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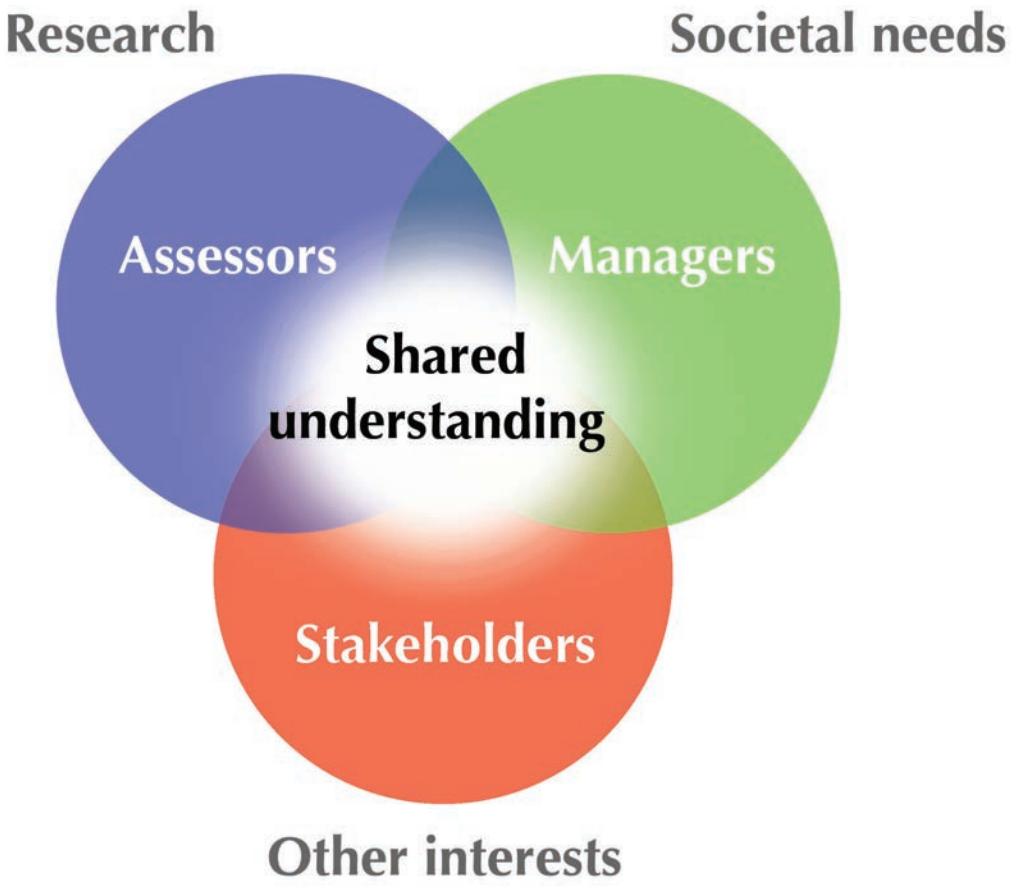
Mikko Pohjola

Assessments are to change the world

Prerequisites for effective environmental health assessment

RESEARCH



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Prerequisites for effective environmental health assessment

ACADEMIC DISSERTATION

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Dedicated to
Whom it may concern

Abstract

Mikko Pohjola. Assessments are to change the world - Prerequisites for effective environmental health assessment. National Institute for Health and Welfare (THL). Research 105. 210 pages. Tampere, Finland 2013.
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This thesis presents the main results of the research conducted in support of developing the open assessment method (http://en.opasnet.org/w/Open_assessment) and the Opasnet web-workspace (http://www.opasnet.org) at the National institute for health and welfare (THL) during 2006 – 2012.

Environmental health assessment is science-based support to decision making. It looks into the characteristics of our living environments, analyses and models how they affect human health, and considers how different decisions and actions influence the environment-health relationships. The information provided by assessments is intended to support knowledge-based decisions and actions particularly in public policy, but also e.g. by decision-makers in business and individual members of the society. In principle, environmental health assessment is a pragmatic endeavour of applying scientific knowledge and means for practical needs.

Due to many complexities related to environmental health assessment, there are several different assessment approaches addressing environment and health. Despite theoretical and practical differences, they share the idea of providing science-based support to decisions on issues of societal relevance. However, many approaches are more based on pushing expert knowledge than responding to the practical needs of decision making. Consequently, tendencies towards i) increased assessment-policy interaction, ii) broad, yet practical, framing and iii) explicit consideration of values have emerged in the recent development of environmental health assessment. Similar characteristics and challenges exist in assessments within other fields related to environment, health and well-being.

Participation of stakeholders and public is a central topic in environmental health assessment and policy. It is seen as essential for democracy, but also as a means for improving assessments and policy making. In practice, participation is still mostly perceived as a burden and it often takes place as a separate process alongside assessment and policy. However, environment and health are relevant to virtually all members of the society, which makes anyone a potentially relevant participant, and openness a necessity. Openness brings about some challenges, but they are mostly practical rather than fundamental in their nature.

The success of environmental health assessments is increasingly considered in terms of their outcomes, i.e. the changes in the world outside the walls of the expert-domain. An outcome-oriented turn is taking place in assessment and its evaluation. Most perspectives to evaluation and management of performance still focus primarily on the assessment procedures and outputs and their technical fea-

tures. Extending the perspective to cover their practical use and its effects requires a thorough account of the interrelations between knowledge and action in a social context. Unfortunately, these aspects are barely even recognized in most approaches to environmental health assessment and modelling.

Broad collaboration and tight linkage with practical implementation of knowledge are essential to effective environmental health assessment, i.e. such that contributes to decisions, their implementation as well as outcomes. However, only few serious developments building on pragmatism and collaboration have emerged following the development of collaborative software, social media, as well as the theories of collective learning. As an example, open assessment method and the Opasnet web-workspace provide an arena for experts, policy makers as well as anyone interested to initiate, follow and contribute to environmental health assessments and policy making. They implement the methods of scientific knowledge creation also in the development of practical solutions to decision problems, not only in the analysis of the underlying environment-health relationships. Easily re-usable modular information objects of Opasnet also reduce work and increase efficiency in future assessments on related topics.

The application and evaluation of Opasnet has shown that open collaboration is feasible in environmental health assessment, although experiences from broad collaboration are still scarce. Openness and transparency are highly appreciated, but even despite the lack of barriers, broad active participation in assessment can be difficult to obtain. Particularly engagement of the intended users of assessment results, e.g. policy makers or industrial decision makers, remains a challenge.

The emerging methods and tools of environmental health assessment make broad collaboration and tight linkage between production and application of knowledge possible. In addition, the development of digital networks and social media has paved the way for open knowledge in the society. However, a broad cultural change from disengagement and withholding of knowledge towards openness, transparency and collaboration is still needed for effective environmental health assessment and policy. The future development should focus particularly on the practices of using knowledge in policy making.

The focus of this research is in environmental health assessment. However, the emphasis is on the creation and application of knowledge in the processes of assessment, policy making and participation. Correspondingly, the characteristics, challenges and solutions identified here are mostly generalisable and applicable to science-policy interaction in general.

Keywords: environmental health assessment, open assessment, Opasnet, effectiveness, evaluation, science-policy interaction, evidence-based policy, collaborative learning

Tiivistelmä

Mikko Pohjola. Arvioinnit muuttamaan maailmaa – Edellytykset vaikuttavalle ympäristöterveysarvioinnille. Terveyden ja hyvinvoinnin laitos (THL). Tutkimus 105. 210 sivua. Helsinki, Suomi 2012.
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Tämä väitöskirja esittää terveyden ja hyvinvoinnin laitoksella vuosina 2006 – 2012 tehdyn avoimen arvioinnin (http://en.opasnet.org/w/Open_assessment) ja Opasnet verkkotyötilan (http://www.opasnet.org) kehitystyön tueksi tehdyn tutkimuksen päätulokset.

Ympäristöterveysarviointi on tieteeseen perustuvaa päätöksenteon tukemista. Se huomioi elinympäristömme ominaisuuksia, analysoi ja mallintaa niiden vaikutuksia ihmisten terveyteen ja tarkastelee kuinka päätökset ja toimenpiteet vaikuttavat ympäristön ja terveyden yhteyksiin. Arvioinnein saatava informaatio on tarkoitettu tukemaan tietoon perustuvia päätöksiä ja toimenpiteitä erityisesti yhteiskunnallisten päättäjien, mutta myös esim. liike-elämän päättäjien ja yksittäisten kansalaisten, toimesta. Pohjimmiltaan ympäristöterveysarviointi on pragmaattista tieteellisen tiedon ja menetelmien soveltamista käytännön tarpeisiin.

Koska ympäristöterveysarviointiin liittyy monenlaista monimutkaisuutta, on olemassa useita lähestymistapoja ympäristöä ja terveyttä koskevaan arviointiin. Teoreettisista ja käytännöllisistä eroista huolimatta niitä yhdistää pyrkimys tarjota tieteeseen perustuvaa tukea yhteiskunnallisesti merkittäviä asioita koskevalle päätöksenteolle. Monet lähestymistavat kuitenkin pyrkivät enemminkin työntämään asiantuntijatietoa kuin vastaamaan päätöksenteon käytännöllisiin tarpeisiin. Tämän johdosta viimeaikaisessa ympäristöterveysarvioinnin kehityksessä on ilmennyt pyrkimyksiä i) arvioinnin ja päätöksenteon parempaan vuorovaikutukseen, ii) arviointien rajaamiseen laajasti, mutta käytännön tarpeet huomioiden sekä iii) arvojen selkeään huomioimiseen. Vastaavia ominaispiirteitä ja haasteita on myös muissa ympäristöön, terveyteen ja hyvinvointiin liittyvissä arvioinneissa.

Sidosryhmien ja kansalaisten osallistuminen on keskeinen aihe ympäristöterveysarvioinnissa ja päätöksenteossa. Se nähdään oleellisesti demokratiaan kuuluvana, mutta myös keinona parantaa arviointeja ja päätöksentekoa. Käytännössä osallistuminen kuitenkin koetaan yhä taakaksi ja usein toteutetaan erillisenä prosessina arvioinnin ja päätöksenteon ohessa. Ympäristö ja terveys ovat kuitenkin lähes kaikkia kansalaisia koskettavia asioita, joten kuka tahansa saattaa olla merkityksellinen osallistuja, ja avoimuus on siksi välttämätöntä. Avoimuuden myötä tulee joitain haasteita, mutta ne ovat luonteeltaan ennemminkin käytännöllisiä kuin perustavanlaatuisia.

Ympäristöterveysarviointien onnistumista tarkastellaan lisääntyvässä määrin niiden aikaansaamien vaikutusten, eli asiantuntijoiden toimintapiirin ulkopuolisessa maailmassa tapahtuvien muutosten, mukaan. Arviointi ja sen tarkastelu on

muuttumassa vaikutuspainotteiseksi. Useimmat suorituskyvyn seurannan ja ohjauksen näkökulmat kuitenkin yhä tarkastelevat pääasiassa arvioinnin menettelytapoja ja tuotoksia sekä niiden teknisiä ominaisuuksia. Näkökulman laajentaminen arviointien soveltamisen sekä siitä seuraavat vaikutukset kattavaksi edellyttää perinpohjaista tiedon ja toiminnan yhteyksien tarkastelua sosiaalisessa viitekehyksessä. Valitettavasti näitä seikkoja tuskin edes huomioidaan useimmissa ympäristöterveysarvioinnin lähestymistavoissa.

