Organisation for Economic Co-operation and Development

ENV/WKP(2018)5

Unclassified **English - Or. English**

31 May 2018

ENVIRONMENT DIRECTORATE

Economic valuation in 1-Methyl-2-pyrrolidone (NMP) regulation

by Alistair Hunt and Nick Dale, University of Bath

JEL codes: Q51, Q52, Q53

Keywords: Cost-benefit analysis, regulatory impact assessment, environmental health valuation, non-market valuation, 1-Methyl-2-pyrrolidone (NMP).

OECD Environment Working Papers are available at www.oecd.org/environment/workingpapers.htm.

JT03432721

OECD ENVIRONMENT WORKING PAPERS

OECD Working Papers should not be reported as representing the official views of the OECD or of its member countries. The opinions expressed and arguments employed are those of the author(s).

OECD Working Papers describe preliminary results or research in progress by the author(s) and are published to stimulate discussion on a broad range of issues on which the OECD works.

This series is designed to make available to a wider readership selected studies on environmental issues prepared for use within the OECD. Authorship is usually collective, but principal author(s) are named. The papers are generally available only in their original language -English or French- with a summary in the other language.

Comments on OECD Working Papers are welcomed, and may be sent to:

OECD Environment Directorate,
2, rue André Pascal, 75775 PARIS CEDEX 16, France
or by e-mail to *env.contact@oecd.org*

OECD Environment Working Papers are published on
www.oecd.org/environment/workingpapers.htm

Foreword

This background paper on *Economic valuation in 1-Methyl-2-pyrrolidone (NMP) regulation* was prepared for the SACAME workshop in Ottawa, Canada of 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 authors 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 1-Methyl-2-pyrrolidone (NMP), an organic solvent, used in a number of sectors. Health risks associated with the manufacture of NMP include the risk of stillbirth and developmental retardation to pregnant workers, as well as a variety of chronic and acute effects, including respiratory effects.

Although NMP regulation exists, economic assessments are almost non-existent; only one study attempts to quantify and monetise the human health impacts of NMP. The analysis was limited by the absence of dose-response relationships for humans to quantify the benefits of avoided cases; therefore breakeven analyses for reductions in low birth weight and pregnancy loss were conducted.

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 better developed.

JEL codes: Q51, Q52, Q53.

Keywords: Cost-benefit analysis, regulatory impact assessment, environmental health valuation, non-market valuation, 1-Methyl-2-pyrrolidone (NMP).

Résumé

Ce document propose un tour d'horizon des évaluations économiques des avantages procurés par les mesures de contrôle de la 1-méthyl-2-pyrrolidone (NMP), solvant organique employé dans un certain nombre de secteurs. Les dangers pour la santé qui lui sont associés sont les risques de mortinaissance ou de retard de croissance chez les enfants des travailleuses enceintes, ainsi qu'une variété d'effets aigus et chroniques, notamment respiratoires.

Si la NMP fait l'objet de dispositions réglementaires, il n'existe en revanche aucune évaluation économique, à l'exception d'une étude effectuée en vue de quantifier les conséquences de la NMP pour la santé humaine et d'en déterminer la valeur monétaire. L'analyse s'est heurtée à l'absence de données sur les relations dose-effet chez l'humain qui auraient permis de chiffrer l'avantage découlant des cas évités. C'est pourquoi on s'est appuyé à la place sur les analyses du point d'équilibre associé au recul du nombre des cas d'insuffisance pondérale à la naissance et de fausses couches.

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, 1-méthyl-2-pyrrolidone (NMP)

Table of contents

Tables

Acronyms and abbreviations

CLP	Classification Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and reproductive toxicant
DALY	Disability Adjusted Life Year
DFA	Damage Function Approach
DNEL	Derived No-Effect Level
ECHA	European Chemicals Agency
LBW	Low Birth Weight
NMP	1-Methyl-2-pyrrolidone (alternatively: N-Methyl-2-pyrrolidone or N-methylpyrrolidone in some sources)
RCR	Risk Characterisation Ratio
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RMO	Risk Management Option
SACAME	Socio-economic Analysis of Chemicals by Allowing a better quantification and monetisation of Morbidity and Environmental impacts
SEAC	Committee for Socio-economic Analysis
SIDS	Screening Information Dataset
TSCA	Toxic Substance Control Act (US)
VSL	Value of Statistical Life
WHO	World Health Organization
WTP	Willingness-to-pay

Executive Summary

This paper focuses on the economic assessment of 1-Methyl-2-pyrrolidone (NMP). It reflects on the economic evidence used in on-going developments in restrictions in terms of occupational exposure limits within the EU under REACH and recent regulatory assessments in North America, and considers best practice to inform future such assessments.

N-Methyl-2-pyrrolidone (NMP) is an organic solvent that is water-miscible. It is used in a number of sectors, including petrochemicals, plastics, the microelectronics fabrication industry, and in the manufacture of various compounds, including pigments, cosmetics, drugs, insecticides, herbicides and fungicides. With production sites in Europe, the United States and Asia-Pacific region, the global NMP market value was estimated at USD 1.07 billion in 2015. Health risks associated with the manufacture of NMP include the risk of stillbirth and developmental retardation to pregnant workers, as well as a variety of chronic and acute effects, including respiratory effects. Available evidence suggests that environmental risks from production, use and disposal of NMP are low. Regulation of NMP currently exists in the EU, North America and Australia, whilst no evidence of regulatory development has been found across the Asian-Pacific region.

Although NMP regulation exists, economic assessments are almost non-existence: only one study – the US EPA economic analysis of the proposed regulation on NMP and Methylene Chloride – attempts to quantify and monetise the human health impacts of NMP. However, the NMP analysis is limited by the absence of dose-response relationships for humans to quantify the benefits of avoided cases, therefore breakeven analyses for reductions in low birth weight and pregnancy loss were conducted instead. Costs included incremental costs associated with the restrictions and the cost of increased health risks from switching to other chemicals. Potential benefits were estimated using cost-of-illness estimates to monetise cases of low birth weight and pregnancy loss. For both fatal and non-fatal health cancers associated with Methylene Chloride, the willingness-to-pay values are dated.

For the current regulatory proposal in the EU, and the recent proposal in the United States, assessments of the costs of regulation have been undertaken. Available studies focus on the compliance costs across producers, employees and the supply chain. This may be expected to introduce a potential bias in regulatory design if the interests of those bearing these costs are given disproportionate weight relative to the less well-defined range of beneficiaries.

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 better developed. The need for better

economic assessment is perhaps greatest in Asia, where the regulatory regime is currently weakest.

JEL codes: Q51, Q52, Q53.

