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Integrated Assessment of Health Risks of Environmental Stressors in Europe

Integrated Project  
Thematic Priority

## D25 Water Assessment Protocol

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# WP3.4 - Water Assessment Protocol (WAP)

## Deliverable D25

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## 1 Foreword

The INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe) project is designed to provide the methods and tools that are essential to enable integrated assessment of environment and health risks in support of the implementation of the European Environment and Health Action Plan. As such, it will develop a methodological framework and sets of tools and indicators for integrated assessment that can be applied across different environmental stressors (including pollutants and physical hazards), exposure pathways (air, water, soil, food) and policy areas. It will review, bring together and enhance the monitoring systems needed to support such analyses, including routine environmental monitoring (ground-based and Earth observation), biomonitoring and health surveillance. The framework, tools and data will be tested and demonstrated through integrated assessments of exposures and health risks in a number of specific policy areas, including transport, housing, agriculture, water, wastes, household chemicals and climate. Results from these will be used both to refine the assessment methods and to provide specific information on health implications of current and potential future policies.

This protocol aims to provide a broad overview of the methodology that will be employed in the assessment of the specific policy area of water. This document has been prepared following considerable refining and redefining of the policy assessment scope in this area, of variables relevant to the process and of stakeholders' roles within it.

While this document aims to provide a set of guidelines for the assessment process, it is not intended to be an entirely rigid set of rules, nor a prescriptive manual of instructions covering every detail of WP3.4's work over the coming 18 months. Rather, it is anticipated that this draft protocol will serve as a working document, informing participants of the detailed suggested outline of the assessment, generating discussion on methodological and practical aspects of it, and providing a basic structure from which subsequent deviations and adaptations may be explicitly made. Members of WP3.4 are invited to comment and edit this document as they see fit, ideally then circulating their suggestions to all other members of WP3.4 by means of email. Following approval of this document in month 18, it will be distributed to WP3.4 stakeholders for their comments, and as such should be considered a public document by that stage.

### 1.1 Links with other work packages

The assessment protocol should also be of interest and utility to those working in SP1 and SP2 (as feedback to their support so far), to SP5 (which will provide common databases to the SP3 work packages), and to SP4, which will be responsible for constructing an integrated assessment toolbox. Members of other work packages are encouraged to use this document as a point of departure for communicating with WP3.4 members and as a means of coordinating extraneous efforts between work packages that arise as the project progresses. It is important that methodological, practical and management issues that may arise between WPs are dealt with as early on in the assessment process as possible and this document should be drafted with this in mind.

The table below indicates the main links in terms of requests for information and support from other WPs.

WP	Request	Timescale*
1.1	Deliverable (paper) on the assessment framework and INTARESE methodology	Urgent
1.2	Guidance on choice of dispersion modelling (air, water, soil) - with WP2.1	1st pass
1.3	Guidance on using toxicological information for health impact assessment	1st pass
	Guidance on how to combine toxicological and epidemiological information	1st pass
	Guidance on expert elicitation	2nd pass
	Guidance on how to use life-tables (with WP2.3)	1st pass
1.4	Guidance and methods for indicator definition and development	Urgent
	Methods for DALY calculation	1st pass
	Methods for monetisation (weighting, discounting etc.)	1st/2nd pass

1.5	Training on uncertainty quantification (as well as characterisation) Guidance on dealing with exposure mixtures	1st pass 1st pass
2.1	Guidance on which dispersion models to use/criteria for dispersion modelling in different media (with WP1.2)	1st pass
2.2	Guidance on how to make use of biomarkers/biomonitoring	2nd pass
2.3	Baseline data on disease/mortality rates (at appropriate resolution/level of aggregation) - to be requested through 'health data templates' Guidance on how to use life-tables (with WP1.3)	1st pass 1st pass
4.1/4.2	Tools for risk and impact assessment (from exposure to health effect/cost) - e.g. based on LSHTM/RIVM spreadsheet models Templates/guidance for describing indicators used in the assessment (with WP1.4?)	1st pass 1st pass
Unknown	How to involve stakeholders in the issue-framing and assessment process Guidance on policy scenario selection, development and comparison	2nd pass Urgent, then 2nd pass

## 1.2 Timetable for WAP

Task	Provisional date
Telephone conference to discuss first draft of WAP	23 <sup>rd</sup> March 2007
Type up and distribute meeting minutes	26 <sup>th</sup> March 2007
JG to attend SP3 meeting in Rome - present draft protocol and work out how other WPs are to contribute to WP3.4 work	28 <sup>th</sup> March 2007
Partners to return first draft of protocol	30 <sup>th</sup> March 2007
In light of Rome meeting and comments/additions from partners, JG to prepare second draft of the protocol	12 <sup>th</sup> April 2007
Second draft sent out to partners for edit	13 <sup>th</sup> April 2007
Second draft of WAP returned by partners with comments/additions	24 <sup>th</sup> April 2007
JG to incorporate partner comments and complete final draft of WAP and then distribute this to partners to approve	28 <sup>th</sup> April 2007
Partners return final draft, JG submits to Project Steering Group	1 <sup>st</sup> May 2007
Refine final draft during workshop at 3rd INTARESE meeting in Brussels	21 <sup>st</sup> May 2007
Final version to be sent out to stakeholders	29 <sup>th</sup> May 2007
Commence first pass assessment according to protocol	29 <sup>th</sup> May 2007

## 2 Executive summary of WP3.4 assessment

The WP3.4 water policy assessment looks at the impact of three specific non-microbial water contaminants (chemical parameters) on the health of the human population of five case study countries – UK, Finland, Spain, Hungary and Romania. The contaminants – arsenic, nitrates and trihalomethanes (THMs) – have been selected on the basis of their likely origins (geogenic, agricultural and anthropogenic, respectively). The decision was made early on to exclude microbial contaminants from this assessment since many of the WP3.4 partner institutions are involved in other high profile European projects on microbial pollution of drinking water (e.g. HiWATE, MICRORISK etc.) and the WP3.4 team's expertise is particularly focused on non-microbial drinking water contaminants.

The assessment will focus on only those chronic health outcomes most conclusively linked to the three contaminants selected:

<b>Arsenic</b>	cancer (bladder, kidney, skin, lung)
<b>Nitrates</b>	methaemoglobinaemia
<b>THMs</b>	perinatal conditions (low birth weight, light for gestational age, stillbirth)
	cancer (bladder)
	congenital malformations

It should be borne in mind that of the above, only those outcomes supported with better quality data will eventually be looked at. WP3.4 is not looking at the acute risks of drinking water contamination (e.g. eczema and other topical skin conditions etc.) since evidence on these associations is currently somewhat inconclusive and data availability poor.

The involvement of stakeholders is important to appropriate selection of case studies, chemical parameters, policy scenarios and risk communication, and subsequently to the success of the assessment. Stakeholders in each of the case study countries were sent a summarised version of a scoping report. Their comments and suggestions were reviewed by WP3.4 and changes incorporated into this protocol. Stakeholders will be consulted at each major step of the assessment process, and their comments and suggestions reviewed by WP3.4.

The assessment is best regarded as an integrated health impact assessment nested within the larger integrated assessment that is INTARESE. The first pass assessment will assume a business-as-usual policy scenario, will make use of current data (and associated forecasting and backcasting methods), and will generate estimations of the excess cases of disease attributable to each of the chemical parameters of interest in each of the five case study countries. The second pass assessment will generate estimates of excess cases of disease for various alternative policy scenarios, and compare these with the business-as-usual policy scenario used in the first pass. The impacts of these excess cases of disease on society in each case study country in terms of both DALYs and economic costs will then be estimated both for the business-as-usual and alternative policy scenarios, thus providing estimates of the burden of disease associated with each disease and each chemical parameter. Methods developed as part of the broader INTARESE project will then be used to integrate the health impacts of each the chemical parameters. Alternative policy scenarios might include shifts in water sources from ground to surface water, increased consumption of bottled water, changes in water disinfection methods (e.g. chlorination to chloramination) etc. The exact choice of alternative policy scenarios will be informed by the results of the first pass assessment, the results and input of other INTARESE work packages, and the suggestions of stakeholders.

This protocol serves to make explicit the intentions of WP3.4 in carrying out its assessment, the general outline of the assessment process, and those gaps that will need to be filled in as the assessment progresses. The document will be made publicly available following any revisions made in the early stages of the first pass assessment, and subsequent to the approval of all those involved in its production.

### 3 The assessment issue

High quality drinking water is essential in maintaining human health and well-being and as such should be safe, wholesome and clean, and acceptable to consumers. The objectives behind existing regulation in developed, industrialised countries are consistent with these goals, generally aiming to protect the public against unsafe drinking water. Considerable efforts are currently being made by a number of different groups, including government (at various levels), the World Health Organisation (WHO), the water industry, consumer groups etc. to safeguard and, where possible, to improve drinking water quality for the consumer.

The European Council Directive 98/83/EC (the Drinking Water Directive or "DWD") on the quality of water intended for human consumption provides the scope for national transpositions of the legislation to guide both consumers and suppliers of drinking water across the EU. Many challenges, however, continue to lay ahead as a result of (anticipated and currently existing) shortages of water supply in certain regions, continued increasing water use, potential adverse health effects of conventional water treatment as recently found by scientific studies and existing pollutants in the water, and the effects of climate change.

Water-related extreme weather events make an increasing impact on human health. The effects of longer term climatic changes on water supplies are far-reaching both geographically and temporally, although the majority of these effects are felt most of all by those living in poverty and social deprivation. According to WHO estimates, within the next fifty years it is anticipated that 40% of the world's population will live in an environment of scarce water resources. The processes of desertification, flooding, drought, pollution of water sources - all of which have been linked to global climate change - have implications for human health in their own right, but also increase demand on water resources. These impacts are increasingly forcing populations and their appointed decision-makers to make difficult choices about water use. Large-scale demographic movement, not necessarily connected to climate change, also exerts considerable influence on water use and, ultimately, on social tension and human health<sup>1</sup>. Whether these movements result from warfare and social unrest - as may be the case in developing countries - or from increased migration or tourism - as in southern Europe, for example - water resource use can be significantly affected and disrupted in both quantitative and qualitative terms. As the quality of water resources available to certain populations diminishes through overuse, poor management and/or pollution, decision-makers find themselves faced with new questions, decisions and concerns over water use.

Particular health concerns at present include water pollutants and contaminants such as pathogens, nitrates, pesticides, polyaromatic hydrocarbons (PAHs), disinfection by-products (DBPs), metals (arsenic, lead, copper, uranium), fluoride, trichloroethene and tetrachloroethene and other volatile organic compounds (VOCs), bromate, acrylamide and endocrine disrupting substances (EDCs) such as pharmaceuticals and natural hormones from various sources. The presence calcium and magnesium (water hardness) and fluoride, however, may have beneficial effects on human health.

Sources of water pollutants and contaminants include geology (arsenic, uranium), agriculture (nitrates, pesticides, EDCs, pathogens), and drinking water treatment and supply networks (DBPs, PAHs, EDCs, lead, pathogens). Pathways of exposure include consumption of drinking water and food, inhalation and absorption through swimming in chlorinated pools and breathing indoor air, for example. Although the main route of exposure is ingestion, skin absorption (DBPs and pesticides) and inhalation (DBPs and other VOCs) may also occur and contribute significantly to personal doses. Climate change may affect not only the availability of suitable water sources, but also the behaviour of consumers (e.g. increases and decreases in ingestion of tap water, increased water use, increased consumption of bottled water). Generally, issues of concern for consumers are not only the potential health effects of contaminants, but also taste and odour of drinking water. Poor taste or odour may lead to increased use of bottled water or to consumers

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<sup>1</sup> Water: A Shared Responsibility. The United Nations World Water Development Report 2. United Nations, 2006.

decreasing their own ingestion - behaviour which may be associated with its own health effects. Potential health effects related to pollution of drinking water include cancer (pesticides, PAHs, and DBPs), reproductive effects (nitrates, pesticides, DBPs and EDCs), infectious disease (pathogens) and child health (nitrates) and particularly include susceptible groups such as pregnant women/foetuses and children (DBPs, nitrates, pesticides). Certain components of drinking water have been associated with positive health effects e.g. the reduction of cardiovascular disease observed with an increase in permanent hardness.

Water quality is generally regulated by means of measured water quality parameters. The transposition of the Drinking Water Directive (98/83/EC) guarantees that there is fairly uniform, reliable routine monitoring of total trihalomethanes (TTHMs), pathogens, pesticides and other water quality parameters in EU countries. A number of chemical parameters are not currently monitored unless it is considered necessary for the protection of human health, at which juncture these parameters may be monitored on a case-by-case basis (art.7 para.6 DWD). In some EU countries, data relating to water quality is compiled into centralised national databases. In others, these data are neither centrally collected nor made readily available to the public, although all EU countries have a mandate to supply this data, however, to the European Commission at regular intervals.

Whilst exposure-response relationships for some of these substances are reasonably well-established, large uncertainties remain for others; for some substances there is little scientific evidence on which to base assessments. Toxicological and epidemiological evidence have often not been effectively combined to underpin policy. In many cases involving complex health effects such as cancers and reproductive effects, potential synergistic effects may also occur, though these too are poorly understood at present. Furthermore, the effects of e.g. climate change are potentially wide-ranging and complex, affecting both water supply (shortage, higher microbial and DBP load) and use (increased need and resulting higher uptake of pollutants and contaminants). Both direct and indirect effects need to be better predicted, including e.g. choices of water sources and changes in water treatment methods (e.g. chlorination, chloramination, chlorine dioxide, ozonation, granulated activated carbon etc.) The need, therefore, is to develop assessments that take account of the latest scientific knowledge and understanding of policy issues, and provide the capacity for updating and revising risk/impact assessment methodologies as new scientific evidence comes to light.

### 3.1 Stakeholders

Stakeholders have been involved in the WP3.4 assessment for a number of reasons. The need for transparency in the assessment is paramount. It would be potentially short-sighted and unwise to go ahead with an assessment on the scale of INTARESE without encouraging stakeholders to review the policy assessment scope - not only can they potentially provide expert guidance and useful feedback on policy questions that they consider important (particularly relevant to the second pass assessment), but as actors in the risk debate these stakeholders' diverging interests and fields of expertise can ensure that the framing of the assessment is appropriate to the problems faced in drinking water pollution and health policy. Uncertainty in risk estimation, for example, produced during the assessment will govern the extent to which it will be necessary to consult with stakeholders, since some of them may ultimately be users of the assessment results and SP4's toolbox and will need to understand the uncertainties present and the context in which they operate.

The key stakeholder groups to be involved in the assessment include those representing government, regulators and watchdogs, consumer organisations, research and data provision and the water industry for each of the five countries in which the assessment is to be carried out. Two further groups have been identified, namely those stakeholders operating at the European and International levels. All these groupings of stakeholders have been selected on the basis of their degree of involvement in the drinking water sector, their own objectives and for their status as potential users of the results of the Intarese project later on. These particular stakeholders were selected in order to present as broad an array of interest in the assessment as possible.

Due to timeframe constraints in the initial scoping phase of the project, these stakeholders were not engaged in a formal way from the very beginning of the project, which may have been desirable. Their participation was first enlisted upon completion of a policy scoping report, which had been abbreviated (and if necessary translated into local languages), and sent out to them for comments. Those stakeholders that did not respond in the first round of comments were sent a reminder email at the end of month 16. Their comments and suggestions have been incorporated into a short report on stakeholder perceptions of the policy scoping document, which is found in Appendices 5 and 6 of this report. Their comments have shaped the development of this water assessment protocol, guiding WP3.4 in making explicit its rationale for the inclusion or exclusion of various issues from the project scope. The water assessment protocol is to be finalised by month 18. The protocol will then be presented to INTARESE users in month 19 and then presented once more to stakeholders that responded in the first phase of consultation. This will give them the opportunity to monitor WP3.4's progress, to ask questions about the direction of the assessment and to comment on it. Their comments will be included in the first pass assessment interim report planned for month 24.

A brief summary of the stakeholders that have been identified and contacted is summarized in the table below. Those stakeholders **highlighted** have responded to the initial phase of stakeholder consultation on the policy scoping document. A more detailed breakdown of all stakeholders is given in Appendix 3. Stakeholders that have not replied at this stage will be contacted again in month 16. Following discussion between WP3.4 partners, subsequent adaptations to the protocol will be made and in the light of these suggestions.



	UK	Hungary	Romania	Finland	Spain	European	International
Government	Department of the Environment, Food and Rural Affairs (Defra) - <a href="#">[LINK]</a> Environment Agency (EA) - <a href="#">[LINK]</a>	Ministry of Environment and Water (Környezetvédelmi és Vízügyi Minisztérium) - <a href="#">[LINK]</a>	Ministry of Environment and Water Management - Department of Water - <a href="#">[LINK]</a>	<a href="#">Ministry of Agriculture and Forestry (MMM)</a> - <a href="#">[LINK]</a> <a href="#">Ministry of Social Affairs and Health (STM)</a> - <a href="#">[LINK]</a>	Ministerio de medio ambiente - <a href="#">[LINK]</a> Ministerio de sanidad y consumo - <a href="#">[LINK]</a>	TBC	-
Regulators and watchdogs	Drinking Water Inspectorate (DWI) - <a href="#">[LINK]</a>	Hungarian Water Centre and Public Archives - Water Directorate - <a href="#">[LINK]</a>	TBC	<a href="#">National Product Control Agency for Welfare and Health (STTV)</a> - <a href="#">[LINK]</a>	Sistema de Información Nacional de Agua de Consumo (SINAC) - <a href="#">[LINK]</a>	<a href="#">European Commission DG Environment Directorate D: Water, Chemicals and Cohesion</a> - <a href="#">[LINK]</a> European Environment Agency - <a href="#">[LINK]</a> <a href="#">European Topic Centre on Water (ETC/WTR)</a> - <a href="#">[LINK]</a>	-
Consumer organizations	Consumer Council for Water (CCWater) - <a href="#">[LINK]</a>	VITUKI Environmental and Water Management Research Institute - <a href="#">[LINK]</a>	TBC	Consumer Agency - <a href="#">[LINK]</a>	Organización de Consumidores y Usuarios (OCU) - <a href="#">[LINK]</a>	TBC	-
Research and data provision	UK Water Industry Research (UKWIR) - <a href="#">[LINK]</a>	HIDRO - <a href="#">[LINK]</a>	TBC	National Public Health Institute (KTL) - Department of Environmental Health - <a href="#">[LINK]</a> Finland's environmental administration (SYKE) - <a href="#">[LINK]</a>	TBC	TBC	<a href="#">World Health Organisation (WHO) - Water Sanitation and Health (WSH)</a> - <a href="#">[LINK]</a>
Water industry	<a href="#">British Water</a> - <a href="#">[LINK]</a> Water UK - <a href="#">[LINK]</a> <a href="#">John Fawell</a> - <a href="#">[LINK]</a>	The Hungarian Professional Association of Water and Sewerage Companies - <a href="#">[LINK]</a>	National Administration of Romanian Waters - <a href="#">[LINK]</a>	Finnish Water and Waste Water Works Association (FIWA) - <a href="#">[LINK]</a> <a href="#">Drinking Water Institute (DWI)</a> - <a href="#">[LINK]</a>	Asociación española de empresas gestoras de los servicios de agua potable a poblaciones (AGA) - <a href="#">[LINK]</a> Asociación española de abastecimiento de agua y saneamiento (AEAS) - <a href="#">[LINK]</a>	<a href="#">European union of national associations of water suppliers and waste water services (EUREAU)</a> - <a href="#">[LINK]</a>	-

## 3.2 Policy context

Council Directive 98/83/EC, the Drinking Water Directive (DWD), concerns the quality of water intended for human consumption. The Directive was initiated in September 1993 when the consultation process was opened. Agreement was reached in November 1998 and the Directive was published in December of the same year. The deadline for the transposition into national legislation was December 2000, with most standards and parametric requirements requiring compliance by December 2003.

Under the legislation, drinking water is defined as '(a) all water either in its original state or after treatment, intended for drinking, cooking, food preparation or other domestic purposes, regardless of its origin and whether it is supplied from a distribution network, from a tanker, or in bottles or containers; (b) all water used in any food-production undertaking for the manufacture, processing, preservation or marketing of products or substances intended for human consumption'. The objective of the Drinking Water Directive is, therefore, to protect the health of drinking water consumers in the European Union, to make sure that water is wholesome and clean, and that it has a pleasant appearance (i.e. free of unacceptable taste, odour and colour).

To ensure that drinking water everywhere in the EU is indeed safe, clean and tasty, the DWD sets standards for the most common substances (so-called parameters) found in drinking water. The DWD decrees that a total of 48 microbiological and chemical parameters be monitored and tested regularly across the EU by those water bodies supplying drinking water to the public. In principle, the WHO guidelines for drinking water have been used as a basis for setting the standards (or parametric values) given for the 48 substances in the Drinking Water Directive.

In translating the DWD into national legislation (transposition of the DWD), Member States of the European Union were allowed to include additional requirements e.g. the regulation of additional substances considered relevant within their territory, or the setting of higher standards than those listed in the DWD. Therefore governments in any member state may apply mandatory water quality standards on drinking water suppliers based directly on European standards derived from the DWD, and on national standards. In addition standards considered non-mandatory from the perspective of the EU might be implemented in national legislation in order to improve the safety of water for human consumption over and above levels set by the DWD. Importantly, EU Member States are not allowed to set lower standards than those prescribed under the DWD since the level of protection of human health should be above a certain minimum across the whole EU.

The competent authorities in any Member State are under mandate to monitor the quality of the drinking water supplied to its citizens: this is to be done at randomly located consumer taps inside either private or public premises. The quality of drinking water used in the food and beverage production industry must also be monitored to ensure that it complies with EU standards. Samples of water intended for human consumption should, according to the DWD, 'be taken so that they are representative of the quality of the water consumed throughout the year'. Member States report these monitoring results to the European Commission at three-yearly intervals.

The Commission assesses the results of water quality monitoring against the standards listed in the DWD. After each reporting cycle the Commission produces a synthesis report, which summarises the quality of drinking water and its improvement at the European level.

## 4 Scope of the assessment

### 4.1 Assessment framework

The issue to be assessed is best illustrated by means of the assessment framework (incorporating the full-chain model), which is shown in figure 1. This was produced and refined through a series of amendments to the policy scoping document; both the framework and the policy scoping document were then presented to a representative group of national and international level stakeholders (see 'Stakeholders' above).

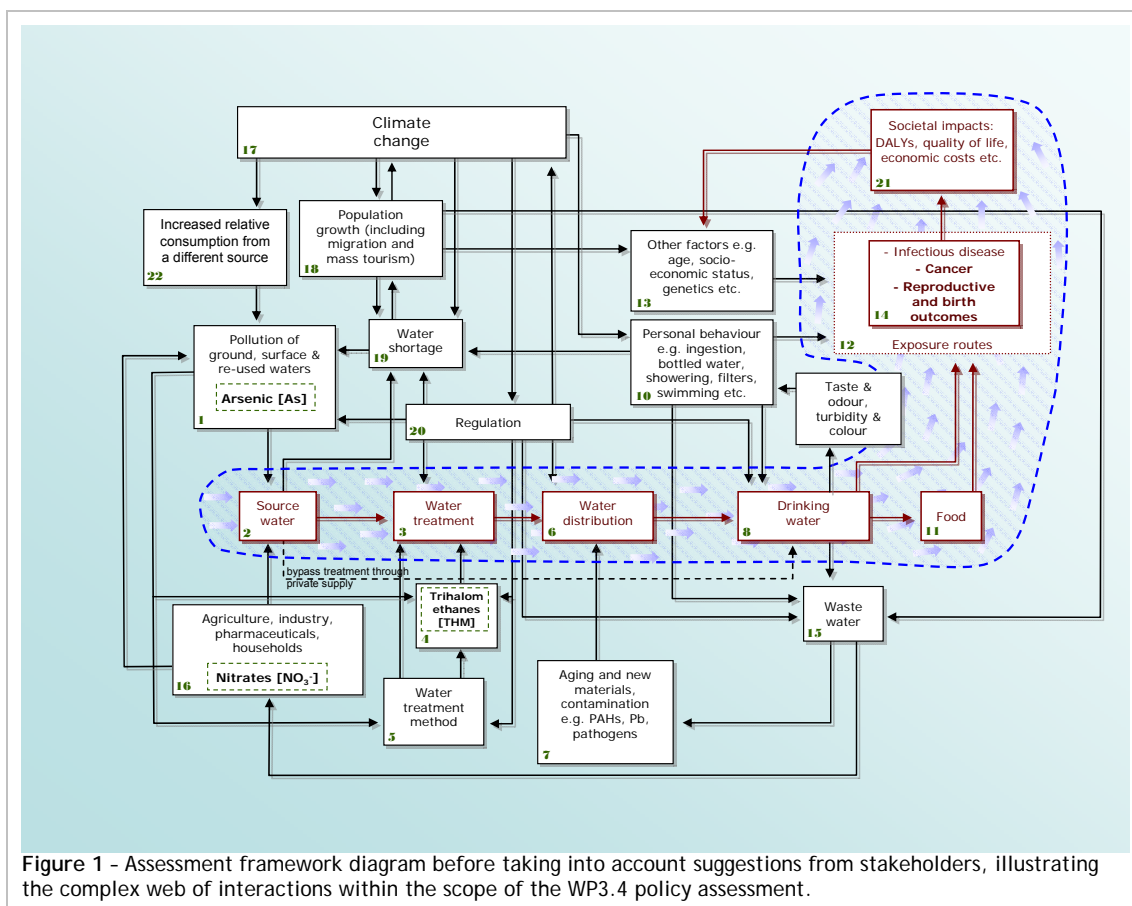


Figure 1 - Assessment framework diagram before taking into account suggestions from stakeholders, illustrating the complex web of interactions within the scope of the WP3.4 policy assessment.