Laajamittainen yhteistyö ja kiinteä yhteys tiedon soveltamiseen ovat oleellisia vaikuttavalle, eli päätöksiä niiden toimeenpanoa sekä seurauksia edistävälle, ympäristöterveysarvioinnille. Kuitenkin vain joitain pragmatismiin ja yhteistyöhön pohjautuvia vakavasti otettavia kehitelmiä on ilmaantunut kollaboratiivisten tietokonesovellusten, sosiaalisen median ja kollektiivisen oppimisen teorioiden kehityksen myötä. Eräänä esimerkkinä avoimen arvioinnin menetelmä ja Opasnet verkkotyötila tarjoavat asiantuntijoille, päättäjille ja kaikille asiasta kiinnostuneille näyttämön, jolla voi käynnistää ja seurata arviointeja sekä niihin osallistumalla vaikuttaa päätöksiin. Ne toteuttavat tieteellisen tiedonhankinnan menetelmiä myös käytännöllisten päätösongelmien ratkaisemiseen, ei vain niihin liittyvien ympäristön ja terveyden yhteyksien analysointiin. Lisäksi, Opasnetin uudelleen käytettävien modulaariset informaatio-olioiden avulla tulevia vastaavaa aihetta käsitteleviä arviointeja saadaan aikaiseksi vähemmällä työllä ja tehokkaammin.

Opasnetin soveltaminen ja sen tarkastelu on osoittanut, että avoin yhteistyö on mahdollista ympäristöterveysarvioinnissa, vaikka kokemukset laajasta osallistumisesta ovatkin vielä vähäisiä. Avoimuutta ja läpinäkyvyyttä arvostetaan, mutta esteiden poistamisesta huolimatta laajan aktiivisen osallistumisen synnyttäminen voi olla vaikeaa. Etenkin arviointitulosten käyttäjiksi tarkoitettujen tahojen, esim. yhteiskunnallisten tai teollisten päättäjien, sitouttaminen on edelleen haasteellista.

Uudet ympäristöterveysarvioinnin menetelmät ja työkalut mahdollistavat laajan yhteistyön ja kiinteän yhteyden tiedon tuotannon ja käytön välillä. Myös digitaalisten tietoverkkojen ja sosiaalisen median kehittyminen on tasoittanut tietä avoimelle tiedolle. Vaikuttavaan ympäristöterveysarviointiin ja päätöksentekoon kuitenkin tarvitaan kulttuurinen muutos sitoutumattomuudesta ja tiedon salailusta kohti avoimuutta, läpinäkyvyyttä ja yhteistyötä. Tulevassa kehitystyössä huomio pitää kiinnittää erityisesti tiedon soveltamisen käytäntöihin päätöksenteossa.

Tämä tutkimus keskittyy ympäristöterveysarviointiin. Painopiste on kuitenkin tiedon käytössä ja hyödyntämisessä arvioinnin, päätöksenteon ja osallistumisen prosesseissa. Täten tunnistetut ominaisuudet, haasteet ja ratkaisut ovat yleistettävissä ja sovellettavissa tieteen ja politiikan vuorovaikutukseen yleisesti.

Avainsanat: ympäristöterveysarviointi, avoin arviointi, Opasnet, vaikuttavuus, evaluointi, tieteen ja politiikan vuorovaikutus, näyttöön perustuva politiikka, kollaboratiivinen oppiminen

Contents

List of original papers

Pohjola, M.V., Leino, O., Kollanus, V., Tuomisto, J.T., Gunnlaugsdóttir, H., Holm, F., Kalogeras, N., Luteijn, J.M., Magnússon, S.H., Odekerken, G., Tijhuis, M.J., Ueland, Ø., White, B.C., Verhagen, H. State of the art in benefit–risk analysis: environmental health. Food and Chemical Toxicology 2012, 50, 40-55. http://dx.doi.org/10.1016/j.fct.2011.06.004

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Abbreviations

AMET	atmospheric model evaluation tool
ANOVA	analysis of variance
ANT	actor-network theory
BENERIS	Benefit–risk assessment for food: an iterative value-of-information approach (research project)
BEPRARIBEAN	Best practices for risk-benefit analysis of foods (research project)
BRAFO	Risk-benefit analysis of foods (research project)
CSA	chemical safety assessment
CSCL	computer supported collaborative learning
CO_2	carbon dioxide
CVD	cardiovascular disease
DALY	disability adjusted life year
DIS	distributed interactive simulation
EADI	European Association of Development Research and Training Institutes
EC	European Community
ECHA	European Chemical Agency
ECLAC	Economic Commission for Latin America & the Caribbean
EEC	European Economic Community
EFSA	European Food Safety Authority
EIA	environmental impact assessment
EMS	environmental modelling and software

EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GHG	greenhouse gas
HIA	health impact assessment
HEIMTSA	Health and environment integrated methodology and toolbox for scenario assessment (research project)
HTA	health technology assessment
HTML	hypertext mark-up language
IAEA	International Atomic Energy Agency
IARU	International Alliance of Research Universities
IEHIA	integrated environmental health impact assessment
IIED	International Institute for Environment and Development
IKM	information and knowledge management
IM	implementation model
INTARESE	integrated assessment of health risks of environmental stressors in Europe (research project)
IPCC	Intergovernmental Panel on Climate Change
ISO	International Organization for Standardization
ITRC	Interstate Technology & Regulatory Council
IRGC	International Risk Governance Council
KPE	Knowledge Practices Environment
KP-Lab	Knowledge practices laboratory (research project)
LCA	life cycle assessment

MNP	Netherlands Environmental Assessment Agency (current acronym for the agency is PBL)
NCM	Nordic Council of Ministers
NEA	Nuclear Energy Agency
NGO	non-governmental organization
NIBR	Norwegian Institute for Urban and Regional Research
NRC	National Research Council (USA)
ODI	Overseas Development Institute
OECD	Organization for Economic Co-operation and Development
PBT	persistent, bioaccumulative, and toxic
PSSP	purpose, structure, state, performance
REA	relational evaluation approach
QA	quality assurance
QALY	quality adjusted life year
QC	quality control
REACH	registration, evaluation, authorization, and restriction of chemical substances (EU)
RCN	Research Council of Norway
RIVM	National Institute for Public Health and the Environment (the Netherlands)
SAIC	Scientific Applications International Corporation
SMAA	stochastic multicriteria acceptability analysis
SYTYKE	Doctoral programme in environmental health, University of Eastern Finland

TEKES	National Technology Agency of Finland
TEKAISU	Assessment of environmental health impacts into all planning and policy making (research project)
THL	National institute for health and welfare (Finland)
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
USA	United States of America
U.S. EPA	United States environmental protection agency
vPvB	very persistent, very bioaccumulative
VWA	Dutch Food and Consumer Product Safety Authority
WHO	World Health Organization
YVA	Ympäristövaikutusten arviointi (Finnish for environmental impact assessment)

1 Introduction

1.1 Environmental health assessment

Environmental health is a scientific discipline that studies the characteristics of our living environments, and how these characteristics affect human health (Frumkin, 2010, Knol 2010). Environmental health assessment applies the knowledge provided by environmental health research, considers how different decisions and actions influence the environment-health relationship, and provides that information to support policy making (Pohjola et al. 2012). The results of environmental health assessments are intended to influence the knowledge-involving decisions and actions particularly in public policy, but also e.g. by decision-makers in business as well as individual members of the society. The purpose of environmental health assessment is thus to improve deliberate plans of actions that guide decisions aiming for desired outcomes (cf. Jones 2009). As is discussed in subsequent chapters, there are several different, more or less overlapping, assessment approaches that address issues relevant to environment and health. These approaches have certain differences e.g. in emphasis, scope, theoretical basis, and context of development and application, but they all share the basic idea of science-based support for decision making on issues of societal relevance.

Fundamentally, environmental health assessment can be characterized as a pragmatic endeavour of applying scientific knowledge and means for supporting the practical needs of decision making upon societally relevant issues related to environment and health. Here, scientific refers to the simple ideas of scientific knowledge creation that all claims are considered tentative, subject to revision on the basis of new evidence, and should be exposed for testing and critique by other investigators. Environmental health assessments typically focus on the issues of interest in environmental health research, but in order to be useful, the information provided to support decision making often needs to be embedded in a context of other relevant influences of decisions and actions and take into account the needs and capabilities of the society also beyond the scope of environmental health. In addition, the issues of environmental health are important to virtually all members of the society, which makes anyone a potentially relevant stakeholder in environmental health assessment and policy. Consequently, there are many kinds of complexities related to the substance, making, communication as well as the implementation of assessments and the information they produce. Due to these complexities, achieving effective environmental health assessments, i.e. such that contribute to policy decisions, their implementations as well as outcomes, can be very challenging.

"Buttons are to keep people warm" is one of the seemingly funny, but fundamentally wise, definitions in the classic children's book A hole is to dig (Krauss and Sendak 1952, Hughes 2009). In essence, it says that the function of a button to fit through a buttonhole gets its meaning from the practical need of keeping jackets closed and thereby protecting people from cold. Thus, buttons are to keep people warm. Although at first it may seem that this little sentence has nothing to do with the topic of this thesis, the following chapters will show how it actually entails an important lesson for the practice and development of environmental health assessment.

1.2 Structure of the thesis

Chapter 2 presents the questions and aims that have been guiding the research described in this thesis. Each of the chapters from 3 to 8 consist of individual articles published in or submitted to scientific journals, thereby comprising the main content of this thesis. Due to the structure, references are listed at the end of each chapter and the figures and tables are numbered within chapters.

In chapter 3, approaches to environmental health assessment are reviewed and analyzed in order to describe the contemporary state of the art in environmental health assessment as well as identify existing tendencies for further development of the field. In this article, the author of this thesis participated in choosing the approaches to be reviewed, designed the framework for analysis, characterized five of the eight approaches, and was the main responsible for compiling the characterizations, drawing conclusions as well as writing the article.

Chapter 4 compiles and compares the results of chapter 3 with five corresponding state of the art reviews from different fields and identifies opportunities for developing the analysis of benefits and risks to support policy making. In this article, the author of this thesis characterized the state of the art in environmental health assessment, was the main responsible for designing the framework for analysis, engaged actively in the identification and description of development opportunities, and took part in writing the final article together with the first author.

Chapter 5 reviews the literature on participation in environmental and environmental health assessment and policy making and proposes a dimensions of openness -framework for the scrutiny of limitations and possibilities for effective participatory assessment. In this article, the author of this thesis has made the review and writing of the article. He is also the main developer of the proposed framework.

Effectiveness is further elaborated in chapter 6, which reviews currently common perspectives to model and assessment performance and discusses their limitations to supporting evaluation and management of model and assessment effectiveness. Also in this article, making of the review, design of the framework for

analysis, drawing of conclusions as well as writing of the article have been mainly conducted by the author of this thesis.

Chapter 7 proposes collective knowledge creation and learning as the conceptual basis for considering environmental health assessment as well as other endeavours of policy support and scrutinizes three novel information systems that build on the idea of collective knowledge creation and learning. In this article, the author of this thesis characterized Opasnet, one of the scrutinized information systems, designed the framework for analysis, and was the main responsible for compiling different parts and writing the article.

Chapter 8 is a case study compiling many aspects brought up in previous chapters. It looks into two assessments on alternative biofuel sources, which apply the principle of openness discussed in chapter 4 by means of Opasnet web-workspace analyzed in chapter 7. The assessments are evaluated according to the dimensions of openness framework proposed in chapter 4 as well as the properties of good assessment framework mentioned in chapter 6. Feasibility and applicability of openness, Opasnet as well as the evaluation frameworks is discussed. In this article, the author of this thesis was responsible for identifying research questions, describing the applied approach to and evaluation of effectiveness, designing the questionnaire, statistical analysis of results, and aiding the first author in compiling different parts and writing the article.

