Organisation for Economic Co-operation and Development

ENV/WKP(2018)8

Unclassified **English - Or. English**

31 May 2018

ENVIRONMENT DIRECTORATE

Economic valuation in formaldehyde regulation

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JEL codes: Q51, Q52, Q53.

Keywords: Cost-benefit analysis, regulatory impact assessment, environmental health valuation, non-market valuation, formaldehyde.

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JT03432724

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Foreword

This background paper on *Economic valuation in formaldehyde regulation* was prepared for the SACAME workshop in Ottawa, Canada, 30-31 August 2017 by Alistair Hunt and Nick Dale of University of Bath, United Kingdom.

The workshop was organised in co-operation between the OECD Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology (Joint Meeting) and Working Party on Integrating Environmental and Economic Policies (WPIEEP), and was hosted by Health Canada, with funding from the European Commission.

The paper was revised and takes into account feedback received from Delegates during and after the workshop, and comments received from the Joint Meeting and WPIEEP by written procedure. The author would like to thank Nils Axel Braathen and Eeva Leinala of the OECD Secretariat for comments on previous versions of the paper. Work on this paper was conducted under the overall responsibility of Nathalie Girouard, Head of the Environmental Performance and Information Division. The indispensable support of Elvira Berrueta Imaz, Natasha Cline-Thomas and Stéphanie Simonin-Edwards in co-ordinating the editing and publication process is gratefully acknowledged.

The opinions expressed and the arguments employed are those of the authors.

Abstract

This paper gives an overview of economic assessments of the benefits of the control of formaldehyde and reflects on developments in its risk management and regulation. Formaldehyde is used in the manufacture of resins, as a disinfectant and fixative and as a preservative in consumer products. Formaldehyde exposure can be harmful to human health; not only is it a carcinogen but it can also impact on female fertility, and cause respiratory conditions as well as a range of less severe, acute conditions such as skin and eye irritations.

The most comprehensive assessment was undertaken for the US regulation of composite wood products. It monetised the benefits of avoided nasopharyngeal cancer and eye irritation but did not monetise the benefits from avoided myeloid leukaemia, respiratory-related effects and reduced fertility. The monetary values that were adopted in the analysis were, however, incomplete across treatment costs, opportunity costs and disutility costs.

A few assessments of the costs of regulation estimate costs of compliance to industry through, for example, changes to production processes, use of raw materials costs of testing, certification and labelling.

Future economic assessments need to better exploit the growing international body of health benefit valuation. Regulatory cost estimation also needs to be expanded to incorporate indirect costs; reliable ways of cost verification need to be developed.

JEL codes: Q51, Q52, Q53.

Keywords: Cost-benefit analysis; regulatory impact assessment; environmental health valuation; non-market valuation, formaldehyde.

Résumé

Ce document propose un tour d'horizon des évaluations économiques des avantages procurés par les mesures de contrôle du formaldéhyde et rend compte des évolutions de la réglementation de cette substance et de la gestion des risques qu'elle présente. Le formaldéhyde est utilisé dans la fabrication de résines, comme désinfectant et fixateur et comme conservateur dans les produits de consommation. L'exposition au formaldéhyde peut être dangereuse pour la santé humaine ; outre ses effets cancérogènes, le formaldéhyde peut altérer la fertilité féminine et causer des pathologies respiratoires ainsi que diverses affections aiguës moins graves, notamment des irritations cutanées et oculaires.

Son évaluation la plus complète a été réalisée aux États-Unis dans le contexte de la réglementation des produits en bois composites. Elle a attribué une valeur monétaire aux avantages correspondant aux cancers du rhinopharynx et aux cas d'irritation des yeux évités, mais pas à ceux correspondant aux cas évités de leucémies myéloïdes, d'effets respiratoires et de baisse de la fertilité. Les valeurs monétaires adoptées dans l'analyse étaient toutefois incomplètes en ce qui concerne tout à la fois les coûts de traitement, les coûts d'opportunité et les coûts de désutilité.

Quelques-unes des évaluations des coûts de la réglementation estiment les coûts de mise en conformité des entreprises correspondant, par exemple, à la modification des procédés de production, des matières premières utilisées et des coûts d'essai, de certification et d'étiquetage.

À l'avenir, les évaluations économiques devront mieux exploiter le corpus international grandissant des études consacrées aux avantages sanitaires. Il convient également de prendre en compte les coûts indirects dans l'estimation des coûts de la réglementation et de mettre au point des méthodes fiables de vérification des coûts.

Codes JEL : Q51, Q52, Q53.

Mots-clés : analyse coûts-avantages ; analyse d'impact de la réglementation ; évaluation des risques sanitaires liés à l'environnement ; évaluation non marchande, formaldéhyde

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Acronyms and abbreviations

CLP	Classification Labelling and Packaging of substances and mixtures regulation
CMR	Carcinogenic, mutagenic and reproductive toxicant
DALY	Disability-adjusted life-year
DFA	Damage function approach
DNEL	Derived no-effect level
ECHA	European Chemicals Agency
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
MUF	Melamine-urea formaldehyde
PF	Phenol formaldehyde
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SACAME	Socio-economic Analysis of Chemicals by Allowing a better quantification and monetisation of Morbidity and Environmental impacts.
UF	Urea formaldehyde
VSL	Value-of-statistical-life
WHO	World Health Organization
WTP	Willingness-to-pay

Executive summary

This study focuses on the economic assessment of formaldehyde regulation and reflects on the recent and on-going developments in its risk management and regulation, especially in the United States in the context of standards for composite wood products and in the EU in the context of REACH substance evaluation.

Formaldehyde is extensively produced industrially worldwide for use in the manufacture of resins, as a disinfectant and fixative and as a preservative in consumer products. The global formaldehyde market was valued at about USD 10.9 billion in revenue generated in 2011. Asia accounts for almost half of global production, followed by Europe (23%) and North America (17%). Formaldehyde exposure can be harmful to human health; not only is it a carcinogen but it can impact on female fertility, and cause respiratory conditions as well as a range of less severe, acute conditions such as skin and eye irritations. There is no current evidence for negative impacts on the wider environment. Whilst legislation on formaldehyde is related to a large range of sectors across a number of OECD countries, there is less regulation in other regions. Where there is regulation, however, it has not generally been informed by economic assessment.

The most comprehensive assessment of social benefits of regulation was undertaken for the US regulation of composite wood products. That analysis monetised the benefits of avoided nasopharyngeal cancer and eye irritation but did not monetise the benefits from avoided myeloid leukaemia, respiratory-related effects and reduced fertility. The monetary values that were adopted in the US EPA analysis are incomplete across the range of the three component costs: treatment costs; opportunity costs and disutility (pain & suffering). Whilst the unit values used were expressed as ranges to reflect the uncertainties in their estimation, it is also noted that the studies from which they were transferred are rather dated and suggest that their temporal and methodological appropriateness may be limited.

For a small number of current and very recent regulatory proposals, assessments of the costs of regulation have been undertaken both in the United States and the EU. These studies include estimates of economic impacts on producers and consumers. The general approach has been to estimate costs of compliance to industry through, for example, changes to production processes, use of raw materials costs of testing, certification and labelling. In both studies, the cost data is understood to be gathered from a sample of affected businesses. However, these data are not well verified. There is therefore a risk of over-estimation, given that the businesses that are potentially negatively impacted may have an incentive to exaggerate the cost relative to the benefits.

Notwithstanding current limitations in the epidemiological evidence, future economic assessments need to better exploit the growing international body of health benefit valuation. Regulatory cost estimation also needs to be expanded to incorporate indirect costs; reliable ways of cost verification need to be developed. The need for better economic assessment is perhaps greatest in Asia, where the majority of formaldehyde production and consumption occurs.

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Keywords: Cost-benefit analysis; regulatory impact assessment; environmental health valuation; non-market valuation, formaldehyde.

Synthèse

Cette étude porte sur l’évaluation économique du formaldéhyde dans le contexte de sa réglementation et rend compte des évolutions récentes et en cours de la gestion et de la réglementation des risques qu’il présente, plus particulièrement aux États-Unis dans le contexte des normes concernant les produits en bois composite, et dans l’UE, dans celui de l’évaluation des substances au titre du règlement REACH.

