which affect trade between the US and the EU and estimated their trade restrictiveness and economic costs. The conclusion was the removal of all actionable NTMs would lead to substantial increases of economic welfare, i.e. the gross domestic product (GDP), in both countries. However, no social impacts of NTMs were analysed. The outline for the future impact assessment presented in the inception report foresees a qualitative social impact analysis of health impacts: "Particular attention will be paid to the more 'intangible' impacts on health and consumer welfare that relate to approximation of standards or regulation. While comprehensive quantification of these effects is unlikely to be possible, taken the issues into consideration in a more qualitative manner in the synopsis of the impact assessment is important to provide the full picture on the expected sustainability impacts at sector level."[327] These studies suggest that if health impacts of NTMs have been analysed in the EU this has only been done qualitatively. The review of further EU publications on TSIAs and other NTM assessments has confirmed that the EU does not analyse and quantify social impacts such as health impacts of NTMs for trade policy purposes.[328] The EU analyses NTM impacts focus on the trade restrictiveness of NTMs and the potential impacts on GDP resulting from the removal or regulatory convergence of NTMs. Thus, it can be concluded that the assessment of trade agreements or trade policies in the EU does not include the quantification or monetisation of social impacts such as health or environmental impacts.

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[324] Ibid., 28.
[325] Koen G. Berden et al., *Non-Tariff Measures in EU-US Trade and Investment–An Economic Analysis*, Final Report (Rotterdam: ECORYS Nederland BV, 2009), https://www.gtap.agecon.purdue.edu/resources/download/5177.pdf.
[326] ECORYS, *Trade Sustainability Impact Assessment on the Transatlantic Trade and Investment Partnership (TTIP) between the European Union and the United States of America*, Final Inception Report (Rotterdam: ECORYS Nederland BV, 2014).
[327] Ibid., 60.
[328] This result was confirmed by email by the Chief Economist Unit of DG Trade. However, the answer cannot be considered as official or representative as validation was not possible.

Health impacts in the regular EU impact assessment framework

As health impacts of NTMs are not analysed within the trade policy context, the general impact assessment framework of the EU is considered to analyse how health impacts of regulations are assessed in the EU. The general Impact Assessment Guidelines follow an integrated approach which requires assessing economic, environmental and social impacts.[329] Furthermore, the guidelines require that an impact assessment should go beyond direct effects of a regulation and also include indirect effects such as side-effects, knock-on effects in other economic sectors.[330] The guidelines accentuate the difference between direct and indirect health impacts; whereas direct health impacts occur if the legislation aims directly at the health impacts whereas indirect impacts occur when these are only a secondary effect.[1] Health impacts are expected to occur mostly in regulations addressing environmental protection, health care, product safety, safety at work, consumer protection.[331]

In order to support the identification of possible social impacts of a regulation the EU provides a list with possible impacts in its assessment guidelines. Selected potential social impacts are listed in the following table to show which kind of impacts are assessed within regular EU impact assessments and whom they might potentially affect. Particularly the first category of social impacts is relevant for the assessment of health impacts of technical regulations like SPS measures.

Table 3-2: Social impacts in EU impact assessments

Assessment of social impacts	
Public health (affecting primarily consumers and society as a whole)	Examples: regulations improving or decreasing life expectancy, mortality or morbidity, regulations leading to health risks due to contaminants/harmful substances e.g. in feed and food or other natural resources like water, air etc., regulations affecting life-style related behaviours such as alcohol and tobacco consumption
Employment and labour markets (affecting society as a whole and producers)	Examples: regulations increasing or decreasing the demand or the supply of labour
Social inclusion and gender equality (affecting primarily society as a whole)	Examples: regulations that increase or decrease effects on particular groups/sectors of the society such as women, children, elderly, vulnerable or poor people, disabled, minorities
Social security and educational systems (affecting primarily consumers and society as a whole)	Examples: regulations affecting the quality of or access to services for education, vocational training, social security

After determining the health impacts that need to be assessed the guidelines require the identification of the affected groups and the assignment of the possible impacts to different

[329] European Commission, *Impact Assessment Guidelines*, 31 ff.
[330] Ibid., 32.
[331] European Commission, *Part III: Annexes to Impact Assessment Guidelines*, 40.

policy options assessed.[332] Furthermore, the likelihood (low, medium, high probability) and the magnitude of these impacts as well as the time period during which the impacts will occur need to be determined.[333] For the most important impacts it is recommended that an in-depth analysis is undertaken to provide monetary or quantified estimates of the expected impacts.[334] The recommended methodologies for this last step will be described in the next subchapter.

3.2.3 Methodologies for the quantification and monetisation of health impacts

This subchapter will describe which methodologies for the quantification and monetisation of health impacts are recommended to be used in EU impact assessments.

The general impact assessment guidelines recommend assessing regulatory impacts in qualitative, quantitative and monetary terms, because an impact assessment is considered to be more convincing the more quantification it can provide.[335] In order to do so the assessment guidelines recommend two general approaches for the in-depth qualitative and quantitative analysis of the most significant impacts: (i) Case studies to assess expected impacts over time or (ii) a quantitative estimation of impacts with different techniques ranging from extrapolation (i.e. using existing data and adapting it to the specific context) to fully-fledged quantitative modelling.[336] [337] Concerning specifically the monetisation of non-market impacts Annexe 9[338] to the guidelines recommends the use of the WTP or the WTA approaches. Suggested techniques for their use are stated preference and revealed preferences methods. Furthermore, particularly for a quantitative assessment of health impacts the Guidelines recommend the following monetary and non-monetary methodologies: QALY, DALY (disability adjusted life years) and HLY (health life years) metrics are recommended for quantitative approaches. 'Accounting style approaches', i.e. COL and Human Capital as well as preference based approaches like the Value of Statistical Life (VOSL) and Value of Statistical Life Year (VOLY) using the concepts of WTP or WTA are suggested for monetary approaches. The guidelines, furthermore, point out that for a comprehensive cost-benefit analysis monetary approaches are necessary.[339] However, non-monetary approaches can also sometimes be monetized if results can be given a monetary value.[340] These recommended methods are in line with the selection of potential methodologies in chapter 2. The guidelines also allow for the use of existing estimates from other policy assessments, if no policy-specific estimates of the health impacts are available.[341] Based on former research the EU

[332] European Commission, *Impact Assessment Guidelines*, 38, 39.
[333] Ibid.
[334] Ibid., 39.
[335] Ibid., 31, 32.
[336] Ibid., 39.
[337] Theoretically, an online platform should be available which provides guidance and best practices about the main steps and which contains indicators, an overview of qualitative and quantitative tools and access to different databases. However, the platform does not seem to be online anymore: http://iatools.jrc.ec.europa.eu/bin/view/IQTool/WebHome.html
[338] European Commission, *Part III: Annexes to Impact Assessment Guidelines*, 40 ff.
[339] Ibid., 41.
[340] Ibid.
[341] Ibid., 44.

established a value of 1-2 million EUR for VOSL and 50.000-100.000 EUR for VOLY in Europe.[342]

The trade specific Trade Sustainability Impact Assessments guidelines provide very little information about methodologies to quantify impacts and no information about methodologies to monetise impacts. The guidelines state that for the preliminary assessment of impacts an analysis of potential economic, social and environmental impacts of the trade negotiations on all parties should be conducted using a quantitative and qualitative assessment.[343] The qualitative assessment refers, however, only to economic impacts and lists computable general equilibrium models, gravity models and studies of specific horizontal or sector issues as possible instruments.[344] It is thereby recognized that the necessary data might be difficult to obtain and that this poses a challenge in developing but also in developed countries and makes quantitative analysis difficult.[345]

The specific guide for assessing social impacts issued by DG SANCO and DG ENV recommends the use of HLY, QALY and DALY to assess health impacts.[346] Additionally, the guidelines explicitly recommend that health costs and benefits should be monetised because this will enable a comparison of effects across sectors.[347] For monetisation techniques the guide refers to Annex 9 of the general Impact Assessment Guidelines which have been described above. The guide also admits, however, that it is not always feasible to monetise benefits and it sometimes might be controversial.[348]

