

TOOL #31. HEALTH IMPACTS

1. INTRODUCTION

The Treaty (Article 168 TFEU) states that a "high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities", which also relates to the approximation of laws in the single market (Article 114 (3) TFEU). Furthermore, the Charter of Fundamental Rights (art. 35) establishes that "everyone has the right of access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices."

Human health is a fundamental value and an investment in economic growth and social cohesion. Healthy individuals are more likely to be employed and less likely to be socially excluded. A healthy workforce is more productive, and healthcare services and health industries (pharmaceuticals, medical devices, and health research) are an important knowledge-intensive economic sector that enables people to maintain and improve their health and creates a steady demand for workers.

2. ARE IMPACTS ON HEALTH POTENTIALLY SIGNIFICANT?

Health impact is a horizontal concern across many policies. In general, health impacts should be examined if a proposal affects or could affect in the short or/and long term the health and safety of individuals or populations or the national healthcare systems. Furthermore, a number of policies not primarily addressed at the healthcare systems are nonetheless influencing the rules that relate to the provision and quality of healthcare services by impacting on their staff, equipment, communication and infrastructure. For example, if a policy changes the rules on lifting weights at work, this may have an effect on staffing a hospital, as more nurses may be needed to lift patients.

EU legislation and policies can have an impact on health, either directly or indirectly. An example for direct impacts is legislation banning asbestos³²². It has a direct health impact, as asbestos was proven to cause cancer. An indirect impact on health could result from a modification of the socio-economic and environmental determinants of health³²³ which also influence morbidity and mortality. Typically improvements in road safety would reduce the number of accidents and the number of people injured in road accidents. Similarly, changes in air quality impact on respiratory conditions.

³²² Directive 1999/77/EC

³²³ For a conceptual clarification on Social Determinants of health and action, see a discussion paper prepared by the WHO (apps.who.int/iris/bitstream/10665/44489/1/9789241500852_eng.pdf) and WHO (2003) The solid facts: social determinants of health (www.euro.who.int/document/e81384.pdf)

Box 1. Questions to help identify whether there might be health-related impacts

Direct impacts

- *Does the option create (or reduce) health risks or does it affect the safety of patients?*

For instance by modifying chemical substances (e.g. chemicals, pesticides in food, contaminants, etc.) or other factors (e.g. radiation, noise etc.) bearing an influence on the natural environment and the human body (e.g. air, soil and water quality, noise, unsafe consumer products³²⁴)

- *Does the option affect the effectiveness and sustainability of healthcare and long-term 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?*

For all direct and indirect effects it should be examined if a specific population (including risk groups such as children, persons with disabilities, (pregnant) women, elderly, low-income groups) or specific geographical areas are affected differently and disproportionately by the option, resulting in increased (or reduced) inequalities in health status³²⁵.

In any case, the identification of significant impacts on health of a proposal/option should be informed by the outcomes of stakeholder consultation. The specific expertise of health stakeholders may prove valuable in identifying and properly assessing the impact on health of a given option.

3. HOW TO ASSESS IMPACTS ON HEALTH?

There is no uniform methodology to analyse and assess impact of policies on human health. The identification of the most appropriate methodology to use will depend on the characteristics or nature of the options under assessment³²⁶. To assess impacts on health

³²⁴ See the Tool #32 on *Consumers*.

³²⁵ Linked to this analysis is also the dimension of discrimination (e.g. in the access to healthcare) on grounds of e.g. racial, ethnic or social, religion, or belief, disability, age or sexual orientation, see possibly other thematic fiche by DG JUST?

³²⁶ For an example of choice of indicators, please see: "Study to measure the implementation of EU health policies at national, regional and local levels, assessing the utility of existing indicators for this task available at: http://ec.europa.eu/health/strategy/evaluation/index_en.htm

it is necessary to have at least a general knowledge of public health³²⁷ policies and health systems³²⁸ and identify the populations and timeframe concerned. These elements are necessary for the estimation of costs and benefits.

