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**32<sup>ND</sup> MEETING OF THE COMMITTEE FOR SOCIO-ECONOMIC ANALYSIS**

**6-15 SEPTEMBER 2016**

**HELSINKI, FINLAND**

<b>Concerns:</b>	<b>Willingness-to-pay values for various health endpoints associated with chemicals exposure</b>
<b>Agenda Point:</b>	<b>6.1.c</b>
<b>Action requested:</b>	<b>For agreement</b>

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<sup>†</sup> This version supersedes an earlier version in which an editorial error occurred in the description of external and internal birth defects.

## REFERENCE WILLINGNESS-TO-PAY VALUES FOR MONETISING CHEMICALS HEALTH IMPACTS

### 1. Background

Reducing the negative health impacts of hazardous substances is a primary objective of the REACH legislation. Having ways to quantify the benefits of controlling the use of such substances is crucial to ensuring that this key objective is met at the same time as another objective—the effective functioning of the EU internal market. Monetary valuation of health impacts is undertaken using willingness-to-pay (WTP) values to assess the economic value of preventing specific health endpoints (intangible costs) and opportunity costing to account for the resources spent on medical treatment and health care (treatment costs) as well as for productivity losses and other non-healthcare related costs associated with specific health endpoints.

In 2012, ECHA commissioned an academic consortium to conduct a two-year, four-Member State research study to estimate WTP values for a range of health endpoints commonly associated with exposure to hazardous substances. In particular, the following health impacts were valued:

- Skin sensitisation and dose toxicity affecting the kidney (ECHA 2014a);
- Fertility and developmental toxicity (ECHA 2014b); and
- Carcinogenicity (ECHA 2014c).

The study findings are documented in three extensive reports and the WTP values derived from the study have been presented in an expert workshop organised by ECHA and critically discussed in a summary report published by ECHA (2016).<sup>1</sup> Readers are referred to these background documents for a more detailed description of the context in which the WTP values were elicited.

### 2. Purpose

The purpose of this note is to establish a set of reference values based on the results of the ECHA study (and the discussions thereof in the summary report) for assessing the intangible costs of impaired health as part of the socio-economic analysis (SEA) in applications for authorisations or restriction dossiers. The reference values will allow the consistent monetisation of health impacts across applications and restriction dossiers. It is, however, not the objective of this note to explain how the reference values should be used in applied SEA. For guidance on the actual conduct of health impact assessments under REACH the reader is referred to the relevant SEA guidance documents.<sup>2</sup>

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<sup>1</sup> The workshop took place on 11-12 January 2016 at ECHA's premises, for details see: [https://echa.europa.eu/news-and-events/events/event-details/-/journal\\_content/56\\_INSTANCE\\_DR2i/title/expert-workshop-on-valuing-the-health-impacts-of-chemicals](https://echa.europa.eu/news-and-events/events/event-details/-/journal_content/56_INSTANCE_DR2i/title/expert-workshop-on-valuing-the-health-impacts-of-chemicals).

<sup>2</sup> See the guidance documents on preparing SEA as part of applications for authorisation: [https://echa.europa.eu/documents/10162/13637/sea\\_authorisations\\_en.pdf](https://echa.europa.eu/documents/10162/13637/sea_authorisations_en.pdf); and restrictions: [https://echa.europa.eu/documents/10162/13641/sea\\_restrictions\\_en.pdf](https://echa.europa.eu/documents/10162/13641/sea_restrictions_en.pdf).

### 3. Reference values

The appendix to this note lists the WTP values (in 2012 €) for various health outcomes as derived by the ECHA study (2014 a, b, c) and the critical summary report (ECHA 2016). When applied, the values therefore need to be inflation-adjusted. Interpretation of these values is supported by the following contextual information, details of which can be found in the ECHA study reports and the summary report.

**Cancer.** WTP to prevent cancer diseases were elicited from an adult population sample (central age: 52 years, range: 45-60 years) of the Czech Republic (n=1,222), Italy (n=685), the Netherlands (n=779) and the United Kingdom (n=721) using a binary discrete choice approach. Data collection took place from March to April 2014 through internet surveys in the respective language. The health endpoint of concern was defined as follows.