Keywords: Cost-benefit analysis, regulatory impact assessment, environmental health valuation, non-market valuation, 1-Methyl-2-pyrrolidone (NMP).

Synthèse

L'objet du présent document est de présenter une évaluation économique de la 1-méthyl-2-pyrrolidone (NMP). L'exercice repose sur les données économiques employées dans le durcissement actuel des limites d'exposition professionnelle applicables dans l'UE en vertu du règlement REACH ainsi que sur des études récentes des réglementations existant en Amérique du Nord. Il y est également question de la meilleure pratique à suivre pour étayer ce type d'évaluation dans l'avenir.

La *N*-méthyl-2-pyrrolidone (NMP) est un solvant organique miscible à l'eau. Elle est employée dans un certain nombre de secteurs, dont la pétrochimie, la fabrication de matières plastiques, la microélectronique et la production de diverses substances entrant dans la composition de pigments, cosmétiques, médicaments, insecticides, herbicides et fongicides. La NMP est produite en Europe, aux États-Unis et dans la région Asie-Pacifique et sa valeur marchande mondiale était estimée à 1.07 milliard USD en 2015. Les dangers pour la santé qui lui sont associés sont les risques de mortinaissance ou de retard de croissance chez les enfants des travailleuses enceintes, ainsi qu'une variété d'effets aigus et chroniques, notamment respiratoires. D'après les éléments d'observation disponibles, la production, l'utilisation et l'élimination de la NMP s'accompagnent de risques écologiques faibles. Pour l'heure, la NMP fait l'objet de dispositions réglementaires au niveau de l'UE, en Amérique du Nord et en Australie, alors qu'aucune mesure dans ce sens ne semble avoir été prise dans la région Asie-Pacifique.

Il n'existe en revanche aucune évaluation économique, à l'exception de celle d'un projet de règlement concernant la NMP et le chlorure de méthylène que l'EPA des États-Unis a effectuée en vue de quantifier les conséquences de la NMP pour la santé humaine et d'en déterminer la valeur monétaire. Toute analyse de la NMP se heurte à l'absence de données sur les relations dose-effet chez l'humain qui auraient permis de chiffrer l'avantage découlant des cas évités. C'est pourquoi on s'appuie à la place sur les analyses du point d'équilibre associé au recul du nombre des cas d'insuffisance pondérale à la naissance et de fausses couches. Les coûts considérés sont les coûts différentiels des restrictions et le coût découlant de l'augmentation des risques pour la santé due au report vers d'autres substances chimiques. Les avantages potentiels ont été calculés à partir des estimations de coûts de morbidité utilisées pour attribuer une valeur monétaire aux cas d'insuffisance pondérale à la naissance et de fausses couches. S'agissant des cancers fatals et non fatals associés au chlorure de méthylène, les valeurs du consentement à payer datent.

Il a été entrepris d'évaluer les coûts de la règlementation découlant de la proposition à l'étude dans l'UE et de celle récemment examinée aux États-Unis. Les études disponibles portent essentiellement sur les coûts de mise en conformité supportés par les producteurs, les employés et la chaîne logistique. L'introduction d'un biais est prévisible au stade de la conception dès lors qu'une importance disproportionnée est accordée aux intérêts de ceux qui supportent ces coûts au détriment de l'éventail, moins bien défini, des bénéficiaires de de la réglementation.

En dépit des limites actuelles des observations épidémiologiques, les évaluations économiques devront dans l'avenir mieux exploiter le corpus grandissant des études consacrées aux avantages pour la santé dans le monde. 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 de vérification des coûts qui soient plus fiables. C'est peut-être en Asie que la nécessité d'améliorer les évaluations économiques est la plus grande dans la mesure où le cadre réglementaire y est actuellement le plus faible.

1. Introduction

This case study has been prepared for the OECD as part of the SACAME (Socio-economic Analysis of Chemicals by Allowing a better quantification and monetisation of Morbidity and Environmental impacts) 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 available economic assessments for 1-Methyl-2-pyrrolidone (NMP) with the aim of providing 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 of these chemicals. NMP is of particular interest due to ongoing developments in restrictions in terms of occupational exposure limits within the EU under REACH with an associated socio economic analyses and recent regulatory assessments in the United States and Canada. A sister case study addresses these aims for formaldehyde (ENV/EPOC/WPIEEP/JM(2017)2/REV1).

Section 2 provides background on the manufacture, uses and disposal of NMP, identifies associated human health and environmental risks/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 NMP including methodology used and values for health 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.

2. Background on NMP

N-Methyl-2-pyrrolidone (NMP) is an organic solvent that is water-miscible. This colourless liquid has a mild amine odour and is used in a number of sectors, including petrochemicals, plastics, the microelectronics fabrication industry, and in the manufacture of various compounds, including pigments, cosmetics, drugs, insecticides, herbicides and fungicides. NMP is increasingly used as a substitute for chlorinated hydrocarbons (Åkesson (2001[1]); ECHA (2014[2])).

2.1. Manufacture and uses

NMP is widely used globally in a range of industrial and consumer applications, generally as an organic solvent, intermediate or surfactant (Environment Canada, 2017[3]). A summary of uses of NMP is given in Table 2.1, which illustrates the range of uses, including in industrial, professional and consumer contexts and sectors.

NMP is a high production volume substance with over 18 000 tonnes per year manufactured in Europe. It is used in industrial and professional settings and may be present in some consumer products. Uses in Europe include those for industrial chemical processes, charging and discharging of substances and mixtures, formulation of preparations, laboratories, construction chemicals, coatings, cleaning agents, functional fluids and agrochemicals (ECHA (2014[2])). Annual global production capacity was 100 000 to 150 000 tonnes in 2007 with production sites in Europe, US and Asia-Pacific region (ECHA (2014[2])). The global NMP market value was estimated at USD 1.07 billion in 2015 and is expected to show significant growth in the next decade due mainly to increased demand from key sectors such petrochemicals, pharmaceuticals and electronics (Grand View Research, 2016[4]).

2.1.1. Disposal

Waste disposal NMP is classified as a combustible liquid. Waste NMP should be stored in approved safety-type disposal cans that are properly labelled as to their contents and hazard. NMP is highly biodegradable and may be treated effectively in an industrial wastewater treatment facility or municipal wastewater plant. Where possible, bio-treatment is recommended. Incineration or landfilling in a licensed facility are other options for when an absorbent has been used to contain an NMP spill (BASF, 1998[5]).