Le formaldéhyde est produit en grandes quantités dans des installations industrielles du monde entier : il est utilisé dans la fabrication de résines, comme désinfectant et fixateur et comme conservateur dans les produits de consommation. Le marché mondial du formaldéhyde a généré environ 10.9 milliards USD de recettes en 2011. L’Asie compte pour presque la moitié de la production mondiale, suivie par l’Europe (23 %) et l’Amérique du Nord (17 %). L’exposition au formaldéhyde peut être dangereuse pour la santé humaine ; outre ses effets cancérigènes, le formaldéhyde peut altérer la fertilité féminine, et causer des pathologies respiratoires ainsi que diverses affections aiguës moins sévères notamment des irritations cutanées et oculaires. Il n’existe pas à l’heure actuelle d’impacts négatifs avérés sur l’environnement. Le formaldéhyde fait l’objet d’une législation dans un large éventail de secteurs dans plusieurs pays de l’OCDE, mais il est moins réglementé dans d’autres régions. De plus, la réglementation, lorsqu’elle existe, n’est généralement pas étayée par une évaluation économique.

L’évaluation la plus complète des avantages procurés à la société par la réglementation a été réalisée aux États-Unis dans le cas des produits en bois composites. Cette analyse a effectué une évaluation monétaire des avantages correspondant aux cancers du rhinopharynx et aux cas d’irritation des yeux évités mais pas à ceux de leucémie myéloïde, aux effets respiratoires associés et à la baisse de fertilité. Les valeurs monétaires adoptées dans l’analyse de l’USEPA sont incomplètes pour les trois types de coûts considérés : coûts de traitement ; coûts d’opportunité et désutilité (souffrance). Bien que les valeurs unitaires soient exprimées sous forme de fourchettes pour rendre compte des incertitudes qui entachent les estimations, il est à noter que les études desquelles elles sont dérivées sont assez anciennes, ce qui donne à penser que leur pertinence temporelle et méthodologique pourrait être limitée.

Les coûts de la réglementation ont été évalués aux États-Unis et dans l’UE pour un petit nombre de projets de réglementation très récents ou à l’étude. Ces évaluations comprennent des estimations des impacts économiques sur les producteurs et les consommateurs. L’approche générale adoptée consiste à estimer les coûts de mise en conformité des entreprises, par exemple, des modifications de procédés de production, des matières premières utilisées et des coûts d’essai, de certification et d’étiquetage. Dans les deux études, les données sur les coûts sont collectées auprès d’un échantillon d’entreprises affectées. Toutefois, ces données ne sont pas bien vérifiées. Il existe par conséquent un risque de surestimation, puisque les entreprises susceptibles de subir des effets négatifs pourraient être incitées à exagérer les coûts par rapport aux avantages.

En dépit des limites actuelles des observations épidémiologiques, les évaluations économiques devront à l'avenir mieux exploiter le corpus international grandissant des études consacrées aux avantages sanitaires. Il convient également de prendre en compte les coûts indirects dans l'estimation des coûts de la réglementation et de mettre au point des méthodes fiables de vérification des coûts. C'est peut-être en Asie, où se concentre la majeure partie de la production et de la consommation de formaldéhyde, que la nécessité d'améliorer les évaluations économiques est la plus grande.

1. Introduction

This case study has been prepared for the OECD as part of the SACAME[1] project which aims to support the socio-economic analysis of chemicals, by allowing a better quantification and monetisation of morbidity and environmental impacts of their production, use and disposal. The study focuses on formaldehyde, which was chosen due to the recent and on-going developments in its risk management and regulation especially in the United States in the context of standards for composite wood products and in the EU in the context of REACH substance evaluation. The particular aim is to review available economic assessments for the regulation of formaldehyde in order to provide the best estimates of the social costs of impacts caused by their production, use and disposal, and to inform on the use of economic valuations related to countries' risk management. A sister case study for the SACAME project addresses these aims for N-Methyl-2-pyrrolidone (NMP) (ENV/EPOC/WPIEEP/JM(2017)5/REV1).

Section 2 provides background on the manufacture, uses and disposal of formaldehyde, identifies associated human health and environmental risks or impacts and summaries the existing restrictions and risk management status in OECD and other countries. Section 3 gives an overview of economic assessments undertaken for formaldehyde including methodology used and values for social costs of impacts, as well as approaches and estimates given for the economic impact of regulations on producers and consumers. Section 4 discusses the findings of the review of existing economic assessments in terms of availability and relative magnitude of values for health and environmental endpoints and economic impacts of regulations, data or methodological gaps, potential for improvement and additional valuations and their role in informing regulatory decision-making. Overall conclusions are drawn in Section 5.

1 Socio-economic Analysis of Chemicals by Allowing a better quantification and monetisation of Morbidity and Environmental impacts.

2. Background on formaldehyde

Formaldehyde is a chemical compound (composed of hydrogen, carbon and oxygen) which is present in all organic forms of life. It is formed primarily by numerous natural sources and anthropogenic activities and is ubiquitously found in the environment as a colourless gas which is flammable and highly reactive at room temperature and is generally quickly broken down by sunlight when present in air, or by bacteria when present in soil or water (ICF, 2013[1]).

2.1. Manufacture and uses

As formaldehyde has many useful chemical properties it is used as an important chemical building block in a great number of applications. In general, formaldehyde is commercialised, in its liquid form, as formalin (ICF, 2013[1]). It is extensively produced industrially worldwide for use in the manufacture of resins, as a disinfectant and fixative and as a preservative in consumer products (WHO, 2010[2]). The summary of uses of formaldehyde given in Table 1 illustrates the range of sectors, upstream forms, intermediate uses and end products that contain formaldehyde. Its use in the production of thermosetting resins accounts for around two thirds of the use of formalin; the three major commercially used resins globally being urea-formaldehyde (UF); melamine formaldehyde (MF); and phenol-formaldehyde (PF). The main intermediate applications of formaldehyde-based resins are in the construction, automotive, aircraft, clothing and healthcare industries.

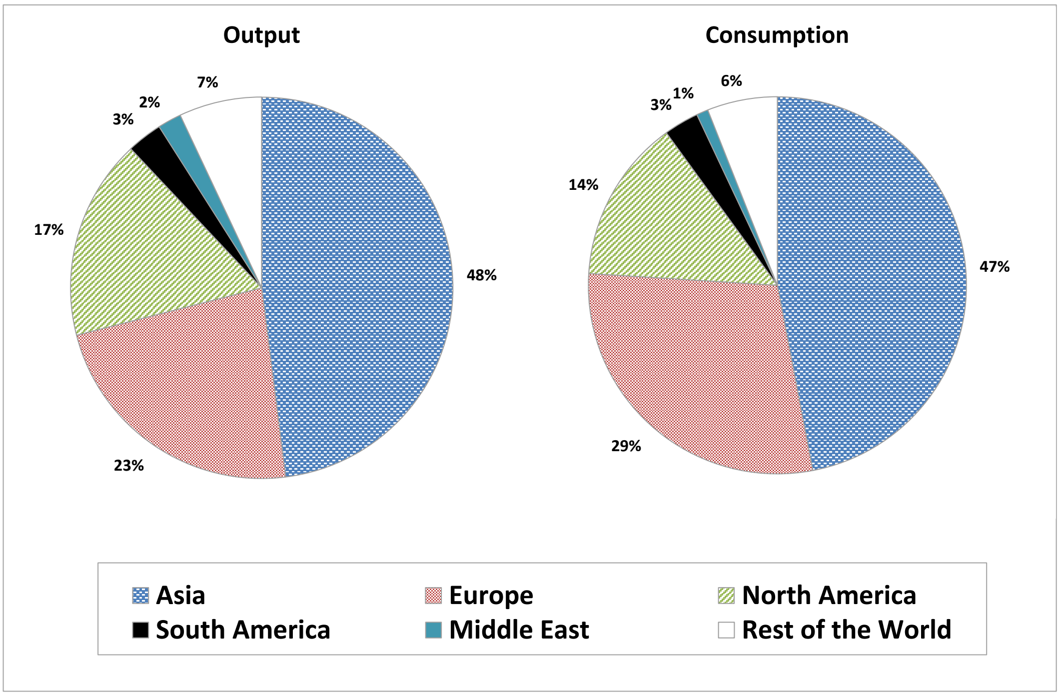
The global formaldehyde market was valued at about USD 10.9 billion in revenue generated in 2011 and is expected to reach about USD 18 billion by 2018 (TMR, 2013[3]). Figure 1 shows global production and consumption shares per world region. The fact that regional production and consumption are very similar in each case suggests there is little inter-regional trade, reflecting its high bulk – low value nature. The figure shows that Asia dominates global production and consumption, accounting for just under one-half of the global totals. Europe and North America constitute the other main regional producers.

