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Cost-benefit analysis (CBA) of health and safety regulations

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This Working Paper at a Glance

Even though trade negotiations have increasingly come to focus on regulatory issues, the full impacts, that is, both social costs and benefits of regulatory changes, often remain unexamined in trade impact assessments. To bridge this gap, we scrutinize the theoretical foundations, methodologies and policymaking applications of cost-benefit analysis (CBA) in the context of health and safety regulations. CBA has become the main approach in economics to quantify the social costs and benefits of regulation. Gaining a thorough understanding of CBA processes, their applications and their limitations provides a valuable foundation for our upcoming research, the integration of the broader impacts of regulations into a global trade model.

FORSCHUNGS-
FÖRDERUNG

Das Working Paper auf einen Blick

Ist die Angleichung unterschiedlicher Gesundheitsstandards zwischen Ländern im Kontext von Freihandelsabkommen ausschließlich positiv zu bewerten, oder besteht hier die Gefahr von Qualitätsverlusten mit hohen sozialen Kosten für die betroffene Bevölkerung? Die Angleichung unterschiedlicher nationaler Regulierungen spielt in der zeitgenössischen Handelspolitik eine wichtige Rolle. In diesem Papier werden Forschungsmethoden wie die Kosten-Nutzen-Analyse, die eine monetäre Bewertung der Auswirkungen von Gesundheitsstandards vornehmen, kritisch bewertet. Die Ergebnisse zeigen, dass die Vorteile von Regulierung deren Kosten deutlich überwiegen. Die handelspolitische Folgenabschätzung muss daher die gesellschaftlichen Kosten regulatorischer Qualitätsverluste systematisch berücksichtigen.

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Executive Summary

This working paper is part of a research project funded by the Hans Böckler Foundation (HBS Project No. 2020-431-3) that seeks to incorporate comprehensive effects of regulations in an economy-wide model for trade impact assessments.

Regulations and standards cause trade costs, and existing modeling approaches routinely focus on the estimation of potential gains from their removal. The omission of obviously existing economic benefits of regulation severely biases essentially all existing impact assessment models that report gains from “deep and comprehensive” free trade agreements (DCFTAs). The problematic nature of this approach has been at the center of the controversy around Transatlantic Trade and Investment Partnership (TTIP) and the EU-Canada free trade agreement (CETA).

In the pursuit of ever freer global markets, Free Trade Agreements (FTAs) have become an increasingly popular policy instrument. The World Trade Organization (WTO) reports that the number of active bilateral or regional FTAs has increased from around 50 in 1990 to 360 in 2023 (WTO 2024). Likewise, FTAs are at the center of the trade policy agenda of the European Union (EU). However, in contrast to traditional FTAs with their focus on tariff removal, the so-called new generation FTAs put the emphasis on the alignment and removal, respectively, of national regulations, or, in trade parlance, “behind-the-border measures” or “non-tariff barriers” (NTBs).

Thus, there is an increasing interconnection of trade liberalization with national policies and consequent macroeconomic, social and distributional as well as ecological effects. The content of DCFTAs potentially impacts core areas of national public policy, like health and consumer protection, labor standards or environmental regulations. The interlinkages between trade liberalization and regulatory change and their full economic and social effects are, however, not captured by prevailing trade impact assessment approaches.

Therefore, a deeper understanding based upon an alternative methodology is needed, which takes the full range of potential social costs and benefits of regulation into account and equips our macroeconomic model for trade impact assessment to provide a more realistic picture of DCFTA impacts on critical areas of public policy. Only on the basis of such an analysis can informed decisions about the appropriate design of these trade agreements be made.

The methodological challenge now consists precisely in identifying the nature of particular benefits of a regulation and in determining the scale and direction of its economic impact relative to its respective costs. To

narrow the scope, our project focuses on regulations that impact (i) human health and safety, as well as (ii) societal trust. A companion working paper delves deeper into the linkages between trust, regulation and trade.

In this working paper, we assess research methods that focus on assessing the comprehensive impacts of regulations, particularly on cost-benefit analysis (CBA). By scrutinizing the theoretical background, the methodologies of CBA and their applications in policymaking, we identify the opportunities and limits of this research approach.

For this purpose, we examine the origins and theoretical foundations of CBA and illustrate the application of CBAs in the area of health and safety regulations, given that these issues have become an important area of CBA research. We further investigate the application of CBAs in regulatory impact assessments (RIA), by comparing the approaches and the recent developments in RIA applications in the EU and the United States. The methodologies and underlying databases of applied EU and U.S. RIAs in the areas of (i) food safety standards (SPS), (ii) chemicals regulations, (iii) standards for safety and health at work and (iv) environmental regulations on air and water pollution are presented.

The findings of this assessment serve as the basis for potential new modeling approaches of costs and benefits of regulatory changes resulting from FTAs, which will be further developed in subsequent phases of the research project.

Generally, CBA is an assessment method that aims at quantifying in monetary terms the value of all consequences of a policy or of various policy options to society. Over the past two decades, the research on CBA has witnessed a substantial surge in interest and has been applied in various research fields, including economics, environmental science and medical science.

Most importantly, the CBA approach has gained much attention as a way of evaluating the impacts of regulations. In particular, CBA is gaining global traction in policymaking processes, serving as the central element of Regulatory Impact Assessments (RIAs). This is because the net benefits resulting from a CBA can act as a pivotal decision-making factor when choosing between various policy options.

We argue that the fundamental concept of evaluating the impacts of regulations through cost-benefit analysis (CBA) is especially interesting when considering the role of regulations and regulatory divergence within the context of FTAs. From the CBA perspective, the treatment of regulations in standard trade impact assessments appears incomplete, since regulatory measures are only seen as barriers to trade and as costs for businesses.

The CBA approach highlights instead, that in the face of market failures such as information asymmetries or negative externalities, regulations prove to be indispensable. It considers the broader impacts on different societal groups, who experience varying costs and benefits from regulations.

Finally, the results of applied CBA and RIA studies mostly suggest that the benefits of regulation clearly exceed the costs. The systematic consideration of regulatory impacts challenges the simplistic assumption that removing or altering regulations that affect trade will inherently result in positive economic and societal outcomes.

CBA has become particularly important for policymaking with respect to health, safety and environmental regulations. While it is widely recognized that these rules and regulations are essential for addressing market failures, CBA is advocated as a means to optimize the design of regulations for maximum efficiency. The application of CBA in RIAs is also promoted as the "economic-scientific" cornerstone for evidence-based policymaking.

The perception of CBA as a central element in policymaking processes is closely tied to its theoretical links to welfare economics, as described in chapter 2. Within this framework, CBA is applied to enhance the efficiency of resource allocation so as to maximize overall societal welfare. This foundation also underpins the development of new CBA methodologies, which measure regulatory benefits via individuals' preferences and "willingness to pay" methods.

The methodological process commonly employed in CBA-based assessment exercises related to human health and safety consists of two steps: First, the analysis of benefits with three key elements: (i) identifying changes in hazardous factors, like pathogens in food or air pollution from regulatory changes; (ii) converting these changes into "health outcomes" such as premature deaths, hospital admissions and lost work days; and (iii) quantifying the benefits, usually in terms of the health issues that have been prevented. Second, the analysis of costs, which encompasses all costs associated with regulatory changes, such as compliance costs for companies.

Various methodologies for estimating health benefits in CBAs are discussed in the literature, but two major methods prevail:

- **"Cost of illness" (COI):** This approach estimates the economic costs associated with injuries, illnesses and premature deaths, by including both direct costs (e.g., medical expenses) and indirect costs (e.g., lost productivity due to morbidity and premature mortality). COI is often referred to as the "human capital" approach because it measures the economic losses due to the reduction of an individual's labor power

and related productivity, although it omits non-monetary aspects of illness (e.g., pain and suffering) and potentially underestimates the effects for non-working population groups.

- **"Value of a Statistical Life" (VSL):** The VSL is part of the "willingness-to-pay" (WTP) approach. WTP represents here the maximum amount of money an individual would voluntarily pay to reduce the risk of negative health outcomes. For valuing mortality risk reductions, the VSL represents the monetary value of avoiding one statistical death in society.

The VSL and WTP approaches have become highly popular as they align with neoclassical welfare economics and policy goals, which generally aim to reduce health risks for the affected population. Given that the VSL often yields substantially higher monetary figures than COI estimations, it plays a significant role in driving benefit estimations, leading to the calculation of high net benefits of a regulatory policy.

In chapter 6, applications of CBA and different methodologies to assess the benefits and costs of specific regulations or policy proposals in the United States and the EU are examined. While both the United States and the EU use RIAs, differences exist. In the United States, RIAs are an essential part of the implementation of regulations by federal agencies and have been required since the 1980s. The benefit estimations in U.S. RIAs largely apply the VSL methodology.

In contrast, RIAs in the EU became more popular only after the 2000s and are used to assess proposals in the primary legislation process. Generally, the EU sees RIAs as evidential reasoning, whereas the United States places greater emphasis on CBA outcomes in policy choices and judicial reviews.

Our examination of RIAs concerning health and safety regulations underscores that CBA applications within RIAs are typically tailored to the specific regulations at hand. RIAs are extensive studies where researchers have the freedom to choose databases and methodologies that suit their analysis. Moreover, the reviewed RIAs illustrate that certain elements on both the cost and benefit sides may defy reasonable quantification.

In such instances, the EU's approach, which places a stronger emphasis on adopting a more holistic perspective that encompasses economic, social and environmental dimensions, and incorporates supplementary techniques like multi-criteria analysis, may be better suited. Moreover, we discuss an evaluation of the economy-wide impacts of regulations based on CBA results using a CGE model.

The CBA approach is, nevertheless, criticized due to its theoretical foundations, but also because of its conceptual and empirical limitations. As discussed in section 2, this includes concerns related to the subjectivity of valuing intangible factors, the discounting of future impacts, distributional inequities and uncertainties in predictions about future effects. Moreover, the historical perspective on the utilization of CBA in RIAs, as discussed in sections 2 and 6, underscores that its applications can be highly politicized, with the applied methodologies and their outcomes serving diverse agendas.

In summary, we find that the core concepts underlying the CBA approach to assessing the effects of regulations encourage the inclusion of various aspects of this research approach into trade assessment models. This includes in particular the analytical structure used by CBAs for health and safety standards, but also CBA methodologies that assess health-related effects on macroeconomic variables such as productivity, labor supply, income or consumption. In the next stages of our project, our objective is to identify and implement methods to assess how changes in health outcomes resulting from regulatory adjustments affect macroeconomic variables in our global trade model.

Zusammenfassung

Dieses Working Paper ist Teil eines von der Hans-Böckler-Stiftung geförderten Forschungsprojekts (Projekt Nr. 2020-431-3). Das Ziel dieses Projekts besteht darin, die umfassenden Auswirkungen von Regulierungen in ein Modell zur Abschätzung von Handelsfolgen einzubeziehen.

Regulierungen und Standards erhöhen die Kosten im internationalen Handel. Bisherige Modelle betonen meist die makroökonomischen Gewinne durch den Abbau von Regulierungen und niedrigere Handelskosten, vernachlässigen jedoch den wirtschaftlichen und gesellschaftlichen Nutzen von Regulierungen. Dieser einseitige Ansatz war auch bei TTIP und CETA umstritten.

Freihandelsabkommen (FHA) sind ein politisches Instrument für Handelsliberalisierung. Die Anzahl von FHA stieg von etwa 50 im Jahr 1990 auf 360 im Jahr 2023 (WTO 2024). Im Gegensatz zu traditionellen FHA, die Zölle beseitigen, fokussieren „tiefgreifende und umfassende“ FHA der neuen Generation auf die Anpassung und Beseitigung nationaler Regulierungen, die mit „nichttarifäre Handelshemmnisse“ verbunden sind.

Dadurch entsteht eine Verknüpfung zwischen Handelsliberalisierung mit nationalen Politiken und deren makroökonomischen, sozialen, verteilungsbezogenen und ökologischen Auswirkungen. Der Inhalt von FHA kann Kernbereiche nationaler Politik wie Gesundheits- und Verbraucherschutz, Arbeitsnormen oder Umweltschutz beeinflussen.