### 4.2 Key elements/relationships

The assessment will focus on the effect that water source (e.g. ground, surface, desalinated water) and treatment method (e.g. chlorine, chlorine dioxide) have on the occurrence of water contaminants (e.g. disinfection by-products, arsenic & nitrates) and associated adverse health outcomes (e.g. cancer, reproductive outcomes). It should be made clear at this stage that the disinfection by-products (DBPs) focused on in this assessment will be total trihalomethanes (TTHMs). The use of these chemicals as a proxy for disinfection by-products has been the focus of considerable criticism and the validity of such a method is of doubtful integrity, but the assessment will still make use of this measure of DBP concentration since TTHM monitoring data is the only mandatory data collected for DBPs under EU legislation at the present time and thus represents the best available technique in using data available at this time.

The initial (first pass) assessment will assume the *status quo* or business-as-usual scenario regarding water sources and treatment methods, thereby estimating the current health impacts (i.e. disease burden) associated with drinking water contamination as it is today, assuming that this generally reflects the impacts of current policy. In the second pass assessment, it will be necessary to incorporate the outcomes of potential policy scenarios. These scenarios might include, for example, the introduction of measures that reduce levels of contaminants in source waters (e.g. through a change in farming practices to

reduce nitrate levels), measures that lead to switching of water sources (e.g. from ground to surface water, or ground to desalinated water in response to increased pressure on water resources), that change the water treatment methods (e.g. from chlorination to chloramination, or from chlorination to ozonation and UV treatment) and improve distribution systems. These scenarios will be modelled by adjusting the source-water concentrations of arsenic and nitrates, and adjusting the levels of DBPs in treated water, which may result due to altered levels of organic matter and/or bromide in source waters. The exact choice of scenarios for the second pass assessment will be based on partners' experiences, evidence that comes to light during the first pass assessment, either in SP3 or other INTARESE WPs, as well as from stakeholders and users engaged in the assessment process. At the end of the second pass assessment it will be possible to comparatively evaluate the individual policy scenarios. Guidance from other WPs should assist in this process.

Given that there are another six policy assessment WPs being carried out under SP3 concentrating on transport, housing, agriculture, chemicals and household products, waste and climate change respectively, there is considerable scope for policy scenarios being used across several work packages. Obvious linkages with WP3.4 and agriculture and climate change come to mind most readily. For example, if WP3.4 was to consider a scenario that was related to climate change, it may be useful if both climate and water work packages were to use the same policy scenario. Other less clear linkages between work packages may come to light in carrying out the first pass assessment. For this reason also WP3.4 will wait until the first pass assessment has been completed until making decisions about exactly which policy scenarios to investigate in the second pass.

Climate change and population growth both act as driving forces in putting pressure on water resources and therefore causing shortages. Cutting-edge toxicological and epidemiological evidence will be employed in assessing the effect that such driving forces mediate on population health.

#### *4.2.1 Logical relationships in the assessment framework*

1. Population growth (18) (including migration and mass tourism) and climate change (17) may lead to water shortages (19) and changes in the selection of drinking water sources (e.g. from ground water to surface water or desalinated water).
2. Source water (2) may be contaminated with naturally occurring substances, such as arsenic, or with anthropogenic contaminants such as nitrates (from agriculture) (16).
3. Water treatment (3) is carried out by a specific water treatment method (5) that removes contaminants from source water to a large extent, but may result in the formation of additional anthropogenic contaminants such as DBPs (4), the relative concentrations of which also depend on pollution of source water with both organic (e.g. humic and fulvic acids) and inorganic compounds (e.g. bromides) (1). The water treatment method (5) used depends on source water characteristics and the technical parameters of the distribution system (construction and materials, size, age etc.) (6), and determines the removal efficiency of contaminants and the formation and occurrence of DBPs (4). The water distribution system may itself add further contaminants to the water supply (e.g. leakage of groundwater into during periods of low drinking water distribution pressure) (7).
4. Drinking water is regulated by water quality guidelines. Regulation (20) has an impact on all stages of the drinking water cycle, including water treatment methods and distribution systems, on pollution of ground surface and re-used waters (1), waste water quality (15) and on water shortages (19), all of which may impact on drinking water quality (8).
5. The consumption of drinking water from the public water supply system depends on personal behaviour (10) and may be determined by e.g. cultural and socioeconomic factors, climate change (17), risk perception and taste and odour (9) of the water. Exposure routes (12) include ingestion, inhalation and skin absorption, all of which may play a role in the uptake of contaminants such as trihalomethanes. Food (11) may also play a minor role.

6. The contaminants taken up throughout the network of pathways and exposure routes may lead to an increased dose in humans and increased risk of health effects such as adverse reproductive outcomes and cancer (14). The dose determines the risk and severity of disease. Some members of the population may be more vulnerable because of e.g. age, socioeconomic status or genetic predisposition (13).
7. Health effects (and precursor physiological responses) result in a range of societal impacts (21), which may be expressed in terms of the aggregate effects on life expectancy or quality of life (e.g. DALYs), economic opportunity, societal and economic costs etc. (which may be estimated in monetary terms), which may also feed back to potentially compound health impacts on certain groups within society more than others (13).
8. Waste water (15) may be re-used as source water and enter the cycle again, which may have implications for the treatment of the water and the final concentrations of pollutants in treated water.

### 4.3 Study area

The assessment will be carried out at the state level and will initially focus on five EU member states: Spain, UK, Finland, Hungary and Romania. These five countries were chosen so as to represent variation in climate, population, infrastructure, history, data availability, economy, (geo) politics, healthcare systems, diet and other factors. This approach provides results tailored to identifiable regions with the EU, each with its own particular water-related issues and will also allow analysis of variation both within and between individual EU member states.

Given that the focus of this assessment is on water intended for human consumption, the level at which this water is distributed and its quality monitored in each country should be defined. In the UK, water monitoring is carried out for each water supply zone, which, 'in relation to a water undertaker and a year, means an area designated for that year by the water undertaker in accordance with regulation 3' and 'an area whose population immediately before the beginning of the year in question is estimated by the water undertaker to exceed 100,000.'<sup>2</sup> The Drinking Water Directive requires that monitoring data is submitted by any party supplying water as either 'individual supplies of water exceeding 1 000 m<sup>3</sup> a day as an average or serving more than 5 000 persons'<sup>3</sup>. Other European countries use alternative terminology to define the zones to which drinking water is supplied, but for the sake of simplicity in this document, the term 'water supply zone' will be used. In Spain, the equivalent spatial unit of interest is the area in which each water company supplies water from a given water source and a given treatment type. In Finland monitoring data is collected according to similar criteria as in the UK (1000 m<sup>3</sup> or 5000 users). The number of the samples per year depends on the amount of drinking water distributed per day. Samples are taken from taps and as such their locations should represent water quality in different parts of the distribution system. Samples are also taken from buildings where a high level of water quality is crucial (e.g. hospitals, schools, food industry etc.) It should be noted that while, for example, it may be appropriate in the UK to work at the water supply zone level, the equivalent spatial units in Finland may be very sparsely populated. In this case it will obviously make more sense to either aggregate zones (if practical) or concentrate on the more densely populated areas of the country. The administration of drinking water distribution in Romania and Hungary has yet to be confirmed.

### 4.4 Study population

The assessment will focus to a large extent on two subgroups of the general population of each of the case study countries:

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<sup>2</sup> The Water Supply (Water Quality) Regulations 2001. Water, England and Wales. 2001 No. 3911 (W.323)

<sup>3</sup> Council Directive 98/83/EC on the quality of water intended for human consumption.

1. Pregnant women and their developing fetuses. This group is of particular relevance since the chemical parameters of interest have been associated with reproductive effects impacting on developing fetuses.
2. Elderly people. Because of the potential carcinogenicity of the chemical parameters of interest and the long latency times associated with cancer, it will be appropriate to estimate previous exposure and assess the cumulative effects of exposure over several decades. This means assuming a posterior perspective for the assessment, for which it will be necessary to take 2001 as a baseline year and make a number of assumptions regarding historical exposure as necessary.
3. Other subgroups may be considered in the assessment. Recent research suggests that certain subgroups of the general population - for example, those characterized for the gene polymorphisms CYP2E1 and GSTM - may be more genetically susceptible to developing cancer. Aetiological reasons for this susceptibility may not always be clear, but epidemiological research has shown that there are associations between individuals carrying certain alleles and subsequently developing specific cancers. Whilst this research is rather poorly developed, it may be possible to conjecture the likely percentages of the study population exhibiting such genetic susceptibility and to factor this into the health impact results of the assessment.

The two main subgroups (pregnant women/foetuses and the elderly) represent populations with different relevant exposure periods because of the short latency period in the case of reproductive outcomes and the extended latency time in the case of cancer outcomes. This will necessitate the assessment of exposure on a long timescale (in the order of two or more decades) for cancer outcomes and a short timescale (in the order of trimesters or even months of pregnancy) for the reproductive outcomes, both estimations may necessitate the use of modelling (as appropriate to the temporal resolution of the available data) so as to arrive at as accurate an estimate of exposure as possible.

#### **4.5 Stakeholders' views on the WP3.4 assessment scope**

Figure 8 in Appendix 6 shows all of the changes suggested by stakeholders. Using this diagram adjustments have been made to the final scoping diagram as shown below in figure 2. The rationale for inclusion or exclusion of suggested additions to the diagram as well as various other points made by the stakeholders is laid out below.

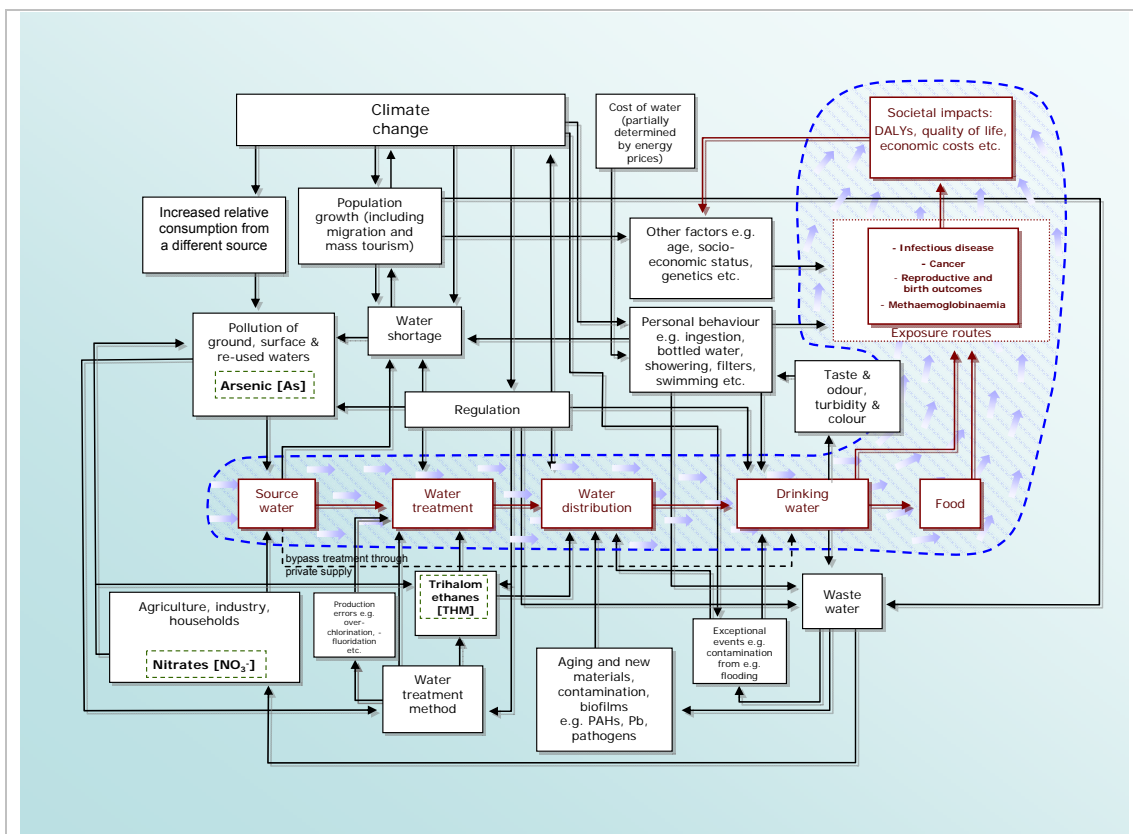


Figure 2 - Framework scoping diagram incorporating suggestions made by stakeholders (see Figure 1 for comparison). Those items incorporated into the diagram include: production errors at plant (over chlorination etc.), biofilms, exceptional events e.g. contamination from flooding, and cost of water.

#### 4.5.1 Framework diagram

See figures 1, 2 and 8 for reference.

Incorporated	Rationale	Excluded	Rationale
Production errors e.g. over-chlorination/ fluoridation etc.	The initial version of the framework diagram had overlooked the relevance of process mistakes in increasing levels of various chemicals in drinking water.	Sabotage	Although sabotage of water supplies is gaining attention in the current political climate, it was considered that since such events have not been carried out in Europe, data on such events is poor. The probability of such an event is also considered extremely low by many of those working in the field. In addition the range of potentially useful chemicals and microbes is extremely wide, making any general conclusions hard to draw.
Biofilms (as a factor in aging materials)	The formation of biofilms is of particular relevance to aging materials in distribution networks and can have implications not only for microbial contamination (and subsequent increases in required chlorine residuals), but also effect the non-microbial composition of drinking water.	Diffuse sources of contamination	This was not included since it was considered as being covered by other variables in the diagram.
Exceptional events e.g. contamination from flooding	Flooding per se had not yet been included in the diagram, although this represents both a potential microbial and non-microbial health risk. The risk		

	of flooding (and drought) is also increasing in many regions, potentially as a result of climate change.		
Cost of water (partially determined by energy prices)	This has been included since the cost of water (both tap and bottled) is a clear driver in people's drinking habits and subsequently their exposure.		

#### ***4.5.2 Microbial risk***

The decision was made early on to exclude microbial contaminants from this assessment since many of the WP3.4 partner institutions are involved in other high profile European projects on microbial pollution of drinking water (e.g. HiWATE, MICRORISK etc.) and the WP3.4 team's expertise is particularly focused on non-microbial drinking water contaminants.

#### ***4.5.3 Acute versus chronic risks***

WP3.4 is not looking at the acute risks of drinking water contamination (e.g. eczema and other topical skin conditions etc.) since evidence on these associations is currently somewhat inconclusive and data availability poor.

#### ***4.5.4 Economic drivers of water contamination and exposure***

In developing its policy scenarios for the second pass assessment, WP3.4 will attempt to consider the various roles played by a number of economic drivers in exposure to water contaminants. There are a whole range of factors that are affected by the relative economic prosperity of a population that may impact on exposure to drinking water contaminants, ranging from the quantity of bottled water consumed to the degree to which water pollution is controlled at source through effective legislation and enforcement.

#### ***4.5.5 Varied performance of water supply systems***

The fact that all water supply systems do not perform equally well was omitted in the policy scoping report. Assessment of the service quality of the supply (interruptions, losses etc) should, therefore, be taken into account. If data are available on the service quality of the supply at the appropriate level, it may be possible to factor this into the assessment.



## 5 Assessment methodology

The WP3.4 assessment essentially follows an exposure-based INTARESE approach that emphasises the importance of the full causal chain between. Figure 1 shows the assessment framework for the water policy assessment. Appendix 1 gives detailed descriptions of all variables (i.e. each box) included in the framework diagram. Appendix 2 is a summary of those variables that make up the focus for the assessment, the methodological steps of which are represented in schematic form in Appendix 4. Note that a framework diagram incorporating all stakeholder comments received thus far is given in Appendix 5.

The following section provides details of how methods/models and data are to be used in quantifying each of the key components of the assessment. The frameworks given in figures 1 and 2 represent considerably complicated views of the assessment, in which variables are multiply interrelated. Figures 3, 4 and 5 present a simplified version of the framework, and incorporate only those variables essential to individual assessments of the chemical parameters of interest i.e. arsenic, disinfection by-products (TTHMs) and nitrates respectively. Note that the causal chain is the main feature common to all of these frameworks.

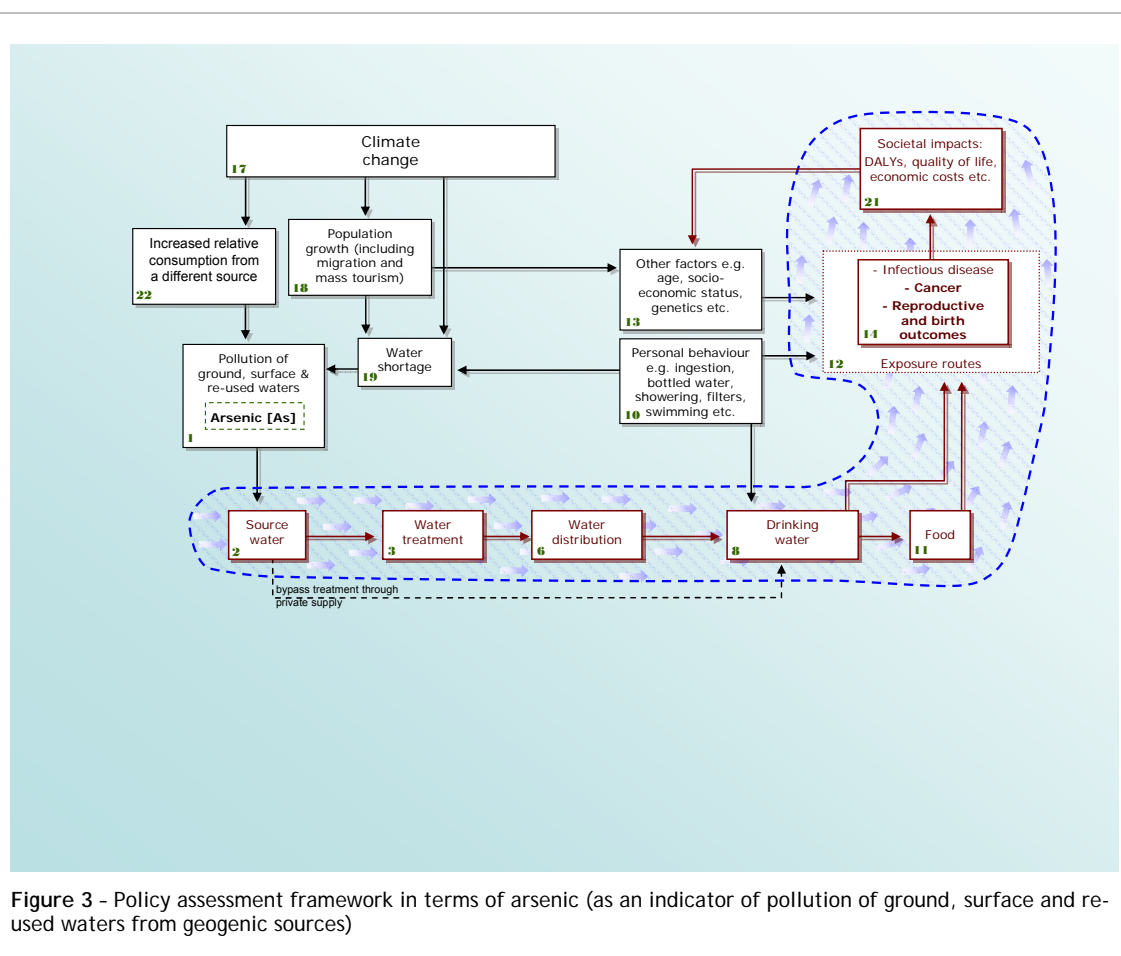


Figure 3 - Policy assessment framework in terms of arsenic (as an indicator of pollution of ground, surface and re-used waters from geogenic sources)

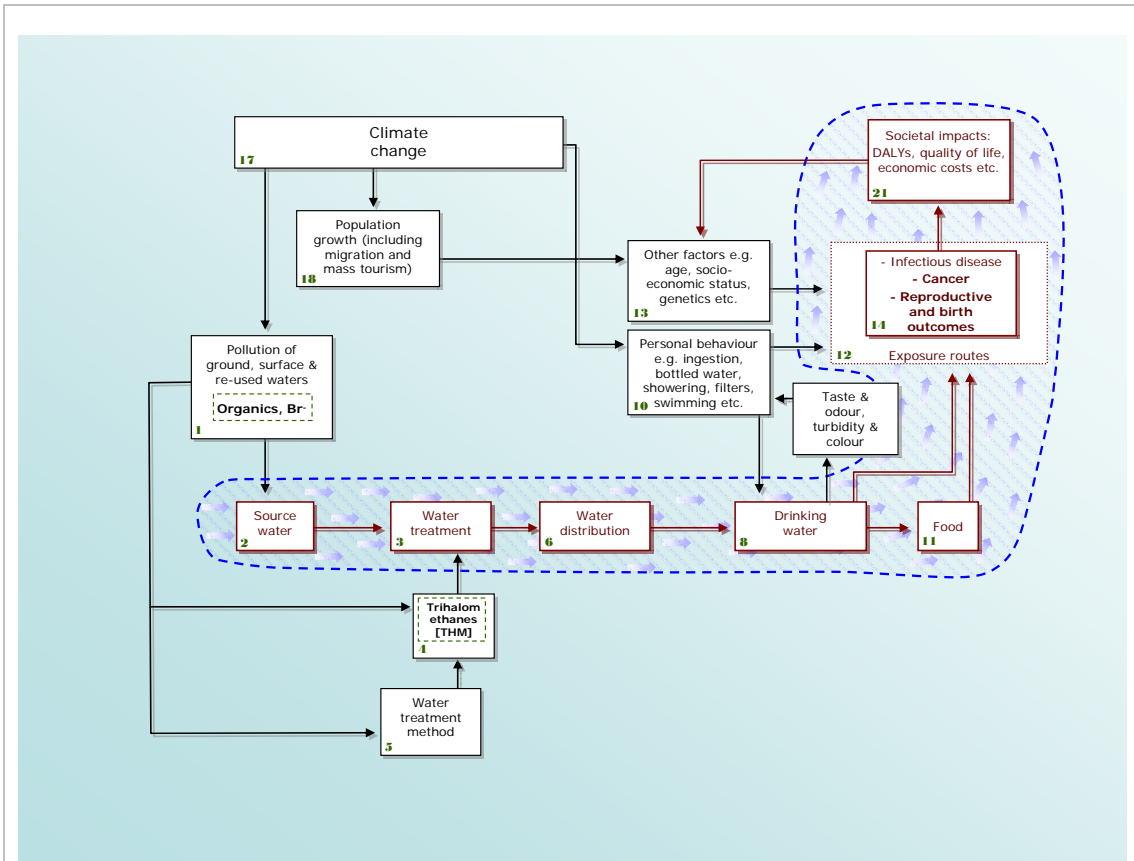


Figure 4 - Policy assessment framework in terms of trihalomethanes (THMs) (as an indicator of disinfection by-products generated in treatment of water for human consumption)

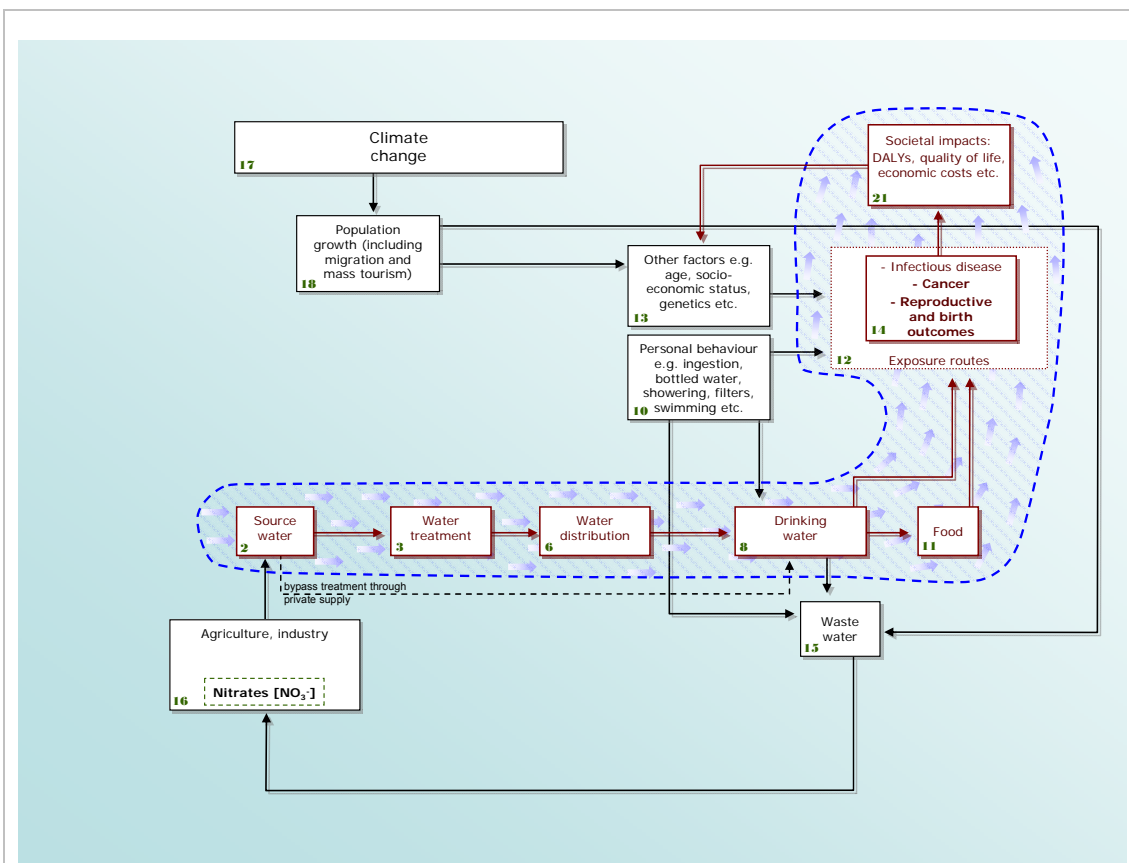


Figure 5 - Policy assessment framework in terms of nitrates (NO<sub>3</sub><sup>-</sup>) (as an indicator of agricultural pollution from fertilisers)

The actual method proposed for the calculation of health impacts associated with the framework to be investigated is given in figure 6.