Table 1. Summary of uses of formaldehyde by sector

Sector	Upstream form	Intermediate uses	End products
		Use in the production of glues and resins	
Construction	Formaldehyde-based resins: Urea formaldehyde (UF); Melamine-urea formaldehyde (MUF); Phenol formaldehyde (PF).	Manufacture of: PB/wood-based panels; Medium-Density Fibreboard (MDF); Oriented Strand Board (OSB); Plywood; Laminates; Fiberglass Insulation.	Furniture; Home construction products.
Automotive	Formaldehyde-based resins and chemicals: MF resins; Phenol formaldehyde (PF) resins; Polyoxymethylenes (POM); Methylene bis (dephenyl di-isocyanate) (MDI); 1,4-Butanediol (BDO); Pentaerythritol; Hexamine.	Manufacture of: Surface coatings; Decorative laminates; Moulded automobile components; Formaldehyde-based thermoplastics; Polyurethane foams (PUF); Polyurethane coatings; Polybutylene terephthalate resins (PBTs); Alkyd resins; Lubricants; Vulcanised rubber.	Many components, for example: Tyres; Brake pads; Interiors; Engine parts; Fuel system components; Foams in car seats Body part adhesives; Bumpers; Engine lubricants
Aircraft	Formaldehyde-based resins and chemicals: Phenol formaldehyde (PF) resins; Polyoxymethylenes (POM); Methylene bis (dephenyl di-isocyanate) (MDI); Pentaerythritol; Hexamine	Manufacture of: High performance thermoplastics; Neopolyol esters; Phenol composites; PUFs.	Many components, for example: Tyres Turbine lubricants; Brake pads; Interior panelling; Seatbelts; Seat foam
Clothing	Urea formaldehyde (UF) resins; MF resins; 1,4-BDO. Tertahydrofuran (THF) resins	Resins used in production of dyes and pigments; Formaldehyde-derivatives (BDO, THF) used in production of spandex fibres and other sportswear materials.	Various clothing items.
		Use as disinfectant and preservative	
Healthcare	Vaccine additives and preservatives	Production of bacterial and viral vaccines. Used to inactivate viruses and to detoxify bacterial toxins.	Vaccines
Cosmetics	Various	Antimicrobial agent	Cosmetics (e.g. soaps, shampoos, hair preparations, deodorants, lotions, make-up, nail products);Mouthwash, toothpaste
Other	Various	Used as: Biocides; Bacteriostatic agents; Preservative.	Bacteriostatic agent in some foods, e.g. cheese; Food industry use for preserving dried foods, disinfecting containers, preserving fish and certain oils and fats, and modifying starch for cold swelling; Rubber industry use as biocide for latex; Sugar industry use as infection inhibitor in producing juices. Funeral services: Formaldehyde-based solutions used in embalming.

Source: Adapted from ICF (2013[1]) and WHO (2010[2]).

Figure 1. Formaldehyde global output and consumption (2008)



Source: IFC (2013[1]), *The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles*.

2.2. Disposal

Formaldehyde and formalin are classified as hazardous waste and are regulated as such in national legislation (in the United States, for example, the CFR Code of Federal Regulations, title 40[2] section 261.33 classifies discarded commercial chemical products and other wastes that contain formaldehyde as hazardous). Appropriate measures must be taken for disposing or neutralising these chemicals by facilities that use them. Hazardous waste contractors may be used to assist in neutralising formalin solutions, rendering them non-hazardous and converting into solids safe for landfill disposal.[3] Since concentrations of formaldehyde in most cosmetics and consumer products are significantly lower than in production-phases, actions for safe consumer use and disposal of these products is generally in the form of labelling requirements for formaldehyde, including safety directions, rather than direct regulation of disposal of products containing formaldehyde (NICNAS, 2006[4]).

2.3. Sources of exposure

Anthropogenic sources of formaldehyde in the environment include direct sources, such as on-site industrial emissions, transport fuel combustion and other combustion processes from power plants and incineration (WHO, 2010[2]). The products and uses identified in

[2] The U.S. Code of Federal Regulations (CFR) Title 40 is the section dealing with protection of environment.

[3] https://www.phoenix.gov/waterservicessite/Documents/092014.pdf

Table 1 are the major indirect sources of formaldehyde, in particular indoors. A distinction can be made between worker exposure, including in manufacturing, formulation, industrial end use and professional end use, and consumer exposure (TNO, 2013[5]), (TNO, 2013[6]), (TNO and RPA, 2013[7]). While indoor sources include combustion processes, such as smoking, heating and cooking, the main non-combustion sources are building materials and consumer products, such as wooden products containing formaldehyde-based resins, textiles, paints, cleaning products, electronic equipment and insecticides (WHO, 2010[2]). Consumer exposure via use of cosmetics and household products has been assessed as much lower than occupational exposure. For example, concentrations of formaldehyde can range from 40% in embalming and film processing activities, to less than 0.2% in most cosmetics and consumer products (NICNAS, 2006[4]).

2.4. Health risks -- impacts of production, use and disposal

Formaldehyde exposure can be harmful to human health at high concentrations. Possible routes of exposure are inhalation, ingestion and dermal absorption, although limited data are available on dermal exposure (WHO, 2010[2]). Table 2 summarises possible health hazards relating to formaldehyde, including acute and chronic effects. Of particular note is its classification as a human carcinogen (Group 1) by IARC based on evidence of nasopharyngeal cancer and myeloid leukaemia (WHO, 2010[2]).

Table 2. Summary of possible health hazards relating to formaldehyde

Type of health effect	Specific conditions
Acute health effects:	Severe irritation of the skin and eyes, with possible eye damage; Irritation of nose, mouth and throat; Inhaling can irritate lungs, causing coughing or shortness of breath.
Chronic health effects:	Cancer hazard proved to cause cancer of the nasopharynx and leukaemia; Reproductive hazard some evidence that it can damage female fertility[4] although not conclusive evidence on whether exposure can cause reproductive or developmental toxicity below concentrations at which significant maternal toxicity is expected.
Other health effects:	Repeated exposure can cause bronchitis to develop, with cough, phlegm and shortness of breath; Skin allergy, leading to serious skin rash and itching; Evidence that formaldehyde can cause asthma attacks.

Source: Summarised from ICF (2013[1]) and Public Health England (2017[8]).

2.5. Environmental risks and impacts of production, use and disposal

Evidence on environmental risks from formaldehyde is more scarce than for health risks, as seems to be the case for the environmental impact of chemicals on the environment more generally (RPA/DHI, (2016[9])). Existing evidence suggests that typical releases of formaldehyde are unlikely to affect plants and wildlife in the vicinity since it is quickly removed from the air by reaction in the atmosphere and broken down in water and soil. While formaldehyde may be involved in the formation of ground level of ozone, it is "not considered likely that Formaldehyde pollution has any effects on the global environment" (Scottish EPA[5]). The Priority Substances List Assessment Report for Environment Canada (2001[10]) concluded that, "based on the information available… formaldehyde is

[4]The review of studies by Public Health England (2017[8]) found there is insufficient evidence to determine as yet whether formaldehyde causes reproductive toxicity.

[5] http://apps.sepa.org.uk/spripa/Pages/SubstanceInformation.aspx?pid=57.

not entering the Canadian environment in a quantity or concentration or under conditions that have or may have an immediate or long-term harmful effect on the environment or its biological diversity". Moreover, the study by Liteplo et al. (2002[11]), using available environmental toxicity data in Canada, found that "formaldehyde is not likely to cause adverse effects on terrestrial or aquatic organisms".