Overall, the general EU impact assessment guidelines including the Annexes provide the best guidance on how to assess, i.e. quantify and monetise health benefits. The guidelines describe a broad range of possible methodologies which can be used to assess non-market impacts of regulations such as health impacts. However, all methodologies are described on very general level and do not give indications which methods are suitable for which kind of assessment or context. In this regard the guidelines state that in the past different methodologies have been used and these experiences can provide guidance on the choice of methods: "[I]t is important to check one's choice of methodology against how similar problems have already been dealt with".[349]

3.2.4 Strengths and weaknesses of the EU impact assessment framework

Jacob et al. evaluate the overall EU impact assessment framework as positive: "The EU approach has evolved as a role model of an integrated approach, with a high implementation rate and high level of transparency. Through the establishment of different initiatives and

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[342] Ibid.
[343] European Commission, External Trade, *Handbook for Trade Sustainability Impact Assessment*, 18.
[344] Ibid.
[345] Ibid., 31.
[346] European Commission, *Guidance for Assessing Social Impacts within the Commission Impact Assessment System*, 30.
[347] Ibid.
[348] Ibid.
[349] European Commission, *Part III: Annexes to Impact Assessment Guidelines*, 43.

institutions—especially the launching of the Impact Assessment Board—the quality of the assessments and their political relevance in the decision-making has improved over time."[350]

Besides, the EU impact assessment framework seems to have three main strengths: Firstly, the comprehensiveness of the impacts which are assessed during an impact assessment process. The EU impact assessment framework covers all three dimensions of sustainability and considers economic, social and environmental impacts (see subchapter 3.2.2.). Secondly, according to the guidelines EU impact assessments cover impacts not only within the EU, but also outside the EU, i.e. impacts on partner countries. Thirdly, the institutionalised involvement of stakeholders in the impact assessment process seems to be strength of the EU impact assessment framework.

These strengths are also supported by the LIASE Network of Excellence which has established a comprehensive website containing a knowledge platform about policy impact assessments.[351] As weaknesses of the EU impact assessment system they point out three aspects which have been found likewise in the foregoing chapter about methodologies.[352] They criticise that the EU does not provide detailed guidelines about which methodology to choose for which situation. Furthermore, the suggested methodologies require extensive data which is often not easily available. Therefore, they conclude that the suggested methodologies are very resource intensive in their implementation. Another critique which focuses particularly in the assessment of health impacts in the EU is that the impact assessment system is perceived to mainly focus on impacts on the economy and the business environment.[353] Therefore, the EU approach could undermine good health policy-making.[354]

3.3 Examples: EU Impact Assessment Reports

The following subchapter describes three selected practical examples of EU impact assessments which assess regulatory health impacts. These examples show how the EC analyses health impacts of regulations. The results are also valuable for an assessment of NTMs because these regulations affect tradable goods and therefore resemble or constitute SPS measures.

In general few of the reports on the webpage[355]of the EC in the areas of Health and Consumer Policy, Agriculture and Rural Development, Maritime Affairs and Fisheries have used

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[350] Klaus Jacob et al., *Integrating the Environment in Regulatory Impact Assessments* (Paris: OECD, 2011), 25.
[351] http://www.liaise-kit.eu/ LIAISE KIT is a knowledge and community platform to support Policy Impact Assessment for Sustainable Development. It provides access to knowledge for decision making, e.g. on models, data sets, methods and experts throughout all steps of policy impact assessment and all dimensions of sustainable development. Furthermore, the LIAISE KIT is a platform where new publications, projects, experts, models, events are announced to the community
[352] "EU Guidelines," *LIASE KIT - Knowledge for Decision Making*, accessed October 27, 2014, http://www.liaise-kit.eu/ia-methods/eu-guidelines.
[353] K. E. Smith et al., "Is the Increasing Policy Use of Impact Assessment in Europe Likely to Undermine Efforts to Achieve Healthy Public Policy?," *Journal of Epidemiology & Community Health* 64, no. 6 (June 1, 2010): 478.
[354] Ibid.
[355] Online EU Impact Assessment Archive: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2014_en.htm

quantitative cost-benefit analyses. If a quantitative analysis has been carried out, mainly the costs of a regulation have been described, often even in monetary terms. The potential benefits, however, have mostly been described in qualitative terms only. The criteria for the selection of the following examples were the following:

(1) The regulation has impacts on public health.

(2) The impact assessment of the regulatory proposal uses a methodology to quantify or monetize the health impacts.

(3) The regulation concerns a tradable good and could therefore constitute an NTM.

The following analysis of impact assessment examples will first describe the regulation at issue and explain why this impact assessment has been selected and, if applicable, what kind of NTM it constitutes. Then it will explain how health impacts have been analysed in the impact assessment and which methodologies have been used. Finally, the impact assessment will be briefly compared to the cost-benefit framework and the methodologies to quantify or monetise health impacts as described in chapter 2.

3.3.1 EU Impact Assessment 1- The Tobacco Products Directive (2012)

The regulation

The first EU impact assessment of 2012 accompanies the proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products, which is hereafter called TPD (Tobacco Products Directive). The Directive 2001/37/EC was adopted in 2001 and updated and revised in 2012. Overall it Directive aims at improving the functioning of the internal market.[356]

The revision of TPD centres around five policy areas: (1) the extension of the coverage of the regulation to include also smokeless tobacco products, nicotine containing products and herbal products for smoking, (2) the harmonisation of packaging & labelling which needs to be updated and extended (the type, size and location of health warnings are already harmonized, but e.g. rules on pictorial health warnings are not), (3) the harmonisation of rules regarding prohibited ingredients/additives and their reporting, (4) shared rules on cross-border distance sales to prevent circumvention of the TPD and (5) the implementation of traceability and security features to avoid illicit trade and circumvention of the TPD.

The regulation has been selected because it aims at reducing negative health impacts which are assessed in the impact assessment by using methodologies to quantify and monetise these values. Furthermore, the TPD concerns tobacco which is a tradable good and the measures

[356] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying the Document Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, SWD(2012) 452 Final, SWD(2012) 453 Final, COM(2012) 788 Final, (Brussels: European Commission, 2012), 1.

which address the harmonisation of packaging and labelling as well as the measures regulating the prohibited ingredients/additives could constitute TBTs or SPS measures.

The assessment of health impacts

Taking into account the aim of the TPD to improve the internal market and achieve a better health protection the impact assessment has analysed economic, social and health impacts.[357] The impacts were divided into direct impacts (i.e. costs and benefits associated with the implementation of the regulation like compliance costs for economic stakeholders and administrative costs for Governments) and indirect impacts (effects on revenue/profits and employment for economic stakeholders and the improvement of public health for Governments and the society).[358]

The impact on public health has been monetised in line with the Commission's impact assessment guidelines. [359] In this regard the following steps have been followed in the assessment:

For the first step it has been assessed how the regulation will impact the tobacco consumption as it is expected that the regulation will reduce smoking (less people will start and some people will quit). Several independent studies analysing experiences and estimates from other countries (Canada, Australia, UK and US) which tried to quantify the impact of labelling and packaging measures were analysed. Based on these studies the tentative contributions of each of the five policy areas of the regulation to the projected decrease of cigarette/tobacco consumption have been estimated and it was calculated that that the regulation would lead to a total reduction in consumption of about 2% (a total of 1.7-2.6%).[360]

As a next step the gain for public health is calculated by estimating the morbidity and mortality risks caused by tobacco. Different studies are described which show that minimum 50% of smokers experience a premature death and that smokers have less average lifetime in good health.[361] One study provides estimates specifically for the EU-27 and concludes that smokers die 14 years earlier than people that never smoked. [362] These estimates are then taken to calculate the saved life-years for the EU: A 2% consumption reduction in the EU will result in 2,4 million people who quit smoking which is then multiplied by 14 saved life years and thus results in 16.8 million life years.

Based on the Impact Assessment Guidelines 2009 it is then calculated how much value these gained life years provide to society. The impact assessment describes the human capital and willingness-to-pay approaches as possible methods to monetise the value of a life. However, the impact assessment concludes that using only the human capital approach does not accord with European values as it would exclude persons which are not part of the work force.[363] The

[357] Ibid., 57.
[358] Ibid., 58.
[359] Ibid., 57.
[360] Ibid., 115.
[361] Ibid., Annex 5, 15.
[362] Ibid.
[363] Ibid., Annex 5, 16, 17.

approach of the EU is to consider the value of a life year which is gained instead of the value of life years lost.[364] The impact assessment guidelines provide values obtained from studies of the research project ExternE: the values range from 50.000 EUR to 100.000 EUR for the value of one statistical life year.[365] The median estimate is calculated as 52.000 EUR independent of the age or place of residence of the victim.[366] These values are then applied to the expected reduction in harmful tobacco consumption leading to an annual benefit for society of 10.3 billion EU for a 2% reduction.