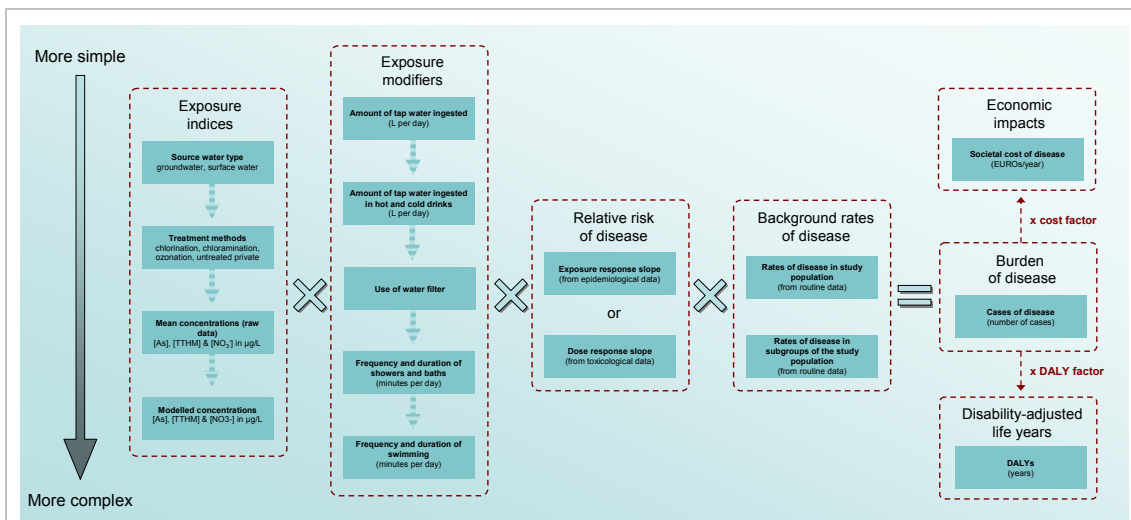


Figure 6 - Proposed overall method for calculating the burden of disease associated with contamination of drinking water by the chemicals. Note that each group of variables represents a hierarchy in the evaluation process ranging from those using the most basic data (at the top) to more complicated and/or more sparse data (at the bottom) i.e. primarily it is possible to use only source water type and amount of tap water ingested together with an appropriate exposure-response function and the background rate of a disease to arrive at a simple estimate of disease burden. At the other end of the scale it is possible to make use of modelled concentrations for a chemical parameter, various measures of exposure (including ingestion, bathing and swimming), using a combination of epidemiological and toxicological data to arrive at an exposure/dose-response function and background rates of disease to estimate a more precise estimate of burden of disease.

The assessment itself will consist of at least two passes. In the first pass, the aim is to arrive at a measure of burden of disease associated with each of the three chemical parameters of interest, assuming a business-as-usual policy scenario. As demonstrated in Figure 6, this assessment will be iterated at increasing levels of complexity, depending on data availability. The second pass assessment will then attempt to both estimate burden of disease assuming alternative policy scenarios, and to estimate the impacts of this in terms of economic and DALY indicators.

## 5.1 Source-exposure

This section provides details of the methods/models and data to be used in quantifying each of the key components in the source-exposure part of the model, how they will be employed, and where they are to be derived from.

It is necessary at this point to make some comment on the general temporal direction of the assessment. In order to estimate health impacts associated with a policy, the assessor must be clear about whether the assessment has a retrospective or prospective viewpoint. Some practitioners consider anything other than retrospective HIA to be a totally different kind of assessment. Given that the WP3.4 assessment is not presented as a straightforward HIA, mainly due to the way in which it is split into two phases, this definition may be overly restrictive in any case. While the WP3.4 assessment need not be fit into the confines of a strict definition of HIA or risk assessment as such, the issues related the temporal framework are key to developing a sound methodology for many steps of the assessment, from estimation of exposure to estimation of impacts.

### 5.1.1 Description of methods

#### **Sources, parameters and demographic data**

Primarily data on **source water type** (groundwater, surface water) and **water treatment type** (e.g. chlorination, chloramination, ozonation, private untreated supply) associated with the appropriate distribution level\* will be gathered for UK, Spain, Finland, Hungary and Romania.

**Annual monitoring data** for the five case study countries will then be collected for the appropriate distribution level\* on the chemical parameters arsenic (As), total trihalomethanes (TTHM) and nitrate (NO<sub>3</sub><sup>-</sup>).

- ☞ [As]<sub>drinking water</sub> (µg/L)
- ☞ [TTHM]<sub>drinking water</sub> (µg/L)
- ☞ [NO<sub>3</sub><sup>-</sup>]<sub>drinking water</sub> (mg/L)

Given the long latency times of cancers, the temporal coverage of all these data (i.e. source type, treatment type and monitoring data) should be as great as possible, and **historical concentrations** of these parameters should ideally be obtained as far back in time as is possible.

Should reliable historical data not be available it may be necessary to assume historically constant concentrations of these parameters in each water supply zone. Modelling of historical concentrations back to 1940 should provide adequate data for better estimating exposure for cancers. Given that such an analysis may present an unlikely representation of the actual concentrations of these substances, these **modelled historical concentrations** could be extrapolated from current monitoring data and weighted according to changes in

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\* Article 13 paragraph 2 of 98/83/EC states that ‘...each Member State shall publish a report every three years on the quality of water intended for human consumption with the objective of informing consumers... Each report shall contain, as a minimum, all individual supplies of water exceeding 1 000 m<sup>3</sup> a day as an average or serving more than 5 000 persons...’

water sources (ratio of ground to surface water) and history of treatment type (i.e. when treatment was introduced, what kind of treatment etc.)<sup>4</sup>

For better classification of exposure during pregnancy (i.e. in connection with adverse reproductive outcomes etc.) it may prove necessary to model concentration data not only spatially (i.e. from water supply means) but also to model concentration data temporally, thus establishing likely concentrations for each trimester or month of pregnancy. For both kinds of modelled data it will be necessary to compare the raw data with the modelled data using ANOVA to see if modelling of the data is helpful in classifying exposure.

**Demographic data** at this level will also be required, including distributions of age, sex and birth rates, as well as rates of stillbirths, low birth weight and low birth rate for gestational age in each water supply zone: it is unlikely that demographic data will be available at the water supply zone level for all countries, since such data is collected through censuses carried out for different administrative units. A means for reconciling the two kinds of data will need to be worked out, by which distributions of population data will need to be attributed to the water supply zone level. WP2.1 is to be responsible for gathering this data.

It may be necessary to assign each water supply zone to a group (high/medium/low) describing [TTHM]<sub>drinking water</sub> rather than use a continuous scale of concentrations (which would potentially present modelled concentrations at a high level of precision but low level of accuracy). In order to assign concentrations to groups, it would be necessary to use nested ANOVA as a means of arriving at groups exhibiting the largest possible degree of between group variance.

Additional data to be provided through literature review will include typical mean [TTHM] in swimming pool water ( $\mu\text{g/L}$ ). Ideally typical means might be estimated at the country level, should such data be available.

#### ***Personal behaviour & exposure data***

Trends in personal behaviour for the study population will then be generated by a process of literature review. Primarily the assessment will focus on ingestion. Literature review and collection of data from any other sources will be used to model population exposure distributions for the following indexes of exposure:

- ☞ Amount of tap water ingested per day (cold drinks) (in L)
- ☞ Amount of tap water ingested per day (hot drinks e.g. tea/coffee) (in L)
- ☞ Consumption of bottled water per day (in L)
- ☞ Use of a granular activated carbon (GAC) filter

It would also be of interest to collect data on ratio of tap water consumption from hot/cold drinks since this has important implications for TTHM levels.

Other modelled population exposure will be required to take into account exposure of the same populations to other sources of (particularly) THMs. These modelled distributions will be arrived at from the following data:

- ☞ Frequency and duration of showers (in minutes/day)
- ☞ Frequency and duration of bathing (in minutes/day)
- ☞ Frequency and duration of swimming (in minutes/day)

Where possible it will also be necessary to make exposure estimates specifically applicable for pregnant women, who have been shown in a number of studies to exhibit specific behavioural patterns (e.g. drinking, swimming etc.). This will be done through a process of literature review.

Simulated exposure of each subgroup to modelled concentrations for each chemical

<sup>4</sup> Villanueva CM, Cantor KP, Grimalt JO, Malats N, Silverman D, Tardon A, Garcia-Closas R, Serra C, Carrato A, Castano-Vinyals G, Marcos R, Rothman N, Real FX, Dosemeci M, Kogevinas M. Bladder cancer and exposure to water disinfection by-products through ingestion, bathing, showering, and swimming in pools. *Am J Epidemiol.* 2007 Jan 15;165(2):148-56

parameter of interest via the ingestion routes at the water supply zone level will be estimated. Where data are not available at the water supply zone level, aggregate country-level data may be used in order to arrive at an appropriate distribution, making use of appropriate guidance in the literature. In all cases, preference will be given to data from those studies considered to be most geographically relevant (i.e. making use of country-specific and/or European data as much as possible). Given that the inhalation and absorption exposure routes are essentially of greatest importance to THM exposure, population exposure distributions will also be modelled for these.

The result of this step of the assessment will be a set of population exposure distributions for each of the parameters of interest measured in  $\mu\text{g}$  per day.

### 5.1.2 Use of proprietary models and their modification

It is not anticipated that the implementation of the WP3.4 methodology will require the use of any proprietary models.

### 5.1.3 Use of routine data

Various sets of routine data will be used in the assessment for each of the case study countries:

- ↪ Routine monitoring data on all three chemical parameters of interest. These are to be obtained from the competent authorities in each of the case study countries, who are obliged under the DWD to regularly monitor drinking water quality. In the UK the data are collated by the Drinking Water Inspectorate, whereas in other European countries (including some of the case study countries) such monitoring data may be held by individual water companies.
- ↪ Demographic data (age, sex, life expectancy at birth, birth rate). This data is to be provided by WP5.1.

The names of these routine databases in each case study country, their providers and brief descriptions/notes, are given in the tables below.

### 5.1.4 Drinking water monitoring routine data

Case study country	Drinking water monitoring database	
UK	<i>Name</i>	Monitoring data for UK drinking water
	<i>Provider</i>	Drinking Water Inspectorate (DWI)
	<i>Desc/notes</i>	This database represents a compilation of quarterly monitoring of drinking water in the UK as provided by water companies to DWI for reporting purposes to UK Government as mandated under national and European legislation.
Spain	<i>Name</i>	Monitoring data for water companies
	<i>Provider</i>	Water companies
	<i>Desc/notes</i>	Very time demanding to collect this data. Difficult to update. There is available data from previous epidemiological studies conducted. The national organism controlling water quality does not provide this data. It's considered confidential and public access is not possible.
Finland	<i>Name</i>	Monitoring data for Finnish drinking water
	<i>Provider</i>	National Public Health Institute, Ministry of Social Affairs and Health, National Product Control Agency for Welfare and Health
	<i>Desc/notes</i>	Data is collected by municipal health protection authority from waterworks producing water for over 5000 consumers or more than 50 m <sup>3</sup> /day. This data is covering about 3.8 million people from Finnish population of 5.2 million. Data has been collected together since 2002.
Hungary	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	
Romania	<i>Name</i>	No details yet available

<i>Provider</i>	
<i>Desc/notes</i>	

### 5.1.5 Purpose-collected data

The use of purpose-collected data is not anticipated for the WP3.4 assessment.

## 5.2 Dose-/exposure-response

WP1.3 recommends that SP3 assessments should primarily make use of up-to-date exposure-response functions (ERF) published by an authoritative or influential institute or organisation e.g. WHO. In the absence of such an ERF it will be necessary to use frequentist systematic review (including meta-/pooled-analyses as appropriate).

As shown in the schematic overall assessment diagram (Appendix 4) an ERF may be arrived at either through review of epidemiological data or, in its absence, through the use of uptake estimates and internal dose-response data (i.e. using toxicological data). Preference will be given throughout the assessment to the use of the former, although uptake modelling may be used in the absence of sufficient data e.g. in the case of mixtures such as THMs.

The steps outlined below indicate briefly how dose-/exposure-response will be estimated for the parameters of interest in WP3.4.

### ***Uptake - dose-response***

Through a process of literature review, uptake factors will be estimated for the study populations for each exposure route i.e. ingestion (drinking, eating & swimming), inhalation (showering, bathing & swimming) and absorption (showering, bathing & swimming).

Uptake/bioavailability can then be used to transform population exposure distribution data ( $\mu\text{g}/\text{L}_{\text{drinking water}}$ ) so as to arrive at estimates of internal doses (or absorbed doses) of the parameters of interest within the population (in  $\mu\text{g}/\text{L}_{\text{blood}}$ ). By carrying out a meta-analysis of toxicological data on each substance for each exposure route, it is theoretically possible to arrive at estimates of response in terms of relative risk or percentage increases in

morbidity per amount of those substances.

### **Exposure-response**

The use of “up-to-date exposure-response functions (ERF) published by an authoritative or influential institute or organisation” advised by WP1.3 is not a possibility for this policy assessment. In order to arrive at ERFs for each of the parameters it will be necessary to carry out systematic reviews of the epidemiological literature for all the health endpoints of interest.

In the case of those health endpoints for which a large quantity of data is available, pooled analysis will be used to derive ERFs e.g. bladder cancer.<sup>5</sup> For health endpoints such as stillbirth, it will be necessary to carry out a full meta-analysis of previous studies.

The fact that data on THMs will only be available to represent a mixture presents a particularly complicated set of issues in terms of setting an ERF. Further advice on the methodological details of how best to derive suitable exposure-response functions for the purposes of the WP3.4 assessment will be sought from WP1.3, which is still working on guidelines relating to this issue.

The ERFs themselves will be presented as a slope of a regression line or a relative risk for a given exchange in exposure including some measure of the uncertainty associated with this number i.e. a confidence interval.<sup>6</sup>

Note: full guidelines on the methodological approaches advised for carrying out systematic reviews are included in the WP1.3 assessment protocol.

#### **5.2.1 Weighting, selection and/or combination of different estimates of dose-response**

In short, it will be necessary to make decisions early on in the assessment as to exactly which kind of exposure we are aiming to model i.e. time-averaged exposure, cumulative exposure or peak exposures. NOTE: We could keep both. The chief factor affecting this choice will be the disease outcome of interest. Awaiting additional guidance from WP1.3. For nitrates only short-term exposure, nitrite may have some long term effects.

### **5.3 Health impacts**

#### **5.3.1 Means of Estimating Disease Burden and/or Health Impact**

##### **Burden of disease estimates**

Burden of disease estimates for each health outcome can be arrived at through the basic formula illustrated in figure 7 (also shown in more detail in figure 5):

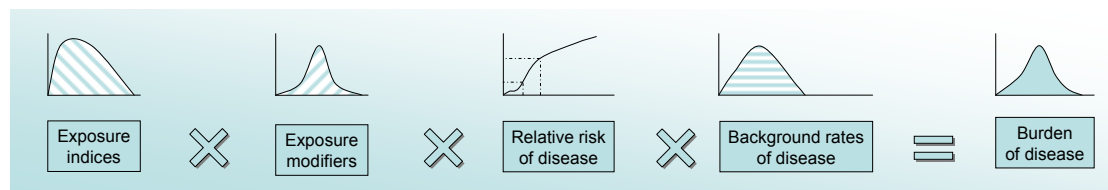


Figure 7 - Simplified schematic formula proposed for estimating burden of disease using probability distributions and hence incorporating variability and uncertainty, which are propagated through the model.

It is apparent that the results of such a process are highly dependent on the choice of distribution that is assigned to any one variable. Where raw data does not serve as a suitable guide, literature review and expert knowledge from within the WP3.4 team will be

<sup>5</sup> Villanueva, CM, Cantor, KP, Cordier, S et al. (2004) "Disinfection by-products and bladder cancer: a pooled analysis" *Epidemiology* 15: 357-367.

<sup>6</sup> Boogaard H, Hoek G, Pekkanen J, Yli-Tuomi T, Pedeli X. Exposure-response assessment protocol. Third draft. *INTARESE internal document*. 19<sup>th</sup> January 2007.



used as the chief means to assess the most appropriate probability distribution for any one variable.

By combining probability distributions attributed to the exposure indices (e.g. source water type, annual mean values for chemical parameter concentrations), modifiers of exposure (i.e. personal behaviour), relative risk of disease (i.e. exposure-response/dose-response slopes) and background rates of disease, we can estimate a level of disease burden for those outcomes of interest. Since each of the variables in this calculation is attributed a probability distribution (representing degrees of variability and uncertainty of raw data, or modelled variability and uncertainty in modelled data), it will be possible to arrive at an estimate of burden of disease represented by a distribution. This will represent the excess number of cases of the disease in the study population accounted for by the water pollutant of interest, and may be presented in statistical terms i.e. a measure of central tendency for that distribution and a measure of variation to indicate its spread.

DALY values may be available for some health outcomes from WHO Global Burden of Disease (GBD) reports. These can be used to translate the excess cases of disease estimated in this step of the assessment into a true measure of burden of disease. Note that this will only be required in the second pass of the assessment and will be carried out following guidance produced by other work packages e.g. WP1.4 (see section 1.1)

The methodological means of disaggregating any one chemical's attributed burden (both for those chemicals with common health outcomes and for those with different outcomes) has yet to be determined.

In order to estimate a meaningful disease burden from a specific risk factor, the exposure distribution of interest should be compared to an alternative (or counterfactual) scenario.<sup>1</sup> The counterfactual scenario to be used in this case is that of policy change which would impact on water quality at the national (i.e. case study) level, or at the European level (which would necessitate change across all case-studies). The two passes of the assessment represent an estimation of disease burden resulting from the business-as-usual, policy situation (first pass) and from alternative policy scenarios (second pass), and the subsequent comparison of these two estimates (see section 4.2).

### 5.3.2 Population health data - sources and characteristics

Routine population health data relating to cancers and reproductive health outcomes (low birth weight, low birth weight for gestational age, methaemoglobinaemia etc.) will be used in assessing the estimates made of disease burden. Sources of this data are indicated in the tables below for each of the case study countries. Please note that this is only listed here for completeness. WP2.3 will be collecting routine population health data on behalf of the SP3 work packages on the basis of a questionnaire, which is attached as Appendix 7.

#### 5.3.3 Cancer

Case study country	Routine health data on disease rates in study population	
UK	<i>Name</i>	National Cancer Registration System databases
	<i>Provider</i>	Office for National Statistics (mortality) & UK Association of Cancer Registries (Incidence)
	<i>Desc/notes</i>	Cancer registration in England is conducted by nine regional registries which collect and collate data on cancers resident in their area, and submit a standard dataset on these registrations to ONS. The national assembly for Wales is now responsible for cancer registration in Wales. The registration system in Scotland is coordinated by the information and statistics division (ISD) of the NHS in Scotland. The national cancer intelligence centre (NCIC) at ONS coordinates the national collation of cancer registration data and carries out a wide range of secondary analysis and research.
Spain	<i>Name</i>	National Epidemiology Centre, Carlos III Health Institute
	<i>Provider</i>	<a href="http://www.isciii.es/htdocs/centros/epidemiologia/epi_cancer.jsp">http://www.isciii.es/htdocs/centros/epidemiologia/epi_cancer.jsp</a>

	<i>Desc/notes</i>	Mortality rates for different cancer sites by province. Incidence rates are only available in cancer registries in 9 provinces. Data is more difficult to obtain.
Finland	<i>Name</i>	Finnish Cancer Registry
	<i>Provider</i>	National Research and Development Centre for Welfare and Health (STAKES), The Cancer Society of Finland
	<i>Desc/notes</i>	The Finnish Cancer Registry is an institute for epidemiological and statistical cancer research, founded in 1952. It maintains a nation-wide database on all cancer cases in Finland since 1953. Mass-Screening Registry is a part of the Finnish Cancer Registry. It maintains a database on the three national cancer screenings that are carried out in Finland. Recently, the Mass-Screening Registry has initiated the nationwide screening programme for colorectal cancer - the first of its kind in the world. The Finnish Cancer Registry is funded by the Cancer Society of Finland and works very closely with all cancer organisations but is administrated by the state-owned National Research and Development Centre for Welfare and Health (STAKES).
Hungary	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	
Romania	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	

### 5.3.4 Reproductive health outcomes

Case study country	Routine health data on reproductive health outcomes	
UK	<i>Name</i>	FM1: Birth Statistics: Births and patterns of family building England and Wales
	<i>Provider</i>	Office for National Statistics (ONS)
	<i>Desc/notes</i>	'This reference volume presents statistics on live and still births occurring annually in England and Wales. Statistics for births in previous years are included to show trends in fertility.  The publication covers birth counts and birth rates tabulated by, among other attributes, parents' age, occurrence within or outside marriage, multiple births, mother's area of residence and country of birth, place of confinement, and father's social class (defined by occupation). Information on the sex ratio and birthweight is also included.' <sup>7</sup>
	<i>Name</i>	NCAS (National Congenital Anomaly System)
	<i>Provider</i>	BINOCAR (British Isles Network of Congenital Anomaly Registers)
	<i>Desc/notes</i>	'Regional and disease specific registers across the British Isles have joined together with the national systems for congenital anomaly data collection for England & Wales and Scotland to form the British Isles Network of Congenital Anomaly Registers.' <sup>8</sup>
Spain	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	
Finland	<i>Name</i>	Medical Birth Register, Register of Congenital Malformations
	<i>Provider</i>	National Research and Development Centre for Welfare and Health (STAKES)

<sup>7</sup> UK Office for National Statistics (accessed 13/02/07) <http://www.statistics.gov.uk/statbase/Product.asp?vlnk=5768>

<sup>8</sup> BINOCAR (British Isles Network of Congenital Anomaly Registers) (accessed 01/03/07) <http://www.binocar.org/index.htm>

	<i>Desc/notes</i>	<p>The Medical Birth Register was established in 1987. The reforms of the Register in 1990, 1996 and 2004 were aimed at improving its reliability. The Register includes data on live births and on stillbirths of fetuses with a birth weight of at least 500 g or with a gestational age of at least 22 weeks, as well as data on the mothers. The Register incorporates a data file on small preterm infants for which data have been collected since 1 November 2004. The data file contains additional data collected by means of a separate form concerning all live births in Finland with a birth weight of less than 1500 g or with a gestational age at birth of less than 32+0 weeks. The data are collected until the infant's age corresponds to 42 weeks' gestation.</p> <p>The Register of Congenital Malformations contains national-level data on congenital chromosomal and structural anomalies detected in stillborn and live born infants and fetuses. Data on some 4000 congenital anomalies are annually reported to the Register, of which some 2000 are major congenital anomalies. The Register of Congenital Malformation was established on 29 December 1962. Registration of anomaly data began on 1 January 1963.</p>
Hungary	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	
Romania	<i>Name</i>	No details yet available
	<i>Provider</i>	
	<i>Desc/notes</i>	

## 5.4 Secondary and subsequent impacts (costs)

### 5.4.1 Estimation of monetary and other impacts

It will not be necessary to estimate economic costs under the first pass assessment. The costing under the second pass assessment will largely be carried out according to methodologies designed by WP1.4 after month 18. The following section describes some of the basic issues to be considered in estimating monetary costs of health impacts.

It is possible to measure the impact of water pollutants on health according to a number of methodologies, which can broadly be divided into local (e.g. national) economic evaluations and more global measures of impact such as disability-adjusted life years (DALYs). Estimation of these local economic costs would entail the estimation of costs through a 'cost of illness' assessment (COI) (otherwise known as 'burden of illness') study. These estimates should combine direct, morbidity and mortality costs, phase-specific costs, long term costs and indirect costs.<sup>9</sup> DALYs are more global in the sense that they provide a comparative measure of health impact relative to a maximum global life expectancy. All of these means of estimating monetary and other secondary/subsequent impacts of disease are limited in terms of the uncertainties associated with them and in terms of the political sensitivity of assumptions that are made in their calculation, hence uncertainty analysis forms a key part of their use and their short-comings should be reported clearly.

The economic analysis to be employed in this assessment will incorporate review of the literature and information held in national databases and registries in order to arrive at estimations of direct costs (those costs associated with use of resources associated with disease and treatment) and indirect/productivity costs (those costs incurred by society related to loss of production owing to disease and treatment). Due to the inherent complexities of estimating intangible costs<sup>10</sup>, this assessment will exclude them from the analysis.

The necessary steps employed in this process, according to Kobelt (2002), are as follows:

<sup>9</sup> Brown ML, Lipscomb J, Snyder C. The Burden of Illness of Cancer: Economic Cost and Quality of Life. *Annu. Rev. Public Health* 2001. 22:91-113

<sup>10</sup> Kobelt G. Health Economics: An Introduction to Economic Evaluation. Second Edition. *Office of Health Economics* 2002.