2.6. Restrictions and risk management status in OECD and other countries.

WHO has set guidelines for indoor air concentrations of formaldehyde of 0.1 mg per m^3 (30 minute average concentration) to prevent sensory irritation in the general population. It was also concluded that this short-term guideline was sufficient to prevent effects on lung function and long-term health effects, including nasopharyngeal cancer and myeloid leukaemia (WHO, 2010[2]). The guidelines have been used to inform national regulation on formaldehyde which has developed over recent decades to apply widely across OECD and other countries. Non-occupational indoor exposure limits have been set at the WHO guideline of 0.1 mg per m^3 by many countries such as the United Kingdom, the People's Republic of China and Japan while some countries have set slightly higher limits, such as Canada, Australia, Germany and Singapore (0.12 mg per m^3) (Tang et al., (2009[12])).

Legislation on formaldehyde is related to a large range of sectors, including industrial chemicals and chemical products, biocides, cosmetics, toys, food, occupational environment and drinking water supply. In the EU, it is subject to regulation under REACH, which aims to improve the protection of human health and the environment from the risks posed by chemicals through the processes of registration, evaluation, authorization and restriction, and classification, labelling and packaging (CLP) regulations. It has been registered under REACH with a DNEL (Derived No-Effect Level) for workers of 0.4 ppm. The DNEL represents the level of exposure above which humans should not be exposed. For consumers, the DNEL is 0.1 mg per m^3, the same as the WHO guideline value.[6]

Formaldehyde is currently the focus of a number of evaluations and consultations regarding risk management and appropriate restrictions in the EU, as follows:

- It has been included for evaluation in the REACH regulation Community Rolling Action Plan (CoRAP). The decision document of October 2015 found that the available data on formaldehyde emissions from main indoor sources were not sufficient to draw conclusions on which are the most important for the purposes of risk assessment and risk management options for consumers (ECHA, 2015[13]). Thus, the European Chemicals Agency (ECHA) has requested the registrants of formaldehyde to provide further information regarding the registered substances and consumer exposure scenarios with a deadline for submissions of October 2017 (ECHA, 2016[14]).
- There are current investigations by ECHA into possible formaldehyde releasers (chemical compounds that slowly release formaldehyde as it decomposes in a product formulation) and their use in the EU. These will support Commission decisions on whether to request ECHA to prepare an Annex XV dossier for restriction on formaldehyde and whether formaldehyde releasers should be part of this restriction dossier.

[6] www.formacare.org/regulatory-information/reach/.

- At the same time, ECHA is screening registration dossiers for formaldehyde releasers beginning with substances listed as formaldehyde releasers in Annex V of the Cosmetic Product Regulation 1223/2009. Additional investigation is being made on formaldehyde releasing biocidal active substances included in the Review Regulation (EU) No 1062/2014 of the EU Biocides Regulation 528/2012 (EU BPR).
- Formaldehyde is also included on the list of substances for which the Commission launched a public consultation due to a possible restriction of CMRs (Carcinogenic, mutagenic and repro-toxic substances) in textile articles and clothing for consumer use according to article 68(2). The consultation ended in March 2016.

The current classification for formaldehyde under CLP Regulation (EU No. 1272/2008) is Carcinogenic 1B,[7] Mutagenic 2,[8] Acute Tox. 3[9] (inhalation, contact with skin, oral), Skin sensitiser 1 and Skin corrosive 1B.[10,11] It was reclassified in 2014 as a Carcinogen Category 1B applying to substances containing 0.1% free formaldehyde or above, with a transition period until January 2016.

A number of other EU Directives and Regulations also relate to formaldehyde, including the Waste Framework Directive and the Seveso III Directive 2012/18/EU and it is indirectly covered in a number of other Directives, due to its classification as a hazardous substance. A detailed description of the current regulatory and risk management status in EU for industrial and professional uses of formaldehyde is given in the risk management option report by (ANSES, 2016[15]).

Since the 1980s, a number of European countries have introduced national regulations on specific products that emit formaldehyde. Formaldehyde emission class E1[12] (0.1 ppm boards) became obligatory for wood-based panels in Austria, Denmark, Germany and Sweden[13] in 1985. Emission classes, E1 and E2, were established by European Standard EN 13986 for wood products used in construction in 2004 and in 2006 emission class E1 became effective for panel production (ICF (2013[1]) and Franklin, (2010[16])). Other countries have also regulated formaldehyde-releasing substances; for example, the Netherlands has legislation on Chipboard ("Warenwet",[14] 1987, quoted in Schuur et al.,

[7] Carcinogenic 1B is defined as substances presumed to have carcinogenic potential for humans largely based on animal evidence.

[8] Mutagenic 2 defined as substances which cause concern for humans owing to the possibility that they may induce heritable mutations in the germ cells of humans.

[9] Under CLP substances can be allocated to one of four toxicity categories based on acute toxicity by the oral, dermal or inhalation route according to a set of numeric criteria.

[10] Skin corrosive substances have three sub categories (1a, 1b and 1c).

[11] https://echa.europa.eu/documents/10162/13641/bd_call_for_evidence_fa_and_releasers_request_en.pdf

[12] Emission classes refer to European standards by which limit values are set for formaldehyde releases.

[13] www.kemi.se/en/directly-to/rules-and-regulations/rules-applicable-in-sweden-only/swedish-restrictions-and-bans.

[14] "Warenwet" are Dutch consumer laws.

(2008[17])) and textiles ("Warenwet", 2001; quoted in Schuur et al., (2008[17])) and there is a ban on use in cosmetics in Sweden.

In the US, a key regulatory development was the introduction of the air toxics control measure to reduce formaldehyde emissions from Composite Wood Products in 2008 by the California Air Resources Board (CARB). This formed the basis for the development of national "Formaldehyde Standards for Composite Wood Products Act" (2010) for various products, such as plywood (PW), Medium Density Fibreboard (MDF) and others. The US EPA is issuing a final rule to implement the Act under which composite wood products that are sold, supplied, offered for sale, manufactured or imported in the United States will need to be labelled as Toxic Substances Control Act (TSCA) Title VI[15] compliant.[16] Formaldehyde is also regulated in waste regulations under the Resource Conservation and Recovery Act (RCRA) controlling hazardous waste, the Clean Water Act (CWA) regulating discharges of hazardous substances and the Clean Air Act (CAA) regulating hazardous air pollutants.[17] Also there are also a number of state-specific restrictions on specific uses of formaldehyde.[18]

Japan has its own rating system for emissions known as the Japanese Industrial Standards (JIS) and Japanese Agricultural Standards (JAS) departments which apply to formaldehyde emitting building materials, Regulation for emissions from wood panels is considered to be the most stringent in the world,[19] for example there is a ban on formaldehyde use in cosmetics.

[15] Title VI refers to the Formaldehyde Standards for Composite Wood Products Act that has been added to the TSCA.

[16] Effective date of the final rule has been delayed from 21 March 2017 to 22 May 2017 according to www.epa.gov/formaldehyde/formaldehyde-emission-standards-composite-wood-products#rule-history.

[17] See www.epa.gov/formaldehyde/laws-and-regulations.

[18] www.saferstates.com/toxic-chemicals/formaldehyde/.

[19] www.sips.org/green-building/formaldehyde-emissions-and-exemptions.

3. Overview of economic assessments

3.1. Outline of types of economic assessment

Economic assessment in the context of production, use and disposal of chemicals commonly focuses on the costs and benefits of proposed regulations or on specific elements of these costs and benefits. Cost-benefit analysis requires estimating monetary values for the social benefits and costs of regulations to arrive at an estimate for net benefits. An overview of types of economic assessment that can be used within CBAs or elsewhere in the valuation of health and environmental endpoints and costs of regulation to stakeholders is given in Table 3.

