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Faculteit Bedrijfseconomische Wetenschappen

master in de toegepaste economische wetenschappen

Masterthesis

How is the Health Impact Assessment integrated in the EU ?

Remco Ackx

Scriptie ingediend tot het behalen van de graad van master in de toegepaste economische wetenschappen, afstudeerrichting beleidsmanagement

PROMOTOR :

Prof. dr. dr. Samantha BIELEN

BEGELEIDER :

Mevrouw Diana-Maria DANCIU

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This master thesis was written during the COVID-19 crisis in 2020-2021. This global health crisis might have had an impact on the (writing) process, the research activities and the research results that are at the basis of this thesis.

Preface

This thesis is my final work of the master degree 'Toegepaste Economische Wetenschappen – Beleidsmanagement' at Hasselt University. It focuses on how EU policy-makers integrate Health Impact Assessment in EU impacts assessments that are used in the EU's policy- and lawmaking cycle. I have been interested in the European Union since high school. The historical background and the workings of the EU are fascinating to me. My interests also lie in health policy, so combing these two subjects was very interesting.

The writing of this thesis was an enjoyable experience and I am grateful that I got to learn more about how the European Union is organized and works. Additionally, learning about how impacts on human health as a consequence of policies at a governmental level are assessed was very interesting.

I would like to thank prof. dr. dr. Samantha Bielen and Ms. Diana Danciu for their advice and feedback. This thesis would not have been completed the way it is without their help. Furthermore, their courses during my study were very enjoyable. I find it unfortunate that only a few lectures could be organized on campus this academic year as a consequence of the COVID-19 crisis. I have missed talking with my fellow students and following lectures in an auditorium.

I would also like to thank my parents for giving me the opportunity to pursue this education. Their support has been very valuable to me.

Samenvatting

Gezondheid is een fundamentele waarde in een mensenleven en in een maatschappij. De Europese Unie geeft daarom aan in artikel 168 van het Verdrag betreffende de Werking van de Europese Unie dat het een hoog niveau van bescherming van menselijke gezondheid zal waarborgen in alle beleidsmaatregelen die het neemt. Om wetgeving en initiatieven van hoge kwaliteit te verzekeren, voert de Europese Commissie Impact Assessments (IAs) uit om op bewijs gebaseerd en transparant te handelen. EU IAs worden voorbereid voor voorstellen van grote beleidsmaatregelen met mogelijke significante economische, sociale en milieu impacts. Vroeger deden EU beleidsmakers dat aan de hand van aparte rapporten, maar sinds 2003 is de EU overgestapt naar een geïntegreerd systeem van IAs.

Sinds de start van het geïntegreerd systeem van IAs ziet de EU dat er veel aandacht wordt besteed aan economische impacts in IAs, maar minder aan andere soorten impacts. In deze masterthesis evalueer ik de kwaliteit van IAs die gepubliceerd werden tussen 2018-2020 inzake het integreren van Health Impact Assessment aan de hand van een 'scorecard' methode. Met de scorecard methode bekijk ik of de IAs voldoen aan tien objectieve sleutelcriteria die ik gebaseerd heb op de richtlijnen die gebruikt worden door EU beleidsmakers om een IA te maken.

Niet alle IAs die gepubliceerd zijn de voorbije drie jaren hebben echter een onderwerp of een beleidsoptie die mogelijks een impact zouden kunnen hebben op de volksgezondheid. Daarom neem ik in deze studie enkel de IAs op die een onderwerp/beleidsoptie bevat die mogelijks een impact heeft op gezondheid. Verder maak ik nog een groepering van de IAs die mogelijks een significante impact hebben op gezondheid.

Resultaten

De Europese Unie zegt in een resolutie over de interpretatie en implementatie van het interinstitutioneel akkoord over beter wetgeven uit 2018 dat EU beleidsmakers meer moet streven naar gebalanceerde IAs. Hierbij werd op het einde van de Juncker Commissie in 2019 door de Europese Commissie ingezien dat men meer aandacht moet gaan hechten aan andere soorten impacts in IAs waaronder gezondheidsimpacts. Analyses over de kwaliteit van IAs focussen zich tot nu toe maar gering op Health Impact Assessment in IAs. Deze paper biedt een dieper onderzoek hiernaar.

Uit mijn onderzoek kan ik meerdere conclusies trekken. Ongeveer de helft van het totaal aantal gepubliceerde IAs heeft elk van de drie jaren (2018, 2019 en 2020) een onderwerp/beleidsoptie die op een bepaalde manier een mogelijke impact zou kunnen hebben op gezondheid. Echter wanneer ik een verdere groepering maak tot de IAs met een onderwerp/beleidsoptie met mogelijke significante gezondheidsimpacts, daalt het aantal IAs aanzienlijk. Dat kan gedeeltelijk verklaard worden door het feit dat de Europese lidstaten de primaire verantwoordelijkheid hebben voor volksgezondheid. Lidstaten zouden al voorzorgsmaatregelen genomen kunnen hebben om de gezond van hun populatie te beschermen. De EU zal namelijk enkel beleidsmaatregelen nemen wanneer het voordeliger zou zijn om op het Europese beleidsniveau te handelen in plaats van elke lidstaat apart. Daarnaast zou een verdere verklaring kunnen zijn dat de EU beleidsmakers volksgezondheid niet genoeg als een belangrijk beleidsobjectief en onderwerp vinden.

Vervolgens vind ik in mijn onderzoek dat de meeste IAs die gepubliceerd werden in de afgelopen drie jaar met een onderwerp/beleidsoptie met mogelijke significante gezondheidsimpacts op een adequate manier voldoen aan de tien sleutelcriteria in de scorecard. Deze tien sleutelcriteria toetsen naar volgende onderdelen in een IA: een duidelijke identificatie van de gezondheidsimpacts, het gebruik en verwijzing naar interne/externe expertise en de kennis van stakeholders, de kwantificatie en monetarisering van de gezondheidsimpacts, een duidelijke verklaring en presentatie van de gemaakte assumpties en de gebuikte methode, de vergelijking van de resultaten met een baseline scenario en tot slot een duidelijke presentatie van de resultaten van de Health Impact Assessment in de IA en in de samenvatting van de IA.

Dit resultaat betekent dat EU beleidsmakers de principes van beter wetgeven inzake Health Impact Assessment volgen. Er blijft echter wel ruimte voor verbetering. Meerdere IAs hebben lage scores op de scorecard-onderdelen die toetsen naar de kwantificatie en monetarisering van de health impacts in de IAs. Ik ondervind dat het soort beleidsgebied waarop een IA focust een mogelijke factor kan zijn die dat resultaat beïnvloedt. Bij meerdere IAs leggen de EU beleidsmakers uit dat bij bepaalde beleidsproblemen (waaronder impacts op gezondheid) het zeer moeilijk of zelfs onmogelijk is om een zinvol direct causaal verband te leggen tussen een beleidsmaatregel en de voordelen die het, vaak pas op lange termijn, kan brengen voor de maatschappij. Voorbeelden hiervan zijn de IAs voor de beleidsmaatregelen die zich focussen op het bestrijden van de klimaatverandering. Deze verklaring komt overeen met de richtlijnen die EU beleidsmakers gebruiken om een IA te maken die aangeven dat EU beleidsmakers enkel significante impacts moeten analyseren waarvoor een degelijke methodologie gebruikt kan worden en waarvoor data met een proportionele kost verkregen kan worden.

Beperkingen

Er zijn echter beperkingen aan de methode die ik gebruikt heb om de kwaliteit te evalueren van IAs inzake het integreren van Health Impact Assessment. Zo is een score in de scorecard voor een IA niet altijd een zinvolle maatstaf voor de kwaliteit ervan. Een IA kan een hoge score krijgen, maar kan toch van een lage kwaliteit zijn als de berekeningen en waarderingen in de IA inaccuraat zijn. Daarnaast kan een IA een lage score krijgen, maar toch van een adequate kwaliteit zijn als de scorecard-onderdelen onkenbaar zijn in dat bepaalde geval. In sommige IAs leggen de EU beleidsmakers bijvoorbeeld uit dat het onmogelijk was om gezondheidsimpacts te kwantificeren en monetariseren. Ondanks deze beperking, vind ik de scorecard methode een zinvolle aanpak om de kwaliteit te evalueren van IAs inzake het integreren van Health Impact Assessment.

Verder onderzoek zou de gegevens van deze studie kunnen gebruiken om een mogelijk time trend in de kwaliteit van IAs inzake het integreren van Health Impact Assessment te meten.

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Introduction

Health is a fundamental value in a person's life and in society. The European Union considers human health as an investment in economic growth and social cohesion. Healthy people are more productive, more likely to be employed and less likely to be socially excluded (European Commission, 2017c). In addition, while the EU sees access to health care as a fundamental right, it also recognizes health as a horizontal concern across a wide range of policies (European Commission, 2017c). Therefore, Article 168 of the Treaty on the Functioning of the European Union states that a: "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities" and thus provides the legal basis for the EU's actions in the field of health (European Commission, 2020d; European Union, 2012).

A key first step in the EU's policy-making process are ex-ante impact assessments (IAs). IAs are part of the Better Regulation Agenda of the EU that aims at ensuring evidence-based and transparent law-making. At the EU level, legislation and initiatives are initiated by proposals published by the European Commission. In order to develop proposals of a high quality and provide better informed decision-making, the Commission carries out IAs for proposals with possible major economic, social and environmental consequences (European Commission). Moreover, the annual Commission Work Programme guides this work (European Commission).

In 2016, the latest Interinstitutional Agreement on Better Law-Making between the European Parliament, the Council and the Commission was signed. This Interinstitutional Agreement on Better Law-Making particularly believes that IAs should not only look at economic impacts, but should pay equal attention to the evaluation of social, health and environmental issues (European Union, 2016).

However, a long standing criticism of EU IAs is the lack of considering impacts that are difficult to monetize (e.g. health impacts). IAs have been successful in assessing economic impacts, but have been weak at integrating/measuring social and environmental impacts, resulting in an unbalanced assessment (Lee & Kirkpatrick, 2006; Salay & Lincoln, 2008; Smith, Fooks, Collin, Weishaar, & Gilmore, 2010; Ståhl, 2010). More specifically, impacts on health have not seemed an important objective and are considered inconsistently in IA reports (Ståhl, 2010). Furthermore, the Juncker Commission concluded that economic impacts still prevailed too much over other impacts in a stocktaking exercise of its Better Regulation activities during its legislative term. An accompanying study by the European Parliamentary Research Service concurred with the stocktaking exercise and stated that impacts could be better taken into account (European Parliamentary Research Service, 2019). The potential barriers to using Health Impact Assessment are lack of expertise and skills, lack of awareness and understanding, lack of resources, no recognized tools or methods, lack of political support, lack of time, other priorities get in the way, not convinced of the benefits and gaps in evidence (Tarkowski & Ricciardi, 2012; WHO, 2010). Considering this issue, the European Parliament reiterated in 2018 its call for a compulsory inclusion in all IAs of a balanced analysis of the medium- to long-term economic, social, environmental and health impacts in a resolution on the interpretation and implementation of the Interinstitutional Agreement on Better Law-Making (European Parliament, 2018). The start of a new legislative term with the Von der Leyen Commission on the 1st of December 2019 provides a political momentum for better cooperation between European institutions and to follow up on the 2018 resolution of the European Parliament (European Parliamentary Research

Service, 2019).

What is the quality of EU impact assessments published between 2018-2020 in terms of integrating Health Impact Assessment? But first in the literature study, what are the current requirements for an EU impact assessment of high quality? And second, what methods exist and/or are currently used to assess health impacts in EU impact assessments? It is not relevant to research the quality of all IAs in terms of integrating Health Impact Assessment. So how many IAs published between 2018-2020 had a topic/an option with possible health-related impacts? And finally, how do the relevant EU IAs published between 2018-2020 score on 10 key objective criteria on integrating Health Impact Assessment based on the Better Regulation Guidelines?