3.1. Methods

Choosing the right methodology for assessing health impacts depends on the specific policy context. First of all, it is recommended to check how the same or similar potential health impacts have already been dealt with in existing Commission IAs, at Member State level or by third parties more generally³²⁹.

To assess direct and indirect health impacts monetary and non-monetary methodologies can be used.

The non-monetary approaches can be used to quantify the health benefits of a given intervention without monetizing it; to compare different intervention for the same specific health problem using cost and health outcomes (cost-effectiveness analysis) or in cases in which it is needed to compare different interventions for different health problems (cost-utility analysis).

The monetary approaches can be used if the aim is to present a comprehensive comparison of costs and benefits, although such analysis may not always prove to be possible or the most appropriate when evaluating options impacting human health (note that monetisation is not suitable when looking at the health of a specific individual).

The IA should aim to quantify the costs of the proposal as well as its benefits as much as possible, and measure impacts concerning implementation of policies to the extent it is proportionate to do so. The IA should be transparent on how data were gathered and from which sources to generate monetised information. In addition uncertainties as regards quantification of costs or benefits (for instance due to the lack of reliable information) should be clearly spelled out to avoid a misleading impression of certainty.

³²⁷ According to the World Health Organisation, public health refers to “all organized measures (whether public or private) to prevent disease, promote health, and prolong life among the population as a whole. Its activities aim to provide conditions in which people can be healthy and focus on entire populations, not on individual patients or diseases. Thus, public health is concerned with the total system and not only the eradication of a particular disease”.

³²⁸ Health systems are defined as those systems that aim to deliver healthcare services to patients – be they preventive, diagnostic, curative, and palliative – whose primary purpose to improve health (see: COM(2014) 215 final).

³²⁹ See for instance the “Public health England” website that provides a gateway to Health Impact Assessments (www.apho.org.uk/default.aspx?RID=44539)

Non-monetary approaches³³⁰

- **Quality Adjusted Life Years (QALY)** measures health *gains*. It uses available information on objective improvements in health/quality of life (QoL) and combines it with the duration of that improvement. The longer the life expectancy, the higher the QALY gain (therefore, a QALY gain would be highest for interventions aimed at children). QALY is commonly used in economic evaluations of specific health interventions (e.g. a medicine may result in QALY gains and its cost-effectiveness is calculated as "EUR per added QALY")³³¹. Values are generally derived from surveys of patients and doctors (stated preferences) and represent an average among different social groups. QALYs allow aggregation over the number of individuals affected. One can use equal weights for each individual or adjust weights to reflect preferences for particular target groups. Future life years may be discounted using a common discount factor.
- **Disability Adjusted Life Years (DALY)** measures the number of quality adjusted years *lost* because of illness/disability in comparison to the benchmark scenario (in general good health status without disability). Originally a measure of the burden of disease³³², it is also used to estimate the cost-effectiveness of interventions in terms of cost per DALY averted are calculated as the sum of Years of Life Lost (YLL – number) and Years Lost due to Disability (YLD). Values for YLL are derived from Life Expectancy, and values for YLD are calculated on the prevalence of specific conditions that are age-weighted and discounted (basing on attitude surveys).
- **Healthy Life Years (HLY)**³³³ indicates the number of years a person of a certain age can expect to live without disability. They are therefore less sensitive to health impacts than QALYs and DALYs. HLY is included in the set of indicators used in the Europe 2020 strategy. In 2012, HLY at birth in the EU was at 61.3 years for males and 61.9 years for females.

Monetary approaches

- **Preference Based approaches.** The aim of the preference based approaches is to compare the benefits of different policy options by placing an implicit monetary value on health benefits as is, for example, often done in the transport sector to inform decision on safety measures. While the use of preference based approaches can raise

³³⁰ For a discussion of the comparative merits of QALYs and DALYs, see: Sassi (2006), Calculating QALYs, comparing QALY and DALY calculations, Health Policy Plan (21/5): 402-408. (doi: 10.1093/heapol/czl018) (<http://heapol.oxfordjournals.org/content/21/5/402.full.pdf+html>)

³³¹ For an example of the use of QALY, see: http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2163_en.pdf and http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2008/sec_2008_2956_en.pdf

³³² See the WHO Global Burden of Disease reports (www.who.int/topics/global_burden_of_disease/ and <http://www.healthdata.org/>) including for additional information on weighting and discounting.

