National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Health Impact Assessment in REACH restriction dossiers

Development of a structured HIA format

RIVM Report 2014-0032

W.P. Jongeneel et al.

National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Health Impact Assessment in REACH restriction dossiers

Development of a structured HIA format

RIVM Report 2014-0032

Colophon

W.P. Jongeneel (author), RIVM
J.K. Verhoeven (author), RIVM
B.G.H. Bokkers (author), RIVM
W. ter Burg (author), RIVM
A.G. Schuur (author), RIVM

Contact:
Rob Jongeneel
Centre for Safety of Substances and Products (VSP)
Rob.Jongeneel@rivm.nl

This investigation has been performed by order and for the account of the Ministry of Health, Welfare and Sports (VWS), within the framework of kennisvraag 5.1.3 Beleidsadvisering Cosmeticabeleid en chemische productveiligheid

This is a publication of:
National Institute for Public Health and the Environment
P.O. Box 1 | 3720 BA Bilthoven
The Netherlands
www.rivm.nl/en

Synopsis

Health Impact Assessment in REACH restriction dossiers

EU legislative measures make it possible to restrict the use of a chemical for specific applications, for example in consumer products. Such policy measures are aimed at limiting human exposure to the chemical concerned. However, the extent of the assumed decrease in adverse health effects is often unknown. The REACH restriction and authorisation processes include an obligation to perform an assessment of the expected health effects, a so-called 'health impact assessment'. RIVM has developed a structured format in order to streamline this assessment. This format helps policy-makers to assess the effects of policy decisions.

The structured format consists of a compact table presenting the key elements of a health impact assessment. It helps to present a concise overview of the expected health impact, together with the relevant assumptions and uncertainties. Adhering to this format ensures that the essential elements of a health impact assessment are addressed and that assumptions are substantiated.

The structured format has been developed based on current literature. In addition, the use of the structured format has been tested on previously performed health impact assessments in REACH restriction dossiers. This resulted in the identification of a number of omissions and points for improvement, followed by a revision of the structured format. The structured format is easy to use for those performing or reviewing a health impact assessment in a REACH restriction dossier or authorisation request.

Keywords: health impact assessment, REACH, chemical legislation, restriction dossier, authorisation

Publiekssamenvatting

Gezondheidseffectschatting in REACH-restrictiedossiers

Het gebruik van chemische stoffen, bijvoorbeeld in consumentenproducten, kan door Europese maatregelen worden beperkt zodat mensen minder aan deze stoffen worden blootgesteld. De mate waarin deze beleidsmaatregelen bijdragen aan een afname van nadelige gezondheidseffecten moet worden onderbouwd. Voor een REACH-restrictiedossier of -autorisatieaanvraag worden de verwachte gezondheidseffecten geanalyseerd met een gezondheidseffectschatting (Health Impact Assessment). Om deze analyse optimaal te kunnen benutten, heeft het RIVM een handzame leidraad ontwikkeld. Hiermee worden beleidsmakers geholpen om de effecten van voorgenomen beleidsmaatregelen te bepalen.

De leidraad bevat een beknopte tabel met de belangrijkste elementen die nodig zijn om te kunnen schatten welke gezondheidseffecten optreden. Het document geeft een helder beeld van de aannames die in de analyse aan de orde zijn. Op deze manier wordt duidelijk of met onzekerheden rekening is gehouden en of de gemaakte aannames zijn onderbouwd.

De leidraad is ontwikkeld op basis van de huidige literatuur. Daarnaast is de leidraad toegepast op schattingen van gezondheidseffecten die voor bestaande restrictiedossiers zijn uitgevoerd. Op die manier zijn omissies en verbeterpunten in kaart gebracht waarmee de leidraad is verbeterd. De tabel kan gemakkelijk toegepast worden door degenen die de gezondheidseffectschattingen opstellen en de commissies die ze beoordelen.

Kernwoorden: Gezondheidseffectschatting, REACH, chemicaliënbeleid, restrictiedossier, autorisatieaanvraag

Contents

List of Abbreviations

BAU	Business as usual
BMD	Benchmark dose
CBA	Cost–benefit analysis
CMR	Carcinogenic, mutagenic or reprotoxic
COI	Cost of illness
DALY	Disability-adjusted life year
DMEL	Derived minimal effect level
DNEL	Derived no-effect level
ECHA	European Chemicals Agency
HIA	Health impact assessment
LOAEL	Lowest observed adverse effect level
NOAEL	No observed adverse effect level
PBT	Persistent, bioaccumulative and toxic
PS	Policy scenario
QALY	Quality-adjusted life year
RAC	Risk Assessment Committee
RCR	Risk characterisation ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EC Regulation No. 1272/2008)
RIVM	National Institute of Public Health and the Environment
RMO	Risk management option
RPA	Risk & Policy Analysts Ltd
SEA	Socio-economic analysis
SEAC	Socio-Economic Analysis Committee
SVHC	Substance of very high concern
TWA	Time weight average
VOLY	Value of statistical life-years lost
VOSL	Value of a statistical life
vPvB	Very persistent and very bioaccumulative
WHO	World Health Organization

Summary

Within the European REACH legislation, assessment of the potential impacts of proposed policy measures is an integral part of the decision-making process. In a socio-economic analysis, one of the impacts assessed is that on human health. This health impact assessment (HIA) describes the expected difference in health in the population between the current situation and the situation after implementation of the proposed policy measure. Such impact assessments are complex and coincide with substantial uncertainties. Therefore, a clear description of and justification for the input parameters used and the assumptions made are vital for a clear understanding of the outcome.

This report focuses on the description and presentation of various elements of the HIA in the background document of a REACH Annex XV restriction dossier. This background document is the basis of the scientific committee's opinion on the proposed restriction. A structured format is proposed to aid the preparation and evaluation of HIAs. This structured format is developed through an iterative approach using existing literature and surveying HIAs in the background documents of previous restriction dossiers. The report does not assess or review the approach, assumptions or values of the HIAs themselves but is intended solely to establish a transparent format that will be useful in practice.

The structured format is a compact table presenting the key elements of an HIA. Four main steps are identified. In the first step, the key elements of the definitions of the goal, scope and scenarios of the HIA are stated. The second step is the impact assessment itself, for which three various detail levels are identified. The third step is the evaluation of the health impact and the fourth and final step is the uncertainty and sensitivity analyses. The table consists of multiple columns, in which it may be stated whether the specific elements of the HIA are defined and justified. This proposed structured format is not intended to judge the definition or justification of the specific elements but to facilitate the reporting of all crucial elements and justification of the input parameters when conducting an HIA.

Not all the elements in the table need to be included in an HIA. However, the table helps to explain why certain elements have or have not been included in a particular case and prevents the omission of crucial elements of an HIA. The table shows the key elements of the HIA that has been performed and ensures that the basic assumptions taken are substantiated, thereby providing a quick overview for a more systematic evaluation.

Our first experiences of using the table in this study to describe HIAs show that it is easy to use. The format presented is a starting point and can be further improved when the table is used in practice. Following this format when preparing or evaluating an HIA within REACH will ensure that all crucial elements are addressed, and assumptions are substantiated. It is recommended that the structured format be included

in the health impact assessment section of restriction dossiers or authorisation requests to provide an overview of the key elements.

1 Introduction

Within several legislative frameworks and in policy decision-making there is a compelling need to assess the impacts of a proposed policy measure before putting the proposed measure into practice. Policy makers need impact assessments to ensure the proportionality of their decisions and in some cases they are even obliged to do so by law. Ideally, such impact assessments will provide insight into the total costs and benefits as well as into the distribution of the effects within society. In practice, such impact assessments are complex and mostly based on assumptions. Uncertainties can be substantial and a change of input parameters and assumptions can lead to substantially different outcomes. Therefore, a transparent presentation of the input to an assessment is essential for a clear understanding of the outcome. This report focuses on impact assessments performed under the European REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) regulation – more specifically, on the health impact assessment (HIA) performed as part of the socio-economic analysis (SEA) included in the background document of REACH Annex XV restriction dossiers.

Looking in more detail at HIAs recently performed within REACH, it can be seen that various approaches, elements and assumptions are applied in these HIAs. Furthermore, the HIAs are reported in various levels of detail and not always in a structured and transparent way. The aim of this report is to provide a structured format for the preparation and evaluation of HIAs within the scope of REACH, and it focuses on the description and presentation of the various elements of an HIA.

1.1 Scope and outline of the report

Our analysis focuses on the description and presentation of the various elements in the HIA included in the background document of a REACH Annex XV restriction dossier. A structured format can support the evaluation of the HIA by the Committee for Socio-economic Analysis (SEAC) and enhance the level of consistency in REACH dossiers. The report will survey several HIAs presented in the final version of background documents publicly available until November 2014. This survey is performed with the aim of developing and evaluating the HIA format, rather than of evaluating the individual assessments. In this report we will not review the current methodologies for conducting an HIA, nor develop new methodologies. Judgements of the quality of the available HIAs and underlying approaches, assumptions and values are also outside the scope of this survey.

This report reflects the outcome of an iterative development and refinement of the structured format. The structured format was developed in parallel with the assessment of the available HIAs. As a result, the structured format was adapted throughout the project as new insights emerged and experience was gained.

Chapter 2 briefly introduces the REACH regulation and health impact assessment. In Chapter 3 some of the available guidance on conducting an HIA within chemical legislation is briefly reviewed. In Chapter 4 the structured format is presented. In Chapter 5 the HIAs included in the background documents surveyed are briefly described and assessed using the structured format. Chapter 6 discusses the format and gives recommendations for further work and possible implementation.

2 The European REACH regulation and health impact assessment

This section will give a brief introduction to the REACH regulation, the restriction and authorisation procedures under REACH, and the concept of an HIA.

2.1 The REACH regulation

A short introduction to the REACH regulation is given on the website of the European Chemicals Agency (ECHA):
REACH is a regulation of the European Union, adopted to improve the protection of human health and the environment from the risks that can be posed by chemicals, while enhancing the competitiveness of the EU chemicals industry. It also promotes alternative methods for the hazard assessment of substances in order to reduce the number of tests on animals. In principle, REACH applies to all chemical substances; not only those used in industrial processes but also in our day-to-day lives, for example in cleaning products, paints as well as in articles such as clothes, furniture and electrical appliances. Therefore, the regulation has an impact on most companies across the EU.

REACH places the burden of proof on companies. To comply with the regulation, companies must identify and manage the risks linked to the substances they manufacture and market in the EU. They have to demonstrate to ECHA how the substance can be safely used, and they must communicate the risk management measures to the users. If the risks cannot be managed, authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones. REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals. It entered into force on 1 June 2007. (ECHA 2015)

More information on REACH is available on the ECHA website: http://www.echa.europa.eu/.

2.2 Restriction or authorisation of substances within REACH

Within the REACH framework manufacturers and importers of chemical substances have the primary responsibility to register their chemicals and provide evidence of their safe use in the registration dossiers. Authorities may evaluate the dossiers and decide on follow-up actions to be taken by single or multiple registrants. In the case of substances posing an unacceptable risk to man or the environment, it is possible to limit or ban the manufacture, placing on the market or use by means of a restriction. Substances may also be identified by authorities as "substances of very high concern" (SVHC), based on their hazardous properties such as carcinogenicity, mutagenicity or reproductive toxicity. Identified SVHCs may be included in Annex XIV of REACH and hence be subject to authorisation.

A restriction can apply to any substance on its own, in a mixture or in an article for one or more specific uses, but it may also cover a whole supply chain and can go as far as to constitute a total ban. Member States of the European Union can propose restrictions if they judge that risks need to be addressed on a community wide basis. In addition, the ECHA can propose a restriction at the request of the European Commission. The Member States or the ECHA should start a restriction procedure when a certain substance, usually with one or more specific uses, poses an unacceptable risk (see Text box 1: Unacceptable risk, health effects and health impact) to human health or the environment.

The authorisation procedure is another route allowing authorities to intervene in the free circulation of chemical substances. In short, the authorisation procedure aims to ensure that the risks from substances of very high concern (SVHCs) are properly controlled and that these substances are progressively replaced by suitable alternatives. Substances with the following hazardous properties can be identified as SVHCs:

1. Substances meeting the criteria for classification as carcinogenic, mutagenic or toxic for reproduction category 1A or 1B (CMR substances).
2. Substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).
3. Substances, identified on a case-by-case basis, for which there is scientific evidence of probable serious effects that cause a level of concern equivalent to CMR or PBT/vPvB substances.

SVHCs may be included in the Candidate list and, if prioritised, become subject to authorisation (Annex XIV). It will then not be possible to use these substances or place them on the market after a given date unless an authorisation is granted for their specific use(s). Authorisation will be granted only if it is shown that socio-economic benefits outweigh the risk to human health or the environment arising from the use of the substance.

This project focuses on restrictions and how HIAs are performed within the SEAs presented in restriction dossiers. Authorisation requests are not covered by this project as at the time of writing the number of granted authorisation requests was small. Nonetheless, the outcome of this project could also be used for the HIAs and SEAs performed within the authorisation procedure.

2.2.1 The restriction procedure

When proposing a restriction, the Member State or the ECHA must justify its concern and the proposed restriction in a restriction dossier. The REACH regulation (Annex XV) states the kind of information that is required in a restriction dossier. It is divided into the following sections:

A. The restriction proposal.
B. Information on hazard and risks.
C. Information on alternatives.
D. Justification for restrictions at community level.
E. Justification that a restriction is the most appropriate community wide measure.
F. Socio-economic analysis (optional).

G. Information on stakeholder consultation.

The restriction dossier is submitted to the ECHA, where two scientific committees check it for conformity to the requirements of Annex XV of the REACH regulation. After a positive conformity check, the proposed restriction is made public for six months, allowing interested third parties to submit comments and information.

The Risk Assessment Committee (RAC) forms and adopts an opinion within nine months of the dossier's submission and evaluates whether the proposed restriction will adequately reduce the risk to human health and the environment. The Socio-economic Analysis Committee (SEAC) forms and adopts an opinion within 12 months of the dossier's submission and evaluates the socio-economic impact of the proposed restriction. Both committees assess the comments and information submitted by third parties during the public consultation period. The ECHA sends the opinions of the RAC and SEAC, along with relevant background documents, to the European Commission. Within three months, the Commission prepares a draft amendment of Annex XVII of REACH to include a new or adapted restriction entry. If neither the Council nor the European Parliament opposes the restriction, the Commission adopts it.

2.2.2 *The socio-economic analysis in restriction proposals*

The SEA helps to identify the socio-economic impacts of a proposed measure through a comparison with the situation in which no action is taken (baseline or "business as usual" (BAU) scenario). It is helpful in decision-making, showing the positive and negative impacts of the measure, and therefore determines the proportionality of the measure for society as a whole. Figure 1 illustrates the general process of an SEA as defined within the REACH framework. As can be noted from Figure 1, performing an SEA is an iterative process.

In an SEA, the impacts of different scenarios are described in comparison with the baseline scenario. Within REACH, the following impact categories are identified: *human health and environment impacts*; *economic impacts*; *social impacts*; *wider economic impacts (trade, competition and economic development)*. In principle, each type of impact is described separately and included in the SEA chapter.

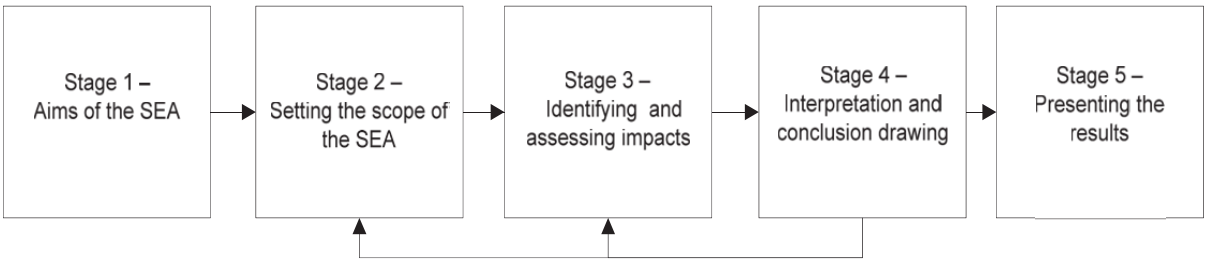

Figure 1: General SEA structure based on ECHA guidance (ECHA 2008)

When the impacts are assessed, the SEAC will evaluate the proportionality of the proposed measure, thereby weighing the estimated impacts (usually positive) of the proposed restriction for human health or the environment against its estimated social and

economic impacts (usually negative). In the case of authorisation applications it is the other way around: where a risk cannot be adequately controlled, the SEAC will weigh the estimated (negative) impacts of a granted authorisation for human health or the environment against its (positive) impacts for society and the economy.