1. Identify (even those considered not to be measurable)
2. Quantify costs (in units such as hospital admissions etc.)
3. Assign value to the different resources used at the opportunity costs
  - micro-costing e.g. using wages to estimate costs
  - macro-costing e.g. cost estimates based on aggregate measures of resources use
4. Deal with differential timing at which resources use can occur.

It is necessary to determine from which perspective costing analysis will be carried out. In a policy-related assessment such as WP3.4, a societal perspective is the most appropriate means of estimating costs associated with burden of disease since it includes all costs regardless of which party incurs them. The only kinds of costs exempt from this perspective are so-called transfer costs i.e. those costs, such as taxes and pensions, which do not result in the exhaustion of resources (such as labour or capital). It is worth noting that these estimations of costs are expressed as the willingness of society (or individuals) to pay for prevention or mitigation of the disease outcome.

Typical societal costs that require incorporation into a cost of illness assessment are:

- ↵ Hospital inpatient care
- ↵ Ambulatory care
- ↵ Drugs
- ↵ Investments into technical and/or service adaptations
- ↵ Informal care
- ↵ Indirect costs

There are two types of COI study: prevalence-based and incidence-based. Prevalence-based COIs account for all costs for a given population during a given time period. An incidence-based COI is more appropriate for WP3.4, since it presents lifetime costs for each patient with a disease (from diagnosis to death), although the lengthy time periods concerned demand more involved cost calculations.

In order to work out costs in a typical top-down prevalence-based COI it is necessary to draw data from various sources. These might include:

- ↵ National health care statistics
- ↵ Patient registries
- ↵ Cohort studies
- ↵ Insurance databases
- ↵ Cancer research organisations

#### ***5.4.2 Data sources***

In order to work out costs in a typical top-down prevalence-based COI it is necessary to draw data from various sources. These might include:

- ↵ National health care statistics
- ↵ Patient registries
- ↵ Cohort studies
- ↵ Insurance databases
- ↵ Cancer research organisations

WP2.3 (Health Surveillance) should provide further guidance on the sources of data that ought to be employed in this kind of assessment.

#### ***5.4.3 Weighting (factoring/discounting)***

Various methods may be employed in weighting estimates of the financial costs of disease burden, including the use of factoring and discounting. As above, WP3.4 will await further instruction from WP1.4.

## 5.5 Validation

### 5.5.1 Review method

Each step of the WP3.4 assessment will be open to several different stages of review by three different parties:

- ✉ WP3.4 partners - those parties involved in WP3.4 are encouraged to review the assessment at every stage of its development and execution.
- ✉ Other INTARESE partners - those both directly and indirectly involved in WP3.4 (i.e. including those relying on WP3.4 data) will be expected comment on the methodology and the findings of the assessment.
- ✉ Stakeholders - their involvement in review of key documentation leading up to the assessment and in consultation during it will govern the degree not only to which the assessment is appropriate to the policy question, but also to which the assessment meets the needs of end users.

### 5.5.2 Validation of the Model

An important and relatively obvious validation method entails starting by comparing the modelled number of health outcomes with the number of observed health outcomes. The relationship should be reasonable.

Furthermore, uncertainty assessment is used for the validation of a model or an assessment. WP 1.5 provides guidelines for helping risk assessors understand and systematically diagnose a broad range of the uncertainties characterising their assessments. Uncertainty in WP 1.5 is perceived as a two-dimensional concept, distinguishing between the Location and the Level of uncertainty. The categories of levels of uncertainties are Statistical Uncertainty (known outcomes, known probabilities), Scenario Uncertainty (known outcomes, unknown probabilities) and Identified Ignorance (unknown outcomes, unknown probabilities). Identifying the different types of uncertainty helps to obtain an overview over the weak and strong parts of an assessment.

Another component of uncertainty analyses is to compare measured and modelled data to validate the model used (e.g. modelling concentrations). This is e.g. done with dispersion models of air pollutants. It surely is more difficult with concentrations in water but as policy scenarios will be modelled in the second pass assessment a comparison should then take place.

Sensitivity analyses show which variable(s) is/are especially important i.e. variables in which small changes subsequently result in large changes in health impacts.

Assumptions have to be made at every step of the assessment. They have to be scrutinised and implications have to be emphasised. Changes in assumptions may also lead to sensitivity analyses.

## 6 Anticipated limitations of the assessment

### 6.1 Major sources of uncertainty

Policy problems may be characterized by uncertainty levels over and above those represented statistically. For example, there may be no credible basis upon which assessors can claim to have considered all possible outcomes or all possible links in the defined policy framework. As such, it is impossible to assign these outcomes a probabilistically determined degree of uncertainty. While quantifiable uncertainties may be included for all of those foreseen components within the given policy assessment framework and be combined in the ultimate estimations of impacts or costs, unidentified uncertainties not included may cause estimates of uncertainty to be significant departures from the 'true' degree of uncertainty that should be included in those estimates. For example, the assumption of linearity between past and future environmental conditions 'breaks down very rapidly in the context of many policy issues, where conditions are far less tractable and circumscribed. In fields such as environmental health, novelty, uniqueness, complexity, irreversibility and incommensurability are often the norm.'<sup>11</sup>

The assessment for WP3.4 will therefore, in common with other risk assessment-type evaluations, be prone a number of limitations relating to uncertainties. Since the INTARESE project is in part being carried to investigate methodological issues in the risk assessment process, it is essential that these limitations are identified, diagnosed, described (quantitatively or qualitatively), minimized and, most importantly, clearly expressed to stakeholders and end-users. Given that SP3 assessments focus specifically on policy, the results of a thorough uncertainty analysis will be extremely useful in making informed policy decisions further down the line. For this reason, the uncertainty associated with the assessment should not necessarily be viewed only in terms of its limiting potential, but rather as an indicator of the extent to which the policy issue at stake is affected by lack of knowledge at the present time. This in itself will serve to prompt research and further work in areas key to each policy area.

#### 6.1.1 *Uncertainty in exposure assessment*

The WP1.5 report quoted above has been distributed amongst SP3 partners. The report outlines a typology for describing uncertainty based on that developed by Walker & Harremoës. This framework distinguishes between two types of uncertainties:

- ↳ **Location** (where uncertainty manifests itself in the model):
  - Context (choice of boundaries of the system)
  - Model structure (parameters, variables and relationships e.g. dose-response or multiple risk factors)
  - Input (data describing the system)
  - Parameters
  - Model outcome (accumulated uncertainty associated with above four types of error)
- ↳ **Level** (an expression of the severity of degree of the model, both statistical and without statistics):
  - Statistical uncertainty (known outcomes, known probabilities)
  - Scenario uncertainty (known outcomes, unknown probabilities)
  - Identified ignorance (unknown outcomes, unknown probabilities)
  - Total ignorance (nothing is known)

For the purposes of describing uncertainties specifically associated with the WP3.4 assessment, however, it is probably most useful to order the uncertainties according to the overall assessment diagram (Appendix 4) while bearing in mind the structure suggested by WP1.5.

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<sup>11</sup> Krayer von Kraus M and Martuzzi M. Cross-cutting issues in Risk Assessment - Integrating Uncertainty to Integrated Assessment. *INTARESE WP1.5 Report 2006.*

### 6.1.2 Scoping

#### Policy and framing

- ↵ The actual framing of the policy assessment is crucial to uncertainties that carry through to estimating risks and burdens of disease. This kind of uncertainty is exacerbated if the policy framework is poorly defined, misunderstood or not accepted by end-users. Failure to take the most relevant and significant policy issues into account in the framing stage may result in the use of inappropriate data, inappropriate models and thus arrive at inappropriate estimates of risk.
- ↵ Uncertainty in methods employed in the development of a science-stakeholder-policy interaction may propagate further uncertainties in subsequent stages of the assessment. It is key to set up a common 'language' with stakeholders with which both assessment and the uncertainty inherent to it can be addressed.
- ↵ The second pass assessment demands the generation of a set of alternative policy scenarios, which might only alter water pollution as an indirect effect of their implementation. The definition of these alternative policy scenarios, and the assumptions made in this step, are also prone to uncertainty in terms of their effect on water pollution and associated health impacts.

### 6.1.3 Sources, parameters & demographics

#### Uncertainties in sources and driving forces

- ↵ As with any monitoring data, analytical quality control may be variable between data sets. The quality and accuracy of the data is controlled in a normative way by European legislation.
- ↵ Availability of monitoring systems; missing data
- ↵ The use of incomparable data between different regions, countries etc. may necessitate the use of modelling or transformation in order to make them comparable.
- ↵ A small but significant minority of consumers drink water provided from private supplies that are not connected to the mains public water supply e.g. from private wells, springs or untreated surface water. The size of this subgroup varies particularly highly between case study countries e.g. between Romania (very significant proportion of population abstracting water privately) and the UK (low percentage of private abstraction). While some case study countries may have estimates of the percentage of such water use, the uncertainty associated with these estimates may be considerable. Defining the exposure of those drinking and/or using private supplies is particularly complicated since water composition often represents highly local conditions i.e. the quality water from neighbouring wells may vary considerably due to depth, local geological and hydraulic conditions, and nearby agricultural runoff. The use of such water represents a minority of people exposed to unknown or ill-defined water quality, which could have particular significance in terms of [As] and [NO<sub>3</sub>], both of which could be present in considerably elevated levels in e.g. industrial and agricultural areas respectively.

### 6.1.4 Interzone mobility

- ↵ Several studies have highlighted to need to consider the fact that the majority of water used by individuals living in any one water supply zone may not be from that supply zone but from elsewhere e.g. at their place of work in another supply zone. While in many cases the water supplied in that zone may come from the same source, this need not necessarily hold true. A proportion of any population may move between water zones with different levels of water pollution over the time periods of interest for the assessment of cancer risks. These movements have a tendency not to equilibrium, but to migration in one direction. Failure to account for the movements of large numbers of people from/into particular areas (which may in themselves be caused in part by issues related to water use) may lead to a lack in accuracy of risk estimates attributed to the populations of those areas.

- ↵ For all three chemical parameters of interest, within- and between-zone variance in water supply zone means will be used to determine the validity of using these means as a descriptor for actual concentrations at consumers' taps.
- ↵ Bayesian hierarchical modelling techniques (as outlined in e.g. Whitaker *et al.* (2004)) may be applied in order to model these sparse routinely collected data (concentrations of the three chemical parameters of interest). This will take into account heterogeneities in these concentrations between water originating from different source types, in their quarterly variation and uncertainty in the true value of no-detects (values reported as below LOD) and rounded measurements. If necessary, probability functions for geographical variation across water supply zones of  $[TTHM]_{\text{drinking water}}$  can be checked against distributions given in the literature.
- ↵ These are currently modelled from sparse sample data. Under current EU legislation, member states are only obliged to sample  $[TTHM]_{\text{total}}$  four times per year from a randomly located consumer tap within water supply zone, each of which should be no serve no more than 50,000 people. If variation across the water supply zone is high, as may be the case particularly for certain THMs, this may represent a significant source of exposure misclassification.
- ↵ The use of total THMs as a proxy for other disinfection by-products has been shown in certain instances to be ill-founded. The relatively high volatility of some THMs results in their distribution (both temporally and spatially) within the supply system that may be considerably unrepresentative of other DBPs of lower vapour pressures.
- ↵ Factors associated with the formation of DBPs are wide-ranging, and include the disinfection process, disinfection chemicals, the water source, pH, temperature, chlorine residual concentration, residence time, reaction time, total organic carbon and bromide concentrations. It is clear that this level of complexity cannot be addressed completely at the level at which this assessment takes place. Data available at this level may restrict the assessment to using only simple exposure indices in the estimation of disease burden.
- ↵ In the case of DBPs, although epidemiological studies have found associations with a number of health outcomes, the putative agents and exact pathways of effect remain largely uncertain.

### 6.1.5 Personal behaviour & exposure

- ↵ The effect of home treatment devices and consumption of bottled water, foods and drinks on total water pollutant exposure.
- ↵ Data on water consumption, usage and habits inside and outside the home.
- ↵ Uncertainty in quantification of the relationship between concentrations of DBPs in water and their eventual uptake.
- ↵ While personal behaviour may represent, in some cases, a detailed insight into personal exposure, the availability of sufficiently detailed data is generally limited to small-scale studies. Extrapolation of small-scale study data to large populations may result in the introduction of significant uncertainty into the model and in exposure misclassification.
- ↵ In the assessment of reproductive health risks it is essential to have detailed exposure data for the expecting mother and foetus. Such detailed information is sparse and small-scale studies may have to be used in lieu of data at the population level. In addition, detailed data for some case study countries may be completely lacking, necessitating the extrapolation of exposure data from studies carried out in other countries. The exposures of this subgroup may, as a result, be even more subject to exposure misclassification.
- ↵ Any modelled exposure distribution is necessarily a simplification of true exposure. The degree to which the modelled data deviates from the true exposure will depend highly on the choice of exposure indices used and the applicability of the model to the true population exposure.
- ↵ Confounders of both exposure and effects.
- ↵ Total THMs represents an uncertain mixture of four chemicals (trichloromethane, bromodichloromethane, dibromochloromethane, tribromomethane), each of which has its own physiochemical characteristics and toxicological profile. The DWD does not explicitly require Member States to monitor concentrations of individual DBPs at



the present time, monitoring instead being carried out using TTHMs as a proxy for these.

#### 6.1.6 Uptake and modelled internal doses (from toxicological data)

- ↖ Extrapolation of relationships from animal studies (from toxicological studies) to human models can introduce significant uncertainty into the assessment. Generally epidemiological data will be used to derive ERFs rather than relying on animal studies.
- ↖ Uncertainty in health effects evidence of short-term and long-term exposures.

#### 6.1.7 Exposure-response (from epidemiological data)

##### Uncertainties specifically related to derivation of exposure-response functions (ERF)

- ↖ In carrying out a meta-analysis of the literature in order to define an ERF for each of the water contaminants it is necessary to bear in mind a whole set of uncertainties that are likely to be associated particularly with epidemiological studies. A document prepared by WP1.5 suggested that those conducting meta-analyses should be wary of the following sources of bias and confounding when collecting studies for review.

Selection bias	- Ascertainment bias	<ul style="list-style-type: none"> <li>▪ Surveillance (detection) bias</li> <li>▪ Referral bias, admission bias</li> <li>▪ Diagnostic bias</li> </ul>
	- Participation bias	<ul style="list-style-type: none"> <li>▪ Self-selection (volunteerism)</li> <li>▪ Non-response bias, refusal bias</li> <li>▪ Healthy worker effect, survival bias</li> </ul>
	- Follow-up bias	
Information bias	- Other kinds of bias	
	- Measurement of bias of exposure	
	- Measurement of bias of health effect	
	- Recall bias	
	- Interviewer bias	
Confounding	- Other kinds of information bias	<ul style="list-style-type: none"> <li>▪ Publication bias</li> </ul>
	- Known confounding factors	
	-Unknown confounding factors	
	-Misclassification of confounding factors	

##### Mixtures

- ↖ Both total THMs and total arsenic in water intended for human consumption can effectively be considered as mixtures. The toxicities of the individual components of each of these parameters vary (particularly with arsenic) and therefore dose-response estimates may need to be weighted according to expected percentages of each chemical (THMs) or species (arsenic). In addition, there may be more than additive response effects to deal with, where toxicities of individual components are greater in the presence of others. It should be noted that while it is possible to collect some routine data on individual THM species in drinking water, there is no such information available on arsenic species, and since arsenic ERFs are not species-specific, such data would potentially be of limited use.
- ↖ There is very little data available to suggest how combined exposures to all the three parameters might be estimated i.e. they may exhibit responses greater than that estimated simply through addition.

#### 6.1.8 Estimation of burden of disease

##### Health impacts

- ↵ Health effects of combined exposures
- ↵ There is little research on the uncertainty surrounding psycho-social health impacts, which present particular methodological problems.
- ↵ Missing exposure-response data

#### Impact Modelling

- ↵ Uncertainty in quantitative health effects and burden of disease data.
- ↵ Identification of activities that differentiate individuals for exposures of interest versus those activities varying little between individuals.
- ↵ How uncertainty in input variables affects outputs from models e.g. use of rank-order correlations to demonstrate apportionment of uncertainty to different variables or other sources (importance analysis).

#### **6.1.9 Estimation of economic costs**

- ↵ There are a number of methodological (and ethical) uncertainties inherent to estimating intangible costs, which raise the question of how (and whether) a life, or suffering or loss of quality of life should be measured.
- ↵ An economic evaluation of health impacts can only be as good in quality terms as the data which has been used in its execution. Providing a highly precise estimate of costs of a disease caused by a water pollutant with very wide bands of uncertainty (i.e. a low accuracy estimate) may undermine communication of the risk to stakeholders.
- ↵ Uncertainty from earlier steps in the assessment carrying through. All uncertainties at each step of the assessment as a whole will gradually be incorporated into uncertain estimates of economic impacts. It is very important that any assumptions that have been made in overcoming uncertainty at each step of the assessment are made explicit such that alternative assumptions might be explored.

#### **6.2 Likely confidence limits to the assessment**

Making a gross estimate of the confidence limits of the assessment at this stage in the assessment process is difficult. Given the range of types of uncertainties that can be accounted for in the model and all of those that boundary effects that remain unaccounted for at this stage (which may also exert a considerable effect on data quality), a making estimate of confidence limits may be at the very least optimistic, and at worst highly inaccurate.

#### **6.3 Gaps in the assessment - omitted exposures**

##### **6.3.1 Microbial pollutants**

Microbial pollution of drinking water in Europe carries a significant burden of disease. Drinking water may be contaminated with pathogens originating in source water, unaffected by treatment processes, in distribution of water and in its use in the domestic environment. An analysis of the risk of microbial pollutants in drinking water has not been included in the assessment scope for a number of reasons. Firstly, the INTARESE project has been carefully designed so as not to repeat research carried out under other FP6 projects. For example, the overall aim of the HiWATE project is to '...investigate potential human health risks associated with long-term exposure to low levels of disinfectants... and disinfectant by-products (DBPs)' and 'will comprise risk/benefit analyses including quantitative assessments of risk associated with microbial contamination of drinking water versus chemical risk and will compare alternative treatment options.' Secondly, the scope of the assessment under WP3.4 is already quite ambitious in terms of breadth and timing. Thirdly, the WP3.4 assessment is making use of expertise in a specifically non-microbial field of research (that of organic/inorganic pollutants) and to include microbes in the assessment would potentially jeopardise efforts to integrate an already complicated mixture of pollutants. In order to minimise the significance of omitting microbial pollutants from the assessment, the clear framing of the policy issue has ensured that health impacts estimated under the WP3.4 assessment will be clearly attributed only to those pollutants, exposure routes, and health outcomes stated in the policy scoping process. In addition,

efforts will be made to integrate results relating to DBPs from INTARESE into the HiWATE project.

### **6.3.2 Other disinfection by-products (DBPs)**

While WP3.4 focuses specifically on trihalomethanes (THMs), there are literally hundreds of other DBPs present in drinking water including haloacetic acids (HAAs), haloacetonitriles (HANs), haloketones (HKs), chlorpicrin (CP) and nitrite<sup>8</sup>, the presence of which relates to a complex interaction of factors ranging from source-water composition to the exact technical parameters of any given drinking water disinfection and distribution system. The main European legislation governing drinking water quality (Council Directive 98/83/EC - the Drinking Water Directive) regulates total THM concentration (that is, total concentration of chloroform, bromoform, dibromochloromethane and bromodichloromethane) and bromate, but does not take into account other disinfection by-products. While much literature points to a link between [TTHM] and certain disease outcomes (notably cancers, reproductive effects and congenital abnormalities), the putative agents remain unclear i.e. these disease outcomes may be linked to one specific THM, a mixture of THMs or any of the other DBPs (or something else apparently unrelated for which TTHMs serves as a proxy).

Total trihalomethane levels have been used as surrogate for total DBP loading of the drinking water supply system, in spite of their sometimes poor correlation with individual DBPs.<sup>12</sup> Concentrations of THMs are, however, generally found in much higher concentrations in chlorinated European drinking water than other by-products, and until aetiological evidence of the putative agent in this complex mixture is discovered, TTHM still serves - albeit with some uncertainty - as a useful proxy for other DBPs.

### **6.3.3 Other organic/inorganic pollutants**

Drinking water may be contaminated to some extent with many chemicals. The DWD itself prescribes maximum concentrations ("parametric values") for 26 chemical "parameters" in order to limit their detrimental effect on health, as well as defining limits on other chemical parameters related to taste and odour.

The omission of a greater number of chemicals from this assessment has been minimised by carefully selecting chemicals that are representative of inorganic and organic pollutants arising from three kinds of sources i.e. geogenic (arsenic), agricultural (NO<sub>3</sub><sup>-</sup>) and anthropogenic (disinfection). While these selected chemicals cannot be expected to serve as proxies for all other chemicals falling within these groupings, their behaviour may at least be roughly indicative of some other closely-related chemicals in drinking water.

### **6.3.4 Exposure pathways**

This assessment focuses on those pathways of exposure regarded as comprising the greater portion of exposure to water pollutants through ingestion, inhalation and absorption. While exposure through drinking, showering, bathing and swimming will be accounted for, less significant sources of exposure for which data is either particularly scant or prone to uncertainty are ignored i.e. washing clothes and dishes, washing children, and cooking.

## **6.4 Gaps in the assessment - omitted health effects**

There are a number of potential health effects that have been associated with each of the chemical parameters of interest, but which will not be covered by this assessment. For example, disinfection by-products have been associated with elevated risks of several different cancers, but the most consistent and significance evidence has been found for an

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<sup>12</sup> Nieuwenhuijsen, M. J., Toledano, M. B., and Elliott, P. (2000). Uptake of chlorination disinfection by-products; a review and a discussion of its implications for exposure assessment in epidemiological studies. *J. Expo. Anal. Environ. Epidemiol.* 10, 586-599.

association with bladder cancer.<sup>13</sup> Efforts will therefore be concentrated on those health effects for which epidemiological, toxicological and aetiological evidence of association is greatest and results are most consistent i.e. where relative risks are highest, are characterised by high levels of confidence and explained by an accepted aetiology.

## 6.5 Expected problems in the assessment process and how they will be resolved

### 6.5.1 Stakeholder disagreement with project scope

While this document is being drafted a number of stakeholders in each of the relevant case study countries have been invited to review the project scope for the WP3.4 assessment. Should there be disagreement over this scope the water assessment protocol will require review in the light of issues raised.

### 6.5.2 Incomplete personal exposure data

Owing to the scale of the case-studies, there will be no data purpose-collected as part of this assessment. In order to work out exposure-response relationships it will be necessary to rely on studies carried out previously, on incomplete datasets of personal behaviour and on other sources of information prone to high levels of uncertainty.

### 6.5.3 Incomplete water sampling data

Under EU law public water supplies must be subject to monitoring at depending on the population supplied and the volume of water produced in any respective supply zone. The samples must be taken from random points within their distribution network i.e. at randomly located consumer taps. While generally such data should be collected on a quarterly basis, Directive 98/83/EC includes a clause that allows discretionary lower frequencies of monitoring in water supply zones where levels of a particular contaminant are consistently lower than the parametric value.<sup>14</sup> Hierarchical modelling (or other statistical techniques) might then be used to generate low values for the data missing for these periods.

Should data not be available for certain water supply zones or regions within any one of the case study countries, the scale of the assessment (i.e. the geographical area and associated study population) will be reduced accordingly. This may have implications for inter-country comparability.

### 6.5.4 Poor quality drinking water monitoring data

As with any monitoring data, analytical quality control may be variable between data sets. Quality of monitoring is to some extent controlled by European legislation 98/83/EC, which dictates acceptable levels of trueness, precision and detection limits for all three parameters of interest as follows<sup>15</sup>:

	Trueness (%)	Precision (%)	LOD (%)
As	10	10	10
Nitrate	10	10	10
TTHM	25	25	10

In order to carry out further statistical transformation of the data, rounding of figures and limits of detection (LOD) or limits of quantification (LOQ) must be taken into consideration

<sup>13</sup> Villanueva CM, Cantor KP, Grimalt JO, Malats N, Silverman D, Tardon A, Garcia-Closas R, Serra C, Carrato A, Castano-Vinyals G, Marcos R, Rothman N, Real FX, Dosemeci M, Kogevinas M. Bladder cancer and exposure to water disinfection by-products through ingestion, bathing, showering, and swimming in pools. *Am J Epidemiol.* 2007 Jan 15;165(2):148-56

<sup>14</sup> European Council Directive 98/83/EC. Annex II. Paragraph 2.

<sup>15</sup> Adapted from Council Directive 98/83/EC. Annex III. Paragraph 2.1.

and assigned values as appropriate. Such values will be arrived at using standard procedures for manipulating rounding and LOD errors in datasets.

#### ***6.5.5 Variation and uncertainty in drinking water monitoring data***

Uncertainty due to analytical quality control etc.

#### ***6.5.6 Historical drinking water quality data***

In order to work out the burden of disease associated with drinking water contaminants in terms of cancer outcomes in the population at risk, it will be necessary to gather historical drinking water quality data. Latency periods are likely to be on the scale of twenty to forty years, so in order to establish cumulative exposure over this timescale large amounts of historical data would be required, including water source, water quality, consumption habits etc. It should be noted that such data may not exist, may be of considerably varying quality and quantity, and thus prone to significant (and potentially inestimable) levels of uncertainty.

#### ***6.5.7 Time-scale issues for cancer outcomes***

There is some degree of uncertainty around which period is most aetiologically relevant to the health outcomes of interest. Although cancers are generally considered to be associated with latency times of several decades, the data which is available on this subject is fraught with uncertainties.