2.1.2. Health risks and impacts

NMP is classified as a skin, eye and possible respiratory irritant and repro-toxic category 1B (defined as substances presumed to be toxic for human reproduction) based on developmental toxicity (insert ref). The ECHA risk assessment considered that the repeated dose toxicity for the general worker population and the developmental toxicity endpoint for pregnant workers are the most critical endpoints (ECHA (2014[2])). Moreover, the US EPA (2015[6]) risk assessment selected developmental toxicity (i.e. reduced foetal body weight and foetal resorption) as the most appropriate critical effect for health effect and risk characterisation. Table 2.2 summarises possible health hazards related to NMP.

Table 2.1. Summary of uses and users of NMP

Use process	Example of use	User or sector
Manufacture	Production of NMP	Manufacturers of NMP
	Generic use (industrial)	
Chemical processes	Synthesis of bulk and fine chemicals, Extraction of petrochemicals, Synthesis and extraction of pharmaceuticals, Synthesis of active ingredients of agrochemicals	Petrochemical, Pharmaceutical, Agrochemical.
Charging and discharging substances and mixtures	Distribution of NMP, (Re)filling	General use applying to all industrial uses Importers and suppliers
Formulation of preparations	Formulation of coatings, cleaners, agrochemicals (co-solvent), pharmaceuticals, membrane production, High performance polymer production	Industrial users including: Non-wire coating formulators, Wire coating formulators, Cleaner products producers, Membrane manufacturers, Polymer producers, Agrochemical formulators, Pharmaceutical sector.
	Industrial Use	
Coatings	Used as solvent in wide range of non-wire coatings (e.g. paints, inks, adhesives) and in wire coatings.[1]	Non-wire coaters: e.g. Automotive/metal, Plastics, Textiles, Foundry, Printing, Wall/concrete, Wood. Wire coaters
Cleaning agents	Used in various types of cleaning processes (e.g. Injection head cleaning, Industrial degreasing) and products (e.g. paint removers and floor strippers)	Petrochemical industry, Electronics and semi-conductor industry, Optical industry, Wire and non-wire coating formulators, Furniture manufacturer, Automotive industry, Maritime industry, Aeronautic industry
Laboratory	R&D of petrochemicals, pharmaceuticals and as a traditional solvent.	Various NMP using industries and lab activities in non-NMP using industries
Functional fluids	Includes use of NMP in cable oils, transfer oils, hydraulic fluids in industrial equipment, coolants, insulators, refrigerants.	General use for many industries
Construction chemicals	Solvent, Cleaner/stripper, Adhesive/binder, De-fluxing, Waterproofing.	Construction industry
	Generic Use (professional)	
Charging and discharging substances and mixtures	Refilling	Applicable to virtually all professional uses. Importers/suppliers
Formulation of preparations	Formulation of coatings, cleaners, agrochemicals.	Professional coaters, cleaners and agricultural chemical formulation.
	Professional	
Coatings	Solvent and water-based coatings, e.g. in paints, inks, adhesives, concrete, wood.	Wide range of sectors e.g. Automotive/metal, Plastics, Leather, Textiles, Foundry, Printing, Construction.
Cleaning agent	Cleaning processes and products as e.g. degreaser, Solvent for plastics, resins, oil and grease.	Wide range, e.g. painting, printing, shoe producers
Agrochemicals	Co-formulant in herbicide, pesticide and fungicide formulations.	Users of agricultural chemical formulations
Functional fluids	Cable oils, Transfer oils, Hydraulic fluids in industrial equipment, Coolants, Insulators, Refrigerants.	Many sectors
Road and construction applications	Use of surface coatings and binders in road and construction activities Including paving, roofing and waterproofing.	Roads and construction

[1] The assessment in AMEC (2013[19]) suggests that non-wire coatings have been or are in the process of being phased out for most uses with the exception of automotive coatings.

	Consumer Use	
Coatings	Printing ink, Inject inks	Consumers
Cleaners	Paint remover, cleaner, graffiti remover	Consumers
Cosmetics	Use of cosmetics	Consumers

Source: Summarised from ECHA (2014[2]), Annex 1.

Table 2.2. Summary of possible human health hazards relating to NMP

Type of health effect	Potential endpoints or specific conditions
Developmental effects	Intra Uterine Growth Retardation (IUGR) Stillbirth
Chronic and acute health effects:	Decrease in body weight Decrease in body weight gain Lack of appetite General loss of well-being Potential effects on organs Respiratory tract irritation

Source: Summarised from ECHA (2014[2]).

2.1.3. Environmental risks or impacts

The available evidence suggests that environmental risks from production, use and disposal of NMP are low. The draft screening assessment by Environment Canada concluded that based on evidence "there is low risk of harm to organisms and the broader integrity of the environment from NMP and it is not entering the 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 or that constitute or may constitute a danger to the environment on which life depends." (Environment Canada, 2017[3])

The conclusion of the US EPA (2015[6]) risk assessment was that based on the available environmental fate data, NMP is expected to have low bioaccumulation potential and low persistence. With regard to soil, it is expected to possess high mobility in soil (releases to soil may volatilise from soil surfaces or migrate through soil and contaminate groundwater). In the atmosphere, it can be expected to dissolve into water droplets, where it will be removed by condensation or further reactions with hydroxyl radicals. The risk assessment also reviewed eco-toxicity studies for NMP for fish, aquatic invertebrates, aquatic plants and birds and concluded that it has low acute and chronic toxicity to aquatic organisms and birds. NMP was also given a low environmental hazard profile in the SIDS Initial Assessment Profile (OECD, 2007[7]).

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

NMP is subject to regulation in EU countries 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, authorisation and restriction, and classification, labelling and packaging (CLP) regulations. Under CLP, it is included in Annex VI, part 3 of Regulation (EC) No 1272/2008 (list of harmonised classification and labelling of hazardous substances) as potentially causing a number of health impacts (ECHA, 2014[2]). A REACH restriction is proposed such that NMP may only be manufactured and used if it can be guaranteed that under normal operating conditions, the

exposure (as 8-hour time-weighted average) will remain below 5 mg per m^3 and peak exposures (15 min short-term exposure limit) must remain below 10 mg per m^3 (ECHA, 2014[2]). European countries also have national NMP limits in place, such as in the United Kingdom where the Health and Safety Executive sets workplace exposure limits as 10 mg per m^3 for an 8 hour time-weighted average and 20 mg per m^3 for 15 min exposure (Health and Safety Executive, 2011[8]).

