Study on the Calculation of the Benefits of Chemical Legislation on Human Health and the Environment

Pre-Workshop Background Paper

prepared for

The Expert Workshop

3 November 2015, Brussels

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Disclaimer

The views and propositions expressed herein are, unless otherwise stated, those of Risk & Policy Analysts and do not necessarily represent any official view of DG Environment or any other organisation mentioned in this report.

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1 Introduction

From the Technical Specifications, the main objective for the study is as follows:

> "*The overarching objective of the study will be to assess the beneficial impact of EU legislation and policies specific to the EU chemical sector related to both the environment and human health, through the definition of a set of indicators.*

In order to accomplish this main objective, the study has to provide four sets of outputs:

i. Propose candidates for a set of indicators. A precondition for the indicators is to a) establish and measure the causal link between chemical substances and their effects on the environment and/or human health and/or b) establish and measure the causal link between chemicals legislation and the reduced effects on the environment and/or human health ;

ii. Among the proposed indicators, the contractor will identify a selection of key indicators;

iii. For the key indicators, the contractor will provide data (preference should be given to the period 2004-2013, but historical data and where possible projections on future developments must also be considered);

iv. Propose a way to update and improve the set of key indicators".

The work to be carried out under the study started with a review of the existing literature and the availability of data; a quantitative assessment of the human health and environmental benefits of EU chemicals legislation based on the identified set of indicators (with preference to the period 2004-2013, but also giving consideration to historical data and where possible projection of trends on future developments); and a methodology for the systematic update and improvement of the key indicators.

The starting point for an assessment of the benefits of chemicals legislation has to be the objectives of the legislation itself, in terms of minimising or reducing exposure to chemical hazards, followed by an understanding of the properties of chemicals that give rise to human health and environmental impacts. The REACH Regulation and the Classification, Labelling and Packaging Regulation (CLP) are the recognised cornerstones of the chemicals acquis and it was agreed during the kick-off meeting that the study would focus on these Regulations. However, benefits are often delivered through synergies with other legislative acts, such as Occupational Health and Safety legislation (e.g. the Chemical Agents Directive, the Carcinogens and Mutagens Directive), the Plant Protection Products Regulation, the Biocidal Products Regulation, the Water Framework Directive, etc.

Thus, although the focus of the study is on REACH and CLP, due to the inter-linkages highlighted above and an inability to separate out the impacts of REACH and CLP vis a vis this other legislation, it was subsequently agreed that the indicators would have to reflect the legislative framework more broadly (see also Section 2.2 below).

2 Methodology

2.1 Literature Review and Screening of Information Sources

The project team reviewed reports and articles that were themselves aimed at developing indicators and/or which represented studies or research aimed at quantifying and monetising the benefits of regulating hazardous chemicals. The results of this exercise are a long list of potential indicators and the identification of databases and sources of values for feeding into their quantification and monetisation. Most importantly, the literature review gave the project team the opportunity to review the multiple different methodologies followed in the past due to the paucity of data.

Two main approaches can be identified from the literature review:

- A "holistic approach", where studies tried to quantify the total benefits of introducing a regulation, e.g. the REACH Regulation, based on assumptions as to the proportion of all impacts due to chemical exposures and that would be reduced by chemicals legislation.

- A "case-study approach", where most of the studies focused on specific chemicals or disease groups for which data are available in order to estimate a subset of the benefits accruing from the legislative framework and to stress the importance of the legislative interventions on certain substances of high concern.

In parallel to the review of the literature, the project team screened several national and pan-European databases in order to identify those that could be used for feeding information into the system of indicators to be developed. Databases that provide data and information on a range of factors were identified, such as:

- emissions of environmental pollutants;
- concentrations of harmful chemicals in the environment;
- uses and levels of production of identified harmful chemicals;
- bio-monitoring data on human and animal tissues; and
- health statistics at global, European and national level.

In screening the information sources, the project team considered the frequency with which the databases are updated, the temporal extent of the database (i.e. the number of years for which data is available), the spatial extent of the database (i.e. whether the data has been georeferenced at a local, regional or national level) and, the extent to which the data and methodologies presented in these sources are relevant and useful to monitoring the benefits of EU chemicals legislation.

Following the literature review work, a brainstorming workshop was held to gain the views of the Commission services' on what the most important criteria are for the selection of indicators. The discussions at the workshop confirmed the importance of ensuring that there is an understanding of how the indicators are related to the different provisions within chemicals legislation. It also suggested that it may be important for the study to recommend exposure/emission based indicators regardless of whether they can or cannot be valued in monetary terms.

2.2 Development of a System of Indicators

Indicators provide evidence that certain results and intended impacts have or have not been achieved. The European Commission's Better Regulation Guidelines (2015) state that for monitoring and evaluation purposes, indicators should refer to the objectives of an "initiative", i.e. a piece of legislation and, they should allow one to measure to what extent those objectives have been achieved. In this respect, they may reflect the achievement of the general objectives of the legislation in terms of its impacts overall (i.e. a high level of protection of human health or the environment), or of the outcomes or observed results of the legislation (i.e. increased risk management and reduction in chemical exposures), or of the outputs associated with specific objectives (i.e. the establishment of a classification and labelling inventory or the restriction of certain SVHCs).

Table 2-1 provides further examples of how these different types of indicators can be linked to the REACH Regulation. For the purposes of this study, all three of these types of indicators are considered relevant. Each type of indicator has a role to play in establishing the benefits, and in combination provide clear links between the actions required by legislation and benefits. Monetisation of benefits will be linked to result and impact indicators, but further details on outputs may help in providing context or the basis for extrapolation and aggregation of benefits from case studies to the broader regulatory context.