#### ***6.5.8 Time-scale resolution issues for reproductive outcomes***

Previous studies have highlighted that different reproductive outcomes are associated with different aetiologically relevant periods. It will be necessary to model drinking water supply zone means for these periods.

#### ***6.5.9 Incompatibilities of individual databases from each case study country***

Available data on each individual chemical parameter of interest from each case study country may be supplied in different formats, at different geographical or temporal scales, with different analytical quality etc.

#### ***6.5.10 Inability to take into account occupational exposure***

Certain subjects in the study population are likely working in professions that result in their significantly greater exposure to water intended for human consumption that contains the chemical parameters of interest (e.g. laundry workers). Estimation of their exposure is outside of the scope of this assessment. The size of such subgroups is assumed to be relatively low in terms of the total population and therefore failing to take their heightened exposure into account should not significantly attenuate estimates of burden of disease.

#### ***6.5.11 Swimming***

A number of studies have shown that swimmers exposure to disinfection by-products from drinking water is significantly overshadowed by that exposure they receive while swimming in chlorinated pools. Survey data and literature review will be used to estimate what proportion of the population uses swimming pools, at what frequency and for what duration. If need be, this group may need to be treated as separate (as a subgroup) from the population of interest, such that ultimately measures of health impacts can be compared.

## 7 Reporting and communication

### 7.1 Work plan for assessment

The table below gives an indication of the expected work to be carried out under WP3.4 as part of the first pass assessment. These dates are to be agreed over months 18 and 19 of the project.

Assessment stage	Tasks	Modelling	Data gathering	Outputs for WP3.4	Historical trends	Temporal trends	Provisional dates	
							Start	Completion
							Scoping	Define purpose of assessment and assessment scope.
	Draw up appropriate scoping framework.			<input checked="" type="checkbox"/>			January 2006	September 2006
	Engage necessary stakeholders in scoping process.						November 2006	February 2007
	Reach consensus between partners						March 2007	May 2007
Sources, parameters & demographic data	Gather data on concentrations of chemical parameters	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
	Gather data on percentage of population connected to private supply		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			
	Gather data on source type of disinfected water		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>		
	Gather data on treatment type used in disinfection		<input checked="" type="checkbox"/>					
	Gather demographic data		<input checked="" type="checkbox"/>		<input checked="" type="checkbox"/>			
	Review literature for typical concentrations of chemical parameters in swimming pools	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
Personal behaviour & exposure data	Gather population data on amount of tap water consumed in hot and cold drinks	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
	Gather population data on amount of bottled water consumed	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
	Review literature to establish specificities of exposure behaviour in pregnant women		<input checked="" type="checkbox"/>					
	Gather data on showering duration and frequency, bathing duration and frequency, dish-washing duration and frequency and swimming duration and frequency	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>			<input checked="" type="checkbox"/>		
Uptake into study populations	Literature review on uptake factors for TTHM through absorption and inhalation	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
	Literature review (using toxicological data) on uptake factors for As, TTHM and NO <sub>3</sub> <sup>-</sup> through ingestion, including any specific data relating to pregnant women (transplacental uptake etc.)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
Modelled internal doses	Model internal dose for As, TTHM and NO <sub>3</sub> <sup>-</sup> from each (applicable) exposure route	<input checked="" type="checkbox"/>						
Exposure-response function	Carry out meta-analyses (for reproductive outcomes) and pooled analyses (for cancer outcomes) of epidemiological literature and derive exposure-response functions for each parameter.	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
	Review the relevant cancer latency periods and the critical developmental periods for reproductive health outcomes		<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>				
Burden of disease estimates	Model disease distributions for exposure to each of the chemical parameters	<input checked="" type="checkbox"/>						
	Model distributions of disease specifically for genetically susceptible subgroup	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>					
	Gather data on background rates of disease outcomes		<input checked="" type="checkbox"/>					
	Review burden of disease literature to obtain DALY weighting for each disease outcome		<input checked="" type="checkbox"/>					

	Model burden of disease related to each chemical parameter	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
Economic Costs	Review literature on economic valuation of disease burden to obtain cost values for each of the disease outcomes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Review of health economics literature to obtain weightings/discounting for health outcomes	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>
	Model economic costs of disease attributed to each chemical parameter	<input checked="" type="checkbox"/>	

In parallel to this process, uncertainties associated with the assessment will be analysed, described and reported etc.

## 7.2 Results communication

### 7.2.1 How will results be made available?

Results will be made available primarily by way of a written report that will be distributed by partners to those stakeholders that were involved in the scoping process, to those sub-projects that will use these results (e.g. SP2, SP5 & SP4) and, of course, to all partners involved in the INTARESE project. In addition, all outputs of WP3.4 will be made available to partners on the INTARESE-Wiki at [www.pyrkilo.fi/intarese/index.php/WP3.4\\_Water](http://www.pyrkilo.fi/intarese/index.php/WP3.4_Water) and also uploaded onto the INTARESE website at [www.intarese.org](http://www.intarese.org). An interim report will be prepared in month 24 (see 'Timeframe for Reporting' below).

The toolbox (SP4) will make direct use of the outputs of SP3 in developing the integrated assessment system. In order to achieve this goal SP3 work packages - including WP3.4 - will be required to supply information on data sources and data characteristics, uncertainty issues and methodology.

### 7.2.2 Timeframe for reporting

The first draft of the water assessment protocol will be completed by mid-February 2007 for distribution to WP3.4 partners. Upon receipt of their comments and suggestions, this document will also be made available to those stakeholders interested in commenting on it. By the end of February 2007 it should be clear which of those stakeholders thus far approached will be interested in participating further in the assessment. A complete final draft of the document will be submitted to the Project Co-ordinator (David Briggs) by 15<sup>th</sup> May 2007 (project month 18) after a two-phase commenting and editing process from the WP3.4 partners. The stages outlining the overall development of this document are listed in the section 'Timetable for WAP' above.

An interim report of the results of the first-pass assessment (month 18 - month 30) will be prepared in month 24 (November 2007). This will be distributed to all SP3 work packages, posted on the INTARESE-Wiki and distributed to SP1, such that lessons learned can be incorporated into their guidelines for improving the assessment methodology for the second-pass assessment (month 30-36).

At month 30 (June 2007) a final report on the first-pass assessment will be completed and delivered to SP3 partners, INTARESE partners and stakeholders. Both stakeholders and partners will be given the chance to comment on the report and to evaluate potential improvements to the assessment methodology ready for the second pass assessment. There will then follow a period of six months for a full review of the methodology (to be carried out at the same time as the second-pass assessment) leading up to submission of the final report in month 36 (November 2008).

## 7.3 Verification of results

### *7.3.1 Method used to verify/review the results*

Each case study will be subjected to the scrutiny of all of the WP3.4 partners by a formal process of review which will take place at the end of the first-pass assessment. All WP3.4 partners will be asked to review the methodology used in carrying out the assessment, make judgements in terms of meeting aims and objectives etc. The interim report will detail this review process more thoroughly.

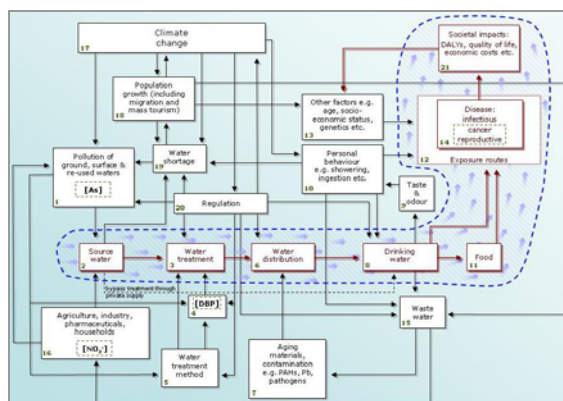
In addition, modelled health outcome frequencies can be compared with disease prevalence measured in the total population of each case-study country, using data from disease registries.

WP1.4 should be supplying information to SP3 on how to carry out verification of its results.



## 8 Appendix 1 - Definitions of variables

The variables defined below are taken from the assessment framework as shown here (see figure 1 for full-size version).



### List of Variables

- 1 *Pollution of ground, surface, & re-used waters e.g. As, Ca, Mg, U, Br*
- 2 *Source water*
- 3 *Water treatment*
- 4 *Disinfection by-products (DBPs)*
- 5 *Water treatment method*
- 6 *Water distribution*
- 7 *Aging materials, contamination e.g. PAHs, Pb, pathogens*
- 8 *Drinking water*
- 9 *Taste/odour*
- 10 *Personal behaviour e.g. showering, ingestion etc.*
- 11 *Food*
- 12 *Exposure routes*
- 13 *Other disease factors e.g. age, socio-economic status, genetics etc.*
- 14 *Disease: cancer, reproductive & infectious*
- 15 *Waste water*
- 16 *Agriculture, industry, pharmaceuticals, households e.g. nitrates, EDCs, pathogens, pesticides*
- 17 *Climate change*
- 18 *Population growth (including migration and mass tourism)*
- 19 *Water shortage*
- 20 *Regulation*

**PLEASE NOTE:** while every effort has been made to preserve a sense of the 'flow' along the causal chain in the numbering of these variables, the mutually interlinked nature of the variables has necessitated certain deviations from this rationale. For this reason, numbering should be regarded only as a means of locating numbers on the framework diagram.

1 Ground, surface, & re-used waters e.g. As, Ca, Mg, U, Br	
Focus and scope <i>'What's the question?'</i>	What are the differences in contaminant concentrations in various source waters?
Description <i>'What do you need to know to understand the question and the answer?'</i>	Influence of geological, hydrogeological, hydrological and waste-water factors on the concentration of contaminants in various source waters.
Definition <i>'How can you derive the answer?'</i>	Monitoring data of source waters individual regions.
Result <i>'What is the answer?'</i>	Source waters contain a number of pollutants, which are related to a number of factors (geological, re-use of waste water etc.)
Units and categories <i>'How to measure it?'</i>	Concentration

2 Source Water	
Focus and scope <i>'What's the question?'</i>	What is the percentage breakdown of different source water types used for drinking water, and what influence might this have on levels of water pollutants in resultant drinking water?
Description <i>'What do you need to know to understand the question and the answer?'</i>	Type of drinking water source: groundwater, surface water (rivers, reservoirs and lakes), desalinated water. Variation in source-water mix: conditions that may dictate switching of water source. Likely pollutants for each type of source water (e.g. levels of organic matter).
Definition <i>'How can you derive the answer?'</i>	Data from regulators and water companies. Previous studies. Data held by European Environment Agency.
Result <i>'What is the answer?'</i>	Types of water sources used across Europe vary greatly depending on local conditions. The presence of pollutants at source can have a great influence on pollutant concentrations in water entering the distribution system, including elevated concentrations of organic substances that react with chlorine to form DBPs.
Units and categories <i>'How to measure it?'</i>	Types of water source Typical pollutant concentrations in each water source

3 Water treatment	
Focus and scope <i>'What's the question?'</i>	What effect does the water treatment itself have on pollutant concentrations in the water?
Description <i>'What do you need to know to understand the question and the answer?'</i>	Pre-treatment/post-treatment concentrations of pollutants of interest.
Definition <i>'How can you derive the answer?'</i>	Monitoring data.
Result <i>'What is the answer?'</i>	Water treatment has a particular role to play in reducing concentrations of certain pollutants present in the source water. At the same time, water purification methods (disinfection) create a host of by-products.
Units and categories <i>'How to measure it?'</i>	Percentage change in concentration, or concentrations pre-/post-treatment.

4 Disinfection by-products (DBPs)	
Focus and scope <i>'What's the question?'</i>	Which DBPs are formed in the water treatment process and at what levels? How do their concentrations change throughout their life in their water distribution network?
Description <i>'What do you need to know to understand the question and the answer?'</i>	Types and amounts of DBPs formed in the treatment and distribution of drinking water.
Definition <i>'How can you derive the answer?'</i>	Data on DBP concentrations at different parts of the distribution network, but specifically at the tap from routinely collected data (TTHMs). Independent study results regarding concentrations of DBPs not yet routinely monitored (e.g. HAAS). DBP Modelling based water source, treatment, temperature, pH, organic matter etc
Result <i>'What is the answer?'</i>	The DBPs formed are likely to be complex mixtures of TTHMs, TCAAs and other organohalides. DBP concentrations vary widely throughout the distribution system depending on a number of factors.
Units and categories <i>'How to measure it?'</i>	Water source (e.g. ground vs surface water) Water treatment (chlorination vs chloramination) Concentration ( $\mu\text{g/l}$ )

5 Water treatment method	
<b>Focus and scope</b> <i>'What's the question?'</i>	What type of water treatment method is employed, which reagents are used (and in what concentration?)
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Types of water treatment methods employed (chlorination, chloramination) Types of reagents used (free chlorine gas, sodium hypochlorite, chloramine, chlorine dioxide, ozone) Other methods employed (UV light) How the treatment method is dictated by the source water employed and the regulative framework.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Information from water companies and/or regulators
<b>Result</b> <i>'What is the answer?'</i>	A number of water treatment methods are available and may be used in combination, the exact choice governed by cost, health considerations and legislative demands.
<b>Units and categories</b> <i>'How to measure it?'</i>	Type of process used (chlorination, ozonation, UV treatment, chloramination etc.) Concentrations used]

6 Water distribution	
<b>Focus and scope</b> <i>'What's the question?'</i>	What role does the water distribution network play in affecting concentrations of pollutants?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	The effect of the network's materials on pollutant concentrations. The length of time water typically spends in the distribution system, and the effect this has on pollutant concentrations. The age of the network, which may lead to different usage.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Monitoring data of pollutant concentrations pre-/post-entry into distribution network.
<b>Result</b> <i>'What is the answer?'</i>	According to various aspects of their construction (which tend to be correlated to the age of the system) and size, water distribution networks have a significant role to play in determining both types and concentrations of contaminants in drinking water.
<b>Units and categories</b> <i>'How to measure it?'</i>	Concentrations of pollutants. Time of residence within distribution network.

7 Aging materials, contamination e.g. PAHs, Pb, pathogens	
<b>Focus and scope</b> <i>'What's the question?'</i>	What and how much/many PAHs, Pb, pathogens etc. are introduced into the water distribution network as a result of distribution network construction materials' type and condition?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Age of distribution infrastructure. Materials employed in distribution. Leakiness of system. Contamination by pathogens from waste water. Presence of pathogens in biofilms within water distribution network.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Information supplied by water companies or government. Monitoring data at tap compared to post-treatment.
<b>Result</b> <i>'What is the answer?'</i>	Age of distribution network largely dictates the materials employed in its construction, and hence pollutant levels in the water being transported. Leaky systems may allow influx of water into system, resulting in contaminant levels in water being increased.
<b>Units and categories</b> <i>'How to measure it?'</i>	Age of infrastructure (years). Types of pipe (lead, iron, polymer etc.). Concentrations of PAH, Pb and pathogen counts attributable to distribution network.

8 Drinking water	
<b>Focus and scope</b> <i>'What's the question?'</i>	How much drinking water is used and for which purposes (including amounts going to waste)?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Personal behaviours relating to water use. Regulation surrounding drinking water use. Amounts of treated drinking water returning as waste water.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Data from surveys, epidemiological studies, regulators etc.
<b>Result</b> <i>'What is the answer?'</i>	Variations in both amounts used and specific uses of water will depend on climate, culture, cost, demographics etc. of any particular region.
<b>Units and categories</b> <i>'How to measure it?'</i>	Quantity (litres) per unit time (day-1).

<b>9 Taste/odour</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	How does taste and odour affect perception of risk of drinking water, and how does this affect personal behaviour relating to drinking water?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Changes in consumption behaviour dependent on taste/odour in water, as well as perception of taste/odour as an indicator of water's healthiness. The source of the taste/odour in the water.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Studies on psychological impact of taste/odour in water supplies. Data from regulators or water companies.
<b>Result</b> <i>'What is the answer?'</i>	Taste and odour can have a significant effect on consumer perceptions of the healthiness of their water supplies, which may in turn result in them changing their water use patterns, water consumption, purchase of bottled water etc.
<b>Units and categories</b> <i>'How to measure it?'</i>	Numbers of complaints issued to water companies/watchdogs on taste/odour issues. Percentage decreases in water use owing to taste/odour issues. Percentage increase in bottle water consumption owing to taste/odour issues.

<b>10 Personal behaviour e.g. showering, ingestion etc.</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	How does the population make use of drinking water in the home? How is the population exposed to drinking water?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Amounts of drinking water used in various different domestic activities (toilets, washing, cooking, dish-washing, cleaning, gardening etc.) Time spent exposed to drinking water (showering and bathing, cooking etc.)
<b>Definition</b> <i>'How can you derive the answer?'</i>	Review of previous studies Available population surveys
<b>Result</b> <i>'What is the answer?'</i>	Source of drinking water (tap/bottle/other) and amount ingested. Duration and frequency of showering, bathing and washing dishes by hand.
<b>Units and categories</b> <i>'How to measure it?'</i>	Amount of drinking water (tap, bottled and other) consumption (litres/day). Frequency and amount of time spent showering,

	bathing and dish-washing by hand (minutes/day).
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<b>11 Food</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	What concentrations of water pollutants are found in food?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	The degree to which cooking/preparation of food in drinking water leads to uptake of/affects concentrations of pollutants in food.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Studies detailing contaminant levels before and after exposure of foodstuffs to drinking water.
<b>Result</b> <i>'What is the answer?'</i>	Some drinking water pollutants may be accumulated in foods during the preparation/cooking process. Others may not enter food and/or be destroyed in cooking.
<b>Units and categories</b> <i>'How to measure it?'</i>	Concentrations or degree of uptake of pollutants by individual foods.

<b>12 Exposure routes</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	What are the possible exposure routes of humans to water pollutants?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	A complete set of exposure routes to water pollutants. The various personal behaviours that govern exposure to water. Uptake coefficients for each of the exposure routes.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Review of previous studies.
<b>Result</b> <i>'What is the answer?'</i>	The three exposure routes are oral, inhalation and dermal, each of which can be further categorised into specific activities. Oral is generally the main route, but for substances such as THM inhalation and skin absorption may be important.
<b>Units and categories</b> <i>'How to measure it?'</i>	Types of exposure route, quantified by uptake factors.

<b>13 Other disease factors e.g. age, socio-economic status, genetics etc.</b>
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<b>Focus and scope</b> <i>'What's the question?'</i>	Which other risk factors may influence or modify disease outcomes attributed to exposure to contaminants in drinking water.
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Relevance of socio-economic, lifestyle, genetic and other factors to the disease outcome of interest.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Review of medical literature to identify risk factors associated with the outcomes of interest (cancer, reproductive, infectious). Previous epidemiological studies dealing with individual disease outcomes and drinking water, including confounding factors and effect modifiers identified. Routinely or ad hoc collected data socio-economic, genetic and other factors.
<b>Result</b> <i>'What is the answer?'</i>	Risk factors associated with cancer and reproductive outcomes (including genetic (CYP2E1 & GSTM), socioeconomic and lifestyle, e.g. smoking, alcohol consumption, vitamin intake etc). Confounders/effect modifiers of the association between the exposure and the outcome.
<b>Units and categories</b> <i>'How to measure it?'</i>	Risk estimate (odds ratio, relative risk) of the disease associated with these risk factors. Genotyping Vitamin use Income or education level

### 14 Disease: cancer, reproductive & infectious

<b>Focus and scope</b> <i>'What's the question?'</i>	What is the proportion and number of population disease cases cancers, reproductive and infectious) attributed to the exposures of interest (nitrates, DBPs, arsenic and pathogens)?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	What is the magnitude of the risk of the disease (cancer, reproductive, infectious) associated with the exposure (nitrates, DBPs, arsenic, pathogens)? What are the levels of contaminants (nitrates, DBPs, arsenic, pathogens) in the drinking water? What is the proportion of subjects exposed? Incidence of water-borne disease (e.g. cryptosporidium, campylobacter, salmonella, shigella, etc.) Incidence of cancers and reproductive diseases associated with water pollutants (e.g. bladder cancer, birth weight)?
<b>Definition</b>	Data from epidemiological studies evaluating the risk

<b>'How can you derive the answer?'</b>	of the disease (cancer, reproductive, infectious) associated with the exposure (nitrates, DBPs, arsenic, pathogens) Available results from studies measuring the contaminants in drinking water Health risk assessment/burden of disease estimates. Available population surveys about drinking water source (bottle, tap, other) Data on source, treatment and quality (levels of contaminants) from water companies or government.
<b>Result</b> <i>'What is the answer?'</i>	Population attributable risk of disease (cancer, reproductive, infectious) to the exposure (nitrates, DBPs, arsenic, pathogens) at country or region level Number of cases of the disease attributed to the exposure at region/country level
<b>Units and categories</b> <i>'How to measure it?'</i>	Risk estimate of the disease associated with the exposure (odds ratio, relative risk etc.) Number of new cases of the disease per year and population at risk Exposure unit in water depending on substance

### 15 Waste water

<b>Focus and scope</b> <i>'What's the question?'</i>	How much waste water is produced as a result of drinking water use, and how do contaminants in this waste water feed back to source water? What is the level of water re-use?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Increases in waste water production related to population growth (including migration/tourism) Regulation of waste water. Influence waste water from various sources has on concentrations of pollutants in source waters Waste water overflow contamination of distribution system. Effects of personal behaviour on quantities of waste water produced. To what extent will pollutants in re-used water enter the drinking water cycle?
<b>Definition</b> <i>'How can you derive the answer?'</i>	Studies of waste water production. Regulator and water company data.
<b>Result</b> <i>'What is the answer?'</i>	Substances in waste water with long half-lives may return to water treatment plants in source water. Substances that are difficult to remove may end up in drinking water
<b>Units and categories</b>	Quantity of wastewater produced per capita, broken

<i>'How to measure it?'</i>	down according to source (domestic, industrial, agricultural etc.) Level of re-use of water (percentage).
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### 16 Agriculture, industry, pharmaceuticals, households e.g. nitrates, EDCs, pathogens, pesticides

<b>Focus and scope</b> <i>'What's the question?'</i>	What influence do waste waters and run-off from agriculture, industry, pharmaceuticals and households have on source water quality? What and how much of the specific substances end up in the source water?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	The types of chemicals attributable specifically to these sources. Concentrations of these chemicals in source water.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Monitoring data supplied by water companies or government.
<b>Result</b> <i>'What is the answer?'</i>	Waste waters and run-off from various human activities contaminate source waters, particularly in the case of surface waters (e.g. nitrates & pesticides from agricultural run-off, pharmaceuticals from domestic waste water etc.) Location of source waters in agricultural areas with high nitrate and pesticide use. Source waters extracted from water bodies downstream (e.g. rivers) of highly populated areas (re-use of water). Source water extracted downstream from industrial areas.
<b>Units and categories</b> <i>'How to measure it?'</i>	Concentrations of nitrates, EDCs, pesticides. Pathogen counts. Estimated measures of re-use of water Estimated agricultural density

### 17 Climate change

<b>Focus and scope</b> <i>'What's the question?'</i>	What effect do changes in climate have on water shortages, water source and water treatment, on personal behaviour, on regulation of drinking water and on migration and mass tourism?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Trends in climate change (temperature, precipitation etc.)
<b>Definition</b>	Data on water shortages (historical and expected).

<i>'How can you derive the answer?'</i>	Data on modelled effects of changes in population size on these shortages. Data on trends in personal behaviour i.e. water use (due to increased temperature in summer, increase rain in winter). Data on flooding and sewage overflow due to flash flooding etc.
<b>Result</b> <i>'What is the answer?'</i>	Climate change increases the shortage of water in certain regions in summer and increases floodwater in winter. Climate change may result in physicochemical changes in source waters, and in their subsequent selection as sources for drinking water. Climate change may result in an increase in disinfection treatment because of increased microbial loading. Personal behaviour is likely to change as a result of hotter summers (increased water use for bathing, drinking etc.) Climate change may make certain regions more attractive to migrants/tourists, who may have considerably different patterns of water use to those of local people.
<b>Units and categories</b> <i>'How to measure it?'</i>	Changes in precipitation (mm/period time) Changes in temperature Changes in extreme weather events (drought, flooding etc.)

### 18 Population growth including migration and mass tourism

<b>Focus and scope</b> <i>'What's the question?'</i>	What effect does population growth, including migration and mass tourism, have on drinking water supply in certain regions?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	The influence that increasing population has on water shortages in the short- (increased demand), medium- and long-term (landscape transformed, natural hydrology altered, water bodies altered, decreased renewal of groundwater) Implications of population growth on source water selection, increased waste water production etc.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Review of previous studies. Census data. Visiting tourist data.
<b>Result</b> <i>'What is the answer?'</i>	Population growth, mass tourism and migration puts pressure on water sources, from both short- to long-term, in terms of quantity, switching to lower quality sources and higher frequency of distribution

	downtime, which may have implications for levels of contaminants in drinking water.
<b>Units and categories</b> <i>'How to measure it?'</i>	Excess amount of water used by migrants/tourists. Population density (and rates of its change)

<b>19 Water shortage</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	What annual percentage of demand is not met by current water supplies, and how is this predicted to change in the next 20 years?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	Degree to which water shortages are affected by personal behaviour relating to water use. Impact of net migration or tourist activity to water demand (including impact of peaks in demand at certain times of year). The effect of regulation on water shortages (e.g. hosepipe bans, grey water use etc.) Effects of switching source water or augmenting current supply with new source water. Implications for re-use of ground and surface waters.
<b>Definition</b> <i>'How can you derive the answer?'</i>	Previous studies.
<b>Result</b> <i>'What is the answer?'</i>	Water shortages are related to a number of demand and supply factors including climate, regulation, source water availability etc.

