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APPROACHES FOR TRANSLATING THE RESULTS OF ENVIRONMENTAL RISK ASSESSMENT FOR USE IN SOCIOECONOMIC IMPACT ASSESSMENT UNDER REACH

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Introduction

A Member State or the European Chemicals Agency (ECHA) can identify a substance for potential Restriction under REACH. The restriction procedure is then as follows:

1. The Member State or ECHA submits a Restriction Dossier to ECHA according to Annex XV of REACH.
2. Two ECHA committees — those for risk assessment (RAC) and for socioeconomic analysis (SEAC) — form an opinion on the proposal in parallel, but with communication over cross-cutting issues.

SEAC must form an opinion about the *appropriateness* and *proportionality* of a proposed risk reduction measure, while RAC must form an opinion on the measure's *adequacy* at reducing the risk. Unfortunately, the outputs from conventional risk assessments are not the same as the impact assessment inputs required for socioeconomic analysis, so the two committees are using two different "currencies" when forming their opinions. This makes it difficult to develop co-ordinated and coherent opinions about Restrictions. Similar translation challenges are also to be expected under the Authorisation process of REACH.

The four main project objectives were:

1. To use a wide range of substances likely to be subject to Restriction or Authorisation to test the utility of relatively simple and **"rapid approaches"** when translating ERA outputs to impact assessments to be used in SEA. These approaches include:
   - Life-cycle Assessment (LCA) using industry-standard software.
   - Use of Species Sensitivity Distributions (SSDs)
   - Exposure-based "proxies" of effect such as changes in volumes of affected media, as generated by probabilistic EUSES modelling.
   - Read-across from similar substances for which there is more information.
2. To take a smaller subset of these substances to test the utility of more **"complex approaches"** such as use of the ecosystem services concept.
3. To consider uncertainty explicitly when developing examples for each substance.
4. To run a focussed one-day workshop with relevant stakeholders at which the project outputs are presented and discussed.

Thirteen chemicals were selected from lists of current and potential Restrictions or Authorisations as candidate chemicals for assessing the value, usefulness and limitations of the rapid approaches. Of these chemicals, four (1,2,4-trichlorobenzene, chloroform, nonylphenol and short-chain chlorinated paraffins) had information on potential substitute chemicals (a consideration of the impact of chemical alternatives is required under an SEA) and were selected for detailed case-studies. 1,2,4-trichlorobenzene and its potential substitute (monochlorobenzene) were additionally appraised using the causal-chains component of Ecosystems Services.

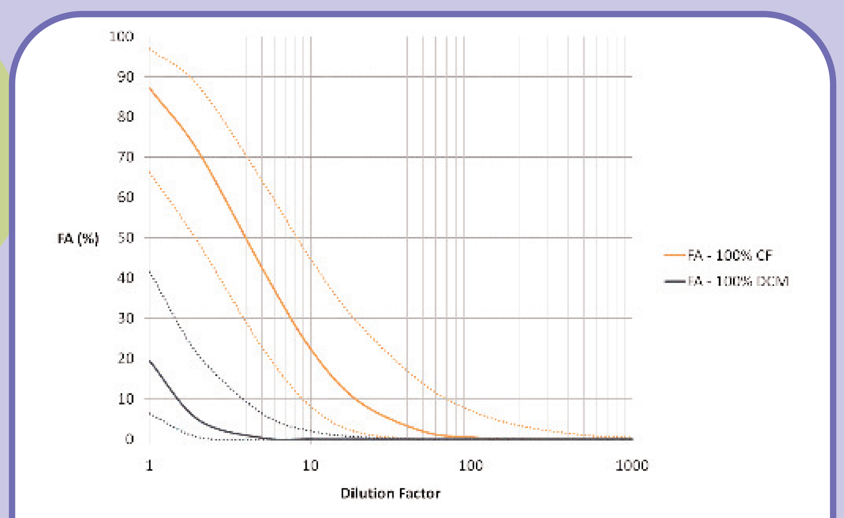

Figure 1. Example Exposure-Based Proxy.

The fraction of species affected under different scenarios of chemical use are identified in the example

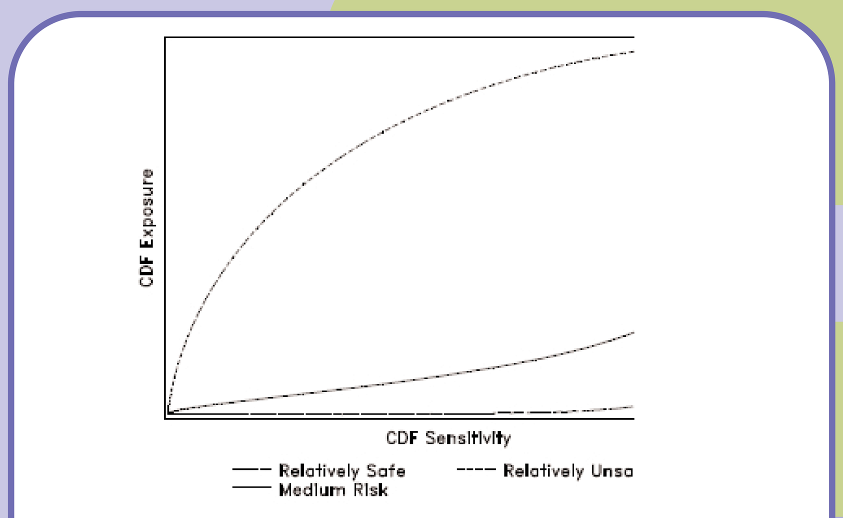

Figure 2. Example EER curve.