The judgement on proportionality is often a complex process, as the assessment and comparison of impacts are subject to uncertainties and assumptions. The SEA gives arguments for a case rather than proof. Great efforts have been made in recent years to compare different types of impact, usually through some form of monetisation. However, this usually introduces a higher level of uncertainty into the final numbers presented. To enable a balanced judgement on proportionality to be made, a clear, structured description of the different impact assessments needs to be available. This description should focus on the scope and scenarios of the impact assessment, the introduction of uncertainties and assumptions, and their influence on the final estimates. Neither a description of the various methodologies for executing an SEA, nor a comparison between the different impacts affecting the judgement on proportionality is within the scope of this report.

2.3 Health impact assessment (HIA)

The most often used definition of HIA is that which appears in the Gothenburg Consensus Paper of 1999: "A combination of procedures, methods and tools by which a policy, programme or project may be judged as to its potential effects on the health of a population, and the distribution of those effects within the population."

The WHO (www.who.int/hia) states that many people and organisations have produced definitions of HIA. Each definition is similar, differing through the emphasis given to particular components of the HIA approach. Other definitions of HIA are: "Assessment of the change in health risk reasonably attributable to a project, programme or policy and undertaken for a specific purpose" (Birley 1995) and "A structured method for assessing and improving the health consequences of projects and policies in the non-health sector. It is a multidisciplinary process combining a range of qualitative and quantitative evidence in a decision making framework" (Lock 2000).

Although definitions of HIA are similar, the method of performing an HIA can differ significantly between various scientific disciplines. Most commonly, HIAs are performed in the field of public or environmental health and assess the potential changes in health of non-health-related measures (e.g. infrastructural changes, housing schemes, transport schemes). In most HIAs, health is defined in holistic terms, including social and mental well-being as well as the absence of disease or infirmity. The socio-environmental model of health by Dahlgren and Whitehead (1991) is usually used (see Figure 2). In this concept, health is determined by biophysical as well as social factors.

The aims of HIAs based on the model of Dahlgren and Whitehead are:

- To reduce or eliminate negative health impacts and maximise the positive health impacts of policies, programmes or projects.
- To reduce health inequalities.

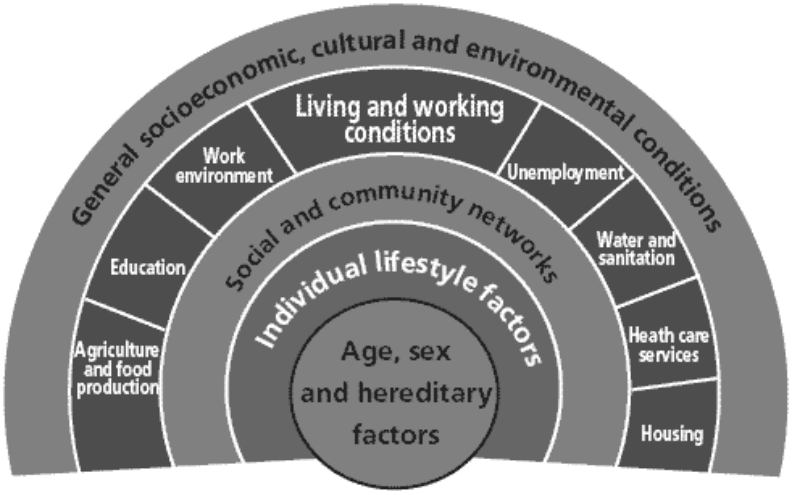

Figure 2: The socio-environmental model of health by Dahlgren and Whitehead (1991).

2.3.1 *Definition of a health impact in REACH*

The HIA definition as used within the context of REACH is more specific and focused than the HIA concept described in Section 2.3, which is more general. To frame an HIA within REACH, the definition of health in this context needs to be established. The legal text does not clearly state what is understood by the term health. However, REACH is formed on a toxicological paradigm; therefore, we can assume that health would be defined as the absence of adverse health effects. In the SEA some of the segments described in Figure 2 are incorporated within the economic and social impacts (e.g. unemployment).

Indeed, the ECHA Guidance on Socio-Economic Analysis – Restrictions (ECHA 2008) defines health impacts as "Impacts on human health including morbidity and mortality effects. Covers health related welfare effects, lost production due to workers' sickness and health care costs*".* In addition, this ECHA Guidance document states in paragraph 1.2.5: "'Net benefits' should take into account reduced risks due to restriction and possible risks caused by the transfer to alternatives." Risk reduction as a benefit had not been mentioned in the definition of health impact; therefore, the role of risk reduction as a health impact is unclear. In our opinion, a reduction in health risks could be regarded as a health impact in the HIA under REACH. It should be noted, however, that a reduction in health risks is not informative on the potential occurrence of adverse health effects in the population (see Text box 1: Unacceptable risk, health effects and health impacts).

Text box 1: Unacceptable risk, health effects and health impacts

The definitions of risk, health effects and health impact may need some clarification. In the assessment of the risk to human health of the use of chemicals, risk is the probability that an adverse (health) effect will occur. Adverse health effects are defined by the WHO as: "the change in the morphology, physiology, growth, development, reproduction or life span of an organism, system, or (sub) population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences" (WHO 2004). There is an unacceptable risk when the probability of the adverse effect occurring exceeds a predefined level determined as acceptable.

Within REACH, risks to human health caused by substances are acceptably low if the estimated exposure to the substance is below the Derived No Effect Level (DNEL). In other words, the probability of adverse effects is in that case acceptably low. This probability is acceptable because the DNEL and exposure are determined using conservative assumptions. By using conservative assumptions, it is assumed that exposures below the DNEL are sufficiently low and will not cause adverse effects. Note that effects might still occur at or below the DNEL (the term "No Effect" in DNEL is somewhat misleading), but they are considered as non-adverse. Only if there is no exposure there can be zero risk.

In contrast, an unacceptable risk under REACH occurs when the estimated exposure is above the DNEL for a certain substance, meaning that the probability of adverse effects is considered to be too high. When there is an unacceptable risk, however, this does not mean that adverse health effects will necessarily occur in the population; only that it cannot be confidently stated that adverse effects will not occur.

In a health impact assessment, health impact can be defined differently. It might be defined as adverse effects that are manifested clinically (i.e. recognised and considered as a disability, disease or illness by a medical professional) or alternatively also include effects at subclinical level (i.e. adverse effects that have not (yet) progressed to the level of a clinical health effect). In addition, reducing the probability of adverse effects (either clinical or subclinical) to an acceptable level could be seen as a health impact.

3 Overview of HIA guidance and practices in the field of chemical legislation

This report discusses the structured presentation and evaluation of an HIA within the framework of the restriction procedure of REACH. No extensive literature search on possible HIA practices in the field of chemical legislation measures has been performed within this project. Instead, the most relevant parts of some key reports are summarised to provide an overview of the general methodology. Furthermore, first-hand experiences of conducting HIAs on single chemicals before the introduction of REACH are described as well as a Dutch standard used to objectively assess the methodology of life cycle analyses (LCAs) of construction projects. These are the first inputs to the development of the structured format.

Although this chapter focuses on HIA methodology, it describes only the main steps. A detailed and comprehensive assessment of health impacts (using e.g. exposure assessment, toxicology, epidemiology, bio- or health statistics and other disciplines) is outside the scope of this report.

3.1 ECHA Guidance on Socio-Economic Analysis – Restriction (2008) and current REACH Annex XV restriction format (2012)

3.1.1 ECHA Guidance

In 2008, the ECHA issued technical guidance on how to prepare an SEA for a restriction dossier (ECHA 2008). The general schemes for identifying and assessing the various impacts are depicted in Table 1 and Figure 3. The aim is to answer the central question: "What are the impacts of the 'proposed restriction' scenario compared with the 'baseline' scenario?" The impacts are determined as the difference between these two scenarios, as defined in stage 2 of the SEA, i.e. the scope of the restriction. For the identification and assessment of the impacts, stage 3 in the SEA, the general scheme is depicted in Table 1.

Table 1: General scheme for the identification and assessment of impacts (ECHA 2008)

1. Identify the relevant impacts	*Create a list of impacts (the ECHA has provided a general checklist)* *Screen the impacts and consider only the major impacts*
2. Collect data	*Analyse the impacts using a stepwise approach* *Focus on the differences in impacts between each scenario* *Try to reduce key uncertainties that may arise in the analysis when it is feasible to do so* *Avoid double counting an impact along the supply chain*
3. Assess impacts	
4. Ensure the consistency of the analysis	*It is very important that all assumptions made during the analysis are documented in a transparent way*

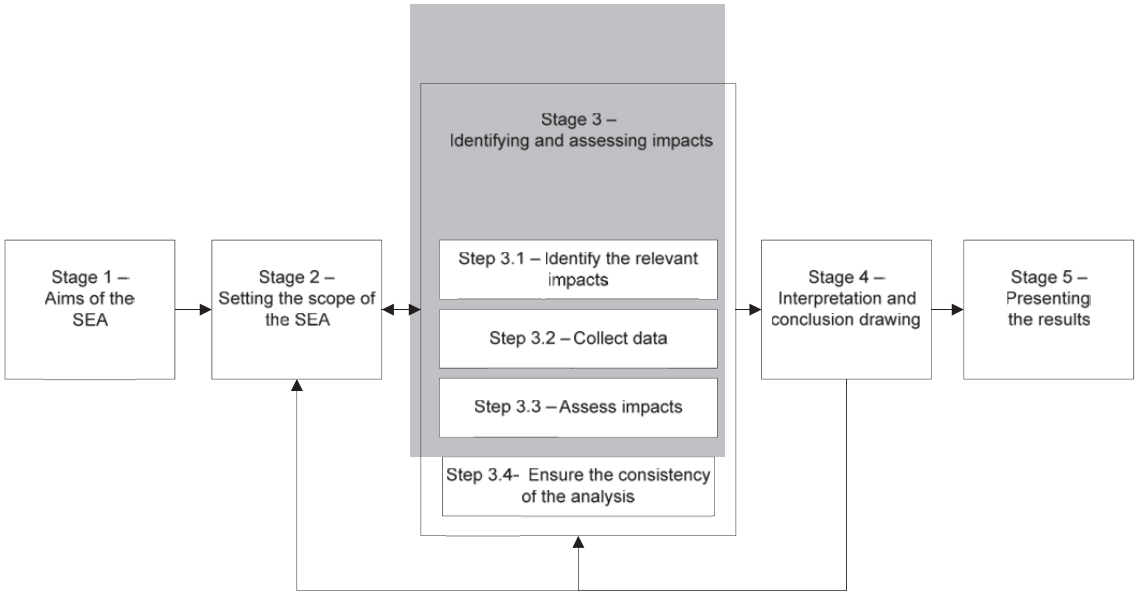

Figure 3: General scheme of an SEA to be included in a restriction dossier (ECHA 2008)

Furthermore, the Guidance makes specific recommendations for the conduct of an environmental or health impact assessment. Figure 4 gives, for example, a more specific scheme for the assessment of health impacts. It describes how the change in the manufacture, import and/or use of a (restricted) substance could affect health and the environment.

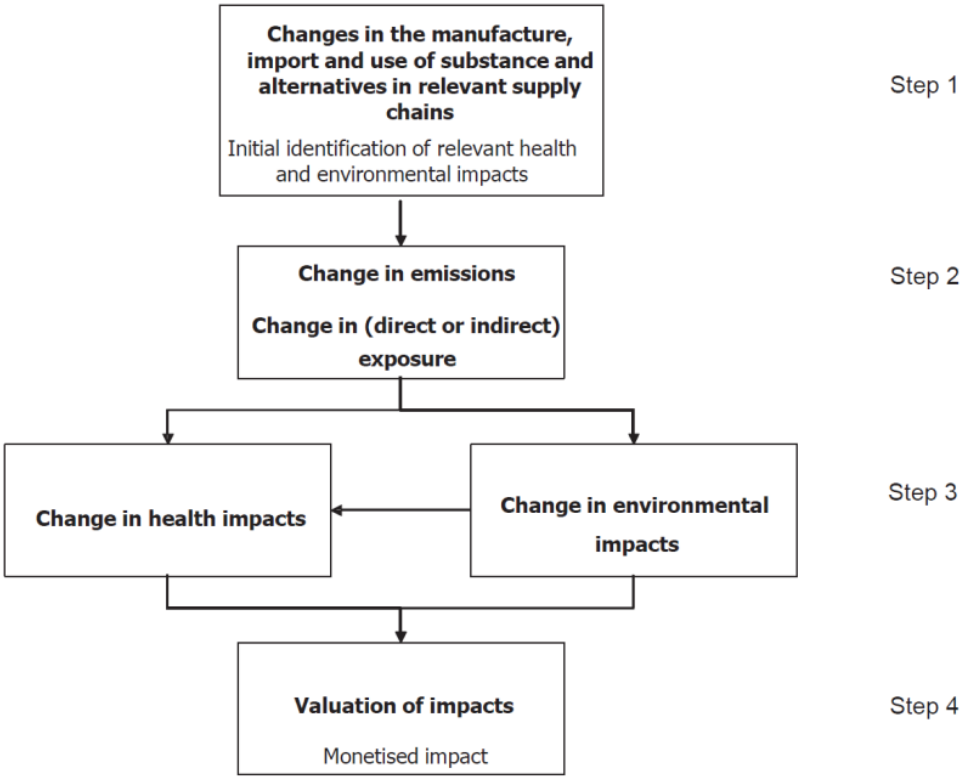

Figure 4: Scheme for assessment of health and environmental impacts (ECHA 2008)

Additionally, it includes the valuation of impacts as the final step in the assessment of health and environmental impacts.

Ideally, all changes to the steps detailed above should be quantified (where suitable data sources exist and where such analysis is possible), practical and proportionate. In practice, this is not always possible. Environmental and health impacts are especially difficult to quantify and in many cases must be assessed using expert judgement. There should be no bias towards impacts that are quantitatively described simply because it has been possible to quantify them. There may be other impacts of greater importance that cannot be readily quantified for reasons of data availability or uncertainty.

The quantification of the change in health impacts depends on step 2, the change in exposure (amount, frequency, duration and rate of uptake) and other types of data:

- Quantitative estimates of the relationship between individual exposure and the incidence of a defined health effect (dose–response relationship).
- An estimate of the total population exposed (and if possible the distribution of exposures within that population).
    - A measure of the actual impact of the health effect (e.g. numbers of life-years lost due to contracting cancer).

The valuation of health impacts entails the prediction of the total health improvement, including morbidity and mortality, changes in health care costs (hospital treatment, medicine, etc.) and changes in production due to sick leave. Depending on the quantification carried out, it may be possible to aggregate the health impacts.

Usually, the results of the assessment will not be one aggregate number but rather a mixture of qualitative, semi-quantitative and quantitative information about the estimated health impact of the proposed restriction. Determining the level of quantification to be used is best achieved through an iterative process starting with a qualitative assessment of the impacts, with further analysis carried out in future iterations if this is necessary to produce adequate support for the decision-making process. In some cases, a qualitative analysis will be sufficient to produce a robust conclusion and, in such cases, further quantification would not be necessary.

The description of the HIA should include a comprehensive narrative description of all the expected changes or impacts:

- The human health endpoints affected both qualitatively and quantitatively.
- The possible values used associated with human health end-points and the estimates of monetised impacts.
- The significance of the impacts.
- The certainty and confidence in the description of the impacts.
- All relevant assumptions/decisions and estimated uncertainties relating to what has been included, measurements, data sources, etc.