<b>Units and categories</b> <i>'How to measure it?'</i>	Percentage shortage relative to demand, measured at the appropriate level (i.e. by country, region, city, water basin etc.)
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<b>20 Regulation</b>	
<b>Focus and scope</b> <i>'What's the question?'</i>	Which concentration thresholds of pollutants do regulations give concerning the treatment, distribution and use of drinking water?
<b>Description</b> <i>'What do you need to know to understand the question and the answer?'</i>	EU legislation and its transposition into national law. What levels of pollutants are currently considered acceptable? What are the current guideline values for individual pollutants? How is climate change currently factored into the water regulatory framework, and how is this likely to change in the future?
<b>Definition</b> <i>'How can you derive the answer?'</i>	Analysis of the regulatory frameworks at the European and national levels.
<b>Result</b> <i>'What is the answer?'</i>	Drinking water is governed by a number of EU Directives (and hence national laws). International organisations such as the WHO also play a role in influencing regulation of drinking water.
<b>Units and categories</b> <i>'How to measure it?'</i>	Concentration thresholds (for monitored concentrations of pollutants) set in current legislation (as well as known planned legislation).

9 **Appendix 2 - Detailed definitions of variables key to the WP3.4 assessment**

1 GEOGENIC POLLUTION OF GROUND, SURFACE, & RE-USED WATERS CONC. OF ARSENIC IN DRINKING WATER AT TAP [As] <sub>DRINKING WATER</sub>	
<i>Type</i>	Emission
<i>Links to other variables</i>	
<i>Detailed definition</i>	Total concentration of arsenic (all species) in drinking water at the consumer's tap
<i>Terms and concepts</i>	Arsenic, geogenic,
<i>Geographical scale</i>	Water supply zone
<i>Averaging period</i>	Annual averaging for cancer outcomes Quarterly averaging for reproductive outcomes
<i>Units of measurement</i>	Micrograms of arsenic per litre of water intended for human consumption (µg/L)
<i>Data needs</i>	Quarterly (if not available, data will be modelled at this temporal frequency). For reproductive outcomes it may be necessary to model data at the monthly scale.
<i>Data sources, availability and quality</i>	Routine data available either from the water companies, who are mandated to collect this data at the water supply zone level under nationally implemented legislation reflecting the requirements of 98/83/EC or from a centralised body that collates these data.
<i>Computation algorithm/model</i>	
<i>Worked example</i>	
<i>Variations and alternatives</i>	Should of [As] <sub>drinking water</sub> not be available for a sufficiently long time period, it may be necessary to model it based on concentrations of other associated elements in drinking water for which measurements are available.

2 SOURCE WATER TYPE	
<i>Type</i>	Emission modifier
<i>Links to other variables</i>	
<i>Detailed definition</i>	The type of source water being used either (a) for municipal drinking water treatment or (b) being used directly by consumers (with or without small-scale local treatment).
<i>Terms and concepts</i>	Groundwater, surface water (rivers, reservoirs, lakes), desalinated water
<i>Geographical scale</i>	Water supply zone
<i>Averaging period</i>	Annual
<i>Units of measurement</i>	Percentage breakdown for population supplied by municipal drinking water produced from groundwater or surface water and population supplied by private supply (ground water).
<i>Data needs</i>	Percentage breakdown of different water sources for last two decades (THIS IS DIFFICULT TASK, REQUIRES INTERVIEW) maybe we should look for future, what if this kind of water will be used for the next 20 years?
<i>Data sources, availability and quality</i>	
<i>Computation algorithm/model</i>	N/a
<i>Worked example</i>	N/a
<i>Variations and alternatives</i>	



4 DISINFECTION BY-PRODUCTS (DBPs) CONC. OF TTHMs IN DRINKING WATER AT TAP [TTHM] <sub>DRINKING WATER</sub>	
<i>Type</i>	Emission
<i>Links to other variables</i>	
<i>Detailed definition</i>	Concentrations of TTHMs, which have been generated through the disinfection process, measured in properties supplied by mains water.
<i>Terms and concepts</i>	TTHMs - total trihalomethanes (e.g. trichloromethane, bromodichloromethane, dibromochloromethane, tribromomethane), in the tap water as a marker of total DBP level. If available THM level in the swimming pool.
<i>Geographical scale</i>	Water supply zone. Swimming pool
<i>Averaging period</i>	Annual averaging for cancer outcomes Quarterly averaging for reproductive outcomes
<i>Units of measurement</i>	Micrograms of total trihalomethanes per litre of water intended for human consumption (µg/L)
<i>Data needs</i>	Available regulatory measurements of THM from water companies, local authorities. Other available THM data from other organisms, research institutes and universities.
<i>Data sources, availability and quality</i>	Routine data available either from the water companies, who are mandated to collect this data at the water supply zone level under nationally implemented legislation reflecting the requirements of 98/83/EC or from a centralised body that collates these data.
<i>Computation algorithm/model</i>	
<i>Worked example</i>	
<i>Variations and alternatives</i>	Concentration of THM is affected by distribution system, typically concentration increases in distribution system. It is not so big problem if we divide the concentrations to low, medium, high categories.

10 PERSONAL BEHAVIOUR SHOWERING, BATHING, INGESTION, SWIMMING	
<i>Type</i>	Exposure modifier
<i>Links to other variables</i>	
<i>Detailed definition</i>	Ingestion: Amount of municipal drinking water consumed Showering, bathing and swimming in the pool. Frequency and duration.
<i>Terms and concepts</i>	Ingestion: 1. Water source of drinking water (municipal, bottled, other) 2. Amount of municipal water consumed (litres/day) Showering, bathing and swimming in the pool: 1. Frequency (times per week or month) 2. Duration (minutes)
<i>Geographical scale</i>	Regional if possible. Otherwise, national
<i>Averaging period</i>	Daily (water consumption), weekly (showering), monthly (bathing and swimming in the pool)
<i>Units of measurement</i>	See "terms and concepts"
<i>Data needs</i>	% of population (general and pregnant women) consuming municipal water Statistics of average frequency and duration of showering and bathing
<i>Data sources, availability and quality</i>	Data available from previous studies, national or regional statistics from public organisms.
<i>Computation algorithm/model</i>	
<i>Worked example</i>	
<i>Variations and alternatives</i>	Exposure assessment to THM could include the exposure to THM through ingestion in the workplace and exposure during swimming in the pool. To simplify I suggest limiting the exposure assessment in the HOUSEHOLD + swimming pool. Affects only THM exposure?

13 OTHER DISEASE FACTORS AGE, SEX, PREGNANCY	
Type	Impact modifier
Links to other variables	
Detailed definition	Confounding variables and effect modifiers that are associated with the health outcomes under study.
Terms and concepts	Both repro and cancer: age, sex, smoking habits (never/ex/current), amount of smoking Specifically for pregnancy outcomes: maternal height and weight, previous pregnancies (parity), alcohol consumption during pregnancy, health care during pregnancy, etc.
Geographical scale	Regional if possible. Otherwise national
Averaging period	Depends on variable.
Units of measurement	Depends on variable.
Data needs	Statistics of the concepts mentioned in "terms and concepts"
Data sources, availability and quality	Available data from previous studies or national/regional statistics.
Computation algorithm/model	
Worked example	
Variations and alternatives	We have to be aware that these variables may be different for cancer and repro outcomes.

14 DISEASE: CANCER AND REPRODUCTIVE OUTCOMES	
Type	Impact
Links to other	

<i>variables</i>	
<i>Detailed definition</i>	Cancer Reproductive health outcomes
<i>Terms and concepts</i>	Bladder cancer and ... pregnancy outcomes
<i>Geographical scale</i>	Regional if possible. Otherwise national data used.
<i>Averaging period</i>	Monthly
<i>Units of measurement</i>	# deaths/cancers/reproductive outcomes per 100.000 inhabitants and year
<i>Data needs</i>	Mortality or incidence for cancer (whatever available), incidence of repro outcomes at regional or national level
<i>Data sources, availability and quality</i>	National or regional death-incidence statistics from health authorities
<i>Computation algorithm/model</i>	
<i>Worked example</i>	
<i>Variations and alternatives</i>	

16 AGRICULTURE, INDUSTRY, PHARMACEUTICALS, HOUSEHOLDS CONC. OF NITRATES IN DRINKING WATER AT TAP [NO <sub>3</sub> ] <sub>DRINKING WATER</sub>	
Type	Emission
Links to other variables	
Detailed definition	Drinking water supply zone quarterly mean nitrate concentration in water intended for human consumption
Terms and concepts	Water intended for human consumption Drinking Water Directive (98/83/EC)
Geographical scale	Water supply zone
Averaging period	Annual averaging for cancer outcomes

	Quarterly averaging for reproductive outcomes Methaemoglobinaemia in bottle-fed infants (short-term exposure)
<i>Units of measurement</i>	Milligrams per litre of water intended for human consumption (mg/L)
<i>Data needs</i>	
<i>Data sources, availability and quality</i>	Routine data available either from the water companies, who are mandated to collect this data at the water supply zone level under nationally implemented legislation reflecting the requirements of 98/83/EC or from a centralised body that collates these data.
<i>Computation</i>	See Whitaker

<i>algorithm/model</i>	
<i>Worked example</i>	
<i>Variations and alternatives</i>	In certain countries (e.g. Romania) privately abstracted water is used by a significant proportion of the population. This may or may not be subject to treatment at source. Typical nitrate concentrations in such water would be useful in comparison with that intended for human consumption and would facilitate a greater understanding of risks associated with drinking such waters.

## 10 Appendix 3 - Stakeholders identified for WP3.4

### 10.1 UK Stakeholders

Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
Government	<b>Department of the Environment, Food and Rural Affairs (Defra)</b> <a href="http://www.defra.gov.uk">www.defra.gov.uk</a>	'Defra's aim is sustainable development - defined as:  'development which enables all people throughout the world to satisfy their basic needs and enjoy a better quality of life without compromising the quality of life of future generations.'  'Defra promotes sustainable development as the way forward for Government.'	Water quality, Marine issues, Flood management, Water resources, Water industry, Water conservation	Regulatory and policy-making role	<b>Peter Jiggins</b>  Water Supply and Regulation Team Department for Environment Food & Rural Affairs Nobel House 17 Smith Square London SW1P 3JR  Tel: 020 7082 8336 Email: <a href="mailto:peter.jiggins@defra.gsi.gov.uk">peter.jiggins@defra.gsi.gov.uk</a>
	<b>Environment Agency (EA)</b> <a href="http://www.environment-agency.gov.uk/">www.environment-agency.gov.uk/</a>	'The Environment Agency is the leading public body for protecting and improving the environment in England and Wales.'	All	Enforcement of legislation (particularly relating to sources of water)	<b>David King</b>  Director of Water Management Environment Agency Rio House, Waterside Drive Aztec West, Almondsbury Bristol BS32 4UD  Tel: 08708 506 506 Email: <a href="mailto:david.king@environment-agency.gov.uk">david.king@environment-agency.gov.uk</a>
Regulators and watchdogs	<b>Drinking Water Inspectorate (DWI)</b> <a href="http://www.dwi.gov.uk">www.dwi.gov.uk</a>	'Drinking water quality in England and Wales is regulated by the government through the Drinking Water Inspectorate (DWI). The Inspectorate was set up in 1990 after the water industry was privatised to operate an independent body with staff experienced in all aspect of water supply. The DWI task is to monitor and check the safety of drinking water.'	Drinking water quality	Enforcement of legislation (particularly relating to drinking water quality)	<b>Professor Jeni Colbourne</b>  Drinking Water Inspectorate Room M03, 55 Whitehall London SW1A 2EY  Email: <a href="mailto:jeni.colbourne@defra.gsi.gov.uk">jeni.colbourne@defra.gsi.gov.uk</a>  <b>Peter Marsden</b> Email: <a href="mailto:peter.marsden@defra.gsi.gov.uk">peter.marsden@defra.gsi.gov.uk</a>
Consumer organisations	<b>Consumer Council for Water (CCWater)</b> <a href="http://www.ccwater.org.uk">www.ccwater.org.uk</a>	'The Consumer Council for Water (CCWater) represents water and sewerage consumers in England and Wales. It took over from WaterVoice on 1 <sup>st</sup> October 2005.  'CCWater is independent of both the water industry and the regulator.'	Health effects Drinking water quality Cost of drinking water	Ensure stakeholder dialogue and engagement of public in decision-making on water quality issues.	<b>??</b>  1st floor, Victoria Square House Victoria Square Birmingham B2 4AJ  Tel: 0845 039 2837 Email: <a href="mailto:enquiries@ccwater.org.uk">enquiries@ccwater.org.uk</a>
Research and data provision	<b>UK Water Industry Research (UKWIR)</b> <a href="http://www.ukwir.org/">www.ukwir.org/</a>	'UKWIR facilitates collaborative research for UK water operators. The UKWIR programme generates sound science for sound regulation and sound practice.'	All	The organisation represents the research interests of water companies.	<b>Dr Mike Farrimond</b>  Director UK Water Industry Research Limited 1 Quenn Anne's Gate London SW1H 9BT  Tel: 020 7344 1868 Email: <a href="mailto:mfarrimond@ukwir.org.uk">mfarrimond@ukwir.org.uk</a>

Water Industry	<b>British Water</b> <a href="http://www.britishwater.co.uk">www.britishwater.co.uk</a>	'British Water is the leading trade association representing the interests of the water and wastewater industry in the UK and overseas. It lobbies governments and regulators on behalf of its members and provides vital information on home and overseas water and wastewater markets - how much is being spent, by whom, where, when, how and on what. British Water represents the interests of the UK water and wastewater industry on UK and European regulations and legislation, terms and conditions of contract and procurement practice, and in the creation of European and International Standards.'	All	Resisting expensive change (e.g. in treatment) where profitability of its members' industries might be compromised	<b>Paul Mullord</b> UK Director British Water 1 Queen Anne's Gate London SW1H 9BT Tel: 020 7957 4554 Email: <a href="mailto:paul.mullord@britishwater.co.uk">paul.mullord@britishwater.co.uk</a>
	<b>Water UK</b> <a href="http://www.water.org.uk">www.water.org.uk</a>	'Water UK is the industry association representing UK statutory water supply and wastewater companies at national and European level. It is funded by its members to influence public policy and opinion to ensure a strong water industry in the interests of all stakeholders. The focus on policy means: identifying gaps or inadequacies; working with members and stakeholders to develop alternatives; and helping deliver the benefits as new approaches are implemented. Our core objective is sustainable water policy – actions and solutions that create lasting benefit by integrating economic, environmental and social objectives.'	All	Resisting expensive change (e.g. in treatment) where profitability of its members' industries might be compromised	<b>Phill Mills</b> Director of Water Services Water UK head office 1 Queen Anne's Gate London SW1H 9BT Tel: 020 7344 1844 Email: <a href="mailto:pmills@water.org.uk">pmills@water.org.uk</a>

## 10.2 Hungarian Stakeholders

Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
Government	Ministry of Environment and Water (Környezetvédelmi és Vízügyi Minisztérium) <a href="http://www.kvvm.hu">www.kvvm.hu</a>	??	??	??	Ministry of Environment and Water Fő utca 44-50. 1011 Budapest Tel: +36 1457 3300 Email: ??
Regulators and watchdogs	Hungarian Water Centre and Public Archives - Water Directorate (Vízügyi Központ és Közgyűjtemények - Vízügyi Igazgatóság) <a href="http://www.ovf.hu">www.ovf.hu</a>	??	??	??	1012. Budapest Márvány utca 1/c Hungary Ms Andrea Nagy Tel: +36 1224 2563 Email: <a href="mailto:nagy.andrea@ovf.hu">nagy.andrea@ovf.hu</a> Head of Water Directorate: Mr György Jakus Email: <a href="mailto:jakus.gyorgy@ovf.hu">jakus.gyorgy@ovf.hu</a> International coordinator: Mr Kálmán Papp <a href="mailto:papp.kalman@ovf.hu">papp.kalman@ovf.hu</a>
Consumer organisations	??	??	??	??	??

Research and data provision	VITUKI Environmental and Water Management Research Institute <a href="http://www.vituki.hu">www.vituki.hu</a>	??	??	??	H-1095 Budapest Kvassay Jenő út 1. Hungary Tel: +36 1215 6140  ??
Water Industry	The Hungarian Professional Association of Water and Sewerage Companies (Magyar Víziközmű Szövetség) <a href="http://www.maviz.org">www.maviz.org</a>	'The Hungarian Water Utility Association is a socially organized professional body, with independent legal entity, which was established in 1990 with a view to act as an independent intermediate, harmonizing and representing interests of the industry, offering trade developing and engineering services.'			1051 Budapest V. ker. Sas u. 25. IV. emelet Hungary  Tel: +36 1353 3241 Email: <a href="mailto:titkarsag@maviz.org">titkarsag@maviz.org</a>

### 10.3 Romanian Stakeholders

Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
Government	Ministry of Environment and Water Management – Department of Water (Ministerul Mediului si Gospodarii Apelor – Departamentul ape) <a href="http://www.mmediu.ro/ape/ape.htm">www.mmediu.ro/ape/ape.htm</a>	??	??	??	Bd. Libertatii nr. 12, Sec. 5 Bucuresti, Romania Tel: +40 316 0215
Regulators and watchdogs	??	??	??	??	??
Consumer organisations	??	??	??	??	??
Research and data provision	<a href="http://www.hidro.ro/">http://www.hidro.ro/</a>	'Research activities and public operational services of national and international interest, for: population and goods protection; improvement of life quality; environment protection.'  'Services for: Water management; Energetics; Environment protection; Transports; Mass-media; Agriculture; Industry; National security; Tourism.'	??	??	??

Water Industry	<p><b>National Administration of Romanian Waters</b></p> <p>Administrația Națională Apele Române  <a href="http://www.rowater.ro">www.rowater.ro</a></p>	??	??	??	<p>Str. Edgar Quinet nr. 6, Sector 1, cod 010018, Bucharest, Romania Tel: +40 21311 0396</p> <p>??</p>
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## 10.4 Finnish Stakeholders

Stakeholder type	Names of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
Government	<p><b>Ministry of Social Affairs and Health (STM)</b>  <a href="http://www.stm.fi">www.stm.fi</a></p>	Ministry of Social Affairs and Health is responsible for management and control of supervision of health protection and subsequent rules and regulations based on it. The Ministry also set national requirements for monitoring obligations and the quality of drinking water.	All		<p><b>Jari Keinänen</b>                      Email: <a href="mailto:Jari.keinänen@stm.fi">Jari.keinänen@stm.fi</a></p>
	<p><b>Ministry of Agriculture and Forestry (MMM)</b>  <a href="http://www.mmm.fi">www.mmm.fi</a></p>	Ministry of Agriculture and Forestry is the leading water resource authority in Finland. The Ministry is responsible for legislation related to water resources management. The Ministry also guides regional environmental authorities in water resource sector.			??
Regulators and watchdogs	<p><b>National Product Control Agency for Welfare and Health (STTV)</b>  <a href="http://www.sttv.fi">www.sttv.fi</a></p>	The National Product Control Agency's (STTV) guiding principle is to prevent health and social detriments caused by alcoholic products, tobacco and chemicals and to promote a safe and healthy environment. STTV is responsible for overseeing and steering the implementation of the Alcohol Act, the Chemicals Act, the Tobacco Act and the Health Protection Act at national level, and for supervisory activities according to the Gene Technology Act. The Product Control Agency is a central office which operates under the Ministry of Social Affairs and Health.		Regulatory, data collection	<p><b>Jarkko Rapala</b>                      Email: <a href="mailto:Jarkko.Rapala@sttv.fi">Jarkko.Rapala@sttv.fi</a></p>
Consumer organisations	<p><b>Consumer Agency</b>  <a href="http://www.kuluttajavirasto.fi">www.kuluttajavirasto.fi</a></p>	The task of the Consumer Agency and Consumer Ombudsman is to ensure consumers' economic, health and legal position and to implement consumer policy.			??
Research and data provision	<p><b>National Public Health Institute (KTL)                      -Department of Environmental Health</b>  <a href="http://www.ktl.fi">www.ktl.fi</a></p>	Environmental health risk analysis forms the umbrella that covers most of the research at KTL Department of Environmental Health. Our Centre of Excellence for Environmental Health Risk Analysis is aimed at improving risk analysis methodology using dioxins and urban air particles as case studies. As environmental health risk analysis must be based on high quality multidisciplinary science, we focus on selected themes and study them from exposures to health effects. The main research themes are air pollution, drinking water, mouldy buildings, chemicals, asthma and allergies, and risk assessment.	All	Research -health effects	<p><b>Terttu Vartiainen</b>                      Email: <a href="mailto:Terttu.Vartiainen@ktl.fi">Terttu.Vartiainen@ktl.fi</a></p>

	<b>Finland's environmental administration (SYKE)</b> <a href="http://www.ymparisto.fi">www.ymparisto.fi</a>	Finland's environmental administration promotes sustainable development and the well-being of all citizens. The environmental administration works to create pleasant residential environments, to safeguard viable natural ecosystems, and to improve housing conditions in Finland.	All	Sources of water, data collection	<b>Erkki Santala</b> Email: <a href="mailto:Erkki.Santala@ymparisto.fi">Erkki.Santala@ymparisto.fi</a>
	<b>Finnish Water and Waste Water Works Association (FIWA)</b> <a href="http://www.vvy.fi">www.vvy.fi</a>	The FIWA is a nationwide joint organization of water and waste water works. The members of FIWA cover about 85 % of the volume of the Finnish water services. The main duties of FIWA are: to promote the common interests of its members, to prepare technical and administrative guidelines for its members use, to promote research activities, to provide information, to advise and to help its members in technical, administrative and juridical matters, to provide supplementary education and training courses for water services personnel, management of international affairs.	All		<b>Riku Vahala</b> Email: <a href="mailto:Riku.Vahala@vvy.fi">Riku.Vahala@vvy.fi</a>
Water Industry	<b>Drinking Water Institute (DWI)</b> <a href="http://www.vesi-instituutti.fi">www.vesi-instituutti.fi</a>	DWI (Drinking Water Institute) is concentrated on materials in contact with drinking water. The main goals are 1) to improve the operation environment of Finnish companies within the subject, 2) develop reliability of drinking water production and distribution systems, and 3) services providing and ensuring clean and safe drinking water. Institute serves all instances that operate within drinking water area.			<b>Marja Luntamo</b> Email: <a href="mailto:Marja.Luntamo@vesi-instituutti.fi">Marja.Luntamo@vesi-instituutti.fi</a>

## 10.5 Spanish Stakeholders

Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
Government	<b>Ministerio de medio ambiente</b> <a href="http://www.mma.es">www.mma.es</a>	Preserve the environment and the natural resources.	- Raw water quality (rivers, aquifers, reservoirs, etc.) - waste water treatment and polluting emissions	- quality control to ensure the accomplishment of standards	??
	<b>Ministerio de sanidad y consumo</b> <a href="http://www.msc.es">www.msc.es</a>	Prevention of disease and promotion of health.	- drinking water quality - health effects	- Regulatory and policy-making role	Margarita Palau. Jefe Servicio. Unidad Agua de Consumo Humano. SG Sanidad Ambiental y Laboral; DG Salud Pública. Paseo del Prado 18-20 28071- Madrid Tel. 91-596.20.91 <a href="mailto:mpalau@msc.es">mpalau@msc.es</a>
Regulators and watchdogs	<b>Sistema de Información Nacional de Agua de Consumo (SINAC)</b> <a href="http://sinac.msc.es/">http://sinac.msc.es/</a>	National information system on drinking water. They collect data on the characteristics and quality of drinking water supply in Spain. Objectives: detect and prevent risks from polluted water; identify the quality and characteristics of the drinking water; facilitate basic information of the supplies and water quality to the citizens; supply information to the authorities and SINAC users on the characteristics of the infrastructures; to facilitate the coordination of surveillance programmes; write periodic reports on the characteristics of the infrastructures and the quality of the drinking water; Inform the European Union and other international organisations.	- drinking water quality	- quality control to ensure the accomplishment of drinking water standards  - Reluctance to provide data.	