Table 2-1: Type of indicators

Type of indicators	Definition	What do they achieve?	Examples
Output indicators	*Relate to the deliverables that the programme is expected to produce*	To measure the specific actions of the legislative mechanisms	No. of substances registered
Result indicators	*Represent the immediate effects of the programme on the direct addressees or recipients*		Level of selected chemicals in human tissues in the EU population
Impact indicators	*Represent the consequences of the programme beyond its direct interaction with the recipients.*	To measure the ultimate effects of legislation	Change in health or environmental outcomes due to the implementation of chemicals legislation

2.3 Towards the Development of Key Indicators

The process of developing, linking and testing different indicators in order to establish measurable links between legislative provisions and benefits is complex but essentially draws on combining two different approaches:

- **Top down approach:** working from specific legislative provisions, identifying suitable indicator datasets that measure the outputs and results of the legislation and then identifying the further information needed to provide a means of calculating impacts in terms of human health and environmental damages avoided; and

- **Bottom up approach:** working from monitoring and other indicator datasets that measure chemicals related impacts (such as rates of diseases, emissions, concentrations in the environment, etc.) to develop a means of calculating the extent to which any observed changes in these impacts can be attributed to the results or outputs associated with legislative provisions.

3 The Key Indicators

3.1 Overview

A system of indicators needs to be able to measure the changes that occur at multiple levels, e.g.:

- Volume of chemicals used, type of use (but also technology, economic factors (e.g. demand), macro factors, etc.);
- Population at risk – e.g. Number of workers, population exposed to diffuse sources;
- Use conditions – Risk Management Measures, technology, working practices (e.g. shift durations);
- Exposures – Baseline, increment, durations;
- Health responses – Changes in cancer risk, changes in disease incidence, etc.;
- Physical impacts – Morbidity, mortality risk, capabilities (ability to work etc.), health service treatments; impacts on environmental quality, yields, reproduction rates, etc.
- Economic impacts – value of illness, risk, lost productivity/lost output, treatment costs, etc.

3.2 Output Indicators

Aim and changes over the period of interest

As indicated above, output indicators are aimed at measuring performance in relation to specific actions of the legislative mechanisms. In order to identify relevant output indicators, the project team looked at the operational objectives of REACH and CLP and how these interact with other legislation. In the simplest terms, EU legislative provisions on chemicals, as a whole, are aimed:

- Identification of substances with hazardous properties; and
- Ensuring that appropriate risk management measures are introduced to reduce exposure of humans and environmental receptors to hazardous substances (either in general or for specific [named] substances (even through substitution).

The combined effect of this 'identify and manage' approach is (intended to be) a reduction in human health and environmental damages from exposure to chemicals, or, more precisely, from exposures at levels sufficient to cause damages.

Over the period of interest for the study (2004 to 2009), the introduction of REACH and CLP are expected to have created human health and environmental benefits through the following outputs:

- An increase in the numbers of substances that are classified for different hazardous endpoints and are, therefore, subject to parallel OSH and environmental regulation – this includes changes in the number of substances that hold Harmonised classifications at the EU level;
- An increase in the numbers of substances for which there is sufficient information to generate a PNEC/DNELs, which can be used for other legislative purposes;
- An increase in the numbers of substances for which a quantitative assessment of risk has been undertaken;

- Through CSAs/CSRs and extended safety data sheets, improvements in the identification and communication of required RMMs for uses of a substance;
- Through voluntary withdrawal of substances from use, registrants no longer supporting certain uses, and withdrawal/substitution due to REACH Restrictions or Authorisation; and
- Through the above, a decrease in the number of substances used in circumstances where human health and/or environmental risks cannot be adequately controlled.

Proposed indicators

Owing to a lack of pre-CLP classification and pre-REACH data on uses and risk management measures in place, it is not possible to develop indicators for all of these. However, it is possible to establish output indicators related to substance classification, Restrictions and Authorisation. Table 3-1 presents the output indicators that are currently being investigated and are proposed as "key indicators" for the purposes of this study.

Table 3-1: Proposed output indicators
1. No. of substances with a harmonised classification – No. of substances with a harmonised classification as "acute toxicity, oral" – No. of substances with a harmonised classification as "aspiration hazard" – No. of substances with a harmonised classification as "acute toxicity, dermal" – No. of substances with a harmonised classification as "skin corrosion/irritation" – No. of substances with a harmonised classification as "sensitisation, skin" – No. of substances with a harmonised classification as "eye damage/eye irritation" – No. of substances with a harmonised classification as "acute toxicity, inhalation" – No. of substances with a harmonised classification as "sensitisation, respiratory" – No. of substances with a harmonised classification as "specific target organ toxicity - single exposure" – No. of substances with a harmonised classification as "specific target organ toxicity - repeated exposure" – No. of substances with a harmonised classification as "germ cell mutagenicity" – No. of substances with a harmonised classification as "carcinogenicity" – No. of substances with a harmonised classification as "reproductive toxicity" – No. of substances with a harmonised classification as "hazardous to the aquatic environment - acute hazard" – No. of substances with a harmonised classification as "hazardous to the aquatic environment - long-term hazard" – No. of substances with a harmonised classification as "hazardous to the ozone layer"
2. Changes No. of substances identified as PBT/vPvB
3. No. of substances with clear evidence of endocrine activity
4. No. of substances restricted on their own, in mixtures or in articles per hazard class
5. No. of SVHCs included in the candidate list for authorisation and in Annex XIV – No. of SVHCs not registered – No. of SVHCs in Annex XIV – No. of SVHCs for which no Application for Authorisation has been made per hazard class – No. of SVHCs for which Applications for Authorisation have been made per hazard class
6. No. of SVHCs with other EU-wide legislative measures (e.g. Biocidal Products Regulation, Plant Protection Products Regulation, Cosmetic Products Regulation, Toy Safety Directive, Environmental Quality Standards Directive, etc.) per hazard class – No. of active substances not approved (Plant Protection Products) – No. of active substances not approved (Biocidal Products)

3.3 Result Indicators

Aims and changes over the period of interest

Result indicators represent the immediate effects of the programme on the direct addressees or recipients. With regard to chemicals legislation, they can therefore be interpreted in terms of changes in chemical exposures:

- In the first instance, the best measure would be changes of exposure to chemicals, as measured by changes in concentrations of chemicals in human and/or animal tissues;
- A related measure would be changes of concentrations of chemicals in environmental media.
- A less reliable indicator would be data on changes in the production of hazardous chemicals or of concentrations of specific chemicals in consumer products.

