POLICY ASSESSMENT PROTOCOLS

GUIDANCE NOTES

1. Purpose of protocols

For the most part, assessment protocols will be based on, and be a natural development from, the scoping reports and conceptual models that have been developed during issue framing. These should have specified the issue to be assessed (and the stakeholders for whom it is relevant), sketched out the assessment framework (the full-chain model), and begun to outline the indicators, methods and data sources to be used in the assessment. The purpose of the protocol is to translate this into a detailed, *a priori* description of the assessment. As such, it will act as the 'rule-book' for the assessment, defining what aspects of the issue are to be assessed, how they will be assessed and what measures will be used to report the results. The protocol will thus be:

1. a reference for all members of the assessment team, to ensure that they follow the same procedures;
2. a document to help in discussions about the assessment with relevant stakeholders;
3. a basis for explaining the assessment procedures to other teams working on similar or related assessments, in order to help achieve consistency;
4. a means of allowing peer scrutiny of the assessment both during and after the project.

Deviations from the protocol will, of course, be possible (and in some cases may be essential), but these should be recorded and justified in updates and annexes to the protocol. The protocol (and updates) should be made public to stakeholders.

2. Contents

The detailed structure and content of the protocols must necessarily vary depending on the assessment, to reflect their different scope and focus, as well as established practice in the specific area of assessment. (To this end, assessment teams should carry out a review of recent risk assessments in their area to identify the current state of the art.) Several broad elements of the protocols can, however, be defined that should be relevant in most circumstances.

i. The assessment issue, including a restatement (based on the scoping report) of:
   - the issue to be assessed;
   - the key stakeholders, and their interests;
   - the policy context within which the assessment will be carried out.

ii. Scope of the assessment, including a restatement (based on the conceptual model and/or scoping report) of:
   - the assessment framework (full-chain diagram);
   - key elements/relationships to be assessed;

- the study area;
- the study population.

iii. Assessment methodology (see 3, below), including a description of the methods/models and data to be used to quantify each of the key components of the assessment and the indicators that will be derived therefrom. These might be arranged in different ways, but would usually follow the source-impact chain:

- source-exposure
- exposure-health effect
- impacts and costs

iv. Anticipated limitations of the assessment, including:

- major sources of uncertainty (and likely confidence limits to the assessment);
- gaps in the assessment (e.g. omitted exposures, health effects);
- expected problems in the assessment process and how these will be resolved.

v. Reporting and communication, including an indication of how the results of the assessment will be presented, disseminated and evaluated/verified (see 4, below).

3. Assessment methodology

In many ways, the key part of the protocol is the assessment methodology, and this is therefore likely to comprise the largest section of the protocol. The aim of these methods is to translate the conceptual model of the issue to be assessed (the assessment framework) into practicality – i.e. to provide the means for computing each component (variable) in the assessment framework. This will normally comprise a suite of data, models and methods to assess exposures and dose (i.e. to represent the source-dose part of the chain), and a second set of methods and data to estimate health effects on the basis of these exposures (i.e. to represent the exposure-health effect part of the chain). Beyond this, assessment should also usually extend to some measure of impacts and monetary or social costs.

To help those involved, the assessment methods (and associated indicators) should be expressed in the form of a clear and concise diagram (e.g. flow chart). This is generated by translating the assessment framework into a set of variables (boxes) and functions (connecting arrows), defining the main elements of the system that will be assessed. To avoid confusion, an agreed and consistent set of symbols and rules for presenting the system diagram needs to be used. A useful source of guidance and tools in this respect is provided by Opasnet (http://en.opasnet.org/w/Main_Page). Many proprietary modelling software tools (e.g. Analytica, ModelMaker) also include their own symbols and rules for designing flow charts. In addition, a wide range of specialist programs for designing and visualising systems models are available (e.g. Smartdraw and eDraw). Where an established house style does not already exist, it is likely to be helpful to use one of these.

To supplement this, and to ensure that all the terms used in the assessment are consistent and explicit, the variables used in the assessment process should also be defined and described. Descriptions should cover the methods/models used to compute or derive the variable, and the data (and associated data sources) on which these are based. 'Variables' in this context may take different forms and serve different roles (often simultaneously); they represent inputs to models (derived variables), interim steps in the calculation process (derived variables) and outputs for reporting (indicators). 'Methods'

and ‘models’ also take many forms; they include any form of assessment or calculation procedure, whether quantitative or qualitative, including expert estimation, extrapolation from or application of estimates from previous studies, and simple arithmetic weighting methods, as well as more sophisticated statistical or physical models. Data, likewise, include both hard (measured) data and qualitative information (e.g. nominal classifications or ordinal rankings of exposure or health effect). A template that can be used for this purpose is presented below, with an example.