In the United States, NMP is subject to a number of regulations at state level. For example, it is listed as a hazardous substance or other pollutant in California and has a permissible exposure limit of 1 ppm as an 8-hour time-weighted average (US EPA, 2017[9]). At national level, the US EPA has identified risks of concern associated with NMP use in paint and coating removal and is proposing Toxics Substance Control Act (TSCA) Section 6 action to prohibit the manufacture (including import), processing, and distribution in commerce of NMP for all consumer and commercial paint and coating removal; to prohibit the use of NMP for all commercial paint and coating removal; to require downstream notification of these prohibitions throughout the supply chain; to require recordkeeping; and to provide a time-limited exemption from these proposed regulations on NMP for coating removal uses critical for national security (US EPA, 2017[9]).

In Australia, NMP has been subject to a Tier II health risk assessment which applies to chemicals identified as needing further investigation under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework. It is currently subject to labelling and related requirements based on a number of health concerns. It is also subject to risk management assessment under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) to determine if current exposure controls are adequate to protect workers and the public when used in domestic products (US EPA (2017[9]) and NICNAS (2017[10])).

In Canada, concentration limits for NMP, in pharmaceutical products, have been adopted with PDE set at 5.3 mg per day with a limit at 530ppm (Health Canada, 2016[11]). A draft screening assessment recently concluded that NMP is not entering the environment in a quantity or concentration or under conditions that constitute a danger in Canada to human life or health (Environment Canada, 2017[3]). Thus, no risk management actions are currently proposed.

Research for this report has not found evidence of regulatory development on NMP in the Asian Pacific region. For example, there appears to be no regulatory limit on the amount of NMP in atmosphere in China.

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.

Economic values for *health benefits* of regulating chemicals can be estimated by use of the damage-function approach (DFA) that is commonly used in the context of air pollution. This approach includes three cost 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 or leisure time, or both, 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[12]). A cost-of-illness approach outlined in the US EPA (2007[13]) handbook can be used in valuing the impacts on human health 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 methods and hedonic pricing (where there are non-monetary benefits from regulation) as indicated in Table 3.1.

Benefit transfer methods can be used in assessing 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[14]) 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 with regulations by the regulated entities (Alberini, 2017[15]).

CBAs and other regulatory impact assessments may also include analysis of the employment effects of proposed regulations and distributional impacts (Alberini, 2017[15]).

Table 3.1. 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[2])	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

3.2. Overview of existing economic assessments regarding NMP

Details of existing economic and regulatory impact studies related to NMP resulting from a review of literature undertaken for this study are given in Table A.1. Key points arising from this review are noted below.

3.2.1. Benefit assessments

- There is a developing literature on monetising the benefits of regulating chemicals but few studies on NMP. The study by RPA/DHI (2016[16]) 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 no specific references to quantifying and monetising the

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

benefits of regulating NMP. A search of the inventory of valuation literature on chemicals (Sørensen et al., 2016[17]) also found no studies relating specifically to NMP.

- The literature review found only one study that quantified or monetised human health impacts of NMP, the US EPA (2017[18]) economic analysis of the proposed regulation on NMP and Methylene Chloride. However, the NMP analysis is somewhat limited by absence of dose-response relationships for humans to quantify the benefits of avoided cases; therefore breakeven analyses for reductions in low birth weight and pregnancy loss were conducted instead. The ECHA (2014[2]) report has a detailed discussion on possibilities for quantifying human health impacts but concludes that there is insufficient data to quantify the potential effects.
- Valuation of environmental or ecosystem impacts was not undertaken in the reviewed studies due to the low risk assessments for NMP.

3.2.2. Cost assessments

Key studies on economic costs of NMP regulation are related to recent developments in the EU and in the United States. In the EU, these studies (ECHA (2014[2]), AMEC (2013[19]) and (AMEC, 2013[20])) are related to proposals for REACH regulation and focus on economic impacts on producers, employees and the supply chain. In the United States, they relate to proposals for TSCA Section 6 regulation NMP and methylene chloride in paint and coating removal (US EPA (2017[18]), (2017[9]) and (2017[21])).

4. Analysis of findings of economic assessments of NMP

The two key sets of studies outlined here are for the REACH dossier proposing restrictions on NMP in the EU and the proposed TSCA Section 6 Action on NMP (along with methylene chloride) in paint and coating removal in the US.

For the REACH proposals, the AMEC (2013[20]) costs study gives an assessment of costs of compliance for three Risk Management Options (RMOs): (i) a concentration limit of 0.3% NMP for all uses in the EU27 (equivalent to a total ban), (ii) a concentration limit of 0.3% NMP for professional uses in the EU27 (a partial ban) and (iii) a harmonised mandatory Derived No-Effect Level (DNEL), along with complementary measures. The assessment included NMP suppliers and producers of cleaning products and non-wire coatings, wire coatings and membranes. The estimates are based on generic cost data and industry consultation on costs of likely responses focused on reformulation (i.e. use of chemical alternatives) and general risk management measures to reduce exposure. These have been scaled up to provide EU-wide estimates. Findings are presented as lower and upper bound estimates for both compliance costs and losses in revenue due to compliance for each RMO (AMEC (2013[20]), Table 6.2) by supplier or user included. The estimates are calculated as 15-year present values for quantified costs for the selected industries (in EUR million). RMOs are then ranked in order of overall economic impact, although it is noted that there is high uncertainty and estimated costs are likely to be under-estimates.

In conclusion, the AMEC (2013[20]) costs analysis ranks RMOs in order of overall economic impact. This is done using the quantified costs to the selected industries as a proxy for overall economic impacts. In decreasing order of impact:

- RMO1 (concentration limit of 0.3% NMP for all uses in the EU27) which has a quantifiable expected 15-year PV cost to the selected industries of EUR 24 – EUR 38 billion;
- RMO3 (10 mg per m^3 limit value), for which this cost is EUR 24 – EUR 37 billion;
- RMO3 (20 mg per m^3 limit value), for which this cost is EUR 96 – EUR 180 million; and
- RMO2 (concentration limit of 0.3% NMP for professional uses in the EU27) for which this cost is EUR 23 – EUR 58 million.

The background document on the proposal on REACH restrictions on NMP in the EU (ECHA, 2014[2]) provides a detailed socio-economic assessment of industry responses to the RMOs, including: substitution of NMP, continued use of NMP with measures to reduce employee exposure, relocation with continued use of NMP and termination of operations with NMP. Socio-economic impacts of RMOs are described in terms of costs (compliance and administrative) and wider socio-economic effects, (including employment, transfer of value added from EU to other countries and supply chain effects) and quantitative estimates are given for selected uses of NMP based on the market- and cost analysis (AMEC (2013[19]) and (2013[20])) although with some variations. Each effect is discussed per RMO and per NMP producer or user sector, with conclusions given on compliance and other costs, turnover potentially affected and potential losses of jobs. The cost results of the full ban and RMO3 (10 mg per m^3 limit value) are dominated by the presumption that such restrictions will result in the closure of wire-coating operations – by far the largest sub-sector affected. It should be noted that employment effects are

identified only qualitatively in this study, and on the basis of impressions given by industry respondents. Future efforts could consider quantitative analysis that adopt methods such as those outlined in Bartik (2012). It is stressed that uncertainties in the quantitative estimates are high and values should be seen as indicative and representing the order of magnitude of socio-economic effects.