The first two types of indicators require information on changes in emissions and exposures and hence rely on the availability of monitoring data. With respect to changes in concentrations of chemicals in human (general population) or animal tissues, the main issue is the availability of biomonitoring data that reflect a time series and their comparability. Biomonitoring surveys are resource-intensive and expensive[1], therefore their availability is limited. The longest experience available in Europe is probably the German Environmental Survey (GerES) and the Environmental Specimen Bank (ESB) that have been active since 1985. Data are available for a limited number of chemicals and comparability of data from different laboratories and years is problematic. There are also issues in the interpretation of such data, due to the limited availability of epidemiological data.

There is also the need to link trends to changes in sources of exposure over time, especially for PBT/vPvB substances, for which uses may have been identified pre-REACH and post-REACH but for which there is a poor understanding of their environmental fate. Lastly, differences and changes in dietary habits across the EU can have a higher influence on exposures, than changes in the concentration of specific chemicals in human tissues driven by legislative action.

Although linkages between chemicals legislation and decreases in exposure can be drawn for some chemicals (see Figure 3-1), human biomonitoring data are only available for 200 of the chemicals currently on the EU market. Moreover, EU-wide harmonisation of human biomonitoring (HBM) is still undergoing (Consortium to Perform Human biomonitoring on a European Scale – COPHES/DEMOCOPHES).

Similarly, assessing changes in concentrations of chemicals in environmental media present similar issues. With regard to other surrogates, changes in the production of hazardous chemicals are influenced by large confounding factors (e.g. macroeconomic situation) while data on concentrations of specific chemicals in consumer products refer to limited subsets of both chemicals and products and the datasets are not systematically updated.

[1] the COPHES project, an overall cost of between €3.7 million to €13.7 million per year has been estimated as the minimum and maximum scenario, respectively, for implementing an HBM programme for the 27 EU Member States.

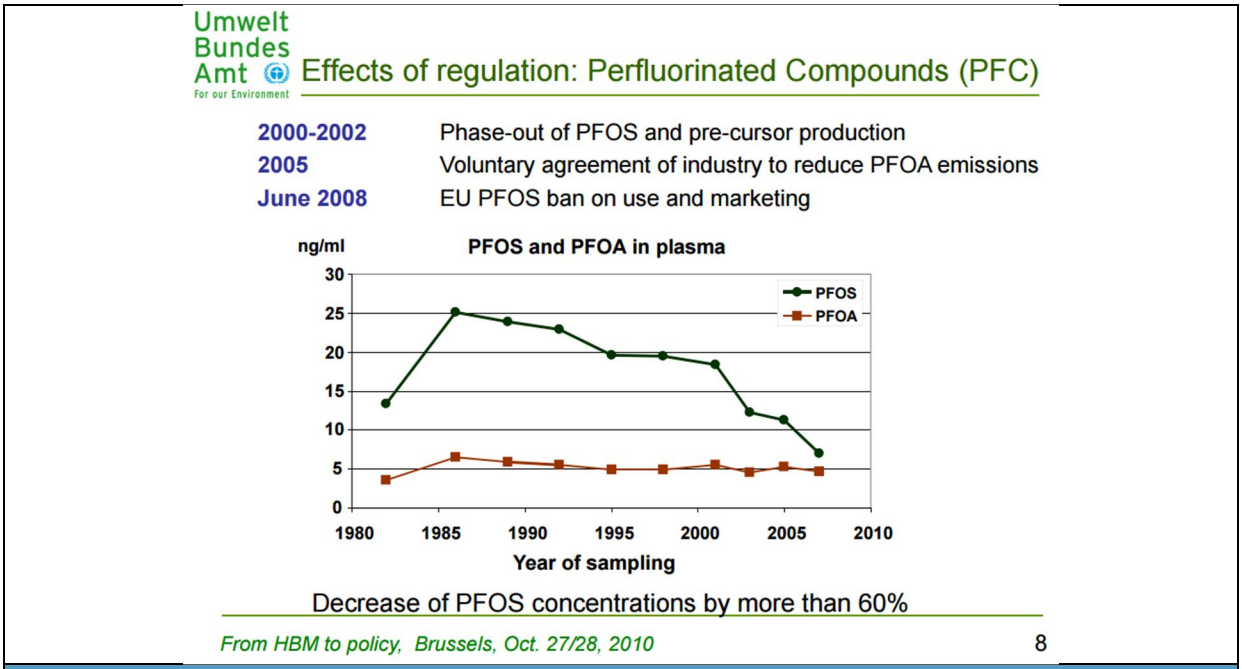

Figure 3-1: Effects of regulation on PFCs – Source: Umwelt Bundes Amt

Proposed indicators

In relation to indicators of change since 2004, there are no human biomonitoring data valid across all of Europe that would provide a complete and continuous picture over time. Some time-limited HBM data are available for mercury, cotinine, cadmium, phthalates and bisphenol A (COPHES/DEMOCOPHES initiatives). These show significant variations across the Member States, highlighting differences in exposure and, consequently, differences in the role that chemicals legislation may play at the national level.

Result indicators can also be defined for specific substances and based on the GerES and ESB experience. Substances for which some retrospective monitoring has been done include: dioxins, furans, dioxin-like PCBs, phthalates, BPA, PFC, flame retardants. Real time monitoring is carried out on heavy metals, persistent organochlorines (DDE, PCB, HCH, HCB), organophosphates, PAHs, PCP and other chlorophenols. Extrapolation to the EU level would rely on the assumption that German HBM data can be representative of the EU situation. Although the use of HBM data to map changes in exposure due to chemicals legislation is limited by their availability, data on current concentrations of chemicals in human bodies can be used for estimating the benefits of regulating those chemicals (see the final DEMOCOPHES report[2]).

With regard to the environment, result indicators can be based on the results of the monitoring programme required by the Water Framework Directive. These have the advantage of being more easily linked to chemicals legislative action, as the classification of substances with respect to environmental hazards is based on aquatic chronic and acute toxicity. In relation to indicators of change since 2004, a comparison of the water chemical status across Europe available from the first and second round (and future rounds) of River Basin Management Plans (RBMPs) could be carried out. An improvement in chemical status in waterbodies across the EU can be valued using WTP

[2] http://www.eu-hbm.info/euresult/media-corner/press-kit

values, thus enabling the estimation of the benefits of chemicals legislation. Unfortunately, the second round of RBMPs is not yet published.