3.1 Source to dose

The chain between source and dose can be characterised by a relatively generic set of links: source activities give rise to emissions or releases, which are then dispersed through the environment, leading to environmental concentrations; human contact with these concentrations results in exposures; inhalation, ingestion or dermal absorption then cause intake.

Each of these links involves a process during which the hazard typically undergoes some degree of diminution or change in terms of its intensity or toxicity. For example, not all of a toxic agent used in, or created during, a manufacturing process is likely to be released into the environment; the link between source and emission is thus characterized by an emission factor (or release efficiency term). Likewise, as it moves through, or stays resident in, the environment the agent is altered, redistributed and lost as a result of dispersion, mixing, decomposition, reformulation and deposition. Concentrations in the environment therefore tend to vary over space and time, and between one micro-environment and another. Human contact with the agent is in turn affected by behavioural factors, such as where and how people spend their time and their lifestyle. Equally, the translation of exposure to intake depends upon individual physiognomy and behaviour – including factors such as inhalation rate, diet and level of personal protection.

As a result, relevant elements of the source-dose chain can be computed through manipulation of a small number of generic variables:

- Source activity (S) – a measure of the intensity of the sources of the agent of concern (e.g. traffic-volume in vehicle kilometres, production level in tonnes or employment level in persons);
- Release efficiency (R) – a measure of the rate of emission into the environment (whether by deliberate or accidental means) per unit of activity (e.g. tonnes/tonne; tonnes/person; kg/km);
- Transfer efficiency (T) – a measure of the rate at which the agent transfers from its release source to any location (dependent on distance and the rates of transport, dilution, decomposition, deposition etc), expressed as a proportion;
- Contact efficiency (C) – a measure of the rate of contact between an individual and the agent in the environment, expressed as a proportion;
- Intake efficiency (I) – a measure of the rate of bodily intake of the agent, following exposure, expressed as a proportion.

Ideally, risk assessment should include some form of modelling of this complete source-dose chain (and all of the associated variables), in order to ensure that doses can always be attributed back to their source, and releases from any single source can be followed through to their intake by humans and thence to their health effects. In some cases, assessment will thus involve the use of a series of linked models: for example, emission models to estimate the releases from source, dispersion models to simulate the transport and fate in the environment, and further models to quantify levels of exposure

and dose. In these situations, choice of model may need to take account not only of the performance and data needs of each individual model, but also of the possibilities for model linkage and interoperability. In other cases, one or more links in the source-dose chain can be omitted, either because it is not relevant to the specific assessment or because appropriate models and data are not available. For example, it may be necessary and possible to estimate environmental concentrations of traffic-related air pollution directly from information on source activity (e.g. using land-use regression models), thereby avoiding the need to model emissions and dispersion. Equally, it may be appropriate in some cases to leap straight to exposure, using data from personal monitoring, or to dose, on the basis of biomonitoring data.

Description of the methods used for this stage in the assessment should therefore cover the variables and associated models and data sources used at each step. Where formal modelling techniques are to be used, such as proprietary dispersion models, reference to the models and their sources is usually all that is required. When models are to be customized, or purpose-designed models developed, more detailed description is needed, including explanation of the physical principles or statistical methods involved. Likewise, where routinely available data are used in their original form, then detailed reference to the source and name of the data sets will usually suffice. Where purpose-collected data are involved, or where data have been customised or adapted, they should be described in full. This should include the methods and criteria used for sampling or data selection, and any preprocessing of the data (e.g. to remove errors, reformat the data, or derive summary statistics).

3.2 Dose to health effect

The step from dose (or exposure) to health effect operates through the application either of some form of dose- (or exposure-) response function, or of a toxicity factor. Two main approaches may be used for deriving these functions: systematic review (including meta-analysis) and expert elicitation. The relevant methods to be used and, if possible, the sources of information to be drawn on (e.g. types of study, experts) should both be described in the protocol. Any criteria or methods to be used to weight, select or combine different estimates should also be outlined.

Where risk assessment is considering single agents, then specific dose-response functions or toxicity factors can be used in these estimates of risk. In integrated assessment, however, combined exposures to different agents (and possibly to exposures at different life-stages) will usually need to be considered. In this case, methods or factors may be needed to allow for interactive or predispositional effects. These, too, need to be described or, where they are unknown, the procedures for deriving them explained.