To address these questions, I take a look at the IAs published between 2018-2020 on the European Commission's website. While the primary responsibility of health lies with the Member States, legislation and initiatives at the EU level that are not particularly aimed at health (care) could potentially have major consequences on the health of citizens in the European Union. Therefore, EU health policy complements national policies and the EU ensures health protection in all policies. In addition, the COVID-19 crisis will possibly have a positive impact on the inclusion and assessment of health impacts in future EU IAs. The worldwide health crisis has increased the attention on health and will possibly raise the political support for distributing more resources and time to Health Impact Assessment.

My paper contributes to the literature on the quality of EU IAs. Since the introduction of IAs in the EU, multiple evaluations have been made about the implementation and the overall quality of these IAs (see, e.g., Alemanno (2009), Bäcklund (2009), Lee and Kirkpatrick (2006), Purnhagen and Feindt (2015), Wilkinson et al. (2004)). This paper provides an analysis of the most recent IA reports and contributes to the scarce literature focused on health in EU IAs (see, e.g., JS Mindell, Boltong, and Forde (2008), Smith et al. (2010), Tarkowski and Ricciardi (2012)). Previous papers on health in EU IAs tend to be surface level evaluations. For example, Ståhl (2010) uses a word search on 'health' as the basis for analysis. Or another strand of literature that looks at EU IAs has health only as a small focus of the research (see, e.g., European Commission (2019), European Parliamentary Research Service (2019)). This paper delivers a more in-depth analysis of health impacts in EU IAs.

In this study, I introduce two categories to distinguish between IAs. The first category includes the IAs with a topic/an option that impacts health in any way. Furthermore, the second category only consists of the IAs with a topic/an option that has possible significant health impacts as a consequence. This way, it becomes possible to evaluate the quality of the relevant IAs in terms of integrating Health Impact Assessment. I use a 'scorecard' method with 10 key objective criteria on integrating Health Impact Assessment that are based on the Better Regulation Guidelines to do this.

The paper will have the following structure. The subsequent section is an overview of the 2017 Better Regulation Guidelines that form the criteria for making an EU IA. Additionally, I look at the evolution that EU IAs have made since the introduction of the integrated system in 2003. The second chapter focusses on the methods that exist and are used in the EU to asses health in IAs. I inquire into previous versions of Health Impact Assessment guidelines and investigate the difficulties and criticism that exist with integrating the assessment of human health. Following sections introduce the IAs included in this study, develop my approach to assess the quality of EU IAs in terms of integrating Health Impact Assessment and show my results. The final section concludes.

Chapter 1 The requirements for an EU IA of high quality

Background

In the past two decades, the international focus on developing and improving the use of evidence-based policy-making across a wide range of public policy initiatives has grown substantially (Lee & Kirkpatrick, 2006). Following the success in the US and other jurisdictions, the European Union was inspired to look at ways to improve the coherence and quality of its legislation (European Parliament, 2015). External demands from Members states, the business lobby and the European Parliament resulted in the origin of the European Commission's Better regulation agenda in 1999 (Senninger & Blom-Hansen, 2020). In 2000, EU ministers of public administration gave a high-level advisory group the task to address this issue. The following year, the Goteborg European Council committed the European Commission to promoting sustainable development and the creation of mechanisms for assessment of all EU policy proposals (Lee & Kirkpatrick, 2006). The recommendations of the so-called Mandelkern group paved the way for establishing procedures to ensure that each major legislative proposal is accompanied by an assessment of the major possible consequences of the measure (Bäcklund, 2009). The Commission established a consultation regime that actively involves interest groups but avoids bias (Senninger & Blom-Hansen, 2020). In 2002, the EU issued a communication on IAs. As a result, the first version of impact assessment guidelines were made to aid Commission officials in organizing, designing, carrying out and/or reviewing an impact assessment (Lee & Kirkpatrick, 2006). In 2003, the first Interinstitutional Agreement on Better Law-Making between the European Commission, the European Parliament and the Council was concluded. With this Interinstitutional Agreement, the three EU institutions recognized the positive influence IAs can have on the quality of legislation and the European Commission began phasing in the new integrated system (European Parliament, 2015). Consequently, the EU addressed the previously experienced shortcomings of single-sector assessments. The new system replaced several separate forms of IAs[1] into a more streamlined assessment process. IAs thereafter assess not only one impact of a measure, but should be an in-depth analysis of the potential major economic, environmental and social impacts (Lee & Kirkpatrick, 2006). The European Commission also committed itself to make the conclusions of the IAs fully and freely available and to explain in every proposal how the IA has influenced it (European Parliament, 2015). Commission officials responsible for making IA reports were initially sceptic about the new system. They found the integrated IAs burdensome and questioned the factual openness of their mandate. This is because when a policy has reached the IA stage, a lot of work and interest has already been invested (Bäcklund, 2009). In the subsequent years, the importance and use of IAs rose considerably. New revised IA guidelines for integrated IAs followed in 2005 and 2009 (Ståhl, 2010). IAs became not only a system to provide a knowledge base for decision-making, but also a tool for communication, improved legitimacy of government and increased unity in European politics (Bäcklund, 2009). In addition, the 2009 IA guidelines changed that IAs are not only required for important legislative proposals, but also for all major delegated acts and implementing acts (Senninger & Blom-Hansen, 2020).

[1] e.g. business impact assessment, environmental assessment, gender assessment, small and medium enterprises assessment, trade impact assessment and regulatory assessment (Lee & Kirkpatrick, 2006).

Recent developments

On the 13th of April 2016, the now implemented Interinstitutional Agreement on Better Law-making was signed by the European Parliament, the Council and the Commission. As a result, the European Commission brought together all previously separate guidance documents[2] into integrated Guidelines. This provided that the different phases of the EU policy-making cycle are more closely interrelated, in order to better recognize the connections and to ensure greater coherence (European Union, 2016). These Guidelines offer advice for EU policy-makers and set out the principles that the Commission has to follow when preparing, evaluating and managing initiatives and legislation. The Guidelines are accompanied with a Toolbox, offering additional detailed guidance, support and practical tools that can be used selectively by Commission officials.

Under the 2016 Interinstitutional Agreement, IAs are part of the EU's Better Regulation agenda that has the goal of ensuring that EU policies and laws achieve their objectives at minimum cost and that political decisions are prepared in an open, transparent and evidence-based manner, backed with the comprehensive involvement of stakeholders. Additionally, IAs help ensure that the EU's interventions comply with the principles of subsidiarity and proportionality, which means acting only at EU level where necessary and in a manner that does not go beyond what is necessary to resolve the problem. In addition, unnecessary regulatory costs should be avoided at all times (European Commission, 2017b).

A new communication on Better Regulation will follow in 2021. The European Commission recognizes the importance of evidence-based decision-making more than ever. The focus of this communication will be on further reducing administrative burdens, simplifying legislation and making consultations more efficient and accessible to stakeholders (European Commission, 2020b).

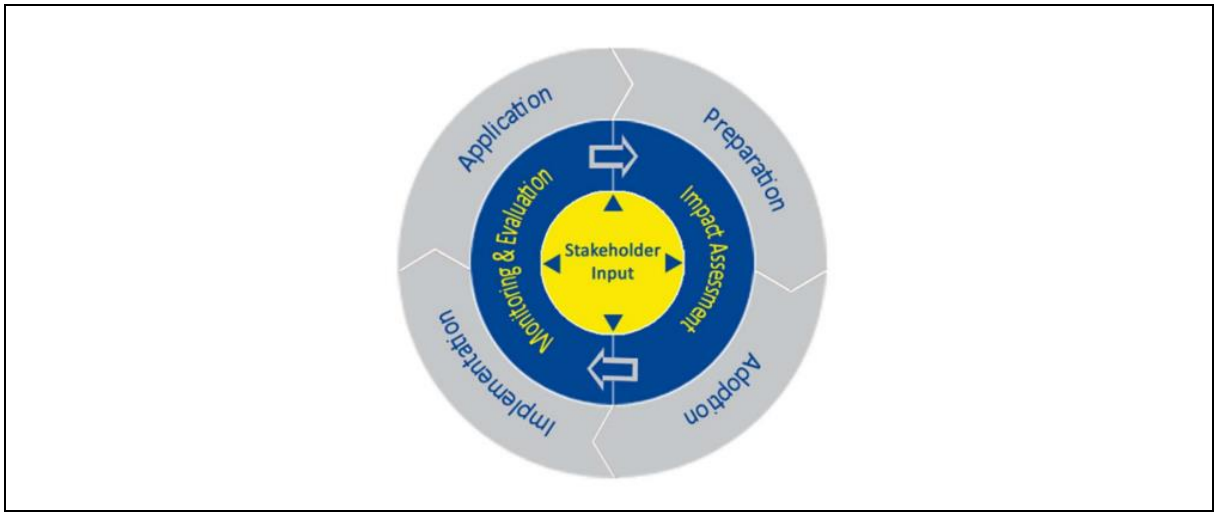
The EU policy and law-making cycle

IAs happen at the beginning of the EU policy and law-making cycle. The European Commission plans, prepares and proposes new EU laws and policies on the basis of the annual Commission Work Programme which contains the political priorities set out by the President (European Commission). IAs are required for Commission initiatives that are likely to entail significant economic, environmental and social consequences (European Commission, 2017b). The Commission, however, does not prepare an IA if there is little choice over the content of the initiative or if the impacts are not significant, hence only when an IA is useful for making a decision. An IA is sometimes also not made when there is a political imperative to move ahead quickly, there are deadlines which cannot be met on the basis of normal planning or an emergency occurs that requires a rapid response (European Commission, 2019). Figure 1 explains perfectly how the different phases of the EU policy-making cycle are related and what the key elements are to provide initiatives and legislation of high quality. Again, this paper focuses on the preparation phase and more specifically IAs. Good regulation is always preceded by good planning. However, planning takes time, needs resources and should seek the appropriate level of political validation. Here, stakeholders' input is an essential element. Consultations with relevant stakeholders will build openness and provide feedback and evidence to support the development of a policy. Besides IAs, the EU Commission also carries out evaluations or

[2] which addressed separately preparation, IAs, evaluation, implementation and stakeholder consultation (European Commission, 2017b).

fitness checks. These evaluations are used to assess how an intervention has performed (or is performing) and check whether there were unintended effects which were not anticipated in the IAs. They are also used to gather evidence on whether an EU intervention is still justified or should be modified. Moreover, an EU intervention will only deliver its full benefits if the policy is implemented and applied correctly. During the policy development, policy-makers should take into account implementation and enforcement issues. This means anticipating the behavior of the Member States and aid them with implementation plans (European Commission, 2017b).

Figure 1 The EU policy and law-making cycle



(European Commission)

The IA Guidelines

Chapter III of the Better Regulation Guidelines sets out the requirements and directives for IAs. Nevertheless, Commission officials should keep in mind that these Guidelines and accompanying Toolbox are not meant to be procedural requirements per se, but should be used in a proportionate way using common sense. The Guidelines state that it is important that an IA starts as early as possible in the policy-making cycle. The IA work is led by the Directorate-General(s) in charge of the responsible legislative initiative. The DGs are early on required to seek confirmation about whether an IA is truly necessary through the political validation process. If validation is given, an inception IA will be prepared by the lead DG, in agreement with the Secretariat-General (European Commission, 2017b). As a consequence, an inter-service group with representatives from all relevant DGs has to be set up with the goal of enforcing the integration between sectors (Bäcklund, 2009). Inception IAs are meant to provide an introduction to the problem, the possible policy solutions and an overview of the planned phases needed to develop the initiative, before a full integrated IA report is made. As a result, consultation of stakeholders will be possible and feedback can be given on the Commission's website (European Commission, 2017b).