Chapter 9 takes an epistemological perspective to environmental health assessment and discusses the implications of the research in the broader context of interaction between science and policy. Chapter 10 then provides conclusions in the form of brief answers to the research questions presented in chapter 2.

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2 Aims of the study

This thesis summarizes some of the most essential results of the research regarding environmental health assessment conducted in support of the development of open assessment method (http://en.opasnet.org/w/Open_assessment) and Opasnet web-workspace (http://www.opasnet.org) at the National institute for health and welfare (THL) during the years 2006-2012. The research has been guided by the following four research questions:

- What is environmental health assessment and what is its purpose?
- What are the different approaches to making environmental health assessment and what limitations do they have?
- What needs and possibilities are there for developing environmental health assessment?
- What challenges are there for developing environmental health assessment in practice, and how can the challenges be overcome?

These questions underlie all parts of this thesis. However, the contents are ordered according to the questions so that the chapters in the beginning, starting from Introduction, primarily address questions 1 and 2, while the emphasis in the later chapters moves towards addressing questions 3 and 4.

Specific methods and frameworks of analysis are described in more detail within each individual article (chapters 3-8), but overall the perspective adopted in this research can be characterized as pragmatic, in the sense of pragmatism e.g. by Charles Sanders Peirce and James Dewey. In brief, it means that theory and practice are not perceived as separate entities, but instead the question in consideration is whether practices are intelligent or uninformed. Knowledge and action are thus seen as deeply intertwined. Altogether, the thesis aims to provide a comprehensive pragmatic account of contemporary approaches to environmental health assessment and guide the way for their future development and practice, for the purpose of enhancing health and well-being in the society. However, the interaction of knowledge and action, particularly assessment and policy, is approached from the point of view assessment. Therefore, the emphasis in this thesis is on the aspects of producing and providing policy-relevant knowledge, rather than seeking and using it. Correspondingly, the social and political science literature on policy and decision processes is addressed to a lesser extent.

3 State of the art in benefit–risk analysis: Environmental health

Pohjola, M.V.[a], Leino, O.[a], Kollanus, V.[a], Tuomisto, J.T.[a], Gunnlaugsdóttir, H.[b], Holm, F.[c], Kalogeras, N.[d], Luteijn, J.M.[e], Magnússon, S.H.[b], Odekerken, G.[d], Tijhuis, M.J.[d,f], Ueland, Ø.[g], White, B.C.[h], Verhagen, H.[f,i,j]

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Abstract

Environmental health assessment covers a broad area: virtually all systematic analysis to support decision making on issues relevant to environment and health. Consequently, various different approaches have been developed and applied for different needs within the broad field. In this paper, we explore the plurality of approaches and attempt to reveal the state-of-the-art in environmental health assessment by characterizing and explicating the similarities and differences between them. A diverse, yet concise, set of approaches to environmental health assessment is analyzed in terms of nine attributes: purpose, problem owner, question, answer, process, use, interaction, performance and establishment. The conclusions of the analysis underline the multitude and complexity of issues in environmental health assessment as well as the variety of perspectives taken to address them. In response to the challenges, a tendency towards developing and applying more inclusive, pragmatic and integrative approaches can be identified. The most interesting aspects of environmental health assessment are found among these emerging approaches: (a) increasing engagement between assessment and management as well as stakeholders, (b) strive for framing assessments according to specific practical policy needs, (c) integration of multiple benefits and risks, as well as (d) explicit incorporation of both scientific facts and value statements in assessment. However, such approaches are yet to become established, and many contemporary mainstream environmental health assessment practices can still be characterized as relatively traditional risk assessment.

3.1 Introduction

The term "environmental health assessment" covers a broad area. In principle, all endeavours of systematic analysis aiming to support decision making on all issues relevant to the relationships between environment and human health could be considered environmental health assessments. Given this breadth and complexity, it is not surprising that a diverse range of approaches building on different grounds and addressing different needs within the field have evolved. They all share the basic idea of applying science-based means and methods for producing knowledge to support decision making on societally relevant issues. Due to differences in emphasis, scope, theoretical basis and context of development and application, the basic idea becomes manifested in different ways in each approach. Figure 1 illustrates the complexity of environmental health field and the domains, as well as limitations, of certain assessment approaches. As can be seen, some approaches focus on risks only, while others consider benefits as well. Approaches also differ in terms of what risks and/or benefits are included for explicit consideration and comparison in an assessment.

This paper reviews a concise set of approaches to environmental health assessment. It does not attempt to be an exhaustive review of all relevant approaches in the field, but an overview of a sufficiently extensive and diverse set of existing approaches so that the plurality of views, as well as the essential characteristics present in contemporary approaches to environmental health assessment, can be explicated. The summary of the overview results provides a general description of contemporary practices and a basis for conclusions on the most essential aspects of environmental health assessment in terms of contemporary and future benefit–risk analysis, within environmental health as well as other domains.

3.2 Framework for analysing approaches to environmental health assessment

The set of approaches selected for the overview is intended to be extensive, diverse, yet concise, in order to be sufficiently representative of the field of environmental health assessment, but still analyzable. The final composition of the set of approaches results from a process of reasoning by the authors, and is based on prior knowledge and experience in the field of environmental health. The guiding principles in choosing approaches were that all the main areas and aspects of environmental health assessment should be covered, but only approaches significantly adding to the diversity of the set were included in the overview.

The final set includes approaches that identify themselves as risk assessment, impact assessment or integrated assessment. Some of the included approaches have been explicitly developed to serve the needs of regulatory work, while some build more on the tradition of academic research. The approaches also vary signif-

icantly in terms of novelty and establishment. As different interpretations on the essence of many of the chosen approaches exist, we have tried to pick the hallmark examples of each. For the sake of transparency and clarity, only as few sources of information as possible have been chosen as the basis for describing and characterizing each approach.

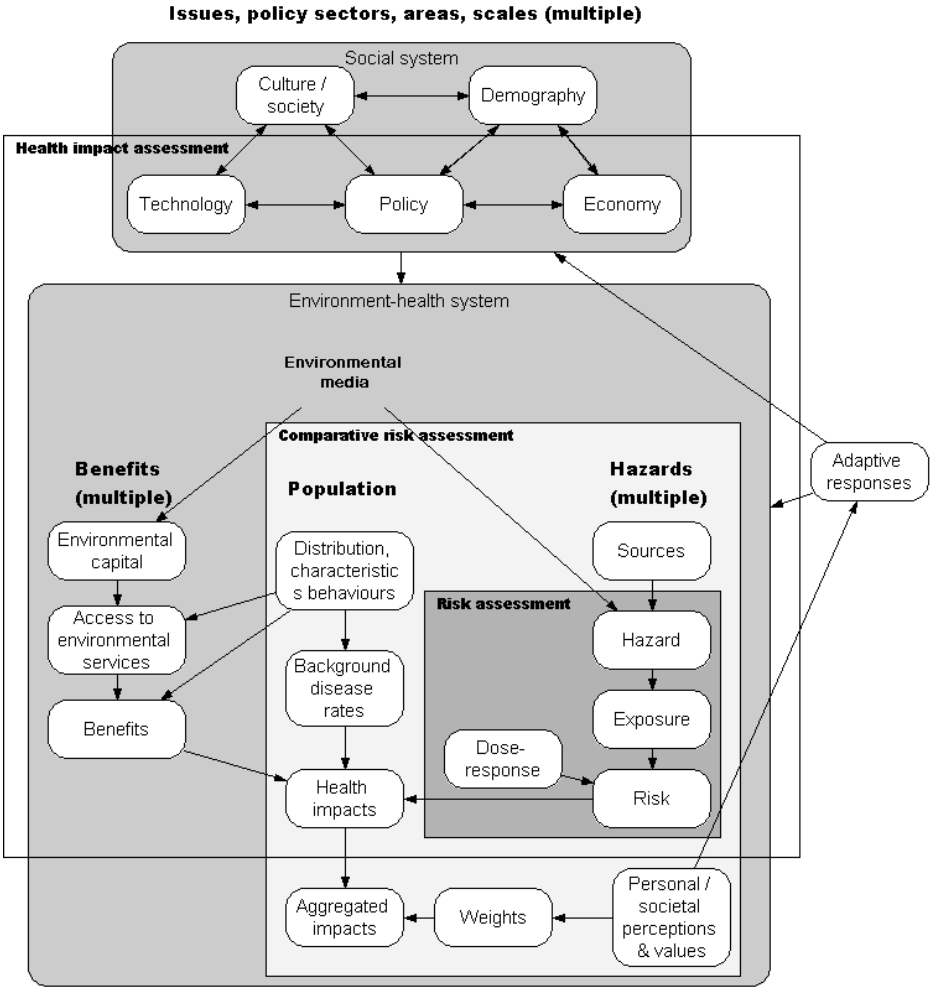

Figure 1. Outline of relevant issues to address in environmental health assessment and coverage of certain common approaches to risk and impact assessment. The figure is adapted from a framework for integrated environmental health impact assessment (Briggs, 2008).

We created a framework for the analysis in order to guarantee a consistent scrutiny across the set of approaches, and to produce comparable characteriza-

tions. The basic structure and the attributes of the framework are adapted from the PSSP (purpose, structure, state, performance) ontology (Pohjola 2003, 2006) developed originally in the context of process design. The attributes address the way each approach frames its purpose, issues of interest, assessment practice, linkage with use, as well as goodness of the assessment process and product. The attributes are presented and briefly explained in Table 1.

Table 1. The framework for characterising approaches to environmental health assessment.

Attribute	Explanation
Purpose	What need(s) does an assessment address?
Problem owner	Who has the intent or responsibility to conduct the assessment?
Question	What are the questions addressed in the assessment? Which issues are considered?
Answer	What kind of information is produced to answer the questions?
Process	What is characteristic to the assessment process?
Use	What are the results used for? Who are the users?
Interaction	What is the primary model of interaction between assessment and using its products? (see Table 2 for options)
Performance	What is the basis for evaluating the goodness of the assessment and its outcomes?
Establishment	Is the approach well recognized? Is it influential? Is it broadly applied?

The characterizations of the different assessment approaches are in the form of freely formatted textual expressions and graphical illustrations, and are primarily based on one or two selected sources of information – books, scientific articles or websites. In cases where these sources do not contain sufficient or explicit descriptions of the characteristics of the approach, additional information sources or author's own interpretations are used as complementary material. In particular, the characterizations of interaction, performance, and establishment often include author judgments informed by the source material and authors' experience within the field.

All process diagrams (Fig. 2, Fig. 3, Fig. 4, Fig. 5, Fig. 6, Fig. 7, Fig. 8 and Fig. 9) have been taken from the primary information sources and modified into the same format, still maintaining their original characteristics. In these diagrams the process of doing work in a part of an assessment is described as either a

thin-border box or a white, bulky arrow. The products of this work (often reports of some kind) are described as thick-border boxes. Information flows between work processes are described with thin solid arrows. Unlike Fig. 2, Fig. 3, Fig. 4, Fig. 5, Fig. 6, Fig. 7, Fig. 8 and Fig. 9, which are process diagrams, Fig. 1 is an influence diagram. It describes real-world phenomena (white nodes) and their causal connections (thin arrows).

The categorization of the models of interaction is an adaptation of a categorization for models of linking knowledge and action developed by van Kerkhoff and Lebel (2006) in the context of sustainable development. The adapted categories of interaction are presented and briefly explained in Table 2. The categories are perceived to form a continuum of increasing engagement and power sharing when moving from trickle-down towards learning.