Es ist daher notwendig, mit Hilfe einer neuen Methodik ein tieferes Verständnis für die Bedeutung von Regulierungen zu entwickeln, um realistischere Bewertungen von FHA auf kritische Politikbereiche zu ermöglichen. Die Herausforderung besteht darin, die Kosten und Nutzen spezifischer Regulierungen zu identifizieren, insbesondere solche, die Gesundheit, Sicherheit und gesellschaftliches Vertrauen beeinflussen. Ein begleitendes Arbeitspapier vertieft zudem die Verbindungen zwischen Vertrauen, Regulierung und Handel.

In diesem Working Paper evaluieren wir Forschungsmethoden, die sich auf die umfassenden Auswirkungen von Regulierungen konzentrieren, insbesondere die Kosten-Nutzen-Analyse („cost-benefit analysis“, kurz CBA). CBA zielt darauf ab, die Konsequenzen einer Politik monetär zu quantifizieren und wird weltweit in der politischen Entscheidungsfindung verwendet, insbesondere als zentrales Element von regulatorischen Folgenabschätzungen,

Wir untersuchen die Ursprünge und theoretischen Grundlagen der CBA und stellend die Methoden und deren Möglichkeiten und Grenzen dar. Zudem werden Anwendung der CBA in regulatorischen Folgenab-

schätzungen in der EU und den USA, speziell in den Bereichen Lebensmittelsicherheitsstandards, Chemikalienregulierungen, Arbeitsnormen und Umweltregulierungen dargestellt.

Der CBA-Absatz hebt hervor, dass Regulierungen angesichts von Marktversagen unverzichtbar sind und dabei Auswirkungen auf verschiedene gesellschaftliche Gruppen haben. Die Ergebnisse angewandter CBA- und RIA-Studien zeigt, dass die Vorteile von Regulierungen die Kosten überwiegen. Die systematische Berücksichtigung regulatorischer Effekte stellt die Annahme in Frage, dass die Beseitigung von Regulierungen zwangsläufig positive wirtschaftliche und gesellschaftliche Ergebnisse bringt.

Durch die genaue Analyse des theoretischen Hintergrunds, der Methoden und ihrer Anwendungen in der politischen Entscheidungsfindung identifizieren wir Chancen und Grenzen dieses Forschungsansatzes. Die Ergebnisse dienen als Grundlage für neue Modellierungsansätze zu den Kosten und Nutzen von regulatorischen Änderungen durch FHAs.

1. Introduction

The impact of regulations has become a major topic in various research areas. In particular, cost-benefit analysis (CBA) is increasingly applied in policymaking processes as a method to assess the benefits and costs of regulations in monetary terms. In this context, research involving CBA has gained significant momentum over the last two decades. There is a vast literature on the theoretical foundations and concepts of CBA and the various methodologies to quantify costs and benefits as well as empirical applications.

The number of publications with the topic “cost-benefit analysis” increased from an average of 1,105 per year between 2000 and 2004 to 6,503 between 2018 and 2022 (Web of Science Core Collection, performed on 2. May 2023). In total, 81,701 publications have been recorded since 2000, with most publications appearing in the journals Sustainability, Journal of Cleaner Production and Pharmaconomics.

In addition, journals such as the Journal of Benefit-Cost Analysis or the European Journal of Risk Regulation specialize in CBA and related topics. The major fields are economics, environmental science/studies and health care/policy services. In particular, the combination of health effects from environmental factors such as air and water pollution has gained much attention in research.

The impact of regulations has also become a major issue in the field of international trade theory and in the context of free trade agreements (FTAs). In contrast to traditional FTAs and their focus on tariff removals, the so-called new generation “deep and comprehensive free trade agreements (DCFTAs) put the emphasis on behind-the-border non-tariff measures (NTMs).

These NTMs are any restrictions to trade in goods, services and investment, including “border measures (customs procedures, etc.) as well as behind-the-border measures flowing from domestic laws, regulations and practices]“ (Berden et al. 2009: xiii). According to this definition, any national regulations that restrict trade due to regulatory divergence are NTMs.

The perspective of regulations as trade restrictions are prevalent in the standard computable general equilibrium (CGE) modeling approaches. These models are designed to show the economy-wide effects of regulatory policy on trade and are a primary method used in trade impact assessments (UNCTAD 2022). They depend on external estimates of the restrictiveness of NTMs, with the gravity model method being the most frequent approach used.

The results of gravity estimations are taken up as ad-valorem tariff equivalents (AVEs) in CGE models and the "actionable part" are integrated as "shadow" export tariffs, import tariffs or iceberg costs (Walmsley/Strutt 2021). While the first two approaches are linked to rents for exporters or importers, the iceberg mechanism leads to a reduction in "dead weight loss" and generates efficiency gains (Raza et al. 2014). Concerns related to and critiques of the appropriateness and welfare implications of the applied methodologies are well-documented (Fugazza/Maur 2008; UNCTAD 2019; Tröster et al. 2023).

While new mechanisms based on consumers' willingness to pay or exporter costs have been proposed for modeling NTMs in partial and general equilibrium models (Van Tongeren/Beghin/Marette 2009; Walmsley/ Strutt 2021), none of these fully consider the comprehensive benefits of regulations. These benefits appear in core areas of national public policies, such as health and consumer protection, labor standards or environmental regulations and are the main drivers of monetized benefits of regulations, which typically exceed the associated costs.

This working paper is part of the research project "Modeling regulatory change in trade impact assessments – Towards a comprehensive and balanced approach" conducted by the Austrian Foundation for Development Research (ÖFSE) and financed by the Hans Böckler Foundation. The project aims to incorporate the comprehensive costs and benefits of regulations into trade impact assessments with a structuralist CGE model on global trade (Raza et al. 2016).

In this paper, we make an initial contribution by analyzing the methodologies applied in CBAs to monetize the impacts of national regulations and the comprehensive effects of changes to regulations on costs and benefits.

For this purpose, we delve into the origins and theoretical foundations of CBA and provide a practical overview of how CBAs are conducted, particularly in the domain of health and safety regulations. These topics have gained prominence in CBA research due to their increasing significance.

Additionally, we explore the application of CBAs in regulatory impact assessments (RIA), This involves a comparative analysis of approaches and recent advancements in RIA practices in both the European Union (EU) and the United States. We also discuss specific EU and U.S. RIAs in the following domains: (i) food safety standards (SPS), (ii) technical standards dealing with sensitive products such as chemicals, (iii) standards for safety and health at work and (iv) air and water pollution.

We show that a detailed understanding of the fundamental processes involved in analyzing regulatory impacts with a CBA approach, along with

the associated methodologies and their application within RIAs, offers valuable means to comprehend the broader role of regulations in trade agreements. This perspective extends beyond their immediate influence on trade costs.

The CBA approach emphasizes the necessity of health, safety and environmental regulations to correct for market failures in these areas, which calls for a detailed analysis of the nature of NTMs. Fundamentally, our analysis of CBA methodologies suggests that regulations trigger costs and benefits, subsequently affecting macroeconomic variables such as productivity, labor force, income, consumption or trade flows. Moreover, specific CBA methodologies for quantifying benefits and costs possess the potential to facilitate the development of innovative approaches aimed at integrating the comprehensive effects of regulatory adjustments into a global trade model.

2. Basics of cost-benefit analysis (CBA)

In general, the CBA approach is an assessment method of projects and policies that quantifies in monetary terms the value of all consequences of a project and policy to all members of society (Boardman et al. 2018). CBA seeks to identify economic but also environmental and other types of impacts of projects, regulations or interventions and shows the net benefits.

The CBA can be used to compare the net benefits of different options in order to identify the most efficient project or policy option. The empirical applications of CBA are, firstly, project proposals, for instance for infrastructure projects. Secondly, CBA "is the principal analytical tool of quantitative [regulatory impact assessments]" (RIAs) (Antle 1999). RIAs are conducted as part of the public decision-making in many policy areas ranging from public healthcare, social welfare programs or environmental policies.

The process of conducting a CBA generally follows several basic steps. These include: (1) determine the purpose and the scope of the analysis, (2) specify the policy options, (3) decide whose gains or losses will be considered, (4) predict benefits and costs over a predefined period into the future, (5) convert any impacts not normally measured in monetary terms into such terms as feasible and appropriate, (6) discount monetized impacts, (7) compute net benefit and/or benefit-cost ratio, (8) perform sensitivity analyses, and (9) interpret results.

What benefits and costs can be quantified and what methodologies are applied, varies with the subject to be assessed and is often highly case-specific (Boardman et al. 2018). If impacts cannot be reasonably monetized, cost-effectiveness analysis or the inclusion of qualitative assessments are alternative approaches (Sunstein 2019).

2.1. Origins and theoretical foundations of CBA

The discussion of the origins of CBA studies is side-lined in many CBA textbooks and articles. Some authors trace it back to early calculations of the benefits and costs of plague control policies in London in the 17th century (Boardman et al. 2018). Others name the applications of CBA studies in the United States in the 1930s (Mishan/Quah 2021). Jiang/

Marggraf (2021), however, draw a line from French engineers and academics that developed CBA calculations for transport projects during the early 18th century to the work of Jules Depuit in 1844.

Independent from this, CBA studies were conducted in the United States around water resource projects (op. cit.), and many scholars name the Flood Control Act in 1936, which required the Army Corps of Engineers to conduct CBAs for their water projects, as a major milestone for practical CBA application (Boardman et al. 2018; Mishan/Quah 2021).

In the 1950s, however, scholars in the United States took up the theoretical concepts and their mathematical formulations by Jules Depuit such as the consumer surplus ("relative utility") and consolidated them with other concepts of welfare economics. These microeconomic theories and principles became the foundation for the theoretical and applied aspects of CBA in the United States (op. cit.; Talvitie 2018).

From a neoclassical economics perspective, the major aim of CBA is the contribution to a "more efficient allocation of resources" (Boardman et. al. 2018: 75). This can be achieved when public policies are designed to maximize overall societal welfare. Welfare economics as a microeconomic approach defines the overall welfare of society as the sum of consumer and producer surplus, which are derived from the aggregated well-being of utility-maximizing individuals and profit-maximizing companies (Boardman et al. 2018; Mishan/Quah 2021).

This theoretical concepts have led directly to the CBA methodologies to measure the benefits of regulations through the expression of individuals' preferences and the concept of "willingness to pay" and the costs of regulations as opportunity costs, as discussed in chapter 4 and 5. However, there is ongoing research on concepts and methodologies, for instance, by the inclusion of results from behavioral economics such as the differences in the valuations of gains and losses by individuals (op. cit.)

The concept of efficiency is key in the neoclassical economic rationale for CBAs. However, the criterion of Pareto efficiency has been dismissed by most scholars in favor of theoretical concepts that speak to the practicality and ease of application of CBA. Boardman et al. (2018) argue that CBA can realistically support a *more* efficient allocation of resources, but might not lead to the *most* efficient due to "political concerns, or other reasons" (p.15).

Efficiency is also the decisive factor in selecting the best policy option. In theory, the Pareto-efficient option out of a CBA should be chosen, in which net benefits allow to compensate those who bear costs so that no one is made worse off and at least one person is better off (Boardman et al. 2018). However, CBA scholars and regulators in the United States advocated for the Kaldor-Hick criterion as the key variable.

Thus, the desirability of a policy or a policy change is given, when the overall benefits to society outweigh the overall costs and the persons adversely affected could potentially be compensated. It is not required that everyone in society is made better off by a policy change. Instead, it focuses on the potential for net benefits, which allows for trade-offs between winners and losers (Mishan/Quah 2021). Consequently, efficiency became more relevant than issues of equity and distributional effects.

The idea of CBA as a tool to advance efficiency on an "economic-scientific" basis (Nicola 2017) has been taken up by the U.S. administration, in many Anglo-American countries and several international organizations from the 1960s onwards. The CBA applications were broadened from infrastructure projects to various government activities from public health to education.

While mainstream economists generally oppose regulations in many fields that could constrain market competition, health, safety and environmental regulations are seen as necessary to overcome market failures (Viscusi/Harrington/Sappington 2018). However, U.S. policymakers and scholars have argued that policymaking and regulations must be grounded in economic and scientific evidence and that social and environmental regulations must prove to be economically efficient.

In the EU, the utilization of cost-benefit analysis (CBA) as a policymaking tool only gained traction in the 2000s and has been characterized by a more cautious approach, with an emphasis on striking a balance between economic priorities and the consideration of social and environmental factors (Bartl 2017). From a legal and economic perspective, Nicola (2017) therefore sees two genealogies to explain the difference between the U.S. and the EU-type CBA approaches (see also chapter 6 for more details).