According to the Guidelines, an IA should be able to answer seven questions in order to be comprehensive, proportionate, transparent, evidence-based, unbiased, prepared collectively with the relevant Commission services, open to stakeholders' views, embedded in the policy cycle and be of high quality. Answering these questions is an iterative process that makes it feasible to narrow the problem, the objectives and the possible solutions down to what is most relevant (European Commission, 2017b). The seven questions are:

1. What is the problem and why is it a problem? A proper definition of the problem and the underlying problem drivers is a crucial first step in an IA. If this is done properly, the proposed initiative will regulate only where necessary and in a proportionate way. It will be clear which, how much and how long individuals, companies or other actors are affected. The analysis will also be specific, be focused and take into account the stakeholders' concerns and other expertise. The first part of the IA should contain three elements: (1) the verification of the existence of the problem and the identification of who is affected, (2) the estimation of the problem's size and an analysis of the underlying causes and (3) the assessment of the EU-dimension and the likelihood that the problem will persist (European Commission, 2017b).

It became clear, even since the first IAs were published, that if this part of the IA is of high quality, that the following parts of the IA tend to be of good quality as well (Lee & Kirkpatrick, 2006). The IA system was new and the experience of using advanced tools was limited. Commission officials still had discussions about the requirements and how the aspect of competitiveness had to be integrated (Bäcklund, 2009). In the more recent IAs published during the Juncker administration, the problem definition scored, on average, as one of the best areas in an IA (European Parliamentary Research Service, 2019).

2. Why should the EU act? The following step helps make clear whether a policy response is called for at the EU level. It therefore makes sure that the initiative complies with the principle of subsidiarity if the EU falls outside its exclusive competence. The EU has to justify the necessity and point out the added value of acting at EU level compared to the action of Member States at central, regional or local levels. In addition, Commission officials always need to check whether the EU has a legal basis. However, having the competence to act is not enough. Checking whether Member States could handle the problem sufficiently on their own, determines the need of the proposal. Union acts can be annulled by the European Court of Justice if it does not respect the principle of subsidiarity (European Commission, 2017b). The Court therefore plays a crucial role in deciding if EU intervention is needed. Concerns about the competence of the Court in policing jurisdictional boundaries have been made, but are unjustified. National courts additionally serve as an external check on the Court, because they are able to disapply EU law if it was enacted outside the EU's legal power. The European Court, however, has been questioned about not having a doctrinal framework that effectively operationalized the EU's commitment to subsidiarity and proportionality in the context of the common market (Kumm, 2006).

This part of IAs in the more recent years were of a satisfactory quality, but there is certainly room for improvement in terms of the explanation and substantiation of the respect of the principles of subsidiarity and proportionality. The Commission recognized this and announced to integrate a new model grid into every IA as a possible measure that could lead to improvements (European Parliamentary Research Service, 2019).

3. What should be achieved? Clearly defining the general and more specific objectives of the proposal is the next step in an IA. The Guidelines state that objectives should be as S.M.A.R.T. as possible (i.e. specific, measurable, achievable, relevant and time-bound). This will ensure that the EU policy intervention is transparent and accountable. Commission officials should identify the level of policy ambition and which criteria that will be used to compare alternative policy options against each other. This stage is also important for setting up the indicators that can be used to evaluate the

development and progress of the proposal at a later stage (i.e. monitoring the success of the initiative assessed) (European Commission, 2017b).

At the beginning of the integrated IA system, some difficulties were experienced in attaining consistency between higher and lower objectives and properly articulating them. The Commission had also not yet developed the identification of quantitative and qualitative indicators that could be use in an IA (Lee & Kirkpatrick, 2006). In the IAs during the Juncker administration, this part was in general just above a satisfactory level. There is a need for more consistency and precision of objectives, as the distinction between the general and specific objectives is not always clear. The objectives in recent IA reports did not always comply with the SMART criteria and were not always option specific as stated in the Guidelines (European Parliamentary Research Service, 2019).

4. What are the various options to achieve the objectives? In this stage, the policy-makers should pick the most relevant options that are necessary/able to achieve the objectives. The Guidelines suggest following an iterative process. Consulting widely about alternatives and thinking outside the box is a good way to start. It is crucial that the Commission officials take into account the stakeholders' views and the political preferences, because this component of the IA tends to be criticized the most if not done properly. A baseline scenario (i.e. the option where nothing changes) should always be made against which the alternative options can be compared. This means anticipating technological or societal developments and taking account of the national and EU policies in place, not considering the implementation of a new policy intervention. EU policy-makers could then even decide that improving or simplifying existing legislation is a better alternative than implementing new initiatives. This follows the reasoning of avoiding unnecessary regulatory costs at all times. In the IA report, the Commission officials should present a clear logic between the problems, its underlying drivers, the objectives and the initiative under consideration. Additionally, the IA report should always justify why some options and their impacts were not looked at intensively and were possibly discarded (European Commission, 2017b).

EU policy-makers tend to make the most mistakes during this part of the IA. In the early integrated IAs, this part of the report was considered the weakest. The range of possible policy options identified was considered to be too narrow, consequently having a significant negative effect on the quality of the following parts of the IA (Lee & Kirkpatrick, 2006). This was still a problem in the IAs published during the Barroso and the subsequent Juncker administration. The range of policy options has improved, but the identification of the alternative options to the preferred option and the presentation of the options are insufficient. As a result, the IA may point to a predetermined choice of action (European Parliament, 2015; European Parliamentary Research Service, 2019). A possible explanation is that Member States' governments remain the agenda-setters on the European level and tend to enact legislation on EU level that would be difficult to enact on national level. This way, governments can avoid being held accountable for European legislative decisions and try blame-shifting when it suits them (Kumm, 2006).

5. What are their economic, social and environmental impacts and who will be effected? This is the part of the IA that I am most interested in in this paper. When all possible policy options have been determined, the policy-makers should assess the significant economic, social and environmental impacts of each option and determine who will be affected (positively and negatively). The Commission officials need to check to what extent a certain option meets the objectives and ask

themselves if these actions can realistically be taken in practice. The EU policy-makers should compare the costs with the benefits of the option and see if there are any implications for certain stakeholders or risks of unintended consequences. Here, the importance of making a baseline scenario becomes clear. All policy options are compared against the baseline alternative to discover the advantages and disadvantages of a certain option. Different options will have different impacts. The Guidelines state that all potentially significant impacts should be identified and assessed qualitatively and quantitatively whenever possible. This means that even though quantification of impacts is not always possible, at least efforts should be made in a systematic manner. Impacts should also be monetized whenever this can be done. Failing to do this could easily undermine the quality and comparison of the options and weaken the Commission's proposal. Therefore, Commission officials should set up a consultation strategy and use internal and external expertise along with stakeholders' knowledge as much as possible. The Guidelines also make a distinction between impacts with a broad nature (i.e. economic, social, environmental) and a specific nature (e.g. health) and specify that the expected magnitude and likelihood and the actors that would be affected should be pinned down for all potential impacts. The Guidelines advise to map out all the results at the end of this analysis (European Commission, 2017b; European Union, 2016).

A vast quantity of literature has commented that the assessment of impacts in an EU IA tends to be unbalanced (e.g. (Bäcklund, 2009; European Commission, 2019; European Parliamentary Research Service, 2019; Lee & Kirkpatrick, 2006; Ståhl, 2010)). Economic impacts are far more often considered and covered more thoroughly than other kinds of impacts (i.e. environmental and social). This was a problem with the first generation of integrated IAs (Lee & Kirkpatrick, 2006). Moreover, it has remained a problem in the more recent IAs published between 2015 and 2018 (European Parliamentary Research Service, 2019). The Commission recognizes the call of individuals, civil society and academia to look more at society as a whole and to not overemphasize the need to quantify everything. Respondents of a public consultation also urged the Commission to pay more attention to the impacts on individuals and pointed out the impact that legislation can have on overlooked areas such as health (European Commission, 2019). In the second chapter of this paper, an overview is given about the reasons of this problem and more specifically how this affects the consideration of health impacts in IAs.

6. How do the different options compare (effectiveness, efficiency and coherence)? EU policy-makers will be able to decide and suggest a preferred option at the end of this stage. This part of the IA should present the relevant information to help them do so based on the impacts on all possible stakeholders that were identified and assessed in the previous stage of the IA. Commission officials should provide a clear comparison of the options, using common criteria, in terms of their effectiveness, efficiency and coherence with the objectives. Moreover, this part of the IA should include whether an option complies with the principle of proportionality. Commonly used methods for comparing options are cost-benefit analysis, cost-effectiveness analysis, compliance cost analysis and multicriteria analysis or a combination of methods. Choosing one or another method (or multiple) depends on the number and nature of the impacts and the objectives. Commission officials should take into account that certain benefits and costs are more difficult to monetize or quantify (e.g. health). Additionally, Commission officials need to ensure that the robustness of the comparison is verified and that the sensitivities and limitations are highlighted. If trade-offs between objectives

had to be made or there are any uncertainties, the IA needs to state them in a clear manner. The Guidelines also advise to make a summary table of the results in order to present the comparison in an accessible way and link this with the previous part of the IA. An IA report is not obligated to choose a preferred option, but should always justify if no preferred option is given (European Commission, 2017b).

This part of IAs published at the beginning of the integrated system was relatively one of the weakest. Most IAs in 2003 had serious deficiencies in the justification of choice of the preferred option (Lee & Kirkpatrick, 2006). In the more recent IAs, some cases were found to lack transparency because of inconsistent data or inaccessible sources (European Parliamentary Research Service, 2019).

7. How will monitoring and subsequent retrospective evaluation be organized? It is crucial for an IA to set up core indicators to keep track of the policy implementation. This way, we can check to what extent an initiative has reached its objectives and what costs and benefits have emerged. The Guidelines say to start at conceiving the situation where the initiative is successful. Then, EU policy-makers can envision what will be different and for whom as a consequence of the implementation of the policy. However, it is likely that the actual results will differ from what was estimated. This could be regardless of the quality of the IA and the proposed initiative. Additionally, it could be problematic when the policy is not achieving its objectives or certain costs are bigger than expected. The EU policy-makers should therefore ask themselves if there are any unexpected exogenous factors influencing the results or if there are any problems with the design of the policy. It is also possible that amendments were introduced during the legislative process or the implementation of the policy was poor. With this stage, Commission officials link the ex-ante assessment of a policy with the ex-post evaluation after the implementation. This helps inform EU policy-makers in the future if or when possible revisions of the policy need to be made (European Commission, 2017b).

The provisions for monitoring in an IA scored, on average, as one of the best areas in the IAs published during the Juncker administration (European Commission, 2019).

Although there is still room for improvement, EU IAs have improved greatly since their introduction. Institutions like the European Court of Auditors have stated that IA reports done by the Commission have improved significantly in quality over time, have brought positive results and operate on a level comparable to that of equivalent national systems (European Parliament, 2015). The OECD even ranks the EU's regulatory policy as one of the very best (European Commission). Respondents in a public consultation were also generally positive about the extent to which the Commission uses evidence and assesses impacts in IAs. Additionality, Commission officials, while still questioning certain aspects, find that the process of making an IA report provides a good, systematic preparation for later negotiations and communication about the Commission's proposals (European Commission, 2019).

The Regulatory Scrutiny Board

The Regulatory Scrutiny Board (RSB) stands at the heart of the EU's policy-making system. It is tasked with auditing or checking the quality of the Commission's staff working documents including IAs. On the basis of the Guidelines, the RSB decides whether an IA report gets a positive opinion, a

positive opinion with reservations or a negative opinion (Senninger & Blom-Hansen, 2020). The RSB has developed 10 quality indicators for IAs (European Commission, 2019). When an IA receives a negative opinion by the RSB, the IA report cannot proceed in the Commission's internal decision-making process. This means that the RSB potentially holds a veto position inside the Commission (Senninger & Blom-Hansen, 2020). Moreover, the EU policy process will be put on hold until the quality of the underlying evidence in the IA reaches an adequate level (European Commission, 2019). Furthermore, it is important that the depth of the analysis matches the importance of the initiative. The Board's opinion will be published and attached with the Commission's final proposal together with the IA report (European Union, 2016).