Table 3. Overview of benefits and costs of regulating chemicals and methods of valuation

Impact category	Type of effect	Affected party	Benefit or cost of regulation	Method of valuation
Human health	- Morbidity: Acute illnesses, chronic illnesses - Reproductive effects - Developmental and neuro-developmental effects - Mortality effects - Cancer (fatal and non-fatal) Subclinical symptoms	General population, consumers, workers	Avoided resource costs	Reduced medical and non-medical costs
			Avoided opportunity costs	Averted loss of productivity e.g. reduced DALYs
			Avoided disutility costs	WTP
Environmental and ecosystems	Effects on agricultural and/or other sector productivity	Producers, consumers	- Avoided treatment costs/substitute input costs - Avoided price effects	Market methods
	Effects on resources with recreational use	Current and potential users of the resource	Improved user welfare, greater use of the resource	Non-market valuation: travel cost method, hedonic pricing, stated preference methods (WTP)
	Effects on aesthetic values (e.g. visibility, odours, water turbidity)	General population	Improved welfare	Non-market valuation: travel cost method, hedonic pricing, stated preference methods (WTP)
	Changes in non-use values	General population	Improved welfare	Non-market valuation: stated preference methods (WTP)
	Effects on ecosystem services (provisioning, regulating and supporting services)[20]	Case specific. Potentially all parties	Avoided loss of ecosystem services. Avoided cost of alternate ecosystem functions	Market methods (for marketed services) and non-market valuation (incl. stated preference methods)
Economic	Effect on production costs	Producers	Cost to comply (e.g. use of alternative chemicals and new production processes)	Market
	Effect on final products	Consumers	Higher product prices	Market
	Wider effects on economy	General population, producers of other sectors	Economic effects on markets	General equilibrium analyses

[20] There is some overlap with recreational use and aesthetic value here as the definition of ecosystem services also usually includes "cultural" services.

Economic values for health benefits of regulating chemicals can be estimated by use of the Damage Function Approach (DFA), which is commonly used in the context of air pollution. This approach includes three costs components in the estimation of costs of health impacts (with and without regulation): (i) resource costs (which includes avertive expenditures, e.g., relocation to area of lower impact and mitigating expenditures, e.g. direct medical and non-medical costs associated with treatment for the health impact), (ii) opportunity costs (which includes costs of loss of productivity and/or leisure time due to the health impact) and (iii) disutility costs (which includes pain, suffering, discomfort and anxiety linked to the health impact) (Hunt et al., 2016$_{[18]}$). A cost of illness approach[21] can be used in valuing the impacts on human health, for example in the US EPA (2013$_{[19]}$) study, and includes estimating medical treatment costs and opportunity costs (e.g. productivity losses)

Economic values for environmental benefits of regulating chemicals can be estimated using market methods (where there are direct economic effects of the use of chemicals, such as on agricultural productivity) or non-market methods, such as stated preference methods (WTP), travel cost method and hedonic pricing (where there are non-monetary benefits from regulation) as indicated in Table 3. Whilst market-derived evidence may be seen to be more reliable, given that it is based on actual transactions, stated preference methods are recognised, in principle, as being better able to isolate preferences relating to specific health conditions, such as those arising from formaldehyde exposure.

Value transfer methods can also be used in assessment of a variety of health and environmental benefits. This is where economic values are adapted from another context to be used in the analysis of impacts of regulation and other risk management measures for chemicals. The challenges in using this approach for estimating the environmental and health benefits of regulating chemicals is discussed in detail in the study by Navrud (2017$_{[20]}$) for the SACAME project.

Cost of regulations may include higher production costs in order to comply (e.g. use of more costly alternative chemicals and new production processes) and higher prices for consumers. The social costs of regulations can be defined as the sum of opportunity costs incurred as a result of the regulations. This is the value lost to society of all of the goods and services not produced and consumed due to compliance of regulations by the regulated entities (Alberini, 2017$_{[21]}$).

There remains a lack of consensus on what is best practice relating to discounting future benefits and costs. Schools of thought differ, for example, as to whether descriptive evidence from the capital market should be used rather than prescriptive estimates based on individual’s preferences regarding future consumption relative to current consumption. Consequently, use of a range of discount rates is likely to be sensible, though there remains the question as to which rate should be given greater weighting.

CBAs and other regulatory impact assessments may also include analysis of the employment effects of proposed regulations and distributional impacts (Alberini, 2017$_{[21]}$).

3.2. Overview of existing economic assessments regarding formaldehyde

Details of existing economic and regulatory impact studies related to formaldehyde resulting from a review of literature undertaken for this study are given in Table 6 in the

[21] A US EPA *Cost of Illness Handbook* is available here.

Annex. The key points arising from this review are summarised in the following paragraphs.

Benefit assessments

There is a developing literature on monetising the benefits of regulating chemicals. For example, the study by Giacomello et al. (2006[22]) aimed to quantify and monetise the environmental and human health benefits which have arisen from chemicals regulation on four example chemicals. But there are few studies on the benefits of regulating formaldehyde. The study by RPA/DHI (2016[9]) contains an extensive literature review of reports and articles aiming to quantify and monetise the benefits of regulating chemicals published over the past 15 years. This includes a number of studies focused on methodologies and estimates of total benefits and costs of regulation (including REACH) for the chemicals sector as a whole, and some case studies, but very few specific references to quantifying and monetising the benefits of regulating formaldehyde. Some studies, such as Prüss-Ustün et al. (2011[23]), include broad estimates of burden of disease attributable to chemicals per type of exposure and chemical groups that include formaldehyde but source estimates do not isolate the effect from formaldehyde alone.

The most comprehensive assessment of social benefits of regulation, and one of the only such studies focusing on formaldehyde found in the literature review, was undertaken for the US regulation of composite wood products, cf. US EPA (2013[19]), (2016[24]) and (2016[25]). The general approach of this analysis was to predict the number of cases avoided for two health effects (nasopharyngeal cancer and eye irritation) and monetises the benefits. This process used risk factors for assessing formaldehyde cancer risk from EPA's Integrated Risk Information System (IRIS) database.[22] The IRIS programme undertook a draft assessment of the potential cancer and non-cancer health effects from chronic exposure to formaldehyde by inhalation[23] which is currently being revised.[24] For the non-cancer benefits assessment concentration-response functions were used to estimate the impact of exposure to formaldehyde on eye irritation. Total human health benefits for avoided eye irritation and nasopharyngeal cancer resulting from reductions in formaldehyde exposure attributable to the final rule were estimated as USD 64 million to USD 186 million per year using a 3% discount rate, and USD 26 million to USD 79 million per year using a 7% discount rate. Additional benefits due to avoided myeloid leukaemia, respiratory-related effects and reduced fertility were not quantified due to insufficient information on their relationship with formaldehyde exposure.

Some studies have used DALY[25] estimates in the assessment of avoided health impacts due to regulation of formaldehyde. For example, the Perouel (2011[26]) study assessed

[22] Links to IRIS database: www.epa.gov/iris and IRIS Chemical Assessment Summary for formaldehyde: https://cfpub.epa.gov/ncea/iris/iris_documents/documents/subst/0419_summary.pdf.

[23] US EPA, IRIS Toxicological Review of Formaldehyde-Inhalation Assessment (2010 External Review Draft): https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=223614.

[24] The benefit estimates used in the final rule document to implement the Formaldehyde Standards for the *Composite Wood Products Act* (US EPA, 2016[24]) used an IRIS inhalation unit risk value of 1.3×10^{-5} per mg per m^3.

[25] Disability Adjusted Life Years (DALYs) are the sum of years of potential life lost due to premature mortality and the years of productive life lost due to disability.

human exposure to formaldehyde via consumer products before and after implementation of three policy measures and health impacts were estimated. It then quantified these impacts in terms of DALYs to allow comparison before and after policy scenario implementation. Under the risk-based scenario, it estimated a total of 700 DALYs for three health effects before implementation and 136 DALYs after implementation. It concluded that "there are significant health benefits associated with the classification of formaldehyde as Carcinogen Category 1, leading to the limit of 0.1% as concentration of formaldehyde in consumer preparations". The Schuur et al. (2008[17]) case study on health impacts (in terms of DALYs) of policy measures related to formaldehyde in selected consumer products in the Netherlands found no DALYs to report for plywood and textiles, and insufficient evidence on which to base a calculation for cosmetics.

Lack of valuation of environmental or ecosystem impacts is related to limited evidence of these impacts, as explained above.

Cost assessments

Key studies on economic impacts of regulation of formaldehyde are ICF (2013[1]), Global Insight (2007) and TNO/RPA (2013[7]). These studies include estimates of economic impacts on producers and consumers. The general approach has been to estimate costs of compliance to industry through, for example, changes to production processes, use of raw materials costs of testing, certification and labelling.