³³³ For general information on HLY, see www.ec.europa.eu/health/indicators/healthy_life_years/index_en.htm; for more specific information on the indicator, see www.ec.europa.eu/eurostat/cache/metadata/en/tsdph100_esmsip.htm

ethical concerns and criticism, they cannot – and do not seek to – place a monetary value on life.

These methods analyse individuals' stated or revealed preferences with respect to small changes in low-probability risks: while no one would trade their life for a sum of money, most people will be prepared to choose between safety equipment with different prices and offering different levels of safety, or between different ways of crossing a street compared to the saving of time. This can be measured by using the concepts of Willingness To Pay (WTP) for an improvement or Willingness To Accept (WTA) compensation for a worsening³³⁴. Two concepts that make use of these methodologies are the Value of a Statistical Life (VOSL) and the Value of a Statistical Life Year (VOLY)^{335, 336}.

Box 2. VOSL and VOLY approaches

Value of Statistical Life (VOSL)

- The VOSL is derived by investigating individuals' *WTP for a lower risk* of mortality, divided by that risk reduction. As such, the VOSL method does not measure the value of a life *per se*, instead it puts a monetary value on the willingness to accept slightly higher or lower levels of risk.
- The OECD has undertaken both a literature review and primary analysis to better understand the right values to use in policymaking. It proposed a range for the average adult VOSL for the EU of USD 1.8 million – 5.4 million (2005-USD), with a base value of USD 3.6 million. These base values and ranges should be updated as new VOSL primary studies are conducted³³⁷.

Value of Statistical Life Year (VOLY)

- The VOLY measures more generally the *WTP for an increase of one additional year of life expectancy*. However, as the VOLY is deemed constant across lifetime, assessments using VOLY and VOSL can produce conflicting results according to the demographics of the population considered.
- Overall, it should be noted that neither VOSL nor VOLY provides a measure of the quality of life. Ideally, a more comprehensive assessment would combine preference-based approaches with non-monetary approaches (outlined in the section above, on Non-monetary approaches).

³³⁴ See Tools #59 on *Methods to estimate costs and benefits*.

³³⁵ For more in-depth analysis of the Value of a Statistical Life, including a discussion of VOLY, see: http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01. For an example of use of VOLY and VSL in a recent cost-benefit analysis on air quality effects on health, see: http://www.iiasa.ac.at/web/home/research/researchPrograms/MitigationofAirPollutionandGreenhousegases/TSAP_CBA_corresponding_to_IIASA11_v2.pdf

³³⁷ http://www.oecd.org/env/tools-evaluation/mortalityriskvaluationinenvironmenthealthandtransportpolicies.htm#Executive_Summary

- **Accounting style' approaches.** The 'accounting style' approaches measure only certain aspects of health impacts and should be therefore treated with caution.

The *Cost of Illness method* is a rather simple measure comprising only the medical expenses related to the incidence of an illness. If an option lowers the rate of occurrence of an illness the saved medical expenses can be estimated and constitute a benefit. Conversely, if an option leads to an aggravation of a health situation, one can state the associated relevant costs.

However, the usefulness of this method is limited as it often does not include other indirect costs to society such as loss of hours worked, or how people value their own health. Also, in some situations it leads to perverse results: for example, an action that kills somebody who otherwise would have spent time in hospital would be seen as a benefit using the COI approach.

The *human capital method* tries to measure the loss of future earnings in case of disability or premature death. It can also be interpreted as a measure of the loss to social welfare caused by death / disability / lower productivity. However, this method leads to different values of lives depending on the projected future earnings (which could raise ethical concerns) and does not account for people who are outside the workforce. Average values could be used to lessen these concerns or if the individuals affected by an option cannot be identified precisely enough.

It is recognised that there are areas in which quantification is particularly complex or where it is inherently difficult to predict with accuracy the potential costs or benefits of a policy option (e.g.: regarding introduction of new products, services or technologies). In this case, quantitative assessments may be presented as ranges to take into account the possible margin of error or uncertainty associated with forecast costs and benefits.