Table 3-3: Premature mortality decreases[367]

	Premature mortality decrease with different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Premature mortality cost due to smoking (million EUR)	511,546	506,379	501,212	496,044	490,877
Net benefit (million EUR)	5,167	10,334	15,501	20,669	25,836

Moreover, other health benefits have been calculated in the impact assessment. Firstly, the health benefits arising from a reduction in health care expenditure have been estimated.[368] Based on clinical evidence six main diseases associated with smoking have been listed and a standard smoking attributable factor for each category has been associated. This has been combined with statistical data of EU public healthcare expenditures which have been attributed to different causes including smoking. As a result it is estimated that 25 billion EUR of healthcare expenditure is spent on treating smoking-attributable diseases. Then the assessment report calculates that a reduction in smoking results in a certain reduction of this health care expenditure. However, it is not explained how this reduction of smoking-attributable health care expenditure is calculated. It is estimated that a reduction of consumption of 2% leads to annual savings in health care expenditure of 506 million EUR.

Secondly, the benefits resulting from higher productivity due to reduced smoking-attributable sickness and deaths causing premature retirement or absenteeism have been estimated. The productivity loss due to premature retirement of paid workforce is based on WHO calculations of years lived with disability and on Eurostat estimations of retired people due to smoking related diseases and of average labour costs.[369] The productivity loss due to absenteeism during active work life is estimated based on GHK calculations about the missing work days in the EU in 2009 caused by diseases related to smoking and based on the lost wages method which takes the average daily salary of an employee to calculate the

[364] Ibid.
[365] Ibid., Annex 5, 17.
[366] Ibid.
[367] Andrew Jarvis et al., *A Study on Liability and the Health Costs of Smoking*, Final Report for DG SANCO European Commission (London: GHK, 2009).
[368] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying the Document Proposal for a Directive of the European Parliament and of the Council on the Approximation of the Laws, Regulations and Administrative Provisions of the Member States Concerning the Manufacture, Presentation and Sale of Tobacco and Related Products*, Annex 5, 19–23.
[369] Ibid., Annex 5, 23.

resulting productivity loss.[370] The estimated reduction of this loss due to a reduction in smoking is again presented in a table, but it is not explained how the reduction is calculated.[371] Overall, it is estimated that a 2% reduction in smoking would lead to a decrease of the annual productivity loss to the EU economy of 165 million EUR.[372] The overall health benefits as described for the whole society and the Government resulting from the TPD are summarised in the final table.

Finally, the impact assessment calculates different social discounting rates to compare costs and benefits that occur at different points in time and calculates the overall net costs and benefits for public health as follows:

Table 3-4: Overall net costs and benefits[373]

	Overall net costs and benefits (in million EUR) with different percentage reduction in tobacco consumption				
	1%	2%	3%	4%	5%
Decrease in excise tax revenues	794	1588	2382	3176	3970
Decrease in health care expenditures	253	506	759	1012	1265
Decrease of productivity loss	83	165	248	331	413
- due to early retirement/deaths	61	122	183	244	305
- due to absenteeism	22	43	65	87	108
Decrease in premature mortality costs	5,167	10,334	15,501	20,699	25,836
Overall net benefit	4,709	9,417	14,126	18,836	23,544
Discounted values	2,016	4,032	6,048	8,064	10,080

The final result of the impact assessment is then presented in a table which shows all policy options for each of the five policy areas as well as the chosen policy option in each category with a short justification.

Practice versus theory

The impact assessment referred to the methodologies provided in the impact assessment guidelines and chose the methodology of estimating a VOLY which is reasonable for the expected health impacts of the TPD. The guidance and estimates for the VOLY provided in the guidelines were used and applied to the expected impacts of the TPD.

The general estimations about the impacts of packaging and labelling on smoking were taken from existing studies undertaken by authorities of other countries. The EU specific calculations and analyses were provided by a specific study on liability and the health costs of smoking commissioned by DG SANCO and undertaken by GHK in association with the University of Exeter (UK) and the Public Health Advocacy Institute (USA).[374] However, it needs to be pointed out that the health impacts have been estimated based on the general

[370] Ibid., Annex 5, 24.
[371] Ibid., Annex 5, 25.
[372] Ibid., Annex 5, 26.
[373] Ibid., 116.
[374] Jarvis et al., *A Study on Liability and the Health Costs of Smoking*.

expected impact of the TPD leading to a 2% reduction of smoking, but no differentiation of impact levels according to the different policy options has been provided. Theoretically the impacts of all different policy options should be assessed, but taking into account that in this case five policy areas with one to four different options were to be analysed, it was probably not feasible to quantify and monetise the expected differentiated impacts for each policy option.

3.3.2 EU Impact Assessment 2 - Control of Salmonella in fresh meat (2011)

The regulation

The European Parliament and Council adopted a legislative measure in 2003 to improve the control of Salmonella and other food-borne zoonotic agents in food (Regulation laying down detailed rules on a Salmonella food safety criterion in fresh meat of fowl of Gallus gallus and turkeys, Regulation (EC) No 2160/2003).[375] The general objective of this regulation is to ensure safe food and improve public health by reducing the overall level of Salmonella in Europe and ensuring absence of Salmonella and controls at critical points all along the food chain.[376] Therefore, a harmonised *Salmonella* food safety criterion for fresh poultry meat sold by refrigeration or by frozen means should be established as well as a trade restriction for non-compliant poultry meat.[377]

Targets for Salmonella reduction and sampling requirements for the first two steps in the food value chain (sampling of salmonella in breeding flocks and broilers/turkeys in slaughterhouses) have already been implemented, but now a harmonised food safety criterion shall be introduced for the final production stage as well (sampling of Salmonella in fresh poultry meat from slaughter to retail).[378] The harmonised food safety criterion will require the absence of *Salmonella* in 25 grams of the fresh poultry meat and set up specific sampling schemes and analytical methods to meet this target.[379] The latter are addressed to ensure that Member States and food business operators as well as non-EU producers interpret the criterion and the establishment of adequate sampling procedures evenly and comparably and thus operate under the same conditions.[380]

The lead Directorate-General for this regulatory proposal is DG SANCO. DG Trade, DG Agriculture and the Secretariat-General formed part of the Impact Assessment Steering Group.

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[375] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying the Document Commission Regulation Laying down Detailed Rules on a Salmonella Food Safety Criterion in Fresh Meat of Fowl of Gallus Gallus and Turkeys* (Brussels: European Commission, 2011), 3.
[376] Ibid., 11.
[377] Ibid., 4.
[378] Ibid., 5.
[379] Ibid., 6.
[380] Ibid., 14.

The regulation has been selected because with its aim to improve public health by reducing Salmonella in food the regulation constitutes an SPS measure. This is supported by the indication in the impact assessment that a WTO SPS consultation will take place.[381]

The assessment of health impacts

The impact assessment analyses the costs and benefits of different sampling methods for testing Salmonella presence in fresh poultry meat.[382] It analyses economic impacts mainly for food business operators (the major part of the testing and sampling costs will be borne by food business operators) as well as social impacts resulting from the application of the food safety criterion which includes health impacts for consumers.[383]

The impact assessment describes very comprehensively the stakeholder groups which are potentially affected by the regulation. The food safety criterion will affect wholesalers and retailers within the EU and third country traders equally which ensures fair competition between meat produced in the EU and imported meat.[384] Poultry slaughterhouses and processing (cutting) plants will be affected by the minimum requirements for sampling and food business operators responsible for sampling and testing will be affected by additional compliance costs.[385] In case of positive samples food business operators might implement corrective measures which might affect as well primary production sectors.[386] Furthermore, competent authorities responsible for verification of the compliance with the food safety criterion as well as for the monitoring of Salmonella presence may be affected indirectly by the regulation.[387] Finally, consumers may be affected negatively if their confidence in the safety of poultry meat might decrease (or increase in the case of some member states) if more cases of Salmonella are detected due to the new regulation.[388] On the other side they might also be affected positively as the measure is expected to decrease *Salmonella* prevalence in the poultry meat leading to a reduction of human salmonellosis cases.[389]

The impact on public health is analysed rather from a long-term than short-term perspective as it is expected that the consequences of a positive, testing and control procedures will improve hygiene along the supply chain and reduce the cases of human salmonellosis.[390] In the main part of the impact assessment the health impacts of the different policy options have been described only qualitatively, the quantification is described in Annex 5.