The use of these types of result indicators should recognise other factors may be having a greater influence on environmental parameters than chemicals legislation. It is typically the case that ecosystems are subjected to multiple pressures that may be having a combined detrimental impact, therefore it can be difficult to determine the proportion of the impact that is caused by emissions of chemicals. Accounting for these alternative factors is important where data permit; alternatively the use of assumptions may be required, which will introduce a degree of uncertainty when estimating benefits.

Table 3-2 sets out the proposed set of results indicators for human health and the environment.

Table 3-2: Proposed results indicators (linked to changes in exposures)
1. Level of selected chemicals in human body tissues in the EU population
2. Level of selected chemicals in tissues samples of animal species - Level of selected chemicals in tissues samples of terrestrial species - Level of selected chemicals in tissues samples of aquatic species
3. Level of selected chemicals in environmental media samples - Level of selected chemicals in ambient air samples - Level of selected chemicals in water and sediment samples - Level of selected chemicals in soil samples - Level of selected chemicals in waste sludge samples
4. Emissions of specific chemicals

3.4 Impact Indicators

Aims and changes over the period of interest

The aim of impact indicators is to provide a measure of the consequences of a legislative act beyond its direct interaction with the recipients. Within the context of this study, this has been interpreted as moving from changes in exposures to changes in effects, either in terms of chemicals related diseases or chemicals related impacts on environmental ecosystems and biota.

Scientists have tried to quantify the effects of exposures to chemicals for several decades. In 1981 the Institute of Medicine developed a new methodology to estimate the "attributable fraction" of the environment to causation of illness, where "*attributable fraction"* is intended as *"the percentage of a particular disease category that would be eliminated if environmental risk factors were reduced to their lowest feasible concentrations*". Studies have been undertaken to try and establish the role of chemical exposures as an environmental risk factors (e.g. Murray and Lopez, 1997 and Prüss Üstun, 2011), with this work leading to estimates of the burden of disease attributable to chemical exposures. Knowing the attributable fraction, the disease rate, the population size and the cost per case, it is possible to calculate the attributable costs, where these refer to discounted lifetime expenditures attributable to a particular disease, expressed in terms of health care costs, the costs of rehabilitation and lost productivity, as well as the "human" or intangible costs of illness (i.e. individual's willingness to pay to avoid a disease or a day's illness).

Following such an approach impact indicators can be defined as those that reflect a:

- Change to the chemicals' attributable fraction of disease burden following a decrease in exposures due to chemicals legislation requirements;
- Change in the attributable fraction of environmental damages (ecosystem or species) following a decrease in exposures due to chemicals legislation requirements.

The main issue in defining impact indicators is therefore the availability of suitable datasets to quantify the chemicals' attributable fractions and to assess the effects of chemicals legislation.

Proposed indicators

Table 3-3 sets out the proposed impact indicators for both health and the environment.

Table 3-3: Impact indicators
1. AF/AN per disease group - AF/AN Respiratory infections and chronic respiratory diseases - AF/AN Congenital anomalies - AF/AN Diseases of the blood - AF/AN Cancers - AF/AN Neuropsychiatric and developmental disorders - AF/AN Sense organ diseases - AF/AN Cardiovascular diseases - AF/AN Diabetes mellitus - AF/AN Endocrine diseases - AF/AN Genito-urinary diseases - AF/AN Digestive diseases - AF/AN Skin diseases - AF/AN Poisonings - AF/AN Injuries
2. Change in water chemical status
3. Change in species diversity

For some of these disease groups, attributable fractions have been calculated and statistics on the number of cases attributable to particular causative chemical substances are available (e.g. occupational skin diseases, occupational asthma, occupational cancer). In these cases, assumptions on the changes in chemicals' attributable fractions due to the chemicals legislation need to be made. For the other disease groups, additional assumptions are needed with regard to the chemicals' attributable fractions. It should be noted though that comparable health statistics across Europe are lacking for some of the diseases. Even for cancer statistics, quality and completeness of registry data may vary and the international comparability of cancer incidence data can also be affected by differences in medical training and practice[3].

With regard to the environment, quality and completeness of databases are an issue. There is a tendency for studies to focus on the local (or case study), regional and national scale with fewer studies undertaken at the European scale (particularly in relation to the impact of chemical substances on habitats/ecosystems). Although some datasets are available (e.g. the number of species threatened in the EU according to Red List data and emissions of substances to different media according to the E-PRTR database), at the European level there are difficulties in making direct linkages between chemical substances and the impacts that these have in the context of the environment.

[3] OECD (2014): Health at a Glance: Europe 2014, OECD Publishing, page 40. Available at: http://ec.europa.eu/health/reports/docs/health_glance_2014_en.pdf

In order to overcome these problems and to identify potential impact indicators that could be used to estimate the benefits of chemicals legislation, the approach outlined in Figure 3-2 has been developed. This process can be followed for each health/environmental endpoint identified as being relevant to chemical exposures; data are needed at each stage to enable the valuation of the benefits attributable to chemicals legislation.

The first step within this process is to identify the measure of the impacts of chemicals on the environment. If an appropriate measure can be identified (or a suitable surrogate is available) then the next stage involves identifying suitable datasets at the EU/national level to enable measurement of the baseline situation. If a suitable dataset is available at the EU level to enable measurement of the baseline, then the next stages involve identifying datasets that enable changes over time to be linked to chemicals/chemical properties and to chemicals legislation specifically. If information can be identified at each of these stages then an indicator can be suggested. Following on from this is the identification of values that can be used to monetise the damages caused by exposure to chemicals. If all of this information can be obtained then it is possible to monetise the damages under the baseline (i.e. no legislation) and with the introduction of chemicals legislation, and hence derive the benefits (or damages avoided) resulting from the introduction of chemicals legislation can be estimated.