Regarding benefits, it should also be noted that this analysis did not include quantitative analysis of human health impacts due to insufficient data to quantify the potential effects.

Current regulatory analyses related to NMP in the United States are focused on the proposed TSCA Section 6 Action on NMP along with methylene chloride in paint and coating removal. In the economic analysis (US EPA, 2017[18]), three regulatory options were analysed for NMP, two requiring prohibition from manufacture, processing and distribution except for certain uses under different downstream notification stipulations and one allowing use under certain restrictions and requirements for manufacturers and users. Costs of these options were estimated based on current usage of NMP and associated costs to all affected parties of the proposed rule and included: (1) costs for manufacturers and processors to reformulate their products and provide downstream notifications, and (2) costs incurred by users (commercial workers and consumers) to switch to alternative products and comply with requirements for personal protective equipment. Incremental costs were calculated for the strategies of affected parties to comply with the rule under three scenarios based on low, high and average unit costs.

Cost estimates of regulatory options in US EPA (2017[18]) were subsequently revised in supplemental analyses (US EPA, 2017[21]) with summary costs given in latest Federal Register document for comment (US EPA, 2017[9]) as follows.

- Total costs of proposed rule under the first option for NMP: USD 2.8 million to USD 51 million annualised over 20 years at 3% and USD 3.4 million to USD 51.1 million annualised over 20 years at 7%.
- Total costs of the proposed rule under the second option for NMP: USD 114.2 million to USD 124.8 million annualised over 20 years at 3% and USD 114.7 million to USD 125.4 million annualised over 20 years at 7%.

Regarding benefits, the health impact analysis in the EPA economic study (US EPA, 2017[18]) found that dose-response relationships for humans were not available to quantify the number of cases of health endpoints that would be avoided if exposure to NMP in paint removers is reduced or eliminated. Thus, benefits from restrictions on NMP could not be quantified. However, the NMP regulatory options are also associated with increased health risks where substitute chemicals may be used, specifically in the furniture refinishing sector. This sector is covered under the regulatory options for paint removers containing NMP. Assuming that some or all users of NMP-based paint removers in the furniture refinishing sector will switch to methylene chloride-based paint removers, which pose significant health risks, the analysis quantified the value of increased cancer risks for the furniture sector. The monetised values for increased cancer risk (weighted by incidence of fatal and non-fatal cases) under the NMP regulatory options were estimated at between USD 94 000 and USD 112 000 using a 3% discount rate and between USD 11 000 and USD 55 000 using a 7% discount rate.

In the absence of dose-response relationships for humans to quantify the benefits of avoided cases, the study conducted breakeven analyses for the impacts of low birth weight and pregnancy loss. This estimated the potential number of cases that may be avoided due to reduced NMP exposure and calculated the range of costs that would result

in positive net benefits (i.e. the range of costs allowing benefits to break even with the costs). Costs included incremental costs associated with the restrictions and the cost of increased health risks from switching to other chemicals. Potential benefits were estimated using cost-of-illness (COI) estimates from the literature (Schmitt et al. (2005[22])) to monetise cases of low birth weight (LBW) and pregnancy loss.

Thus, net benefits were estimated based on incremental costs for industry and consumers of each NMP regulatory option and the monetised values for increased cancer risk of using alternatives, and setting this against the potential benefits of avoided cases of LBW and pregnancy losses. It found that the potential benefits of avoided cases of LBW (below USD 2 million) are less than industry costs (except when using the higher of the two COI estimates adopted and if NMP is responsible for 100% of all-cause LBW in the exposed population). It also found that the quantified benefits would be unlikely to exceed costs, for any percentage of pregnancy losses. Therefore, it concluded that it is unlikely that these benefits would break even with costs. However, the study stresses that the currently monetised benefits significantly underestimates the benefits of avoiding NMP-induced adverse outcomes on health and quality of life.

Table 5 summarises the data used to estimate benefits in the US EPA study (US EPA, 2017[18]). 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). In the case of low birth weight, only cost-of-illness components were considered; WTP was neglected.

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 liver and lung cancers 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 value for WTP of USD 0.82 per micro-risk reduction and a high surrogate estimate of USD 5.69.

It is also the case that the studies for both fatal and non-fatal health cancers 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 (2010[23]) 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 NMP regulation: up-dating practice and evidence

In the sub-sections below we briefly summarise the prospects for valuation of health risks potentially relevant to NMP regulatory analysis.

4.1.1. Developmental effects: Intra uterine growth retardation and stillbirth

The main consequence of Intra Uterine Growth Retardation is low birth weight. As reported in ECHA (2016[24]) there are a handful of studies that have attempted valuation of low birth weight, the most prominent being Ščasný and Zvěřinová (2014[25]) and Nastis and Crocker (2007[26]). The latter study used a production function approach to estimate the value a pregnant woman attaches to own-health relative to the health of the foetus she

carries. The study finds a ratio of 6:1 between the health of the unborn child and her own health but does not give any monetary valuation results. In contrast, ECHA (2016[24]) evaluating the study by Ščasný and Zvěřinová that it commissioned, derives a central value for risk of very low birth weight of EUR 126 100. This data should be considered in future regulatory assessments of NMP, additional to the cost-of-illness approach used in US EPA (2017[18]). For stillbirth, in the absence of any monetary valuation data on this end-point, it seems defensible to use unit values relating to parents valuation of children's lives. As captured – for example – by the concept of child premium additional to an adult VSL. Given the qualified evidence for such a premium, this may be used in sensitivity analysis (OECD, 2010[27]).

4.1.2. Decrease in body weight, loss of appetite and well-being

The lack of epidemiological evidence as to whether – and to what extent – decrease in body weight and associated conditions can be caused by contact with NMP is reflected in an absence of valuation data that relates to these conditions. In the first instance, however, an approximation could be estimated if QALY or DALY weights were to exist that equated these conditions with others for whom there are monetary valuation data. Findings from this exercise should then be checked against a primary valuation study set up in geographical contexts of most relevance to populations potentially impacted by NMP. As with developmental end-points it seems most beneficial for this study to take the form of a stated preference exercise since these conditions are likely to be relatively familiar to adult respondents.