2.2. Limits of cost-benefit analysis

The theoretical foundations of CBA are criticized by many scholars. For instance, Ackerman/Heinzerling (2004) present several conceptual issues regarding CBA and highlight the limitations and potential shortcomings of CBA as a decision-making tool, particularly when dealing with complex and multifaceted issues.

First, assigning monetary value to many intangible factors, such as human life, environmental quality or cultural heritage, is inherently subjective and controversial. Different individuals and societies may have divergent perspectives on how to value these factors, leading to potential biases and disputes in CBA outcomes. The methodologies to derive these values

based on the preferences of the individuals such as willingness to pay are theoretically flawed.

Secondly, CBA employs discounting to account for the time value of money, giving less weight to future costs and benefits compared to present ones. Ackerman/Heinzerling (2004) argue that discounting future generations' costs and benefits may undervalue the long-term impacts of policies, particularly for issues like climate change or intergenerational equity.

Thirdly, there are distributional concerns: CBA typically focuses on overall net benefits, without explicitly considering the distribution of costs and benefits among different individuals or groups. This can result in inequitable outcomes, as the analysis may favor policies that generate large overall benefits but disproportionately harm vulnerable or marginalized populations (op. cit.). In particular, the focus on the Kaldor-Hicks criterion as the central principle of policy selection has emphasized the superiority of overall economic efficiency over equity and distributional aspects (Nicola 2017).

Fourth, CBA relies on assumptions and predictions, which are often uncertain and rather speculative (Bartl 2017). Ackerman/Heinzerling (2004) contend that CBA can give a false sense of certainty, as it presents precise estimates and ratios that may not accurately reflect the inherent uncertainty and irreversibility of policy choices. CBA should therefore be conducted with supplementary uncertainty analysis (EPA 2011).

Beyond the conceptual limitations, there are also empirical boundaries due to the limited availability of data and required inputs, as discussed below in the context of RIAs. This is most relevant for benefit monetarization, while compliance costs are typically easier to assess.

Therefore, Sunstein (2019) dismisses benefit calculations and advocates instead for cost-efficiency analysis, which identifies the policy option that achieves a predefined policy goal at the lowest costs. Ackerman/Heinzerling (2004) argue that CBAs can be efficiency analyses that need to be complemented by other approaches that account for values and concerns beyond the narrow economic framework. An important extension to CBAs could be multi-goal analysis given that other goals other than efficiency matter.[1]

1 The possibilities to use multi-goal analysis in the context of trade impact assessments will be discussed in later papers.

3. CBA of health and safety regulations

CBA of regulations concerning human health and safety typically follow an analysis process with several steps (Figure 1). The basis is the development of scenarios, which requires an initial understanding of the policy and its options and the identification of potentially affected benefit and cost categories (Boardman et al. 2018).

Both benefit and cost categories can include various components when comprehensive social benefits and costs are considered. Therefore, most applications restrict the types of benefits and costs due to methodological and/or data limitations in the monetary valuation of these effects.

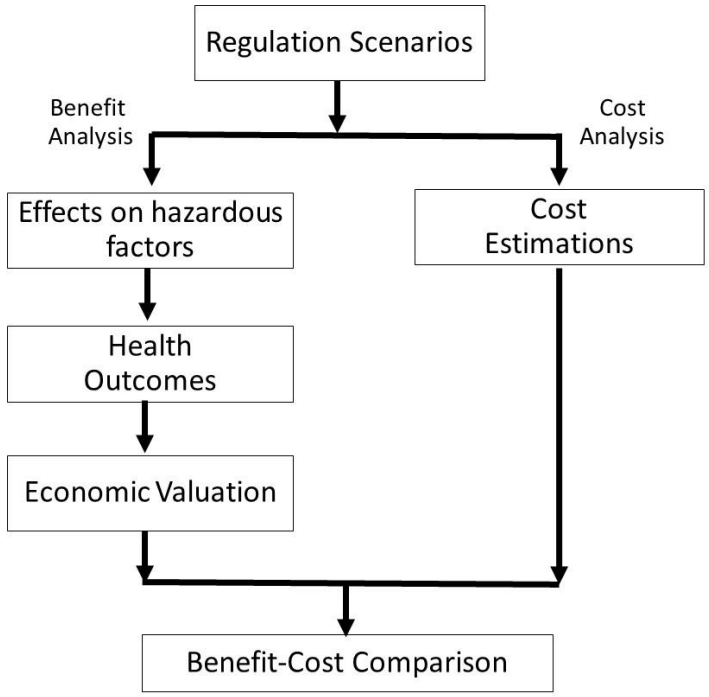
On the one branch of the CBA analysis process of health-affecting policies, the benefit analysis starts with the assessment of changes to hazardous factors such as pathogen levels in the case of food safety standards or effects on pollutants in the case of environmental regulations (Crutchfield et al. 1997; EPA 2011).

Next, the impact of these changes is translated to “health outcomes” (also called health endpoints) including variables such as premature mortality, hospital admissions, lost work or school days. In environmental regulation assessments, this step is conducted based on pollution exposure–response functions. In other cases, foodborne disease incidences and premature deaths data are linked to changes in pathogen levels, or dose-response relations are assessed on health effects from the exposure to chemicals (ECHA 2016).

These health outcomes can be used directly to calculate non-monetary benefit estimates such as Disability-Adjusted Life Years (DALYs) (WHO 2020). For a monetary measurement of benefits, several methodologies can be applied to express the changes in health outcomes in monetary terms. These can either monetize the effects as changes to incomes and expenditures (cost-of-illness approach, COI) or alternatively assess the value of changes to health risks (willingness to pay approach WTP).

The WTP approach claims to be better aligned with policy goals as regulations reduce the risk of adverse health effects incurred by the affected population rather than preventing identifiable cases with certainty (Robinson/Hammitt 2018). In many applications, monetary methodologies are mixed to cover the full range of different health outcomes. Moreover, monetary and non-monetary approaches can be linked, as discussed below.

Figure 1: Schematic of CBA of health-affecting policies



Source: Authors' own elaboration based on Crutchfield et al. 1997; EPA 2011

On the other side, cost analysis includes all costs associated with changes to regulations. These include in most CBAs at least direct costs borne by both industry and the consumers that are directly affected by the regulation, as well as administrative costs borne by taxpayers (Antle 1999). Direct costs are mostly compliance costs, that consist of one-time capital costs and recurring operating costs due to labor, input and maintenance expenditures.

Compliance costs can be assessed using survey data from companies, which serve as the basis for an industry and sector-wide estimation (accounting approach, Antle 1999). In an engineering cost assessment, compliance costs are estimated based on input costs and quantitative models of production processes for plants with varying baseline characteristics, which are aggregated according to the heterogeneity of companies in the sector (EPA 2010). In addition, costs of a regulation might be borne by private households and costs for government entities might occur for inspections and quality controls.

Beyond direct costs, economy-wide, indirect costs could be considered, which are incurred when goods and services will not be produced

and consumed, as regulation requires reallocation of resources (opportunity costs). Furthermore, distributive impacts and indirect effects can be assessed, which requires other models in the estimation of costs such as partial equilibrium, input-output or CGE models (op. cit.).

All steps of the CBA assessment come with uncertainties, as they require assumptions and rely on the availability and quality of underlying data and parameters applied in the models. A CBA should therefore include a supporting uncertainty analysis (EPA 2011).

4. Methodologies of health benefit estimations in CBAs

A major challenge for CBAs of regulations that affect human health and safety is “how to give value to changes in health status” (Mishan/Quah 2021: 260). Regulatory impact assessments employ various methodologies, encompassing both monetary and non-monetary measures, to assess different types of health outcomes (Table).

Table 1: Methodologies of Health Benefit Estimations in CBAs

Effects / Approaches	Death	Medical Expenses	Productivity loss	Disutility
Monetary				
Cost of illness (COI)	×	×	×	
Friction-Cost approach (FCA)			×	
Willingness to pay (WTP)				
Mortality value of statistical life (VSL)	×*			
Morbidity		×	×	×
Nonmonetary				
Quality-Adjusted life years (QALYs)	×		×	×
Disability-Adjusted life years (DALYs)	×		×	×
Mixed				
Monetized quality-adjusted life years (MQALYs)	×*		×	×

*Notes: *Related to the reduction of mortality risks*
Source: Authors’ own elaboration

The major difference among monetary metrics is the use of accounting approaches to measure the costs of adverse health effects and the value

of avoiding these effects. Studies often employ a combination of different approaches to account for key health endpoints such as premature mortality, medical expenses and opportunity costs resulting from foregone wages and productivity losses.

U.S. federal agencies have historically used cost-of-illness estimates, which have its origins in the 1960s in the United States. Since the 1990s, the value of a statistical life (VSL) estimates, which express the value of reduced risk of death as a monetary measure, have replaced the income-based COI measure of costs associated with premature death. Non-monetary measures such as the Quality-Adjusted Life Years (QALY) metrics are increasingly used to assess the comprehensive burdens of illnesses on society (Robinson/Hammitt 2013).

4.1. Cost-of-illness (COI) approach

The basic approach to monetize the benefits of avoided injuries, illnesses and premature deaths is the estimation of the costs of illness This metric has two components and measures all the economic costs associated with treatment and time lost due to illness.

The first component are direct costs of medical expenditure for physician services, medication, hospital stays and other treatment-related activities paid by patients, their families and/or third parties such as insurance companies and employers. Second, indirect costs as the value of forgone market income and lost productivity due to morbidity (the impact of the illness on the ability to work or perform daily activities) and premature mortality (the economic value of lost years of life) (Buzby et al. 1996; Crutchfield et al. 1997; Robinson/Hammitt 2013).

The rationale for the productivity loss component in the COI is that “the withdrawal of an individual’s labor due to premature death or permanent disability results in a loss to society of that individual’s future production” (Pike/Grosse 2018: 4). The COI is also known as “human capital” approach, as illness- and death-related productivity losses are associated with changes to human capital (Pike/Grosse 2018). The underlying assumption of the indirect cost components in the COI approach is that the market goods and services produced by an individual during his lifetime reflect his value to society (Mishan/Quah 2021).

The basis of calculations in many studies is the full cost of employee compensation that include payroll taxes and other employer-paid benefits (Robinson/Hammitt 2013). The COI estimate provides a relatively straightforward accounting approach to be applied and explained, which nevertheless relies on various economic data and projections.

For instance, the costs of premature mortality are equivalent to the individual's present value of future economic production over the expected remaining lifetime at a given age and sex. This estimation requires future market production projections based on labor force participation and employment rates, life table survival probabilities and hourly gross earnings, categorized by age and sex (Pike/Grosse 2018).

The COI approach on indirect costs is not limited to wages major to avoid underestimation of total costs for society. U.S. studies typically consider the adverse effects of illness and premature death on unpaid work through opportunity cost (own or imputed wages) or replacement cost methods (average wage in similar services). COI studies in European countries are instead mostly focused on paid work, which is more relevant in cases of illness with short-term effects (op. cit.; Tranmer et al. 2005).

Even though the COI is widely applied, the method is also criticized for i) methodological assumption, ii) the missing coverage of important burdens of health effects and utility/wellbeing (see also discussion on WTP methods below) and iii) the potential inaccurate reporting of costs for particular parts of the population.

First, the COI assumes that the direct and indirect costs approximate the market value of reduced health, despite potential distortions in medical and labor markets (Kuchler/Golan 1999). The estimations mainly reflect current wage and medical expenditure structures, with limited consideration for projected changes in wages and medical advancements (op. cit.; EPA 2010). The COI also overlooks that individuals' health expenditures contribute to contribute to the incomes in other sectors in a general equilibrium framework.

Second, earnings are a proxy for the market value of livelihood rather than a value of life per se (Tranmer et al. 2005). The COI method does not cover other elements of illnesses such as pain and suffering that affect wellbeing (Kuchler/Golan 1999; EPA 2010). More generally, measuring the value of the individual to society in terms of income ignores the individualistic perspective of welfare economics and the theory of value (Freeman/Herriges/Kling 2014).

Third, scholars emphasize the impact of unequal wage distribution, leading to the undervaluation of health for specific societal groups, notably women and migrants. COI measurements also tend to overlook the very young and elderly individuals who are often affected by illnesses and premature death, as the focus primarily centers on wage incomes. This is further connected to the uneven distribution of health expenditures, which closely correlates with income levels (Kuchler/Golan 1999). Similarly, the COI approach suggests that illnesses are more severe in high-income countries compared to low-income nations (Tranmer et al. 2005).