A review of the available data indicates that it may be possible to provide quantitative data on the following:

- Freshwater organisms and fish: data similar to that used for the marine example given above exist and could be used to develop estimates of the benefits of chemicals legislation, particularly linked to the Water Framework Directive;
- Terrestrial environment: data exists on the number of plant species that are affected by pollution but again there is no information on trends over time. For terrestrial invertebrates, data exist on changes in species over time and on the number of species affected by chemicals pollution; there are difficulties in linking chemicals legislation to these data as several species continue to show declines in populations;
- Secondary effects on predators (mammals and birds): data on the % of species that are considered to be impacted by pollution, although this cannot be tracked over time in terms of changes.

It may only be possible, however, to place a monetary value on the impacts on freshwater organisms at the EU level. A case study approach would have to be applied for the terrestrial environment and to assess any benefits in relation to secondary effects on predators.

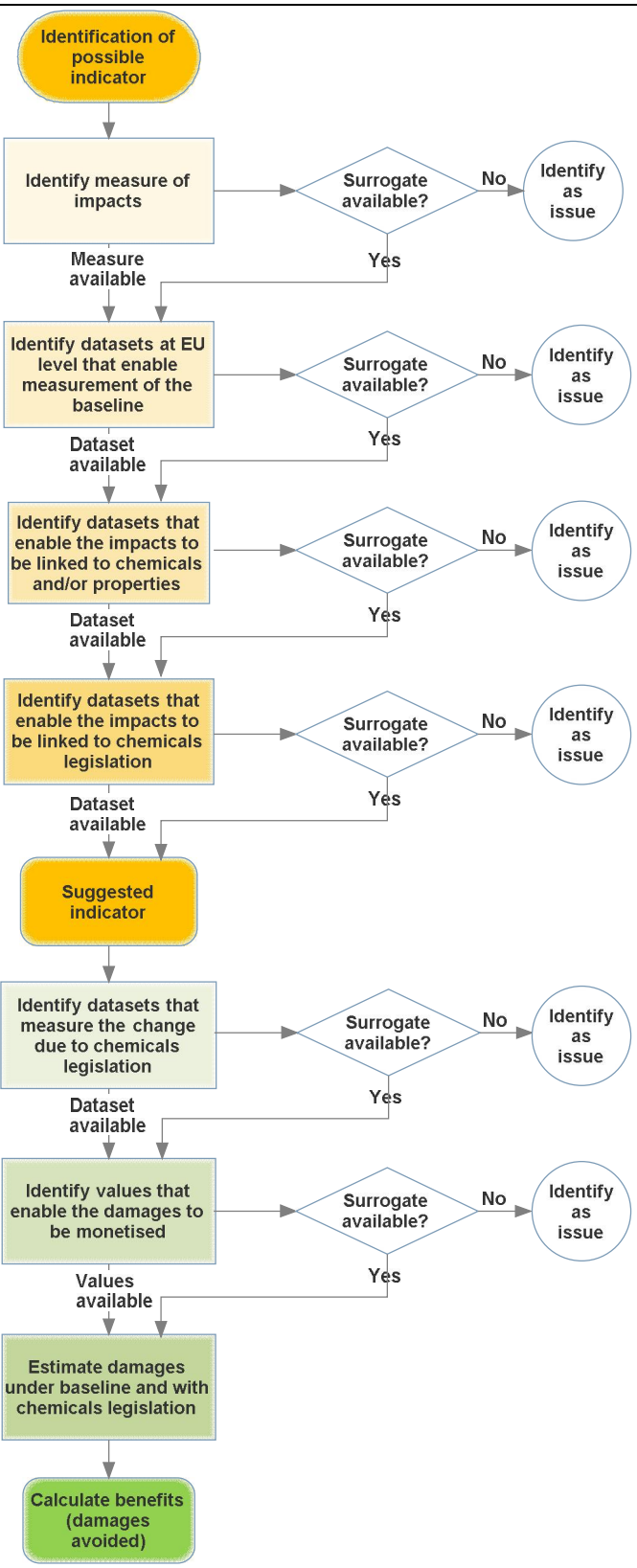

Figure 3-2: Overview of approach used to identify indicators to determine the environmental benefits of chemicals legislation

4 Quantification of the Human Health and Environmental Benefits

4.1 Introduction

This section provides two examples of how we are developing the impact indicators, for consideration by the Workshop. In essence, we are seeking views on the following:

- Are the approaches set out here appropriate?
- Are there alternatives, better approaches?
- Is it appropriate to use these types of approaches to develop estimates of the benefits of all chemicals legislation for the period 2004 to 2013?

4.2 Health example: occupational skin diseases

Skin diseases or skin disorders can be defined as any medical condition affecting the skin. When referring to the worker population, occupational (or work-related) skin diseases "*may be defined as any disorder of the skin which is caused by or made worse by work or workplace activity*"[4].

Table 4-1 presents the substance classifications considered for the skin disease group and that can be used to make the linkage between chemicals legislative initiatives and changes in health impacts.

Table 4-1: Hazard classes and hazard statements classification relevant to skin diseases

Disease group	Hazard class	HS	Hazard statement
Skin diseases	Skin corrosion/irritation 1A, 1B, 1C	H314	Causes severe skin burns and eye damage
	Skin corrosion/irritation 2	H315	Causes skin irritation
	Sensitisation, skin 1, 1A, 1B	H317	May cause an allergic skin reaction

Statistics on the incidence[5] of occupational skin disease are available in Great Britain through the EPIDERM scheme of the Health and Occupation Research Network (THOR), in which dermatologists report new cases. Data are also available through the THOR-GP scheme, where general practitioners (GPs) report the cases for which enough concern triggered a visit to the GP and that were subsequently diagnosed and attributed to work. Information on prevalence[6] is based on the Self-reported Work-related Illness (SWI) annual survey and from assessments for Industrial Injury and Disablement Benefit (IIDB) (HSE, 2014).