Consumer organisations	<b>Organización de Consumidores y Usuarios (OCU)</b> <a href="http://www.ocu.org">www.ocu.org</a>	Consumers and users organization. Private non-profit organisation created in 1975 with the objective of informing the consumers and defending their interests. They have two main tools: a journal and consult service to the members of the organization.	- drinking water quality - health effects - cost of drinking water	- A priori willingness to provide data. - Ensure stakeholder dialogue and engagement of public in decision-making on water quality issues.	C/ Albarracín, 21 28037 Madrid Eva Jiménez 91 722 60 61 <a href="mailto:ejimenez@ocu.org">ejimenez@ocu.org</a>
Research and data provision		The big companies have their own labs with their own I + D (research and development) activity, but it is not integrated in a national organization. I could mention a main water company if necessary. They have a lot of power.	- drinking water quality - health effects - cost of treatment and distribution - cost of drinking water		
Water industry	<b>Asociación española de empresas gestoras de los servicios de agua potable a poblaciones (AGA)</b> <a href="http://www.asoaga.com">www.asoaga.com</a>	Spanish association of managers of drinking water supply to the population. Founded in 1995 to promote and defend the interests of companies involved in the management of water on its integral cycle: obtaining raw water, treatment, supply, management of wastewater network and treatment. The association is composed by 65 companies (private, public or mixed) supplying urban areas covering about 75% of Spanish population.	- all	- Resisting expensive change where profitability of its members' industries might be compromised	Sor Ángela de la Cruz, 2, 13º. 28020-Madrid Tel 915 700 001 Fax. 915 794 508 <a href="mailto:aga@asoaga.com">aga@asoaga.com</a>
	<b>Asociación española de abastecimiento de agua y saneamiento (AEAS)</b> <a href="http://www.aeas.es">www.aeas.es</a>	Spanish association of supply and treatment. Objectives: solution analysis for different aspects of integrated water cycle; knowledge exchange (research, teaching, management of technical, human, legal, administrative and economical aspects; collaboration with the public administration in legislation, regulation and technical update; promote communication between professionals and users.	- all		Sor Ángela de la Cruz, 2, 13º. 28020-Madrid Tel 914 490 910 Fax. 915 713 523 <a href="mailto:aeas@aeas.es">aeas@aeas.es</a>

## 10.6 EU Stakeholders

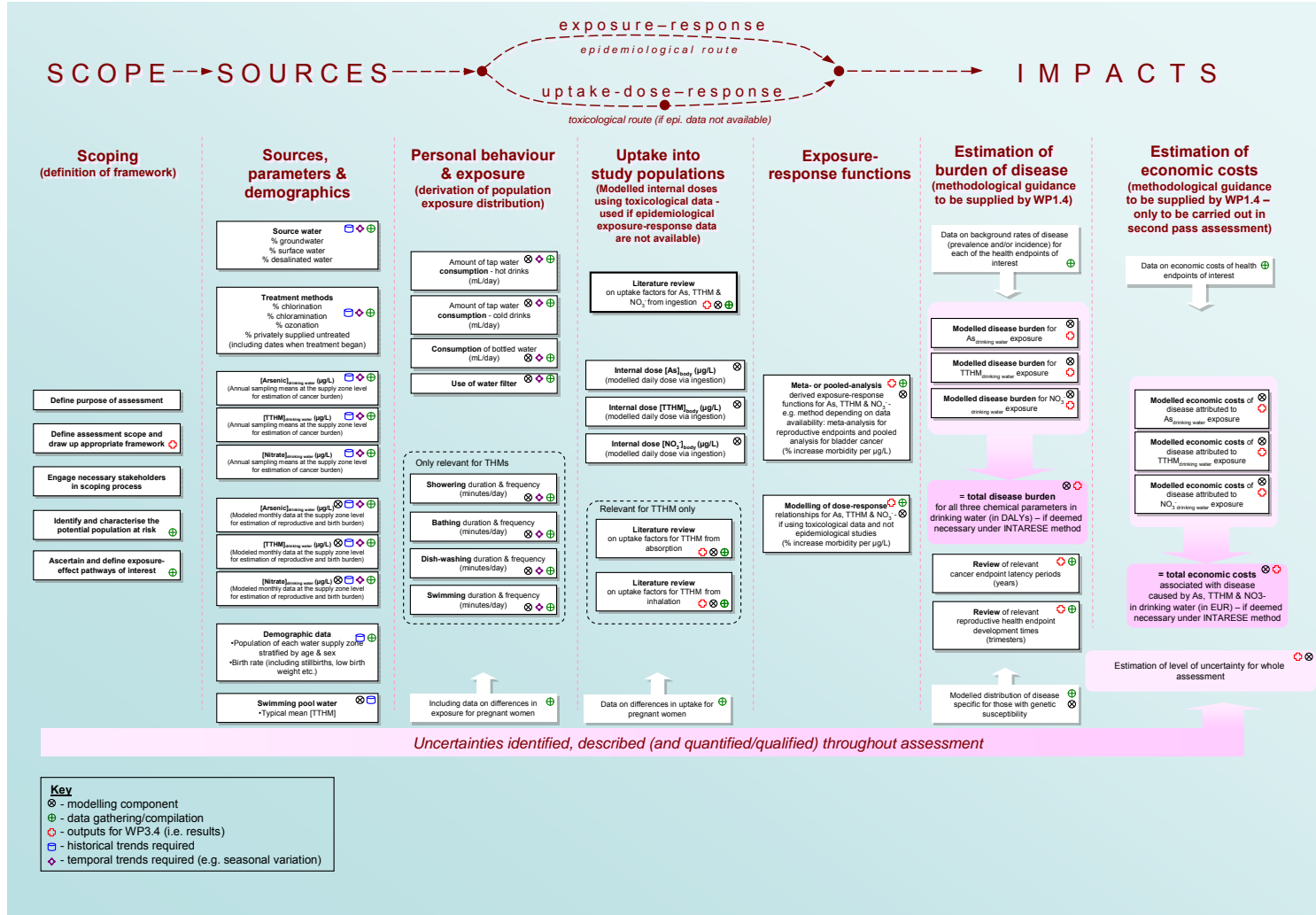
Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
EU regulators	<b>European Commission DG Environment Directorate D: Water, Chemicals and Cohesion</b> <a href="http://ec.europa.eu/dgs/environment/directory.htm#d">http://ec.europa.eu/dgs/environment/directory.htm#d</a>	'The Commission assesses the results of Member States' water quality monitoring against the standards in the Drinking Water Directive. After each reporting cycle the Commission produces a synthesis report, which summarises the quality of drinking water and its improvement at a European level. The synthesis reports are available to the public and can be found on this site for the reporting periods 1993-1995 and for the period 1996-1998. The report on the next period covering the years 1999-2001 is currently being prepared and will be published on this site early 2006.'	Drinking water quality	Policy-making and legislation.	<b>Peter Gammeltoft</b> European Commission Environment DG Head of Unit Office BU-9 3/147 Brussels Belgium  Tel: +32 2 299 11 11 Email: <a href="mailto:peter.gammeltoft@ec.europa.eu">peter.gammeltoft@ec.europa.eu</a>
	<b>European Environment Agency</b> <a href="http://www.eea.europa.eu/">http://www.eea.europa.eu/</a>	'The EEA aims to support sustainable development and to help achieve significant and measurable improvement in Europe's environment through the provision of timely, targeted, relevant and reliable information to policy making agents and the public.'			Data gathering role.

	<p><b>European Topic Centre on Water (ETC/WTR)</b>  <a href="http://water.eionet.europa.eu/">http://water.eionet.europa.eu/</a></p>	<p>'The European Topic Centre on Water (ETC/WTR) is an international consortium brought together to support the European Environment Agency (EEA) in its mission to deliver timely, targeted, relevant and reliable information to policy-makers and the public for the development and implementation of sound environmental policies in the European Union and other EEA member countries. The intention is to establish a seamless environmental information system to assist the Commission and EEA member countries in their attempts to improve the environment, move towards sustainability and integrate environmental policies with other sectors such as economic, social, transport, industry, energy and agriculture.'</p>	Drinking water quality issues	Provision of information to EU policy-makers.	<p><b>Ruth Cullingford</b>                      Email: <a href="mailto:cullingford_r@wrcplc.co.uk">cullingford_r@wrcplc.co.uk</a></p> <p><b>Tim Lack</b>                      Email: <a href="mailto:lack@wrcplc.co.uk">lack@wrcplc.co.uk</a></p> <p><b>Steve Nixon</b>                      Email: <a href="mailto:nixon@wrcplc.co.uk">nixon@wrcplc.co.uk</a></p> <p><b>János Fehér</b>                      Email: <a href="mailto:feher.janos@vituki-consult.hu">feher.janos@vituki-consult.hu</a></p> <p><b>Concepcion Marcuello</b>                      Email: <a href="mailto:concepcion.marcuello@cedex.es">concepcion.marcuello@cedex.es</a></p>
Water industry	<p><b>European union of national associations of water suppliers and waste water services (EUREAU)</b>  <a href="http://www.eureau.org">http://www.eureau.org</a></p>	<p>'Our members collectively provide sustainable water services to around 450 million European citizens and reflect the diversity of the European water services sector. As the focus of a European network, Eureau represents a unique concentration of technical, scientific and managerial knowledge and practical experience in water services.'</p> <p>'Eureau aims for a provision of reliable and high quality water supply and waste water services which:</p> <ul style="list-style-type: none"> <li>• protect public health</li> <li>• fully respect the natural environment</li> <li>• Support economic development</li> <li>• are socially acceptable.'</li> </ul>	All		<p><b>Mr Dominique Gate!</b>                      Veolia Water – Technical Dept.                      Tel: +33 17133 3282                      Email: <a href="mailto:dominique.gatel@veoliaeau.fr">dominique.gatel@veoliaeau.fr</a></p> <p><b>Mr Daniel Villessot</b>                      Email: <a href="mailto:daniel.villessot@yonnaise-des-eaux.fr">daniel.villessot@yonnaise-des-eaux.fr</a></p>

## 10.7 International Stakeholders

Stakeholder type	Name of national organisation (web address if available)	Role/institutional aims and objectives	Assumed aspects/issues of interest to the stakeholder	Anticipated positions on these issues/aspects	Contact details (name & email)
International Organisations	<p><b>World Health Organisation (WHO) – Water Sanitation and Health (WSH)</b>  <a href="http://www.who.int/water_sanitation_health/en/">http://www.who.int/water_sanitation_health/en/</a></p>	<p>WHO works on aspects of water, sanitation and hygiene where the health burden is high, where interventions could make a major difference and where the present state of knowledge is poor'</p> <p>'work on water sanitation and hygiene includes the six core functions of WHO:</p> <ul style="list-style-type: none"> <li>• articulating consistent, ethical and evidence-based policy and advocacy positions;</li> <li>• managing information by assessing trends and comparing performance; setting the agenda for, and stimulating, research and development;</li> <li>• catalysing change through technical and policy support, in ways that stimulate cooperation and action and help to build sustainable national and intercountry capacity;</li> <li>• negotiating and sustaining national and global partnerships;</li> <li>• setting, validating, monitoring and pursuing the proper implementation of norms and standards;</li> <li>• stimulating the development and testing of new technologies, tools and guidelines.'</li> </ul>	<ul style="list-style-type: none"> <li>• All</li> </ul>	<ul style="list-style-type: none"> <li>• ?</li> </ul>	<p><b>Jamie Bartram</b></p> <p>Email: <a href="mailto:bartramj@who.int">bartramj@who.int</a></p>

# 11 Appendix 4 - Overall assessment diagram



## 12 Appendix 5 - Compiled stakeholder responses to WP3.4 Scoping Report

### *WP3.4 Policy Scoping Stakeholders Report*

#### 12.1 National Stakeholders

##### *12.1.1 UK Stakeholders*

John Fawell - Independent consultant	
1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	Yes but the framework on its own doesn't mean very much.
2 Which aspects, if any, of the framework diagram are unclear to you?	The detail underneath and the substances to be considered are vital, e.g. arsenic is entirely natural. It is essential that there is actual measurement. I would be very concerned about many assumptions. Many of the comments relate to exposures that have not only been well studied but show a lack of regard for biological plausibility. As far as I am aware, unless science has been changed completely, dose is still the key in toxicity. Simple correlations are not sufficient.
3 What, if anything, is missing from the framework diagram?	Diffuse sources of contamination. Consideration of other sources of exposure, not just food.
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	Microbiology.
5 Please add any additional comments or questions as you see fit.	It is difficult to comment without some examples of what might be looked at and how exposure will be measured.

##### *12.1.2 Finnish Stakeholders*

Jari Keinänen - Ministry of Social Affairs and Health (STM)	
1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	Yes.
2 Which aspects, if any, of the framework diagram are unclear to you?	-
3 What, if anything, is missing from the framework diagram?	Exceptional situations (others than waste water) affecting the contamination of raw water or drinking water could be mentioned separately in diagram.
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	Exposure to contaminants and water treatment.
5 Please add any additional comments or questions as you see fit.	-

Minna Haski - Ministry of Agriculture and Forestry (MMM)	
1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	-
2 Which aspects, if any, of the framework diagram are unclear to you?	Is the model strictly limited on drinking water health effects? Is the aspect Finland, Europe or global?
3 What, if anything, is missing from the framework diagram?	How about the effects of climate change on flooding and drought, which may also have health effects?

4 Which aspects of the framework diagram would consider of highest priority to the assessment?	-
5 Please add any additional comments or questions as you see fit.	-

**Tiina Torkkeli-Pitkäranta - National Product Control Agency for Welfare and Health (STTV)**

1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	Yes.
2 Which aspects, if any, of the framework diagram are unclear to you?	-
3 What, if anything, is missing from the framework diagram?	-
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	-
5 Please add any additional comments or questions as you see fit.	Basically the model looks good.

**Minna Keinänen-Toivola - Drinking Water Institute (DWI)**

1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	Basically, the framework is ok. Some things are a bit too detailed, such as examples. The problems are not necessary the same in every country. F.e. DHBs, nitrates and lead are mentioned are mentioned, but actually they are not that problematic and risky, for example in Finland.
2 Which aspects, if any, of the framework diagram are unclear to you?	There are several stages from climate change to DHPs. It's difficult to see what issues are on the same "level". Climate change f.e. is a background issue that effects all operations and is a risk, whereas certain parameters such as pathogens can be an acute risk.
3 What, if anything, is missing from the framework diagram?	<ol style="list-style-type: none"> <li>1. Biofilms, emerging pathogens (f.e. Legionella, Mycobacteria).</li> <li>2. Interactions of water and materials, such us leaching of metals.</li> <li>3. Technical quality of water (service life of materials, hardness vs. heart diseases?)</li> <li>4. What is acute risk vs. life time risks?</li> <li>5. Solutions to risks</li> </ol>
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	Water distribution systems; interactions of materials and drinking water.
5 Please add any additional comments or questions as you see fit.	It was not totally clear what is the idea of this project. What is the planned practical outcome of the project? Aspects of UK are maybe too strong.

### **12.1.3 Spanish Stakeholders**

**Margarita Palau - SINAC and Ministry of Health**

1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	-
2 Which aspects, if any, of the framework diagram are unclear to you?	Regulation: if refers to norms, arrows should go everywhere, since practically everything is regulated and legislated, whether in the ambit of health or environment.
3 What, if anything, is missing from the	↳ In the box "Agriculture, Industry...": change pesticides by the Spanish term of

framework diagram?	<p>plaguicidas.</p> <ul style="list-style-type: none"> <li>↳ In the box "DBPs": you should add other by-products apart from those from disinfection.</li> <li>↳ In the box "Drinking Water", change for the term "water for human consumption".</li> <li>↳ In the box "old materials": they are not exclusively old materials. There are products of the construction that can give migrations problems, biofilms and the lack of periodic cleaning of deposits also in the deterioration of the distributed water.</li> <li>↳ In the box "Personal Behavior": I would add habits and citizen awareness that affect directly in the bigger or smaller demand of water.</li> <li>↳ In the box "taste and odour": the consumers not only pay attention to these two parameters, but also to the organoleptics in general including also turbidity and color.</li> <li>↳ In the box "disease": I would put the risks of carcinogenicity, mutagenicity and alteration of the reproduction as well as short and long term toxic effects. That way you would include all the aspects that can affect the population health and not only through ingestion but also by inhalation way and dermal absorption.</li> </ul> <p>Delete the following arrows:</p> <ul style="list-style-type: none"> <li>↳ FROM CLIMATE CHANGE TO WATER POLLUTION: the water pollution will be caused by the population growth but not directly by the climate change.</li> <li>↳ FROM WASTE WATER TO MATERIALS: the waste water affects the water in origin but not to the water directly distributed.</li> <li>↳ FROM WATER SHORTAGE TO POPULATION GROWTH: the arrow that needs to be kept is the other, but the lack of water doesn't have any influence in having a bigger or smaller growth of population but the other way around.</li> </ul>
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	
5 Please add any additional comments or questions as you see fit.	<ol style="list-style-type: none"> <li>1. At the moment almost a 80% of surface water and almost a 5% of desalted water is being used, therefore the affirmation in brackets is not true.</li> <li>2. The pollution by pesticides is becoming very important, in particular due to herbicides that go to surface and ground waters. I believe it should be added in addition to nitrates.</li> <li>3. I think other by-products should be added and not only those of the disinfection. As well as migrations of materials installed from the water-treatment plant to the faucet of the consumer.</li> <li>4. The legislation affects also the water in origin, the treatment of waste water, the control and surveillance of water quality for human consumption.</li> <li>5. I believe that there are more contaminants that trihalometans that affect more directly people health at short term like for example the microbiologic contaminants.</li> <li>6. I would put the risks of carcinogenicity, mutagenicity and reproduction as well as toxic effects at short and long term (these terms are used in the legislation of risk assessment of chemical substances). This way you include all aspects that can affect population health and not only by intake way but also inhalation and dermal absorption.</li> <li>7. Nothing to say</li> <li>8. You could add something about the future in re-using waste waters (regenerated waters). That would solve many situations of water shortages and re-charge of aquifers.</li> </ol>

### 12.1.4 Romanian Stakeholders

1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	-
2 Which aspects, if any, of the framework diagram are unclear to you?	-
3 What, if anything, is missing from the framework diagram?	-

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4 Which aspects of the framework diagram would consider of highest priority to the assessment? -

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5 Please add any additional comments or questions as you see fit. -

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### 12.1.5 Hungarian Stakeholders

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1 Does the framework provide a useable, realistic representation of the current situation? Please comment. -

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2 Which aspects, if any, of the framework diagram are unclear to you? -

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3 What, if anything, is missing from the framework diagram? -

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4 Which aspects of the framework diagram would consider of highest priority to the assessment? -

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5 Please add any additional comments or questions as you see fit. -

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## 12.2 International Stakeholders

### 12.2.1 European

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Jan Cortvriend - Water Unit, DG Environment

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1 Does the framework provide a useable, realistic representation of the current situation? Please comment. -

It is a realistic model. Note that normally no re-used water is used for the preparation of drinking water drinking water in the EU.

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2 Which aspects, if any, of the framework diagram are unclear to you? -

I do not understand the link from climate change towards population growth and mass tourism. On migration the link is clear. Please take into account the possibility of source water contamination by sabotage. The water-treatment may cause pollution itself by excessive chlorination, and uncontrolled fluoridation. Also the water plant may deposit into the water chemicals like monoacrylamide (and others) by wrong use of chemicals during the preparation process. In the distribution phase, THMs may originate due to over-disinfection or nitrites may come up as a result of on anaerobe reaction. In the distribution cycle also endocrine disrupters may enter the water (next to led) as a result of contact of water with certain plastic pipes.

---

3 What, if anything, is missing from the framework diagram? -

See answer to question 2. I allowed myself to add some comments on the project graph and scanned this for you (see attached document and reactions on further questions). During the production cycle, a risk analysis and management plan should exist (which I depicted with little flags). See WHO literature relating to Water Safety Plans.  
Do you take into account bottled (and mineral) water?

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4 Which aspects of the framework diagram would consider of highest priority to the assessment? -

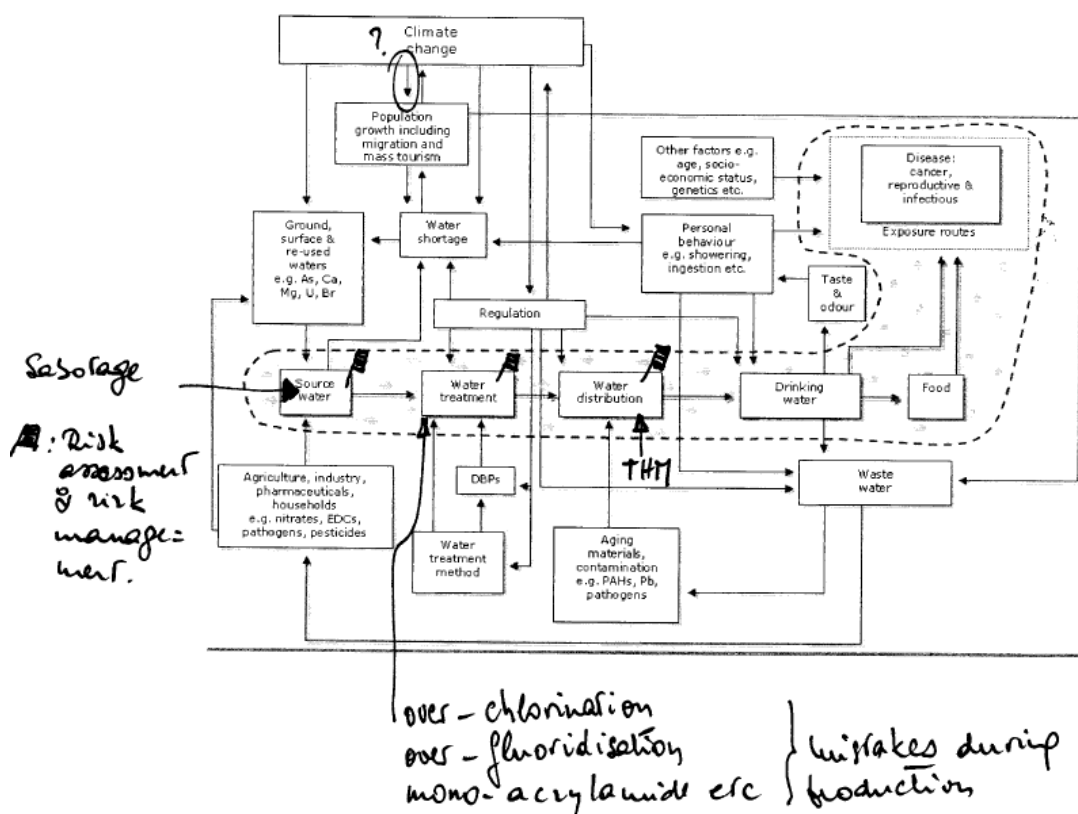
Mass tourism, migration, resulting in depletion of natural water stocks; new technologies to prepare drinking water and their impact upon environment, existence of a risk analysis and management.

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5 Please add any additional comments or questions as you see fit. -

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Happy to talk this through.



Dominique Gatel - Veolia Water/EUREAU

<p>1 Does the framework provide a useable, realistic representation of the current situation? Please comment.</p>	<p>Yes. I would also suggest the addition of an arrow certainly from the box "Agriculture, industry etc." towards the box "Water treatment method". There could also be an arrow from the box "Ground, surface, ..." towards this same "Water treatment method" box. One could also add an arrow from box "Agriculture, industry etc" towards "water distribution" (symmetrical to that of Waste water to "Aging material...").</p> <p>Also, the "Regulation" box now concerns source water and its potential contaminants (think of the Water Framework Directive, the Priority Substance Directive, GWD etc.).</p>
<p>2 Which aspects, if any, of the framework diagram are unclear to you?</p>	<p>None.</p>
<p>3 What, if anything, is missing from the framework diagram?</p>	<p>-</p>
<p>4 Which aspects of the framework diagram would consider of highest priority to the assessment?</p>	<p>Source water composition &amp; potential impact on the burden of disease, taking account presumptive removal by treatment (e.g. for pesticides: 90%).</p>
<p>5 Please add any additional comments or questions as you see fit.</p>	<p>-</p>

János Fehér - European Topic Centre on Water (ETC/WTR)

<p>1 Does the framework provide a useable, realistic representation of the current situation? Please comment.</p>	<p>In general the framework provides a good representation of the current situation. I assume that similar explanations are available for other specific areas than water.</p>
<p>2 Which aspects, if any, of the framework diagram are unclear to you?</p>	<p>After a relatively quick overview of the three page long WP3 Water Policy Scoping Final documentation it seems to me that the strength of actual economy of a country in concern gets low or just hidden consideration in the diagram: i.e.: it is a growing evidence that in Central and Eastern European countries mineral or bottled water consumption acceleratingly increases. The increased consumption is highly related</p>



	with increasing economic strength of these countries and the direct use of water from public water supply networks for drinking purpose is decreasing and thus changing the traditional exposure routes to water. The strength of the economy is also dominant factor for regulation and enforcement of pollution abatements.
3 What, if anything, is missing from the framework diagram?	See comments in Q2 box.
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	Source water protection, water and waste water treatment.
5 Please add any additional comments or questions as you see fit.	Can you please send me some more information what way you are thinking of the involvement of the stakeholders in the implementation of the project.

### 12.2.2 Global

Roger Aertgeerts - World Health Organisation

1 Does the framework provide a useable, realistic representation of the current situation? Please comment.	Yes, although I would have liked to see a differentiation between regional (EU) and national/local regulation.
2 Which aspects, if any, of the framework diagram are unclear to you?	Why is the disease outcome limited to non-communicable diseases? The region still suffers from the basic water-related diseases (v hepatitis, typhoid, cholera, ECEH, shigellosis) and sees an increase in emerging diseases such as campylo, crypto and giardiasis. Recent communications from German researchers also drew the attention to the link between viral infections and climate change, while a body of literature exists that draws the attention to emerging chemical toxins linked to changing ecosystems i.e. cyanobacteria and their toxins.
3 What, if anything, is missing from the framework diagram?	The diagram seems to be developed on a one-size-fits-all approach. I would plead for recognition of the specificity of water supply in rural areas, particularly Romania, where significant portions of the population do not have access in-house to water supply. Such conditions are not to be compared with those of water supply in a country like the UK and ought to be given special recognition. In personal behaviour, hand washing should be taken up as a special item. Similarly, differentiation should be made in the different levels of sanitation, starting with access to improved sources of sanitation, between the different countries giving particular attention to sanitation in rural areas of Romania. The situation there is not to be compared with those in countries that have benefited from the EU UWWDD. The issue of water shortage can not be seen as a stand alone issue with climate change and population growth/tourism as the main drivers. Agriculture and the different types of irrigation if left unchanged is one of the main drivers but controllable. Also I wonder whether population growth per se is a main driver, or whether changing living standards especially in the new EU countries is a main driver. I do not have the relevant literature at hand, but would argue that increase in water consumption of a stable population through access to ever more water-intensive household equipment (washers, dryers, personal irrigation tools, car washes etc etc) is not a stronger driver than population growth as such. Another driver which is not taken up is the cost of energy in the different countries. Energy prices and their reflection in the unit price of water are a major determinant of water consumption.
4 Which aspects of the framework diagram would consider of highest priority to the assessment?	As a totally neutral WHO staff member, I would suggest that the link between water and disease is the highest priority ;-).
5 Please add any additional comments or questions as you see fit.	The diagram seems to presume that all water supply systems perform equally well. This is definitively not so. Assessment of the service quality of the supply (interruptions, losses etc) should also be taken into account.