The RSB originates from a reform in 2015 of its predecessor the Impact Assessment Board. The Impact Assessment Board was an institution initially consisting of five, but since 2012 of four rotating members. These members were drawn from a permanent pool of eight Commission directors and were responsible for different areas of expertise. Half of the rotating members of the Board were assigned to look at macro- and microeconomics, while the rest of the members shared the social and environmental areas (European Parliament, 2015). This could be one of the reasons why economic impacts in IAs have carried or still carry more weight than the other impacts. It shows that the European Commission is/was more worried about the economic consequences of an EU initiative.

The 2015 reform improved the independence of the RSB by adding external members. This means that the RSB now is a semi-independent body within the Commission. It consists of three Commission officials, three members recruited from outside the EU's institutions and the Commission's Director-General. The RSB is an active watchdog whose opinions on IAs are highly critical (Senninger & Blom-Hansen, 2020). The Board publishes annual reports on its work including recommendations for IAs. In 2018, the RSB highlighted that the problem definition, use of evaluation, the design of options and their comparison were the weakest areas of IAs. The most common reasons for a negative opinion by the Board were issues regarding coherence, presentation, relevance and EU added value. The Board also pointed out that often either data were unavailable or were not compared against a baseline (European Commission, 2019).

The existence of the Board has improved the quality of draft IAs. Commission officials see the regulatory scrutiny process as an excellent preparation for the negotiations with the European Parliament and the Council. However, some issues have remained. Some Commission officials have cited that the RSB does not apply its standards consistently. Particularly its demands for quantified information fluctuates between IAs. As a result, Commission officials find that still too many IAs remain of unsatisfactory quality (European Commission, 2019).

The international focus on improving the quality of legislation in an evidence-based way has increased substantially in the past two decades. In the EU, an Interinstitutional Agreement on Better Law-Making between the three EU institutions and the Commission's Better Regulation agenda has resulted in improved procedures across the whole EU policy-making cycle. EU IAs provide an ex-ante evaluation of the possible significant economic, social and environmental impacts of a certain initiative. The Commission published Better Regulation Guidelines to help Commission officials in this process. The Guidelines state that an IA should answer seven questions in order to be of high quality and correctly follow the principles of Better Regulation. In this paper, I am mostly interested in the part in IAs that is the assessment of the impacts. However, it is also important to take account of

other areas in the IA and the IA as a whole. Commission officials have struggled in providing a balanced assessment ever since the introduction of the integrated IA system. Economic impacts tend to be considered more and covered more thoroughly compared to social and environmental impacts. In the next chapter, I delve deeper into the reasons why IAs are unbalanced and particularly how this affects the assessment of health impacts in IAs.

Health at the EU level

Although Member States have the primary responsibility for health, the EU plays a crucial role in creating an environment that fosters the promotion and protection of human health (Salay & Lincoln, 2008). Over the years, public health has taken a prominent position on the EU agenda (European Parliament, 2021). The increasing prevalence of preventable chronic diseases such as heart disease, stroke, diabetes, obesity, cancer and even multimorbidity[3] seriously affects the quality of people's lives across the ageing European population (Salay & Lincoln, 2008; WHO, 2016). EU health policy serves to complement national policies and can be adopted under the Treaty on the Functioning of the European Union: Article 168 (protection of public health), Article 114 (approximation of laws) and Article 153 (social policy). Focused on areas involving health at the EU level are patients' rights in cross border healthcare, pharmaceuticals, medical devices, serious cross border threats, tobacco and processes involving organs, blood, tissues and cells. The European Commission additionally promotes investments in health as a way of achieving smart, sustainable and inclusive growth (European Commission). Investing in public health has major returns on investment. Every euro that is put into public health results into an average return of 14 euros to the economy. In addition, GDP increases up to 4% with every additional average year of life expectancy (eu4health Civil Society Alliance, 2019). The recent EU4Health programme is the EU's response to the COVID-19 crisis and provides financing to EU countries, health organizations and NGO's (European Commission, 2020c). EU4Health is the fourth and largest health programme as of yet and intends to promote innovation in health care and strengthen the resilience of the EU's health systems (European Commission, 2020a). The ongoing COVID-19 pandemic does not reduce the probability of new pandemics or the likelihood that other low probability, high-impact health risks might hit our society in the future. To better protect ourselves, changes in our health systems are necessary to eliminate the existing vulnerabilities (OECD, 2020).

However, many risk factors are affected by policies outside the health sector (Salay & Lincoln, 2008). For example, environmental and lifestyle risk factors have major impacts on the health of people. Hundreds of thousands of individuals across the EU die each year as a consequence of air pollution, tobacco, alcohol consumption, unhealthy diets and lack of physical activity (OECD, 2020). The EU recognizes this and states in article 168 TFEU that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities" (European Commission, 2017c). This is called the Health in All Policies (HiAP) approach. By codifying this approach in the EU treaty and also in the Charter on Fundamental Rights, the cross-sectoral nature of public health issues is taken into account. EU policy-makers should therefore aim to integrate health aspects in all relevant policies (European Parliament, 2021).

To help ensure this, the EU uses Health Impact Assessment to define the effects (positive and negative) on health a policy, programme or project may have and to estimate the distribution of these effects within the population (Jennifer Mindell & Joffe, 2003). This way, policy-makers gather and interpret evidence about possible health impacts with the aim of helping themselves choose how

[3] This means that the same individual has two or more chronic conditions and will, as a result, require complex and ongoing care (WHO, 2016).

to best mitigate harm and maximize the benefits to health. In addition, Health Impact Assessment is utilized to find and minimize inequalities between groups of individuals and countries. Moreover, Health Impact Assessments have evolved from using mostly biomedical models to socio-economic and environmental models of health. Considerations of toxic, infectious and other hazards used to be the most common focus of an Health Impact Assessment, while now wider determinants of health such as employment, transport and housing are usually the focus of an Health Impact Assessment. Policy-makers have also changed in not only using Health Impact Assessment for assessing health impacts of specific projects, but of broader initiatives and policies as well (JS Mindell et al., 2008). The World health organization (WHO) promotes Health Impact Assessment as a method to ensure that policy-makers from a wide variety of sectors are adequality conscious of the health consequences of their policies (Smith et al., 2010).

Health Impact Assessment should not be confused with Health Technology Assessment (HTA). Health Technology assessment is used to evaluate the added value of new health technology in comparison with other new or existing health technologies (European Commission). In relation to Health Impact Assessment, Health Technology Assessment plays an important role. Methods typically used for Health Technology Assessment can also be utilized in Health Impact Assessment (European Commission, 2017c). Some of these methods are summarized in table 1.

The Directorate-General responsible for public health at the EU level is DG Health and Food Safety (DG SANTE). the role of DG SANTE is to support the efforts of Member States in improving and protecting the health of their populations. It additionally helps EU countries to ensure the accessibility, effectiveness and resilience of their health systems. The tasks of the DG are proposing legislation, conducting health promotion activities, providing financial support and coordinating and facilitating the exchange of best practices between EU countries and health experts (European Commission). DG SANTE was previously known as the Directorate-General for Health and Consumers (DG SANCO) until 2014 (European Commission).

Health Impact Assessment before the integrated system

The assessment of the health impacts at the EU level can be dated back to the 1950s, when the European Coal and Steel Community put occupational health and safety on their agenda. The treaty of Rome, and as a result the founding of the European Economic Community, increased the attention to health protection and the safety of workers. Public health was subsequently included in the Maastricht Treaty in 1993, in the Amsterdam Treaty in 1997 and can now be found in Article 168 TFEU. With the Maastricht Treaty, the more systemic work that considers the health impacts of activities in non-health sectors began. The European Commission started making annual reports on health aspects of Commission policies in these sectors with the goal of better integrating health across the European Community. However after four years, the Commission stopped publishing the annual reports. The reports were considered to be extensive and descriptive, but lacked analysis of how the integration of health could be improved and what could be done better. The last report in 1999 suggested to introduce more specific work on health requirements (Ståhl, 2010).

In 2001, DG SANCO (now DG SANTE) published a guide on assessing health impacts of policies. The guide provided a generic methodology on Health Impact Assessment for policy-makers to use in EU policy development and was part of the Policy Health Impact Assessment for the European Union project under the then implemented EC Public Health strategy (European

Commission, 2001).

The EU policy Health Impact Assessment (EPHIA) methodology in the 2001 guide consists of multiple stages: *screening*, *scoping*, *conduct assessment*, *report on health impacts and policy options*, *monitoring* and an *impact and outcome evaluation* (European Commission, 2001).

The assessment procedure in the 2001 guide was to be understood by the EU policy-makers as an iterative and learning process. The 2001 guide states that there are 3 different 'units of analysis' that the methodology could be applied to assess potential health impacts. They are (1) at Europe wide level, (2) at Europe and regional level and (3) at Europe wide level and nation state level. The first option estimates the health impacts of a policy for the European population as a whole. Next, the second option takes into account the possible differences in health impacts of a policy that could occur between countries or regions. Lastly, the third option is chosen when the significance of the policy or the variability across Member States is high, in order to be in line with the principle of subsidiarity (European Commission, 2001).

The following step in the 2001 guide is analyzing the policy. Policy-makers should according to the 2001 guide identify the rationale, context and strategies of the policy and the relationship of the policy with other policies. The populations and sub-populations who are affected and the key informant and stakeholder sample groups should also be recognized. In addition, the policy-makers should according to the 2001 guide picture the health and socio-demographic context of the policy. This 'profiling' helps better understand the potential health impacts and identify the groups in the population who will be affected. To do this, data-collection is needed on a number of relevant indicators that are measurable variables that reflect the state of a person or a community. Examples given in the 2001 guide are healthy life expectancy at birth, occupational morbidity and trends in employment. The 2001 guide refers to available international databases such as EUROSTAT, OECD, WHO and national level databases (European Commission, 2001).

The quantitative approaches given in the 2001 guide to quantify health impacts of a policy are forecasting, scenario building, mathematical modelling and health economics approaches such as cost benefit analysis ('willingness to pay'). Besides the quantitative data gathered from existing databases, policy-makers should in most cases also add qualitative data gathered through the participative approaches mentioned in the 2001 guide. This provides depth, a detailed understanding of people's perceptions on health impacts and a perspective on health inequalities.

The next step in the 2001 is the impact analysis. Policy-makers should use the data that they gathered to define: the health impacts, the direction of change (health gain or loss), the scale (severity of the impact and the size of the affected population), the likelihood of impact and the latency (immediate, short, medium or long term). The 2001 guide advises to use matrices or causal webs to visualize the key results of this stage. Policy-makers should additionally according to the 2001 guide construct several scenarios to forecast possible health outcome changes as a consequence of the policy. At least two scenarios should be considered: a basic scenario outlining the health outcomes without policy implementation at a defined future point in time and a second scenario describing the situation with assumed full implementation of the policy. In addition, creating additional scenarios according to the 2001 guide enables the estimation of the effect of different policy options (European Commission, 2001).

When all evidence is collected and the health impacts have been defined, the policy-makers should determine the most important potential health impacts using a ranking process. Here, the

strength of the evidence, the likelihood of impact, the scale of the health impacts, the relevance and the contribution to reducing/increasing health inequalities should be taken into account according to the 2001 guide. The 2001 guide stresses that strong qualitative evidence carries an equal weight compared to strong quantitative evidence. In this stage, key informant and stakeholders should be involved (European Commission, 2001).

The final two steps in the assessment procedure in the 2001 guide are the development of recommendations and the process evaluation. Recommendations according to the 2001 guide can be seen as proposals for alternative and/or additional action for the policy. This way, health gains can be maximized and adverse health effects can be mitigated as much as possible. Policy-makers should allocate appropriate resources to the recommendations stage, because it is as important as the identification of the impacts according to the 2001 guide. Finally, a process evaluation is done during the assessment procedure to identify lessons learnt to help with future Health Impact Assessments (European Commission, 2001).