According to the HSE, "*EPIDERM provides by far the largest numbers of actual reported cases of skin disease and, though restricted to more severe cases and subject to a degree of underreporting, provides the best basis for more detailed analyses such as by occupational group or causal agent*". With regard to THOR-GP, due to the small sample of GPs participating in the scheme, the overall estimates of the burden of the occupational skin diseases in Great Britain is imprecise.

[4] HSE (2014): Work-related skin disease in Great Britain 2014. Health and Safety Executive. Available at: http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf

[5] Number of new cases occurring each year.

[6] The proportion of the population currently with the disease.

The data on the incidence of occupational skin diseases gathered from the different sources, although varying considerably, are consistent. The IIDB scheme typically identifies only the most severe cases of dermatitis for which a disablement benefit is granted. Statistical analysis of the self-reported occupational skin diseases suggests that there are around 5,000 new cases per year[7], while dermatologists diagnosed around 1,300 new cases in 2013. However, EPIDERM "*inevitably substantially underestimates the true incidence of work-related disease – particularly for those conditions such as contact dermatitis where there may be substantial numbers of less serious cases*" (HSE, 2014). In terms of the prevalence of skin diseases, HSE statistical analysis of the data suggests that there are around 12,000 workers[8] with skin problems caused or made worse by their work.

To estimate the benefits of the avoidance of future cases of skin disease, data on the 'sickness absence days' certified due to occupational skin diseases (around 2% of the total sickness absence days)[9] are also of interest.

The HSE reports statistics on skin disorders by cause for the years 2005 to 2013. In order to deal with cases with more than one causative substance, we calculated the percentage of cases attributed to chemicals, non-chemical factors and unknown causes and applied these to the total number of cases reported. Based on these data, the attributable fraction of occupational skin diseases to chemicals exposure is estimated at 65%.

We then applied the percentage of cases attributed to chemical substances to the total number of individuals with diagnosed skin conditions between 1998 and 2013[10]. As mentioned above, EPIDERM data are likely to underestimate the true incidence of work-related disease. The Self-reported Work-related Illness (SWI) annual survey presents data on incidence and prevalence for the years 2006-2013 in the UK. In order to extrapolate to the EU level, we applied the average rate per 100,000 workers to the EU28 workers population of 217,715,800[11] and multiplied the result for the percentage of cases attributed to chemical substances (65%).

Assuming that the incidence of skin disorders in the EU28 is equal to the incidence in the UK, and that the number of self-reported new cases would follow the same pattern, the number of new self-reported skin conditions in the EU28 in 2013 would be 25,000 (95% C.I.: 15,000-37,000).

In terms of prevalence (the proportion of the population currently with the disease), statistics on the rates of self-reported skin conditions caused or made worse by work for people working in the last 12 months are available for the UK for the period 2005-2012[12]. The average rates per 100,000 workers have been applied to the EU28 workers population and multiplied for the percentage of cases attributed to chemical substances, resulting in around 57,000 workers with occupational skin disorders in the EU28 in 2012. Estimates for incidence (in green) and prevalence (that is the incidence plus the number of cases from the previous years – in red) of occupational skin disorders in the EU28 are presented in Figure 4-1.[13]

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7 95% Confidence Interval: 3000-7000. Source: HSE (2014)

8 95% Confidence interval 9,000 to 15,000. Source: HSE (2014).

9 http://www.hse.gov.uk/statistics/causdis/dermatitis/skin.pdf

10 UK HSE THORS01 statistics. Available at: http://www.hse.gov.uk/Statistics/tables/index.htm

11 Eurostat statistics – Employment – Labour Force Survey (lfsa_emp), year 2013.

12 HSE UK SWIT3W12_3YR provides the averaged 3 year estimates based on overlapping time periods. It has been assumed that the rates presented refer to the central year period. Available at: http://www.hse.gov.uk/Statistics/tables/index.htm

13 *"(…) prevalence includes new and pre-existing cases whereas incidence includes new cases only."* Source: U.S. Centers for Diseases Control and Prevention - Principles of Epidemiology in Public Health Practice,

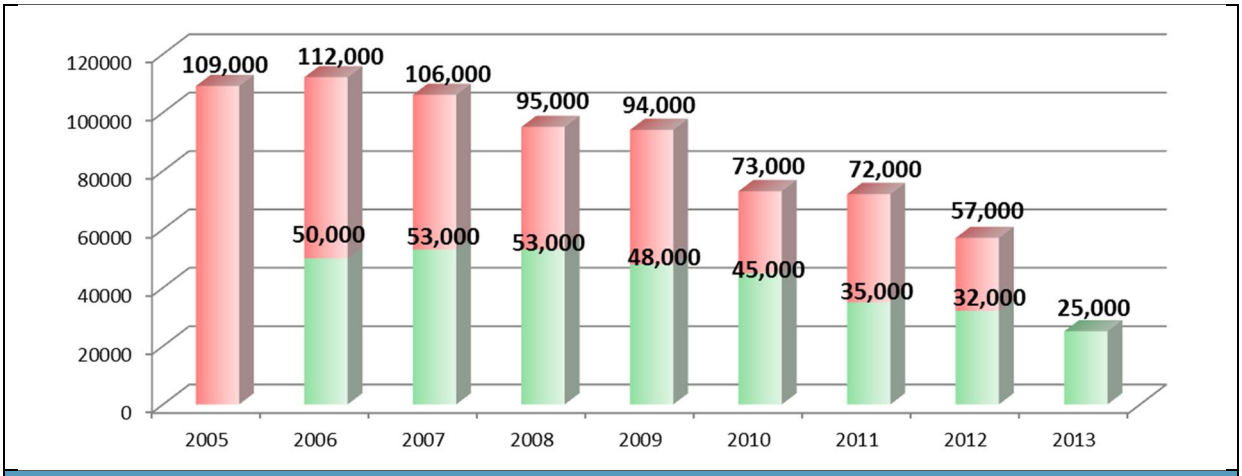

Figure 4-1: Incidence and prevalence estimates of occupational skin disorders in the EU28
Notes: Incidence data for 2005 and prevalence data for 2013 are not available.