The US EPA (2013[19]) and (2016[25]) studies have extensive economic analysis for the supply chain (manufacturers, fabricators, wholesalers and retailers) though not for consumers. This assessment considered the costs to laminated product producers under a range of options to address formaldehyde emissions, including the option chosen for the final rule. Estimates were made for the size of the laminated product producer industry and its use of UF resins, and the costs of testing, certification, and switching to a PF resin or a resin with no added formaldehyde. Based on these estimates, the aggregate annualised costs for laminated product producers were estimated as USD 26 million to USD 72 million with a 3% discount rate, and USD 26 million to USD 62 million with a 7% discount rate; these two sets of results suggesting that this is not a like-for-like comparison.

Other studies, such as McLeod (2013[27]), focus on costs and benefits to producers in specific sectors of adapting to formaldehyde regulations.

4. Analysis of findings of economic assessments of formaldehyde

This section looks to scrutinise the coverage and quality of economic data used to date, and that available for future assessments. However, the previous section highlights that economic assessment of regulation of formaldehyde is in its infancy. Just two studies found in the literature review have undertaken an analysis of both the costs and benefits of proposed regulation: TNO/RPA (2013[7]) for EU regulation and US EPA (2013[19]) and (2016[25]) for regulation of composite wood products in United States. Furthermore, the US EPA study is the only one that attempts to quantify the benefits in monetary terms. In order to draw out lessons for future analyses of formaldehyde regulation, this section therefore gives most attention to these two studies. Findings are then placed in the context of the wider literature.

Table 4 identifies the coverage of cost data included in the economic assessments that have been undertaken in the EU and United States. In both cases, the focus is primarily on the direct costs, identified as likely to be incurred by manufacturers and other producers. The TNO/RPA study on the EU also identifies the potential financial costs associated with the loss of market share and international competitiveness, though it does not estimate the net impacts of these on producer surplus and consumer surplus. The TNO/RPA study also separately identifies that there may be higher prices borne by consumers insofar as higher production costs are passed on in this form, though the potential for double-counting is not made explicit. Again, the net changes in producer and consumer surpluses are not estimated. The TNO/RPA study does not include the temporal dimension, incorporating discounting.

In both studies, the cost data is understood to be gathered from a sample of affected businesses. However, it is not made clear whether, and how, these data are verified. Consequently, there seems to be a risk of bias towards over-estimation, given that the businesses that are potentially negatively impacted may have an incentive to exaggerate the cost relative to the benefits. Though this limitation is not easily avoided without losing trust in the industry, economic assessments could usefully make these challenges explicit.

Table 4. Summary of cost data used in economic assessments of formaldehyde regulations

Study & Risk	Type: Capital	Type: Operational	Source of cost data	Treatment of time and uncertainty
TNO/RPA (2013[7]) Assessment of alternative regulation scenarios in EU. Occupational exposure	**Manufacturers** Yes. Described as one-off investments. Average of sample data used to estimate aggregate cost for EU **Use as an intermediate** Yes. Described as one-off investments. Average of sample data used to estimate aggregate cost for EU	**Manufacturers** Yes. Based on one survey response and one estimate by industry representative. Aggregated for EU. **Use as an intermediate** No. Two responses elicited but judged to be unreliable.	**Manufacturers** Questionnaire for formaldehyde producers and downstream users (20 responses); survey for wood based panel manufacturers. **Use as an intermediate** Questionnaire for intermediate users (24 responses (70 in EU in total)); survey for wood based panel manufacturers and fertiliser producers	**Uncertainty** Level of investments need to meet proposed regulation not known. Representativeness and extrapolation. High, medium and low estimates provided, reflecting ranges in questionnaire responses. **Time** No discounting undertaken.
TNO/RPA (2013[7]) Consumer exposure: scenarios for wood-based panels in EU	**Manufacturers** Yes. Described as one-off investments. Average of sample data used to estimate aggregate cost for EU **Wood based panel producers** Yes. Described as one-off investments. Average of sample data used to estimate aggregate cost for EU	**Manufacturers** Yes. Based on responses to questionnaire. Aggregated for EU. **Wood based panel producers** Yes. Based on responses to questionnaire. Aggregated for EU. Quantified costs to consumer in terms of higher prices as a result of operational costs being passed on (from Global Insight, 2007; details not accessed).	**Manufacturers** Questionnaire for formaldehyde producers and downstream users (20 responses). **Wood based panel producers** Questionnaire for wood based panel manufacturers (12 responses,50% of EU industry)	**Uncertainty** Other costs noted but not quantified. Include: loss of market; impacts on R&D; administrative burdens. **Time** No discounting undertaken.
US EPA (2013[19]) Economic analysis of options for implementing the Formaldehyde Standards for Composite Wood Products Act.	Yes. Costs defined for Year 1 in analysis but not specified, i.e. investment costs assumed not to be needed in compliance. Derived unit costs used to generate aggregate costs for US.	Yes. Defined for years 2-30. Costs of switching to new (non-formaldehyde-based) resin. Also, detailed description of costs of administration and testing. Derived unit costs used to generate aggregate costs for US	Not stated explicitly but we assume that these were derived from survey of producer groupings undertaken as part of assessment.	**Uncertainty** Low and High estimates provided, but reflecting uncertainty in number of entities affected rather than in unit costs. **Time** Costs for 30 year period. Discounted at 3% and 7%. Annualised costs estimated.

Table 5 summarises the data used to estimate benefits in the two studies – TNO/RPA (2013[7]) and US EPA (2013[19]); (2016[25]). The US EPA study is the only one to include quantitative estimates of benefits in its overall appraisal of the regulations considered. Whilst a number of potential health impacts are not quantified and monetised due to the lack of quantitative evidence regarding the number of cases (avoided) that might arise from the regulations, it is also worth noting that the monetary values that are adopted in the US EPA analysis are incomplete across the range of the three component costs: treatment costs; opportunity costs and dis-utility (pain & suffering).

A further source of uncertainty is introduced in the non-fatal unit value estimation since the studies from which the values are transferred actually value a different health end-point. The lack of availability of WTP estimates to avoid the risk of non-fatal nasopharyngeal cancer meant that two surrogate estimates are used based on the WTP of avoiding chronic bronchitis and curable lymphoma (lymph cancer). The WTP value of avoiding a non-fatal case of nasopharyngeal cancer was estimated using a low surrogate values for WTP of USD 0.82 per micro-risk reduction and a high surrogate estimate of USD 5.69. Similarly for eye irritation, based on WTP estimates of a minor restricted activity day, the analysis uses USD 28 as the value of an avoided case of eye irritation. Whilst there are some common symptoms, and it appears a reasonable substitute in the absence of other evidence, it is likely to introduce a bias in the valuation.

It is also the case that the studies for both fatal and non-fatal health end-points are rather dated. Whilst all values have been up-dated to current prices, it seems likely that the more recent evidence on unit values better reflects advances in non-market valuation methodologies, as well as individuals' preferences. US EPA (2014[28]) acknowledges this and highlights a number of possible contextual factors that may be expected to influence mortality risk WTP values.

4.1. Benefit estimation of formaldehyde regulation: up-dating practice and evidence

The sub-sections below briefly summarise the prospects for valuation of health risks that are potentially relevant to formaldehyde regulation.

Cancer: nasopharynx and leukaemia

The unit value used to represent fatal nasopharyngeal cancer in US EPA (2016[25]) is that currently recommended by the US EPA for all mortality risk valuation. However, the agency recognises that there is a growing body of cancer risk valuation studies that may provide sufficient evidence to discriminate cancer-related mortality risk values from non-cancer related values, (US EPA, 2010[29]). US EPA (2010[29]) suggests that a premium of 50% on top of the base VSL currently used may be suitable. This finding concurs with current EU practice but differs from that found in a wide-ranging OECD review (Lindhjem et al., 2011[30]) which suggests no premium to be justified.