Overall, the COI approach identifies and measures the direction and magnitude of economic flows related to health effects. As the only measure, it assesses the direct health benefits through avoided medical expenditures. The indirect effects of foregone wage incomes and productivity losses bring the COI closer to a full accounting of the losses borne by individuals suffering illness than simply assessing medical costs. The COI approach is most relevant for the cases of illnesses with short- to mid-term health effects with sufficient incidence-based data and detailed income data available.

4.2. Friction-cost approach (FCA)

The friction cost approach targets the role of productivity changes in COI approach, whose indirect costs represent potential rather than actual costs, taking into account the degree of scarcity of labor in the economy and the friction-search mechanism. Thus, unemployed workers and the firm-level workforce reduces the actual loss of productivity from illness-caused absence from work as jobs can be filled internally or with unemployed persons (Koopmanschap/Rutten 1996).

In the case of premature death, the COI values the productivity loss of a dead individual from the time of death to the age of retirement, discounted to present value. The friction-cost approach FCA assumes that positions can be readily replaced, either by someone who is already employed or by an unemployed individual. In the case of short-term absences, the companies' internal labor reserve can replace the open position or employees can make up the productivity losses when they return to the workplace.

From the perspective of firms, the only additional resource costs are the productivity lost in the friction period until a replacement worker is found plus the additional cost of replacing the worker, for instance expenditures for trainings. Thus, productivity changes are only transitory (Pike/Grosse 2018; Tranmer et al. 2005). The data requirement to estimate the productivity costs in the FCA are the sum of the value of production loss during the friction period, the extra costs needed to re-establish the production level, and the cost of hiring and replacing an individual (if the absence is permanent) (op. cit.).

The estimated productivity losses by the FCA are significantly smaller compared to the human capital approach in the COI approach. However, the FCA takes a microeconomic perspective of the firm in conjunction with a labor market model that challenges the neoclassical assumption of full employment and equality of labor costs and marginal value of a worker.

The macroeconomic perspective of the human capital approach in the COI methodology and the effects of lost household productivity due to illnesses and premature mortality is not part of the FCA (Pike/Grosse 2018; Tranmer et al. 2005).

4.3. Willingness-to-pay approaches

An alternative approach to assess the burdens of nonfatal health effects is the willingness-to-pay approach (WTP) (or the equivalent willing-to-accept approach, WTA). In the case of health, the WTP is the largest amount of money an individual would voluntarily pay to obtain an improvement (or to avoid a decrement) in health. WTA is the smallest amount of money the individual would voluntarily accept as compensation to forego an improvement (or to endure a decrement) in health.

The WTP concept is most commonly used because it expresses the amount of money an individual is willing to pay to reduce the risk of being affected by all types of negative consequences of an illness (Freeman/Herriges/Kling 2014; Hoffmann/Maculloch/Batz 2015; Kuchler/Golan 1999; Robinson/Hammitt 2013; EPA 2010).

The WTP is the preferred measure for nonfatal and fatal health effects from a neoclassical welfare economics perspective. The WTP is based on the assumption that each individual is the best judge of his or her own welfare. Thus, the monetary value of a risk reduction is most appropriately defined as the change in wealth that has the same effect on one's utility as the risk change (Robinson/Hammitt 2013). The WTP approach is also in accordance with policy goals, which aim to reduce the risk of adverse health effects incurred by the affected population rather than to prevent identifiable cases with certainty (Robinson/Hammitt 2018).

Furthermore, WTP estimates can potentially reveal the effects of illnesses more comprehensively than the COI approach. WTP estimates ideally express the monetary value to avoid four components of illness: medical expenses, the lost wages resulting from the inability to work, the disutility from illnesses such as discomfort, anxiety, pain and suffering, and averting expenditures and activities to prevent diseases (Freeman/Herriges/Kling 2014; EPA 2010).

The WTP approach can be used to cover both, morbidity and mortality risks. However, it is conceptually simpler to monetize the mortality risk, expressed as the "Value of a Statistical Life" (VSL), as it has a clearly defined outcome. In comparison, morbidity risks are related to various issues, depending also on the type of disease assessed.

4.3.1. Valuing mortality risk reductions

The VSL has become the most important economic parameter in the evaluation of the benefits of policies that reduce the risk of death. The VSL is based on the rationale that individuals make a trade-off between mortality risk and wealth. The value of this reduced risk of mortality is expressed as the aggregate of individuals' WTP for these small reductions in risk. In other words, the VSL is the monetary value of avoiding one statistical death in society (Andersson/Hole/Svensson 2019).

Following Viscusi/Harrington/Sappington 2018, the calculation of the VSL is straightforward, as it is the result of the WTP response divided by the size of the risk reduction:

$$Value\ of\ a\ statistical\ life = \frac{WTP}{Size\ of\ risk\ reduction}$$

Freeman/Herriges/Kling (2014: 193–194) give an illustrative example:

> "For example, suppose that there were a group of 10,000 people, each of whom has a probability of .0004 of dying during the next year. Suppose a pollution control policy would reduce that probability to .0003, a change of .0001 (1 in 10,000). Furthermore, suppose that each individual in that group expresses a willingness to pay $500 for this policy. Since the policy would affect all of the people equally, it is a form of collective good for the group. The total willingness to pay of the group is $5 million. If the policy is adopted, there will be on average one less death during the year. Thus, the total willingness to pay for the policy resulting in one less death is $5 million. This is the value of statistical life."

There are numerous examples in the literature that illustrate the VSL (see for instance (Mishan/Quah 2021; Robinson/Hammitt 2018; Viscusi/Harrington/Sappington 2018). The terminology VSL incorporates the risk of misinterpretation of the concept. Even though the VSL contains the word "life" it is not a monetary value placed ex post on a life. The term "statistical" is used to emphasize the role of probability and highlights the fact that it considers unidentified, rather than identified, lives (Andersson/Hole/Svensson 2019; Robinson/Hammitt 2018). To avoid misunderstandings, some authors prefer the term "value-of-mortality risk" (Freeman/Herriges/Kling 2014).

Two different methodologies exist for empirical research to assess the WTP for a small change in mortality risk: revealed preference evidence and stated preference evidence.

Revealed preference methods infer willingness to pay based on individuals' actual behavior in markets related to health risks and include approaches such as hedonic pricing techniques (Andersson/Hole/Svensson

2019). These studies chiefly rely on labor market estimates that have been facilitated by the availability of extensive and accurate occupational risk and employment data, particularly in the United States. The rationale for this approach is that more dangerous or hazardous jobs are less desirable to workers and require higher wages.

The interrelation between wages and health risks could be identified through the collection of wage and health risk combinations (hedonic equilibrium wage locus) in which the number of workers willing to take the jobs equals the number of jobs at the specific wage-safety situation. The VSL follows from the slope of the hedonic equilibrium wage locus (Kniesner/Viscusi 2019). Alternatively, the degree of risk could be related to the additional amount that a worker would demand to accept a higher risk of death in his job (Mishan/Quah 2021).

The actual VSL is however typically estimated in a regression analysis with the dependent variable being the real wage regressed against work-related fatality rates and demographic variables (age, education) and other job characteristic variables (such as non-fatal injury risk, workers' compensation insurance coverage and industry and occupation indicators). The VSL can then be derived from the change in the wage per one unit change fatality risk measure (Kniesner/Viscusi 2019). However, the illustrative examples of the hedonic equilibrium wage locus and the degree of risk/compensation combinations highlight that the VSL also depends strongly on the initial level of risk and the magnitude of changes to risk.

In addition, product market studies link product prices to risk levels. The underlying idea is that safer goods and services cost more to create, but are more highly valued by their consumers and, in turn, have higher prices. Thus, there is a relation between risk, willingness to pay or the time and efforts to use safety devices such as bike helmets, smoke detectors, seatbelts or airbags (op. cit.).

Stated preference studies rely on hypothetical decisions instead of actual behavior. These estimates are derived from surveys in which respondents make choices involving trade-offs between wealth and health risks (Andersson/Hole/Svensson 2019; Freeman/Herriges/Kling 2014). These methods prove particularly valuable when investigating risk outcomes lacking informative market data and for countries where risk and employment data are ill-suited for obtaining revealed preference evidence (Kniesner/Viscusi 2019).

The surveys can use the contingent valuation method (CVM) or discrete choice experiments (DCE). In the CVM, respondents are presented with a hypothetical policy scenario and asked to indicate their maximum WTP for the policy (open-ended CVM) or to decide whether they would

be willing to pay a certain amount if the policy were introduced (closed-ended CVM).

In the DCE, respondents have a choice of scenarios that differ in their characteristics, including their cost to the individual. Respondents are then asked to choose their preferred option. Therefore, the main difference between the two methods is that CVM asks participants what they are willing to pay, while DCE asks them to make a choice based on trade-offs between the attributes of each scenario (see also examples of CVM and DCE questions in (Andersson/Hole/Svensson 2019)). Stated preference surveys can be used to derive VSL with regard to the risk of death from different types of diseases (infections or cancer) (Freeman/Herriges/Kling 2014).

There exists a wide range of VSL estimations in the literature, and in particular, stated preference studies can be applied for specific purposes. The VSL is usually not explicitly calculated within a CBA. Instead, VSL figures are commonly adopted from pre-existing studies or adjusted to fit the specific context of the CAB through a process known as “benefit transfer.”

The EPA largely relies on the average estimates of 26 studies conducted from the 1970s to the early 1990s as their default value of mortality risk changes of 7.6 million dollars (in 2006 dollar terms), updated to the year of the analysis. Out of these 26 studies, only six are based on stated preferences (EPA 2011, 2014). Thus, the results from revealed preference methods are the most influential in the US, but also for CBAs in other countries as the U.S. VSL is transferred with adjustments where the VSL estimation is not feasible, too time-consuming or too expensive (Mishan/Quah 2021).

It is also possible to derive VSL estimates for a country from the stated preference studies from different countries and survey methodologies through meta-regression. This requires, however, sophisticated benefit transfer methods, which consider country and study-specific factors. An example for OECD countries shows that a VSL for the OECD as a whole ranges from 1.5 to 4.5 million dollars (base value 3.0 million dollars) and for the EU between 1.8 to 5.4 million dollars (base value 3.6 million dollars) in 2005 dollars (OECD 2012).

Despite the methods to combine different VSL estimations, substantial heterogeneity remains in the VSL both within and across countries due to a number of factors, such as differences in income, age, occupation, race, gender and cultural background. For instance, the VSL should increase with income if reducing mortality risks is a normal economic good and is

likely to vary with age both because the amount of remaining life expectancy declines with age and because economic resources and family obligations vary with age (Albertini/Scasny 2020).

As a result, the VSL estimates are diverse and context-specific, reflecting the heterogeneity of the underlying preferences, valuations and risk perceptions of individuals and societies. Another factor that contributes to the variety of VSL estimates are the methodological and data differences across studies, such as sample sizes, estimation and survey techniques, and fatality risk data sources used for estimation (Kniesner/Viscusi 2019).

4.3.2. Valuing morbidity risk reductions

WTP estimates are also the preferred approach to discover the comprehensive burdens of non-fatal health effects including medical expenses, the lost wages resulting from the inability to work, the disutility from illnesses such as discomfort, anxiety, pain and suffering, and averting expenditures and activities to prevent diseases (Freeman/Herriges/Kling 2014; EPA 2010).

It is, however, more challenging to derive solid WTP of illness risks compared to the mortality risks. Morbidity risk WTP studies have to address heterogeneity issues concerning the different components of burdens but also the different types of diseases ranging from infectious diseases with acute, but mild conditions to diseases with chronic conditions and lifelong effects (Robinson/Hammitt 2018).

The approaches for valuing nonfatal health risk reductions are very similar to the stated preferences approach for valuing mortality risk reductions. Even though there are a variety of studies that estimate WTP for morbidity risk reduction, particularly from the field of environmental health assessment and occupational safety studies (ECHA 2016; Hunt/Ferguson 2010), the studies are often too specific for evaluating a policy in a CBA.

WTP estimates are available only for single diseases and conditions, for instance the WTP of avoided allergy and symptom days due to Chromium VI in leather articles, while other components of the health effects are not covered (ECHA 2016).

4.4. Non-monetary measures

There are a variety of ways that health effects can be measured without using monetary valuation, most prominent are the quality-adjusted life years (QALYs) and the disability-adjusted life years (DALYs). Both

measures are time-based measures that are applied in cost-effectiveness assessments as an alternative to CBAs.