In order to monetise the impact of occupational skin disorders, we calculated the medical treatment costs and the productivity losses due to skin conditions. The UK National Health System (NHS) reference costs[14] provide a basis for calculating the unit cost for the treatment of skin disorders. Reference costs are the average unit cost to the NHS of providing secondary healthcare to NHS patients. The weighted average treatment unit cost for skin disorders has been calculated weighting the average unit cost across the number of treatments. This is equal to £1,598 or €2,157[15]. The average unit cost for diagnosing a skin disorder[16] is £122 or €165. Assuming that these average unit costs for diagnosing and for treating skin disorders are the same in the EU28, and that the decrease in occupational skin diseases is fully attributable to the chemicals legislation, the benefits of the latter accrue to over €120 million in the period 2006-2012 only in treatment cost savings. Over the same period, there was a decrease of around 2.6 million of cases of sick leaves attributable to skin diseases, accruing to around €312 million in productivity loss savings. Considering also a WTP value to avoid a single episode of acute mild dermatitis of €227, the total cost savings due to the restriction/withdrawal of some skin sensitisers and the improvement of RMMs due the chemicals legislation are valued as creating benefits of around €446 million for the period 2006-2012.

4.3 Environment example: marine organisms

Table 4-2 presents the different steps followed in calculating the initial estimate for benefits from chemicals legislation for marine ecosystems (around €7.5 billion), taken from a 2007 survey of people in the UK, Portugal and Poland to avoid increased levels of species loss (i.e. a reduction of species richness) for different marine taxa[17]. The study considered a broader set of marine species, including marine mammals, fish, birds, invertebrates and algae, with the WTP asking what a

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Third Edition, An Introduction to Applied Epidemiology and Biostatistics. Available at: http://www.cdc.gov/ophss/csels/dsepd/ss1978/lesson3/section2.html

[14] Available at: https://www.gov.uk/government/collections/nhs-reference-costs

[15] Applying an exchange rate GBP/EUR: 1.35.

[16] JC45A - Standard Patch Test.

[17] Ressurreicao et al (2012): Different cultures, different values: The role of cultural variation in public's WTP for marine species conservation, Biological Conservation, 145, 148-159.

respondent's maximum WTP would be, in a once only payment, to avoid a decline in the number of a taxon by 10% and 25%. The study found that respondents across the three locations had different preferences for the different marine taxa, suggesting that cultural differences may be important drivers of valuation. For all three locations though the study also found significant WTP valuations for both residents and visitors to the sites where face to face surveys were undertaken. For marine fish, the figures range from means values of €22 – 68 for residents and visitors (all figures normalised against US purchasing power) to the Gulf of Gdansk in Poland; these WTP figures reflect a one-off payment to avoid increased species loss. Importantly though, the study also found that WTP was insensitive to the level of loss of species richness, with many respondents indicating that loss of one species could be as bad as losing several. This therefore suggests that these WTP estimates may reflect a total budget for avoiding increased species loss.

Based on this study a figure of €22 per household has been used here to provide an estimate of the benefits of reducing chemical related threats to marine fish and their associated ecosystems by chemical pressures (as 5% of marine fish species are considered to be affected by chemical pollution and 19% of coastal and transitional waters fail good status in 2009 due to chemical pressures). Note although only 5% of marine fish species have been identified as being at affected by chemical pollution, it considered reasonable to adopt this WTP figure here as it reflects on threats to marine fish and does not include additional amounts for other marine flora and fauna (if WTP across all taxa assessed by the study are added together, the total per household figure more than doubles). Furthermore, this figure is taken from the results for Poland, which had the lowest WTP values of the three countries.

Assuming that the WFD, agreement of harmonised classifications for acute aquatic toxicity and measures under other legislation (such as Biocides), which have reduced chemical discharges to the aquatic environment, have delivered a 10% reduction in threats to the marine environment, leads to EU-wide benefit estimates of €7.5 billion. These benefits would relate to a one-off payment and would reflect a reduction in the threat from chemicals on marine species across a range of taxa, including marine fish.

It is of note that the WTP figures quoted above are similar to those found in a range of other studies: WTP values found in relation to the Water Framework Directive and the improvement of water body status to good across 5 EU countries; on the restoration of sustainable populations of short-nosed sturgeon in the US; and on the benefits of removing micropollutants (a range of pharmaceuticals and pesticides) at sewage treatment plants to reduce their concentrations in the environment (rivers and lakes) and in drinking water in Switzerland.

Table 4-2: Estimating the benefits of chemicals legislation on marine organisms

Process stage	Data used	Assumptions & summary of calculations
Number of marine species	IUCN Red List Data[1]	988 native marine fish species in the EU of which 59 are threatened according to Red List data
Number of marine fish threatened by anthropogenic pressures	IUCN Red List Data[2]	988 native marine fish species of which 52 (of 5.3%) are affected by pollution (in the form of sewage, run off, oil spills (e.g. the Prestige oil spill in 2002), nutrient loads, sedimentation, herbicides, pesticides and noise pollution. Of these 52 species five are threatened, or around 10%
Number of marine species affected by chemical pollution	Based on WFD ecological status data	3.27% of coastal and transitional waters (by area) failing to meet good ecological status (this covers all pressures, including hydromorphological pressures)
WFD monitoring – failure of good	Based on WFD data of chemical	0.6% of coastal and transitional waters failing good chemical status (by area) across the EU. This provides an estimate of around 19% of