The guide of 2001, however, was not widely promoted. This was because at the same time there were talks at the EU policy-making level aimed at more comprehensive assessment procedures (Ståhl, 2010).

Health Impact Assessment in the integrated system

The introduction of the new system of EU IAs means that Health Impact Assessment is part of the integrated IA reports. The public health community was at the beginning relatively disengaged from the development of the integrated IA tool. It was not clear at that moment if the EU would stick with the single-sector type IAs or fully transition to the integrated IAs. The 2001 HIA guide was published just before the introduction of the integrated system (Ståhl, 2010). The integrated system, however, has the advantage of lessening the burden on officials who were previously required to carry out a large number of IAs before their proposal could be used in the decision-making process (Jennifer Mindell & Joffe, 2003).

In the second half of 2006, Finland held the EU's presidency and chose 'Health in All Polices' (HiAP) as the main health theme. Concerns were raised that EU policies did not consider health appropriately and the role of IAs was questioned from a HIA perspective. There was an implementation shortfall experienced in how health was integrated in the Community policies. From a public health point of view, policy development at the EU level did not make use of the available structures and mechanisms in the best possible manner (Puska & Ståhl, 2010). IA reports were not being utilized equally in the European Commission, Council and Parliament. Problems seemed to be analyzed and framed in line with the perspective of whichever DG was conducting the IA. DG SANCO would pay attention to health in IAs, while other DGs would do so rarely (Ståhl, 2010). For example, IAs concerning the agricultural sector focused mainly on economic or regional policy interests and health impacts were viewed as secondary (Puska & Ståhl, 2010).

The recent literature focused on health in EU integrated IAs can be divided into three categories. First, there are opinions and articles on the barriers, challenges and possible improvements of Health Impact Assessment in EU integrated IAs (see, e.g., (Fischer & Cave, 2018; Puska & Ståhl, 2010; Salay & Lincoln, 2008; Smith et al., 2010; Tarkowski & Ricciardi, 2012)). Second, the European Commission and other non-governmental institutions (e.g. WHO, OECD) have looked at social and health impacts in their evaluations of EU integrated IAs. The stocktaking exercise

of the Better Regulation activities of the EU at the end of the Juncker administration acknowledges the impact that their legislation can have on health and that impacts in IAs could be better taken into account (European Commission, 2019). Third, quantitative academic literature is scarce and possibly outdated. Ståhl (2010), for example, performed a content analysis on 32 assessments using a word search on the word 'health'. This paper provides a more in-depth and up-to-date research.

As noted in the first chapter of this paper, an integrated IA report maps out the potential broader economic, social and environmental impacts of a certain policy proposal. Public health and health system impacts are considered to fall under the category of social impacts (Ståhl, 2010). The Better Regulation Guidelines, however, also place impacts on health under impacts of a specific nature (European Commission, 2017b). Furthermore, questions were given to the policy-makers in previous versions of the Guidelines to help them identify impacts (European Commission, 2009). The questions on *Public health and safety* in the 2009 IA Guidelines were:

- *Does the option affect the health and safety of individuals/populations, including life expectancy, mortality and morbidity, through impacts on the socio-economic environment (working environment, income, education, occupation, nutrition)?*
- *Does the option increase or decrease the likelihood of health risks due to substances harmful to the natural environment?*
- *Does it affect health due to changes in the amount of noise, air, water or soil quality?*
- *Will it affect health due to changes energy use and/or waste disposal?*
- *Does the option affect lifestyle-related determinants of health such as diet, physical activity or use of tobacco, alcohol, or drugs?*
- *Are there specific effects on particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.)?*

Additional questions relating to human health can also found in the categories: *Standards and rights related to job quality*, *Air quality* and *Access to and effects on social protection, health and educational systems* (European Commission, 2009). The current version of the IA Guidelines does not include these questions anymore. Instead, they have been moved to *Tool #19 Identification/screening of impacts* of the Better Regulation Toolbox (European Commission, 2017a). The questions in category *Public health and safety* have remained the same, but have been extended with questions on health systems:

- *Does the option affect the quality and/or access to health services and the financing and organisation of health systems?*
- *Does the option affect the cross-border provision of services, referrals across-borders and cooperation in border regions?*

Tools used in the assessment of health

The first chapter of this paper provides an overview of chapter 3 of the Better Regulation Guidelines on carrying out IAs. However, there exist additional documents that complement these Guidelines called the Better Regulation Toolbox. The Toolbox provides guidance, tips and best practice examples that can be used selectively by EU policy-makers. Moreover, chapter 2 of the Better Regulation Toolbox presents tools for making an IA report and Tool #31 specifically covers health impacts. The

Toolbox states that EU legislation and policies can impact health in a direct and/or indirect manner. Banning asbestos, that was proven to cause cancer, is an example of EU legislation that directly affects health. Examples of indirect impacts mainly result from changes in the socio-economic and environmental determinants of health (e.g. improving road safety, changing air quality and improving working conditions). According to the Toolbox, Commission officials should always check whether a specific population, risk group or geographical area is affected differently for both direct and indirect health impacts. Here, stakeholder consultation should be used as much as possible (European Commission, 2017c). The Toolbox provides following questions to help EU policy-makers in identifying whether there might be health-related impacts as a consequence of a policy:

Direct impacts

- *Does the option create (or reduce) health risks or does it affect the safety of patients?*
- *Does the option affect the effectiveness and sustainability of healthcare and longterm care services?*
- *Does the option affect the access of certain populations (including vulnerable ones) to medicinal products and information, health or long-term care services? In particular by impacting on their availability, quality, affordability and cost?*

Indirect impacts

- *Does the option influence the socio-economic environment that can determine health status? In particular working conditions, income, education and training, housing, nutrition, energy consumption, transport, etc.*
- *Does the option directly or indirectly target population's lifestyle-related determinants of health such as diet, physical activity, use of tobacco, alcohol or drugs?*

Next, Tool #31 provides the methods that can be utilized for estimating health impacts. Choosing the right methodology according to the Toolbox depends on the specific policy context. EU policy-makers are therefore recommended by the Toolbox to look at how similar potential health impacts have already been assessed in existing EU IAs, by Member States or by third parties. The Toolbox provides non-monetary and monetary methodologies that can be used to assess direct and indirect health impacts. Non-monetary approaches use cost and health outcomes when comparing different interventions with the same specific health problem (cost-effectiveness analysis). Additionally, non-monetary methods can also be utilized to compare different interventions for different health problems (cost-utility analysis). With non-monetary approaches, health impacts/benefits of a given intervention can be quantified without monetizing it. Furthermore, the Toolbox says that monetary approaches are useful if the aim of the analysis in an IA is to provide an extensive comparison of costs and benefits. Monetization of human health may, however, not always be possible or the most appropriate to do according to the Toolbox (especially when looking at the health of a specific individual). For example, policy-makers using the Human Capital approach will measure different values of people's lives depending on their projected future earnings. The use of monetary approaches is therefore not always deemed ethical and can raise considerable criticism (European Commission, 2017c). In the table below, a summary is given of all the methods that can be found in Tool #31 of the Better Regulation Toolbox.

Table 1 Summary of the HIA methods given in Tool #31 of the Better Regulation Toolbox

Methods	
Non-monetary approaches	
Quality Adjusted Life Years (QALY)	measures health gains using data on quality of life (QoL) combined with the duration of the improvement. Values are derived from surveys of patients and doctors (stated preferences) and reflect the averages of certain social groups. <u>Advantage</u>: • allows aggregation over the number of individuals affected (use equal weights or adjust weights to reflect preferences).
Disability Adjusted Life Years (DALY)	measures the number of quality adjusted years lost because of illness in comparison to a good health status without disability (= measure of the burden of disease). Also utilized to calculate the cost-effectiveness of interventions.
Healthy Life Years (HLY)	indicates the number of years an individual of a certain age can expect to live without disability. <u>Disadvantage:</u> • less sensitive to health impacts than QALYs and DALYs
Monetary approaches	
<u>Preference Based approaches</u> analyze individuals' stated or revealed preferences	
Value of Statistical Life (VOSL)	= individuals' Willingness To Pay (WTP) for a lower risk of mortality divided by the risk reduction <u>Disadvantages:</u> • ethical concerns and criticism • not a measure of the quality of life
Value of Statistical Life Year (VOLY)	measures more generally the Willingness To Pay (WTP) for an increase of one additional year of life expectancy. <u>Disadvantages:</u> • ethical concerns and criticism • not a measure of the quality of life
<u>Accounting style' approaches</u> measure only certain aspects of health impacts	
Cost of Illness method	<u>Advantage:</u> • simple <u>Disadvantages:</u> • comprises only the medical expenses related to the incidence of an illness. • usefulness is limited, it does not include other indirect costs to society. • ethical concerns
Human Capital method	measures the loss of future earnings (or the loss to social welfare) in case of disability or premature death. <u>Disadvantage:</u> ethical concerns

Criticism and difficulties with assessing health

There exist several reasons why health might have been neglected over the years in EU IAs. These reasons can stem from the inherent difficulties of assessing health impacts at the governmental level. The WHO, for example, has recognized multiple barriers to using Health Impact Assessment in policy-making: lack of relevant skills and expertise, lack of awareness and understanding, lack of resources, lack of recognized tools or methods, lack of political support, lack of time, other priorities get in the way, not convinced of benefits and gaps in the evidence (WHO, 2010). Overall, policy-makers tend to avoid integrating social impacts (i.e. health) in their assessments, even when this is explicitly required in guidelines or frameworks (OECD, 2016). Health Impact Assessment was largely developed to assess local health impacts. As a consequence, concerns have been raised about whether Health Impact Assessment can usefully be adapted to national and international levels (Tarkowski & Ricciardi, 2012).

These problems can be identified in the specific procedural and contextual challenges at the EU level that have caused policy-makers to include health impacts in an insufficient way in EU IAs. Before the integrated system, Health Impact Assessment had to compete with several other sorts of IAs such as environmental, social and business. These other single-sector type IAs all had legal obligations to be implemented by EU officials preparing policy proposals (Tarkowski & Ricciardi, 2012). Whereas the legal obligation for Health Impact Assessment (i.e. article 168 TFEU) did not exist or is seriously questioned. This means that Health Impact Assessment has been seen as a rather voluntary tool (Salay & Lincoln, 2008; Smith et al., 2010; Tarkowski & Ricciardi, 2012). In order to solve this problem, the EU made the decision to introduce the integrated system of IAs (Tarkowski & Ricciardi, 2012). In addition, health has historically been a relatively low priority at the EU level and has been subject to a narrow and medicalized policy focus. The public health community tends to be more engaged on setting up mechanisms for Health Impact Assessment at member state-level. Public health advocates have shown a broader tendency to not focus on European level discussions about health policy (Smith et al., 2010).

Furthermore, integrating Health Impact Assessment within other impacts assessments (such as the EU integrated IA) risks a tokenistic consideration of health[4] (Jenny Mindell, Boaz, Joffe, Curtis, & Birley, 2004). The reason for this may be the following: the objectives of the various types of 'sectors' (i.e. economic, social, environmental and health) within specific policy frameworks have shown to not always be fully compatible (Fischer & Cave, 2018; WHO, 2014). In addition, critics have argued that lobby groups have had a substantial influence on the initiation and creation of IAs. Large corporations (e.g. in the food, alcohol, tobacco, chemical, energy and transport sectors) played a fundamental role in promoting IAs at the EU level. As a consequence, the EU integrated IA tool incorporates a comprehensive form of Business Impact Assessment (BIA), while it only includes certain aspects of Health Impact Assessment (Smith et al., 2010).

[4] In other words, policy-makers might only consider health impacts as a symbolic gesture.