The ECHA Guidance on SEAs for restriction proposals provides a more detailed description of the various steps and recommendations, as well as a template for reporting an SEA (see Text box 2).

Text box 2: Reporting template from ECHA Guidance on Socio-Economic Analysis – Restrictions (ECHA 2008)

Reporting Template SEA – RESTRICTIONS

1. SUMMARY OF THE SEA

2. AIMS AND SCOPE OF THE SEA
    - 2.1. The aim of the SEA
    - 2.2. Definition of the "baseline" scenario
    - 2.3. Definition of the "proposed restriction" scenario
    - 2.4. Set out the time and geographical boundaries of the SEA

3. ANALYSIS OF THE IMPACTS
    - 3.1. Economic impacts
    - 3.2. Environmental risks
    - 3.3. Human health risks
    - 3.4. Social impacts
    - 3.5. Wider economic impacts

4. COMPARING THE SCENARIOS
    - 4.1. Key assumptions used in the SEA
    - 4.2. Results of uncertainty analysis
    - 4.3. SEA results

5. CONCLUSIONS

APPENDICES:
    - A.1 LIST OF DATA SOURCES
    - A.2 DATA COLLECTION APPROACH
    - A.3 ORGANISATIONS CONSULTED

3.1.2 REACH Annex XV restriction format

The current Annex XV restriction reporting format (ECHA 2012) has been developed through a merger of the format for a restriction report taken from the Guidance on Annex XV for restrictions and the reporting format of the Guidance on SEA – Restrictions. Figure 5 depicts the current restriction format and the correspondence between the relevant sections in the Guidance on Annex XV for restrictions and the Guidance on SEA – Restrictions. Section F contains the SEA, including the HIA.

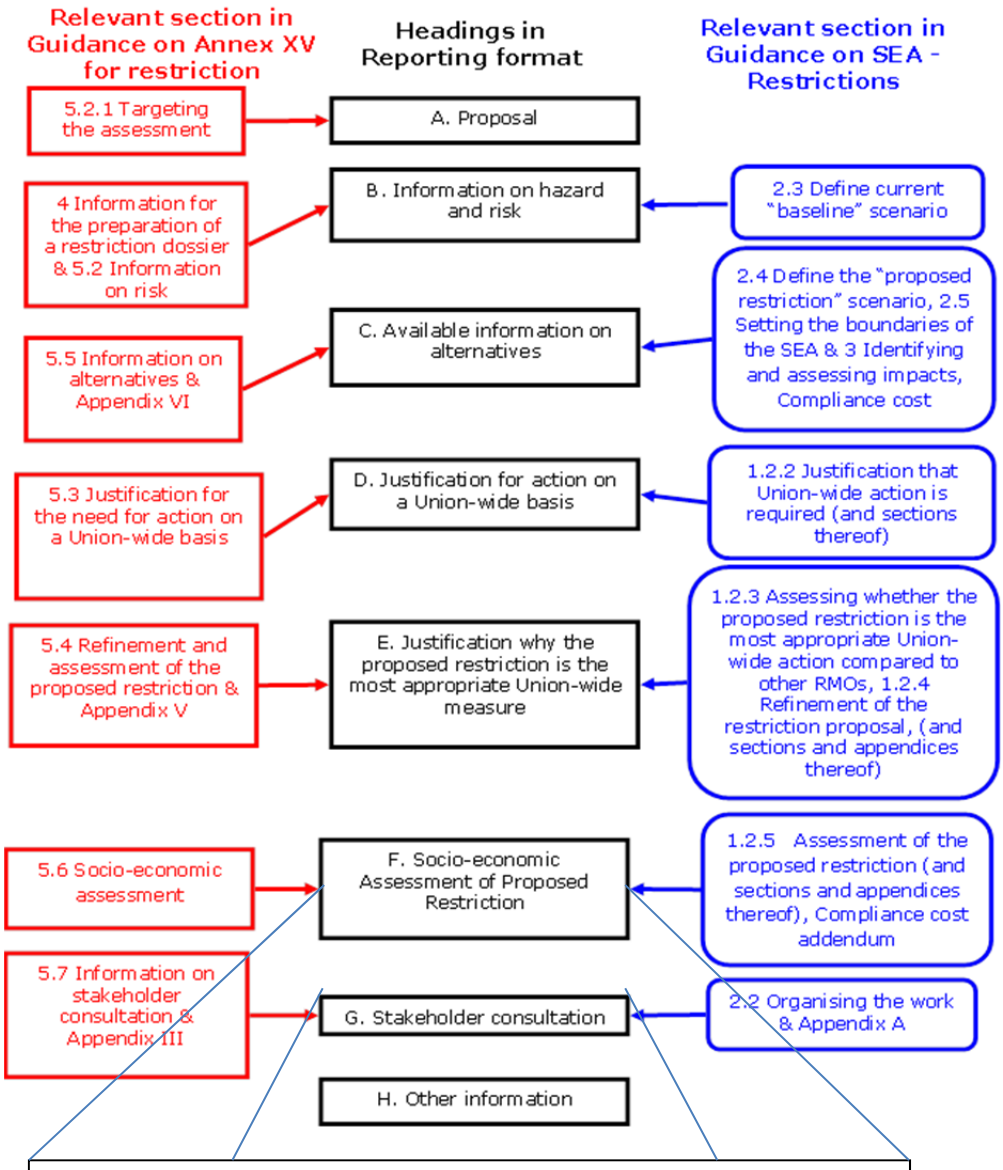

Figure 5: REACH restriction format with reference to the relevant element from ECHA Guidance on Annex XV and SEA – Restrictions (adapted from ECHA 2012)

3.2 Assessing the Health and Environmental Impacts in the Context of the Socioeconomic Analysis Under REACH (RPA 2011)

Based on the ECHA Guidance mentioned above, Risk & Policy Analysts Ltd (RPA) prepared a report for the Directorate-General for Environment of the European Commission on the assessment of health and environmental impacts in the context of SEAs under REACH. One of the goals of the RPA report was to provide a logical framework for the identification and assessment of health and environmental impacts and for the comparison between them and other socio-economic impacts.

Prior to the development of a logical framework, an extensive literature review was conducted to identify issues and possible data gaps that required consideration for future SEAs. The key findings of RPA regarding human health regarding exposure and hazard are summarised in Table 2.

Table 2: Issues for consideration regarding HIAs from the RPA literature review (summarized from RPA 2011)

<table>
<tr><th>Exposure</th><th>Hazard</th></tr>
<tr><td rowspan="4">Numerous methods can be applied; the choice of method is likely to be driven by the available data and the health metric stemming from the hazard assessment.

The approaches to predict exposures are similar for workers, consumers and public health, but data availability problems and the need to make additional assumptions when modelling consumer and public health introduce further uncertainties into the end estimates.

Even though models are available for carrying out the exposure assessment, it is also clear that non-model-based approaches are needed for some aspects of consumer exposure.</td><td>Data from epidemiological studies can be historical and, in general, is unavailable for the chemicals subject to REACH restriction. Even fewer direct human studies are likely to be available to provide a dose–response function.</td></tr>
<tr><td>Toxicological studies result in a DNEL that incorporates assessment factors to reflect uncertainty and to ensure a protective estimate. To quantify impacts, it may be appropriate to use the LOAEL or BMD and to collect data on effect levels above these.</td></tr>
<tr><td>Uncertainties surrounding NOAELs, LOAELs and BMD levels should be made clear and quantified where possible. An impact assessment should not include only “worst-case” assumptions but also “best estimates”.</td></tr>
<tr><td>There are cases where the risk characterisation will be qualitative (e.g. some carcinogens and certain irritants and sensitisers).</td></tr>
</table>

RPA also reports on the SEA methods used in the reviewed literature, ranging from hazard-based risk ranking methods to more quantitative approaches such as the use of Disabled Adjusted Life-Years (DALYs) and monetary valuation within a cost–benefit analysis (CBA) framework. The key findings of RPA regarding these methods in the context of SEAs under REACH are:

- Risk ranking methods are used in other fields to provide a non-economic way of assessing the acceptability of risks to both workers and the public. There may be merit in exploring how these approaches could be applied within the context of REACH to provide some form of decision matrix or a set of benchmarks for use by decision makers.

- Both one- and multi-dimensional measures of effectiveness are used in HIA. Both have merits and can be appropriate depending on the health risk issues under consideration. Increasingly, analysts are turning to the use of DALYs and Quality Adjusted Life-Years (QALYs) to measure both the change in the number of cases and the impacts that the associated health effects have on an individual's well-being prior to death. In the context of REACH, DALYs in particular may be useful, as they reflect problems in society that relate to time lost in good health but that do not lead to death.

- Of the monetary valuation methods, the Cost of Illness (COI) approach has been most widely used, in part due to the fact that it relies on actual or observed data. The collection of COI data is also likely to be less resource-intensive than the use of surveys or complex statistical analyses. This type of approach can be combined with the use of DALYs, Value of a Statistical Life (VOSL) or Value of
- counting.

- Benefit transfer-based approaches using existing VOSLs (or VOLYs derived from these) are also used extensively, drawing on wage risk premiums or stated preferences studies. However, the limited number of studies relevant to the type of health endpoints associated with the chemicals of concern under REACH will restrict the degree to which benefit transfer approaches can be used as a valuation method for morbidity effects and effects associated with exposure to mutagens and reproductive substances.

The overall aim of the RPA's logical framework was to provide a basis for ensuring that SEAs prepared under REACH generate the type of information required by decision makers to make robust decisions on risk versus socio-economic trade-offs. The logical framework described is consistent with the ECHA Guidance on preparing SEAs for restriction proposals and authorisation requests. The five main steps in the logical framework for assessing health and environmental impacts are summarised as follows:

Step 1: Characterisation and scoping assessment – using the available data to define the scope of the impact assessment to be carried out (linked to stage 2 in Figure 3)

Step 2: Qualitative to semi-quantitative assessment of impacts – drawing data from the chemical safety assessment and other sources to provide a detailed description of potential impacts (linked to stage 3 of Figure 3)

Step 3: Quantitative assessment of exposures and impact – where feasible and appropriate, developing further quantitative data to support decision-making. This may take place on two levels: comparison against benchmarks, or predictions of changes in the population or stock at risk; and quantification of the associated impacts on that population or environmental stock

Step 4: Valuation of impacts – estimating the economic value of the impacts using methods and units of measurement appropriate to health or the environment (e.g. willingness to pay values, health care costs, market value of changes in productivity, etc.).

Step 5: Comparative analysis – analysing the changes in health or environmental effects and determining whether the net change is positive or negative.

A more detailed and in-depth description of the logical framework can be found in the RPA report. When RPA applied the proposed framework in two case studies, some issues emerged. One of the key findings was that the process relies on a range of information from existing sources such as the REACH Chemical Safety Assessment; however, it also demands additional information in order to produce robust conclusions.

This additional information includes:

- The amount of substance produced/used and the supply chain patterns.
- The number of workers exposed within particular sectors.
- Occupational and environmental exposure patterns and available exposure measurement data.
- The efficiency of available personal protective equipment and levels of use compliance.
- Realistic derived minimum effect characteristics.
- Detailed information on endpoint-specific dose–response characteristics.

RPA identified key areas for the improvement of SEAs. The relevant areas for the development of HIA are:

Interpretation of toxic endpoints in relation to human health impacts
There is a need to establish scientifically agreed linkages between the toxicity endpoints included in the animal test designs used for risk assessment, and the human health outcomes to which they may be correlated. The development of guidance on appropriate methods to undertake inter-species extrapolation in the context of HIA (as opposed to risk assessment) would be helpful.

Estimation of exposure
There are limitations in the existing models and difficulties in establishing robust exposure estimates for the human population. The limitations and uncertainties that surround different models and approaches should be more accurately defined. Further research on the added value of a probabilistic (non-deterministic) approach, in respect to both the effects of substances and the estimation of exposure, would be beneficial. A comparison of the different methods or approaches to

estimating exposure could illustrate the assumptions and uncertainties relating to:

- the type of assumptions that may have to be made;
- the level of data required by the different approaches and where the data can sourced from;
- the different ways in which the outputs can be used.

3.3 From risk assessment to environmental impact assessment of chemical substances (RIVM 2012)

In 2012, the National Institute for Public Health and the Environment (RIVM) of the Netherlands published a report entitled From risk assessment to environmental impact assessment of chemical substances. Methodology development to be used in socio-economic analysis for REACH (Verhoeven, Bakker et al. 2012). Although this report focused on environmental impact assessment, it integrated the information and results from the ECHA Guidance document Socio-Economic Analysis – Restriction and the RPA report to further refine impact assessment methodology within SEA. The main steps in the RIVM impact assessment methodology are:

Step 1: Scope and scenario definition – A minimum of two scenarios are defined. In the case of a restriction, the business as usual (BAU) scenario represents the situation in which no policy action is taken and the policy scenario (PS) represents the situation in which a restriction is introduced. The subsequent steps in the methodology are performed for both scenarios.

Step 2: Exposure and hazard estimation – This is comparable to what is generally done in risk assessment, except that in impact assessment we strive for realistic estimates instead of worst-case estimates.

Step 3: Determination of endpoints and assessment methods – This is done on the basis of data availability, the substance characteristics and the proportionality of the assessment in terms of required inputs and obtained outputs to come to conclusive results.

Step 4: Assessment of environmental impacts – This involves the possibility of a ranking of the PBT characteristics of substances and an impact assessment based on a deterministic or probabilistic approach.

Step 5: Uncertainty assessment – A standard table was developed, which can be used to identify and document the main sources of uncertainty, providing a good comparison between BAU and PS, including relative uncertainties.

Step 6: Overall comparison – A comparison of the relative impact scores of the two scenarios is made, using the information acquired from the previous steps.

Except for step 4, the assessment of environmental impacts, this methodology is applicable to HIA as well. The basis of this methodology is the definition of (alternative) scenarios of chemical use and emissions.

This starting point can also be used as the basis for the estimation of other impact categories like human health. The methodology developed emphasises the importance of the uncertainty analysis as part of the overall impact assessment. As in all scenario-based assessments, which use a wide range of input parameters and models, there will inherently be a wide variation in sources of uncertainty that might influence the results.

The testing of this methodology in three case studies revealed several issues regarding, for example, data availability, uncertainty and the actual meaning (or practical value) of the results. It showed the importance of a robust uncertainty analysis in an assessment where a variety of input data, models and methods are used and connected, for a full understanding of the results.

3.4 Health impact assessment of policy measures for chemicals in non-food consumer products (RIVM/TNO 2008)

In 2008, the Dutch Applied Science institute TNO and RIVM published a report on the health impact of policy measures for single chemicals in non-food consumer products (Schuur, Preller et al. 2008). It was commissioned by the Ministry of Health, Welfare and Sport. Policy makers wanted to know, besides the cost, the potential health gain of the policy measures. The HIAs in this report were not performed within the REACH context, as at that time REACH was still in its pre-registration phase. Nonetheless, this report is useful in identifying practical problems in the performance of an HIA on single chemicals in consumer products. Such assessments had not previously been performed. The report described several case studies, each evaluating a policy measure targeted at a specific substance or substance group. Nine case studies, i.e. nine substances or substance groups, were analysed.

The general approach to each case study was to determine the effect of the policy measure on the following:

- The estimation of exposure (measured or estimated data on the substance in the product, frequency and duration of exposure, size of the exposed population).
- The estimation of the difference in margin of safety before and after the policy measure (risk assessment).
- The estimation of the health gain (the change in incidence of effect/disease before and after the policy measure) expressed in DALYs.

In each case study, the health gain is, as far as possible, expressed in DALYs. A summary of the HIAs was presented, with a more detailed description in the Annexes. Furthermore, a table was provided with a reliability score for the exposure estimate, health effect assessment, DALY calculation and overall reliability (low, middle or high). The reliability scores were based on expert judgement.

The report analysed the different case studies, and the following tendencies were noted (although it was pointed out that the number of case studies was too small for general conclusions to be drawn):

- Policy measures relating to substances in products that are used occasionally, i.e. acute exposures, did not result in a great health gain in terms of DALYs. This was due to the small target population and the fact that the health effects are of a short duration.
- In contrast, policy measures relating to substances in products that are used over a prolonged period (or daily), such as clothes, jewellery or cosmetics, resulted in a greater health gain in terms of DALYs.