4.1.3. Respiratory irritation

There exists a small body of evidence of WTP estimates that relate to respiratory irritation. As outlined in the discussion of skin and eye irritation in the companion paper on Formaldehyde, these irritative conditions map reasonably closely to the generic end-points – Restricted Activity Days (RADs) and Minor Restricted Activity Days (MRADs) – used in the assessment of air quality regulations. Principal studies in Europe and North America include Ready et al. (2004[28]), and Johnson et al. (2000[29]) and Berger et al. (1987[30]), respectively. However, these studies are now quite old; new primary studies should look to capture contemporary preferences as well as better data on the financial costs of illness.

4.1.4. Cancer: liver and lung

Whilst NMP is not currently associated with cancer impacts, US EPA (2017[18]) uses cancer unit values to identify the opportunity cost of NMP regulation – in this case the health impact of product substitutes. The unit value used to represent fatal liver and lung cancer in US EPA (2017[18]) 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[23]). This survey of the US evidence 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 (OECD, 2012[31]) which suggests no premium to be justified.

In the case of lung cancer, there is a small range of studies that attempt to value this end-point directly – a sample is given in Table 4.1. Whilst these studies provide a useful

reference range of values generated on the basis of contrasting methods, the diversity of contexts in which they were undertaken means that the absolute values have only limited weight in policy appraisal. These studies do however provide a useful benchmark for future studies. They – along with other cancer risk valuation studies – also provide a reference point for the design of studies relating to the valuation of liver cancer risks, of which there appears to be an absence.

Table 4.1. Studies that estimate the WTP to avoid lung cancer

Study ref.	Good valued	Location	Valuation method	Results (Mean USD 2010)
Priez and Jeanrenaud (1999[32])	95% risk reduction of contracting lung cancer	Switzerland	CV (Payment card) Private good	VSC 0.37 - 0.43 million
Aimola (1998[33])	50 % risk reduction of death from cancer	Sicily	CV (OE & Payment card versions) Public good	VSL 0.44 million
Åkerman, Johnson and Bergman (1991[34])	50 % risk reduction of lung cancer	Sollentuna, Sweden	Avertive behaviour	VSL 0.26 million (40-year old, 3% discount rate)
Jan et al. (2005[35])	50 % risk reduction of lung cancer	Taiwan	CV Private good	VSC 0.015 - 2.5 million
Hammitt & Liu (2004[36])	2/100,000 and 8/100,000 risk reduction	Taiwan	CV Private good Acute = 2-3 years LE Latent = 20 years + LE	VSL 1.75 million (acute); 1.32 million (latent)
Cameron et al. (2009[37])	1/1000,000	US	CE Private & Public goods	VSC 1 million

Note: VSL: Value of a Statistical Life; VSL: Value of a Statistical Cancer case.
Source: Based on Hunt (2011[38]).

Table 4.2. Summary of benefit data used in economic assessments of NMP regulations

Study & Risk	Impact	Metric/Valuation	Methodology
US EPA (2017[18]) Economic analysis of options for the proposed TSCA Section 6 Action on NMP	Liver and lung cancer fatal & non-fatal	Liver and lung cancers fatal: WTP (USD 9.77 million). Omits treatment costs Liver and lung cancers non-fatal: WTP. Assumed to encompass COI cost components.	WTP derived from Weibull-mean of sample of VSL estimates from wage-risk and contingent valuation studies made in 1974-1991, in US EPA (2010[23]). WTP range derived from Magat et al. (1996[39]), WTP to avoid curable lymphoma, and Viscusi et al. (1991[40]), WTP to avoid chronic bronchitis. Treatment costs derived from costs associated with component parts of treatment processes Schmitt et al. (2005[22]).
	Low birth weight risk	Low birth weight risk: COI approach Treatment costs only	

5. Conclusions

The preceding sections present data reported in economic assessments of NMP regulation to date. The evidence base on both the costs and benefits is shown to be centred primarily on one study undertaken by the US EPA. 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 NMP.

- Available studies focus on economic costs of regulation (producers, employees and the supply chain) of NMP in the EU and US. This may be expected to introduce a potential bias in regulatory design if the interests of those bearing these costs are given disproportionate weight relative to the less well defined range of beneficiaries.
- The dose-response functions required to quantify human health impacts of NMP do not appear – in the main – to be defined sufficiently for valuation to be undertaken and benefits estimated. For example, the socio-economic assessment of the proposed EU restriction in ECHA (2014[2]), section F1, concludes: "no quantitative human health impact assessment has been prepared for this document. The choice not to do this was made as the available data was found insufficient to quantify the potential effects. The main reason was that no quantitative relationship could be derived between human health effects and exposure. Quantitative impacts would be so uncertain that the numbers would not have an actual meaning. Instead of going for quantitative impacts, an (extensive) qualitative description was given next to some alternative quantitative proxies of the potential health effects (risk reduction potential, population of workers for which the risk is reduced) to provide insight in the magnitude of the potential effects." ECHA ((2014[2]), Section F, p. 265).
- That notwithstanding, it remains useful to do as the US analysis does and undertake sensitivity analysis, using evidence on health end-points that is more robust. In these cases, there exists sufficient evidence on monetary valuation for indicative analysis to be undertaken. For example, ECHA (2016[24]) provides unit values that could be transferred to the context of NMP regulatory analysis.
- Existing studies indicate low environmental impacts (Environment Canada, (2017[3]) and US EPA (2015[6])), though confidence in their findings is not high. Further evidence would therefore be useful to add to future regulatory assessments.
- In the US context, there exists a direct link between the findings of the regulatory assessment contained in US EPA (2010[23]) and (2017[18]) and the proposed rule: Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a) (US EPA, 2017[9]). Given the attention now given to economic assessment in REACH and the energies put into monetary valuation of potential health impacts (ECHA, 2016[24]), it seems likely that European regulations will be similarly evaluated.

- Research Gaps: Given that there is significant production and consumption of formaldehyde in Asia and a seeming lack of economic analysis of their impacts it is suggested that economic analysis of both the cost and benefit components be expanded into this region. Primary research studies in Asian producer countries are likely to be particularly valuable.