Box 3. Assessment of Impacts Health vs Health Technology Assessment

- The assessment of impacts on health can build on methods typically used for Health Technology Assessment (HTA).
- HTA is the systematic evaluation of properties, effects, and/or impacts of health technology (diagnostic and treatment methods, medical equipment, pharmaceuticals, etc.) which often relies on economic modelling for the quantification results. For instance, Quality Adjusted Life Years (QALYs, see below), are often used in HTA in relation with reimbursement decisions. In this context, substantial research was conducted on the concept of monetary thresholds for QALYs (i.e. threshold below which an intervention would be cost-effective). Dialysis costs (USD 50,000 / QALY in the USA; GBP 20,000 to 30, 0000 in the UK; and EUR 10,000 to 80,000 in the NL) have been used as a standard to retrospectively analyse reimbursement decisions. The WHO has emphasised the importance to adjust the threshold to the income of the country (suggesting using 3 times GDP per Capita instead)³³⁸. However, there are only a limited number of countries that define such threshold in practice.
- Overall, HTA tools can be useful to quantify the effects of a proposal on health. However, these tools should be used carefully outside the HTA context due to a

³³⁸ <http://www.who.int/choice/cost-effectiveness/en/>

number of methodological constraints (e.g. the intervention population for HTA is very precisely defined, as well as the timing and nature of interventions etc.).

4. CONTEXT SPECIFIC ESTIMATES

Where policy specific estimates of the health impacts can be obtained – and are considered reliable – they should be used in the impact assessment. However, where no such research has been undertaken, prior estimates from other policy areas indicated above should be used as approximations.

In all circumstances, both the quantitative and monetary estimates should be mentioned. For example the estimate of the number of lives that would be saved should be presented together with the monetary value assumed for the benefits.

In any case, the monetary results (costs and benefits) should be discounted, and sensitivity analysis to see how changes in the parameters affect the results should be performed. The European Network for Health Technology Assessment (EUnetHTA) works on elaborating methodological guidelines for health economic evaluations (including a reflection on discounting³³⁹).

The European Chemicals Agency (ECHA) has developed reference WTP values for the monetisation of health endpoints by Member States (when preparing "restrictions" on the use of chemicals)³⁴⁰. These are presented in the table below:

Health outcome	Value (in 2012 €) ^f
Premature death (generic) ^b	€3,500,000 (lower value) €5,000,000 (higher value)
Cancer morbidity (generic) ^c	€410,000/case
Statistical pregnancy ^d	€21,600/case (lower value) €40,700/case (higher value)
Very low birth weight ^e	€126,200/case (lower value) €405,500/case (higher value)
Birth defect, minor ^e	€4,300/case (lower value) €41,800/case (higher value)
Birth defect, major external ^e	€25,700/case (lower value) €329,800/case (higher value)
Birth defect, major internal ^e	€128,200/case (lower value) €711,800/case (higher value)
Mild, acute dermatitis (two weeks) ^f	€227/case

³³⁹ <http://www.eunetha.eu/>

³⁴⁰ https://echa.europa.eu/documents/10162/13637/seac_reference_wtp_values_en.pdf/403429a1-b45f-4122-ba34-77b71ee9f7c9

Severe, chronic dermatitis (periodic flare ups) ^f	€1,800/year (lower value) €12,000/year (higher value)
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^a 2012 is used as baseline year because the survey studies were conducted then. It should be noted though that the values need to be inflation-adjusted when used in applications for authorisations or restriction proposals;

^b This value represents the marginal trade-off between survival probability and income (also known as “Value of Statistical Life” or “Value of a Prevented Fatality”). Notably, the VSL values obtained in ECHA (2014c) are consistent with recent meta-analyses of VSL studies, see Section 4 of ECHA (2016) for references;

^c This value expresses the WTP to avoid any disutility caused by the cancer morbidity in addition to premature death, see ECHA (2014c) and Section 4 of ECHA (2016) for more details;

^d This value reflects the WTP of couples with infertility problems to conceive, see ECHA (2014b) and Section 3 of ECHA (2016) for more details;

^e Detailed descriptions of the symptoms evaluated are given in ECHA (2014b);

^f Detailed descriptions of the symptoms evaluated are given in ECHA (2014a).