In the report, the authors found it not possible to design a single "blue print" for assessing the health consequences of a measure although the methodology followed is very basic and is applicable to all cases. In every case study, different information was (un)available and as a consequence, different approaches were followed for the analysis. In some cases, it was possible to estimate in a quantitative way the potential effect of an implemented measure; in other cases the outcome of the exercise is no more than an effort to estimate its order of magnitude. The followed methodology is derived from the risk assessment framework and does not necessary match the needs of the impact assessment.

The report stated that the use of DALYs, developed to compare different diseases/health effects with each other, might not be the most relevant way to demonstrate the value of policy measures. The DALY approach does not reflect the secondary aspects of adverse outcomes that might be relevant to policy makers. It is designed from a clinical point of view using defined human diseases (allowing the comparison of their impact and severity). The cases studied often started with toxicological or physiological effects observed in animal studies; the DALY approach requires the translation of such effects into "diseases". The authors struggled to define how the uncertainties and assumptions of the DALY calculation should be communicated, as no common method was available.

3.5 Life cycle analysis (LCA) reviewing document (SBK)

This document was published by the Dutch Building Quality foundation. It serves as an example of an elaborate structured format and was brought to the attention of the authors during the project. This format was developed in The Netherlands to review the environmental impact assessment (using an LCA) of construction products. The reviewing party needs to fill out tables that contain the data quality conditions to be complied with. The reviewer should indicate whether the data complies with the set criteria (yes or no) and, if not, provide a justification for this failure. The table consists of several sections, such as aim, use, function and functional unit, system boundaries, data quality and gathering, calculation processes, validation of data, life cycle analysis assessment and interpretation.

3.6 Overall reflection on the presented information

The information presented in paragraphs 3.1–3.5 represents only a part of the literature available on this topic. Nevertheless, the information presents an overview of relevant recent developments from the

perspectives of Member States, the ECHA and stakeholders. All reports use more or less the same general assessment methodology. The ECHA's guidance provides the basic impact assessment steps. The reports by RPA and the RIVM refine these steps and provide more considerations and recommendations. The RIVM/TNO report highlights the various difficulties that can arise during an HIA of single chemicals.

The methodologies from these reports provide guidance for the performance of an HIA in the context of REACH and have proved to be useful when applied by case studies. On the other hand, the methodologies are very general. The methodology, techniques and scientific disciplines that need to be used within the various HIAs are case-specific and mostly driven by data (un)availability. Therefore, it is not possible to provide guidance on a detailed level. Consequently, this makes it difficult to perform a new HIA, as there is no uniform working procedure at a detailed level.

In some of the case studies mentioned in the reports discussed above, the applied methodologies revealed several difficulties. As expected, most issues relate to data (un)availability. Besides that, a different issue is the need to describe the various types of uncertainty and assumptions is highlighted. A table describing the assumptions and choices made at every step, as introduced in the 2012 RIVM report, can be very helpful to the interpretation of the result of an HIA. In the same report another, more fundamental, issue relating to the actual meaning (or practical value) of the results emerged.

The ECHA guidance mentions an iterative process, first to assess the impacts qualitatively, then to analyse them quantitatively and finally to valuate the impacts. This tiered approach is based on data availability, practicality and appropriateness with the goal to adequately support decision-making.

The above-mentioned reports provide a useful theoretical framework within which to perform and report on HIAs. The Dutch report on the use of LCAs for construction products provides an example of how to objectively assess methodologies and data quality. Although data quality itself will not be assessed within the structured format presented in Chapter 4, the principle to objectively assess methodologies and data quality was put forward. The principle of the LCA reviewing format was combined with the theoretical concepts presented here and further refined when applied to the HIAs in the background documents.

4 Structured format

In this report, a format is developed with the aim of structuring the preparation and evaluation of HIAs within the scope of European chemicals regulation (REACH). The focus is on the description and presentation of the various elements within the HIA. Furthermore, the format may enhance the consistency of HIAs in restriction dossiers within REACH. As already mentioned, this format is the result of an iterative process in which the theory presented in Chapter 3 and insights gained from the HIAs of proposed restrictions are used. The individual elements included in this structured format are based on the background information presented in Chapter 3 and expert judgement by the authors of this report.

Four main steps are identified for the description and presentation of an HIA. The first step is to set the scene for the HIA. This is a crucial step, as it determines the boundaries of the HIA and the context of the outcome. The first step includes the goal, scope and scenario definitions of the HIA. The goal of the HIA should be clear and reflect the position of the HIA within the SEA as a whole. This step should also contain a description and justification of the level of detail. The level of detail can vary depending on the aim of the SEA; for instance due to data (un)availability or an already confirmed political agreement on the necessity of the proposed measure. The definition of scope will determine the boundary conditions of the HIA with respect to population, location, period and health endpoints. The scenario definitions identify the baseline scenario (BAU), including anticipated trends, and the PS (usually the proposed restriction).

The second step consists of the impact assessment itself. In this step the impact of the proposed restriction on the selected health endpoint(s) is determined within the physical and policy boundaries stated in the first step. Within the impact assessment phase, three levels of detail are deduced from the theory and practical experience. It is not necessary to assess the HIA on all three detail levels, or alternatively, describe detail levels one and two first before conducting an HIA at detail level three. The appropriate level of detail of the HIA depends on the purpose of the SEA and is established in the first step. In one HIA, several health impacts can be assessed at three different detail levels.

The first detail level is a qualitative description of the exposure assessment, health effect assessment and subsequent impact assessment. The second and the third detail levels are quantitative. The second detail level measures risk reduction in terms of impact. At this detail level, the proposed restriction is aimed at risk reduction, i.e. a risk has been identified and the proposed restriction aims to reduce the risk to an acceptable level. The exposure assessment is performed quantitatively and the health effect assessment is usually based on a DNEL. The impact assessment describes the population at risk in the baseline scenario and for which the proposed restriction should reduce the risk. Furthermore, the impact assessment should mention the human health condition associated with the risk. The third detail level

quantifies health effects using a human dose–response function (3a) or observed clinical cases (3b) (see Figure 6). Both approaches aim to estimate the same health impact but from a different starting point. In method 3a, the health effect assessment consists of a dose–response function derived from epidemiological or animal data. The health effect can be a health endpoint (e.g. sensitisation, cancer case) or a degree of health effect (e.g. reduction in red blood cells, reduction in lung capacity). In method 3b, the exposure assessment can be quantitative or qualitative; describing the target population. The health effect assessment describes the population in which the clinical cases are observed; how these cases can be extrapolated to the target population and to what extent the observed cases can be attributed to the exposure. In both 3a and 3b, the impact assessment describes the population affected by the exposure in terms of the associated health effects. In theory, the health impact should remain the same whether method 3a or 3b is used. The impact assessment can consist of a description of several populations each with their own health effect, depending on the type of health effects and the methodology used.

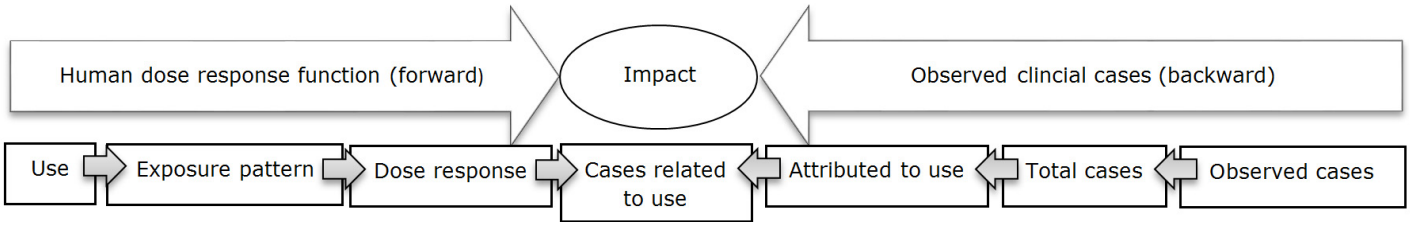

Figure 6: Illustrative representation of the third detail level of an HIA: using a human dose–response function (3a) versus observed clinical cases (3b).

The third step involves the valuation of the health impact. The type of valuation of the health impact is determined by the followed SEA methodology. Usually, this involves a cost–benefit analysis (CBA), whereby an attempt is made to monetise the quantified impacts. This monetisation can be conducted by various methods; therefore, the chosen method and how it relates to the health impact should be described. Any discounting of the monetised health impact should be considered within the SEA and the proportionality judgement.

The fourth and last step entails the sensitivity and uncertainty analyses of the HIA. This step relates to the robustness and the level of uncertainty of the HIA. With a sensitivity analysis, the factors that might influence the outcome significantly if changed slightly are identified. This provides insight into the critical determinants of the HIA. The uncertainty analysis describes the level of certainty in the estimates used in the HIA. These two analyses will put the result of the HIA into perspective and increase transparency.

The elements of the structured format are explained and further elaborated in Table 3. The identified elements state the type of information that is needed but do not reflect on the level of detail of the element. For instance, the exposure assessment of detail levels two and three contain the same elements. Although the same elements are mentioned, the level of detail to describe these elements can vary between detail levels two and three.

Table 3: Definition of HIA elements

Element	*Description*
Step 1: Goal, scope and scenario definitions	
Goal	
Aim	The aim of the HIA: why it is needed to know the health impacts and how the results are to be used.
Context within the SEA	What the SEA as a whole looks like, which other impacts are assessed and what SEA assessment tool is used to compare the different impacts. How the HIA fits into the SEA considering the overall aim of the SEA.
Desired HIA detail	The level of detail that is desired in the HIA to fit the purpose of the SEA as a whole. The type of information needed from the HIA to help the SEA to support decision-making.
Data availability	Description of the information needed for the desired level of detail. This information should be available with sufficient quality and certainty.
Scope	
Population	Description of the (sub) population for which the HIA is to be conducted. Depending on the proposed policy measure and associated health impact, the HIA can be for a specific gender, age group or working population, etc.
Geographic boundary	Description of the geographic boundary within which the HIA is to be conducted (usually the EU-28 by default).
Period	Description of the period over which the HIA is to be conducted, usually determined by the timeframe over which health effects are expected.
Possible health endpoints	All the health endpoints related to the substance to be assessed.
Most relevant health endpoint(s)	Selection of the most relevant health endpoint(s) related to the substance to be included in the HIA. This relates to the expected extent of exposure or observed clinical cases.
Scenario definitions	
Baseline scenario	The situation in the absence of the proposed policy measure.
Future trends in baseline scenario	Any relevant impending legislation or modification to existing legislation and trends in the use of the substance (quantities, population or behavioural changes that influence exposure) that are expected to come into effect over the timescale of the HIA.
Policy scenario	The expected situation after the introduction of the proposed policy measure.

Element	*Description*
Alternative policy scenarios	The situation after the implementation of other policy measures or risk management options (RMOs) that might be appropriate.
Step 2: Impact assessment	
Detail level 1: Qualitative assessment	
Exposure assessment	Qualitative description of the change in exposure characteristics due to the policy scenario (e.g. which population is exposed, to what extent, how often and for how long).
Health effect assessment	Qualitative description of the hazard properties of the substance (e.g. potency or other indicators of dose response, severity and type of effect).
Impact assessment	Qualitative description of the expected impact on the exposed population of the policy scenario, combining the exposure and the health effects assessments.
Detail level 2: Quantitative assessment based on risk reduction	
Exposure assessment	
Target population	Description of the population the exposure assessment applies to (e.g. type of population, specific activities involved, only the high exposed portion).
Frequency of exposure	Description of the frequency of exposure events.
Exposure duration	Description of the duration of an exposure event.
Level of exposure	The level of exposure for the specified target population.
Health effect assessment	
Toxicological limit value (DNEL) derivation	Description of the method of deriving the limit value(s) for the most relevant health endpoint(s). In REACH the limit value is the DNEL. However, depending on the selected health endpoints, multiple DNELs can be derived for various effects.
Impact assessment	
Population size with associated risk reduction	Description of the number of people to which the impact (risk reduction) applies and corresponding critical human health condition at risk for this population.
Detail level 3a: Quantitative assessment based on human dose–response function	
Exposure assessment	

Element	*Description*
Target population	Description of the population the exposure assessment applies to (e.g. type of population, specific activities involved, only the high exposed portion).
Frequency of exposure	Description of the frequency of exposure events.
Exposure duration	Description of the duration of an exposure event.
Level of exposure	The level of exposure for the specified target population.
Health effect assessment	
Dose–response relationship	Description of the relationship between exposure and the relevant health endpoint or degree of health effect.
Impact assessment	
Population size with associated health effect	Description of the number of people to which the impact (the relevant health endpoint or degree of health effect) applies.
Detail level 3b: Quantitative assessment based on observed clinical cases	
Exposure assessment	
Target population	Description of the exposed population (e.g. type of population, specific activities involved).
Health effect assessment	
Population of observed cases	Description of the population in which cases have been observed (patients of a specific clinic, general population, people registered for health care, etc.)
Extrapolation to the target population	Description of the method used to extrapolate the number of observed cases in a specific population to arrive at a total number of cases in the target population (from region to EU, from patients to general public, etc.)
Attribution to the exposure in question	Description of the fraction of observed cases in the target population linked to the exposure in question.
Impact assessment	
Population size with associated health effect	Description of the number of people to which the impact (the relevant health endpoint or degree of health effect) applies.
Step 3: Valuation of impact	
Type of methodology used for valuation	Methodology used to value the aggregated impacts (if applicable) or single health endpoint.
Effect–value relationship	The relationship between the impact or health endpoint and the valuation.
Step 4: Sensitivity and uncertainty analysis	

Element	*Description*
Sensitivity analysis on key parameters	Determination of the sensitivity of the outcomes of an analysis to changes in key parameters.
Uncertainty analysis	Description of the level of confidence in key parameters or HIA elements.

The structured format is presented in Table 4. The first column contains the elements defined in Table 3. The second column enables the maker or assessor to state whether the parameter is defined in the HIA. The third column enables the maker or assessor to state whether a justification is given for the defined parameter. The last column is for additional relevant remarks. The structured format is not intended to be used to express agreement or disagreement with a definition or justification. It aims to ensure the systematic preparation or evaluation of an HIA.

Table 4: Structured format for an HIA

Element	*Defined (yes/no)*	*Justification (yes/no)*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim			
Context within SEA			
Desired HIA detail			
Data availability			
Scope			
Population			
Geographic boundary			
Period			
Possible health endpoints			
Most relevant health endpoints			
Scenario definitions			
Baseline scenario			
Future trends in baseline scenario			
Policy scenario			
Alternative policy scenarios			
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment			
Health effect assessment			
Impact assessment			
Detail level 2: Quantitative assessment based on risk reduction			
Exposure assessment			
Frequency of exposure			
Target population			
Exposure duration			
Level of exposure			
Health effect assessment			
DNEL derivation			
Impact assessment			
Population size with associated risk reduction			
Detail level 3a: Quantitative assessment based on human dose–response function			

Element	*Defined (yes/no)*	*Justification (yes/no)*	*Additional remarks*
Exposure assessment			
Frequency of exposure			
Target population			
Exposure duration			
Level of exposure			
Health effect assessment			
Dose–response relationship			
Impact assessment			
Population size with associated health effect			
Detail level 3b: Quantitative assessment based on observed clinical cases			
Exposure assessment			
Target population			
Health effect assessment			
Population of observed cases			
Extrapolation to the target population			
Attribution to the exposure in question			
Impact assessment			
Population size with associated health effect			
Step 3: Valuation of impact			
Methodology used for valuation			
Effect–value relationship			
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters			
Uncertainty analysis			

5 HIAs described in the background documents of REACH restriction dossiers

5.1 Survey of REACH restriction dossiers

Since 2010, REACH Annex XV dossiers proposing a restriction have been submitted to the ECHA, reviewed by the RAC and SEAC and passed on to the European Commission for decision-making. Through this process, experience has been gained in the conduct and evaluation of HIAs within the context of REACH, as well as in the use of HIA results in the comparison of impacts within the SEA. There has also been an increase in knowledge of how these results help to derive conclusions on the proportionality of the proposed restrictions. This report concerns the all HIAs described in the background documents up until November 2014 of REACH restriction dossiers, its aim being to ascertain whether the structured format presented in Chapter 4 should be used for the description and presentation of the various elements within the HIAs. The final version of each background document, containing the HIA with the relevant modifications by the RAC and SEAC, has been used for the survey. It is emphasised that it is *not* the aim of the current survey to judge the quality and the choices made by those submitting a dossier regarding the elements of a particular HIA. The restriction proposal on DIBP, DBP, BBP, DEHP was excluded, as the RAC did not identify a risk and a subsequent estimation of health benefits was not possible, according to the SEAC.