Both measures claim to provide a way of measuring the overall impact of diseases and health conditions by combining both objective and subjective measures (Freeman/Herriges/Kling 2014; Hoffmann/Anekwe 2013; Robinson/Hammitt 2013).

Conceptually, the non-monetary measures incorporate a trade-off. Instead of exchanging health-risk reduction against wealth as in the WTP approach, it is a trade-off between different health states of varying duration (Mishan/Quah 2021). For instance, the QALYs assume that preferences over health and longevity depend only on health consequences and do not depend on other characteristics of the individual or the risk as the WTP (Hammitt 2002).

The QALYs are calculated by multiplying the duration of a health state as the objective element, by the utility score associated with that health state, and the so-called health-related quality of life (HRQL) as the subjective element of the measure. The HRQL is based on surveys of people's self-reported levels of pain, discomfort or other negative impacts on quality of life resulting from a particular disease or health condition. The survey may also include assessments of the ability to perform daily activities of living or to participate in social activities.

The HRQL outcomes range between 0 (death) and 1 (perfect health). QALYs estimate the overall welfare impact of health changes, including changes in both quantity (years of life) and quality of life. The effects of policies can be calculated by comparing the QALYs with and without intervention (Freeman/Herriges/Kling 2014; Hammitt 2002; Hoffmann/Anekwe 2013).

DALYs are calculated by summing the years of life lost (YLLs) due to premature mortality and the years lived with disability (YLDs). One DALY represents the loss of the equivalent of one year of full health. YLLs are calculated as the difference between a reference life expectancy and the age at death, weighted by a factor reflecting the reduced health in years of life due to disease or injury. YLDs are derived by multiplying the prevalence of a health condition by the disability weight associated with that condition and the duration of the condition. The disability weight reflects the severity of the health state on a scale from 0 to 1, where 0 is equivalent to full health and 1 is equivalent to death.

DALYs are mainly used to compare the magnitude of different health problems within and across countries. In addition, it can be used to compare the burden of diseases that cause premature death but little disability (such as drowning or measles) to that of diseases that do not cause death

but do cause disability (such as cataracts causing blindness) (op. cit.; Robinson/Hammitt 2018; WTO 2012).

4.5. Interrelations of different benefit measures and mixed applications

The different methodologies to assess the burdens of illness effects – or in other words the benefits of avoiding these adverse health effects – differ not only in the values they assign to different components of non-fatal and fatal health effects, but most importantly in their ability to capture specific components of these effects and in their theoretical foundations.

While the COI is based on the human capital theory, the WTP-based methods are grounded in microeconomic welfare economics. It is, therefore, argued, that the latter methods are most suitable to the underlying theoretical framework of CBAs (Freeman/Herriges/Kling 2014; EPA 2010).

However, most CBA and RIA studies combine the estimates of different methodologies to overcome the weaknesses of the single approaches. For instance, Hoffmann/Maculloch/Batz (2015) use the COI to capture medical expenditures and income losses and the VSL to monetize the mortality risk in order to derive the economic burden of major foodborne illnesses in the United States.

The CBA of comprehensive regulations that target multiple issues such as the U.S. Clean Air Act (EPA 2011), the EU Clean Air Policy Package (Vrontisi et al. 2016) and the REACH (ECHA 2016) regulation also combine COI, VSL and morbidity WTP estimates to derive the benefits of these regulations (see details below).

There are also attempts to combine monetary and non-monetary measures as both cover specific aspects of burdens of illnesses. An approach to monetizing QALYs and DALYs is to estimate the value of a statistical life year (VSLY). This involves assigning a monetary value to a single year of healthy life, which can then be used to monetize the gains in QALYs or losses in DALYs resulting from a particular intervention.

For example, if the VSLY is estimated to be 100,000 dollars and a particular intervention results in a gain of five QALYs, the value of the intervention would be estimated to be 500,000 dollars (Freeman/Herriges/Kling 2014).

It is important to note that monetizing QALYs and DALYs is controversial, particularly because both approaches have different theoretical foundations, making the results inconsistent with the benefit-cost analysis

framework (Robinson/Hammitt 2013). Beyond other conceptual challenges, for instance, the use of constant VSLY over a lifetime, it remains debatable whether it is appropriate to use the VSL (WTP to reduce small risks of death) as a proxy for WTP to reduce risk of nonfatal illness (Hoffmann/Anekwe 2013).

In contrast to the extensive discussions and numerous studies on the burden of illness or the benefits of regulations to reduce health risks, there is little description of the methods used to estimate the costs of regulations. These include compliance costs, administrative costs as well as opportunity and social costs (EPA 2010). In CBA and RIA, the cost estimations are often performed in a very case-specific way.

As indicated in chapter 2, regulatory compliance costs borne by firms and administrative costs are most commonly assessed. Compliance costs, which consist of one-time capital costs and recurring operating costs due to labor, input and maintenance expenditures, can be estimated through company surveys about these cost categories (accounting approach) or through engineering cost assessments based on input costs and quantitative models of production processes (engineering approach) (op. cit.). Both methodologies result in sectoral cost estimations, by considering the heterogeneity of companies in the sector.

CBA of regulations with broad impacts and multiple stakeholders in the economy, such as the U.S. Clean Air Act Amendments or the EU Clean Air Policy Package, assesses direct compliance costs through a combination of different cost estimations.

For instance, in the CBA on the Clean Air Act Amendments (CAAA) (EPA 2011) regulations are assessed for six source categories that are responsible for emissions such as industrial point sources, on-road engines or electric generating units and for different types of emission. Unit costs were estimated by collecting information on the costs associated with specific control measures required by CAAA regulations, or costs were calculated using estimates of the average cost per ton of pollutant emission reduced. In addition, the costs were modeled in different EPA-own emissions reduction models.

Similarly, cost estimations for the CBA of the EU Clean Air Policy Package require inputs from the air pollution mitigation model GAINS that estimates abatement costs for 5 key air pollutants for companies and private households in the EU (Vrontisi et al. 2016).

Outside CBA and RIA studies, compliance costs to regulations are assessed in studies on exporters that have to comply with regulations and standards set by importing countries. These estimations are typically based on surveys and show that exporters have to carry significant compliance costs.

For the example of agricultural exports from Tunisia to the EU, Tröster et al. (2023) show that export companies spend up to five percent of sales for wages of employees engaged in these processes and need more chemical and services inputs. The report also includes a literature review on compliance cost estimations for different countries and in the context of association agreements between the EU and Eastern European countries and in the EU enlargement in the 2000s.

EPA (2010) recommends the use of partial equilibrium, econometric, input-output or CGE models to analyze other types of costs, including opportunity costs (which refer to the foregone benefits that result from allocating resources elsewhere) and social costs (which occur when costs are passed on to consumers through higher prices for goods and services). In particular, when sectors are highly interconnected with other sectors in the economy, the impact on total costs could be assessed by applying CGE models.

5. Methodologies of regulatory cost estimations in CBA

In theory, regulatory costs are derived from the concept of opportunity cost, which places a value on the inputs required to implement policies. Thereby, "the opportunity cost of using an input to implement a policy is its value in its best alternative use." (Boardman et al. 2018: 31)

In contrast to the numerous empirical studies that monetized the burden of illness - or in other words, the benefits of health-risk reducing regulations - and costs of adverse health effects, methodologies to estimate the costs of regulations are hardly ever described.

For example, one of the standard textbooks on CBAs by Boardman et al. (2018) contains no chapter nor an extensive debate about regulatory cost evaluation. In many cases, only the type of costs associated with regulations are listed. These include compliance costs, administrative costs as well as opportunity and social costs (EPA 2010).

As indicated in chapter 3, regulatory compliance costs borne by firms and administrative costs are most commonly assessed. Compliance costs, which consist of one-time capital costs and recurring operating costs due to labor, input and maintenance expenditures, can estimated through company surveys about these cost categories (accounting approach). Alternatively, engineering cost assessments based on input costs and quantitative models of production processes (engineering approach) (op. cit.). Both methodologies result in sectoral cost estimations, by considering the heterogeneity of companies in the sector.

In cases of CBA of regulations with comprehensive effects and different actors in the economy, the direct compliance costs are assessed through a combination of different cost estimations. For instance, in the CBA on CAAA (EPA 2011) six source categories that are responsible for emissions such as industrial point sources, on-road engines or electric generating units, and different types of emissions are assessed. Unit costs were estimated by collecting information on the costs associated with specific control or abatement measures required by CAAA regulations, or costs were calculated using estimates of the average cost per ton of pollutant emission reduced.

In addition, costs were modeled in different EPA-own emissions reduction models. Similarly, cost estimations for the CBA of the EU Clean Air Policy Package require input from the air pollution mitigation model GAINS that estimates abatement costs for five key air pollutants for companies and private households in the EU (Vrontisi et al. 2016).

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The EPA (2010) recommends using partial equilibrium models, input-output econometric models or CGE models to analyze other types of costs, including opportunity costs (referring to the benefits lost by allocating resources elsewhere) and social costs (arising when costs are passed on to consumers through higher prices for goods and services). In particular, when sectors have strong linkages to other sectors in the economy, the overall cost effects could be assessed through CGE model applications.

6. CBA applications in regulatory impact assessments (RIAs)

The major applications of CBA are regulatory impact assessments (RIAs). Starting in the United States in the 1970s, RIAs are perceived not only as a tool but as a general concept of "evidence-based policymaking" (OECD 2020; Rantala/Alasuutari/Kuorikoski 2023). RIAs can be used to select the most suitable policy option for new regulations, but also for the re-assessment of current regulations and potential adjustments.

RIAs are supposed to enable regulators and policymakers to identify market-oriented and less-burdensome alternative regulatory options, gather and analyze information to assess the impact of regulations on society, and to make regulatory decision-making more transparent and accountable (Nicola 2017).

Various methods are available to assess the impact of regulations and their options, but CBA remains the most relevant methodology in RIAs.[2] CBA is perceived as a neutral and quasi-scientific numerical exercise that can legitimize policy actions (op. cit.).

However, RIAs are tools that can be highly politicized, and the CBA outcome can be utilized for different purposes, as demonstrated during the Trump administration (Livermore/Revesz 2020). Therefore, organizations such as the OECD and the EU advocate for stakeholder involvement and for using the outcomes of CBAs as just one factor in the policymaking process.

Government institutions have developed processes on how to conduct RIAs (Abelson 2020), such as U.S. agencies (EPA 2010; HHS 2016), the European Commission, national governments and ministries or the OECD (OECD 2020). As theoretical work on CBAs, numerous empirical CBAs and benefit estimations or estimations of variables such as social discount rates are conducted independently from RIAs, new conceptual approaches and methodologies affect government guidelines, which are therefore updated on occasion (Groom et al. 2022; McGartland et al. 2017).

Although RIA are widely used in many countries, the origins and the applications and role of CBA vary. Nicola (2017) traces the first CBA applications back to the 20th century "socialization" of private law, which put forth economic and social aspects for regulations.

2 Occasionally the terms CBA and RIA are used interchangeably.

The second strain emerged particularly in the 1970s and is linked to the Chicago Law and Economics approach to private law and the theoretical framework of neoclassical welfare economics. While the first strain has been the basis for the approach to RIAs, the second has prevailed in U.S. RIAs. However, the approaches to RIAs on both sides of the Atlantic have evolved further.

6.1. RIAs in the United States and the EU

The growing importance of cost-benefit analysis (CBA) in the United States began in the 1970s during the Ford and Carter administrations. This was spurred by the emergence of major risk and environmental regulation agencies, including the Environmental Protection Agency (EPA), the National Highway Traffic Safety Administration, the Consumer Product Safety Commission and the Occupational Safety and Health Administration (OSHA) (Viscusi/Harrington/Sappington 2018). These agencies play a crucial role in creating regulatory actions by making rules for the implementation of laws by specifying requirements and conditions (ITU 2014).

In theory, CBAs were supposed to make these regulations as efficient as possible. In 1982, the Reagan administration mandated that major new regulations must pass a monetized benefit-cost test, which was controlled by the Office of Information and Regulatory Affairs (OIRA), which is part of the White House's Office of Management and Budget (OMB).

The OIRA is responsible also for establishing and enforcing regulatory assessment standards. An official reason for the use of CBAs and the control mechanism at that time was to prevent undue influence from political forces on bureaucrats. However, the approach also faced criticism and controversy as a tool to justify deregulation (Antle 1999; Nicola 2017).