Table 2. The models of interaction between the assessment process and the use of the products of assessment.

Linkage	Explanation
Trickle-down	Assessor's responsibility ends at publication of results. Good results are assumed to be taken up by users without additional efforts.
Transfer and translate	One-way transfer and adaptation of results to meet assumed needs and capabilities of assumed users.
Participation	Individual or small-group level engagement on specific topics or issues. Participants have some power to define assessment problems.
Integration	Organization-level engagement. Shared agendas, aims and problem definition among assessors and users.
Negotiation	Strong engagement on different levels, interaction an ongoing process. Assessment information as one of the inputs to guide action.
Learning	Strong engagement on different levels, interaction an ongoing process. Assessors and users share learning experiences and implement them in their respective contexts. Learning in itself a valued goal.

The main characteristics of the selected assessment approaches are summarized and combined for comparison and synthesis. The purpose of the overview is not to rank the different approaches, but to highlight the essential similarities and differences between them, and to represent the plurality of views on environmental health assessment. Some of the most interesting findings are also taken for a further scrutiny. Finally, conclusions regarding the aspects of environmental health assessment that other fields of assessment, e.g. food benefit–risk assessment, could benefit taking account of are drawn based on the overview summary.

3.3 Approaches to environmental health assessment

This chapter contains the characterizations of eight different approaches to environmental health assessment: Red Book risk assessment (NRC, 1983), Understanding risk (NRC, 1996), IRGC (International Risk Governance Council) risk governance framework (IRGC, 2005), Chemical risk assessment: REACH (Registration, evaluation, authorization, and restriction of chemical substances) (ECHA 2008a), Environmental impact assessment (EIA): YVA (Ympäristövaikutusten arviointi, Finnish for EIA) (Act on Environmental Impact Assessment Procedure 468/1994, revised 267/1999 and 458/2006; EIA Decree 794/1994, revised 268/1999 and 713/2006), Health impact assessment (WHO, 1999), Integrated environmental health impact assessment (Briggs, 2008), and Open assessment (Opasnet website; Tuomisto and Pohjola (Eds.), 2007). The main characteristics of all approaches are summarized in Tables 3a and 3b and discussed in chapter 4.

3.3.1 Red Book risk assessment

In 1983, the Committee on the Institutional Means for Assessment of Risk to Public Health in the National Research Council (NRC) in the United States of America (USA) published a report commonly referred to as the ‘‘Red Book’’, which explored the intricate relations between science and policy in assessing adverse health effects associated with human exposure to toxic substances (NRC, 1983). This description of a systematic process that separates risk assessment from policy making and unifies the risk assessment guidelines for all regulatory agencies can be considered as the cornerstone of contemporary risk assessment.

The purpose of a risk assessment is to characterize the potential adverse health effects of environmental hazards and the uncertainties related to the assessment. The assessment is produced to serve the needs of risk management, i.e. the process of evaluating alternative regulatory actions and selecting among them. Risk management is an agency decision making process that entails consideration of political, social, economic, and engineering information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. Risk assessment and risk management are considered as independent entities. The problem owners in risk assessment process are the scientific experts dealing with the issue. Respectively, the decision making problems in risk management are owned by the public officials in the agencies responsible for dealing with the particular issue.

Risk assessment aims to answer the question: what is the estimated incidence of an adverse effect in a given population? As an answer, the assessment provides an estimate of the risk.

The risk assessment process (Fig. 2) consists of four steps: hazard identification (does the agent cause an adverse effect?), dose– response assessment (what is the relationship between dose and incidence in humans?), exposure assessment

(what exposures are currently experienced or anticipated under different conditions?), and risk characterization, which summarizes the results of the previous steps. Risk assessment is considered to be a strictly scientific process conducted by experts, and it should be separated from the decision making and risk management to safeguard the objectivity and credibility of the assessment.

Risk assessment results are used in a federal agency policy decision making process. In the risk management process, agency decisions and actions are taken based on the risk estimates considered together with information on regulatory options and their potential public health, economic, social, and political consequences. In principle, the risk management addresses the question: ‘‘which regulatory option regarding the risk should be chosen?’’.

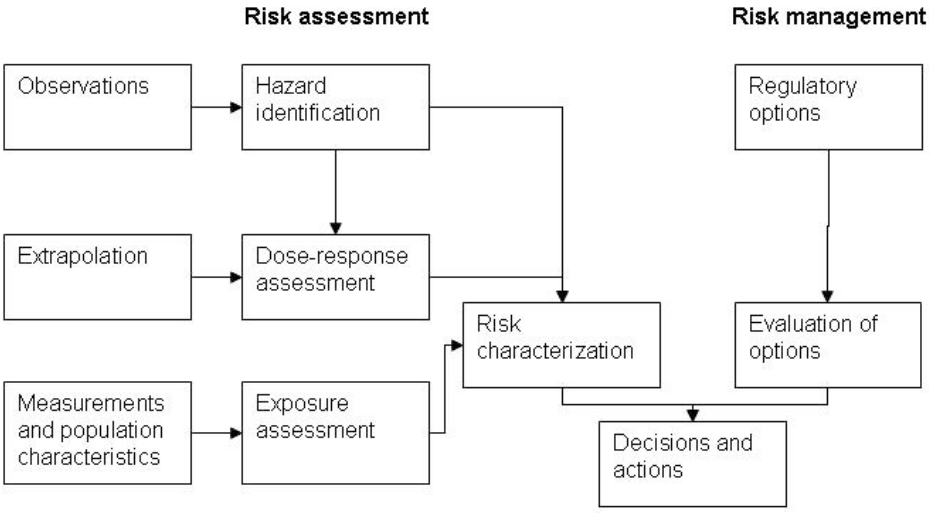

Figure 2. The Red Book risk assessment process. For an explanation of formatting, see chapter 2.

The model of interaction is best described as transfer and translate. Results of an assessment are intended and targeted for a predefined need, but there is no interaction between the assessment process and use, not to mention stakeholders, besides transferring of the risk assessment results to the risk management process. The performance of risk assessment is evaluated based on an uncertainty analysis of the estimates produced in the risk characterization step. Goodness of the decisions made based on the risk estimates is an issue belonging to the risk management process and it is not considered as an aspect of assessment performance.

The Red Book approach is the cornerstone of nearly all contemporary risk assessment related practices. Despite its several recognized limitations, practical implementations of the Red Book approach can be seen everywhere where risk

assessment is being practiced. The approach is undoubtedly established and forms the core of most subsequently developed risk and related assessment approaches. For example, a good account of application of the Red Book principles in food and nutrition risk assessment is given in Tijhuis et al. (this issue).

3.3.2 Understanding risk

In 1996, the Committee on Risk Characterization of the National Research Council (NRC) in USA published a report ''Understanding Risk: Informing Decisions in a Democratic Society'' (NRC, 1996). This report can be considered as a follow-up on the Red Book assessment framework (NRC, 1983). It focuses on re-interpreting risk characterization as an analytic-deliberative process between public officials, scientists, and stakeholders.

The purpose of the analytic-deliberative process is to improve decision making upon risks. The essential role of risk characterization is to integrate risk assessment (understanding) and risk management (action) into one risk decision process, and thereby enhance practical understanding of risks and their management options. The application area of the approach is not limited as such, but in the report the Committee positioned their considerations explicitly within the field of governmental and industry level risk management, particularly in the context of the USA. The problem owners are the public officials with a legislative mandate to protect the public health.

Risk characterization is considered as a decision-driven activity, where a diagnosis of the decision situation is needed already in a problem formulation stage. The questions addressed may be related to many different kinds of risk-related issues, for example regulating industrial processes; setting emissions standards; taxing emissions and effluents; establishing cancer potency values; informing individuals at risk; improving risk analysis techniques (e.g. selection of default assumptions) or guidelines for making inferences from data; or creating policy strategies or implementation. The questions asked in different cases may be formulated in different ways. As answers, the analytic-deliberative process synthesizes information gathered and interpreted concerning the decision options chosen for consideration. No complete agreement or single solution is required, or even expected, to be achieved.

Analytic-deliberative risk characterization is an iterative process of problem framing, process design, option and outcome selection, information gathering, and synthesis, which ultimately leads to a decision by the responsible actors (Fig. 3). The analytic-deliberative process also extends to implementation and evaluation of the decision made.

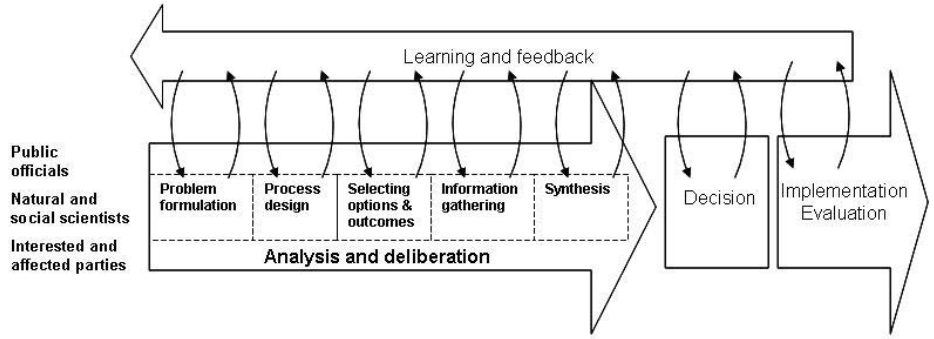

Figure 3. The analytic-deliberative risk decision process. For an explanation of formatting, see chapter 2.

The public officials with a legislative mandate to protect the public use the assessment results in their decision making. The model of interaction is best described as negotiation. The analytic- deliberative process is an on-going process between public officials, experts, and other stakeholders that takes learning and feedback into account. The actual decision making and use of produced information, however, takes place outside the analytic-deliberative process, and the results of risk characterization are considered as only one of the inputs into the decision making.

Because the analytic-deliberative process extends to the implementation and evaluation of the decision made, the performance of the assessment process is addressed in terms of the goodness of implemented decisions. As the name, analytic-deliberative process implies, evaluation is based on both analytical data and interpretation. On the other hand, the analytic-deliberative process is, in itself, a process of interpreting the quality of knowledge obtained by scientific risk assessment and the deliberating the implications of the knowledge quality to decision making regarding the specific issues.

The report ‘‘Understanding risk’’ has gained considerable recognition among professionals working in the related fields, particularly in the USA. On the other hand, despite that the approach builds on the cornerstone of the contemporary risk assessment (the Red Book approach), broad scale implementation of the analytic-deliberative process as described by the report is rare, and the establishment of the approach can not be considered very strong. However, it can be considered to have significantly influenced the development and implementation of several subsequently developed risk assessment, risk management and related approaches and practices.

3.3.3 IRGC risk governance framework

The International Risk Governance Council (IRGC), founded in 2003, is a private, independent, not-for-profit Foundation based in Geneva, Switzerland. Its mission is to support governments, industry, non-governmental organizations (NGOs) and other organizations in their efforts to deal with major and global risks facing society and to foster public confidence in risk governance. The IRGC risk governance framework was published in an IRGC white paper in 2005 (IRGC, 2005). The white paper intends to provide an integrated, holistic and structured approach, a framework, by which risk issues and the governance processes and structures pertaining to them can be investigated.