References

Aimola, A. (1998), "Individual WTPs for reductions in cancer death risks", in Bishop, R. and D. Romano (eds.), *Environmental Resource Valuation: Application of the Contingent Valuation Method in Italy*, http://www.springer.com/us/book/9780792381433. [33]

Åkerman, J. et al. (1991), "Paying for Safety: Voluntary Reduction of Residential Radon Risks", *Land Economics*, Vol. 67/4, http://www.jstor.org/stable/3146550, pp. 435-446. [34]

Åkesson, B. (2001), *Concise International Chemical Assessment Document 35: N-Methyl-2-pyrrolidone*, World Health Organization, Geneva, http://www.who.int/ipcs/publications/cicad/en/cicad35.pdf. [1]

Alberini, A. (2017), "Measuring the economic value of the effects of chemicals on ecological systems and human health", *OECD Environment Working Papers*, No. 116, OECD Publishing, Paris, http://dx.doi.org/10.1787/9dc90f8d-en. [15]

AMEC (2013), *RIVM - NMP Restriction Dossier: Appendix A -- Market Analysis -- Public version*, RIVM, Bilthoven. [19]

AMEC (2013), *RIVM - NMP Restriction Dossier: Appendix B -- Cost Analysis -- Public version*, RIVM, Bilthoven. [20]

BASF (1998), *N-Methylpyrrolidone Storage and Handling*, BASF, Mount Olive, NJ, https://compchemmpi.wikispaces.com/file/view/nmp_brochure_bio.pdf. [5]

Berger, M. et al. (1987), "Valuing Changes in Health Risks: A Comparison of Alternative Measures", *Southern Economic Journal*, Vol. 53/4, pp. 967-984. [30]

Camboni, M. et al. (2016), *Study on the Calculation of the Benefits of Chemicals Legislation on Human Health and the Environment Development of a System of Indicators Final Report*, European Commission, Brussels, http://dx.doi.org/10.2779/034894. [16]

Cameron, T., J. Deshazo and E. Johnson (2009), "Willingness to Pay for Health Risk Reductions: Differences by Type of Illness", *University of Oregon working paper*, University of Oregon, Eugene, http://pages.uoregon.edu/cameron/WEAI_AERE_2009/paper_Johnson.pdf. [37]

ECHA (2016), *Valuing selected health impacts of chemicals -- Summary of the Results and a Critical Review of the ECHA study*, ECHA, Helsinki, https://echa.europa.eu/support/socio-economic-analysis-in-reach/willingness-to-pay-to-avoid-certain-health-impacts. [24]

ECHA (2014), *Background document to the Opinion on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP)*, European Chemicals Agency, Helsinki, https://echa.europa.eu/documents/10162/a3e8fb17-d794-493c-a5ac-8cce41def0c7. [2]

Environment Canada (2017), *Draft Screening Assessment -- 2-Pyrrolidinone, 1-methyl- (NMP) and 2-Pyrrolidinone, 1-ethyl- (NEP)*, Environment Canada, Ottawa, http://www.ec.gc.ca/ese-ees/65CB2E52-9213-4DF0-A3C1-9B0CD361CEB1/DRP-DSAR-NMP-NEP_EN-2017-02-01.pdf. [3]

Grand View Research (2016), *N-Methyl-2-Pyrrolidone (NMP) Market Analysis By Application*, http://www.grandviewresearch.com/industry-analysis/n-methyl-2-pyrrolidone-nmp-market[(accessed on 26 July 2017). [4]

Hammitt, J. and J. Liu (2004), "Effects of Disease Type and Latency on the Value of Mortality Risk", *The Journal of Risk and Uncertainty*, Vol. 28/1, pp. 73-95, http://dx.doi.org/10.1023/B:RISK.0000009437.24783.e1. [36]

Health and Safety Executive (2011), *Workplace Exposure Limits*, Health and Safety Executive, London, http://www.hse.gov.uk/pUbns/priced/eh40.pdf. [8]

Health Canada (2016), *Impurities: Guideline for Residual Solvents -- ICH Topic Q3C(R5)*, Health Canada, Ottawa, http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/ich/qual/q3cr5-step4etape-eng.pdf. [11]

Hunt, A. (2011), "Policy Interventions to Address Health Impacts Associated with Air Pollution, Unsafe Water Supply and Sanitation, and Hazardous Chemicals", http://dx.doi.org/10.1787/5kg9qx8dsx43-en. [38]

Hunt, A. et al. (2016), "Social Costs of Morbidity Impacts of Air Pollution", *OECD Environment Working Papers*, No. 99, OECD, Paris, http://dx.doi.org/10.1787/5jm55j7cq0lv-en. [12]

Jan, M., T. Fu and C. Huang (2005), "Willingness to pay for low-lung-cancer-risk cigarettes in Taiwan", *Health Economics*, Vol. 14, pp. 55-67, http://dx.doi.org/10.1002/hec.894. [35]

Johnson, F., M. Banzhaf and W. Desvousges (2000), "Willingness to pay for improved respiratory and cardiovascular health: A multiple-format, stated-preference approach", *Health Economics*, Vol. 9, pp. 295-317, http://dx.doi.org/10.1002/1099-1050(200006)9:4<295::AID-HEC520>3.0.CO;2-D. [29]

Magat, W., W. Viscusi and J. Huber (1996), "A Reference Lottery Metric for Valuing Health", *Management Science*, Vol. 42/8, http://www.jstor.org/stable/2634447, pp. 1118-1130. [39]

Nastis, S. and T. Crocker (2007), "A note on parental and child risk valuation", *Environmental and Resource Economics*, Vol. 38, pp. 119-134, http://dx.doi.org/10.1007/s10640-006-9060-9. [26]

Navrud, S. (2017), "Possibilities and challenges in transfer and generalisation of monetary estimates for environmental and health benefits of regulating chemicals", *OECD Environment Working Papers*, No. 119, OECD, Paris, http://dx.doi.org/10.1787/95c2b371-en. [14]

NICNAS (2017), *Human Health Tier III assessment for 2-Pyrrolidinone, 1-methyl- - NICNAS*, https://www.nicnas.gov.au/chemical-information/imap-assessments/imap-assessments/tier-iii-human-health/2-pyrrolidinone,-1-methyl- (accessed on 27 July 2017). [10]

OECD (2012), *Mortality Risk Valuation in Environment, Health and Transport Policies*, OECD Publishing, Paris, http://dx.doi.org/10.1787/10.1787/9789264130807-en. [31]

OECD (2010), *Valuation of Environment-Related Health Risks for Children*, OECD Publishing, Paris, http://dx.doi.org/10.1787/9789264038042-en. [27]

OECD (2007), *1-methyl-2-pyrrolidone, SIDS Initial Assessment Report for SIAM 24*, OECD, Paris, http://webnet.oecd.org/hpv/ui/handler.axd?id=84daa4ac-feb7-4b5a-9839-206d17914e42. [7]

Priez, F. and C. Jeanrenaud (1999), "Human Costs of Chronic Bronchitis in Switzerland", *Swiss Journal of Economics and Statistics*, Vol. 135/3, pp. 287-301. [32]

Ready, R. et al. (2004), "Benefit transfer in Europe: How reliable are transfers between countries?", *Environmental and Resource Economics*, Vol. 29, pp. 67-82, [28]

http://dx.doi.org/10.1023/B:EARE.0000035441.37039.8a.