During presidencies of the Democratic Party, the use of CBA in policy-making and the oversight by the Office of Information and Regulatory Affairs (OIRA) under the White House was solidified. The Government Performance and Results Act in 1993 under President Clinton restricted the need for RIAs to significant regulations that may have an annual effect on the economy of at least 100 million dollars or other substantial effects on jobs or specific sectors (McElfish 2017). Further, the Presidents Clinton, Obama and Biden strengthened qualitative methods, the role of behavioral economics and the consideration of distributional aspects in U.S. RIAs.

Under President Trump, however, the deregulatory agenda focused on regulatory costs and for every new regulation, two existing rules should

be eliminated (Krutilla/Graham 2023; Livermore/Revesz 2020). Generally, advocates in favor of CBA as part of RIAs highlight the progressive development of the methodologies and the broadening of the concepts away from pure neoclassical welfare economics. Furthermore, Livermore/Revesz (2020) emphasized that RIAs also enabled various environmental regulations in the first place because they demonstrated large net benefit to society.

In the EU, several member-states such as the UK and the Netherlands were frontrunners of RIAs in national policymaking processes since the 1970s and 80s with a focus on assessing the regulatory impact on business. First attempts on the EU level followed this approach with the Business Impact Assessment (BIA) in 1986, which focused on compliance costs only and did not consider societal welfare impacts (Weiland 2022).

Only in the late 1990s, the European Commission (EC) and several member states triggered a process to establish a systematic assessment of the potential impacts of proposed EU regulations before their adoption. Also growing skepticism against the EU in many member states was conducive to this, as the EC saw RIAs as a way to justify EU regulations as being cost-efficient (Pircher 2023). The EC subsequently adopted an integrated RIA model that covers the economic, social and environmental impacts of regulatory proposals as part of a wider "Action Plan for Better Regulation" in 2003 (Weiland 2022).

The EU RIA approach has been continuously developed further in procedural and methodological terms, and the EC Impact Assessment Guidelines have been revised in 2009 and 2021. In the current system, the lead Commission service determines the need for a Regulatory Impact Assessment (RIA) early in the internal political validation process. An inception impact assessment (IIA) is published for all proposals subject to an impact assessment, outlining the policy problem, options and expected impacts. Following public feedback, the Commission conducts a full impact assessment, including data collection, consultations and expert input.

The results are summarized in an impact assessment report reviewed by the Regulatory Scrutiny Board (RSB), which has been introduced as part of the Better Regulation Package of 2015. After internal consultation, the regulatory proposal and its accompanying impact assessment are published for feedback and sent to co-legislators for negotiation (OECD 2019).

With the Better Regulation Initiative, the EC "seeks to design and prepare EU policies and laws in such a way that they achieve their objectives in the most efficient way. 'Better regulation' is not about regulating or de-

regulating. It is a way of working that allows political decisions to be prepared in an open and transparent manner, informed by the best available evidence, including via the comprehensive involvement of stakeholders." (EC 2021a: 5). The evidence includes the "quantification of impacts, including costs and benefits" (ibid.: 7), but also opinions, stakeholder inputs as well as scientific and expert advice. Further, the evaluation methodologies include multi-criteria analysis and CBA and should consider distributional impacts (EC 2021b).

There remains skepticism about the actual focus of the comprehensive RIA approach. Firstly, the EC initiated several programs to target "red tape," for instance through the REFIT program, in which RIAs are used to evaluate current regulations, or the "one-in, one-out" principle for regulations in the same policy area (op. cit.). Further, the EC has recently communicated the renewed focus on a growth-enhancing regulatory framework as part of its competitiveness strategy (EC 2023). Secondly, the structure, the review processes and the influence of the Regulatory Scrutiny Board are criticized as biased toward the more business-friendly EC positions in the policymaking process (Pircher 2023).

As the different origins and developments in RIAs and the applications of CBAs with these assessments indicate, there are several differences between the United States and the EU approaches. In the policy process, the U.S. RIAs do not apply to primary legislation. The U.S. agency system requires RIAs for the implementation of regulations.

In the EU, RIAs are required for proposals of primary legislation. As the scope of the requirements and methodologies in the EU RIAs is broader, the role of monetized costs and benefits is much weaker compared to the United States (Krutilla/Graham 2023), as the EU approach is a system with multiple objectives (Weiland 2022).

For instance, many U.S. agencies recommend in their guidelines to use specific VSL estimations for the monetarization of benefits (EPA 2014; HHS 2016), while the EU guidelines are open to different types of evaluation methods (EC 2021b) and only around 35 percent of EU RIAs have fully quantified benefits.

Thus, Radaelli (2007) argues that the EU Better Regulation initiative is a "meta-regulation" discourse, which influences the regulatory process, rather than providing substantive regulation. Further, the creation of "evidence" as the basis for policymaking is much broader in the EU and is part of the political debate through negotiations and stakeholder participation (Capano/Lippi 2017). Rantala/Alasuutari/Kuorikoski (2023) therefore speak in the EU context of "RIA as evidential reasoning" rather than "evidence-based RIA."

This is seemingly in contrast to the U.S. approach that emphasizes the monetized impacts as the basis for choosing policy options and in which CBA results are prominently presented in the final rules. Furthermore, CBA outcomes are also considered in the judicial review of a final regulation (Krutilla/Graham 2023; Nicola 2017).

However, the political influence on the guidelines and review of RIAs as well as the impact of theoretical concepts and scholars on the applied methodologies, call into question the evidence-based nature of U.S. RIAs (Livermore/Revesz 2020). The differences between the two RIA systems were also highlighted in the debates around TTIP and regulatory cooperation (Bartl 2017).

6.2. Selected RIAs on health and safety regulations

Despite the general guidelines for methodologies and processes of RIAs, the specific RIAs are often very case-specific and many aspects, in particular benefits, are not or only partially monetized due to the lack of data or other methodological limits. Moreover, RIAs are conducted primarily for regulations with comprehensive effects on multiple actors in a society, which makes the monetarization of many components of benefits and costs highly complex (EPA 2011; Vrontisi et al. 2016).

We focus on covering RIA of regulations that do have or are likely to have significant impacts on human health. These are to be found particularly in (i) food safety standards (SPS), (ii) technical standards dealing with sensitive products such as pharmaceuticals and chemicals, (iii) standards for health and safety at work and (iv) air and water pollution.

Generally, all regulations in these areas concerning human health are related to market failures. In food safety, regulation is driven by the information asymmetry between consumers and producers and by administration. In the case of product safety, regulations address information asymmetry as well as consumer and worker behavior.

Health and safety at work regulations also arise from information asymmetry and the objective of improving information and behavioral requirements. Air and Water Pollution regulations are necessary due to the absence of markets for contaminants as externalities of economic activities and the lack of market-based compensation for pollution victims (Viscusi/Harrington/Sappington 2018).

The regulatory aims vary across these areas. Food safety regulations aim to reduce the risk of hazards associated with food consumption. Prod-

uct Safety regulations focus on reducing health risks, improving information flow and imposing behavioral requirements on producers and consumers. Health and safety at work regulations aim to enhance workplace safety by providing better information and imposing behavioral requirements on workers and producers. Environmental regulations on air and water pollution aim to prevent externalities caused by pollution.

The link to trade also varies across these domains. Food safety regulations have a strong link to trade due to the implementation of Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) measures. Product Safety regulations have an indirect link to trade, specifically regarding chemicals associated with occupational safety.

Safety and health at work regulations are linked to social standards in Trade and Sustainable Development (TSD) chapters of FTAs. Air and Water Pollution regulations have implications for general or sectoral competitiveness. The CBA approaches employed in these areas involve methods such as cost-of-illness (COI) and Willingness to Pay (WTP). risk-benefit analysis and revealed Value of Statistical Life (VSL). The methodologies are often mixed to cover specific contexts.

Table 2: Types of regulations focused on safety and health

	Food Safety	**Product Safety (Chemicals)**	**Safety and Health at Work**	**Air and Water Pollution**
Why regulation?	Information asymmetry	Information asymmetry and consumer/ worker behavior	Information asymmetry, worker behavior	No markets for contaminants, no market-based compensation of the victims of pollution
Regulatory aim	Reduce risk of hazards	Reduce health risks, better information, behavioral requirements	Better information, behavioral requirements	Avoid externalities
Affected actors	Consumers, producers, administration	Consumers, producers, administration, workers	Workers, producers, administration	Consumers, workers, producers, administration
Direct link to trade	Strong (SPS, TBT)	Indirect	Weak (TSD regulations)	Weak
CBA approaches	COI / WTP	COI / WTP Risk-benefit	COI / WTP Revealed VSL	COI / WTP

Source: Authors' own elaboration

6.2.1. Food safety standards

Food safety standards are part of sanitary and phytosanitary (SPS) measures. In the context of international trade, the Agreement on the Application of Sanitary and Phytosanitary Measures sets out the basic rules for food safety and animal and plant health standards. In the SPS Agreement, sanitary and phytosanitary measures are defined as any measures applied

- to protect human or animal life from risks arising from additives, contaminants, toxins or disease-causing organisms in their food;
- to protect human life from plant- or animal-carried diseases;
- to protect animal or plant life from pests, diseases or disease-causing organisms;
- to prevent or limit other damage to a country from the entry, establishment or spread of pests.

Food safety standards target in particular the first point regarding human risks arising from additives, contaminants, toxins or disease-causing organisms in food. The SPS Agreement acknowledges the fact that some trade restrictions may be necessary to ensure food safety and animal and plant health protection but aims to ensure that the measures are applied for no other purpose and are not more trade restrictive than required to meet their health objectives. Governments should justify the choice of their policies based on scientific evidence, for instance through CBAs (WTO 2022).

Food safety regulations became an important political and academic issue in the 1990s, when, first, consumer concerns increasingly shifted from the availability of food to food quality, including attributes such as taste, nutritional content and safety. Second, governments have been striving to improve the effectiveness, efficiency and transparency of regulations to reduce budget costs.

Consequently, the introduction of new food safety regulations in the United States and EU member states was supported by RIAs and other assessments (Antle 1999; Henson/Holt/Northen 1999; Valeeva/Meuwissen/Huirne 2004) such as the economic assessment of the Hazard Analysis and Critical Control Points (HACCP) Systems in the United States (Crutchfield et al. 1997; USDA 1996). The European Commission published its White Paper on Food Safety in 2000.

It is generally accepted that regulations are necessary to establish food safety, as market mechanisms do not guarantee an optimal level of food safety for society because of information problems and transaction costs. The insufficient market working is mainly caused by asymmetry in information about food safety between producers and consumers (Valeeva/ Meuwissen/Huirne 2004).

Food is an experience good in that the consumer can determine whether it causes illness only after it is consumed, and food is a credence good in that the consumer frequently cannot tell with certainty whether it actually caused an illness (Beghin et al. 2012; Roberts/Buzby/Lichtenberg 2003). Even though safe food can be defined as food that is wholesome and that does not exceed an acceptable level of risk associated with pathogenic organisms or chemical and physical hazards, the acceptable (tolerable) levels of food safety hazards are difficult to set (Valeeva/Meuwissen/Huirne 2004).

The objective of food safety regulations is the reduction of foodborne illnesses from the three groups of hazards (chemical, microbiological and physical), recognizing that a full elimination of this risk is not feasible. At-

taining acceptable levels of food safety hazards involves prevention, elimination or reduction of the hazards by means of a set of diverse actions and activities, i.e., a set of control measures.

The distinctive nature of the hazards affects the effectiveness and efficiency of the available alternative measures, with considerable differences between chemical and microbiological hazards. Economic assessments with CBAs could therefore support decisions on policies that ensure food safety, for example, through the choices of which pathogens and chemicals to regulate, what levels of contamination to allow and what foods to target first (Roberts/Buzby/Lichtenberg 2003).

In the late 1990s and the 2000s, a wide range of studies and academic articles accompanied the economic assessments of food safety standards by discussing the applied methodologies to assess the costs and benefits of such regulations (Antle 1999; Ollinger/Moore 2009; Roberts/Buzby/Lichtenberg 2003; Unnevehr/Jensen 2001).