The purpose of the risk governance framework is to integrate scientific, economic, social and cultural aspects and include the effective engagement of stakeholders. The framework reflects IRGC's own priorities, which are the improvement of risk governance strategies for risks with international implications and which have the potential to harm human health and safety, the economy, the environment, and/or the fabric of society at large. It particularly emphasizes dealing with so called 'systemic risks' (OECD, 2003). Furthermore, it places most attention on risk areas of global relevance (i.e. transboundary, international and ubiquitous risks) which additionally include large-scale effects (including low-probability, high-consequence outcomes), require multiple stakeholder involvement, lack a superior decision-making authority, and have a potential to cause wide-ranging concerns and outrage. Depending on the issue the problem owners can be various, e.g. members of governmental bodies, scientific communities, business organizations, NGOs or the civil society.

The questions asked in the IRGC risk governance framework do not cover all risk areas but its efforts are confined to (predominantly negatively evaluated) risks that lead to physical consequences in terms of human life, health, and the natural and built environment. It also addresses impacts on financial assets, economic investments, social institutions, cultural heritage or psychological well-being as long as these impacts are associated with the physical consequences. By linking risk governance with societal context, the framework reflects the important role of risk–benefit evaluation and the need for resolving risk–risk trade-offs. The pre-assessment phase frames the issue (what risks, what boundaries, who are stakeholders, what is the capability to address the problem). Scientific risk assessment describes and quantifies the physical aspects (potential damages, probability of occurrence, cause-effect relationships, measures to tackle the problem). In contrast, concern assessment describes societal and psychological aspects (public concerns and perceptions, social response, roles of institutions, governance structures, media, stakeholder objectives and values, inequities). Characterization and evaluation look at the societal outcomes in the arena of possible actions (economic, environmental, quality of life, ethical issues, risk reduction, substitution, or

compensation, stakeholder commitment). Risk management considers aspects of decision making related to the issue (responsible parties, management options, priorities, trade-offs, effectiveness of measures).

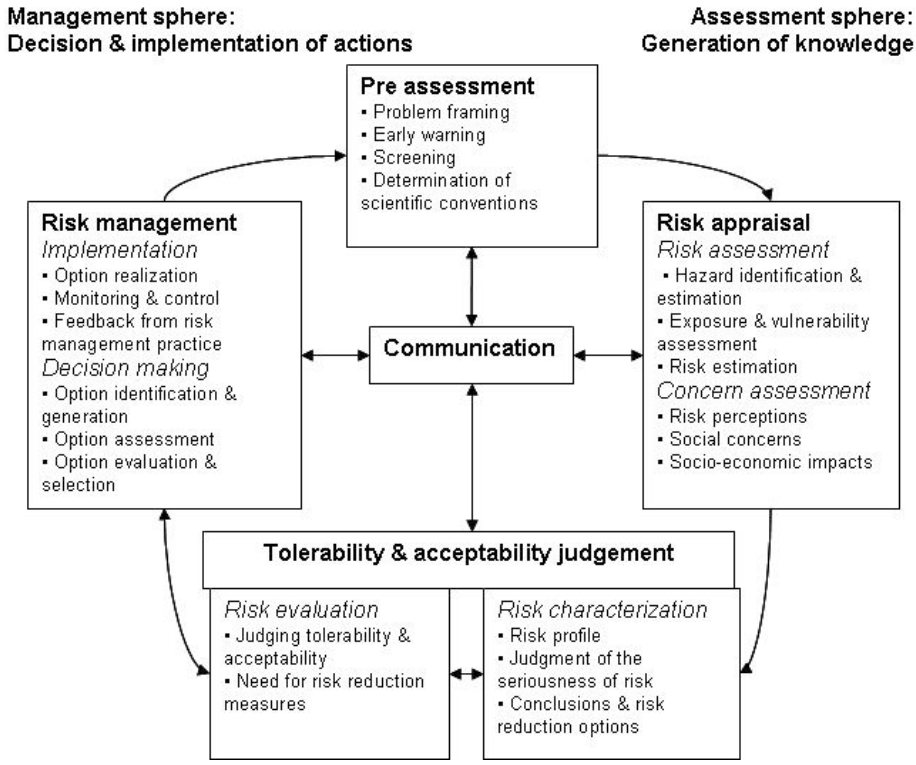

Figure 4. The IRGC risk governance framework. For an explanation of formatting, see chapter 2.

The answers to risk questions always refer to a combination of two components: the likelihood of potential consequences and the severity of consequences of human activities and/or natural events. Such consequences can be positive or negative, depending on the values that people associate with them. Investigating systemic risks goes beyond the usual agent-consequence analysis and focuses on interdependencies and spillovers between risk clusters. IRGC's approach puts particular emphasis on categorizing the knowledge about the cause-effect relationships considered in the assessment sphere. The risks can be categorized as simple, complex, uncertain, or ambiguous. The categorization of risks can be used as the basis for choosing risk management strategies and deciding on the appropriate level of stakeholder involvement.

The process of handling systemic risks is a holistic approach to hazard identification, risk assessment, concern assessment, tolerability/ acceptability judgments and risk management (Fig. 4). The process breaks down into three main phases: 'pre-assessment', 'appraisal', and 'management'. A further phase, consisting of 'characterization' and 'evaluation' of risk, is placed between the appraisal and management phases and, depending on whether those charged with the assessment or those responsible for management are better equipped to perform the associated tasks, can be assigned to either of them. The risk process has 'communication' as a companion to all phases of addressing and handling risk and is itself of a cyclical nature. However, the clear sequence of phases and steps offered by this process is primarily a logical and functional one and will not always correspond to reality.

The concept of risk governance comprises a broad picture of risk: not only does it include what has been termed 'risk management' or 'risk analysis', it also looks at how risk-related decision making unfolds when a range of actors is involved. Governing choices in modern societies is seen as interplay between governmental institutions, economic forces and civil society actors (such as NGOs).

The intended use of the framework or assessments conducted according to its principles has not been explicitly specified. In principle, the range of users can be as broad as the range of problem owners, but particularly those with the power to influence and manage systemic risks in a global context.

The model of interaction is best described as participation. Multiple stakeholders and different aspects of risk are integrated into a single framework. The framework does, however, build on relatively sharp demarcations between expert-driven risk assessment practices, decision maker-driven risk management practices, and distinct practices of stakeholder involvement.

Performance is evaluated separately for the assessment sphere and the management sphere. The state and quality of the knowledge applied in the risk assessment is evaluated in terms of complexity, uncertainty, and ambiguity, and the results of the evaluation serve as an important input into the risk characterization and evaluation phase. In the risk management phase, performance is evaluated by a procedure adopted from the decision theory. Risk management options are generated, assessed, evaluated, selected, implemented, and monitored. The view on the risk management performance can be characterized as a checklist-type quality assurance procedure that ensures that all steps in the sequence have been given proper attention. However, the practical work is not meant to be based strictly on the sequence. Rather, it is a dynamic process where different steps are iteratively improved whenever new information and understanding becomes available.

IRGC was founded in 2003 and the risk governance framework published in 2005. Hence, the framework can be considered as a relatively novel construct. However, the framework appears to be well recognized among actors in environmental health assessment, and can be assumed to have influenced the thinking in

this field. However, because the framework does not describe any specific assessment or governance practice, it is difficult to estimate to what the extent it has been applied in practice. Therefore, in terms of establishment the framework could be considered a relatively well-established theoretical construct, but not broadly applied in practice.

3.3.4 Chemical safety assessment: REACH

Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) is a European Community Regulation on chemicals and their safe use. It aims to improve the protection of human health and the environment through better and earlier identification of the intrinsic properties of chemical substances. Under REACH, a chemical safety assessment (ECHA 2008a) is required if a substance is manufactured or imported into the European Union (EU) at 10 tons or more per year per registrant. Comprehensive description, guidance and documentation on REACH can be found from the European Chemicals Agency website (http://echa.europa.eu/).

The purpose of the assessment (Chemical Safety Assessment, CSA) is to evaluate risks arising from the manufacture and use of a substance, and to define conditions under which the manufacture and use are safe in terms of both human health and the environment. The assessment covers the manufacture, all identified uses (processing, formulation, consumption, storage, keeping, treatment, filling production of an article or any other utilization) and the life cycle stages resulting from these, and health risks are evaluated for workers, consumers, and those exposed through the environment. The novelty of REACH is that the responsibility to assess and manage the risks is placed on industry. Hence, the problem owner is the manufacturer or importer of the chemical substance.

The question asked in the assessment is whether a chemical substance poses a health or environmental hazard, and if so, what uses and use conditions can be considered safe in terms of both human health and the environment. As an answer, the substance is classified and labelled according to hazards related to its use. If a substance meets certain classification criteria in regard to the potential hazards, safe exposure scenarios and use conditions are described.

The assessment process consists of a hazard assessment, exposure assessment and risk characterization (Fig. 5). The latter two are conducted only for substances classified as dangerous (based on Directive 67/548/EEC), PBT (persistent, bioaccumulative and toxic) or vPvB (high persistency and high tendency to bioaccumulate, but not necessarily proven toxicity) in the hazard assessment. Exposure scenarios are defined and exposure estimated based on all identified uses, use conditions and life stages of the substance. Risk is characterized by comparing the estimated exposures to safe exposure levels. Risks are considered to be adequately controlled when exposures do not exceed the safe levels, or the emissions and

exposures are minimized or avoided. If risks are not under control, the assessment is refined by obtaining better data on the substance properties or exposures, or changing the manufacturing or use conditions. This iterative process continues until the risks are shown to be under control, and a so-called final exposure scenario is defined. If risks can not be shown to be controlled for a specific use, and no more iterations are possible or economically viable, the chemical safety report must advise against the use of the chemical.

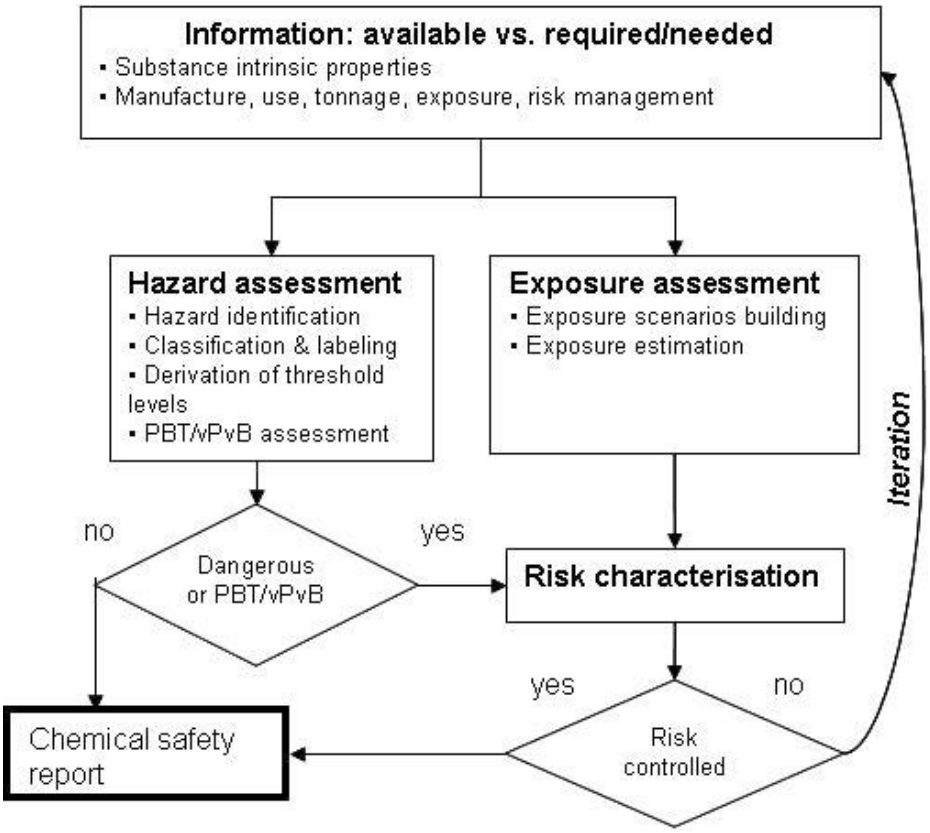

Figure 5. The chemical safety assessment process in REACH. For an explanation of formatting, see chapter 2.