Table 4-2: Estimating the benefits of chemicals legislation on marine organisms		
Process stage	**Data used**	**Assumptions & summary of calculations**
chemical status	status	failures being due to chemical pressures (from 3.27% divided by 0.64%)
Change in marine fish species due to chemical pollution	Based on above data	Based on the above, it is reasonable to assume that chemical pressures are contributing to the current threatened status of one or more fish species
WFD monitoring – change in waterbodies failing good chemical status	ECHA Classification & Labelling Inventory database[3]	461 chemicals covered by WFD and other legislation out of 15,246 listed on the ECHA Classification & Labelling Inventory database as having aquatic acute 1 toxicity, or 194 of 1,232 harmonised substances (3% to 16%), and of 1,102 substances with a harmonised classification for aquatic chronic 1 and 2 toxicity. This is surrogate data intended to give an indication of the benefits based on the proportion of regulated chemicals. Ideally an approach would be used whereby comparison of the chemical status of waterbodies from the first round of WFD RBMPs with the second round of RBMPs is made. However, data from the second round of RBMPs are not yet available.
Value for protection of marine fish from chemical pollution	Value for reducing threats to marine species by 10%	€22 per household (updated from 2007 $US figures) multiplied over 216 million households giving baseline damages of €47.5 billion (assuming no legislation). Based on the number of substances having a harmonised classification and that are controlled under the WFD or through risk management measured introduced in response to the harmonised classification, it can then be assumed that current chemicals legislation has reduced damages by between 3% to 16% (assumed 16% here)
Damages: baseline and with legislation	Based on above data	Damages under baseline: €47.5 billion Damages with legislation: €40.0 billion
Benefits	Based on above data	Benefits from the reduction in threat to 10% of marine fish (and other) species: €7.5 billion

[1] European Commission (2015): European Red List – Geographic Patterns and Major Threats. Available at: http://ec.europa.eu/environment/nature/conservation/species/redlist/marine_fishes/geographic_patterns.htm

[2] http://ec.europa.eu/environment/nature/conservation/species/redlist/marine_fishes/major_threats.htm

[3] ECHA (2015): C&L Inventory. Available at: http://echa.europa.eu/information-on-chemicals/cl-inventory-database

[4] Kotchen MJ & Reiling SD (2000): Environmental attitudes, motivations, and contingent valuation of non-use values: a case study involving endangered species, Ecological Economics, 32, pp93-107. Available at: http://thacher.us/jenn/Econ542/Articles/KotchenReiling2000.pdf. Note values have been converted from US$ to € using Purchasing Power Parities and historic exchange rate based on: http://stats.oecd.org/Index.aspx?datasetcode=SNA_TABLE4#

5 Key questions for workshop participants

5.1 Questions for the first panel discussion

1. The study team has based the identification of indicators on the concepts of "output", "result" and "impact", in line with the Commission's Better Regulation guidelines.

    a. Output: Are the proposed output indicators important to understanding the benefits of chemicals legislation? Should they be given more or less focus compared to the result and impact indicators?
    b. Result: Should result indicators be developed for workers or human health more generally? Should these rely on biomonitoring data or other data? Should result indicators be developed for the environment based on the available EU-wide monitoring data?
    c. Impact: Are the proposed impact indicators useful? How much focus should be placed on quantifying impacts as opposed to quantifying changes in exposures?

2. Should the indicators be more specific to individual pieces of legislation?

    a. Should we be REACH and CLP specific?
    b. Or should they relate to a broader set of legislation together?

3. Are there key indicators that are missing from the lists proposed here?

5.2 Questions for the second panel discussion

4. The study team has focused on result and impact indicators that reflect changes in emissions, exposures and concentrations in the environment or humans (e.g. changes in the incidence or prevalence of diseases that can be linked to chemicals exposures) at the EU level, rather than those that could act as the basis for a case study approach. Do you think this is appropriate?

5. If a case study approach were to be adopted, are there certain sets of chemicals that should act as the focus?

6. Is it possible to use a single substance case study as a proxy for the benefits of reducing exposures to other substances with similar properties?

7. How important are confounding factors (e.g. economic situation, technology, working conditions and procedures) arising from the linkages between chemicals legislation and changes that may have occurred due to economic conditions or technological changes?

    a. Do you agree that we should ignore their potential influence and highlight the uncertainty that this introduces into end estimates of benefits?
    b. Or do you believe that we should only quantify and monetise those benefits where we believe confounding is likely to be minimised?

5.3 Breakout session: Worker Health

8. Are there missing output and result indicators in relation to workers health?

9. An example set of calculations for an impact indicator related to skin diseases is provided in Section 4 above.

    a. Do you think this approach is robust and credible?
    b. Are there alternative approaches?

10. Are there other types of human health effects that should be addressed using this type of approach, taking into account reliability considerations (please refer to Table 3.3)?

11. What sources of data are available that the study team may not have identified from an internet search?

12. Should the project team develop estimates reflecting different sets of assumptions as to the attributable fractions of impacts associated to chemical exposures and reduced by chemicals legislation?

13. Overall, has the study team focused on the right kinds of indicators?

5.4 Breakout session: Consumers and the general population

14. Are there missing output and result indicators in relation to public and consumer health? Should a distinction be made between consumers and the general population?

15. An example set of calculations for an impact indicator related to skin diseases for workers was provided in Section 4 above. A similar type of approach could be applied to assessing benefits for the general population for a limited set of chemicals based on HBM data.

    a. Do you think this approach is robust and credible?
    b. Are there alternative approaches?

16. Would a case study approach be more appropriate?

17. Are there other types of human health effects should be addressed using this type of approach, taking into account reliability considerations (please refer to Table 3.3)?

18. Should the project team estimate the benefits of different sets of assumptions as to the attributable fractions of impacts being associated to chemical exposures and reduced by chemicals legislation?

19. What types of human health effects should act as the focus of the assessment to ensure the reliability of the indicators?

20. Overall, has the study team focused on the right kinds of indicators?

5.5 Breakout session: Environment

21. Are there missing environmental output and result indicators for the environment?

22. Should trend data on environmental concentrations at the EU level be used to act as the basis for environmental 'result' indicators? Or can member state level data be used as a proxy?

23. An example set of calculations for an impact indicator related to reductions in impacts on the marine environment through chemicals is also provided in Section 4 above.

    a. Do you think that this approach is robust and credible?
    b. Are there alternative approaches?

24. Would a case study approach be better for highlighting environmental benefits?

25. What other types of environmental effects could act as the focus of such a quantitative and monetised assessment, taking into account reliability considerations? Do the data exist to support their use? Would it be possible to use them for illustrating changes in exposure over the period from 2004 to 2013?

26. How should the project team deal with confounding factors arising from the linkages between chemicals legislation and changes that may have occurred due to economic conditions or technological changes?

27. Overall, has the study team focused on the right kinds of indicators?

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