### 12.3 Framework diagram incorporating all stakeholder comments

Figure 8 illustrates how the incorporation of all stakeholders' comments may influence the layout of the framework diagram.

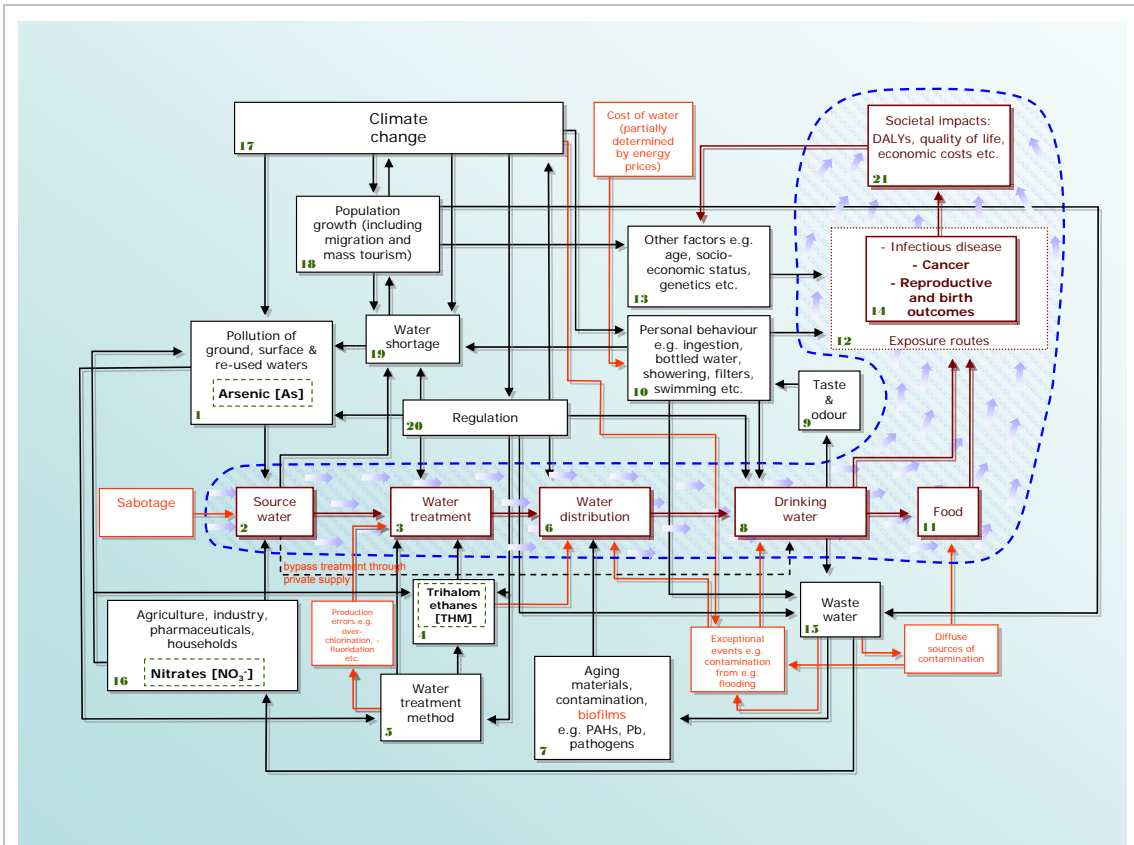
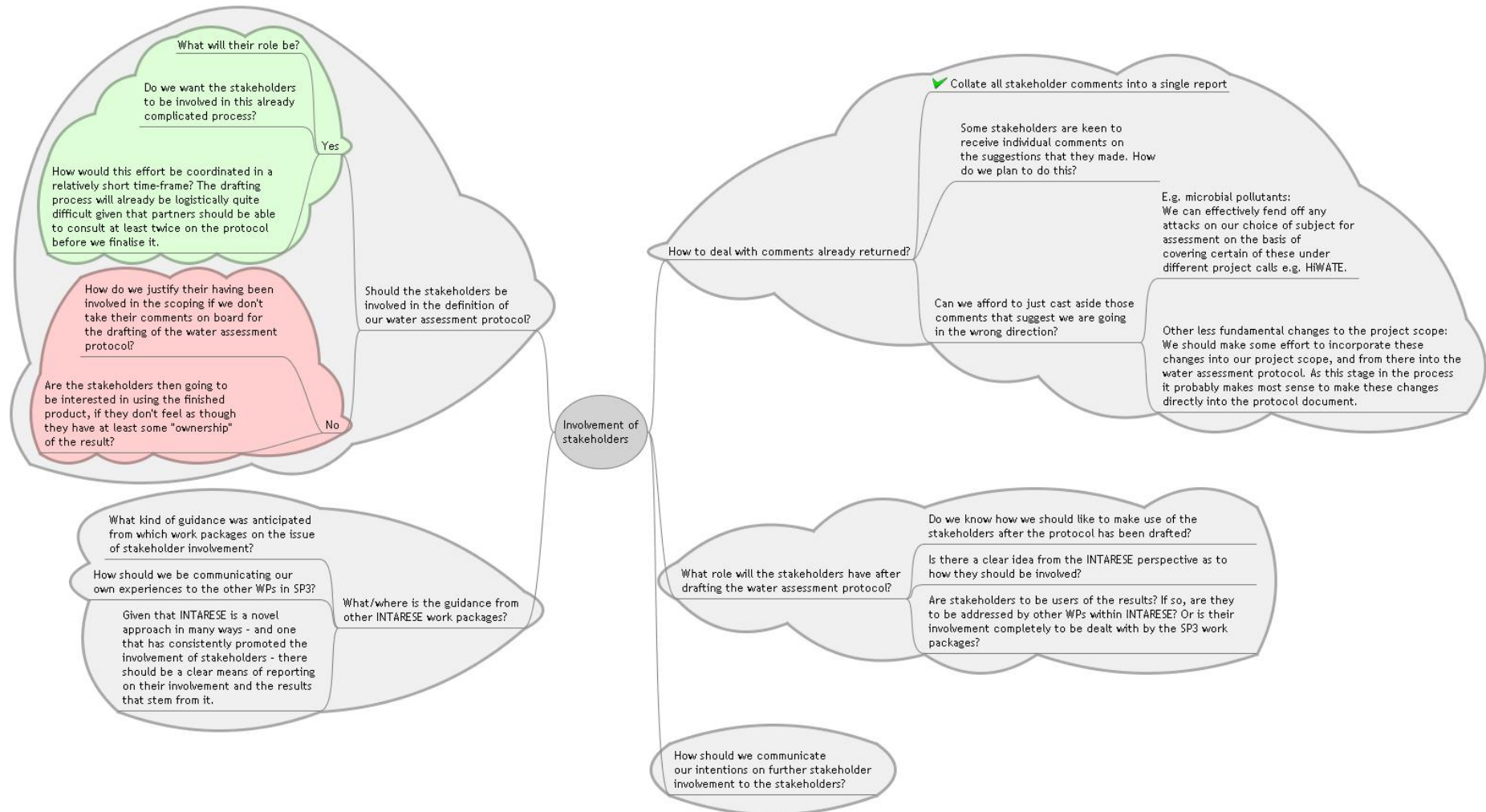


Figure 8 - Framework diagram incorporating all stakeholders' additions/changes

### 13 Appendix 6 - Dealing with Stakeholder Response



### 13.1 How to deal with comments already returned?

- ↪ Collate all stakeholder comments into a single report

Already done

- ↪ Some stakeholders are keen to receive individual comments on the suggestions that they made. How do we plan to do this?
- ↪ Can we afford to just cast aside those comments that suggest we are going in the wrong direction?

E.g. microbial pollutants: We can effectively fend off any attacks on our choice of subject for assessment on the basis of covering certain of these under different project calls e.g. HiWATE.

Other less fundamental changes to the project scope: We should make some effort to incorporate these changes into our project scope, and from there into the water assessment protocol. As this stage in the process it probably makes most sense to make these changes directly into the protocol document.

- ↪ Should the stakeholders be involved in the definition of our water assessment protocol?

Yes

1. What will their role be?
2. Do we want the stakeholders to be involved in this already complicated process?
3. How would this effort be coordinated in a relatively short time-frame? The drafting process will already be logistically quite difficult given that partners should be able to consult at least twice on the protocol before we finalise it.

No

1. How do we justify their having been involved in the scoping if we don't take their comments on board for the drafting of the water assessment protocol?
2. Are the stakeholders then going to be interested in using the finished product, if they don't feel as though they have at least some "ownership" of the result?
3. What role will the stakeholders have after drafting the water assessment protocol?

- ↪ Do we know how we should like to make use of the stakeholders after the protocol has been drafted?

- ↪ Is there a clear idea from the INTARESE perspective as to how they should be involved?

- ↪ Are stakeholders to be users of the results? If so, are they to be addressed by other WPs within INTARESE? Or is their involvement completely to be dealt with by the SP3 work packages?

- ↪ What/where is the guidance from other INTARESE work packages?

1. What kind of guidance was anticipated from which work packages on the issue of stakeholder involvement?

2. How should we be communicating our own experiences to the other WPs in SP3?
  3. Given that INTARESE is a novel approach in many ways - and one that has consistently promoted the involvement of stakeholders - there should be a clear means of reporting on their involvement and the results that stem from it.
- ↳ How should we communicate our intentions on further stakeholder involvement to the stakeholders?

## 14 Appendix 7 - Population health data request from WP3.4 to WP2.3

WP3.4 will request the following data from WP2.3.

		Health Indicator 1	Health Indicator 2	Health Indicator 3	Health Indicator 4	Health Indicator 5	Health Indicator 6	Health Indicator 7	Health Indicator 8	Health Indicator 9	Health Indicator 10
<b>Health Indicator &amp; ICD10 code</b>	ICD10 codes from <a href="http://www.who.int/classifications/apps/icd/icd10online/">http://www.who.int/classifications/apps/icd/icd10online/</a>	<b>C67.*</b> Malignant neoplasm of bladder Both morbidity (incidence) and mortality data	<b>C64.*</b> Malignant neoplasm of kidney, except renal pelvis Both morbidity (incidence) and mortality data	<b>C44.*</b> Other malignant neoplasms of skin Both morbidity (incidence) and mortality data	<b>C34.*</b> Malignant neoplasm of bronchus and lung Both morbidity (incidence) and mortality data	<b>P07.*</b> Disorders related to short gestation and low birth weight, not elsewhere classified Both morbidity (incidence) and mortality data	<b>Z37.*</b> Outcome of delivery (stillbirth) Both morbidity (incidence) and mortality data	<b>P05.*</b> Slow fetal growth and fetal malnutrition Both morbidity (incidence) and mortality data	<b>P59.*</b> Neonatal jaundice from other and unspecified causes Both morbidity (incidence) and mortality data	<b>Q00 - Q99</b> Congenital malformations, deformations and chromosomal abnormalities Both morbidity (incidence) and mortality data	<b>D74.*</b> Methaemoglobin aemia Both morbidity (incidence) and mortality data
<b>Geographical area of concern</b>	Geographical or administrative boundaries (level of analysis)	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK	National level for Finland, Hungary, Romania, Spain, UK
<b>Time Features</b>	Time span for which the health data is required	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent	1990-most recent
	Time resolution needed	monthly	monthly	monthly	monthly	monthly	monthly	monthly	monthly	monthly	monthly
<b>Other Features</b>	Gender	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed	Male/female needed

	Age	Population age in 5-year classes	Population age in 5-year classes	Population age in 5-year classes	Population age in 5-year classes	Prenatal/perinatal health outcome - gestation time if available - please advise	Prenatal/perinatal health outcome - gestation time if available - please advise	Prenatal/perinatal health outcome - gestation time if available - please advise	Prenatal/perinatal health outcome - gestation time if available - please advise	Prenatal/perinatal health outcome - gestation time if available - please advise	Prenatal/perinatal health outcome - gestation time if available - please advise
	Other features	No	No	No	No	No	No	No	No	No	No
Comment	Any other information or comments	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	See notes 1 and 2 below	WP3.4 is still not entirely sure which specific health endpoints from this large category to look at. We are awaiting advice from partners/ stakeholders/ other WPs before confirming which outcomes we will look at.	See notes 1 and 2 below

Note 1: It would be useful to have data from 1990 so as to look at trends, although we may eventually model using only 2001-present data.

Note 2: The ICD10 code provided is in the form of a general category, rather than a very specific outcome, since this reflects the nature of the epidemiology studies that we will be making use of.

15 **Appendix 8 - Detailed breakdown of health outcomes to be looked at in WP3.4 assessment**

Head category	ICD10 code - broad category	Outcome name - broad category	Narrow category (see note below)	Narrow category outcome names	Include the following narrow subcategories	Vast majority of cases represented by particular narrow subcategory?	Exclude the following narrow subcategories
Q00 - Q99 Congenital malformations, deformations and chromosomal abnormalities	Q35-Q37	Cleft lip and cleft palate	Q35.*	Cleft palate	Q35.1 Cleft hard palate Q35.3 Cleft soft palate Q35.5 Cleft hard palate with cleft soft palate Q35.7 Cleft uvula Q35.9 Cleft palate, unspecified	No data	None
			Q36.*	Cleft lip	Q36.0 Cleft lip, bilateral Q36.1 Cleft lip, median Q36.9 Cleft lip, unilateral	No data	None
			Q37.*	Cleft palate with cleft lip	Q37.0 Cleft hard palate with bilateral cleft lip Q37.1 Cleft hard palate with unilateral cleft lip Q37.2 Cleft soft palate with bilateral cleft lip Q37.3 Cleft soft palate with unilateral cleft lip Q37.4 Cleft hard and soft palate with bilateral cleft lip Q37.5 Cleft hard and soft palate with unilateral cleft lip Q37.8 Unspecified cleft palate with bilateral cleft lip Q37.9 Unspecified cleft palate with unilateral cleft lip	No data	None
Q65-Q79	Congenital malformations and deformations of the musculoskeletal system	Q79.*	Congenital malformations of the musculoskeletal system, not elsewhere classified	Q79.0 Congenital diaphragmatic hernia Q79.1 Other congenital malformations of diaphragm Q79.2 Exomphalos Q79.3 Gastroschisis	No data	Q79.4 Prune belly syndrome Q79.5 Other congenital malformations of abdominal wall Q79.6 Ehlers-Danlos syndrome Q79.8 Other congenital malformations of musculoskeletal system Q79.9 Congenital malformation of musculoskeletal system, unspecified	
Q20-Q28	Congenital malformations of the circulatory system	Q20.*	Congenital malformations of cardiac chambers and connections	Q20.0 Common arterial trunk Q20.1 Double outlet right ventricle Q20.2 Double outlet left ventricle Q20.3 Discordant ventriculoarterial connection Q20.4 Double inlet ventricle Q20.5 Discordant atrioventricular connection Q20.6 Isomerism of atrial appendages Q20.8 Other congenital malformations of cardiac chambers and connections Q20.9 Congenital malformation of cardiac chambers and connections, unspecified	No data	None	



		Q21.*	Congenital malformations of cardiac septa	Q21.1 Atrial septal defect Q21.2 Atrioventricular septal defect Q21.3 Tetralogy of Fallot Q21.4 Aortopulmonary septal defect Q21.8 Other congenital malformations of cardiac septa Q21.9 Congenital malformation of cardiac septum, unspecified	No data	Q21.0 Ventricular septal defect Q21.1 Atrial septal defect Q21.4 Aortopulmonary septal defect Q21.8 Other congenital malformations of cardiac septa Q21.9 Congenital malformation of cardiac septum, unspecified
		Q22.*	Congenital malformations of pulmonary and tricuspid valves	Q22.0 Pulmonary valve atresia Q22.1 Congenital pulmonary valve stenosis Q22.2 Congenital pulmonary valve insufficiency Q22.3 Other congenital malformations of pulmonary valve Q22.4 Congenital tricuspid stenosis Q22.5 Ebstein's anomaly Q22.6 Hypoplastic right heart syndrome Q22.8 Other congenital malformations of tricuspid valve Q22.9 Congenital malformation of tricuspid valve, unspecified	No data	None
		Q23.*	Congenital malformations of aortic and mitral valves	Q23.0 Congenital stenosis of aortic valve Q23.1 Congenital insufficiency of aortic valve Q23.2 Congenital mitral stenosis Q23.3 Congenital mitral insufficiency Q23.4 Hypoplastic left heart syndrome Q23.8 Other congenital malformations of aortic and mitral valves Q23.9 Congenital malformation of aortic and mitral valves, unspecified	No data	None
		Q25.*	Congenital malformations of great arteries	Q25.1 Coarctation of aorta Q25.2 Atresia of aorta Q25.3 Stenosis of aorta Q25.4 Other congenital malformations of aorta Q25.5 Atresia of pulmonary artery Q25.6 Stenosis of pulmonary artery Q25.7 Other congenital malformations of pulmonary artery Q25.8 Other congenital malformations of great arteries Q25.9 Congenital malformation of great arteries, unspecified	No data	Q25.0 Patent ductus arteriosus
		Q26.*	Congenital malformations of great veins	Q26.0 Congenital stenosis of vena cava Q26.1 Persistent left superior vena cava Q26.2 Total anomalous pulmonary venous connection Q26.3 Partial anomalous pulmonary venous connection Q26.4 Anomalous pulmonary venous connection, unspecified Q26.5 Anomalous portal venous connection Q26.6 Portal vein-hepatic artery fistula Q26.8 Other congenital malformations of great veins Q26.9 Congenital malformation of great vein, unspecified	No data	None
Q30-Q34	Congenital malformations of the respiratory system	Q33.*	Congenital malformations of lung	Q33.0 Congenital cystic lung Q33.1 Accessory lobe of lung Q33.2 Sequestration of lung Q33.3 Agenesis of lung Q33.4 Congenital bronchiectasis Q33.5 Ectopic tissue in lung Q33.6 Hypoplasia and dysplasia of lung Q33.8 Other congenital malformations of lung Q33.9 Congenital malformation of lung, unspecified	No data	None

Q38-Q45	Other congenital malformations of the digestive system	Q39.*	Congenital malformations of oesophagus	Q39.0 Atresia of oesophagus without fistula Q39.1 Atresia of oesophagus with tracheo-oesophageal fistula Q39.2 Congenital tracheo-oesophageal fistula without atresia Q39.3 Congenital stenosis and stricture of oesophagus Q39.4 Oesophageal web Q39.5 Congenital dilatation of oesophagus Q39.6 Diverticulum of oesophagus Q39.8 Other congenital malformations of oesophagus Q39.9 Congenital malformation of oesophagus, unspecified	No data	None
Q00-Q07	Congenital malformations of the nervous system	Q00.*	Anencephaly and similar malformations	Q00.0 Anencephaly Q00.1 Craniorachischisis Q00.2 Iniencephaly	No data	None
		Q01.*	Encephalocele	Q01.0 Frontal encephalocele Q01.1 Nasofrontal encephalocele Q01.2 Occipital encephalocele Q01.8 Encephalocele of other sites Q01.9 Encephalocele, unspecified	No data	None
		Q05.*	Spina bifida	Q05.0 Cervical spina bifida with hydrocephalus Q05.1 Thoracic spina bifida with hydrocephalus Q05.2 Lumbar spina bifida with hydrocephalus Q05.3 Sacral spina bifida with hydrocephalus Q05.4 Unspecified spina bifida with hydrocephalus Q05.5 Cervical spina bifida without hydrocephalus Q05.6 Thoracic spina bifida without hydrocephalus Q05.7 Lumbar spina bifida without hydrocephalus Q05.8 Sacral spina bifida without hydrocephalus Q05.9 Spina bifida, unspecified	No data	None
Q60 - Q64	Congenital malformations of the urinary system	Q60.*	Renal agenesis and other reduction defects of kidney	Q60.0 Renal agenesis, unilateral Q60.1 Renal agenesis, bilateral Q60.2 Renal agenesis, unspecified Q60.3 Renal hypoplasia, unilateral Q60.4 Renal hypoplasia, bilateral Q60.5 Renal hypoplasia, unspecified Q60.6 Potter's syndrome	No data	None
		Q61.*	Cystic kidney disease	Q61.0 Congenital single renal cyst Q61.1 Polycystic kidney, autosomal recessive Q61.2 Polycystic kidney, autosomal dominant Q61.3 Polycystic kidney, unspecified Q61.4 Renal dysplasia Q61.5 Medullary cystic kidney Q61.8 Other cystic kidney diseases Q61.9 Cystic kidney disease, unspecified	No data	None
		Q62.*	Congenital obstructive defects of renal pelvis and congenital malformations of ureter	Q62.1 Atresia and stenosis of ureter Q62.2 Congenital megaloureter Q62.3 Other obstructive defects of renal pelvis and ureter Q62.4 Ageneration of ureter Q62.5 Duplication of ureter Q62.6 Malposition of ureter Q62.7 Congenital vesico-uretero-renal reflux Q62.8 Other congenital malformations of ureter	No data	Q62.0 Congenital hydronephrosis
		Q64.*	Other congenital malformations of urinary system	Q64.1 Exstrophy of urinary bladder Q64.2 Congenital posterior urethral valves Q64.3 Other atresia and stenosis of urethra and bladder neck Q64.4 Malformation of urachus Q64.5 Congenital absence of bladder and urethra Q64.6 Congenital diverticulum of bladder Q64.7 Other congenital malformations of bladder and urethra	No data	Q64.0 Epispadias Q64.8 Other specified congenital malformations of urinary system Q64.9 Congenital malformation of urinary system, unspecified

<b>C00-D48</b> Neoplasms	C00-C75	Malignant neoplasms, stated or presumed to be primary, of specified sites, except of lymphoid, haematopoietic and related tissue	C67.*	Malignant neoplasm of bladder	C67.0 Trigone of bladder C67.1 Dome of bladder C67.2 Lateral wall of bladder C67.3 Anterior wall of bladder C67.4 Posterior wall of bladder C67.5 Bladder neck C67.6 Ureteric orifice C67.7 Urachus C67.8 Overlapping lesion of bladder C67.9 Bladder, unspecified	C67.9 Bladder, unspecified	None
			C44.*	Other malignant neoplasms of skin	C44.0 Skin of lip C44.1 Skin of eyelid, including canthus C44.2 Skin of ear and external auricular canal C44.3 Skin of other and unspecified parts of face C44.4 Skin of scalp and neck C44.5 Skin of trunk C44.6 Skin of upper limb, including shoulder C44.7 Skin of lower limb, including hip C44.8 Overlapping lesion of skin C44.9 Malignant neoplasm of skin, unspecified	C44.3 Skin of other and unspecified parts of face	
			C34.*	Malignant neoplasm of bronchus and lung	C34.0 Main bronchus C34.1 Upper lobe, bronchus or lung C34.2 Middle lobe, bronchus or lung C34.3 Lower lobe, bronchus or lung C34.8 Overlapping lesion of bronchus and lung C34.9 Bronchus or lung, unspecified	No	None
			C22.*	Malignant neoplasm of liver and intrahepatic bile ducts	C22.0 Liver cell carcinoma C22.1 Intrahepatic bile duct carcinoma C22.2 Hepatoblastoma C22.3 Angiosarcoma of liver C22.4 Other sarcomas of liver C22.7 Other specified carcinomas of liver C22.9 Liver, unspecified	C22.0 Liver cell carcinoma C22.1 Intrahepatic bile duct carcinoma	None
			C64.*	Malignant neoplasm of kidney, except renal pelvis	C64 Malignant neoplasm of kidney, except renal pelvis	No	None
			<b>P00-P96</b> Certain conditions originating in the perinatal period	P05-P08	Disorders related to length of gestation and fetal growth	P05.*	Slow fetal growth and fetal malnutrition
P07.*	Disorders related to short gestation and low birth weight, not elsewhere classified	P07.0 Extremely low birth weight P07.1 Other low birth weight				No data	P07.2 Extreme immaturity P07.3 Other preterm infants

<b>Z00-Z99</b> Factors influencing health status and contact with health services	Z30-Z39	Persons encountering health services in circumstances related to reproduction	Z37.*	Outcome of delivery	Z37.1 Single stillbirth Z37.3 Twins, one liveborn and one stillborn Z37.4 Twins, both stillborn Z37.7 Other multiple births, all stillborn	No data	Z37.0 Single live birth Z37.2 Twins, both liveborn Z37.5 Other multiple births, all liveborn Z37.6 Other multiple births, some liveborn Z37.9 Outcome of delivery, unspecified
<b>D50-D89</b> Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism	D70-D77	Other diseases of blood and blood-forming organs	D74.*	Methaemoglobinaemia	D74.8 Other methaemoglobinaemias D74.9 Methaemoglobinaemia, unspecified	No data	D74.0 Congenital methaemoglobinaemia
<b>P00-P96</b> Certain conditions originating in the perinatal period	P50-P61	Haemorrhagic and haematological disorders of fetus and newborn	P59.*	Neonatal jaundice from other and unspecified causes	P59.0 Neonatal jaundice associated with preterm delivery P59.1 Inspissated bile syndrome P59.2 Neonatal jaundice from other and unspecified hepatocellular damage P59.3 Neonatal jaundice from breast milk inhibitor P59.8 Neonatal jaundice from other specified causes P59.9 Neonatal jaundice, unspecified	No data	