Assessment results are used in communicating the substance properties and safe use conditions (operational conditions and required risk management measures) to the downstream users in the supply chain. The CSA is also used as an important source of information in substance evaluations conducted by the REACH authorities. Substance evaluations are performed for all priority substanc-

es. These are substances for which there is some health or environmental concern and which meet the priority criteria developed by the REACH authorities.

The model of interaction adopted by the approach is best described as transfer and translate, although to some extent also as participation. Manufacturers and importers of the same substance are encouraged to work in collaboration when conducting the risk assessment. The assessor collects information on the exposure conditions along the supply chain, and may establish a dialog with representative customers in doing so. The downstream users also have the right to notify the assessor regarding their own uses of the substance. When the assessment is completed, the assessor is obliged to communicate the results to the downstream users.

The performance of the assessment is formally evaluated by the REACH authorities. The quality of information used has to meet the minimum information requirements. Uncertainty analysis is recommended but voluntary. The European Chemicals Agency (ECHA) performs compliance checks for a selection of registration dossiers (including the CSA). It is stated in the guidance document on dossier and substance evaluation that the percentage of checked dossiers is not to be lower than 5% of all dossiers received by the agency for each tonnage band, and that both random and non-random selection methods are applied. The aim of the process is to ensure that all required information is included in the dossier, and that this information is adequate. The contents of the CSA are also further reviewed by REACH authorities in case a substance evaluation is conducted.

Implementation of REACH is still in the beginning stages. Therefore, the assessment process has not yet been implemented to a large extent in practice. However, due to its regulatory status in EU, the methodology will become widely established in the following years.

3.3.5 Environmental impact assessment: YVA

YVA is a Finnish regulatory framework for environmental impact assessment (Act on Environmental Impact Assessment Procedure 468/1994, revised 267/1999 and 458/2006; EIA Decree 794/ 1994, revised 268/1999 and 713/2006). It is a national implementation of the European EIA Directive (Council Directive 85/337/EEC of 27 June 1985 on the assessment of the effects of certain public and private projects on the environment, amend. 97/11EC, 2003/ 35/EC and 2009/31/EC), and can therefore be here assumed to somewhat representative of the whole target area of the directive as well as the mainstream theories of EIA underlying the directive. The aim of the YVA regulation is to promote consideration of environmental issues, including environmental health issues, when deciding upon permissions and constraints for activities, which may have wide societal and environmental implications. The framework emphasizes information flow and public participation in impact assessments. The main specific characteristics of YVA in regard to the European EIA Directive are its confinement to large projects (only approximately

50 assessments/year), and legal requirement for participation in 2 phases (Jantunen and Hokkanen, 2010).

The purpose of an YVA assessment is to evaluate all potential environmental impacts of a proposed large-scale project. The assessment should take into account health, environmental and social impacts as well as technical and economical issues. Problem owners are the ones with the intent to plan and execute the project and they have the legal obligation to initiate the assessment process.

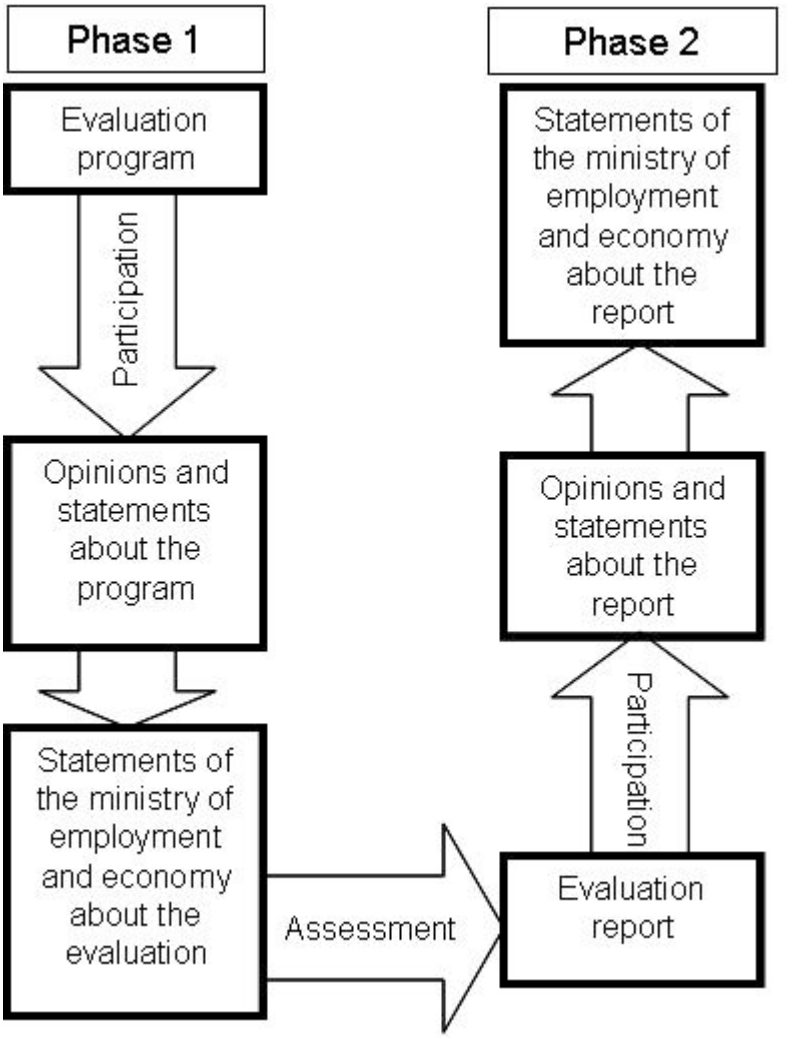

Figure 6. The Finnish environmental impact assessment procedure (YVA). For an explanation of formatting, see chapter 2.

The YVA process addresses questions related to potential impacts of planned projects on human and animal health and well being, environment (e.g. soil, water, air, climate, and vegetation), composition of society (e.g. building, landscape, cultural heritage) and exploitation of natural resources. Annually between 30–50 projects undergo the assessment prescribed by the EIA act in Finland (Pölönen et al., 2010). Smaller projects undergo a lighter environmental assessment procedure in the form of the environmental permit system. Answers are provided as impact estimates and a synthesis of all quantitative/qualitative information gathered concerning the potential impacts of the planned activity, possible alternative activities, and in a situation where no activity takes place.

The assessment process is divided into two phases, planning of the assessment as well as execution and reporting the assessment (Fig. 6). In the planning phase, an evaluation program is constructed based on all available information on the project and potential issues related to it. Statements on the evaluation program are requested from the stakeholders by an appointed liaison authority, typically an unbiased, neutral expert from a regional environmental administration or from the ministry of employment and the economy. After this, the assessment is conducted and reported. The final evaluation report should contain detailed information on all the relevant issues, such as technical applications, land use, environmental protection, comparison of alternatives, and suggestions for a follow-up program. However, there are no specific legal requirements for the contents of the assessment. Statements on the final assessment report are again requested from the stakeholders by the liaison authority.

Information produced in the assessment is used by the public officials responsible for making the decision about permission and possible restrictions for project execution. There is no legal requirement to comply with the conclusions of the assessment, but the assessment results, including also stakeholder statements, must be taken account of in the decision making process by an authority. The model of interaction can be described on one hand as participation and as transfer and translate on the other. The procedure enables and emphasizes public participation, and there are no restrictions on who can be considered a stakeholder. All interest groups, particularly people living near the site of the planned activity, are given a possibility to state their opinions and concerns. Participation is arranged in the form of public hearings, small group discussions and public gatherings at certain phases along the assessment process. The possible impact of the stakeholder statements in the assessment and related decision making and follow-up is often, however, unclear. Despite the participatory approach towards the public, the interaction between YVA assessment and the related decision making has been identified to be weak (Pölönen et al., 2010).

Performance evaluation is based on quality control by the contact official. However, stakeholders can also give comments on the quality of the assessment.

The framework is widely established in Finland due to its regulatory status. Similar kinds of environmental impact assessment practices also take place in all EU member states under the same EIA Directive as well as many other countries. However, due to the variation in the scale and nature of projects and the lack of legally binding requirements for the assessment contents and the use of assessment results in related decision making and follow-up, application of environmental impact assessment can vary widely. An interesting research project on the effectiveness of YVA has recently been carried out and a summary of the results have been reported by Pölönen et al. (2010).

3.3.6 Health impact assessment

Health, social, economic and other policies in both the public and private sectors are closely interrelated, and proposed decisions in one sector may impact objectives on other sectors. Health Impact Assessment (HIA), as proposed by the World Health Organization (WHO) (WHO, 1999, http://www.who.int/hia/en/), is a combination of procedures, methods and tools for judging the potential health effects of a policy, program or project on a population, particularly on vulnerable or disadvantaged groups. Hence, it is a tool to dynamically improve health and well-being across sectors. However, it should be noted that many people and organizations have proposed definitions for HIA, and there is no 'correct definition' but rather a variety of ways in which HIA can be described.

The purpose of HIA is to inform decision makers about the potential health effects of a policy, program or project, particularly on vulnerable or disadvantaged population groups, and to provide recommendations for maximizing the proposal's positive and minimizing the negative health effects. It also aims to address inequalities in the potential health impacts and to promote joined-up working and participation. Problem owners are those with an interest or mandate to deal with the specific issue at hand, for example project managers or governmental institutes. They can thus be either those with the means to assess the issue or those with the means to make decisions upon the issue.

The ultimate question asked is of the form: ''How to maximize a proposals positive health effects and minimize its negative health effects?'' HIA is thus a positive approach, as it does not only look for negative impacts. Issues addressed can be various, for example building a new road near residential areas, increasing runway and passenger capacity at an airport, common agricultural policy or a local village school policy for safer routes to school. Answer is provided by highlighting the relevant positive and negative health impacts and their distribution in the population and identifying the vulnerable population groups. Recommendations are given concerning the decision at hand. Health impact estimates can be qualitative or quantitative. In terms of quantification, WHO has strongly promoted the

use of a disability adjusted life year (DALY), which is a summary measure of population health.

The starting point of a HIA process often is a proposal or a suggestion of making changes in an existing policy, or of launching a completely new policy or project. An assessment should preferably be conducted in early stages to better support decision making. While there is no single agreed method for undertaking HIA, a general pattern has emerged. Guidance documents often break the process into four, five or six stages (Fig. 7). Despite the differing number of stages, it is important to note that there are no large differences between the methods. The work is often done in three tiers, starting from a crude estimation of health impacts and moving onto in-depth analyzes and reviews of the impacts. In the screening phase, potential linkages between a policy, program or project and health are sought, and different aspects of health that could be affected are identified. If potential health impacts are identified, the process continues to a scoping phase. The aim of the scoping is to define the question addressed in the assessment, and to identify further information needs. Population subgroups of special interest and the degree of participation are also addressed. Once scoping is defined an appraisal phase, where health hazards are identified and evidence of impact is considered, is conducted. When moving towards policy or program implementation, HIA process continues with reporting and monitoring. Reporting aims at developing recommendations for reducing hazards and/or improving health. Finally, monitoring of the implementation of the proposal ensures that any recommendations that decisionmakers agreed to, actually occur. Stakeholders are given an opportunity to express their opinion concerning the results. Ultimately, the goal of HIA is to create a continually developing process.