5. INFORMATION SOURCES AND BACKGROUND MATERIAL

5.1. Consultation

- DG SANTE can assist in identifying appropriate health policy stakeholders at EU level, who would be able to help determining or evaluating a possible impact on health. For health impacts related to environmental impacts, DG Environment can assist in identifying appropriate stakeholders at EU level.
- The **EU Health Policy Forum**³⁴¹ is a group of about 50 European stakeholder organisations committed to health: public-health non-governmental organisations and patients' organisations, organisations representing health professionals and trade unions, health service providers, health insurance bodies and businesses.
- The independent non-food **scientific committees**³⁴² provide scientific advice on consumer safety, public health and the environment when the Commission prepares proposals.
- SANTE's **Expert Panel on effective ways of investing in health** can provide advice on direct and indirect health impacts and other health and healthcare related topics.

Finally, the **HTA Network**³⁴³ and the Joint Action on HTA³⁴⁴ can help identifying or gathering relevant Health Technology Assessment (HTA).³⁴⁵

³⁴¹ http://ec.europa.eu/health/interest_groups/eu_health_forum/policy_forum/index_en.htm

³⁴² Scientific Committee on Consumer Safety (SCCS), Scientific Committee on Health and Environmental Risks (SCHER), Scientific Committee on Emerging and Newly Identified Health Risks (SCENHIR).

³⁴³ The Health Technology Assessment Network is a voluntary Network set up under Article 15 of Directive 2011/24. It gathers mainly Ministries of Health or authorities responsible for decisions on HTA, appointed by Member States. Its scope of activities is on strategic issues. It is supported by the Joint Action on HTA (EUnetHTA- see below) for technical issues. http://ec.europa.eu/health/technology_assessment/policy/network/index_en.htm

³⁴⁴ EUnetHTA is a Joint Action, co –funded by the Health Programme of the European Commissions (DG SANTE) and participating organisations. It gathers mainly national and regional HTA bodies, performing HTA at national/regional level. Its scope of activities is on scientific and technical issues. (see: <http://www.EUnetHTA.eu>)

5.2. Methodological tools

Health and the Environment

- HEIMTSA (Health and Environment Integrated Methodology and Toolbox for Scenario Assessment): a first attempt at monetising a range of health impacts³⁴⁶
- INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe)³⁴⁷
- Risk Assessment from Policy to Impact Dimension (RAPID) 2009-2012³⁴⁸

URGENCHE/PURGE & EU (methodologies for quantifying the health impact under different policy scenarios for the reduction of greenhouse gas emissions / methodological framework to assess the overall risks and benefits for health of GHG mitigation policies).

Economic valuation

- National Institute for Health and Care Excellence: How NICE measures value for money in relation to public health interventions³⁴⁹
- WHO Guide to Cost effectiveness³⁵⁰

Health Impact Assessments

- Health Impact Assessment website of 'Public Health England'³⁵¹
- DYNAMO-HIA (2011) Development of a dynamic modelling tool to assess health impact of policies
- European Policy Health Impact Assessment – EPHIA (2004)³⁵²

³⁴⁵ Health Technology Assessment (HTA) is a multidisciplinary process that summarises information about the medical, social, economic and ethical issues and impacts related to the use of a health technology (e.g. a medicine, medical equipment or rehabilitation method).