In Annex 5 first of all the cases of human salmonellosis per year for the EU-27 were estimated using studies from the UK and the Netherlands and the European Food Safety Agency (EFSA)/European Centre for Disease Prevention and Control Community report on

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[381] Ibid., 3.
[382] Ibid., 6.
[383] Ibid., 12.
[384] Ibid., 8.
[385] Ibid.
[386] Ibid.
[387] Ibid.
[388] Ibid.
[389] Ibid.
[390] Ibid., 4.

trends and sources of zoonoses, zoonotic agents in the EU in 2008.[391] Then the mortality and hospitalisation during outbreaks of human salmonellosis were reported based on zoonoses monitoring reports (mortality: 1/1000; hospitalisation: 15%-20%).[392]

In order to quantify and monetise the expected impact from human salmonellosis the EC requested a scientific opinion from the EFSA. The "Scientific Opinion on a quantitative estimation of the public health impact of setting a new target for the reduction of Salmonella in laying hens" was published in 2010 in the EFSA Journal.[393] In this EFSA study the estimated burden from two Dutch studies was extrapolated to the EU-27. The result is an estimated annual disease burden of 0.2-0.5 million DALYs and total annual costs between 0.2 and 3 billion EUR.[394]

The two studies on which EFSA based its DALY and cost extrapolation estimate the disease burden and costs of selected foodborne pathogens in the Netherlands. The first study assessed the disease burden in DALYs by estimating the incidence of gastrointestinal infectious disease due to Campylobacter, Salmonella and Shigella based on an update of a Dutch community-based study about national incidence data on foodborne disease.[395] Furthermore, the study estimated the burden of post-infectious irritable bowel syndrome (PI-IBS) caused by salmonella and concluded that the latter increased the burden of disease for Salmonella to 1686 DALYs.[396] The second study estimated the cost-of-illness by accumulating direct health care costs (e.g. medical consultation, hospitalization, drugs), direct non-health care costs (e.g. travel costs) and indirect non-health care costs (e.g. patient's productivity losses).[397] The study provides the corresponding cost vectors for each cost category[398] and comes to the conclusion that the overall cost estimate for salmonella is 10.8 million EUR.[399]

The impact assessment then compares the result of this study with the results of three other studies. Firstly, the results of a Finnish study regarding the economic impact of Finland's Salmonella control programme for broilers are extrapolated to the EU-27 by applying the calculated costs per case (outpatient, hospitalised cases, deaths and unreported cases) to the numbers of cases in the EU found in the EU 2007 zoonoses monitoring report.[400] Secondly, the estimated costs of Salmonellosis in the UK and the Netherlands are reported and

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[391] Ibid., Annex 3, 41.
[392] Ibid.
[393] EFSA Panel on Biological Hazards (BIOHAZ), "Scientific Opinion on a Quantitative Estimation of the Public Health Impact of Setting a New Target for the Reduction of Salmonella in Laying Hens", *EFSA Journal* 8, no. 4 (2010): 1–86.
[394] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying the Document Commission Regulation Laying down Detailed Rules on a Salmonella Food Safety Criterion in Fresh Meat of Fowl of Gallus Gallus and Turkeys*, Annex 3, 41, 42.
[395] J.A. Haagsma et al., "Disease burden of post-infectious irritable bowel syndrome in The Netherlands", *Journal of Epidemiology & Infection*, no. 139 (2010): 1650–1656, 1652.
[396] Ibid. 1653.
[397] J.A. Haagsma et al., *Disease burden and costs of selected foodborne pathogens in the Netherlands, 2006*, RIVM Report 330331001/2009, (Bilthoven: RIVM, 2009), 16.
[398] Ibid., 17.
[399] Ibid., 78.
[400] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying the Document Commission Regulation Laying down Detailed Rules on a Salmonella Food Safety Criterion in Fresh Meat of Fowl of Gallus Gallus and Turkeys*, Annex 3, 42.

extrapolated at the EU level. In the end a combination of all these results is presented as the range of possible monetised health impacts: "In summary, an overall cost of salmonellosis at EU level is estimated by EFSA between 0.2 and 3 billion EUR, being most likely about 400 to 900 million € based on additional Finnish and British studies."[401]

After comparing the results of the 6 different policy options in a scorecard analysis in the end of the impact assessment, policy option 3 is considered as the preferred option.[402] Policy option 3 includes detailed rules on the two most important Salmonella strains, it prescribes 5 samples per batch and sets up weekly sampling procedures which can be reduced based on favourable outcomes.[403] Regarding the ranking of the options and the weight given to the scorecard categories it is explained that the harmonisation of trade was considered as "predominant" for the ranking and that legal/political aspects were given high weight as well. Subsequently, the further ranking was "based on the balance between costs and public health impact".[404]

Practice versus theory

Although this regulation targets explicitly public health the quantification and monetisation of health impacts remains rather limited. Data for the quantification and monetisation is mainly drawn from reports of different member states and from scientific opinions of EFSA and is then extrapolated to the EU-27. However, the data sources and extrapolation are described very briefly and the description of the data is partially imprecise as it is not always clear to the reader which types of zoonoses, which time periods and which affected groups (i.e. EU-27, Dutch population etc.) it is referred to. The methodology of quantifying health impacts as DALYs is used, but not further described similarly as the monetisation of the DALY values. In the final evaluation of the policy options no net impact is calculated, but a scorecard analysis with qualitative descriptions of the evaluation criteria is used.

3.3.3 EU Impact Assessment 3 – REACH (2011)

REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) is an EU system in force since 2007 which shall ensure the safe use of chemicals. Under Annex XVII of the REACH Regulation a new amendment has been proposed which shall prohibit the use of cadmium and its compounds in all types of jewellery products.[405] As this regulation constitutes a prohibition of harmful substances it could either be a TBT or a SPS measure, depending on the precise text and specified objective of the regulation.

An impact assessment for the amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and restriction of

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[401] Ibid.
[402] Ibid., 20.
[403] Ibid., 21.
[404] Ibid.
[405] "REACH System for Safer Use of Chemicals – Frequently Asked Questions," *Europa Press Releases Database*, accessed October 7, 2014, http://europa.eu/rapid/press-release_MEMO-10-631_en.htm?locale=fr.

Chemicals (REACH) as regards Annex XVII (Cadmium) was carried out in 2011.[406] In the impact assessment health, environmental and socio-economic impacts were analysed.[407] For the socio-economic assessment external expertise was taken into account commissioning Risk & Policy Analysts Limited, (RPA Ltd) to carry out a study.[408] In this study different disease burdens and their economic costs were estimated for the professional and hobby use of brazing alloys containing cadmium and two long-term effects, i.e. lung cancer and emphysema were analysed.

For the calculation of the health impacts of the cadmium exposure an attributable fraction model was used from the Imperial College London and the Health and Safety Laboratory. The model is used to "derive estimates of the number of deaths for particular types of cancer […] that can be attributed to exposure to a given agent over a defined period".[409] Based on the CAREX database[410] which provides data on workers exposure to cadmium in the EU-15 a baseline for the health burden caused by lung cancer was established for workers in the EU-15.[411] The same calculation was then carried out with two scenarios of possible cadmium exposure reductions (a 'maximum potential reduction' and a 'more realistic' scenario) resulting from the new regulation.[412] This led to two results of potential reductions (reduction of 6 and 29 deaths) in annual lung cancer deaths.[413] A similar estimation was made for occupationally induced emphysema and for the risk of mortality associated with exposure to cadmium for hobby users.[414] The results are shown in the following table:

Table 3-5: Predicted Reduction in Health Burden with Restriction on Cadmium in Brazing[415]

Predicted Health Benefits: Reduction in Health Burden with Restrictions on Cadmium in Brazing				
	Excess mortalities/cases for different scenarios		**Cases per annum over 20 years**	
	Low Exposure	**High Exposure**	**Low Exposure**	**High Exposure**
Professional use				
Lung cancer	6	29	6	29
Emphysema	9	15	9	15

[406] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying Document to the Commission Regulation (EU) Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as Regards Annex XVII (Cadmium)*, SEC(2011) 633 Final (Brussels: European Commission, 2011), 18.
[407] Ibid.
[408] Ibid., 4.
[409] Ibid., 56.
[410] The CAREX (CARcinogen EXposure) database provides selected exposure data and documented estimates of the number of exposed workers by country, carcinogen, and industry: http://www.ttl.fi/en/chemical_safety/carex/description_of_carex/pages/default.aspx
[411] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying Document to the Commission Regulation (EU) Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as Regards Annex XVII (Cadmium)*, 56.
[412] Ibid., 57.
[413] Ibid., 58.
[414] Ibid., 64.
[415] Ibid., 65.