The primary users of the assessment results are intended to be those who decide upon the particular policy, program, or project. They are expected to take the assessment results into consideration, to weigh the population health interest against any other interests related to the issue at hand, and to adjust the policy, program or project to maximize the positive and minimize the negative health impacts. The model of interaction is best described as participation. The assessment is mainly carried out as collaboration between scientific experts, but other stakeholders are also given an opportunity to participate in the process. HIA clearly intends to be policy-relevant and tightly bound with policy making, but as such it contains no measures for guaranteeing involvement or use of assessment results by policy makers.

Performance can be evaluated in terms of the process, its immediate impacts, and its long-term outcomes. There are four values that link the assessment to the policy environment in which it is being undertaken: democracy, equity, sustainable development, and ethical use of evidence. People are to be democratically allowed to participate in the development and implementation of policies, pro-

grams or projects that may impact on their lives. Equity rises from the idea that the assessment addresses the distribution of impacts in the population, and puts a particular emphasis on the potential effects on the vulnerable sub-groups (in terms of age, gender, ethnic background or socio-economic status). Sustainable development means that both short and long-term, as well as the obvious and less obvious, impacts are to be considered. Ethical use of evidence refers to using best available quantitative and qualitative evidence.

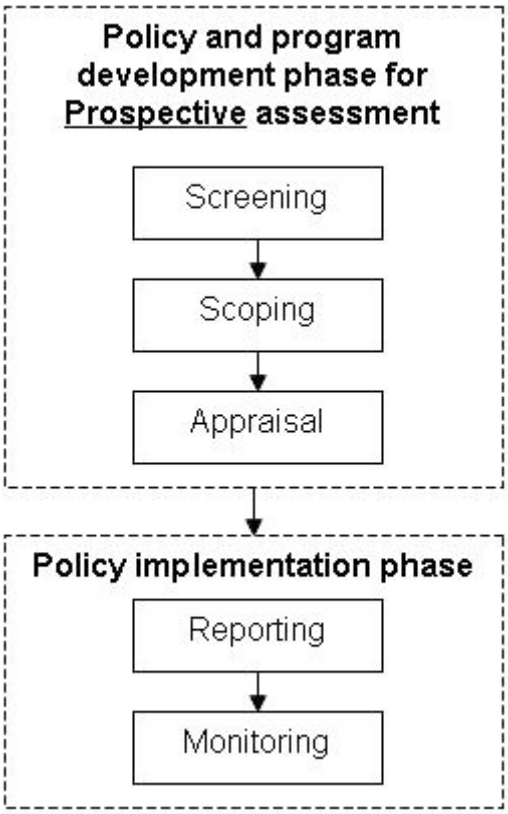

Figure 7. The health impact assessment process as defined by WHO. For an explanation of formatting, see chapter 2.

HIA is a well established approach, and it is high on the agenda of some governments in Europe (at national, regional and local levels) and international organizations including WHO and the World Bank. A similarly increased interest is reflected in the research field. The WHO approach to HIA, examples of its application, and international policies in its support are nicely described on the WHO website (http://www.who.int/hia/en/).

3.3.7 Integrated environmental health assessment

Integrated environmental health impact assessment (IEHIA) is an assessment approach developed in two EU funded research projects: INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe, 2005–2011) and HEIMTSA (Health and Environment Integrated Methodology and Toolbox for Scenario Assessment, 2007–2011). The IEHIA approach has been described in a peer-reviewed journal article by the INTARESE project coordinator, Professor David Briggs (2008). IEHIA is an approach that extends the principles of integrated assessment, developed mainly in the field of environmental policy, to issues of human health.

The purpose of IEHIA is to inform policies addressing systemic risks. These policies are more wide-ranging in scope, more collaborative and more precautionary than traditionally perceived, and address complex risks within wide social, economic, and environmental contexts. IEHIA assesses interventions affecting the environment and, subsequently, human health and well-being. Impacts can be due to traditional chemical hazards or other types of factors (e.g. traffic accidents), and can be direct or indirect in their nature. Human behaviours and perceptions, as well as personal characteristics, attitudes, and values are also considered. Assessment takes account of the complexities, interdependencies and uncertainties of the real world. Integration of issues can occur in many ways, e.g. across different sources, health outcomes, sectors of administration, geographical regions, and time. The framework builds on traditional risk assessment methods, but expands them to cover more complex, multi-sectoral issues and policies (cf. Fig. 1).

The problem owners are not explicitly listed, but it appears that the approach sees the scientists as problem owners. It is their task to identify policy needs to be addressed by means of assessment. Assessment results are intended to be of use to policy makers and they, as well as other stakeholders, are engaged already in framing of the assessment problem at hand.

Different types of questions can be asked. Diagnostic assessments aim to identify and prioritize policy actions by determining whether a problem exists, and if so, its magnitude and causes. Prognostic assessments help to choose between options by evaluating and comparing the potential implications of new policies. Summative assessments evaluate the effectiveness of existing policies, and, therefore, inform decision-making on adjustments to prevailing policies. Assessment models how interventions feed through the environment to affect health and answers are often given in the form of evaluations and comparisons of different policy scenarios. Outcomes are usually presented as impact measures. The impact indicators are selected at the issue-framing stage, and may differ substantially depending on the nature of the analysis and the stakeholders or users concerned. Indicators may be performance-based (distance from a legislative target), accepta-

bility related (e.g. based on public opinions), health impact measures (number of mortality/morbidity cases, disability adjusted life years), or economic measures.

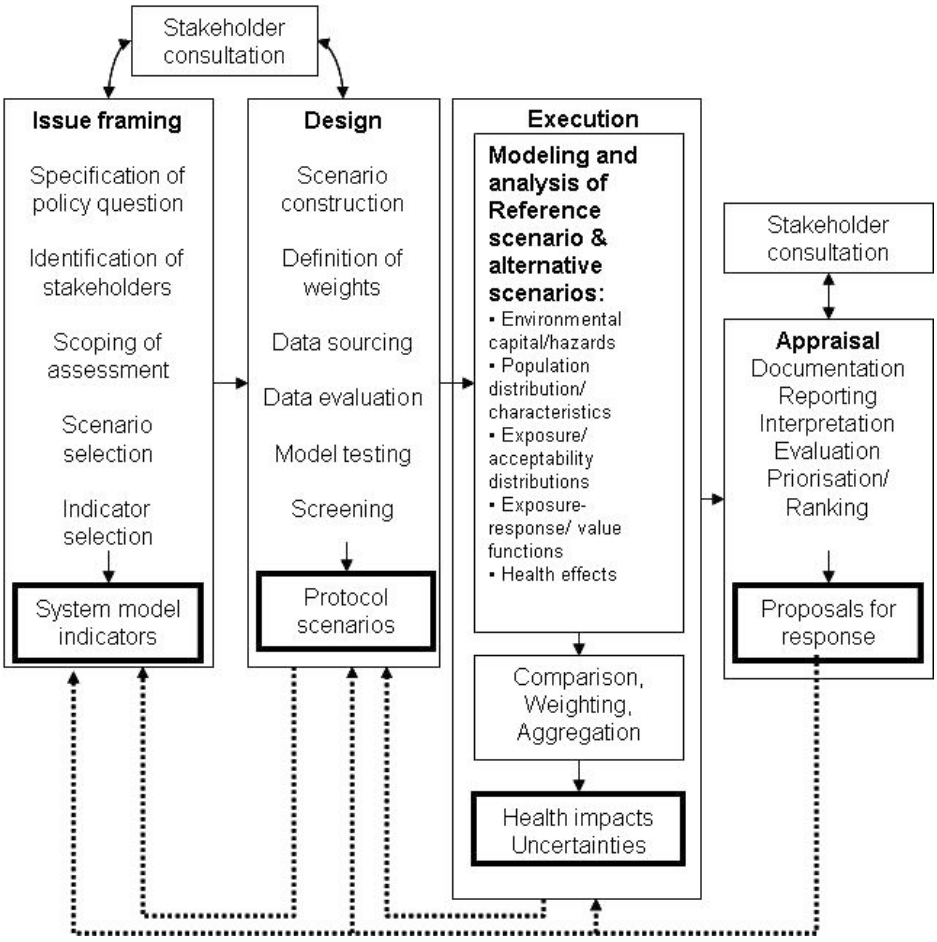

Figure 8. The integrated environmental health impact assessment process. For an explanation of formatting, see chapter 2.

The assessment process is much more extensive compared with the traditional risk assessment. More attention is focused on the earlier stages of analysis in order to ensure that the issue at hand is fully defined and agreed upon, and that an appropriate form of assessment is chosen. Effort is also put into the interpretation and evaluation of the results to make sure that they are properly understood and accepted by the stakeholders involved in the process. The assessment procedure consists of four-stages: issue framing, design, execution and appraisal (Fig. 8).

The object of IEHIA is to inform policy making on systemic risks, but the approach does not explicitly specify what kind of policy processes the assessment results are intended to be used and how. However, the framework description implies that IEHIA serves in particular the needs of institutional policy making on regional, national, and EU-level issues of environmental and health relevance.

The model of interaction is best described as integration. Interaction with users and other stakeholders takes place in the issue framing and design phases of the assessment, as well as in appraisal of the assessment results. The framework acknowledges that methods enabling wider public participation in the assessment process are emerging (e.g. citizen panels and interactive websites). However, the core of the process, assessment execution, is considered to be an exclusive expert process.

The performance of an assessment is considered in terms of uncertainty of the assessment results. In the appraisal stage, the stakeholders can also express their views on the results and their implications for action. Appraisal also provides closure to the assessment process by linking the results back to the original objectives defined in the issue framing, and thereby help to ensure the acceptance of the outcomes by the stakeholders.

The framework has been developing in the INTARESE and HEIMTSA projects since 2005. As the projects are still on-going, its application has thus far been limited to the assessment case studies conducted within these projects. In terms of establishment, IEHIA can be characterized as a novel approach that has not yet gained much popularity in the field of environmental health, and examples of its application are few. However, the framework builds and extends on a combination of well established, even traditional, approaches of risk, impact, and integrated assessment.

3.3.8 Open assessment

Open assessment is an approach to environmental health assessment developed in the National Institute for Health and Welfare in Finland in collaboration with multiple partners in several projects funded by the EU, the Academy of Finland, and the Finnish Funding Agency for Technology and Innovation (TEKES). The methodological foundation was addressed particularly in the EU-funded BENERIS project (Benefit–Risk Asessment of Food: An iterative Value- of-Information approach, 2006–2009). The characterization of open assessment is based on information available in the Opasnet web-workspace (http://en.opasnet.org) and a report on Open risk assessment (Tuomisto and Pohjola (Eds.), 2007). The approach has been developed in the context of environmental health, but the method is applicable in all kinds of systematic knowledge creation. The approach implements the idea of mass collaboration (Tapscott and Williams, 2007) as an open trialogical process of collective knowledge creation (Hakkarainen and Paavola,

2009; Paavola and Hakkarainen, 2009) to support decision making on issues with high societal relevance.

The primary purpose of open assessment is to improve societal decisions through generation of shared knowledge and understanding among experts, decision makers, and stakeholders. A more detailed purpose of a particular assessment is always defined according to the specific problem at hand. The problem owners in an open assessment can be anyone, for example scientific experts, political decision makers, business organizations, NGOs, or members of the civil society at large.