The HIA is described in section F of the background document. Therefore, the assessment of the description and justification of the various elements of the HIA is predominantly based on the information provided in section F. In addition, sections B and E were screened to see whether missing HIA elements were stated in other sections of the background document. If this was the case, it was concluded that, although those elements were not defined in the HIA as such, they could be deduced from the other sections.

NOTE: This survey on HIAs in background documents was performed during the iterative process of developing the HIA structured format (see Table 4). The aim of the analysis was to learn from HIAs already described in section F of background documents in order to improve the proposed structured format, not to assess the HIAs or the opinions of the SEAC.

5.2 Lead in jewellery articles

5.2.1 Summary of the proposed restriction

This restriction proposal was submitted by France in 2010. It proposed a restriction on the use of lead in jewellery articles according to its lead content. Although other effects may be relevant and other risks may be present in other subpopulations, in this proposal concern was focused on the risk of neurological health effects in children who put jewellery containing lead into their mouths. The proposed restriction would prohibit the placing on the market of lead in any individual part of

jewellery articles if the concentration of lead (expressed as metal) in such a part is equal to or greater than 0.05% by weight (ECHA 2011).

5.2.2 *Summary of the HIA in the background document*

Goal, scope and scenario definitions

Goal

The SEA section states the intention to perform a partial CBA. The purpose of this partial CBA is illustrative: to give an indication of the order of magnitude of the most important elements. In fact, a break-even analysis is performed, as general SEA methodology. The aim of the HIA is to calculate the level at which cognitive ability (IQ) impacts equate to the total additional cost of the proposed restriction. The level of detail needed in the HIA for it to be adequate for the SEA as a whole is not mentioned. Consequently, a reflection on the data requirements and availability of the required data to meet the desired level of detail in the HIA is not available.

Scope

The scope is defined in several places in the HIA section. The HIA is aimed at children between the ages of six months and three years in the European Union, as the sensitivity of the brain to lead is greatest during the first two years of life, although the exact time distribution of IQ damage is not known. For the purpose of the break-even calculations in this analysis, the exposure duration is set at one year. This allows a direct comparison with annualised costs without the need to make any adjustments for the different time frames. The introduction states what health effect, i.e. IQ reduction, is covered by the HIA and which other health effects exist that are not taken into account in the assessment. A justification for selecting IQ as the most relevant health endpoint is presented.

Scenario definitions

The general baseline scenario of the SEA is described in section E of the background document. In the HIA various exposure profiles are derived that serve as variations of the general baseline scenario in order to assess the health impact. These exposure scenarios vary in how many children need to insert the jewellery into their mouths for a certain period of time and a certain number of times per year to reach a break-even point between costs and benefits. The policy scenario is the proposed restriction. No possible future trends in the baseline scenarios (the various exposure profiles) are discussed. No alternative policy scenario is described.

Impact assessment (detail level 3a: quantitative assessment)

Exposure assessment
Two approaches are taken to the exposure assessment. The first approach is to assess the different possible exposure scenarios that would reach the break-even point in costs and benefits. The second approach is to estimate the actual mouthing (exposure duration and frequency) and compare these with the various break-even exposure scenarios. In both approaches, the frequency and duration of exposure events are defined and justified. The target populations of the SEA are defined as children in the EU between the ages of 0.5 and 3 years and, depending on the exposure profile, a smaller part of this population. The exposure level is calculated on the basis of the migration rate of lead, the surface area of a typical piece of jewellery and the average body weight of a child in this age range. Justification for the different estimates is sometimes given in section F and sometimes in other sections of the background document.

Health effect assessment
The dose–response function (relationship between lead exposure and IQ effect) is defined and justified. The dose–response function is described in a two-step process that consists of, first, a description of the relationship between IQ and blood lead levels and, second, a description of the relationship between blood lead levels and (oral) lead exposure.

Impact assessment
In this HIA, due to the break-even approach adopted in the SEA, the degree of IQ loss in the population is fixed (at 460 IQ points loss). This health impact is based on the cost estimate of the restriction and the subsequent valuation of the impact. The population size for the health impact is determined by the target population with a particular exposure profile.

Valuation of impact
The health impact, lowered IQ due to lead exposure, is valued in terms of cost to society so that the estimate can be compared with the cost of the restriction. IQ loss is valued using estimates of reduction in lifetime earnings. The SEAC explains why estimating IQ reduction in terms of lifetime earnings is a suitable method of monetising the societal costs of lowered IQ. The estimate of the value of the reduction in earnings per IQ point is based on a brief review of the available literature on this subject.

Sensitivity and uncertainty analyses
The HIA includes a sensitivity analysis in which the impact of varying some of the key parameters of the break-even analysis can be seen. Not all parameters are subject to the sensitivity analysis, and no justification is provided for the selection of the parameters. No description of the level of confidence in key assumptions, such as the one included in the sensitivity analysis, is present. Nor is a justification for not conducting an uncertainty analysis.

Table 5: Structured format table of the key descriptive parameters of the HIA of lead in jewellery

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	Yes	Yes	
Context within SEA	Yes	Yes	
Desired HIA detail	No	No	
Data availability	No	No	
Scope			
Population	Yes	Yes	
Geographic boundary	Yes	Yes	
Period	Yes	Yes	
Possible health endpoints	Yes	Yes	
Most relevant health endpoints	Yes	Yes	
Scenario definitions			
Baseline scenario	Yes	Yes	Several variations of the general baseline scenario are derived based on exposure profiles
Future trends in baseline scenario	No	No	
Policy scenario	Yes	Yes	
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment	*NP*		
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3a: Quantitative assessment based on human dose–response function			
Exposure assessment			
Frequency of exposure	Yes	Yes	
Target population	Yes	Yes	
Exposure duration	Yes	Yes	
Level of exposure	Yes	Partially	Justification of some parameters is given in other sections

Element	*Defined*	*Justification*	*Additional remarks*
Health effect assessment			
Dose–response relationship	Yes	Yes	
Impact assessment			
Population size with associated health effect	Yes	Yes	
Step 3: Valuation of impact			
Methodology used for valuation	Yes	Yes	
Effect–value relationship	Yes	Yes	
Step 4: Sensitivity and uncertainty analysis			
Sensitivity analysis on key parameters	Yes	No	
Uncertainty analysis	No	No	

NP = Not performed

5.3 Polyaromatic hydrocarbons (PAHs) in consumer articles

5.3.1 Summary of the proposed restriction

The restriction dossier was submitted in 2010 by Germany directly to the Commission since it concerns the restriction of harmonised classified CMR substances in consumer articles. The so-called fast track route to a restriction for CMR substances, art. 68(2), was followed, thereby bypassing the scientific committees of the RAC and SEAC. The restriction dossier focused on eight polyaromatic hydrocarbons (PAHs): Benzo[a]pyrene, Benzo[e]pyrene, Benzo[a]anthracene, Chrysene, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene and Dibenzo[a,h]anthracene. The proposed restriction would prohibit placement on the market of articles containing any of the PAHs listed above at levels above the limit of quantitation (0.2 mg/kg) that could be used by consumers. Note: the German restriction dossier (BAuA 2010) is the basis for this evaluation. It did not change during the restriction procedure. However, the final restriction issued by the Commission does present a different concentration limit, i.e. 1 mg/kg (sum of all substances) and 0.5 mg/kg (substance specific) instead of the proposed 0.2 mg/kg (the limit of quantification).

5.3.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The aim of the HIA is to qualitatively describe the human health benefits of the proposed restriction. The SEA is not described, nor the context of the HIA within the SEA as a whole. Although DMELs are derived for the individual substances and information on exposure in the population was available, additional cancer cases from the PAHs exposure are not calculated or used in the HIA. According to the background document, quantification was not deemed appropriate because the exact number of affected products and affected consumers as well as the length and frequency of consumer exposure to these products cannot be determined with certainty.

Scope
The HIA describes two population groups (children and workers) for which the proposed restriction would have an especially positive impact. No particular geographical boundary is defined but from previous sections it can be assumed to be the entire EU. No period is defined. The relevant health endpoints for PAHs are defined, but neither a justification for these nor a discussion of other possible health endpoints related to PAHs is included.

Scenario definitions
The HIA does not explicitly state a baseline scenario; the general baseline scenario of the SEA is described in section E of the background document. The general baseline scenario is the continuous presence of PAHs in articles because of contamination during the production of rubber. The policy scenario is not explicitly defined in the HIA section; however, it can be deduced from section E that the proposed restriction is the policy scenario. No alternative policy scenario is assessed. Future trends in the baseline scenario are not mentioned.

Impact assessment (detail level 1: qualitative assessment)

Exposure assessment
The HIA states that current concentrations of PAHs are high in rubber articles and there is a wide range of relevant products. In particular, children may handle PAH-contaminated toys for prolonged periods, playing with them for an average of 15,000 hours up to the age of six years. Children may also put toys and other products into their mouths, implying multiple relevant exposure routes. Justification is provided for the playing time of children; the remaining characteristics are not justified specifically in the HIA but can be deduced from other sections of the background document. For workers, the type of worker activity (producing or assembling products) and sector (upstream or downstream parts of relevant supply chains) that might involve a benefit from reduced exposure due to the proposed restriction are described.

Health effect assessment
The health effects of exposure to PAHs are defined in the HIA as risks of illness and early death due to cancer. No justification or reference is given for the derivation of these health effects.

Impact assessment
The impact assessment of the proposed restriction is based on a qualitative description of risk. Reducing exposure as a result of lowering content limits would also decrease risk. Therefore, it is anticipated that the proposed reduction in the concentration limit will result in significant health benefits among children and relevant workers in the EU.

Valuation of impact
The health impact of the restriction is not appraised. No justification is provided.

Sensitivity and uncertainty analyses
No sensitivity or uncertainty analyses are performed within the HIA. Justification for this is not provided.

Table 6: Key descriptive parameters of the HIA of Polyaromatic hydrocarbons (PAHs) in consumer articles

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	Yes	Yes	
Context within SEA	No	No	
Desired HIA detail	Yes	Yes	
Data availability	Yes	Yes	
Scope			
Population	Yes	Yes	
Geographic boundary	No	No	Not explicitly defined and justified in section F, but can be deduced from the other sections.
Period	No	No	
Possible health endpoints	No	No	
Most relevant health endpoints	Yes	No	
Scenario definitions			
Baseline scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from the other sections.
Future trends in baseline scenario	No	No	
Policy scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from the other sections.
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment	Yes	Partially	Justification of some statements described in other sections.
Health effect assessment	Yes	No	
Impact assessment	Yes	Yes	
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3: Quantitative assessment based on health effects	*NP*		
Step 3: Valuation of impact			
Methodology used for valuation	No	No	

Element	*Defined*	*Justification*	*Additional remarks*
Effect–value relationship	No	No	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	No	No	
Uncertainty analysis	No	No	

NP = Not performed

5.4 Mercury in measuring devices

5.4.1 Summary of the proposed restriction

The restriction concerns the industrial and professional uses of mercury in measuring devices (ECHA 2011). The focus is on the assessment of the technical and economic feasibility of alternatives to mercury devices. According to a clause in an existing restriction on mercury in measuring devices, the Commission was obliged to carry out a review of the availability of reliable safer alternatives to mercury-containing measuring devices that are technically and economically feasible and to present, if appropriate, a proposal to extend the existing restriction, when such alternatives become available. The restriction dossier for mercury in measuring devices was prepared by the ECHA at the request of the Commission and submitted in 2010.

5.4.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The aim of the HIA is described in the human health and environmental impacts section. It notes that the specific human health or environmental impacts of introducing the restriction could not be quantified. Furthermore, it was not considered proportionate to even aim at such quantification. Reference is made to section B, where it is stated that the general goal is to comply with an existing restriction (Entry 18a Annex XVII).

Scope

The scope of the HIA is the same as the proposed restriction, looking at mercury in devices to be used for measurement in the EU between 2015 and 2034. No specific populations or possible or relevant health endpoints are mentioned in the HIA.

Scenario definitions

No baseline scenario or reference to such is mentioned in the HIA section. The policy scenario is stated as the proposed restriction. Trends or alternative policy scenarios are not discussed in the HIA.

Impact assessment (detail level 1: qualitative assessment)

Exposure assessment

Exposure to (methyl)mercury is not quantitatively described in the HIA section. The focus of the exposure assessment is on the minimisation of mercury emissions to the environment. The proposed restriction is estimated to reduce the amount of mercury in the EU market (in devices

to be used for measurement) by 60 tonnes between 2015 and 2034. Reference to section B is provided for more detail.

Health effect assessment
The health effects of exposure to (methyl)mercury are not described in the HIA section but reference is made to section B.

Impact assessment
The human health impacts of introducing a restriction are not quantified. The potential population exposed and associated health effects are not qualitatively described. According to the dossier, it is evident that not releasing (60 tonnes of) mercury onto the market will have a positive impact on human health. The estimated amounts of mercury in different devices are used to illustrate the risk reduction capacity of the restriction.

Valuation of impact
The impact is not monetised, because human health impacts are not quantified.

Sensitivity and uncertainty analyses
No uncertainty or sensitivity analyses are performed. Justification for this is not provided.

Table 7: Key descriptive parameters of the HIA of mercury in measuring devices

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	Yes	Yes	Only technical and economic feasibility of alternatives is required
Context within SEA	Yes	Yes	
Desired HIA detail	No	Yes	
Data availability	No	Yes	
Scope			
Population	No	No	
Geographic boundary	Yes	Yes	
Period	No	No	Not mentioned explicitly in HIA
Possible health endpoints	No	No	
Most relevant health endpoints	No	No	
Scenario definitions			
Baseline scenario	No	No	
Future trends in baseline scenario	No	No	
Policy scenario	Yes	Yes	
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment	Partially	Yes	Limited to the reduction (in volume) of mercury released onto the market
Health effect assessment	No	Yes	
Impact assessment	No	Yes	
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3: Quantitative assessment based on health effects	*NP*		
Step 3: Valuation of impact			
Methodology used for valuation	No	Yes	
Effect–value relationship	No	Yes	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	No	No	
Uncertainty analysis	No	No	

NP = Not performed

5.5 Manufacture and use of phenylmercury compounds

5.5.1 Summary of the proposed restriction

In this dossier, it is proposed to restrict the manufacture and use of five phenylmercury compounds to reduce the overall output of mercury to the environment and hence to reduce the impact of mercury on health and the environment in Europe and globally (ECHA 2011). The reason for proposing a Community-wide restriction on these substances relates as much to their potential to degrade and release of mercury to the environment, as to exposure to them by humans, including exposure via the environment, in particular from methylmercury. The restriction dossier for phenylmercury was submitted by Norway in 2010.

5.5.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The qualitative HIA provided in the dossier does not state a particular aim of the HIA. Nor does the HIA section state the context of the HIA within the SEA as a whole, the level of detail needed or the availability of data.

Scope

The scope, i.e. the population, geographical boundary and period, of the HIA is not provided. The possible health endpoints related to phenylmercury are not defined; however, reference is made to the high toxicity of methylmercury, in particular for the nervous system.

Scenario definitions

No baseline scenario or reference to such is included in the HIA section. Although not explicitly mentioned in the HIA, the policy scenario consists of reducing and eventually eliminating releases of mercury from the five phenylmercury compounds. Trends or alternative policy scenarios are not discussed in the HIA.