Hobby use					
5% DIY (do it yourself) boiler makers[416]	Crude death rate	1.4	1.7	0.07	0.09
	Age standardised	0.88	1.04	0.04	0.05

In order to monetise these estimations of health benefits of the regulation three possible categories of costs are suggested and explained, i.e.health service costs, productivity costs and the value of the lost HRQL to the individual, but only the latter is calculated.[417]

At first the health impact of cancer related mortality is evaluated and the VOSL and VOLY figures provided by the Strategic Environmental Assessment Guidance for preparing a Restrictions Dossier (by the European Chemicals Agency) are provided in the report. These values for mortality and morbidity consist of central and sensitivity values, are linked to exposure to environmental pollution and account for some expenditure for health care costs, as well as productivity costs and the lost quality of life.[418] However, these VOLY and VOSL estimations do not specifically refer to cancer. Therefore, the recommendation by DG ENV is followed and a 50% cancer premium is added to the general WTP figures to take the illness before the actual death into account.[419] Regarding non-fatal effects of cancer the report does not provide any estimates and states that no reliable willingness-to-pay estimates are available for this scenario.[420]

In a second step the health impacts of occupational emphysema are valuated. Estimates are used from a summary report of four burden of illness studies assessing chronic obstructive pulmonary diseases (emphysema is a type of this disease). In this summary report estimates for the direct and indirect costs per year per patient for the economic burden of chronic obstructive pulmonary diseases are provided.[421] The impact assessment indicates that actually the WTP for the lost life quality should be added, but no reliable data for QALYs lost due to emphysema could be found.[422]

Based on these calculations estimated values for each avoided disease case (cancer and emphysema related mortality as well as mortality risk for hobby users) are provided and combined with the estimations of avoided cases for professional and hobby users. Finally, these estimations are discounted at the 4% European Commission rate.[423]

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[416] Affected by exceedance of European tolerable weekly intake
[417] European Commission, *Commission Staff Working Document - Impact Assessment - Accompanying Document to the Commission Regulation (EU) Amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as Regards Annex XVII (Cadmium)*, 65.
[418] Ibid., 66.
[419] Ibid.
[420] Ibid.
[421] Ibid., 67.
[422] Ibid.
[423] Ibid.

As a result of the overall impact assessment as preferred option the complete restriction of cadmium in jewelleries was proposed and for PVC an extension of the existing cadmium limit was proposed for all PVC articles for a 10 year period for specified building products.[424]

Practice versus theory

The assessment of the socio-economic impacts was carried out by an external consultancy (Risk & Policy Analysts Limited, (RPA Ltd)). They referred to well established methodologies like VOSL, VOLY and QALYs and used these as far as data was available or adapted the estimations as e.g. using the cancer premium. Taking into account time and resource constraints they tried use the available data as good as possible to monetise as precisely as possible the health benefits of the implementation of the amendment. In the overall impact assessment no net value was calculated in the end, but an overview table was provided with the calculated costs and benefits for each policy option.[425]

3.4 Conclusion

In sum, it has been shown that the EU does not carry out assessments of health impacts for trade policy purposes. Therefore, the comprehensive general EU impact assessment framework has been described as an alternative, including the methodologies which are recommended to be used for the assessment of health impacts. Three examples of existing impact assessments have been described which show how the described methods are applied in practice. As these regulations affect tradable goods, it can be assumed that methodologies could also be applied to assess NTMs. It has to be remarked, however, that only few EU impact assessments monetise health impacts of regulations. One reason might be that the suggested methods are complex and data-intensive. Therefore, one has to be aware that the application of these methods to NTMs will not be possible on a large scale, but only to assess selected, prioritized NTMs.

[424] Ibid., 28, 31.
[425] Ibid., 32.

4 Assessment of health impacts in developing countries

With a rising share in international trade the significance of NTMs is also increasing for developing countries. When a developing country is involved in a trade negotiation which addresses NTMs it must decide about its position regarding the removal, convergence or maintenance of NTMs. As a foundation for policy decisions it is helpful to have tools to analyse the net welfare impact of NTMs. One possible tool currently used in regulatory impact assessments in developed countries is the cost-benefit framework as described in the foregoing chapters. However, this raises the question of whether this cost-benefit analysis framework is useful for developing countries and if so, what should they take into account when applying it? Developing countries often have different political, economic and social conditions which shape their policy-making process. Do these factors affect the suitability of the cost-benefit approach and how would it have to be adapted?

The following chapter makes suggestions for how developing countries might approach the assessment of regulatory health impacts by taking these constraints into account. The chapter will first consider which different framework conditions and constraints should be taken into account for developing countries and what conclusions can be drawn from the European impact assessment framework. It will then present a simplified cost-benefit framework that shows the general steps which could be followed to assess the health impacts of a regulation and reflect what methodologies are seen as useful. Finally, data sources for the main methodologies which can be used as a basis for regulatory assessments will be provided. These might be transferred to a developing country context.

Due to the very diverse social, cultural, political and economic contexts of developing countries the following chapter is based on very general framework criteria which may matter for some but not necessarily for all countries. As a consequence the conclusions drawn and observations made might not be valid for all developing countries. Please note that other the approaches of other countries e.g. from the UK or the US experiences are also worth looking into. These countries apparently draw more heavily on internal expertise than the European Commission which draws significantly on external expertise from consultancies.

4.1 Different contextual conditions for (trade) policy-making in developing countries

Different contextual frameworks in countries may lead to different challenges as well as needs for policy-making. Krieger et al. point out that "[f]or developing countries, Eurocentric policy and programme HIA [health impact assessments] are luxuries that are not the immediate horizon".[426] Guidance on health impact assessment is primarily developed by analysts from high-HDI countries and consequently based on the evidence and experience gained in these

[426] Gary R. Krieger et al., "Health Impact Assessment in Developing Countries," in *Health Impact Assessment: Past Achievement, Current Understanding and Future Progress in Health Impact Assessment*, ed. John Kemm (Oxford: Oxford University Press, 2013), 271.

countries.[427] Only 6% of the work published on health impact assessments refer specifically to settings in developing countries.[428] Therefore, Winkler et al. suggest that the recommended methods should be expanded upon while more research on the question of which method makes sense in what context and for what purpose is carried out.[429]

As this paper addresses the question how health impacts can be assessed within a cost-benefit framework in order to use the results for trade negotiations, in the following chapter the main challenges for developing countries regarding policy-making in general as well as policy-making in the areas of trade policy and public health will be described. Subsequently, conclusions will be drawn about which of these factors may influence the capacity of developing countries to carry out cost-benefit analyses of health impacts for the negotiation of trade policies and what this means for the use of the different methodologies.