Table 5. Summary of benefit data used in economic assessments of formaldehyde regulations

Study & Risk	Impact	Metric/Valuation	Methodology
TNO/RPA (2013[7]) Assessment of alternative regulation scenarios in EU: Occupational	Respiratory conditions	Metric: number of people – range of 25% to 80% of factory operators estimated to be potentially at risk	Authors' judgement.
TNO/RPA (2013[7]) Assessment of alternative regulation scenarios in EU: Consumer products	Nasal irritation Skin sensitisation Eye irritation	No EU estimates. Study of French female population quoted, (Perouel, 2011[26]) Metric: Disability-adjusted life year (DALY)	Qualitative summary based on authors' judgement
US EPA (2013[19]); (2016[25]) Economic analysis of options for implementing the Formaldehyde Standards for Composite Wood Products Act	Nasopharyngeal cancer fatal & non-fatal Eye irritation Respiratory effects and reduced fertility in women (qualitative only) 40 year benefit assessment period	Nasopharyngeal cancer – fatal: WTP (USD 9.77 million). Omits treatment costs. Nasopharyngeal cancer non-fatal: COI approach (2013 version) Treatment costs + Opportunity costs. WTP (2016 version) Eye irritation: WTP	WTP derived from Weibull-mean of sample of VSL estimates from wage-risk and contingent valuation studies made in 1974-1991, in US EPA (2014[28]). Treatment costs derived from two surveys of costs associated with component parts of treatment processes. Opportunity costs derived for values of work & leisure time, costed as wages plus employment benefits, and wages, respectively. Estimates from mean national wage levels. A range derived from Magat et al. (1996[31]) WTP to avoid curable lymphoma, and Viscusi et al. (1991[32]) WTP to avoid chronic bronchitis From IEc (1993), quoted in US EPA (2016[25]), derived from Tolley (1986[33]) and Weitzel (1990), quoted in US EPA (2016[25]), WTP estimates of minor respiratory restricted activity days.

Non-fatal cases of nasopharyngeal cancer are valued in US EPA (2013[19]) and (2016[25]) using a cost of illness and WTP approach, respectively. Indeed, the Magat et al. (1996[31]) study, adopted in US EPA (2016[25]) appears to be one of the few studies that separately identifies the morbidity component of cancer. However, the difficulty in isolating morbidity components from mortality components has increasingly been recognised, so that a number of more recent studies look to measure the WTP to avoid a risk of cancer, combining morbidity and mortality components. A Canadian study (Adamowicz et al. (2011[34])), in the context of bladder cancer caused by water pollution) finds that the value of a statistical cancer case (VSCC) is 15% – 30% of a cancer VSL. Contrastingly, a study undertaken across Europe (Alberini and Ščasný, 2014[35]) finds that VSCC is around 8% of the cancer VSL.

Whilst the ideal would be to identify unit values for specific cancer types of interest – here, nasopharyngeal cancer and leukaemia – the paucity of evidence for these types suggests that for the time being it may be more reliable to rely on the informal meta-analyses undertaken over a larger range of cancer and associated valuation studies. However, going forward, new empirical research might usefully a) continue to explore the merits of combining values in a VSCC, and b) deriving WTP for a range of cancers specific to the chemical(s) of interest.

Skin or eye irritation

The US EPA (2013[19]) and (2016[25]) studies adopt a WTP value for avoiding a minor restricted activity day as a proxy for skin and eye irritation from Tolley et al. (1986[33]). This study, published later as (Berger et al., 1987[36]) does in fact value eye irritation separately – at USD 16.00 per day, and so could have been used. Whilst other eye irritation WTP studies are scarce, there is a more substantial literature regarding skin irritation. ECHA (2016[37]) review a number of studies including its own that benefits from a relatively large sample size. It finds a central value of USD 240 per acute episode of mild dermatitis lasting two weeks.

In the first instance, the values from these, and other, studies could be adopted on a benefit function basis to the formaldehyde regulatory assessment context in the US and elsewhere. In the future, location-specific studies that evolve current stated preference methods should be undertaken.

Other health impacts not currently valued

As highlighted earlier in this paper, there remain a number of health impacts of formaldehyde that are thought to be relevant to regulatory assessment but which – due to lack of epidemiological evidence - are not currently quantifiable. These health impacts include nose/mouth/throat irritation, risks to female fertility, bronchitis, pulmonary function, skin allergies and asthma attacks. It is expected that as epidemiological evidence develops, valuation data for these end-points will be needed. In fact, there exists a relevant literature on female fertility, (ECHA, 2016[37]), bronchitis, (e.g. (Bloyd et al., 1996[38]) in United States; Maca et al. (2011[39]) in Europe), pulmonary function (Cameron, DeShazo and Stiffler, 2010[40]), skin allergy (ECHA, 2016[37]) and asthma attacks (e.g. Dickie & Messman (2004[41])) that may at least be used in benefit transfer exercises. That said, the number of studies remains limited and, to some degree at least, dated – thereby limiting their transferability. Primary studies undertaken in the context needed therefore remain a future priority.

5. Conclusions

The preceding sections present data reported in economic assessments of formaldehyde regulation to date. The evidence-base on both the costs and benefits is shown to be rather sparse with little scope, therefore, to undertake cross-study comparisons of either methodologies or results. However, there are a number of conclusions that can be drawn with the intention of their being potentially useful in informing future economic assessments of formaldehyde in the same or different countries and regions.

Due to data limitations, even the most comprehensive study on impacts of formaldehyde regulation (US EPA, 2016[25]) could only value benefits from two health effects – nasopharyngeal cancer and eye irritation – whereas the draft 2010 IRIS assessment identified seven categories of potential non-cancer health outcomes from formaldehyde exposure: (1) sensory irritation; (2) upper respiratory tract pathology; (3) pulmonary function effects; (4) asthma and allergic sensitisation (atopy); (5) immune function effects; (6) neurological and behavioural toxicity; and (7) developmental and reproductive toxicity. It is suggested that there currently exist estimates or close proxy estimates, for end-points (1) to (4), and (7), that could be adopted in future analyses. For example, the ECHA (2016[37]) study derives WTP values for about 20 health outcomes, including acute and chronic dermatitis, cancer risks, fertility risks, birth defects and very low birth weight, and respiratory sensitisation for private and public good contexts. In addition, the OECD database of Value of Statistical Life (VSL) estimates provides the results of stated preference studies.[26] Thus, there may be potential for further economic analysis in the context of formaldehyde given availability of appropriate background data on health impacts per country, sector, use, etc. Data are also available from various sources on amounts of formaldehyde in use (see e.g. ICF (2013[1]) for estimates of amounts used in EU for three sectors and the SPIN database for Nordic countries[27]). For end-points (5) and (6), the evidence remains limited. A review by RPA/DHI (2016[42]) finds that "for long latency diseases, valuation is much more difficult and requires…large scale valuation studies".

There is a dearth of studies with regard to the effects on the environment of formaldehyde, and hazardous industrial chemicals more generally. In this respect, RPA/DHI (2016[42]) highlight that chemicals that are persistent and bio-accumulative pose particular valuation difficulties with this being an area requiring much further research given the regulatory priority for addressing such chemical hazards.

It is evident that economic analysis has informed legislative guidance on the use of formaldehyde. This is clear in the US experience where the findings of US EPA (2013[19]) and (2016[25]) appear to have been closely considered in the development of the US Composite Wood Products Act (See US EPA (2013[19]) and (2016[25])). In the European

[26] www.oecd.org/env/tools-evaluation/env-value-statistical-life.htm.

[27] http://195.215.202.233/DotNetNuke/default.aspx.

context, it appears likely that the data collected in TNO/RPA (2013[7]) is being considered in on-going regulatory development. Indeed, TNO/RPA (2013[7]) states: "The data generated under the present study is intended to inform the work of the authorities within the Substance Evaluation Procedure. If, after review of the available and new risk assessment data, the evaluating Member State(s) consider that the use of a substance poses a risk, they may then proceed with follow-up actions to address the concern, which may include (ECHA, nd3): (i) a proposal for harmonised classification and labelling; (ii) a proposal to identify the substance as a substance of very high concern (SVHC) and subsequently a need for authorisation; (iii) a proposal to restrict the substance;(iv) actions outside the scope of REACH such as a proposal for EU-wide occupational exposure limits, national measures or voluntary industry actions."

Research Gaps: Given that there is significant production and consumption of formaldehyde in Asia (shown in Figure 1) and a seeming lack of economic analysis of health impacts it is suggested that economic analysis of both the cost and benefit components be expanded into this region. Whilst there is likely to be a certain homogeneity between cost estimates in American, EU and Asian contexts, cultural and other socio-economic differences suggest that health and environmental benefit estimates may differ significantly from N. American and EU estimates, and that primary research studies in Asian producer countries might be valuable.