This chapter provides an overview of the methods that are used by EU policy-makers to assess health impacts in EU IAs. Although Member States have the ultimate responsibility for health, its importance has been growing at the EU level (European Parliament, 2021). The overall ageing European population and the ongoing COVID-19 crisis have strengthened the position public health has on the EU agenda. EU health policy serves to complement national policies and mainly focusses on patients' rights in cross border healthcare, pharmaceuticals, medical devices, serious cross border threats, tobacco and processes involving organs, blood, tissues and cells (European Commission). To do this effectively, the EU Commission uses Health Impact Assessment to define the effects (positive and negative) on health a policy, programme or project may have and to estimate the distribution of these effects within the population (Jennifer Mindell & Joffe, 2003). In 2001, the EU Commission published an HIA guide and methodology to provide help for policy-makers in assessing the health implications of an initiative (European Commission, 2001). However, this guide was never widely promoted, because at the same time discussions were held aimed at more comprehensive assessment procedures (Ståhl, 2010). As a result, Health Impact Assessment was integrated in the currently used integrated IAs. The EU Commission uses a checklist approach with questions to identify the (direct and indirect) health impacts of a policy. The Better Regulation Toolbox complements the IA Guidelines that was discussed in chapter 1. The Guidelines requires Commission officials to quantify impacts as much as possible (European Commission, 2017b). Tool #31 of the Toolbox aims to further help Commission officials in identifying and assessing health impacts. It provides monetary and non-monetary methods to do so (European Commission, 2017c). The integrated system was introduced to solve the previously experienced problems of using single-sector type IAs. But from a public health and HIA perspective, the integrated IAs still have disadvantages.

Chapter 3 Health in EU IAs published between 2018-2020

Introduction

In order to evaluate the integration of Health Impact Assessment in EU IAs, a selection should first be made from published IAs on the basis of their relevance to human health. This study will focus on the IA reports that were published in the past three years. Between 2018 and 2020 a total of 119 IA reports were published on the European Commission's website[5]. IAs vary from a wide range of policy topics and all reports include various policy options that impact society in a different way. For this reason, it is important to make a distinction between IA reports when assessing a certain aspect. In the case of this study, it would not be relevant to evaluate IAs related to for example finance, the internal market, competition, tax and commerce that have no impacts on human health in any way. The following table indicates the number of IA reports that were published in each specific year.

Table 2 Number of IAs published between 2018-2020

How many IAs were published?		
2018	2019	2020
81	18	20

The European Commission made the revised Better Regulation Guidelines public in 2017. However, it is not clear-cut when and in which IAs the Commission officials started using the new Guidelines. Furthermore, the time needed to make and finish an IA tends to differ from case to case. For this reason, not all IA reports included in this study were made under the most recent Better Regulation procedures. However, I take the 2017 Guidelines as the most refined criteria for making an EU IA. In other words, if an IA complies with the principles that are laid out in the 2017 Guidelines, even if the IA was initiated before the publication of the Guidelines in 2017, I presume the IA to be of a high quality.

At the end of 2019, the Juncker administration came to an end and the Von der Leyen Commission took its place. This explains in all likelihood why substantially more IA reports were published in 2018. The same happened encompassing the end of the five-year EU institutional cycle of the Barroso Commission and the start of the Juncker Commission: 97 IAs were published in 2013, while only 25 were published in 2014.

In this research, I introduce two categories to make a clear distinction between IAs with a topic/an option with health-related impacts. The first category contains the IAs with a topic/an option that possibly affects human health in any way. Furthermore, the second category comprises only the IAs with topics/options that have a possible significant impact on health.

Category 1

The criteria that were used to select the IAs included in the first category of this study are based on the questions given in the Better Regulation Toolbox to help EU policy-makers in identifying health-related impacts[6]. I focused on the introduction, the problem definition, the area *Why should the EU*

[5] Disclaimer. The interface of the European Commission's website where IA reports can be found changed considerably during the writing of this thesis and after the IAs were extracted.
[6] See supra.

act? and the options to decide whether an IA could have possible impacts on human health. An IA was included in this study if the topic/an option of the IA in these areas showed to impact following factors in a health-related way[7]:

Table 3 Health determinants

• socio-economic environment (working environment, income, education, occupation, nutrition) • substances harmful to the natural environment • noise, air, water or soil quality • lifestyle-related determinants of health (such as diet, physical activity or use of tobacco, alcohol or drugs) • particular risk groups (determined by age, gender, disability, social group, mobility, region, etc.) • the quality and/or access to health services and the financing and organisation of health systems • cross-border provision of services, referrals across-borders and cooperation in border regions

The IAs that are a part of this research are listed in annex 1. The following table summarizes these results.

Table 4 Summary of category 1

How many IAs had a topic that affects human health and/or healthcare in any way?		
2018	2019	2020
44	17	9

The policy topics of the IAs range from improving the safety of the road infrastructure in the European Union to establishing various funds. I included IAs with topics revolving around climate change and CO2 reduction, because I believe these topics form an increasing risk to human health.

Evidently, because substantially more IAs were published in the year 2018, a lot more IAs had topics/options with possible health-related impacts. In 2019, the European Commission published multiple separate IAs on laying out ecodesign requirements for a range of household appliances. This explains why in this specific year a lot of IA reports assessed a topic impacting health compared to the total amount of IAs published. Grouping these IAs into one would drastically drop the number of total IAs with a topic/an option that possibly impact human health to eight IAs. As a result, I conclude that the amount of IAs with a topic/option that possibly impact human health in any way is close to half of the total amount of IAs published in every one of the past three years.

Category 2

The second category contains only the IAs with a topic/an option that could be considered to have possible significant impacts on human health. In the second part of this research, I evaluate the

[7] These factors were picked from the questions given in the Better Regulation Toolbox. See supra.

quality of IAs in terms of integrating Health Impact Assessment. The 2017 Guidelines require Commission officials to only assess the possible significant impacts of a policy in an IA. As a consequence, it would not be relevant to evaluate the quality of IAs in terms of integrating health for IAs with a topic/an option that only has a minor impact on health. For example, an IA on the ecodesign requirements for a certain household appliance with minimal expected changes to human health is not included in this category. In addition, IAs relating to the Multiannual Financial Framework (MFF) are not included in the second category as they are outside the scope of this research.

Evaluating if an IA has a topic/an option with possible significant health impacts is not an straightforward task. The European Commission does not exactly define what a significant health impact is and does not provide a threshold in the Better Regulation Guidelines or in the Toolbox. Commission officials are given flexibility in analyzing the significance of impacts. To provide a systematic approach in this study, the IAs in the second category were chosen during the selection of the IAs of the first category. This was done by eliminating the IAs in the first category that showed and/or stated, in the areas used to select these IA into the first category[8], to not have a topic/an option with possible significant health impacts. In addition, the consultation synopsis found in annex 2 of an IA was used whenever this was possible to confirm that the topic/an option has no possible significant health impacts. The IAs included in the second category are evidently also included in the first category.

The IAs included in the second category can be found in annex 1. The results of the second category are summarized in the following table.

Table 5 Summary of category 2

How many IAs had options that could be considered to have significant impacts on human health?		
2018	2019	2020
13	2	3

The number of IAs with a topic/an option that has possible significant health impacts drastically drop compared to the number of IAs with a topic/option that possibly have health impacts in any way. This could be in line with the fact that Member States have the ultimate responsibility for the health protection of their populations and that the European Union only implements policies that possibly could have significant health impacts when it is clear that there could be EU added value. Member States could, in other words, already have measures in place to protect the health of their citizens. However, it could also be argued that the EU does not consider the protection of public health as an important policy objective.

Next, I look at which Directorate-General was the lead DG of a particular IA that is included in the second category. These results can be found in annex 1. Furthermore, table 6 shows which DGs published IAs that are included in the second category and how many. This way, the range of policy topics that have possible significant impacts on health becomes clear.

[8] See supra.

Table 6 Number of IAs per DG

Lead DG	Number of IAs in category 2
DG Climate Action (CLIMA)	1
DG Employment, Social Affairs and Inclusion (EMPL)	3
DG Energy (ENER)	1
DG Environment (ENV)	5
DG Financial Stability, Financial Services and Capital Markets Union (FISMA)	1
DG Health and Food Safety (SANTE)	2
DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)	2
DG Mobility and Transport (MOVE)	3

DG ENV published the most IAs with a topic/an option with possible significant impacts on human health in the past three years. The increased focus on climate change on the European level that also resulted in the European Green Deal could be an explanation. Next, DG EMPL and DG MOVE published the second most IAs with a topic/an option with possible significant health impacts. Notably, the Directorate-General responsible for health DG SANTE only published two IA reports in the past three years. Furthermore, DG GROW published two IAs and DG FISMA published one IA that are included in the category of this study.

These results are in line with the fact that human health is affected by a wide range of policy topics beyond the health(care) sector. This follows the Health in All Policies approach of the European Union.

It would not be relevant to assess the quality in terms of integrating Health Impact Assessment of all IAs published in the past three years. Certain policy topics have no impact on human health in any way. For this reason, I introduce two categories in this study to extract the right IAs and to make a distinction. The first category includes all IA reports that have a topic/an option that possibly affect human health in any way. Furthermore, the second category makes a further distinction out of the first category IAs and only includes IAs with a topic/an option with possible significant health impacts. I find that in each of the three years about half of the total amount IA reports published have a topic/an option with a possible impact on health in any way. When selecting the IAs with a topic/an option that has a possible significant health impact, the number of IA reports considerably drop. This could be in line with the fact that the European Union only complements Member States with policies that impact public health when there is EU added value. However, another explanation could be that the EU does not consider public health enough as an important policy objective and topic.

Chapter 4 The quality of EU IAs in terms of integrating Health Impact Assessment

Introduction

Now that the IAs with a topic/an option that could be considered to have possible significant health impacts are selected, it is possible to evaluate the quality of these IAs in terms of assessing health impacts. This study will provide an evaluation of IAs in terms of integrating Health Impact Assessment in the most recent three years (2018, 2019 and 2020). This way, it becomes clear where EU policy-makers stand at integrating Health Impact Assessment in EU IAs.

Method

Cecot, Hahn, Renda, and Schrefler (2008) explain that there exist three ways to assess the quality of IAs/economic analyses. One method would be to let experts examine the assumptions and results of analyses. The advantages of this method is that it provides an in-depth evaluation of particular issues relevant to a specific regulation and that an expert can differentiate IAs of a bad quality in terms of the assumptions and methods used in the IA. However, the disadvantage of this way of evaluating the quality of an IA is that the results can be subjective and, as a result, are more difficult to generalize or replicate.

A second method would be to use an estimate of some parameter of a certain ex-ante IA and compare it with the ex-post analysis of the policy. This way, by evaluating the net benefits or cost-effectiveness of an IA the actual observed measure is used to assess the quality of the IA. To do this, the assumption has to be made that the ex-post estimate is a better measure of the actual impact of the policy compared to the ex-ante measure. As a result, an IA when using this method is of a high quality when the ex-ante measure is similar to the ex-post measure. However, the disadvantages of this approach are that the results are dependent on the available information at the time of the evaluation and that an ex-post measure can turn out to be less accurate than the ex-ante measure. Moreover, EU policy-makers use this method. They set up the ex-post analysis in the monitoring and evaluation area of an IA[9].

A third method, which is the method that is used in this study, is using a 'scorecard' to evaluate the quality of IAs. With a scorecard, it is possible for a non-specialist to synthesize information consistently and to assess whether an IA meets key objective criteria. In this study, 10 key criteria based on the Better Regulation principles found in the 2017 Better Regulation Guidelines are used. The advantages of this method are that the results are easy to generalize and replicate and that it allows for a comparison of a large number of analyses. However, the disadvantage of this approach is that a score may not always provide a useful measure of quality. In other words, an IA could receive a high score, but still be of poor quality if its calculations and estimates are inaccurate. Similarly, an IA with a low score could still be of an adequate quality if the scorecard items that the IA did not include were unknowable. To partly solve this, I use the opinions of the RSB as a starting point of the evaluation of a specific IA. This way, I utilize expertise of a very high quality. If the opinion of the RSB indicates a shortcoming that is related to one of the 10 key criteria, I take it into account. In this study, I refer to scores on the scorecard as an indication of the quality of the IAs despite the drawbacks of the method. This will ensure simplicity, but I also believe that the scorecard

[9] See chapter 1.

method is useful.