One critical factor for general policy-making and policy implementation in developing countries can be a lack of sufficient resources to manage their policy affairs and formulate and implement policies successfully. The lack of adequate resources includes human as well as material resources (i.e. a sufficient number of trained and equipped staff), adequate authorities who ensure that policies are implemented how they were intended and necessary facilities like land, equipment, buildings.[430] The OECD describes the lack of skills at an individual level, weak organizational capacities and procedures at the organizational level and little incentives and governance structures to create an enabling environment for policy-makers as the major challenges for capacity development in developing countries.[431] The introduction of a regulatory impact assessment can therefore be particularly challenging for countries with limited experience of economic analysis of regulations, unclear regulatory processes and poor stakeholder consultation processes.[432]

Looking specifically at challenges for trade policy-making, Craig van Grasstek identifies in particular the following two challenges:[433] Firstly, the collection and analysis of relevant data often poses a challenge. Considering the resource constraints in developing countries and as an alternative to developing of one's own data system, the data provided by international organizations is readily available. Secondly, successful trade policy making depends critically on effective domestic communication, i.e. communication and coordination between government ministries as well as communication between the government and the private sector and civil society. Inter-ministerial coordination is not only important in trade policy per se, but also regarding policy measures in areas of environmental, social or cultural policies

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[427] Mirko S. Winkler et al., "Untapped Potential of Health Impact Assessment," *Bulletin of the World Health Organization*, accessed October 27, 2014, http://www.who.int/bulletin/volumes/91/4/12-112318/en/.
[428] Krieger et al., "Health Impact Assessment in Developing Countries," 266.
[429] Winkler et al., "Untapped Potential of Health Impact Assessment."
[430] Taiwo Makinde, "Problems of Policy Implementation in Developing Nations: The Nigerian Experience," *Journal of Social Science* 11, no. 1 (2005): 63, 64.
[431] Organisation for Economic Development and Co-operation (OECD), *The Challenge of Capacity Development - Working Towards Good Practice* (Paris: OECD Publishing, 2006), 13.
[432] Claudio M. Radaelli, "Diffusion without Convergence: How Political Context Shapes the Adoption of Regulatory Impact Assessment," *Journal of European Public Policy* 12, no. 5 (October 2005): 724, 725.
[433] Craig VanGrasstek, *The Challenges of Trade Policymaking: Analysis, Communication and Representation*, United Nations Conference on Trade and Development - Policy Issues in International Trade and Commodities Study Series, No 36 (New York and Geneva: United Nations, 2008), 19–23.

which are not primarily aimed at taxing or regulating trade, but which nonetheless have a significant effect on trade of goods. The above two challenges should also be taken into account when considering how developing countries can analyse regulatory health impacts for the purpose of trade policy-making.

Finally, regarding challenges for evidence-based policy-making particularly in the field of public health, Pappaioanou et al. identify the three challenges in developing countries: the capacity of decision-makers to identify, interpret and use the correct data, the capacity of technical experts to deliver timely, accurate data for the decision-makers and the capacity of the health information system which should guarantee the gathering, assessment and reporting of the necessary health data for policy-making.[434]

Overall, the lack of technical skills in decision-makers and technical advisors, the lack of data collection and data availability and the lack of institutional capacities such as communication and coordination procedures between ministries and with non-governmental stakeholders may be some of the main challenges affecting cost-benefit analyses of regulations with health impacts for trade policy-making.

Two main conclusions can be drawn from this: firstly, taking into account these resource constraints, it is advisable to consider carefully which NTMs need to be analysed comprehensively. This may be necessary for NTMs which are expected to have significant social impacts, or because they are of particular political interest for society or the countries involved in the trade negotiation. Secondly, if the decision is taken to assess the net welfare impacts of a specific NTM, it is necessary to consider the best approach to do this by taking into account its specific needs and constraints. A cost-benefit framework which is feasible for developing countries facing the described constraints ideally fulfils the following criteria:

(1) Few and simple analytical steps to follow

(2) Use of methodologies with a wide applicability and a low data-intensity

(3) And/or use of existing values (i) from specific studies or (ii) from sources that provide ready-made estimates (as far as possible)

Based on conclusions drawn from the EU health impact assessments in the next subchapter, the following subchapters will make suggestions for approaches to cost-benefit assessments regarding these three criteria.

4.2 Conclusions from the EU approach

Three conclusions for developing countries can be drawn from the EU examples of cost-benefit analyses of health impacts. The first and most important conclusion is that the three EU examples of health impact assessments use data from existing studies or ready-made VSL values. None of the impact assessments analysed in chapter 3 had carried out individual

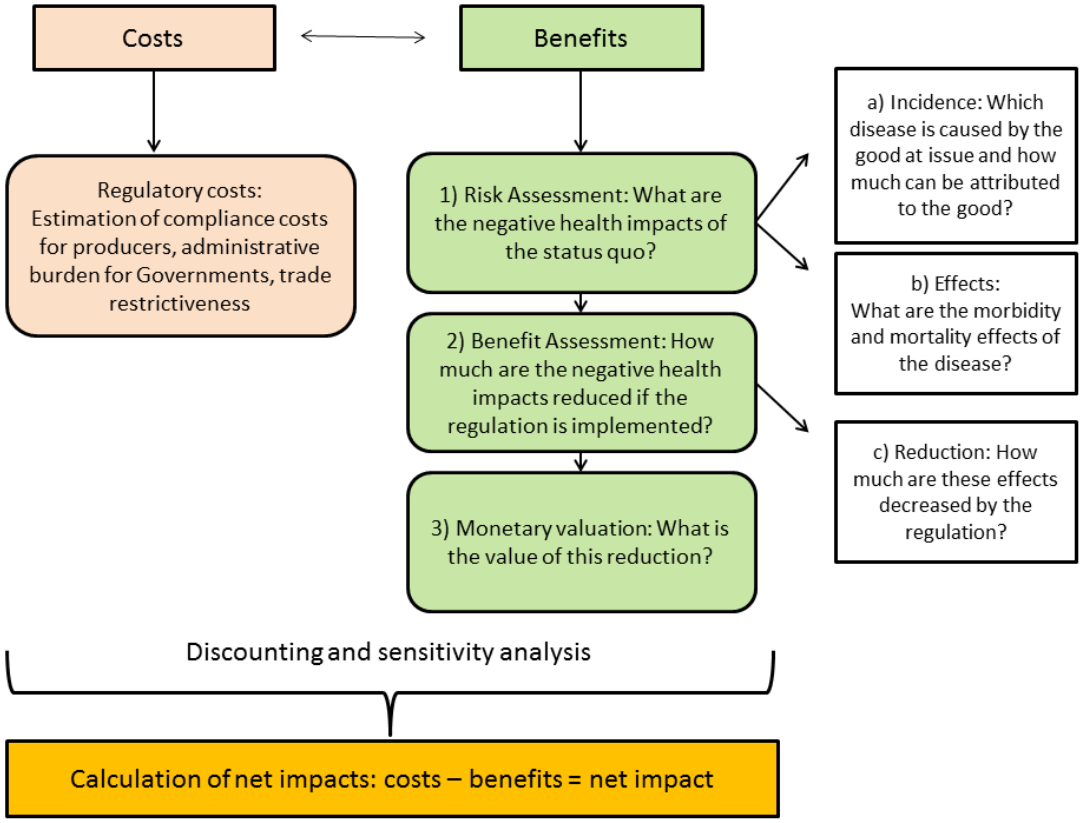
[434] Marguerite Pappaioanou et al., "Strengthening Capacity in Developing Countries for Evidence-Based Public Health: The Data for Decision-Making Project," *Social Science & Medicine* 57, no. 10 (November 2003): 1927.

studies of case-specific estimates. Although the transfer of existing estimates from one context to another might not be as accurate as estimating case-specific values, it is a valuable approach if the different contexts are taken into consideration and the data is adapted to the specific case at issue. Secondly, the EU impact assessment guidelines recommend prioritising impacts. Only a small share of impact assessments monetise health impacts for a full cost-benefit analysis, others describe these impacts qualitatively. Therefore, another conclusion may be to prioritise well in terms of the selection of NTMs as well as in terms of the selection of impacts which will be assessed in order to use scarce resource efficiently. Even in the EU where there are less financial limitations, the practice does not fulfil the level of quantitative analysis which the guidelines assume. Finally, the EU guidelines recognise that the quantification and monetisation of non-market impacts for the purpose of cost-benefit analyses is complex and resource-intensive. As far as possible the guidelines intend to provide the analyst with guidance regarding the main steps to follow, such as which questions to ask when determining social or environmental impacts and which methodologies may be useful to assess non-market impacts. Specific guidance at hand might therefore make an assessment of social impacts generally easier.

4.3 Main analytical steps for the assessment of regulatory health impacts

Regarding the first criteria to reduce the complexity of cost-benefit analyses for health impacts, the steps and criteria to analyse when carrying out a cost-benefit analysis as described in chapter 2 can be simplified. A simplification of a complex process reduces the accuracy and validity of its outcomes, but a rough estimation of the potential health impacts of a regulation is preferable to no estimation at all. As has been pointed out in subchapter 2.1., a cost-benefit analysis serves the purpose to improve informed decision-making, but it does not substitute the decision-making itself. The following a figure focuses on the main analytical steps and the key questions to ask during the assessment of regulatory health impacts.