³⁴⁶ <http://www.heimtsa.eu/>

³⁴⁷ <http://www.intarese.org/about>

³⁴⁸ http://www.sdu.dk/en/om_sdu/institutter_centre/ist_sundhedstjenesteforsk/forskning/forskningsenheder/sundhedsfremme/forskningsprojekter/rapid

³⁴⁹ <http://publications.nice.org.uk/how-nice-measures-value-for-money-in-relation-to-public-health-interventions-lgb10b/introduction>

³⁵⁰ http://www.who.int/choice/publications/p_2003_generalised_cea.pdf

³⁵¹ http://www.apho.org.uk/default.aspx?QN=P_HIA

- WHO toolbox on Health Impact Assessment³⁵³
- Health inequalities in Health Impact Assessments³⁵⁴
- EU Health Systems Performance Assessment tool³⁵⁵

5.3. Studies

- ECHA (2016) Valuing selected health impacts of chemicals.
- OECD (2012) Mortality Risk Valuation in Environment, Health and Transport Policies³⁵⁶
- EU-OSHA (2014) Estimating the cost of accidents and ill-health at work: A review of methodologies³⁵⁷
- European Observatory on Health Systems (2007) study on the effectiveness of HIA³⁵⁸
- Marsh et al. (2012) Estimating cost-effectiveness in public health: a summary of modelling and valuation methods³⁵⁹
- Roberta Ara, Allan Wailoo (2012) Using Health State Utility Values in Models Exploring the Cost-Effectiveness of Health Technologies³⁶⁰
- Divajeva et al (2014) Economics of chronic diseases protocol: cost-effectiveness modelling and the future burden of non-communicable disease in Europe³⁶¹

³⁵² http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_a6_frep_11_en.pdf and http://ec.europa.eu/health/ph_projects/2001/monitoring/fp_monitoring_2001_frep_11_en.pdf

³⁵³ <http://www.who.int/hia/tools/en/>

³⁵⁴ <http://www.equityaction-project.eu/about/health-inequalities>

³⁵⁵ http://ec.europa.eu/health/health_policies/impact/assessment_tool/index_en.htm

³⁵⁶ http://www.oecd-ilibrary.org/environment/mortality-risk-valuation-in-environment-health-and-transport-policies_9789264130807-en;jsessionid=5b4ha1811u6rm.x-oecd-live-01

³⁵⁷ <https://osha.europa.eu/en/publications/reports/estimating-the-costs-of-accidents-and-ill-health-at-work/view>

³⁵⁸ <http://www.euro.who.int/en/about-us/partners/observatory/studies/effectiveness-of-health-impact-assessment-the>

³⁵⁹ <http://www.healtheconomicsreview.com/content/2/1/17>

³⁶⁰ <http://www.sciencedirect.com/science/article/pii/S1098301512016087>

³⁶¹ www.biomedcentral.com/1471-2458/14/456

- CEPS, Economisti Associati (2013) Assessing The Costs And Benefits Of Regulation³⁶²

5.4. Data sources

- EUROSTAT : Including the European Core Health Indicators (ECHI)³⁶³,
- Health at a glance: Europe – an EU publication, issued once in 2 years in collaboration with the OECD³⁶⁴,
- OECD Health Statistics (on Health Expenditure, Health care resources, Health care activities)³⁶⁵
- WHO, WHO Regional office for Europe³⁶⁶
- European Observatory on Health Systems and Policies³⁶⁷
- The Cost-Effectiveness Analysis (CEA) Registry, Boston, MA³⁶⁸.
- The Cochrane Collaboration – systematic reviews³⁶⁹
- PubMed - the free US resource for research and medical publications³⁷⁰

³⁶² www.ec.europa.eu/smart-regulation/impact/commission_guidelines/docs/131210_cba_study_sg_final.pdf

³⁶³ http://ec.europa.eu/health/indicators/echi/list/index_en.htm and http://epp.eurostat.ec.europa.eu/portal/page/portal/health/health_care/data/database

³⁶⁴ http://ec.europa.eu/health/reports/european/health_glance_2012_en.htm and <http://www.oecd.org/els/health-systems/health-at-a-glance.htm>

³⁶⁵ <http://www.oecd.org/health/health-systems/>

³⁶⁶ <http://www.who.int/research/en/> and <http://www.euro.who.int/InformationSources>

³⁶⁷ http://www.euro.who.int/observatorv/publications/20020522_1

³⁶⁸ <https://research.tufts-nemc.org/cear4/Home.aspx>

³⁶⁹ <http://www.cochrane.org/>

³⁷⁰ pubmed.gov