Impact assessment (detail level 1: qualitative assessment)

Exposure assessment

The HIA qualitatively describes the potential exposure of humans. Phenylmercury acetate can be released from articles into the indoor environment. Furthermore, exposure of humans to methylmercury is possible through biotransformation of phenylmercury substances via the environment.

Health effect assessment

The health effects of exposure to phenylmercury are not described in the HIA section. It is noted that methylmercury is highly toxic, in particular for the (developing) nervous system.

Impact assessment

The human health impact of introducing a restriction is not quantified. It is stated that "alternatives [to phenylmercury compounds] are expected to pose significantly lower health risks than those of mercury". This leads to the conclusion that "the proposed restriction would be expected to result in a net benefit in terms of human health impacts."

Valuation of impact
In section F it is not considered feasible – based on currently available approaches to the assessment of the impact of reducing emissions of mercury – to quantify the reduction in adverse health effects per se (i.e. damage avoided) that would be achieved through restricting the use of these compounds. In addition, it is stated that "an estimation of the annual emission of mercury that is avoided by the restriction proposal is considered to be a useful indicator of the environmental (and indirectly human) impacts".

Sensitivity and uncertainty analyses
No uncertainty or sensitivity analyses are performed. Justification for this is not provided.

Table 8: Key descriptive parameters of the HIA of phenylmercury compounds

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	No	No	
Context within SEA	No	No	
Desired HIA detail	No	No	
Data availability	No	No	
Scope			
Population	No	No	
Geographic boundary	No	No	
Period	No	No	
Possible health endpoints	No	No	
Most relevant health endpoints	Yes	No	
Scenario definitions			
Baseline scenario	No	No	
Future trends in baseline scenario	No	No	
Policy scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment	Partially	No	Only potential exposure to humans; no population defined
Health effect assessment	Partially	No	No specific health effect defined
Impact assessment	Partially	No	No specific health effect or population defined

Element	*Defined*	*Justification*	*Additional remarks*
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3: Quantitative assessment based on health effects	*NP*		
Step 3: Valuation of impact			
Methodology used for valuation	No	Yes	
Effect–value relationship	No	Yes	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	No	No	
Uncertainty analysis	No	No	

NP = Not performed

5.6 Dimethylfumarate (DMFu) in articles

5.6.1 Summary of the proposed restriction

This restriction dossier was submitted by France in 2010. It proposes to restrict the placing on the market and use of DMFu in articles (ECHA 2011). DMFu is used to prevent the formation of mould, mainly during the transport of articles from Asia to Europe. The main reason for the proposed restriction is the presumed risk to consumers of developing (allergic) skin dermatitis after contact with DMFu. The proposal in fact is a continuation and formalisation of an existing temporary EU ban implemented in March 2009 (Product Safety Directive, decision 2009/251/EC). Note: the HIA section in the background document states only: "Covered under Section E". For practical reasons we therefore used section E, in this case, as a proxy for the HIA.

5.6.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

In section E, no reference is made to the aim or purpose of the HIA within the SEA as a whole. The health impact in section E is described qualitatively. No justification is given for this level of detail.

Scope

In section E only a partial HIA is described. Some elements of an HIA are stated, such as the population (consumers) and geographic boundary (EU-wide) targeted by the proposal. No period is made explicit. Health endpoints related to DMFu are defined (skin irritation and sensitisation), but no justification or discussion of other possible health endpoints related to DMFu is given.

Scenario definitions

Section E identifies the different scenarios. The proposal is in fact a continuation and formalisation of an existing temporary ban. The baseline scenario is the situation if the temporary ban is lifted and no other EU or national regulation is put in place. The policy scenario, the proposed restriction, is described in section E. Alternative policy

scenarios are defined as the usual RMOs in section E but not in relation to an HIA, as the proposed restriction is seen as the most adequate measure.

Impact assessment (detail level 1: qualitative assessment)

Exposure assessment
A quantitative exposure assessment is not performed as no formal assessment of consumer exposure to DMFu is available. Instead, the concentration of the substance in products is used as a proxy. The proposed restriction will reduce exposure to DMFu as articles will not contain more than 0.1 mg/kg of this substance.

Health effect assessment
Section E states that DMFu is an apparent sensitizer. When present in furniture materials and shoes, it can cause symptoms such as dermatitis following dermal exposure.

Impact assessment
The population at risk consists of all potential consumers across the EU. Not only consumers but also workers are expected to be protected by such a restriction. This proposal would also positively affect the health of the workers who are currently exposed to DMFu, although no information on occupational exposure is available. The impacted population size is not described, which is justified by the lack of relevant information (the number of people exposed to DMFu in articles in the baseline scenario and the probability of consumers contracting dermatitis following use of articles containing DMFu). It is expected that the limit of 0.1 mg/kg will allow an adequate control of the identified risks, which are skin irritation and skin sensitisation.

Valuation of impact
The health impact valuation is described qualitatively with justification as to why a quantitative valuation was not possible. The qualitative description is based on compensation payments in the UK due to DMFu in sofas. Furthermore, the costs to health services and costs to companies of product recall are referred to.

Sensitivity and uncertainty analyses
No uncertainty or sensitivity analyses are performed. Justification for this is not provided.

Table 9: Key descriptive parameters of the HIA of dimethylfumarate (DMFu) as described in section E

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	No	No	
Context within SEA	No	No	
Desired HIA detail	No	No	
Data availability	Yes	Yes	
Scope			
Population	Yes	Yes	
Geographic boundary	Yes	Yes	
Period	No	No	
Possible health endpoints	No	No	
Most relevant health endpoints	Yes	No	
Scenario definitions			
Baseline scenario	Yes	Yes	
Future trends in baseline scenario	Yes	Yes	
Policy scenario	Yes	Yes	
Alternative policy scenarios	No	Yes	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment	Yes	Yes	
Health effect assessment	Yes	Yes	
Impact assessment	Yes	Yes	
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3: Quantitative assessment based on health effects	*NP*		
Step 3: Valuation of impact			
Methodology used for valuation	No	Yes	A qualitative valuation of the impact is performed
Effect–value relationship	No	Yes	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	No	No	
Uncertainty analysis	No	No	

NP = Not performed

5.7 Chromium in leather articles

5.7.1 Summary of the proposed restriction

The restriction dossier was submitted by Denmark in 2012 and proposes a restriction of the use of chromium in leather articles. The concern of the proposal focuses on skin sensitisation among the entire EU population. The proposed restriction would prohibit the placement on the market of leather articles, or leather parts of articles, containing

chromium VI in concentrations ≥3 mg/kg (0.0003%) that come into contact with the skin (ECHA 2012).

5.7.2 *Summary of the HIA in the background document*

Goal, scope and scenario definitions

Goal
The HIA section does not specify the aim of the HIA, its context within the SEA as a whole, the required level of detail or the availability of data. However, some of this information can be deduced from information provided in other sections of the background document. From section E, it appears that the SEA is envisaged as a CBA, balancing a long-term reduction in health costs with a short-term increase in production costs. No further detail is provided.

Scope
The scope of the HIA is not explicitly stated. From the preceding sections it becomes clear that the scope involves all EU-27 citizens that might become sensitised and those with an existing chromium allergy. The period used for the HIA is defined: health impacts are expressed per year, with total impacts assessed over a period of 20 years. The justification for the period is not explicitly stated but can be deduced from the text. The main health effect, skin sensitisation, is defined and reference is made to section B for justification. Other human health impacts are not defined in the HIA, but reference is made to section B.

Scenario definitions
The HIA does not explicitly state a baseline or policy scenario but the scenarios can be assumed from the text. The general baseline scenario is the existing situation, based on the number of known chromium allergy cases and assuming that 45% of them are due to chromium in leather articles. The policy scenario is the proposed restriction and assumes an 80% reduction in new cases. These assumptions are justified in other sections of the background document. The baseline scenario includes existing bans (Germany), which are expected to gradually reduce the number of new cases in the coming years. No alternative policy scenarios are assessed.

Impact assessment (detail level 3b: quantitative assessment)

Exposure assessment
A specific description of the population that can be exposed is not provided in section F, although it can be deduced from section B.

Health effect assessment
The HIA is based on surveys estimating the number of people with a chromium allergy and from that figure estimating the development of the incidence of chromium allergy. A detailed assessment is described in section B and the main outcome is summarised in section F. This summary describes the population in terms of observed cases (for the incidence figure) and the attribution of the incidence figure to the exposure in question. Neither the method used for the extrapolation nor the basis for the prevalence figure is described in the summary, but both are explained in previous sections.

It is expected that other consumers will develop health effects (severe dermatitis) until they are diagnosed with chromium allergy. Patients with an existing chromium allergy are expected to take all reasonable actions to avoid leather articles potentially containing chromium (VI) and therefore will not develop health effects attributed to leather articles. Justification for this approach is provided.

Impact assessment
Incidence and prevalence rates from surveys together with expert opinion are used to estimate the number of new cases of chromium allergy due to leather articles and the number of existing cases of chromium allergy in the EU. The HIA assesses the health impact of the proposed restriction as the reduction in the number of new cases of chromium allergy attributed to leather articles in the EU and the population of consumers with a current chromium allergy that would incur a welfare loss because they cannot wear leather articles. All parameters are defined and justified.

Valuation of impact
The valuation methodology is defined and justified in the HIA section of the background document. For existing cases, the consumer surplus approach is used, based upon the assumption that all those with a chromium allergy currently avoid leather articles containing chromium (VI) to prevent allergic symptoms. With regard to new cases of chromium allergy, individuals are less likely to be able to avoid exposure by changing their behaviour, because they are unaware of the source of the problem. In that case, the welfare loss is valued as direct costs due to health care and medication, and for indirect costs as a consequence of production loss/working time lost and loss of welfare. The various cost elements for the welfare loss of new allergies are defined and justification is provided.

Sensitivity and uncertainty analyses
The HIA includes a sensitivity analysis in which the impact of varying the key parameters is studied. The selection of main parameters for the analysis is justified on the basis of their relevance to the results and the level of uncertainty. A table is provided with the main data elements of the HIA and their level of uncertainty.

Table 10: Structured format table of the key descriptive parameters of the HIA of chromium in leather articles

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	No	No	
Context within SEA	No	No	
Desired HIA detail	No	No	
Data availability	No	No	
Scope			
Population	No	No	Not explicitly defined and justified in section F, but can be deduced from the other sections
Geographic boundary	No	No	
Period	Yes	Yes	
Possible health endpoints	No	Yes	
Most relevant health endpoints	Yes	Yes	
Scenario definitions			
Baseline scenario	Partially	Yes	Scenarios as such are not explicitly defined in section F, but they can be assumed from the text. References to other sections for more detail are provided
Future trends in baseline scenario	Partially	Yes	
Policy scenario	Partially	Yes	
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment	*NP*		
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3b: Quantitative assessment based on observed clinical cases			
Exposure assessment			
Target population	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Health effect assessment			
Population of observed cases	Partially	No	Only summarised in section F; defined

Element	*Defined*	*Justification*	*Additional remarks*
Extrapolation to the target population	No	No	and justified in other sections
Attribution to the exposure in question	Yes	No	
Impact assessment			
Population size with associated health effect	Yes	Yes	
Step 3: Valuation of impact			
Methodology used for valuation	Yes	Yes	
Effect–value relationship	Yes	Yes	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	Yes	Yes	
Uncertainty analysis	Yes	Yes	

NP = Not performed

5.8 Lead in articles for consumer use

5.8.1 Summary of the proposed restriction

The restriction dossier was submitted by Sweden in 2012 and proposes a restriction on the use of lead and its compounds in articles that children can put in their mouths. Children are exposed to lead through sucking and chewing articles containing lead, and the resulting risk of IQ deficits is assessed. For this, the same estimates that formed the basis of the proposed restriction of lead in jewellery were used. The proposed restriction would prohibit the placement on the market of articles and accessible parts of articles containing lead and its compounds at concentrations equal to or greater than 0.05% by weight that are supplied to the general public and that children can put in their mouths (ECHA 2014).

5.8.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The HIA section states the aim of the HIA and its context within the SEA as a whole. The goal of the SEA is to make a partial CBA with a break-even analysis. The approach uses a three-step model to estimate the behaviour needed for the break-even point (zero net benefit). The required level of detail for the HIA is not stated and it is unclear whether sufficient data was available to conduct the HIA.

Scope

The scope of the HIA is not explicitly stated; however, from the text it becomes clear that the population is children between 6 and 36 months that may put consumer articles containing lead in their mouths. The geographic boundary is the EU-27 and the period is defined as one year. No explicit justification is given for the chosen period. The relevant health endpoint is neurotoxicity. Various other health effects are mentioned qualitatively and it is stated that they are not quantified for the purpose of this restriction proposal as the estimated benefits already outweigh the cost.

Scenario definitions
The general baseline scenario of the SEA is described in section E. The HIA does not explicitly state a baseline scenario. The general baseline scenario is current IQ loss as a consequence of exposure to lead via mouthing. The policy scenario is not explicitly defined in the HIA section; however, it can be deduced from section E that the proposed restriction is the policy scenario. No alternative policy scenario is assessed, and no mention is made of future trends in the baseline scenario.

Impact assessment (detail level 3a: quantitative assessment)

Exposure assessment
The exposure assessment is based on two approaches. The first approach is to calculate the exposure scenario that would reach the break-even point between costs and benefits. The second approach is to estimate the actual mouthing (exposure duration and frequency) and compare these with the various break-even exposure scenarios. In both approaches, the frequency of exposure events and the exposure duration per event are defined and justified. The target population is children in the EU between the ages of 0.5 and 3 years. The exposure level is calculated on the basis of the migration rate of lead in an article containing 1% lead, the surface area of a typical piece and the average body weight of a child within this age range. All these parameters are defined. The justification for the migration rate is given in the HIA section, the other justifications in other sections.

Health effect assessment
The health effect assessed is IQ loss as a consequence of neurotoxicity. The dose–response function (relationship between lead exposure and IQ effects) is briefly defined and justified in the HIA section. The dose–response function is described as the result of a two-step process that requires, first, a description of the relationship between IQ and blood lead levels and, second, a description of the relationship between blood lead levels and lead intake.

Impact assessment
In this HIA, due to the break-even approach in the SEA, the degree of IQ loss in the population is fixed (at 3067 IQ points loss). This health impact is based on the cost estimate of imposing the restriction and the valuation of the subsequent impact. The population size for the health impact is determined by the target population of the exposure assessment, i.e. every child in the EU between the ages of 0.5 and 3 years. The significance of the health impact and the population size is justified in the HIA section.

Valuation of impact
The methodology for the valuation of the health impact is defined and based on the assumption that cognitive ability, measured by IQ, affects lifetime productivity. No justification was found for using this approach to monetise the societal costs of lowered IQ. The estimate of the value of the reduction of earnings per IQ point is justified on the basis of a review of the available literature on this subject.

Sensitivity and uncertainty analyses
A sensitivity analysis on the break-even exposure duration is undertaken using a low/medium/high scenario. No justification is given for the selection of the key parameters. Uncertainties in the data are described where this seemed appropriate. However, an uncertainty analysis as such, such as a summarising table with the main data elements of the HIA and their level of uncertainty, is not provided.

Table 11: Key descriptive parameters of the HIA of lead in consumer articles

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	Yes	Yes	
Context within SEA	Yes	Yes	
Desired HIA detail	No	No	
Data availability	No	No	
Scope			
Population	Yes	No	
Geographic boundary	Yes	Yes	
Period	Yes	No	
Possible health endpoints	Yes	Yes	
Most relevant health endpoints	Yes	Yes	
Scenario definitions			
Baseline scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Future trends in baseline scenario	No	No	
Policy scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Alternative policy scenarios	No	No	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment	*NP*		
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3a: Quantitative assessment based on human dose–response function			
Exposure assessment			
Frequency of exposure	Yes	Yes	
Target population	Yes	Yes	

Element	*Defined*	*Justification*	*Additional remarks*
Exposure duration	Yes	Yes	
Level of exposure	Yes	Yes	Justification of some parameters in other sections
Health effect assessment			
Dose–response relationship	Yes	Yes	
Impact assessment			
Population size with associated health effect	Yes	Yes	
Step 3: Valuation of impact			
Methodology used for valuation	Yes	No	
Effect–value relationship	Yes	Yes	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	Yes	No	
Uncertainty analysis	Partially	No	

NP = Not performed

5.9 1,4-Dichlorobenzene (DCB)

5.9.1 Summary of the proposed restriction

The restriction dossier was submitted by the ECHA in 2012 upon a request from the Commission. The main reason for the proposed restriction is the possible risks to consumers arising from the non-genotoxic carcinogenic effects of 1,4-dichlorobenzene (DCB). The restriction dossier targets the use of DCB in air fresheners and deodorisers by the general public and professionals working in public areas where DCB is used for that purpose. The proposed restriction would prohibit the placement on the market, or use of DCB in a concentration equal to or greater than 1% by weight where the substance or the mixture is intended to be used as an air freshener or deodoriser in toilets, homes, offices or other indoor public areas (ECHA 2013).