#### Generic form of cancer:

<i>Incidence rate</i>	<ul style="list-style-type: none"><li>• Probability of developing cancer within the next 5 years; baseline risk communicated was 25 in 1,000; reductions ranged from 0 to 5 in 1,000</li></ul>
<i>5-year survival rate</i>	<ul style="list-style-type: none"><li>• Probability to survive over the next 5 years if one develops cancer; baseline risk communicated was 60%; reductions ranged from 0 to 20%</li></ul>
<i>Effects of cancer on everyday activities</i>	<ul style="list-style-type: none"><li>• Activities were described as ranging from fully active to confined to bed half of the time</li></ul>
<i>Pain associated with cancer</i>	<ul style="list-style-type: none"><li>• Pain was described as ranging from mild to moderate</li></ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"><li>• Usual activities – slight or severe problems may occur with usual activities, such as working, studying, doing housework, taking care of children, performing leisure activities, doing sports, preparing meals, shopping, and bathing and getting dressed ("self-care").</li><li>• Impossibility to practice self-care – In extreme cases, one may be completely disabled and thus unable to do any of the usual activities – not even bathing and getting dressed, or walking for short distances. Some other people have reported virtually no disruption of usual activities. Others had to restrict daily activities only for a limited period of time, such as when they were undergoing treatment or recuperating from surgery.</li><li>• Inability to take care of children, elderly parents or other dependents.</li><li>• In some cases, cancer can lead to anxiety and depression.</li><li>• Some cancers can be very painful; others, less so. Treatment may be painful as well. Pain medication is usually given to help manage pain.</li><li>• Treatment may be uncomfortable, cause nausea, dizziness and weakness.</li><li>• Some people who have cancer feel that their illness makes them socially isolated (cancer can restrict social life, disrupt interactions with family and friends).</li><li>• Cancer may force people to miss work because of treatment, recovery time and illness to the point that one may no longer be able to keep the job.</li><li>• Even if cancer was treated or removed, one may worry all the time about the possibility of it coming back after treatment.</li></ul>

**Infertility and developmental outcomes.** The couple's WTP to prevent various forms of birth defects (incl. low birth weight) and infertility problems were elicited from an adult population sample (age range: 18-65 years, oversampling of respondents of childbearing age) of respondents from the Czech Republic (n=1,380), Italy (n=1,236), the Netherlands (n=645) and the United Kingdom (n=727) using seven discrete choice protocols with both multinomial and binary choices. Data collection took place from February to June 2014 through internet surveys in the respective language. Respondents were either offered a 'private good' in the form of a hypothetical vitamin complex which would, at a given cost, increase the probability of conception or reduce the risk of developmental outcomes; or they were offered a 'public good' in the form of a set of stricter regulations on chemicals in products which would result in similar improvements in the respective health condition,

but across the whole EU population and in the form of a price increase in certain products. The proposed reference WTP values include results from both the public and private good scenario. The health endpoints valued were described as follows.

#### Conception problems/infertility:

<i>Probability of conception</i>	<ul style="list-style-type: none"> <li>• Decreases with age</li> <li>• Increases with the time a couple have been trying to conceive</li> <li>• Increases with frequency of sexual intercourse</li> <li>• Partly determined by lifestyle and other factors</li> </ul>
<i>Infertility</i>	<ul style="list-style-type: none"> <li>• Failure to conceive after <math>\geq 12</math> months of regular unprotected sex</li> <li>• Problem can be due to the female or the male partner</li> </ul>
<i>Treatment</i>	<ul style="list-style-type: none"> <li>• Drug treatments that alter levels of reproductive hormones</li> <li>• Medical procedures involving the manipulation of sperm, eggs and embryos, such as in vitro fertilization (IVF)</li> </ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"> <li>• Impact on the sexual life of the couple (planning of intercourse)</li> <li>• Sexual dysfunction, depression, anxiety</li> </ul>

#### Minor birth defects:

<i>Description</i>	<ul style="list-style-type: none"> <li>• Abnormal structure of an otherwise healthy part of the body</li> <li>• Most frequent in areas of complex body parts (face and limbs)</li> <li>• Examples: abnormally decreased/ increased distance between eyes, low-set ears, fingers fused together, accumulation of fluid in a body cavity, hole located on the lower back, third nipple</li> </ul>
<i>Number of cases</i>	<ul style="list-style-type: none"> <li>• 139 per 1,000 births in Europe</li> </ul>
<i>Treatment</i>	<ul style="list-style-type: none"> <li>• Most of the defects can be easily removed and/or treated</li> </ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"> <li>• No permanent consequence for normal life expectancy</li> <li>• Minimal functional or cosmetic significance</li> </ul>