All assessments generally show that food safety regulations bring a net benefit to society. For instance, the results of the U.S. Department of Agriculture's HACCP RIA indicated that the benefits of implementing such a system outweighed the costs, provided the four pathogens were reduced by 17 percent or more (Crutchfield et al. 1997), even though all results come with large uncertainties (Roberts/Buzby/Lichtenberg 2003). The CBA approaches for the HACCP regulations in the late 1990s and early 2000s provide good examples of the multiple stakeholders affected and the comprehensive impacts, of both benefits and costs.

We look at the two examples of RIAs in the United States and the EU on food safety standards.

The recent U.S. RIAs in this area relate to the rulemaking based on the "Food Safety Modernization Act" of 2011, while the EU conducts RIAs on selected secondary legislations with the General Food Laws. In the case of the United States, the selected example is the RIA carried out by the Food and Drug Administration (FDA) on the final rule on "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," which seeks to minimize the risk of serious adverse health consequences or death from consumption of contaminated produce.[3]

As indicated above, RIAs are part of the rulemaking process in the United States and require a step-by-step procedure, which means that CBA results will change until a final rule is published. In this example, FDA is the agency responsible for developing regulations to implement the Food Safety Modernization Act of 2011, which is intended to increase the safety and security of the food supply. FDA has developed seven rules for

3 All FDA RIAs are available at FDA 2024.

implementation – including this example – and is conducting a RIA for each rule (FDA 2015).

The RIAs and the final rules are reviewed and approved by the OIRA and public comments on the proposed rules and RIAs are considered by the agencies (ITU 2014). As the proposed rules and underlying data are adjusted in response to comments, the CBA results change accordingly. The final rule explicitly refers to the costs and benefit estimations of the final RIA (FDA 2015).

The first step in the U.S. RIA process is a comprehensive preliminary regulatory impact analysis (PRIA) that includes the regulatory options with rough cost and benefit calculations and a proposed rule with detailed costs and benefits (FDA 2013). The benefits of the proposed rule are derived from the decrease in the incidence of illnesses related to microbial contamination of a specific product. This requires the identification of illnesses from microbial contamination attributable to that produce, the days of illness as well as the hospitalization and death rates for each of the illnesses.

With the assumption of how much the new rule will lower the cases of illness, the economic impact is calculated with the Quality-Adjusted Life Days (QALD) for each illness, the VSL and the direct medical costs. Thus, the FDA uses a monetized QALD measure by dividing the VSLY by 365 days. On the cost side, the multiple activities on the farms from hygiene measures to recordkeeping and the costs for equipment and buildings are calculated in detail. The costs are differentiated according to farm size. The costs are also estimated for farms abroad that export to the United States.

The preliminary RIA showed annual benefits of 1.03 billion dollars by preventing 1.75 million illnesses per year and annual costs of 459 million dollars (op. cit.). In contrast, the final rule states 331,964 averted illnesses per year with a value of 925 million dollars annually and costs of 366 million dollars per year (FDA 2015).

Thus, the CBA estimations have changed during the policymaking process, particularly with regard to the estimated averted illnesses, but higher dollar estimations of the costs of illnesses, combined with new data and estimation methods, result in almost constant benefit values (FDA 2018). These changes reflect the adjustments of the rule that require a recalculation of the CBA estimates on a new data basis.

On the EU side, RIAs are conducted for new or amended secondary food regulations.[4] The framework of the General Food Laws Regulation

4 All EU RIAs can be accessed at EC 2024 with “RIA” as a search term.

((EC) No 178/2002) has been evaluated in the context of the REFIT program but without cost and benefit quantifications. Instead, surveys are used that indicate that the benefits exceed the costs of the regulation (EC 2018b).

An example of a RIA on secondary food regulations is that on trans fat (EC 2019). It assesses social impacts through direct and indirect health care costs and disability-adjusted life years, given that the level of industrial trans fat intake has detrimental effects on health. The economic impacts include direct costs for businesses and public authorities, impacts on consumers such as higher prices, competitiveness and trade impacts as well as impacts on small and medium enterprises (op. cit.).

The analysis of environmental impacts indicates that the EU RIAs are potentially more comprehensive and follow multi-goal objectives. For all impacts, monetized measures are used to compare different options including voluntary agreements or legally binding measures on the limits of trans fat contents, obligatory declaration of trans fats and the voluntary or legally binding prohibition of hydrogenated oils. The estimated cost and benefits show a clear preference for legally binding measures (Option 1b) or prohibitions (Options 3b) (see Table 3).

Table 3: Costs and benefits of different trans fat policy options

	Option 1a	Option 1b	Option 2	Option 3a	Option 3b
Administrative and compliance costs	50m	297m	9826m	59m	346m
Health-related savings	11,078m	94,008m	15,353m	11,078m	94,008m
Ratio of monetised benefits to costs	222	317	1.6	189	272

Source: EC 2019: 64

The health-related savings are direct healthcare costs related to the use of health resources (i.e., primary care costs, outpatient costs, emergency costs and medication used during hospitalization) and indirect costs related to the disease, such as the loss of productivity and informal care. The calculations of the benefits are conducted with an adjusted model by the EC's Joint Research Centre (JRC) that links trans fat contents and coronary heart disease and reports changes in health treatment costs and disability-adjusted life years as a non-monetary benefit (ibid.: annex 4).

Thus, this RIA does not rely on VSL estimates but rather uses cost of productivity losses due to premature deaths. The costs are calculated also based on a separate JRC model, which takes into account the specific

structure of the food sector. The effects on competitiveness and trade are assessed qualitatively, stating positive effects (better access to markets with regulations on trans fats) and negative impacts (impacts on imports, adverse effects from higher costs on competitiveness).

In comparison, the CBA results play a major role in the U.S. RIAs on food regulations. They serve to propose a rule and are adjusted to the final rule and prominently show up in the final rule. The methodologies applied for benefits quantification are based on the VSL, which is also indirectly used to monetize the QALY/QALD measure.

The EU RIA on a food safety standard is not showing up in the final regulations, even though the recommended legally binding limits are taken up. However, the RIA and the CBA calculations are one input in the policymaking process. Further, the methodologies to quantify benefits do not take up the VSL approach.

6.2.2. Safety and health regulations on chemicals

CBAs are a common tool to inform public policymaking concerning the production, utilization and disposal of chemicals. In such analyses, the economic values of changes in human health and environmental outcomes from various policy alternatives are compared to the associated costs. Key inputs in this process are assessments of human exposure to specific chemicals and the expected health incidents (Chiu 2017). However, obtaining such data may not always be straightforward when calculating economy-wide effects.

Prominent examples of chemical regulations and the accompanying CBAs within the context of policymaking processes are the REACH regulation in the European Union (EU) and the Toxic Substances Control Act (TSCA) in the United States. The EU's REACH regulation, an acronym for registration, evaluation, authorization and restriction of chemicals, establishes a regulatory framework for the entire EU to manage and control the risks posed to human health and the environment by chemicals.

The policymaking process for REACH began with a proposal from the European Commission in 2003, and the regulation became effective in 2007 (Gabbert et al. 2014; Getzner/Schulz-Zak 2018). The scope of the REACH regulation is comprehensive, encompassing most chemical substances and mixtures manufactured, imported or used within the EU market. This includes the uses by both industrial entities and private consumers and places particular emphasis on substances of very high concern (SVHCs), which are subject to evaluation, authorization or restriction processes.

The CBAs within the framework of REACH are pertinent in two key respects. First, they are instrumental in quantifying the net benefits stemming from regulations that impact all chemicals and their users. This entails evaluating the comprehensive ramifications of the REACH regulation on various stakeholders, including chemical corporations, their workforce and private consumers. Secondly, CBAs are applied for assessing the costs and benefits associated with specific drivers of the regulations, such as the authorization or restriction of hazardous chemicals (Ciatti et al. 2021).

On the benefit side, REACH CBAs typically include avoided health impacts from improved worker safety, avoided leisure or home accidents and productivity gains generated by registration, information, authorization and restriction processes. Furthermore, these analyses can factor in the productivity-enhancing effects of the REACH regulations, which stem from innovations, as well as environmental impacts (op. cit.).

Cost estimations involve accounting for compliance expenses incurred by companies, notably the testing and registration costs, along with the operational costs associated with managing the newly established European Chemicals Agency (ECHA) and other regulatory bodies in member states.

In the early stages, impact assessments, such as the one conducted by the European Commission (EC) in 2003, centered on the anticipated costs of REACH due to the limited information available regarding the properties of chemicals (EC 2003). This information was expected to be acquired progressively through the compilation of dossiers related to chemical risk in the course of REACH's implementation.

The initial EC CBA estimated costs of 2.3 billion euros for testing and registration, based on a business impact study. Employing a microeconomic model tailored to the chemical industry, the total costs for the sector and its upstream users were projected to reach up to 5.2 billion euros in scenarios involving the withdrawal of specific chemicals. Additionally, the EC CBA delved into discussions about the implications for innovation, competitiveness and the potential health benefits.

Other studies conducted comprehensive CBAs, for instance, Getzner/ Schulz-Zak (2018) for the case of Austria. In this study, the authors compile the health benefits from various sources and integrate data from diverse sources. They assess the health effects on workers by estimating the proportion of cancer cases officially recognized as occupational diseases related to chemicals, as documented in the literature.

Furthermore, the authors utilize a database detailing other occupational skin and respiratory diseases attributed to chemical exposure in Austria. The occurrences of allergies and multiple chemical sensitivities

as well as the cases of poisoning and burns in chemicals-related home accidents are also included. Out of these disease estimations, the corresponding types of medical treatments have to be derived and related to their costs.

In the case of mortality from cancer, the authors employ VSL estimations for Austria. Furthermore, the study approximates environmental benefits by considering reduced expenses arising from decreased soil and water contamination, as well as the treatment of chemical waste. Lastly, the authors also factor in the advantages accruing to businesses due to productivity enhancements stemming from new production technologies.

On the cost side, Getzner/Schulz-Zak (2018) assess the compliance costs associated with REACH by conducting surveys among companies within the chemical industry. The results include the expenditures on dossiers on chemicals, fees or consultancy services. However, these costs are not categorized by their sources, such as higher labor costs.

The overall cost estimate is further corroborated by data from the European Chemicals Agency (ECHA), and two distinct scenarios are developed for all pertinent sectors. Overall, the authors report a net benefit of approximately 2.9 billion euros for the Austrian economy up to the year 2044, with a cost-benefit ratio of 1 to 10.6. This result is primarily driven by the VSL estimates concerning cancer mortality and the associated health costs incurred due to cancer cases.

Another application of CBA in the context of REACH was undertaken by ECHA, specifically focusing on the costs and benefits of proposed chemical restrictions since 2000 (ECHA 2021). The basis are REACH restriction dossiers and the opinions provided by ECHA's Committees for Risk Assessment and for the Socio-Economic Analysis, which are part of the restriction processes.

Among the 33 restriction proposals included in ECHA (2021), all provided cost estimations, while only 12 quantified benefits. The primary sources of regulatory costs are substitution costs incurred by the industry when transitioning to alternative substances. Benefits, when quantified, are based on diverse methodologies, including VSL, costs associated with changes in IQ points, COI, WTP to avoid allergy and symptoms days and monetized values of QALY changes. In the 12 cases where both costs and benefits were monetized, the cumulative net benefits amount to 1.6 billion euros, a cost-benefit ratio of 1 to 4.6.

6.2.3. Safety and health at work

Regulations on occupational safety and health are rules and standards established by regulatory bodies to safeguard the well-being and safety of workers within their workplaces. These regulations have a twofold objective: preventing workplace accidents, injuries and illnesses, and fostering a safe and healthy working environment for employees.

In the United States, the Occupational Safety and Health Administration (OSHA) is responsible for developing and enforcing workplace safety and health regulations on a federal and state level. Furthermore, OSHA conducts RIAs on proposed rules (Federal Register 2024). In the EU, the European Agency for Safety and Health at Work (EU-OSHA) is a specialized EU agency promoting and improving occupational safety and health across Europe. The EU-OSHA also compiles data and produces reports concerning occupational safety and health in Europe (EU-OSHA 2023).

An illustrative example of a comprehensive RIA within this context is the evaluation of amendments to the EU directive regarding the protection of workers from risks associated with exposure to carcinogens or mutagens in the workplace (EC 2018a). This assessment delves into the economic, social and environmental effects of regulations of varying occupational exposure limit values (OELs) for five carcinogens. These carcinogens are of paramount significance in safeguarding workers and impact over one million workers within the EU.