5.9.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The HIA of DCB is part of the SEA of the restriction dossier, which focuses on economic and health impacts. The aim of the HIA and its context within the SEA as a whole are not described. The level of detail of the HIA required for the SEA is not stated, nor whether appropriate data is available.

Scope

The population of the HIA is the number of consumers and professionals possibly exposed to DCB from the use of air refreshers and deodorisers in toilets, homes and public areas. The geographic boundary is not explicitly stated in the HIA, but from previous sections in the background document it can be assumed to be EU-27. The period is the year 2012 with justification given. Several health endpoints related to

DCB are defined and the most relevant health endpoint, carcinogenicity, is identified on the basis of the risk assessment, including the risk characterisation, provided for this endpoint.

Scenario definitions
The general baseline scenario is described in section E and the HIA refers to this baseline scenario. The general baseline scenario describes a declining trend in the use of DCB generally and in air refreshers and deodorisers specifically, but only a marginal one. Several policy scenarios are defined and assessed, targeting either consumers, workers or both.

Impact assessment (detail level 1: qualitative assessment)

Exposure assessment
In the HIA, the exposed population was estimated as the users of toilet blocks and air fresheners in public areas, i.e. consumers and workers, including toilet attendants/cleaners, who are exposed to DCB. The exposure level is defined as a range including realistic as well as worst-case scenarios. Frequency and duration of exposure are not defined within the HIA but reference is made to section B.

Health effect assessment
The reason for the restriction dossier was the carcinogenic effect of DCB. In the HIA, an adjusted LOAEL for inhalation based on animal studies of carcinogenicity as well as of toxicity for the liver and kidney was derived for consumers and workers. No justification could be found for the use of this LOAEL.

Impact assessment
Reference is made to the populations (consumers and workers) that are estimated to be exposed above the DNELs (population at risk). However, the data from the risk assessment is used for describing impacts on human health only in a qualitative manner. Justification is provided, as the quantification of impacts from exceedance of the DNEL is not straightforward. The possible impact on human health is quantitatively described by the margins of safety between the modelled exposures and the adjusted inhalation LOAEL for consumers and workers. No further justification is provided for this margin of safety approach. The health impact is qualitatively defined as the induction of cancer in some individuals who are repeatedly exposed to high levels of DCB.

Valuation of impact
The health impact of the restriction is not appraised. No justification for this is provided.

Sensitivity and uncertainty analysis
In the HIA section no sensitivity or uncertainty analyses re performed. Justification is not provided.

Table 12: Key descriptive parameters of the HIA of 1,4-Dichlorobenzene (DCB)

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definition			
Goal			
Aim	No	No	
Context within SEA	No	No	
Desired HIA detail	No	No	
Data availability	No	No	
Scope			
Population	Yes	Yes	
Geographic boundary	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Period	Yes	Yes	
Possible health endpoints	Yes	Yes	
Most relevant health endpoints	Yes	Yes	
Scenario definition			
Baseline scenario	No	Yes	Reference is made to other sections
Future trends in baseline scenario	Yes	Yes	
Policy scenario	Yes	Yes	
Alternative policy scenarios	Yes	Yes	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment			
Exposure assessment	Yes	Yes	The population and level of exposure are described quantitatively. Justification of some parameters is given in other sections
Health effect assessment	Yes	No	The LOAEL for carcinogenicity and toxicity for liver and kidney is provided quantitatively
Impact assessment	Yes	Yes	Justification is given only for the qualitative approach
Detail level 2: Quantitative assessment based on risk reduction	*NP*		
Detail level 3: Quantitative assessment based on health effects	*NP*		

Element	*Defined*	*Justification*	*Additional remarks*
Step 3: Valuation of impact			
Methodology used for valuation	No	No	
Effect–value relationship	No	No	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	No	No	
Uncertainty analysis	No	No	

NP = Not performed

5.10 Manufacturing and industrial or professional use of N-methylpyrrolidone (NMP)

5.10.1 Summary of the proposed restriction

The restriction dossier for NMP was submitted in 2013 by the Netherlands. The proposal was to restrict the inhalation exposure over an 8h-TWA (time weighted average) to below the level of a predefined DNEL (set in the dossier) and to ensure that dermal exposure is avoided through the implementation of protective measures. NMP is a reproduction toxic substance causing developmental effects (classified as reprotoxic category 1B), but also shows irritation effects. The restriction focuses on the manufacture of NMP and its industrial and professional uses, assuming that NMP will not be used in consumer products in view of the 0.3% content limit due to its classification (ECHA 2014).

5.10.2 Summary of the HIA in the background document

Goal, scope and scenario definitions

Goal

The goal of the restriction dossier is to reduce the risks of developmental effects (pregnant women and their offspring) and against general toxicity from the use of NMP in occupational settings. The aim of the HIA is described at the beginning of section F: "discuss the health effects as potential positive effects of the various RMOs". The context of the HIA within the SEA as a whole is not discussed. The level of detail of the HIA and whether sufficient data is available for the desired level of detail is discussed throughout the HIA in an iterative process.

Scope

The scope of the HIA is defined as the population (workers) and the geographical boundaries (Europe) addressed. In the sensitivity analysis a period of 2011–2016 is defined without further justification. Throughout the HIA, the possible health endpoints are defined for different exposure patterns and subpopulations (e.g. pregnant workers). Relevant health endpoints further considered in the HIA are defined and justified.

Scenario definition

The general baseline scenario of the SEA is described in section E. The HIA does not explicitly state a baseline scenario. The general baseline scenario describes future trends in the use of NMP. Several policy scenarios are defined in the HIA, based upon the various RMOs: (1) a

total ban, (2) restriction on use of NMP with certain derogations, (3) harmonised DNEL and (4) authorisation. The third option reflects the proposed restriction.

Impact assessment (detail level 2: risk reduction)

Exposure assessment
The exposure assessment is based on the exposure assessment in the registration dossier. In the HIA only the estimated 75^{th}–90^{th} percentile of the 8h-TWA level of exposure is defined for each specific working activity. It was acknowledged by the dossier submitter that the exposure assessments from the registration dossier may have been conservative estimates. Reference to section B is made for the exposure estimates, where the relevant input parameters for the modelling can be found.

Health effect assessment
The various health effects of NMP found in animal studies are discussed in the HIA. Based on their relevance to humans, relevant human endpoints to consider in the HIA are defined. In addition, DNELs for pregnant workers and workers in general are defined. However, the associated critical effects corresponding to the different DNELs derived are not stated in the HIA.

Impact assessment
The impact assessment is based on the risk reduction of the proposed restriction, where all exposures must result in risk characterisation ratios (RCRs) below 1. The risk reduction would apply to almost all workers exposed. The sizes of the populations at risk (all workers and female workers of childbearing age) were estimated from industry figures but could not be stated for reasons of confidentiality. The corresponding critical human endpoints for the populations at risk are not defined in the HIA.

Valuation of impact
The health impact of the restriction is not appraised. No justification is provided.

Sensitivity and uncertainty analyses
A sensitivity analysis is performed on different baseline trends. No justification is given for the selection of the parameters, nor reasons why these should be the key parameters. No description of the level of confidence in the key parameters was found. A justification for not conducting an uncertainty analysis was not found either.

Table 13: Key descriptive parameters of the HIA of N-methylpyrrolidone (NMP)

Element	*Defined*	*Justification*	*Additional remarks*
Step 1: Goal, scope and scenario definitions			
Goal			
Aim	Yes	Yes	
Context within SEA	No	No	
Desired HIA detail	Yes	Yes	Explanation was given for the (im)possibility of the various detail levels
Data availability	Yes	Yes	
Scope			
Population	Yes	Yes	
Geographic boundary	Yes	Yes	
Period	Yes	No	
Possible health endpoints	Yes	Yes	
Most relevant health endpoints	Yes	Yes	
Scenario definitions			
Baseline scenario	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Future trends in baseline scenario	No	No	
Policy scenario	Yes	Yes	
Alternative policy scenarios	Yes	Yes	
Step 2: Impact assessment			
Detail level 1: Qualitative assessment	*NP*		
Detail level 2: Quantitative assessment based on risk reduction			
Exposure assessment			
Frequency of exposure	No	No	Not explicitly defined and justified in section F, but can be deduced from other sections
Target population	Yes	No	
Exposure duration	No	No	
Level of exposure	Yes	Yes	
Health effect assessment			
DNEL derivation	Partial	No	No reference to underlying critical effect(s)
Impact assessment			
Population size with associated risk reduction	Partial	Yes	No reference to the health effect the population is at risk of
Detail level 3: Quantitative assessment based on health effects	*NP*		

Element	*Defined*	*Justification*	*Additional remarks*
Step 3: Valuation of impact			
Methodology used for valuation	No	No	
Effect–value relationship	No	No	
Step 4: Sensitivity and uncertainty analyses			
Sensitivity analysis on key parameters	Yes	No	
Uncertainty analysis	No	No	

NP = Not performed

5.11 Observations

A summary of the HIAs surveyed is presented in the overview tables in Annex I (Table 14 and Table 15). No in-depth analysis of the HIAs surveyed was conducted due to the limited number of HIAs described and the qualitative nature of this review. Furthermore, the aim of this project is not to assess the quality of the HIAs as described in the background documents but to develop a structured format for their presentation. Instead, some general observations are stated.

Some elements of the HIA are more often defined than others: for example the aim, population, geographic boundary, period, policy scenario, and most relevant health end points. When elements are not defined, a justification is usually not provided. In particular, various scenario definitions (baseline scenario, future trends and alternative policy scenarios) are not often given in the HIAs. These elements are sometimes described in other sections of the background document and this could explain why they are not explicitly defined in the HIA.

The aim of the HIA is often not defined or justified. The justification for the scope of the HIA might not be stated in some cases, as this would be assumed by default, such as the geographical boundary. Another observation concerns the health endpoints used in the HIA. The most relevant endpoints are usually defined, but a discussion of the other health endpoints and a justification of the selection of the most relevant health endpoints are not often provided.

Another observation concerns the sensitivity and uncertainty analyses. Parameters in the sensitivity analysis are not usually accompanied by a justification of the selection of those parameters. An uncertainty analysis is generally not performed and reasons for not performing such an analysis are not provided.

The survey shows that HIAs performed at the first detail level (qualitative) do not valuate the impact or perform a sensitivity and uncertainty analysis. Justification for not defining the value of the impact is sometimes provided, but not for not performing a sensitivity or uncertainty analysis. The lack of definition of those elements might be due to the fact that sensitivity and uncertainty analyses are usually performed with quantitative calculations, but such a reasoning is not provided as justification.

6 Discussion and recommendations

In REACH restriction dossiers (and authorisation requests), the HIA is an important part of the SEA. The HIA pictures the expected health benefits (or costs) of the regulatory action and is thereby part of a cost–benefit analysis that can be used to judge the proportionality of the proposed regulatory action. Various methodological approaches, elements and assumptions were encountered in the HIAs submitted under REACH. Furthermore, the HIAs are often reported in various levels of detail and not always in a structured and transparent way. This project aimed to develop a structured format for HIAs within the context of SEAs under REACH. The structured format does not propose new HIA methods, but follows existing guidelines. It does, however, provide a more consistent and transparent way of preparing and evaluating an HIA.

Definition of a health impact
The second chapter of this report introduces the concept of HIA and shows that the elements that define an HIA are dependent on the context in which the HIA is performed. In most HIAs, health is defined from a holistic viewpoint, including social and mental well-being and not merely the absence of disease or infirmity (see Figure 2). The definition of health within the HIA shapes the overall boundaries of what are considered to be health impacts. Within the SEAs of REACH restriction dossiers, the definition of health, and thus of health impacts, is not totally clear from the ECHA Guidance on Socio-economic Analysis – Restrictions (ECHA 2008). Different views exist as to whether or not risk reduction should be seen as a health impact and therefore taken into account when conducting an HIA. In this report, a health impact is defined by clinical effects, subclinical effects or a risk reduction for a (sub)clinical effect on a specified population.

The structured format
The structured format was developed in parallel with a survey of existing HIAs within the background documents of restriction dossiers and the format was refined on the basis of the experiences of reviewing the existing cases in an iterative process. The goal of the HIA survey was not to evaluate the quality of the HIAs or to produce comprehensive summaries of the HIAs, but to find a common structure for the presentation of HIAs that can be of use in preparing or evaluating HIAs. The work resulted in a structured format that is a relatively simple one-page table presenting the elements of the HIA and allowing the opportunity to explain whether elements have been defined and justified in a specific HIA case. Besides that, the table permits the inclusion of additional justification or comments per element in a separate column. In so doing, the structure aims to allow the elements of the HIA to be reported and potentially evaluated in a consistent and transparent way.

First experiences in this project with the use of the format for evaluation purposes showed that it is easy to use and helps the reader to get an impression of the basic elements of the HIA and some of the basic assumptions made, thereby providing a quick overview for systematic evaluation of the main elements. Not all the elements in the format

need to be included in an HIA; however, the format facilitates reporting of all crucial elements and reminds users to explain why certain elements have or have not been included in a particular case.

In this HIA survey, the format was used in a relative narrow way, only indicating whether elements had been defined (yes/no) and whether the elements used had been justified (yes/no). Throughout the assessment of the HIAs it was found that such binary responses could not always be applied and in some cases *partially* was used instead. The format might also be extended to include the actual values of elements, with an additional column for the justification of these elements. The commenting column then could be used to evaluate the appropriateness or quality of the values used. Such an extension of the table is assumed to be valuable; however, within the scope of this project this could not be done. Likewise, the usefulness of the format (whether narrow or extended) in preparing new HIAs and evaluating existing HIAs needs further research and the number of existing HIAs surveyed is too small to draw firm conclusions on its usefulness.

It is not intended to present a definitive format here, but rather to provide a starting point that will help to structure HIAs within SEAs and REACH in the future. Applying the format may enable further refinement and improvement of the format. Obtaining further experience in using the format could indicate whether any other adjustments are required.

Goal and scope definition
As expected at the start of this project, the survey of HIAs in restriction dossiers using the structured format reveals wide variety in health impact analyses, from pure qualitative analyses to partial quantitative risk- or health effect-based assessments. One or the other is not right or wrong, but the form chosen seems to depend mainly on the availability of data in the specific case.

The results of an HIA serve the purpose (goal) of assisting in the judgement of the proportionality of the proposed regulatory action within the context of an SEA. This context will define what type of SEA and what level of detail in the HIA are required for judgements on proportionality. Therefore, framing the HIA within the context of the SEA as a whole is necessary and was included as one of the elements of the structured format as part of the goal description. The survey of cases shows that a complete goal definition of the HIA is often not provided. This lack in reporting might be caused by the fact that the restriction dossier format does not invite such definitions. This can be seen from Figure 5 in this report, where no place for goal definition has been specified. It might be that authors do have an idea of the goal of their HIA but have not defined it explicitly. This makes it difficult to assess whether the HIAs performed are fit for purpose.

The survey shows that the scope and the (baseline and policy) scenarios of the SEA and, with these, the scope and scenarios that form the basis of the HIA, are often not clearly defined in the HIA. The scope and scenario definitions are often spread over various sections of the dossier and often specified in terms of the restriction proposal itself. This makes it unclear what scope and scenarios are actually used in the HIA, as

these do not automatically follow from the scope and scenarios of the restriction proposal itself. Again, the reason for such an unstructured and scattered presentation of the scope and scenarios might be that the restriction dossier format (see Figure 5) does not invite a structural definition of these elements.