#### External birth defects:

<i>Description</i>	<ul style="list-style-type: none"> <li>• Defects of the skull, face, hands and feet</li> <li>• Examples: limb defects (limb reduction; complete absence of a limb; club foot – foot is twisted at the ankle); conjoined twins; cleft lip or/ and palate; small eye, absence of one or both eyes</li> </ul>
<i>Number of cases</i>	<ul style="list-style-type: none"> <li>• 6 per 1,000 births in Europe</li> </ul>
<i>Treatment</i>	<ul style="list-style-type: none"> <li>• Can be surgically repaired to some extent</li> </ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"> <li>• Hospitalisation, surgery</li> <li>• Lower satisfaction with facial and body appearance</li> <li>• Depression, anxiety, behavioural problems</li> </ul>

#### Internal birth defects:

<i>Description</i>	<ul style="list-style-type: none"> <li>• Defects that affect body organs and systems: heart, nervous, respiratory, digestive and urinary systems and genitals</li> <li>• Metabolism failure (problems with accumulation of substances or reduced ability to synthesize essential compounds)</li> <li>• Blood diseases and genetic diseases (e.g. cystic fibrosis – thick, sticky mucus in the lungs and other areas of the body; haemophilia – impaired ability to stop bleeding)</li> </ul>
<i>Number of cases</i>	<ul style="list-style-type: none"> <li>• 15 per 1,000 births in Europe</li> </ul>
<i>Treatment</i>	<ul style="list-style-type: none"> <li>• Surgery transplantation in case the defect cannot be repaired; sometimes other medical treatment is available: diet, medication, enzyme replacement therapy, gene therapy (use of DNA as an agent to treat disease)</li> </ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"> <li>• May result in long-term disability or even premature death</li> <li>• Hospitalisation, long-term treatment, surgery and on-going care</li> <li>• Lifelong monitoring, an increased risk of other health problems, especially serious infections</li> <li>• Exercise restrictions, poor adjustment to demands of daily living</li> <li>• Psychological and social problems</li> </ul>

Very low birth weight:

	Neurosensory problems	Behavioural and social competence problems	Intellectual and learning disabilities
Description	<ul style="list-style-type: none"> <li>• Cerebral palsy (motor conditions that cause physical disability)</li> <li>• Hydrocephalus (fluid collecting in the brain), blindness or deafness, and epilepsy (neurological disorder characterized by seizures of different types from inattentive staring to unconsciousness)</li> </ul>	<ul style="list-style-type: none"> <li>• Behavioural problems</li> <li>• Hyperactivity and attentional weaknesses</li> <li>• Disruptive behaviour</li> <li>• Impulsivity</li> </ul>	<ul style="list-style-type: none"> <li>• Sub average intellectual functioning (IQ &lt; 70)</li> <li>• Poorer language abilities</li> <li>• Poorer memory, motor coordination and problem solving abilities</li> <li>• Learning problems, low achievements in reading, spelling and maths</li> </ul>
Share of children that have these health problems	<ul style="list-style-type: none"> <li>• 10% for very low birth weight vs Less than 1% for normal birth weight</li> </ul>	<ul style="list-style-type: none"> <li>• 16% for very low birth weight vs 7% for normal weight</li> </ul>	<ul style="list-style-type: none"> <li>• Subnormal intelligence (IQ &lt;70): 7% for very low birth weight vs 2% for normal birth weight</li> <li>• School problems: 34% for very low birth weight vs 14% for normal birth weight</li> </ul>
Treatment	<ul style="list-style-type: none"> <li>• Not curable – only improvement possible</li> <li>• Rehabilitation –physical therapy</li> <li>• Remediation of impairments and disabilities, medicines, orthopaedic surgery, pain management</li> </ul>	<ul style="list-style-type: none"> <li>• Not curable - only improvement possible</li> <li>• Medication, diet, psychotherapy, education or training to reduce negative impacts on life</li> </ul>	<ul style="list-style-type: none"> <li>• Special education assistance and help</li> </ul>
Quality of life impact	<ul style="list-style-type: none"> <li>• More impaired self-reported health and functional status</li> <li>• Usage of more medications, feeding tubes</li> <li>• Respiratory problems, disorder of motor functions</li> <li>• Need of assistance</li> </ul>	<ul style="list-style-type: none"> <li>• Social problems, difficulty organizing tasks and activities</li> <li>• Antisocial behaviour</li> <li>• Special educational needs</li> <li>• Diminished school performance, reduction in vocational achievement</li> </ul>	<ul style="list-style-type: none"> <li>• Impairments in life skills</li> <li>• Communication, self-care, home living, social or interpersonal skills</li> <li>• School problems - grade repetition or placement in special education programs</li> </ul>