The scorecard in this study is divided into three areas. The first area of the scorecard focusses on the identification of the health impacts in the area *What are the impacts of the policy option?* of the IA. I evaluate if the IA has identified who's health specifically is affected and if internal/external expertise and stakeholders' knowledge is used and referred to. In multiple IAs, it is also relevant to take account of other areas such as the problem definition and the annex *Who is affected and how?*. It is possible this way to evaluate whether health impacts are identified in the IA, but are not only considered by the Commission officials in the IA as a symbolic symbol. The focus of this area in the scorecard is important, because these factors in an IA set up the following areas in the IA (i.e. the quantification of the health impacts) and it also allows me to evaluate to a certain degree the qualitative analysis of the health impacts in the IA.

Furthermore, the second area of the scorecard focusses on the methods that are used to assess the health impacts in the IA. I assess if the Commission officials have quantified and/or monetized (at least some) health impacts. In addition, I evaluate if these results are given in the IA. Moreover, I look at if the assumptions on which the quantification of the health impacts relies on are clearly presented and if the method that was used to quantify these health impacts is justified and explained in the IA report. More specifically, I focus on the area *What are the impacts of the policy option?* and annex 4 *Analytical methods* of the IA to assess these scorecard items.

Lastly, the third area of the scorecard focusses on the presentation of the results of the assessed health impacts. I look at if the health impacts are compared to the baseline scenario and if the results of the Health Impact Assessment are presented in a way which is accessible to a non-specialist. The areas in the IA report that I focused on for these scorecard items are *What are the impacts of the policy option?*, *How do the options compare?* and *Preferred option*, but I additionally focused on other areas varying from case to case depending on if it was useful. In addition, I assess if the results of the Health Impact Assessment in the IA are given in the executive summary of the IA. The executive summary of an IA is important, because it provides an accessible overview of the main findings of the IA to the EU policy-makers and to the public.

Results

My results demonstrate that most IAs adequately meet the 10 key objective criteria used in this study based on the Better Regulation Guidelines, but that there is still room for improvement for EU IAs in terms of integrating Health Impact Assessment. The IAs have in general the least amount of scores in the second area of the scorecard. Multiple IAs do not quantify and/or monetize health impacts. As a consequence, these IAs mostly do not justify and explain the methods used to assess the health impacts and do also not present the underlying assumptions of the quantification. In addition, I find that the kind of policy topic where the IA focusses on can possibly be a factor that influences the quality of an IA in terms of integrating Health Impact Assessment. I also find that the Regulatory Scrutiny Board (RSB) plays an important role in improving the quality of IAs in terms of integrating Health Impact Assessment.

Table 7 shows the results of the scorecard. An 'X' is given in the scorecard when the IA includes the scorecard item, while a 'O' is given when the IA does not. To measure the overall quality, I create an index of the 10 key criteria used in the scorecard, normalizing it to range from zero to one.

Table 7 Scorecard		2018													2019		2020		
Area	IA number (see annex 1):	3	4	7	10	15	17	20	21	23	26/41	27/42	28	46	50	52	64	66	70
1	Identified who's health specifically is affected (positively and/or negatively)	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	Made use of and referred to internal/external expertise and stakeholders' knowledge related to health	X	X	X	X	X	X	X	X	X	X	X	O	X	X	X	X	X	X
2	Quantified (at least some) health impacts	O	X	O	X	X	X	X	X	O	O	O	O	O	X	X	X	X	O
	Monetized (at least some) health impacts	O	X	O	X	X	X	X	X	O	O	O	O	O	X	X	X	X	O
	Provided the point estimate or the range of health impacts	O	X	O	X	X	X	X	X	O	O	O	O	O	X	X	X	X	O
	Assumptions on which the quantification of the health impacts relies on are clearly presented	O	X	O	X	X	X	X	X	O	O	O	O	O	X	X	X	X	O
	Justified and explained the choice of method that was used to assess the health impacts	X	X	X	X	X	X	X	X	X	O	O	O	X	X	X	X	X	O
3	Compared the results of the health impacts with the reference of the baseline	X	X	X	X	X	X	X	X	X	O	X	O	X	X	X	X	X	O
	Presented the results of the Health Impact Assessment in a way which is accessible to a non-specialist	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	O	X	O
	The results of the Health Impact Assessment are presented in the executive summary.	X	X	O	X	X	X	O	X	X	O	O	O	X	X	X	O	X	O
	Overall score:	0.6	1	0.5	1	1	1	0.9	1	0.6	0.3	0.4	0.2	0.6	1	1	0.8	1	0.2

Table 8 summarizes the results of the scorecard evaluation. This way, it is possible to analyze the quality of the specific areas used in the scorecard.

Table 8 Summary statistics of the scorecard evaluation

Summary statistics			
Area	Item	Item description	Number of IAs that include scorecard item (n = 18)
1	1	Identified who's health specifically is affected (positively and/or negatively)	18
	2	Made use of and referred to internal/external expertise and stakeholders' knowledge related to health	17
2	3	Quantified (at least some) health impacts	10
	4	Monetized (at least some) health impacts	10
	5	Provided the point estimate or the range of health impacts	10
	6	Assumptions on which the quantification of the health impacts relies on are clearly presented	10
	7	Justified and explained the choice of method that was used to assess the health impacts	14
3	8	Compared the results of the health impacts with the reference of the baseline	15
	9	Presented the results of the health impact analysis in a way which is accessible to a non-specialist	16
	10	The results of the Health Impact Assessment are presented in the executive summary.	11

Area 1

Nearly all IAs score well on the scorecard items in the first area. This means that Commission officials could be considered to be good at identifying health impacts in EU IAs. This is important, because it improves the overall comparison of the options in the IA and strengthens the case for the Commission's proposal of the legislation or initiative later on in the policy-making process.

However, it could still be the case in some IAs that Commission officials only include health in the IA as a symbolic gesture. This could explain why some IAs do not score well on the subsequent areas of the scorecard. It could be argued that in certain IAs the Commission officials should have broadened the scope of their research.

Area 2

The second area was in general the weakest area in the IAs. The Better Regulation Guidelines recognize that quantification and/or monetization is not always possible or proportionate in every analysis. However, if no impacts are quantified in the IA report, impacts should at least be assessed qualitatively and the reasons for not having undertaken the quantification should be clearly explained. For this reason, some IAs got a point on the scorecard item relating to the explanation of

the methods used, but do not receive a point on the scorecard items relating to the quantification or monetization of the health impacts. These IAs clearly explain why no quantification or monetization was possible. In these cases, the Commission officials in general argue that the required data to assess the health impacts does not exist or that the data cannot be collected at a proportionate cost.

Area 3

Most IAs compare the health impacts of the policy options with a baseline scenario. Even when a certain IA does not quantify or monetize the health impacts, the Commission officials still in most cases mention the expected evolution of the health impacts that are as a consequence of a policy option. Furthermore, most IA reports also present the results in a way which is accessible to a non-specialist. The most used way in the IAs to present the results in an accessible way is summarizing the results in a table with plusses and minuses to indicate the evolution of the health impacts that are as a consequence of a certain policy option. In addition, all IAs that quantified and monetized the health impacts include the results in the executive summary. However, the Commission officials do not provide the calculations of the health impacts in all executive summaries of these IAs. They only describe the expected changes in health outcomes.

Scores per Directorate-General

Some further insight can be gained into the results of this study by analyzing the scores of the IAs that were published per lead DG. Table 9 categorizes the scores of the IAs published by each lead DG.

Table 9 Summary of scores per DG

Lead DG	Scores
DG Climate Action (CLIMA)	0.8
DG Employment, Social Affairs and Inclusion (EMPL)	0.5, 1, 1
DG Energy (ENER)	1
DG Environment (ENV)	1, 0.3, 0.4, 0.6, 0.2
DG Financial Stability, Financial Services and Capital Markets Union (FISMA)	0.6
DG Health and Food Safety (SANTE)	0.6, 1
DG Internal Market, Industry, Entrepreneurship and SMEs (GROW)	1, 0.2
DG Mobility and Transport (MOVE)	0.9, 1, 1

As noted in the previous chapter, the DG that published the most IAs with a topic/an option that could be considered to have possible significant health impacts is DG ENV. The IAs that were published by DG ENV as the lead DG get relatively low scores overall on the scorecard items in this study. In some of these IAs, the Commission officials indicate that quantification of the health impacts is not possible or that further research should be done before the health impacts can be better explained and quantified. The Commission officials argue in some IAs that often in the case of health and environmental issues it is extremely difficult or even impossible to establish a meaningful direct

causal link between a certain option and the benefit it possibly, often only after a long time, can bring to society.

Moreover, DG EMPL and DG MOVE that published the second most IAs that are included in the second category[10] of this study have relatively high scores on the scorecard. It could be argued that in these policy areas it is easier or more straightforward to quantify and monetize health impacts. For example, the IAs that were published by DG MOVE as the lead DG relate to transportation and road safety. In most of these IAs, the health outcomes are expressed in road fatalities or number of accidents. Commission officials are able in these IAs to provide a Health Impact Assessment with more concrete results of the health impacts.

These results could mean that some DGs spend more resources on the assessment of human health in the IAs that they publish as lead DG. However, it is also possible that there are inherent difficulties in certain policy areas that make assessing health impacts difficult or even impossible. This could be in line with the fact that the Better Regulation Guidelines only request the Commission officials to analyze significant impacts to the degree that a sound methodology can be used and that the data can be gathered at a proportionate cost.

The role of the RSB

The RSB played an important role in improving the quality in terms of integrating Health Impact Assessment in multiple IAs. In every IA report, Commission officials indicate at the beginning of the annexes the corrections they made as a consequence of the opinion(s) of the RSB. I found that the RSB in multiple cases helped improve the quality relating to the 10 key criteria used in the scorecard in this study. The RSB is especially critical in multiple IAs about the lack of use of internal/external expertise and stakeholders' knowledge related to health. As a consequence, the Commission officials added and better referred to scientific evidence and stakeholders' views in the IAs and explained in more detail how stakeholders' concerns were addressed. The Commission officials also improved the identification of the health impacts in certain IAs as a consequence of the opinion of the RSB by better explaining the health impacts compared to the baseline and by better examining the different impacts on various categories of affected stakeholders. In addition, the RSB indicates in certain cases the lack of explanation of the methods used and the assumptions made to assess the health impacts. The Commission officials therefore added sensitivity analyses and better explained their methods in the IAs. These IA reports are as a result more transparent. Besides the 10 key criteria used in this study, the RSB also comments on the quality of the content of the Health Impact Assessment in the IAs. The RSB identifies the need for the addition of qualitative analyses of health impacts in certain IAs. In addition, the RSB acknowledges in several IAs the challenges to quantify certain kinds of impacts (incl. health). This might additionally explain why the IAs got low scores in general on the second area of the scorecard.

[10] See annex 1.

Conclusion

I draw several conclusions from my analysis of the quality of IAs in terms of integrating Health Impact Assessment. About half of the total amount of IAs published between 2018-2020 by the European Commission have a topic/an option with possible health-related impacts in any way. This is in line with the Health in All Policies approach of the EU that identifies that policies in non-health (care) sectors can have impacts on human health.

The Better Regulation Guidelines, however, indicate that EU policy-makers should assess the possible significant impacts that are as a consequence of a policy. After selecting the IAs with a topic/an option that has a possible significant health impact, the number of IAs considerably drop. This could partly be explained by the fact that Member States have the primary responsibility for public health and that they possibly already have measures in place to protect the health of their citizens. Another explanation could be that the EU does not consider the protection of human health enough as an important policy objective or topic.