Ščasný, M. and I. Zvěřinová (2014), *Stated-preference study to examine the economic value of benefits of avoiding selected adverse human health outcomes due to exposure to chemicals in the European Union*, Charles University in Prague, Prague, https://echa.europa.eu/documents/10162/13630/study_economic_benefits_avoiding_adverse_health_outcomes_2_en.pdf. [25]

Schmitt, S., L. Sneed and C. Phibbs (2005), "Costs of Newborn Care in California: A Population-Based Study", *Pediatrics*, Vol. 117/1, pp. 154-160, http://dx.doi.org/10.1542/peds.2005-0484. [22]

Sørensen, M. et al. (2016), *Valuation Literature on Chemicals: A Description of an Inventory of Valuation Literature on Chemicals*, Nordic Council of Ministers, Copenhagen, http://dx.doi.org/10.6027/NA2017-903. [17]

US EPA (2017), *Economic Analysis of Proposed TSCA Section 6 Action on Methylene Chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal*, US Environment Protection Agency, Washington, DC, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0270. [18]

US EPA (2017), *Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)*, Federal Register, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0001. [9]

US EPA (2017), *Supplemental Analysis for Paint Remover Section 6 Economic Analysis: Co-Proposal*, US EPA, Washington, DC, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0060. [21]

US EPA (2015), *TSCA Work Plan Chemical Risk Assessment N-Methylpyrrolidone: Paint Stripper Use*, US Environment Protection Agency, Washington, DC, https://www.epa.gov/sites/production/files/2015-11/documents/nmp_ra_3_23_15_final.pdf. [6]

US EPA (2010), *Guidelines for Preparing Economic Analyses, updated May 2014*, US EPA, National Center for Environmental Economics. [23]

US EPA (2007), *Cost of Illness Handbook*, US EPA, Washington, DC, https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0018. [13]

Viscusi, W., W. Magat and J. Huber (1991), "Pricing Environmental Health Risks: Survey Assessments of Risk-Risk and Risk-Dollar Trade-Offs for Chronic Bronchitis"", *Journal of Environmental Economics and Management*, Vol. 21, pp. 32-51. [40]

Annex 1: Details of Relevant Studies

Table A.1. NMP-related economic and regulatory impact studies

Bibliographic details of study	Focus of study			Methodology	Key Results	Comment	Web links to study
	Stage of life cycle: Production, uses, disposal.	Impacts: Health, environmental, economic (Industry and consumer)	Region or Country				
AMEC (2013[19]) RIVM - NMP Restriction Dossier Appendix A: Market Analysis.	NMP suppliers and a representative sample of key downstream users	Economic (Industry)	EU (includes some global production data)	Purpose of the market analysis was to provide background information to be used to scale up estimated RMO cost data from individual consultees to EU industry level. Market and potential market effects in general	Market data for selected industries. With lower and upper bound figures for number of companies using NMP, number of potentially exposed workers and production value related to NMP production or use.	Market analysis is an appendix to the REACH Annex XV restriction dossier. Some data are deleted in the public version of the report for confidentiality reasons.	n/a
AMEC (2013[20]) RIVM - NMP Restriction Dossier Appendix B: Cost Analysis.	NMP-using industries (non-wire coatings, wire coatings, cleaning products, membranes).N	Economic (Industry)	EU	Analysis of compliance cost and loss of revenue for 3 RMOs using industry data and data from the Market Analysis report (AMEC, 2013[19]).Industry consultation on likely responses to the	15-year PV cost of compliance and loss of revenue to selected='selected='selected'' industries: RMO1 = EUR 24-38 billion; RMO3 (10 mg/m3 limit value) = EUR 24-37 billion; RMO3 (20 mg/m3 limit	Cost analysis is an appendix to the REACH Annex XV restriction dossier.	n/a

	MP suppliers (manufacturers and importers)			RMOs and associated costs form basis of the cost analysis.	value) = EUR 96-180 million; RMO2 = EUR 23-58 million.		
ECHA (2014[2]) Background document to the Opinion on the Annex XV dossier proposing restrictions on 1-methyl-2-pyrrolidone (NMP)	NMP suppliers NMP-using industries	Economic (Industry)	EU	Analysis of costs (compliance and administrative) and wider socio-economic impacts (which includes employment effects and supply chain effects) for 4 RMOs	For each RMO estimates are given of potential costs and wider socio-economic effects (compliance cost and relocation cost estimates given as 15 year PV, turnover potentially affected given as annual figure). Qualitative assessment of human health benefits.	Uses quantitative estimates of economic impacts from market and cost analysis (AMEC, 2013[19]) and (AMEC, 2013[20]). Some data are deleted for confidentiality reasons. No quantitative human health impact assessment due to insufficient available data to quantify the potential effects.	
US EPA (2017[18]) Economic Analysis of Proposed TSCA Section 6 Action on methylene chloride and N-Methylpyrrolidone (NMP) in Paint and Coating Removal (RIN 2070-AK07)	Production and use (Paint and Coating Removal)	Economic (industry and consumer), health.	United States	Net benefits of 3 regulatory options were estimated based on incremental costs for industry and consumers and the monetised values for increased cancer risk of using alternatives, and potential benefits of avoided cases of LBW and pregnancy losses (using break even analyses).	Potential benefits of avoided cases of LBW and pregnancy losses unlikely to exceed costs.	Estimates of health benefits limited in terms of dose response data availability and coverage of range of potential health impacts.	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0270
US EPA (2017[9]), Methylene chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a)	Production and use (Paint and Coating Removal)	Economic (industry and consumer), health.	United States	As for US EPA (2017[18]) with updates from supplemental analyses.	Total costs of first option estimated as $2,763,000 to USD 51 070 000 annualised over 20 years at 3% and USD 3 361 000 to USD 51 163,000 annualised over 20 years at 7%. Total costs of second option estimated as USD 114 196 000 to	Results quoted include supplemental economic analysis to the US EPA (2017[18]) study. This is additional costs and benefits for the second proposed option for NMP in paint and coating removal by commercial	https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0231-0001

		USD 124 893 000 annualised over 20 years at 3% and USD 114 658 000 to USD 125 438 000 annualised over 20 years at 7%.	and consumer users in (US EPA, 2017[21]).