**Dermatitis.** WTP to prevent two forms of dermatitis from occurring were elicited from an adult population sample (central age: 42 years, range: 18-65 years) of the Czech Republic (n=904), Italy (n=1,024), the Netherlands (n=700) and the United Kingdom (n=1,006) using a matching method (by applying contingent valuation with a two way payment ladder). Data collection took place from October 2013 to February 2014 through internet surveys in the respective language. The health endpoints valued were described as follows.

Mild acute dermatitis (single and repeated episodes):

Symptoms	<ul style="list-style-type: none"> <li>• Itchy, burning skin</li> <li>• Red rashes, small blisters</li> <li>• Blisters burst open, forming scabs and scales</li> </ul>
Area	<ul style="list-style-type: none"> <li>• Less than 10% of the body</li> </ul>
Duration	<ul style="list-style-type: none"> <li>• Two weeks</li> </ul>
Frequency	<ul style="list-style-type: none"> <li>• Once</li> </ul>
Treatment	<ul style="list-style-type: none"> <li>• Application of skin creams frequently throughout the day</li> <li>• Treatment with antihistamines and local corticosteroids</li> </ul>
Quality of life impact	<ul style="list-style-type: none"> <li>• Skin soreness from scratching</li> <li>• Sleep disturbance</li> <li>• Possible medicinal side effects such as drowsiness</li> </ul>

#### Severe chronic dermatitis:

<i>Symptoms</i>	<ul style="list-style-type: none"><li>• As for mild, acute dermatitis</li><li>• Massive swelling, skin lesions, scabs and scales during flare-ups</li></ul>
<i>Area</i>	<ul style="list-style-type: none"><li>• Less than 10% of the body</li><li>• Over 10% of the body during flare-ups</li></ul>
<i>Duration</i>	<ul style="list-style-type: none"><li>• Permanently</li></ul>
<i>Frequency</i>	<ul style="list-style-type: none"><li>• Flare-ups approximately twice per year</li></ul>
<i>Treatment</i>	<ul style="list-style-type: none"><li>• Daily application of skin creams, treatment with antihistamines and local corticosteroids</li><li>• Hospitalisation for one week during flare-up and treatment with phototherapy and oral or injectable corticosteroids</li></ul>
<i>Quality of life impact</i>	<ul style="list-style-type: none"><li>• As for mild, acute dermatitis, plus</li><li>• Inability to work in certain types of occupation during flare-ups</li><li>• Unpleasant and unsightly appearance</li><li>• Limits on leisure activities</li></ul>

SEAC notes that the valuation of some of the above health endpoints, particularly those related to reprotoxicity (2014b), is novel and it is therefore difficult to assess the validity of the respective WTP values. As far as these health endpoints concern an unborn child, they affect not only the respondent but also his or her partner.<sup>3</sup> It is important to note that the corresponding WTP value is that of a couple and should be counted only once per planned but unconceived child. That is, in order to value one infertility case, the value per statistical pregnancy should be multiplied by the average number of children per parent.

More generally, SEAC acknowledges the difficulties in trying to elicit WTP values for health endpoints associated with exposure to chemical substances and stresses that care is needed with the exact interpretation and use of the proposed reference values. Nonetheless, SEAC finds that for the purpose of conducting SEA under REACH the proposed reference values are the best ones available at the moment. They should therefore be taken as a starting point in the monetisation of health impacts.<sup>4</sup>

The existence of reference values does not preclude the use of other values. However, applicants or submitters of restriction proposals should then justify why those values are more appropriate and carry out a sensitivity analysis using the reference values. Whilst the WTP values listed in the appendix will serve as reference for SEAC's evaluation of dossiers, the list of health endpoints for which values are available is not exhaustive. In case that WTP values for specific endpoints are missing, either because the endpoint was not valued in the ECHA study or because the values obtained were seen as unreliable, analysts should explain based on which assumptions they valued these health endpoints.