Figure 4-1: Main analytical steps for assessing regulatory health impacts of an NTM[435]



The figure summarizes the process of a cost-benefit analysis of health impacts of an NTM as described in the previous chapters. Part of the assessment of health impacts are (1) the analysis of the mortality and morbidity effects of the good that is affected by the regulation at issue. Once these effects have been determined, (2) it must be assessed how much these risks can be reduced by implementing the regulation. This risk reduction constitutes the regulations for health benefits; finally, (3) risk reduction needs to be monetised in order to make the benefits comparable to the costs of the regulation. The figure summarizes a general cost-benefit framework by focusing on the key steps and key questions. Simplifying the overall process does, however, also reduce the accuracy of the outcomes and still requires implementing the most complex and challenging analytical steps of the overall cost-benefit framework.

4.4 Suitability of methodologies for developing countries

This subchapter assesses the methods for the quantification and monetisation of health benefits described in chapter 2, regarding the second criteria which may make a cost-benefit framework feasible for developing countries: the wide applicability and low data-intensity of the methodologies used. This criterion is most important if a developing country decides to use a cost-benefit analysis and estimate the necessary values itself. The chapter will take into account developing countries' constraints as described above in subchapter 4.1. and will

[435] Summary by author.

discuss which measurements and methodologies might be suitable for developing countries and why.

Despite the ethical controversy about the approach "value of a statistical life", the method is widely used by governments to measure health impacts. One advantage of this approach is that it can generally be applied independent of the subject matter which makes the methodology suitable for most cases where the value of a statistical life or the value of a life year needs to be estimated. This does not mean that estimated values can be simply transferred from one context to another. In this case the four main factors described in subchapter 2.4.1. need to be taken into account, which might make it necessary to adjust a VSL value to specific situations (income, risk levels, latency in the occurrence of the negative health impacts and the age of the affected people).[436] The stated and revealed preference methods to carry out the studies and experiments to obtain the VSL/VLY estimates are complicated, time-, cost- and data-intensive. The data-intensity might even make it impossible to calculate the VSL ad hoc for an ex ante impact assessment.[437] Therefore, some governments such as the European Union provide pre-estimated median values in Impact Assessment Guidelines which can be used ad hoc for an impact assessment. Assuming that developing countries face capacity and resource constraints as described in subchapter 4.1., an alternative to estimating median values is to use pre-estimated values from other countries or international institutions like the OECD. In this case the VSL is a composite index which depends on contextual variables e.g. income or age. Thus, the estimates must be adapted to the national context and the situation at issue.

When assessing the applicability and data-intensity of the methodologies for the QALY and DALY approach, the advantage of these metrics is that they account for morbidity effects and not only for mortality effects as found in the VSL/VSLY. However, this second dimension also makes the metrics more difficult to apply and narrows the scope of application of estimates. The valuation of each health state based on a health-related quality of life (HRQL) index is complex and a weight has to be elicited for each defined abstract health state or for each illnesses or disease. Thus, if a regulation reduces a specific health risk, the QALY values for this specific health risk are needed. Comparing QALY and DALY estimates, Zarate suggests that the DALY measurement might be more suitable for developing countries as the measurement of disability-adjusted life-years measures the life quality from the negative side and almost 90% of the global disease burden is accounted for by developing countries.[438] Furthermore, he argues that whereas a value for a DALY has been suggested, the value for a QALY is not known in many countries.[439]

The main approaches VSL/VLY and QALY/DALY which are used in industrialized countries such as the EU are, from a technical point of view, also suitable for health impact assessments in developing countries. The application of VSL/VLY is wider than that of the

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[436] Miller, Robinson, and Lawrence, *Valuing Health for Regulatory Cost-Effectiveness Analysis*, 295; Pearce, Atkinson, and Mourato, *Cost-Benefit Analysis and the Environment*, 193.
[437] Renda et al., *Assessing the Costs and Benefits of Regulation*, 134.
[438] V. Zarate, "DALYs And QALYs In Developing Countries," *Health Affairs* 26, no. 4 (July 1, 2007): 1197.
[439] Ibid., 1198.

QALY/DALY metrics as the latter are closer linked to the types of illness based on which their weights are estimated. In return QALY/DALY metrics enable a more differentiated measurement of health impacts as they also include a measure of morbidity. The data-intensity is high for both groups of metrics if a country intends to elicit its own estimates. The prevalent role of these four types of metrics in the field of health economics has the advantage that extensive literature, experiences and studies with estimated values exist. Thus, developing countries can try to encounter the challenge of the data-intensity of these approaches by using pre-existing estimates.

4.5 Sources for transfers of data estimates

As discussed in subchapters 4.1. and 4.4. the lack of technical skills and resources for data collection and data evaluation as well as the data-intensity of the main methodologies to assess health impacts have led to the conclusion that it is helpful to have sources (i) with estimates from studies which could be used and transferred to the context at issue and/or (ii) with ready-made values. Thus, this subchapter will provide criteria which have to be taken into account when transferring data from one context to another and aims to provide selected sources where values and studies for the evaluation of health impacts can be found. Regarding the latter, please note that most studies and data estimations have been made in and for developed countries.

The approach of transferring results of existing studies to a new assessment and using the estimated values as proxies for this new assessment is carried out widely in the field of health evaluation.[440] The existing studies and values should, however, be reviewed in terms of their applicability and transferability and refer to circumstance as similar as possible to the current case at issue. Renda et al. recommend that the following three criteria should be analysed: (i) whether the case study is similar to the current situation with regard to the good or service under examination and in terms of the socio-economic conditions (e.g. demographic characteristics or economic conditions), (ii) the quality of the selected study in terms of the comprehensiveness and the quality of the data and (iii) whether the welfare measures are comparable to the current policy case.[441]

The OECD established a meta-analysis of different VSL values and established a guide that provides a list of criteria to consider when specifically transferring VSL estimates in particular from one national context to another environment.

[440] Renda et al., *Assessing the Costs and Benefits of Regulation*, 142.
[441] Ibid.

Table 4-1: Recommendations for adjusting VSL base values[442]

Adjustment factor	*Recommendation for adjustment*
Population characteristics	
Income	For transfers between countries the VSL should be adjusted for differences in GDP per capita (for details see publication).
Age	If the regulation is targeted to reduce risks for children the VSL has to be adpated (for details see OECD publication).
Risk characteristics	
Risk perception related to risk source/cause	A sensitivity analysis can be carried out to account for differences regarding lower values for environmental than for health or traffic risks.
Morbidity prior to death	If the regulation addresses cancer risks and/or risks which are dreaded similarly because they cause morbidity risk prior to death, the VSL base value does not need to be adjusted, but additional morbidity costs prior to death should be added separately.
Other characteristics	
Increased income over time	If GDP per capita has increased the VSL base value needs to be adjusted with the same percentage increase.
Inflation	Adjustments for inflation can be based on the Consumer Price Index (CPI).

The OECD guide presents the criteria that need to be considered in three categories: population characteristics, risk characteristics and other adjustments. The most important adjustment factors in each category are presented in the table above (for more details and other adjustment factors see the original table). In the category for population characteristics the differences in income and age between the populations, the estimates that were originally elicited and the target population need to be taken into account. Furthermore, regarding the risk characteristics, seniority must be given to the differences in risk perceptions caused by different risk sources, and adjustments for morbidity effects prior to death need to be accounted for. In the third category the VSL estimates need to be adjusted for income increases and inflation.

In the following section, examples will be discussed for the two sets of sources that can help an impact assessment of health benefits of NTMs: (i) sources with estimates from studies that

[442] OECD, *Mortality Risk Valuation in Environment, Health and Transport Policies* (Paris: Organisation for Economic Co-operation and Development, 2012), 139, http://www.oecd-ilibrary.org/;jsessionid=adndimqi1r6an.x-oecd-live-01content/book/9789264130807-en.

can be used and transferred to the context at issue and (ii) sources with abstract ready-made value estimates.