For each substance, the assessment encompasses a baseline scenario based on current policies and measures, alongside three alternative options, each with distinct OELs. This undertaking necessitates a multifaceted evaluation integrating exposure-risk relationships, which show the excess risk of developing cancer due to occupational exposure, and dose-response relationships for non-cancer health endpoints.

When combined with workforce data and assumptions such as the duration of exposure, the resulting outcomes encompass the number of new cases for each health endpoint over the 60-year assessment period, along with the corresponding direct, indirect and intangible costs (refer to Table 4 and methodological details in EC, 2018c).

Table 4: Approach to the monetization of ill health effects

Category	Cost	Notes
Direct	Healthcare	Cost of medical treatment, including hospitalisation, surgery, consultations, radiation therapy, chemotherapy/immunotherapy, etc.
	Informal care[13]	Opportunity cost of unpaid care (i.e. the monetary value of the working and/or leisure time that relatives or friends provide to those with cancer)
	Cost for employers (e.g. liability insurance)	Cost to employers due to insurance payments and absence from work
Indirect	Mortality – productivity loss	The economic loss to society due to premature death
	Morbidity – lost working days	Loss of earnings and output due to absence from work due to illness or treatment
Intangible	Approach 1 WTP: Mortality	A monetary value of the impact on quality of life of affected workers
	Approach 1 WTP: Morbidity	
	Approach 2 DALY: Mortality	
	Approach 2 DALY: Morbidity	

Source: EC 2018c: 18

For each carcinogen, a matrix containing all impacts for the different options is provided, which states costs and benefits relative to the baseline scenario. These impacts include a range of economic, social and environmental variables, some of which are quantifiable, while others have no or limited reported impacts.

The economic impacts of exposure limits include compliance costs, benefits from reduced cancer cases and other diseases leading to cost savings for employers and the public sector (see table 4). Furthermore, the effects on the EU internal market, international competitiveness and small and medium enterprises are considered. The social impacts comprise avoided illness costs for workers and families, including intangible costs measured in terms of VSL and DALY. Overall, the presented RIA offers a comprehensive overview of the potential effects of different exposure limits for workers exposed to specific carcinogens.

The RIA is also supported by methodological background information detailing the assumptions and models used to quantify costs and benefits, as well as the values associated with VSL and monetarized DALY (EC 2018c). Moreover, the impact matrix serves as the foundation for a multi-criteria analysis aimed at identifying the preferred policy option.

For this purpose, the various impact variables are combined to rank the policy options based on their effectiveness (measured by the number of deaths and cases of ill health), efficiency (net benefits) and coherence

(alignment with other EU objectives), as compared to the baseline scenario. This RIA structure is in accordance with the RIA guidelines of the European Commission (EC 2021a).

6.2.4. Environmental regulations

Environmental regulations, such as the Clean Air Act, have significantly benefited from the application of cost-benefit analysis (CBA) in the policymaking process. The results provided by the CBA studies conducted by the Environmental Protection Agency (EPA) have served as compelling evidence that these regulations offer substantial societal advantages and net benefits, primarily driven by the reduction of illness effects caused by air or water pollution. CBA results of similar EU environmental regulations support these findings (Vrontisi et al. 2016).

The Clean Air Act Amendments (CAAA) of 1990 made it necessary for the EPA to create regular CBA reports outside the regulatory policymaking process. These studies aim to offer detailed cost and benefits estimations and improvements in human health, welfare and ecological resources. In addition, an evaluation of the broader impacts on the U.S. economy is conducted using a CGE model.

In the 2011 CBA on the CAAA (EPA 2011), the analytical process of CBA as discussed in chapter 3 is applied by the EPA. For the benefit estimations, first emissions are estimated and used in an air quality model. Next, the air quality results are related to health and other welfare outcomes, which are monetized if possible. The costs are derived in a modeling approach for different sectors and actors, as discussed in chapter 5.

The comparison of the cost and benefit estimations for the period from 1990 to 2020 show clear positive net benefits. The main benefits estimate exceeds costs by a factor of more than 30 to one. The monetized benefits are driven primarily by the avoided mortality due to better air quality and especially lower levels of particulate matter due to stricter emission rules. According to the CBA, the CAAA regulations prevent 230,000 premature deaths annually. This avoided mortality is monetized with VSL estimations, which sum up to more than 90 percent of the estimated benefits.[5]

Given that the CAAA form a comprehensive regulation that affects all sectors of the U.S. economy, including industry as well as individual households, the EPA uses a CGE model to supplement the CBA (ibid.: chapter 8). The EPA has developed its own CGE model (EMPAX-CGE)

5 The use and results of CBA by the EPA have also been subject to criticism, particularly during the Trump administration (McCarthy/Lattanzio 2017)

based on standard, neoclassical assumptions for the U.S. economy as a whole and five U.S. regions.

On the benefit side, changes in the medical expenditures associated with pollution-related illness, in workers' time endowment due to pollution-related mortality, and in workers' time endowment due to pollution-related morbidity are incorporated into the model. Thereby, the major channels of benefit effects are changes in the labor supply and changes in consumption patterns. On the costs side, the expenditures assessed in the CBA are included.

The CGE model results are reported for the expenditure effects, which would cause a decline in U.S. GDP by 0.5 percent. When taking into account positive labor supply and consumption effects due to avoided mortality and morbidity, GDP would only grow slightly by 0.02 percent. Thus, the macroeconomic benefit effects can compensate for the expenditure effects, but the large cost-benefit ratio as stated in the CBA which was driven by the VSL values is not accounted for in the CGE modeling exercise (ibid.: 8–23).

6.3. Insights on RIAs

Regulatory Impact Assessments (RIAs) have gained global significance as they serve as fundamental tools for evidence-based policy development. However, disparities exist in their utilization between the United States and the EU. In the United States, cost-benefit analyses are integral to rulemaking, where federal agencies define rule specifications and conditions. CBAs are adapted during this process to quantify the concrete net benefits associated with various rule designs as shown in the example of food safety regulations.

On the other hand, in the EU, RIAs are mandated for primary legislative proposals. EU RIAs encompass a broader range of requirements and methodologies, with a relatively diminished emphasis on monetized costs and benefits compared to the U.S. approach (see for instance the EC RIA the protection of workers from risks associated with exposure to carcinogens or mutagens in the workplace in 6.2.4). Nevertheless, RIAs became more important in the EU policymaking over the last two decades.

The various examples of Regulatory Impact Assessments (RIAs) presented in this chapter shed light on recurring trends in the outcomes and the inherent challenges faced by RIAs.

Firstly, it is evident that benefit calculations are significantly influenced by VSL estimates. While this approach is predominantly employed in U.S. RIAs, it is increasingly finding application in the EU as well.

Secondly, it is crucial to recognize that each RIA is a distinct evaluation, intricately linked to the nature and complexity of the regulation under scrutiny, data availability and the methodological preferences of the researchers overseeing the assessments. These factors heavily shape the RIA process and its outcomes. Thirdly, the multifaceted nature of regulations often renders certain aspects impossible to quantify in monetary terms.

To address this, some EU RIAs have tried to recognize the aspects that cannot be measured precisely by including qualitative evaluations using multi-criteria analysis (see also 6.2.3). This approach allows for a more comprehensive evaluation of the regulation's effects, transcending the limitations of purely monetary assessments. Finally, selected RIA studies also aim to include economy-wide effects and apply CGE models.

7. Discussion and outlook

The CBA approach has gained much attention as a way to evaluate the impacts of regulations. Even though the CBA approach is criticized due to its theoretical foundations, as well as due to its conceptual and empirical limitations, the rationale for and the procedures of CBAs question the basic assumptions of how regulatory changes are taken up in conventional CGE modeling of trade impact assessments.

From the CBA perspective, the conceptual approach on the role and effects of regulations adopted in trade impact assessments appears incomplete, since regulatory measures are perceived solely as restrictions on business activity and thus as barriers to trade. By integrating the CBA perspective into trade modeling, it becomes clear that changes in regulations through FTAs affect both benefits and costs.

Boardman et al. (2018) list major steps and basics of CBA that provide important entry points to how CBA approaches and applications in RIAs can be taken up in the context of FTAs and NTMs modeling. First, the purpose of a CBA needs to be explained. This relates to the question about the rationale for considering a change in a policy.

In standard CGE models, the rationale for changes in regulations is based on the perception of regulatory differences or NTMs as “sand in the wheels” or “frictions” to trade. Changes in NTMs could therefore foster trade, lead to a more efficient allocation of production and consumption, and thus increase welfare. Other policy impacts are not considered.

Beghin et al. (2012: 358), therefore, argue that in a trade-focused welfare analysis, it is “not clear a priori that the trade impacts of the concerned regulations are informative on allocative efficiency, or that removal of associated NTMs that affect trade would achieve efficiency gains relative to the welfare level under existing regulations.”

Related to the purpose of CBAs, Boardman et al. (2018) also raise the point that the *prima facie* rationales for regulations are market or government failures. Thus, regulations are the first-best options to correct market failures such as information asymmetries or negative externalities (WTO 2012). By overcoming these market failures, national policy measures can increase social welfare and are “a way of bringing the outcomes of a decentralized market economy more closely into line with social objectives that may not otherwise be achieved” (Maur/Shepherd 2011: 198).

Changes in national regulations based on the argument of trade-reducing effects of NTMs dismisse the role of regulations to overcome market failures, which are essential to the functioning of the market in the first place. This also questions the typical approach adopted in CGE models

assuming a certain actionability of regulations that reduces the restrictiveness of NTMs without considering other effects of changes in regulations.

The CBA analyst must decide who has standing, that is, whose benefits and costs should be included and counted. In a setting of international trade, changes in regulations will have an impact on domestic actors as in the usual CBA approach, but also on actors in FTA partner countries, and potentially even on actors worldwide.

Beghin et al. (2012) suggest “modules” for calculating the costs and benefits of regulatory changes affecting (a) domestic consumers, (b) domestic producers, (c) domestic government and (d) foreign producers. A scenario with changing regulations, affecting two or more economies in an FTA might add more actors and groups with a standing and requires the assessment of more comprehensive impacts resulting from regulatory changes.

The positive net benefits and the high cost-benefit ratios of regulations shown in many CBA and RIAs (see chapter 6) indicate that the inclusion of benefits might be highly relevant to understanding the potential effects of regulatory adjustments through DCFTAs. However, the survey of CBA approaches in chapter 4 reveals that cutting-edge methodologies of benefit estimations focus on monetarization of risk reduction.

The most prominent approach draws on the concept of VSL, which is firmly grounded in microeconomic theory and in particular in welfare economics. The core of the underlying theoretical argument captures the risk-reducing effects of changes to health and safety regulations. These benefit metrics drive the monetized benefits in CBA studies. The outcome of these WTP approaches builds, however, on a trade-off between wealth and risk and does *not* imply an impact on macroeconomic variables.

Other approaches, however, point a way forward for a possible integration of CBA concepts in CGE models.

First, compliance cost estimations of CBAs can be integrated into CGE models, as discussed in chapter 5 and applied to the case of the EU-Tunisia DCFTA in Tröster et al. (2023).

Second, mortality and morbidity affect several macroeconomic variables for instance in changes to expenditures on medical services, the changes in labor supply and labor productivity. As shown in the example of the CBA on the Clean Air Act Amendments (EPA 2011), the CBA results can also be integrated into a national CGE model.

As shown in chapter 6, CBAs and RIAs have specific and burdensome data requirements. For instance, the calculation of benefit measures of health and safety regulations based on medical costs and COI impacts requires data on the cases of illness and deaths related to hazards and wage data. Data availability has improved, as most countries apply CBAs

in RIAs. However, despite improving coverage on, for example, the burden of foodborne diseases (WHO 2020), most data are available only on a case or country level. This renders their application in CGE model studies challenging. Similarly, compliance cost estimations are often case-specific and based on survey data or model estimations.

Looking ahead, our task in the next project work package is to identify and implement ways in which changes in health outcomes due to regulatory adjustment impact macroeconomic variables, which then can be integrated into the ÖFSE Global Trade Model. For this purpose, the analytical process of CBAs and CBA methodologies that assess health-related effects on macroeconomic variables such as productivity, labor supply, income or consumption is a valuable entry point.

The applied CBAs and RIAs are important references to identify methodologies and data, even though many aspects have to be simplified to be applicable in a CGE model set-up. Most importantly, selected CGE applications based on CBAs are available and require further research on similar modeling approaches in the context of health effects.

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