A definition at the start of section F of the background document explaining the goal, scope and scenarios of the SEA and HIA performed and connecting this explicitly to the proposed restriction would improve the assessment of the SEA and HIA as part of the restriction proposals. It would also facilitate the interpretation of the HIA (and SEA) results in relation to the proportionality of the proposed risk management measure. Note that, although HIA has been the focus of this project and recommendations with respect to the goal and scope definition come from that focus, the goal and scope definition are important for the SEA as a whole, of which the HIA is an essential part. Defining goal and scope at the level of the SEA might be more appropriate than doing so at the level of the HIA only. The need to define goal, scope and scenarios before starting an SEA was recognised in 2008, when the SEA guidance for restrictions was published. These elements were explicitly taken up in the reporting format of SEAs, as presented in Text box 2 of this report (Note: goal is defined as aim). Strangely, however, this "aim and scope" section was not taken over into the format of the restriction dossier, as presented in Figure 5. At this moment (2015), the ECHA is in the process of updating the restriction dossier format and some improvements are expected.

HIA elements and uncertainties
The structured format lists the elements that were used in the HIAs surveyed. The HIAs described show variation in the elements used and the survey indicates that a justification of the elements used is not always provided. Elements of the goal, scope, scenario definitions, valuation and uncertainty analysis are more often not defined or justified than the elements of exposure, hazard and risk or effect assessment (as can be seen from Tables 14 and 15). This could be explained by the fact that risk assessment forms the basis of restriction reports and that there is more experience with risk assessment than with SEA and HIA. Improving the justification of the HIA elements could increase the robustness and transparency of the HIA results. The general lack of justification might be explained by the fact that there is, at the moment, no uniform and structured approach to an HIA.

The lack of justification of some elements might also be related to the fact that relevant information for the HIA is scattered over the dossier and that this information is not explicitly referred to in the HIA. Some of the elements required in an HIA serve various purposes in the background document. For example, exposure and hazard assessments are primarily performed for the purpose of the obligatory and essential risk assessment and not for the purpose of the HIA. Being aware of this and recognising the need to explicitly refer to elements relevant to the HIA that are presented in other sections (for other purposes) might help to further improve HIAs. The format developed in this report may enable more structured and transparent HIA reporting. It could also be used to consistently check whether all desired information is included in an HIA.

The expert preparing an HIA often faces a problem of lack of information. In such cases, it is accepted that experts make assumptions (e.g. by using expert elicitation methods), provided that they are clearly reported. The survey showed that uncertainty and sensitivity analyses are not always performed within the HIAs. Uncertainty and sensitivity analyses are deemed important, as many parameters are used in HIAs and the justification of these parameters is not always provided. The value of the parameters used might therefore be uncertain. A sensitivity analysis is often performed only for certain parameters and justification for the choice of these parameters is not always provided.

Conclusion
Overall, the survey showed the variety in the content of HIAs performed in the context of REACH restriction dossiers. Information required for the HIA was usually scattered throughout the background document and not all HIA elements were defined in the HIA/SEA section. The restriction dossier format does not explicitly require the statement of the goal, scope and scenario definitions of the HIA or SEA. Uncertainty and sensitivity analyses are not always performed and justification for this is generally not provided.

The structured format was developed from the existing guidance and improved during the survey of the HIAs in an iterative process. It could aid in the preparation or evaluation of an HIA by explaining why certain elements have or have not been included and therefore increase the robustness and transparency of the HIA results. The format presented provides a starting point and can be further improved in practice. Use of this format when starting or assessing an HIA within REACH prevents crucial elements of the HIA from being omitted. It is recommended that the structured format be included in the HIA section of restriction dossiers and authorisation requests to provide a quick overview of the basic elements of the HIA.

7 References

BAuA (2010). ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION (BENZO[A]PYRENE CAS No: 50-32-8 EINECS No: 200-028-5) (BENZO[E]PYRENE CAS No: 192-97-2 EINECS No: 205-892-7) (BENZO[A]ANTHRACENE CAS No: 56-55-3 EINECS No: 200-280-6) (DIBENZO[A,H]ANTHRACENE CAS No: 53-70-3 EINECS No: 200-181-8) (BENZO[B]FLUORANTHENE CAS No: 205-99-2 EINECS No: 205-911-9) (BENZO[J]FLUORANTHENE CAS No: 205-82-3 EINECS No: 205-910-3) (BENZO[K]FLUORANTHENE CAS No: 207-08-9 EINECS No: 205-916-6) (CHRYSENE CAS No: 218-01-9 EINECS No: 205-923-4). Dortmund, Bundesanstalt für Arbeitsschutz und Arbeitsmedizin. **VERSION NUMBER: 1**.

Birley, M. H. (1995). The Health Impact Assessment of Development Projects. London, HMSO books.

Dahlgren, G. and M. Whitehead (1991). Policies and strategies to promote social equity in health. Stockholm, Institute for Future Studies.

ECHA (2008). Guidance on Socio-economic Analysis - Restrictions. Guidance for the implementation of REACH. Helsinki, European Chemicals Agency.

ECHA (2011). Background document to the opinions on the Annex XV dossier proposing restrictions on Dimethylfumarate (DMFu). Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000001305-83-04/S1 ECHA/SEAC/RES-O-0000001412-86-03/F**.

ECHA (2011). Background document to the opinions on the Annex XV dossier proposing restrictions on five Phenylmercury compounds. Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000001362-83-02/S1 ECHA/SEAC/ RES-O-0000001362-83-03/S1**.

ECHA (2011). Background document to the opinions on the Annex XV dossier proposing restrictions on Lead and its compounds in jewellery Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000001304-85-03/S1 ECHA/SEAC/RES-O-0000001304-85-04/S1**.

ECHA (2011). Background document to the opinions on the Annex XV dossier proposing restrictions on Mercury in measuring devices. Helsinki, European Chemicals Agency. **ECHA/RAC/ RES-O-0000001363-81-02/F ECHA/SEAC/ RES-O-0000001363-81-03/S1**.

ECHA (2012). ADDENDUM TO THE GUIDANCE ON ANNEX XV FOR RESTRICTIONS AND TO THE GUIDANCE ON SOCIO-ECONOMIC ANALYSIS (SEA) – RESTRICTIONS. EXPLANATORY NOTE FORMAT OF ANNEX XV RESTRICTION REPORT. Helsinki, European Chemicals Agency **Version 1.1**.

ECHA (2012). Background document to the opinions on the Annex XV dossier proposing restrictions on Chromium VI in leather articles. Helsinki, European Chemicals Agency. **ECHA/RAC/ RES-O-0000001412-86-09/S1 ECHA/SEAC/RES-O-0000002419-71-02/S2**.

ECHA (2013). Background Document to the opinions on the Annex XV dossier proposing restrictions on 1,4-dichlorobenzene. Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000003486-69-01/F ECHA/SEAC/RES-O-0000003486-69-02/F**.

ECHA (2014). Background document to the opinions on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP). Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000005316-76-01/F ECHA/SEAC/RES-O-0000005316-76-02/F**.
ECHA (2014). Background document to the opinions on the Annex XV dossier proposing restrictions on Lead and its compounds in articles intended for consumer use. Helsinki, European Chemicals Agency. **ECHA/RAC/RES-O-0000003487-67-04/F ECHA/SEAC/ RES-O-0000003487-67-05/F**.
ECHA. (2015). "Understanding REACH." Retrieved 20-03-2015, from http://echa.europa.eu/web/guest/regulations/reach/understanding-reach.
Lock, K. (2000). "Health impact assessment." British Medical Journal **320**(7246): 1395-1398.
RPA (2011). Assessing the Health and Environmental Impacts in the Context of the Socioeconomic Analysis Under REACH. Part 1: Literature Review and Recommendations and Part 2: The Proposed Logic Framework and Supporting Case Studies. London, Risk & Policy Analysts Ltd,. **ENV.D.1./SER/2009/0085r. Final Report.**
SBK. (November 2014). "SBK-Toetsingsprotocol opname data in de Nationale Milieudatabase version 2.0." Retrieved 24-12-2014, from www.milieudatabase.nl/.
Schuur, A. G., L. Preller, W. ter Burg, P. G. N. Kramers, E. D. Kroese, J. G. M. van Engelen, R. A. Bausch-Goldbohm, H. J. van Kranen and M. T. M. van Raaij (2008). Health impact assessment of policy measures for chemicals in non-food consumer products. Bilthoven, National Institute for Public Health and the Environment. **RIVM report 320015001/2008**.
Verhoeven, J. K., J. Bakker, Y. Bruinen de Bruin, E. A. Hogendoorn, J. A. de Knecht, W. J. G. M. Peijnenburg, L. Postuma, J. Struijs, T. G. Vermeire, H. J. van Wijnen and D. de Zwart (2012). From risk assessment to enviromental impact assessment of chemica substances *Methodology development to be used in socio-economic analysis for REACH*. Bilthoven, National Institute for Public Health and the Environment **RIVM report 601353002/2012**.
WHO (2004). IPCS Risk Assessment Terminology. Geneva, World Health Organization. **Harmonization Project Document No. 1**.

Annex I: Summary tables

In Table 14 an overview is given of the number of times an element has been fully, partially or not defined and/or justified. In Table 15 the structured format tables of all nine HIAs are put together to give a global overview. In this table, for better visualisation, a yes is transformed into a + sign, a no is transformed into a – sign and "partial" has been truncated to pt. Additional remarks are not included and the different detail levels of the impact assessment are grouped for easier comparison.

Table 14: An overview of the number of times a parameter is fully, partially or not defined or justified in the nine HIAs analysed

Elements	Defined			Justified		
	Yes	*No*	*Par-tial*	*Yes*	*No*	*Par-tial*
Step 1: Goal, scope and scenario definitions						
Goal						
Aim	5	4		5	4	
Context within SEA	3	6		3	6	
Desired HIA detail	3	6		4	5	
Data availability	3	6		4	5	
Scope						
Population	5	4		5	4	
Geographic boundary	5	4		5	4	
Period	6	3		4	5	
Possible health endpoints	4	5		5	4	
Most relevant health endpoints	8	1		5	4	
Scenario definitions						
Baseline scenario	2	6	1	4	5	
Future trends in baseline scenario	2	6	1	3	6	
Policy scenario	5	3	1	6	3	
Alternative policy scenarios	2	7		3	6	
Step 2: Impact assessment						
Detail level 1: Qualitative assessment						
Exposure assessment	3		2	3	1	1
Health effect assessment	3	1	1	2	3	
Impact assessment	3	1	1	4	1	
Detail level 2:Quantitative assessment based on risk reduction						
Exposure assessment						
Frequency of exposure		1			1	
Target population		1			1	
Exposure duration		1			1	
Level of exposure	1			1		
Health effect assessment						
DNEL derivation			1		1	

Elements	Defined			Justified		
	Yes	*No*	*Par-tial*	*Yes*	*No*	*Par-tial*
Impact assessment						
Population size with associated risk reduction			1	1		
Detail level 3a: Quantitative assessment based on human dose–response function						
Exposure assessment						
Frequency of exposure	2			2		
Target population	2			2		
Exposure duration	2			2		
Level of exposure	2			1		1
Health effect assessment						
Dose–response relationship	2			2		
Impact assessment						
Population size with associated health effect	2			2		
Detail level 3b: Quantitative assessment based on observed clinical cases						
Exposure assessment						
Target population		1			1	
Health effect assessment						
Population of observed cases			1		1	
Extrapolation to the target population		1			1	
Attribution to the exposure in question	1				1	
Impact assessment						
Population size with associated health effect	1			1		
Step 3: Valuation of impact						
Methodology used for valuation	3	6		5	4	
Effect–value relationship	3	6		6	3	
Step 4: Sensitivity and uncertainty analyses						
Sensitivity analysis on key parameters	4	5		1	8	
Uncertainty analysis	1	7	1	1	8	

Table 15: Summary of the nine structured formats (5.2 to 5.10) from the assessed HIAs grouped by detail level

	Defined									*Justified*								
Detail level	*1*					*2*	*3*			*1*					*2*	*3*		
Structured format / **Element**	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*
Step 1: Goal, scope and scenario definitions																		
Goal																		
Aim	+	+	-	-	-	+	+	-	+	+	+	-	-	-	+	+	-	+
Context within SEA	-	+	-	-	-		+	-	+	-	+	-	-	-		+	-	+
Desired HIA detail	+	-	-	+	-	+	-	-	-	+	+	-	+	-	+	-	-	-
Data availability	+	-	-	+	-	+	-	-	-	+	+	-	+	-	+	-	-	-
Scope																		
Population	+	-	-	+	+	+	+	-	+	+	-	-	+	+	+	+	-	-
Geographic boundary	-	+	-	+	-	+	+	-	+	-	+	-	+	-	+	+	-	+
Period	-	+	-	-	+	+	+	+	+	-	+	-	-	+	-	+	+	-
Possible health endpoints	-	-	-	-	+	+	+	-	+	-	-	-	-	+	+	+	+	+
Most relevant health endpoints	+	-	+	+	+	+	+	+	+	-	-	-	-	+	+	+	+	+
Scenario definitions																		
Baseline scenario	-	-	-	+	-	-	+	Pt.	-	-	-	-	+	+	-	+	+	-
Future trends in baseline scenario	-	-	-	+	+	-	-	Pt.	-	-	-	-	+	+	-	-	+	-
Policy scenario	-	+	-	+	+	+	+	Pt.	-	-	+	-	+	+	+	+	+	-
Alternative policy scenarios	-	-	-	-	+	+	-	-	-	-	-	-	+	+	+	-	-	-
Step 2: Impact assessment																		
Detail level 1: Qualitative assessment																		
Exposure assessment	+	Pt.	Pt.	+	+					Pt.	+	-	+	+				
Health effect assessment	+	-	Pt.	+	+					-	+	-	+	-				
Impact assessment	+	-	Pt.	+	+					+	+	-	+	+				
Detail level 2: Quantitative assessment based on risk reduction																		
Exposure assessment																		
Frequency of exposure						-									-			

Element	Defined									Justified								
Detail level	*1*					*2*	*3*			*1*					*2*	*3*		
Structured format	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*
Target population						-									-			
Exposure duration						-									-			
Level of exposure						+									+			
Health effect assessment																		
DNEL derivation						+									-			
Impact assessment																		
Population size with associated risk reduction						+									+			
Detail level 3a: Quantitative assessment based on human dose–response function																		
Exposure assessment																		
Frequency of exposure							+		+							+		+
Target population							+		+							+		+
Exposure duration							+		+							+		+
Level of exposure							+		+							Pt.		+
Health effect assessment																		
Dose–response relationship							+		+							+		+
Impact assessment																		
Population size with associated health impact							+		+							+		+
Detail level 3b: Quantitative assessment based on observed clinical cases																		
Exposure assessment																		
Target population								-									-	
Health effect assessment																		
Population of observed cases								Pt.									-	
Extrapolation to the target population								-									-	

Element	Defined									Justified								
Detail level	*1*					*2*	*3*			*1*					*2*	*3*		
Structured format	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*	*5.3*	*5.4*	*5.5*	*5.6*	*5.9*	*5.10*	*5.2*	*5.7*	*5.8*
Attribution to the exposure in question								+									-	
Impact assessment																		
Population size with associated health effect								+									+	
Step 3: Valuation of impact																		
Methodology used for valuation	-	-	-	-	-	-	+	+	+	-	+	+	+	-	-	+	+	-
Effect–value relationship	-	-	-	-	-	-	+	+	+	-	+	+	+	-	-	+	+	+
Sensitivity and uncertainty analyses																		
Sensitivity analysis on elements	-	-	-	-	-	+	+	+	+	-	-	-	-	-	-	-	+	-
Uncertainty analysis	-	-	-	-	-	-	-	+	Pt.	-	-	-	-	-	-	-	+	-

+ = Yes

- = No

Pt. = Partially

RIVM

Committed to health and sustainability