Regarding the first set of sources various web-based sources for textual research exist which can be consulted regarding studies and reports of health impacts in similar contexts that have estimated VSLs, VSLYs, QALYs, DALYs or monetary values for the latter two. One institutional source is, for example, the WHO Regional Office for Europe that established the Health Evidence Network (HEN). The HEN provides a 'Sources of Evidence Database'[443] that comprises resources and publications categorized by institutions and field of public health. Under the category "food safety" for example, studies about disease burdens of specific contaminants can be found. Another source in this group is PubMed. This is a service of the US National Library of Medicine® that provides an online catalogue for biomedical literature from MEDLINE (a bibliographic database), life science journals and online books. Searching for keywords such as QALY and cancer provides the available clinical trials and reviews in the online catalogue.[444] Other useful databases containing health economics literature are for example the NHS Economic Evaluation Database (NHS EED)[445], the Health Economic Evaluations Database (HEED)[446] and the CEA Registry[447] issued by the Harvard Center for Risk Analysis and the Harvard School of Public Health. Useful for research about existing studies and data on health impacts can also be publications and websites provided by national institutes or governmental agencies. The Canadian National Collaborating Centre for Healthy Public Policy (NCCHPP), funded by the Health Agency of Canada, has published an inventory of resources for health impact assessments.[448] Another example is Public Health England (PHE) which is as an executive agency of the Department of Health, England and provides the "HIA Gateway". This website includes reports, guides and evidence for health impact assessments from different countries regarding different topics that can have an impact health, though these topics are rather of a general nature (e.g. transport, education etc.).[449] More general information can be found on the knowledge platform about policy impact assessments published by the LIASE Network of Excellence.[450]

Regarding the second set of sources it is more difficult to find sources with abstract ready-made value estimates. For VSL or VLY estimates an OECD meta-analysis[451] of VSL estimates can be consulted or country specific values can be researched in countries with similar conditions and adjusted to the specific context at issue. The EU published VSL/VLY estimates in its Impact Assessment Guidelines. DALY estimates are published by the WHO in

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[443] HEN Sources of Evidence Database: http://data.euro.who.int/HEN/Search/HenSearch.aspx
[444] PubMed Website: http://www.ncbi.nlm.nih.gov/PubMed
[445] NHS EED Website: http://www.crd.york.ac.uk/crdweb/
[446] HEED Website: http://onlinelibrary.wiley.com/book/10.1002/9780470510933
[447] CEA Registry Website: https://research.tufts-nemc.org/cear4/default.aspx
[448] Julie Lauzière, *Health Impact Assessment (HIA): Inventory of Resources* (Quebec: National Collaborating Centre for Healthy Public Policy, 2009).
[449] HIA Gateway Website: http://www.apho.org.uk/default.aspx?RID=40141
[450] http://www.liaise-kit.eu/ LIAISE KIT is a knowledge and community platform to support Policy Impact Assessment for Sustainable Development. It provides access to knowledge for decision making, e.g. on models, data sets, methods and experts throughout all steps of policy impact assessment and all dimensions of sustainable development. Furthermore, the LIAISE KIT is a platform where new publications, projects, experts, models, events are announced to the community
[451] OECD Meta-Analysis: http://www.oecd.org/env/tools-evaluation/vsl.htm

its Global Health Estimates (GHE) that contains global, regional and country data for download for all-cause mortality, deaths and DALYs by age, sex and cause.[452]

4.6 Conclusion

Developing countries face particular challenges for policy-making which can be summarised as the lack of personnel capacities such as technical skills of decision-makers and technical advisors, the lack of data collection and data availability as such. Furthermore, the lack of institutional capacities such as communication and coordination procedures between ministries and with non-governmental stakeholders can pose a challenge. The conclusion is that a cost-benefit framework can be useful for developing countries to assess non-market impacts of NTMs, but to carry out studies to elicit estimates of regulatory health benefits requires a high level of technical skill, financial resources and statistical data as well as time. A cost-benefit framework which is suitable for an environment with limited resources would therefore ideally fulfil three criteria to make it more suitable to their context: (1) It comprises few and simple analytical steps to follow, (2) it uses methodologies for the quantification and monetisation of impacts with a wide applicability and a low data-intensity and/or (3) it uses existing values from specific studies or from sources that provide ready-made estimates (as far as possible).

[452] WHO Global Burden of Disease Website: http://www.who.int/healthinfo/global_burden_disease/en/

5 Conclusion

NTMs play an increasingly important role in trade policy-making and international trade negotiations. SPS measures and TBTs aim to overcome market failures and pursue public policy objectives. As a result, these technical regulations do not only have trade impacts, but can also have social welfare impacts. An SPS measure which reduces health risks from food products provides benefits for public health and increases social welfare. A cost-benefit analysis can be carried out in order to assess whether the costs or benefits of an NTM prevail. For this purpose the non-market impacts of an NTM need to be quantified and monetised. The main concepts used to quantify health impacts are the QALY and DALY metrics as well as the WTP, VSL and VSLY approaches. Which of these metrics is the most suitable depends on the impact to be analysed and the available data, time and resources. Judgments about which assumptions and individual characteristics need to be taken into account have to be considered as well. Overall, the analysis of the cost-benefit framework and the methodologies which are used to assess health impacts indicates that this type of analysis is complex, time- and resource-intensive.

The results are confirmed when comparing the theoretical concepts to their practical application in the European Union. For trade policy making the European Commission focusses on the economic impacts and does not assess health impacts of NTMs. However, health impacts are assessed by the European Commission as part of the assessment of general regulations. The analysis of the general EU impact assessment guidelines and their implementation has shown that the concept of the cost-benefit framework and the described methodologies are reflected in the EU practice. Yet, only few EU impact assessments monetise health impacts of regulations. Three regulations that affect tradable goods (tobacco products, fresh meat and jewellery products) have been selected to analyse the EU-approach regarding the assessment of health impacts. The three impact assessments are considered to be transferable to the assessment of NTMs because in fact, the assessed regulations constitute NTMs. The three regulations at issue satisfy the UNCTAD definition of NTMs as they can "potentially have an economic effect on international trade in goods" [453]. As a consequence, the cost-benefit framework and methodologies used in the three impact assessments can also be utilized to assess health impacts of NTMs. Due to their complexity and resource-intensity the application of these methods to NTMs is not seen as possible on a large scale, but useful and justifiable to assess selected, prioritized NTMs.

The transferability of the described cost-benefit framework and the methodologies to value health impacts of NTMs in developing countries with limited resources is possible in theory, but is considered to be difficult in practice. Estimates for the evaluation of regulatory health benefits can be surveyed, but this requires a high level of technical skill, financial resources and statistical data as well as an adequate time-frame. A cost-benefit framework which is suitable for an environment with limited resources therefore requires few and simple

[453] United Nations Conference on Trade and Development (UNCTAD), *Classification of Non-Tariff Measures: February 2012 Version*, 1.

analytical steps and will benefit from methodologies with a wide applicability and a low data-intensity. Another approach to make cost-benefit analyses manageable for developing countries with limited resources is to use estimates from existing studies in similar cases or general "ready-made" values. Yet, it also has to be taken into account that the transfer of estimates and values requires an adaptation of this data to the national context and reduces the accuracy of the results.

It can be summed up that the concept of cost-benefit analyses and the related methodologies can be transferred from the public policy field to the analysis of NTMs. Three examples of practical health impact assessments in the EU which can be applied to NTMs have been analysed in this paper. As a cost-benefit analysis and the assessment of health benefits is technically complex as well as time- and resource-intensive, it is seen as useful only for selected and prioritized NTMs and is not suitable for a large scale application. Governments in developing countries which face limited resources can focus on selected NTMs and use as far as possible pre-existing estimates for their assessment of health impacts.

Despite these challenges it is desirable that trade economists widen the scope of their analyses beyond purely economic impacts of NTMs when dealing with trade negotiations. Concepts of other economic disciplines like the cost-benefit framework can be used to achieve more holistic assessment results and to reflect reality more accurately. For policy decisions about the removal, harmonisation or maintenance of NTMs, their overall national welfare impacts need to be taken into account. Accounting for social and environmental impacts can lead to other assessment results than purely economic assessments and can show policy-makers and trade negotiators if welfare benefits of an NTM outweigh its economic costs.

Finally, the question remains of how far the decisions about the removal of NTMs are determined by the political economy context of the trade negotiation and whether it makes sense to carry out a complex cost-benefit analysis of an NTM. In this regard please note that the purpose of a cost-benefit analysis is to create more informed and evidence-based decision-making, but it does not substitute the decision itself. A cost-benefit analysis can only be a complementary tool, though an important informative tool, which can show the importance of non-market impacts and support the decision-making process.

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