ECHA intends to fill in this gap and to derive (or update) values for relevant endpoints either through the conduct of original WTP studies or through value transfer as appropriate. Further, it is stressed that each of the listed health endpoints will most likely induce treatment, healthcare and other opportunity costs, which are not covered by the respective WTP values. For guidance on the quantification of tangible costs, the reader is referred to the SEA guidance documents and to recent cost-of-illness studies.

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<sup>3</sup> SEAC notes that infertility may result in consequences far beyond those captured by the WTP value for a particular health endpoint such as infertility. Thus, whilst making use of the proposed WTP values for infertility, SEAC will remain aware of this specificity in its assessments of the reprotoxic impacts of chemicals.

<sup>4</sup> Footnote 36 on p. 133 of the *Guidance on the preparation of socio-economic analysis as part of an application for authorisation* states that if an analyst considers "using any of the unit costs [for mortality and morbidity] used in this section [Annex B.1], it is recommended to check if these values have been "superseded" by more recent studies". The set of reference values proposed in this note supports the analyst in doing so.

## References

- ECHA (2016) Valuing selected health impacts of chemicals. Summary of the Results and Critical Review of the ECHA Study. February 2016. Available at:  
[http://echa.europa.eu/documents/10162/13630/echa\\_review\\_wtp\\_en.pdf](http://echa.europa.eu/documents/10162/13630/echa_review_wtp_en.pdf)
- ECHA (2014a) 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 – Part I: Sensitisation and dose toxicity. Available at:  
[http://echa.europa.eu/documents/10162/13630/study\\_economic\\_benefits\\_avoiding\\_adverse\\_health\\_outcomes\\_1\\_en.pdf](http://echa.europa.eu/documents/10162/13630/study_economic_benefits_avoiding_adverse_health_outcomes_1_en.pdf)
- ECHA (2014b) 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 – Part II: Fertility and developmental toxicity. Available at:  
[http://echa.europa.eu/documents/10162/13630/study\\_economic\\_benefits\\_avoiding\\_adverse\\_health\\_outcomes\\_2\\_en.pdf](http://echa.europa.eu/documents/10162/13630/study_economic_benefits_avoiding_adverse_health_outcomes_2_en.pdf)
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[http://echa.europa.eu/documents/10162/13630/study\\_economic\\_benefits\\_avoiding\\_adverse\\_health\\_outcomes\\_3\\_en.pdf](http://echa.europa.eu/documents/10162/13630/study_economic_benefits_avoiding_adverse_health_outcomes_3_en.pdf)

## Appendix

### Reference willingness-to-pay values for various health endpoints associated with exposure to hazardous substances

Health endpoint	Reference value (in 2012 €)
Premature death <sup>a</sup>	€3,500,000 (lower value) €5,000,000 (higher value)
Cancer morbidity (generic) <sup>b</sup>	€410,000 (central value)
Statistical pregnancy <sup>c</sup>	€22,000/case (lower value) €41,000/case (higher value)
Very low birth weight	€126,000/case (lower value) €405,000/case (higher value)
Minor birth defect	€4,300/case (lower value) €43,000/case (higher value)
External birth defect	€26,000/case (lower value) €330,000/case (higher value)
Internal birth defect	€128,000/case (lower value) €712,000/case (higher value)
Mild, acute dermatitis (two weeks)	€250/case (central value)
Severe, chronic dermatitis (periodic flare ups)	€2,000/year (lower value) €12,000/year (higher value)

*Table notes:*

<sup>a</sup> This value represents the marginal trade-off between survival probability and income (also known as "Value of Statistical Life" or "Value of a Prevented Fatality") elicited in the context of cancer, see ECHA (2014c) and Section 4 of ECHA (2016) for details;

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

<sup>c</sup> This value reflects the WTP of couples with infertility problems to conceive, see ECHA (2014b) and Section 3 of ECHA (2016) for a detailed discussion.