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Annex A. Details of relevant studies

Table 6. Formaldehyde-related economic and regulatory impact studies

	Focus of study						
Bibliographic details of study	Stage of life cycle: Production, uses, disposal.	Impacts: Health, environmental, economic (Industry and consumer)	Region or country	Methodology	Key Results	Comment	Web links to study
Global Insight (2007), Socio-Economic Benefits of Formaldehyde to the European Union (EU 25) and Norway	Production and consumer use	Economic impacts	EU and Norway	Findings reported in ICF (2013[1]) but full report not available from Formacare website. Thus methodology is not known.	Estimates of about EUR 330 billion worth of lost sales resulting from ban on formaldehyde. Consumers would have to spend an additional EUR 29.4 billion per year if formaldehyde-based products were replaced by substitute materials	Findings of this Formacare (representing key European producers of formaldehyde) commissioned study are reported in ICF (2013[1]). Focus is on industry revenue, consumer and employment impacts of a ban.	Full report not accessed from links given in ICF (2013[1]).
Global Insight (2005), Socio-Economic Benefits of Formaldehyde to	Production and consumer use	Economic impacts	United States and Canada	n/a	n/a	Study referenced in (Athanassiadou, Tsiantzi and Markessini, 2009[43]) but not assessed.	

the United States and Canada							
ICF (2013[1]), The potential impact on industrial competitiveness of restrictions on certain CMR 1A and 1B substances in articles - Scoping study for the application of art. 68.2 of REACH to CMR substances requiring priority action.	Production and Use	Impacts of restrictions on industrial competitiveness	EU	Assessment of presence of formaldehyde in EU market for wood-based furniture, automobiles and mattresses. Stakeholder consultation of likely response of industry to restrictions on these products. Qualitative assessment of economic and social impacts of restrictions (largely based on responses from stakeholder consultation).	Qualitative conclusions on restriction impacts: Higher production costs owing to costly alternatives and new production processes Higher prices for consumers. Difficult to quantify benefits	Health impacts outlined but not quantified or monetised. Limited coverage of environmental issues.	http://ec.europa.eu/DocsRoom/documents/13035/attachments/1/Translations Accessed: 30.3.17
(Perouel, 2011[26]) Health impacts of Regulative Policies on use of Formaldehyde in Consumer Products.	Consumer Use	Health risks and health impacts caused by formaldehyde: Ocular and nasal irritation, skin sensitization, nasopharyngeal cancer	Europe	Scenario analysis of BAU and classification as Carcinogen Category 1.Included impact assessment of scenarios on DALYs and uncertainty analysis.	DALYs 700 in total for the three health effects before implementation and 136 after.	Results used to inform cost-benefit analysis of options for risk management by TNO/RPA (2013[7])	www.integrated-assessment.eu/eu/indexf306.html?q='content'/health_impacts_regulative_policies_use_formaldehyde_consumer_products Accessed: 21.3.17
McLeod, R. (2013[27]), Cost-Benefit Analysis of Three Selected FWPA Projects: On board computers, formaldehyde testing of wood	Production	Economic impacts	Australia	Estimation of cost-benefit ratios and IRRs for panel manufacturers adapting to import requirements in the US market for low formaldehyde emission panel products.	NPV from FWPA's investment is AUD 0.16 million after 30 years.		

panels and vineyard post treatment.							
Prüss-Ustün et al. (2011[23]), Knowns and unknowns on burden of disease due to chemicals: a systematic review	All	Health	Global	Broad estimation of global disease due to chemicals using available disease burden estimates in terms of deaths and DALYS. Formaldehyde included under indoor air pollutants from solid fuel combustion and second-hand smoke.	Total deaths and DALYs from indoor air pollutants and second-hand smoke for a number of chemicals including formaldehyde. Disease burden from emissions from building materials and household products is not included.	Study uses death and DALYs data from WHO and other sources but these seem to be broad estimates that do not isolate the effect from formaldehyde.	www.ehjournal.net/content/10/1/9
RPA/DHI (2016[9]), Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment: Development of a System of Indicators	Focus on worker exposure	Health	EU	Monetisation of benefits of EU chemicals legislation for health (skin disease and asthma) Calculation of medical treatment costs, productivity loss and WTP to avoid a health impacts.	Total cost savings for skin disease and asthma attributed to exposure to chemical substances over the period 2004-2013 in the EU28.	Savings estimates are given as totals for avoidance of exposure to a number of chemicals, including formaldehyde.	
Schuur et al. (2008[17]), Health impact assessment of policy measures for chemicals in non-food consumer products	Consumer use	Health (chipboard, textiles and cosmetics)	Netherlands	Quantify the potential health gain as a result of policy measures in terms of DALYs.	Exposure via plywood not high and prolonged enough to induce local nasal tumours. Dermal exposure via textiles, MOS calculations show no concern for sensitization, thus no DALY calculated.	One of nine case studies in Schuur et al. (2008[17]). Included as an example of a carcinogenic compound with exposure from multiple consumer products.	www.rivm.nl/en/Documents_and_publications/Scientific/Reports/2009/januari/Health_impact_assessment_of_policy_measures_for_chemicals_in_non_food_consumer_products

					For cosmetics, insufficient data available. Therefore, no DALY calculated.		
TNO/RPA (2013[7]), Annex 1: Cost-Benefit Analysis of Proposed Risk Management Options for Workers	Production/manufacturers	Economic impacts (industry and workers)	EU	Assessment of costs and benefits under 3 scenarios (baseline, risk based and authorisation)	Estimation of costs of scenarios to sectors. Benefits reported as % of workers that may benefit from scenarios.	Since health benefits are not monetised there is no direct comparison of cost v benefits.	
TNO/RPA (2013[7]), Annex 2: Cost-Benefit Analysis of Proposed Risk Management Options for Consumers	Consumer use	Economic impacts (industry and consumers)	EU	Assessment of costs and benefits under 3 scenarios (baseline, risk based and authorisation)	Estimation of costs of production changes and substitution of materials under scenarios. Benefits reported as changes in DALYs (from (Perouel, 2011[26])).	Since health benefits are not monetised there is no direct comparison of cost v benefits.	
US EPA (2013[19]), Economic Analysis of Formaldehyde Standards for Composite Wood Products Act Implementing Regulations Proposed Rule	Production	Economic: Costs assessed for to Manufacturers, fabricators, wholesalers and retailers. Health focus on: nasopharyngeal cancer and eye irritation.	United States	Total annualised costs of compliance with the rule (includes changes to production process, costs of testing, third-party certification, labelling, and chain of custody activities) assessed for 13 analytical (policy) options each with high and low end scenarios. Total Annualised Benefits for all options for avoided cases of cancer and eye irritation, using cost of	Net benefits negative for all the options	Report states that conclusion might change if additional health benefits could be quantified. Economic analysis reported in US EPA (2016a and 2016b) updates this analysis	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2012-0018-0484

				illness approach.			
US EPA (2016[24]), Formaldehyde Emission Standards for Composite Wood Products	Production and sale of hardwood plywood, medium-density fiber-board, and particleboard, and finished goods containing these products	Economic: Costs assessed for to Manufacturers, fabricators, wholesalers and retailers. Health focus on: nasopharyngeal cancer and eye irritation	United States	Costs of compliance with rule include changes to production process and raw materials, testing and other required activities. Benefits estimates include valuation of the avoided cases of nasopharyngeal cancer (how valued?) and eye irritation (WTP).Estimation of incremental cost to US firms of complying with the requirements of the rule compared to the activities that firms are already undertaking.	Estimated annualised benefits (due to avoided incidence of eye irritation and nasopharyngeal cancer) are USD 64 million to USD 186 million per year using a 3% discount rate, and USD 26 million to USD 79 million per year using a 7% discount rate. The annualised costs of this rule are estimated at USD 38 million to USD 83 million per year using a 3% discount rate, and USD 43 million to USD 78 million per year using a 7% discount rate.	Quantified costs of rule may exceed the quantified benefits under certain conditions. However, there are additional benefits of avoiding some health effects (including myeloid leukaemia, respiratory related effects and reduced fertility) that are not quantified due to insufficient data. Thus, overall conclusion by EPA is that when unquantified benefits are included the benefits of the rule justify its costs.	https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0461 For detailed report of economic analysis see US EPA (2016[25]) at: https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0461-0037.