In this research I use a scorecard method to evaluate the quality of EU IAs in terms of integrating Health Impact Assessment. I find that most IAs published between 2018-2020 that have a topic/an option with possible significant health impacts adequately meet the 10 key objective criteria on integrating Health Impact Assessment that are based on the Better Regulation Guidelines by the European Commission. This means that Commission officials in general follow the Better Regulation principles of the EU. The 10 key objective criteria that are based on the Better Regulation Guidelines focus on following items in an IA: a clear identification of the health impacts, use and referral to expertise and stakeholders' knowledge related to health, quantification and/or monetization of the health impacts, clear explanation and presentation of the assumptions made and methods used to assess the health impacts, comparison with a baseline scenario and a clear presentation of the results in the IA report and the executive summary.

However, there is still room for improvement for the quality of EU IAs in terms of integrating Health Impact Assessment. The IAs have relatively low scores in general on the second area in the scorecard which is focused on quantification and monetization of the health impacts. One explanation is that there exist inherent problems with certain policy areas that make adequately assessing health impacts difficult. For example, in certain IAs the Commission officials argue that for certain health issues it is extremely difficult or even impossible to establish a meaningful direct causal link between a certain option and the benefit it possibly, often only after a long time, can bring to society. This is in line with the fact that the Better Regulation Guidelines only request the Commission officials to analyze significant impacts for which a sound methodology can be used and data can be gathered at a proportionate cost. For this reason, the Better Regulation Guidelines find it important that the Commission officials also use qualitative analyses to assess health impacts.

There are certain shortcomings in the methodology used in this study to evaluate the quality of EU IAs in terms of integrating Health Impact Assessment. A score given in the scorecard to an IA may not always provide a useful measure of quality. An IA could receive a high score, but still be of poor quality if its calculations and estimates are inaccurate. Similarly, an IA with a low score could still be of an adequate quality if the scorecard items that the IA did not include were unknowable. This is the case in the IAs where the Commission officials do not quantify or monetize the health impacts because no sound methodology exist and data cannot be gathered at a proportionate cost.

I believe that the Regulatory Scrutiny Board is a good critic on the quality of EU IAs in terms of integrating Health Impact Assessment. It may, however, be beneficial to the EU if more resources were spend within/on the RSB on better scrutinizing the quality of IAs in terms of integrating Health Impact Assessment and other kinds of IA. This will result in balanced IAs where EU policy-makers more equally assess the economic, environmental and social impacts. In addition, the European Commission would clearly show this way that it is concerned with impacts on health as a consequence of EU policy measures.

Future research could use the results of this study to measure a possible time trend in the quality of IAs in terms of integrating Health Impact Assessment. The COVID-19 crisis might result in the EU spending more resources on scientific research relating to Health Impact Assessment in IAs.

In addition, future research could be done using a different method to evaluate the quality of the IAs included in this study. An expert could examine the quality of the IAs in terms of the assumptions made and the methods used to perform the Health Impact Assessment. Furthermore, an expert is also able to precisely decide and evaluate if a law or an initiative has possible impacts on health that are significant. This way, it could more clearly be analyzed if Commission officials properly performed a Health Impact Assessment in the IAs compared to the available data and methodologies that exist.

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Annexes

Annex 1

IAs included in category 1 and category 2.	
	IA accompanying the
2018	'(X)' *means that the IA is also included in category 2.*
1	Proposal for a COUNCIL REGULATION on establishing the European High Performance Computing Joint Undertaking
2	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on port reception facilities for the delivery of waste from ships, repealing Directive 2000/59/EC and amending Directive 2009/16/EC and Directive 2010/65/EU
3 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU Lead DG: DG SANTE
4 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the quality of water intended for human consumption (recast) Lead DG: DG ENV
5	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a multi-annual plan for the fisheries exploiting demersal stocks in the western Mediterranean Sea
6	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 810/2009 establishing a Community Code on Visas (Visa Code)
7 (X)	Proposal for a COUNCIL RECOMMENDATION on access to social protection for workers and the self-employed Lead DG: DG EMPL
8	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a European Labour Authority
9	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a multiannual plan for fish stocks in the Western Waters and adjacent waters, and for fisheries exploiting those stocks, amending Regulation (EU) 2016/1139 establishing a multiannual plan for the Baltic Sea, and repealing Regulations (EC) No 811/2004, (EC) No 2166/2005, (EC) No 388/2006, (EC) 509/2007 and (EC) 1300/2008)
10 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work Lead DG: DG EMPL
11	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on unfair trading practices in business-to-business relationships in the food supply chain
12	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the marketing and use of explosives precursors, amending Annex XVII to Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013 on the marketing and use of explosives precursors
13	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the protection of persons reporting on breaches of Union law
14	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the re-use of public sector information (recast)
15 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on type-approval requirements for motor vehicles and their trailers, and systems, components and separate technical units intended for such vehicles, as regards their general safety and the protection of vehicle occupants and vulnerable road users, amending Regulation (EU) 2018/… and repealing Regulations (EC) No 78/2009, (EC) No 79/2009 and (EC) No 661/2009 Lead DG: DG GROW
16	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 767/2008, Regulation (EC) No 810/2009, Regulation (EU) 2017/2226, Regulation (EU) 2016/399, Regulation XX/2018 [Interoperability Regulation], and Decision 2004/512/EC and repealing Council Decision 2008/633/JHA
17 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the labelling of tyres with respect to fuel efficiency and other essential parameters and repealing Regulation (EC) No 1222/2009

	Lead DG: DG ENER
18	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL setting CO2 emission performance standards for new heavy-duty vehicles
19	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on electronic freight transport information
20 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on streamlining measures for advancing the realisation of the trans-European transport network Lead DG: DG MOVE
21 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2008/96/EC on road infrastructure safety management Lead DG: DG MOVE
22	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of a framework to facilitate sustainable investment
23 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2009/103/EC of the European Parliament and the Council of 16 September 2009 relating to insurance against civil liability in respect of the use of motor vehicles, and the enforcement of the obligation to ensure against such liability Lead DG: DG FISMA
24	Proposal for a COUNCIL DIRECTIVE laying down the general arrangements for excise duty (recast)
25	Proposal for a COUNCIL DIRECTIVE amending Directive 92/83/EEC on the harmonization of the structures of excise duties on alcohol and alcoholic beverages
26 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the reduction of the impact of certain plastic products on the environment Lead DG: DG ENV
27 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on minimum requirements for water reuse Lead DG: DG ENV
28 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products Lead DG: DG GROW
29	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Regional Development Fund and on the Cohesion Fund
30	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Social Fund Plus (ESF+)
31	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Council Regulation (EC) No 1224/2009, and amending Council Regulations (EC) No 768/2005, (EC) No 1967/2006, (EC) No 1005/2008, and Regulation (EU) No 2016/1139 of the European Parliament and of the Council as regards fisheries control
32	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council
33	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing a Programme for the Environment and Climate Action (LIFE) and repealing Regulation (EU) No 1293/2013
34	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing rules on support for strategic plans to be drawn up by Member States under the Common agricultural policy (CAP Strategic Plans) and financed by the European Agricultural Guarantee Fund (EAGF) and by the European Agricultural Fund for Rural Development (EAFRD) and repealing Regulation (EU) No 1305/2013 of the European Parliament and of the Council and Regulation (EU) No 1307/2013 of the European Parliament and of the Council
35	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the Programme for single market, competitiveness of enterprises, including small and medium-sized enterprises, and European statistics and repealing Regulations (EU) No 99/2013, (EU) No 1287/2013, (EU) No 254/2014, (EU) No 258/2014, (EU) No 652/2014 and (EU) 2017/826

36	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination
37	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the 'Customs' programme for cooperation in the field of customs
38	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the InvestEU Programme
39	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Council Directive amending Directive 92/83/EEC on the harmonization of the structures of excise duties on alcohol and alcoholic beverages
40	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Maritime and Fisheries Fund and repealing Regulation (EU) No 508/2014 of the European Parliament and of the Council
41 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the reduction of the impact of certain plastic products on the environment* Lead DG: DG ENV
42 (X)	Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse* Lead DG: DG ENV
43	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres A contribution from the European Commission to the Leaders' meeting in Salzburg on 19-20 September 2018
44	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the Neighbourhood, Development and International Cooperation Instrument
45	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the European Cybersecurity Industrial, Technology and Research Competence Centre and the Network of National Coordination Centres
46 (X)	COMMISSION REGULATION (EU) …/… amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances Lead DG: DG ENV
2019	
47	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Regulation (EU) 2015/757 in order to take appropriate account of the global data collection system for ship fuel oil consumption data
48	COMMISSION DELEGATED DECISION (EU) …/… supplementing Directive 2003/87/EC of the European Parliament and of the Council concerning the determination of sectors and subsectors deemed at risk of carbon leakage for the period 2021 to 2030
49	COMMISSION DELEGATED REGULATION (EU) …/... supplementing Directive 2003/87/EC of the European Parliament and of the Council with regard to the operation of the Innovation Fund
50 (X)	COMMISSION DELEGATED REGULATION (EU) …/... supplementing Directive 2010/40/EU of the European Parliament and of the Council with regard to the deployment and operational use of cooperative intelligent transport systems Lead DG: DG MOVE
51	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for servers and data storage products pursuant to Directive 2009/125/EC of the European Parliament and of the Council and amending Commission Regulation (EU) No 617/2013
52 (X)	COMMISSION REGULATION (EU) …/… amending Annex III to Regulation (EC) No 1925/2006 of the European Parliament and of the Council as regards trans fat, other than trans fat naturally occurring in fat of animal origin Lead DG: DG SANTE
53	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Institute of Innovation and Technology (recast)
54	COMMISSION STAFF WORKING DOCUMENT IMPACT ASSESSMENT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Institute of Innovation and Technology (recast) and Proposal for a Decision of the European Parliament and of the Council on the Strategic Innovation Agenda of the

	European Institute of Innovation and Technology (EIT) 2021-2027: Boosting the Innovation Talent and Capacity of Europe
55	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for light sources and separate control gears pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulations (EC) No 244/2009, (EC) No 245/2009 and (EU) No 1194/2012
56	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for electronic displays pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EC) 642/2009
57	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for refrigerating appliances with a direct sales function pursuant to Directive 2009/125/EC of the European Parliament and of the Council
58	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for household washing machines and household washer-dryers pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1015/2010
59	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for household dishwashers pursuant to Directive 2009/125/EC of the European Parliament and of the Council amending Commission Regulation (EC) No 1275/2008 and repealing Commission Regulation (EU) No 1016/2010
60	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for external power supplies pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 278/2009
61	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for electric motors and variable speed drives pursuant to Directive 2009/125/EC of the European Parliament and of the Council, amending Regulation (EC) No 641/2009 with regard to ecodesign requirements for glandless standalone circulators and glandless circulators integrated in products and repealing Commission Regulation (EC) No 640/2009
62	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for refrigerating appliances pursuant to Directive 2009/125/EC of the European Parliament and of the Council and repealing Commission Regulation (EC) No 643/2009
63	COMMISSION REGULATION (EU) …/… laying down ecodesign requirements for welding equipment pursuant to Directive 2009/125/EC of the European Parliament and of the Council
2020	
64 (X)	COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS Stepping up Europe's 2030 climate ambition Investing in a climate-neutral future for the benefit of our people Lead DG: DG CLIMA
65	COMMUNICATION FROM THE COMMISSION Guidelines on certain State aid measures in the context of the system for greenhouse gas emission allowance trading post 2021
66 (X)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL amending Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Lead DG: DG EMPL
67	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on adequate minimum wages in the European Union
68	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013
69	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on European data governance (Data Governance Act)
70 (X)	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL concerning batteries and waste batteries, repealing Directive 2006/66/EC and amending Regulation (EU) No 2019/1020 Lead DG: DG ENV
71	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the resilience of critical entities

72	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on measures for a high common level of cybersecurity across the Union, repealing Directive (EU) 2016/1148

**Disclaimer. The interface of the European Commission's website changed considerably during the writing of this study and after the IAs were extracted.*
**IA 27 and 42 are the same IA. It was published twice on the European Commission's website.*
**IA 26 and 41 are the same IA. It was published twice on the European Commission's website.*