In the same way, the statistical methods or algorithms to be used to translate the measures of exposure or dose into health risk or impact should be described. In this context it is important to recognise that assessments will not only be made of relative or excess risk; estimates will also usually be needed of the attributable health burden or impact. These require information on the population numbers and distribution and the underlying disease rate across the study population. Sources and characteristics of these data should be specified in each case.

3.3 Secondary and subsequent impacts

Most integrated impact assessments do not stop at estimation of the direct effects associated with individual health outcomes, but proceed to estimate aggregated impacts, in terms of the overall burden of disease (expressed, for example as DALYs or QALYs) or monetary costs and benefits. Where this is to

be done, the relevant methods and data sources again need to be described. In the case of DALYs and QALYs, for example, this should usually include description of the methods and data sources used for estimation of severity weights; likewise where monetary valuation is being used it should also specify any weights or factors to be used in this process (e.g. discount rates, cost of life), and/or the data sources and methods used to derive them.

4. Limitations

Expected limitations of the assessment need to be specified, in order to highlight in advance issues that may need special attention, to avoid unfair criticism of the assessment protocol, and to ensure that relevant limitations arte taken into account in interpreting and using the results of the assessment.

Uncertainty is likely to be a major element of these limitations. Guidance on how to specify and assess uncertainties is being developed by WP1.5, and the classification of uncertainties that this has identified should be followed as far as possible. Methods for assessing, mitigating and reporting these uncertainties should be given.

5. Dissemination, reporting and verification

Planned methods for communicating and verifying the results of the assessment also need to be briefly described. This should include explanation of how the results will be made available, in what form, to whom, and when. In general, the minimum requirement would be to provide the results to the stakeholders involved in the assessment framing and protocol development.

A description should also be given of any planned procedures for verifying the results, either via a formal process of validation or by external review and evaluation. In the former case, information should be given on the sources of the reference data to be used for validation, and the methods and performance measures to be used. In the latter case, information is needed on who will be invited to provide evaluations, how this will be done, and what use will be made of the feedback.

Template for describing variables and models

VARIABLE NAME	
Type	
Links to other variables	
Detailed definition	
Terms and concepts	
Geographical scale	
Averaging period	
Units of measurement	
Data needs	
Data sources, availability and quality	
Computation algorithm/model	
Worked example	
Variations and alternatives	

PM2.5 EMISSIONS FROM ROAD TRAFFIC	
Type	Emission
Links to other variables	Links information on road traffic flows and emission rates to atmospheric concentrations, via dispersion model
Detailed definition	Annual mass of emissions of PM2.5 um from road traffic in London
Terms and concepts	PM2.5: primary particles with equivalent aerodynamic diameter of 2.5 um Road traffic: all vehicles using public roads (i.e. excludes agricultural, garden and other off-road vehicles)
Geographical scale	Street link
Averaging period	Year
Units of measurement	Tonnes/year
Data needs/ input variables	Traffic flows (vehicles/year) for each major vehicle group (motorcycles, cars, light goods and public service, heavy goods and public service) Length of each road link (to which traffic flow data relate) Traffic speed – average speed of vehicles on each road link Emission factors – emission rate per km travelled for each vehicle group, by speed
Data sources	Road data: national Ordnance Survey Landline data (2003), accurate to 1 metre. Traffic flows and speed: Transport for London database (2005) Emission factors: EMIT database (2006)
Computation algorithm/model	Emissions (E) are computed as the sum of the products of road length (L), traffic flows (V) and emission factor (F) for each vehicle group (g) on each road link: $E = k\sum_{g=1}^{M} L.F_g.V_g$ where *k* represents a weighting factor to convert to emissions in tonnes/year
Worked example	Road length = 0.4 km Motorcycles = 60 vehicles/day; emission factor (at 50 km/hr) = 0.02 g/km Cars = 14000 vehicles/day; emission factor = 0.01 g/km LGV = 6400 vehicles/day; emission factor = 0.025 g/km HGV = 420 vehicles/day; emission factor = 0.1 g/km Emissions = 0.000365*((60*0.02)+(14000*0.01)+(6400*0.025)+(420*0.1))*0.4 =0.05 tonnes/year
Limitations and uncertainties	The main uncertainties are likely to be associated with the emission factors and traffic flow data. Emission factors will vary according to speed, road conditions, temperature and vehicle condition. Estimated uncertainties for annual averages are ca. 25%. Traffic flow data are based on sample counts and are subject to sampling and interpolation error. Estimated uncertainties for annual averages are ca. 20%.
Proxies and alternatives	If detailed data on traffic flows are unavailable, estimates may be made by assigning average flows to roads according to road type, using national statistics.