Three different scenarios of chemical use are identified in the example: relatively safe, medium risk and relatively unsafe.

Ecosystems Services

Ecosystem services are defined by the Millennium Ecosystem Assessment (MA; 2005) as: *The benefits people obtain from ecosystems. These include provisioning services such as food and water; regulating services such as regulation of floods, drought, land degradation, and disease; supporting services such as soil formation and nutrient cycling; and cultural services such as recreational, spiritual, religious, and other nonmaterial benefits.*

The MA categorises ecosystem services into four broad areas: provisioning, regulating, cultural, and supporting. Each service has sub-categories. For instance regulating includes climate regulation, water regulation, water purification and waste treatment, erosion regulation and natural hazard regulation (Table 1).

The ecosystems services concept of "causal chains" can be usefully applied as an alternative tool for communicating the risk or impact of a chemical (especially for those not familiar with the concepts and terminology of an environmental risk assessment), but offers no additional analytical benefit over conventional risk assessment. Whilst the impacts of a chemical on ecosystems services (e.g. purification and detoxification or regeneration and production) can be identified using a causal chain, the technique offers no additional means to "value" the impact of a chemical on the particular ecosystem service. Legitimate questions that are relevant for impact assessment such as "how many sewage treatment works might be impacted and for how long?" or "how many fish populations will be impacted and to what extent?" will remain unanswered.

Life Cycle Impact Assessment

Life Cycle Assessment or Analysis (LCA) is a technique for modelling the often complex interactions between a product and the environment from "cradle to grave" or "cradle to gate" (partial life cycle). It assesses the impact associated with all stages of a production process from raw materials, through processing, manufacture, distribution, use, repair and ultimately disposal (including recycling).

Life Cycle Impact Assessment (LCIA) techniques can be usefully applied to normalise the environmental impact of chemical emissions and express this impact in terms of equivalents (such as volume of media affected, or percentage of species affected). However, application of LCIA critically depends on the availability of data for the chemical of interest in LCIA databases. The methodologies and calculations underpinning the LCIA are also not readily available for an assessment of assumptions and limitations. Based on the experience of this project, LCIA parameter data is unlikely to be readily available for the majority of chemicals currently considered for Restrictions or Authorisations under REACH. Whilst chemical specific data can be added to LCIA software databases on an ad-hoc basis it is unclear if there is sufficient time, expertise and underpinning data available to develop the required parameter data for individual chemicals given the short timescales required by REACH.

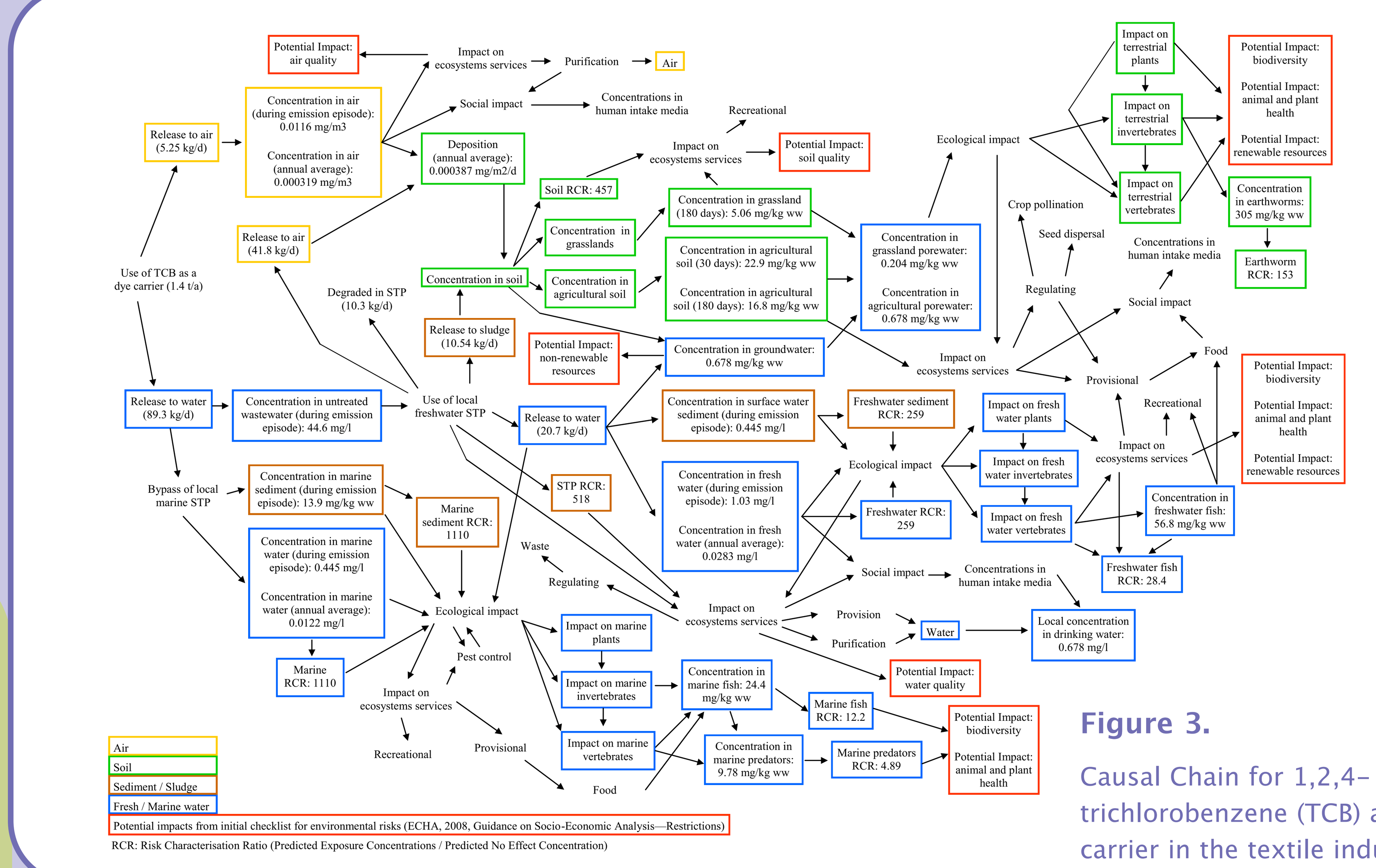

Figure 3.

Causal Chain for 1,2,4-trichlorobenzene (TCB) as a dye carrier in the textile industry

Exposure-based Proxies & Probabilistic Risk Assessment

The key benefit of adopting LCIA methods under SEA is the concept of normalising the impact of a chemical in terms of equivalents (i.e. comparing the impact of a chemical to a reference chemical) or the volume of media affected. Whilst it may not be feasible to undertake full LCIA under REACH, the results of the detailed case-studies shows that normalisation of the outputs of conventional environmental risk assessment can be readily undertaken using either an "exposure-based proxy" or "Estimated Ecological Risk" approach (after Aldenburg et al. 2002).

The volume of affected media can be considered a proxy for information considered to be directly relevant to SEA, such as the severity and extent of impacts from a particular chemical. Relative changes in the volumes of affected media in different environmental compartments (i.e. aquatic, terrestrial, and atmospheric) under various Risk Management Options (including the use of substitute chemicals) may also be compared and these types of measures may be more useful during SEA than simple measures of risk such as PEC/PNEC ratios (Figure 1).

"Estimated Ecological Risk" (EER) is the mean probability that a randomly drawn species would be affected by a randomly drawn exposure and is expressed as a percentage. The approach is analogous to the approach adopted by the EUFRAM project (www.eufram.com) for pesticides risk assessment. EER is calculated by plotting Fraction Affected (FA) values from an SSD against exposure concentration distribution (ECD) values. The area under the curve is equal to the EER (Figure 2). Three different scenarios of chemical use are identified in the example: relatively safe, medium risk and relatively unsafe.

Conclusions and Recomendations

1. At the present time, LCIA and Ecosystem Services are limited in their applicability and ability to support SEA much beyond more conventional methods of risk assessment. Primarily this is because of data limitations. Should sufficient additional data be made available, particularly for LCIA, then these methodologies should be reappraised.
2. Application of probabilistic methods in combination with species sensitivity distributions (use of dose-response curves from individual tests for those substances with low amounts of test data) to calculate the notional fraction of species affected in the environment, or amounts of media affected for a particular emission level could potentially be beneficial in SEA, as long as these measures were not misinterpreted.
3. Additional consideration of "non-threshold" chemicals (i.e. PBT and vPvB chemicals) under the REACH authorisation regime, and their appraisal within SEA is required.

Table 1. Categories of Ecosystems goods and services

Purification and Detoxification	*filtration, purification and detoxification of air, water and soils*
Cycling Processes	*nutrient cycling, nitrogen fixation, carbon sequestration, soil formation*
Regulation and Stabilisation	pest and disease control, climate regulation, mitigation of storms and floods, erosion control, regulation of rainfall and water supply
Habitat Provision	*refuge for animals and plants, storehouse for genetic material*
Regeneration and Production	*production of biomass providing raw materials and food, pollination and seed dispersal*
Information/Life-fulfilling	*aesthetic, recreational, cultural and spiritual role, education and research*

Reference:

Aldenberg T, Jaworska JS, Traas TP. 2002. Normal species sensitivity distributions and probabilistic ecological risk assessment. In: Posthuma L, Suter II GW, Traas TP, eds. Species Sensitivity Distributions in Ecotoxicology. Boca Raton, USA: Lewis Publishers. p. 49-102.

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