The formulation of assessment questions is not strictly determined, but typically they are of the form: ''given the defined problem, which action should be taken?''. In principle, any issues can be addressed. The question formulated for a particular assessment should include a description of the purpose, boundaries, scenarios, and intended use(s) of the assessment. Typically, the answers provide recommendations and reasoning for certain decision/action options (or sets of options) to be taken, although the specific format of the answer depends on the assessment question. Often they include causal network descriptions of factors relevant to the outcome of interest and results of different analyses, e.g. value of information analysis, on parts of or the whole network. Sufficient answers to questions in open assessment often requires aggregation, weighing, and comparison of multiple risks, impacts, costs and benefits as well as explicit consideration of value statements.

The phases of open assessment process resemble those of most assessment approaches: (1) issue framing, (2) designing variables, (3) executing variables and analyses, and (4) reporting, through which the process progresses in iterative cycles. What is distinctive for open assessment is that it considers assessments as open collaborative processes of creating shared knowledge and understanding. Openness means welcoming all types of knowledge, possessed by all kinds of actors and found from all types of sources, into a systematic analysis. Exclusion of participants or inputs is allowed only based on well-argued, explicated and cogent reasons. The open process brings scientific experts, decision makers, and stakeholders to the same collaborative process. Collaboration is facilitated by the Opasnet web-workspace (http://en.opasnet.org), consisting of a wiki-interface, a modelling environment, and a database (see Fig. 9).

Both the use process and the users can be any, depending on the problem addressed, but they should be explicitly specified for each assessment. Societally important decisions are made by decision makers in policy and business, but also by lay-people in their everyday lives. The intended user may be, but is not necessarily, the same as problem owner. There can also be multiple secondary uses and users for assessment results.

The model of interaction that open assessment builds on is learning. To enhance effectiveness of assessments, it is essential that intended users are strongly engaged in the assessment process, and that their needs and capabilities are taken account of in all phases of the assessment process.

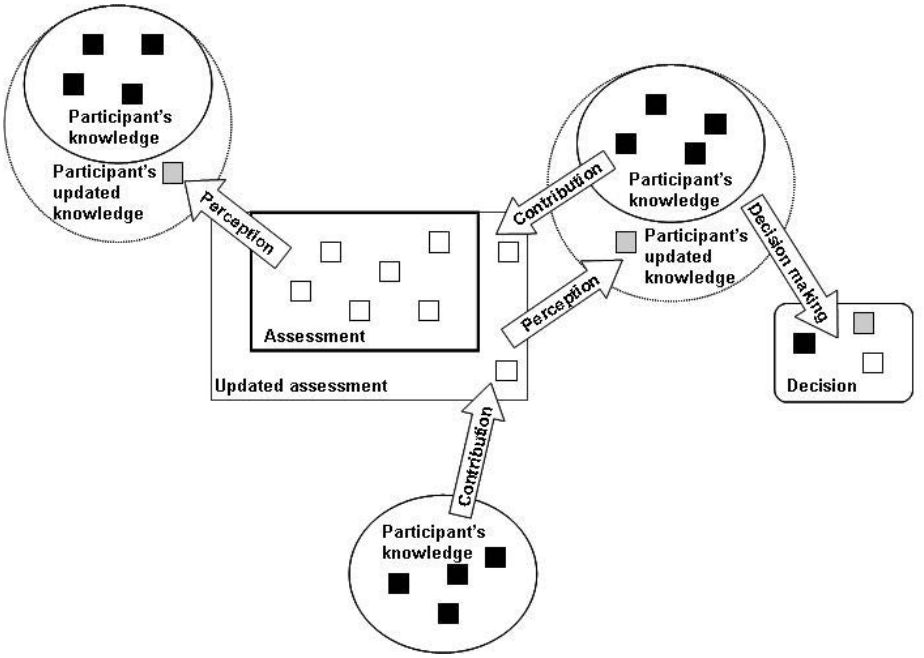

Figure 9. Collaborative knowledge creation in open assessment. Adapted from an illustration of collaborative knowledge building with wikis (Cress and Kimmerle, 2008). For an explanation of formatting, see chapter 2.

In an open collaborative process, all information is continuously subject to open criticism. Performance of an assessment is evaluated in terms of (a) quality of the information produced, (b) applicability of the information in the intended use context, and (c) efficiency of the assessment process. The performance evaluation framework is used as a means for evaluating past assessments, but also, and in particular, as a means to guide design and execution of assessments. All assessment participants can rate the information produced in terms of its scientific quality and usefulness with I rating tool in the Opasnet web-workspace.

The systematic development of open assessment began in 2006. The ideas, theories and technological enablers that differentiate open assessment from the mainstream assessment approaches can all be considered emergent. Open assessment and Opasnet have been developed and tested in several assessments and research projects. They begin to be ready for a full-scale use, but experiences on

broad participation are still limited. In terms of establishment, open assessment can be described as a novel, emergent approach that has not yet gained much popularity in the field of environmental health assessment, and examples of its application are still few.

3.4 Comparison of main characteristics of approaches to environmental health assessment

The main characteristics of the assessment approaches are summarized in Tables 3, 4 and 5 below according to the attributes of the analysis framework. The variability in scope and aggregation as well as consideration of risks and benefits among the approaches is described in Table 6. Different information sources provided quite varying kinds of descriptions of different approaches and emphasized different aspects. Therefore some interpretation by authors was necessary in order to achieve complete and balanced characterizations of each approach. However, all in all the applied analysis framework can be said to have produced clear and comparable information. The characterizations are discussed below first attribute by attribute, then across the range of attributes, and finally in terms of the big picture provided by the analysis.

From Table 3 it can be observed that the purpose definitions are relatively similar across the range of approaches. The importance of supporting societally relevant decision making is addressed in every single one, although some approaches define their scope quite narrowly while others very broadly. The main differences between approaches emerge from the means for striving towards fulfilment of the stated purposes. The problem owners in different approaches vary from scientists in charge of the assessment to policy makers with a mandate to take action upon the issue at hand and onto the operators whose projects or products are being assessed. The most flexible approaches allow assessments where the problem owner can be anyone. Variation exists also in the questions asked and answers provided in assessment. While some approaches focus on estimating impacts or risks, others aim also to complement the estimates with explicit guidance on which decisions and actions to pursue and which not.

Table 3. Summary of main characteristics of assessment approaches in terms of purpose, problem owner, question, and answer.

Approach	Purpose	Problem owner	Question	Answer
Red Book risk assessment	Produce health risk estimates to support regulatory decisions on governmental and industry-level health risk issues	Scientists assess, policy makers in federal agencies decide	What is the estimated incidence of adverse effect caused by a substance?	Health risk estimate
Understanding risk	Develop understanding on practical choices regarding governmental and industry-level health risk issues	Public officials with a legislative mandate to protect the public	What is the optimal risk management decision?	(Not necessarily conclusive) synthesis of information gathered and interpreted regarding different decision options
IRGC risk governance framework	Improve governance of systemic risks Anyone to whom systemic risks are of relevance	What risks, effects and concerns?	Benefits vs. risks or risks vs. risks? What actions?	Estimates of chance and severity of consequences: positive or negative.
Chemical safety assessment: REACH	Regulatory assessment and management of health and environmental risks from the manufacture and use of chemical substances in the EU	Manufacturer or importer of a chemical substance	Does a substance pose a health or environmental hazard? What are the safe manufacture/use conditions for a potentially hazardous substance?	Classification and labelling of the substance. Acceptable manufacture/use conditions
Environmental impact assessment: YVA	Regulatory evaluation of potential environmental impacts of large developments to support decisions on the terms for executing the project	Project manager	What are the environmental (health and ecological), impacts of executing a planned project?	Impact estimates for (i) planned activity, (ii) possible alternative activities, (iii) no activity (obligatory)

Health impact assessment	Assessment of health impacts of policies, plans and programmes to (i) increase knowledge about potential impacts, (ii) inform decision-makers and affected people, (iii) facilitate adjustment of proposed policies, (iv) mitigate negative and maximize positive impacts	Health officials and professionals	What are the health impacts of a policy/plan/program?	Estimates of direct and indirect health impacts, their distribution in population, and proposals for improvement
Integrated environmental health impact assessment	To inform policies addressing systemic risk(s)	Scientists assess on behalf of users and stakeholders	Is there a problem, and what are its magnitude and causes? What are the potential implications of a new policy? Are existing policies effective?	Performance-based metrics and/or health impact metrics
Open assessment	To improve decisions on societally relevant problems regarding environment and health	Anyone	Given the defined problem(s), which action(s) should be taken?	Recommendation and reasoning for preferred decision options

Table 4. Summary of main characteristics of assessment approaches in terms of process, use, performance, and establishment..

Approach	Process	Use	Performance	Establishment
Red Book risk assessment	Risk assessment and risk management strictly separated	Policy decisions by public officials	Uncertainty of risk estimates	Cornerstone of contemporary risk assessment
Understanding risk	Risk assessment and management bridged with analytic-deliberative risk characterization	Policy decisions by public officials	Analytic-deliberative interpretation of the quality of knowledge and evaluation of decisions	Well recognized and influential, rarely implemented as such
IRGC risk governance framework	Risk governance cycle across risk assessment and management	Institutional and other decision making processes that address systemic, global risks	Quality of knowledge about hazards and risks; simple, complex, uncertain, ambiguous. Quality assurance procedure for risk management options	Framework is well recognized, but not easily applicable as such
Chemical safety assessment: REACH	Integrated risk assessment and management	Information on acceptable manufacture/use conditions for the supply-chain. Evaluation and authorization of the substance by REACH authorities	Standard information requirements for assessments. Quality control and review by REACH authorities	Recently developed, but will be widely used due to its regulatory status. Built on traditional methods

Environmental impact assessment: YVA	Two phase assessment process with public hearings before and after the assessment	Environmental permits. Also project planning, public awareness and political decision making. Assessment must be addressed, but not necessarily complied with, in regulatory decision-making	Quality control by the liaison authority. Statements from stakeholders, public critique	Widely used in Finland due to its regulatory status. Similar approaches common in EU and elsewhere
Health impact assessment	Assessment addressing both pre- and post implementation phase	Evaluation of policies, plans and programmes by health officials and policy makers	Democracy in policy-making, equity in population, sustainable development, ethical use of evidence. Open appraisal of assessment report by public	High on the agenda of some governments and international organizations. Several examples of application exist
Integrated environmental health impact assessment	Integrated assessment for policy on environment and health	Primarily regional, national, or EU-level institutional decision making	Uncertainty analysis, outcomes vs. defined goals, stakeholder acceptance	Novel, but extending on well-established approaches
Open assessment	Collaborative knowledge creation among experts, policy makers, and stakeholders	Multiple possible uses and users depending on problems addressed. User engagement important	Evaluation of (i) quality of content, (ii) applicability, (iii) efficiency of assessments intertwined in the assessment process	Novel and building on emergent approaches, ideas, and technologies

Table 5. Primary models of interaction between assessment and use of its results in different approaches.

Approach	Trickle-down	Transfer and translate	Participation	Integration	Negotiation	Learning
Red Book risk assessment		X				
Understanding risk					X	
IRGC risk governance framework			X			
Chemical safety assessment: REACH		X				
Environmental impact assessment: YVA			X			
Health impact assessment			X			
Integrated environmental health impact assessment				X		
Open assessment						X

Table 4 illustrates some further differences among the approaches. The process conceptualizations vary from strict separation of risk assessment and management processes to intertwined assessment and decision making. The perspectives towards public participation and stakeholder involvement vary similarly between limiting the assessment to exclusive expert process and complete openness. Intended uses are in concordance with the purpose definitions, although some approaches explicate certain specific uses while the most flexible approaches allow for broad ranges of possible uses. Considering the variability in process descriptions and interaction models (Table 5) adopted, it may be observed that different approaches adopt quite different means for attempting to serve relatively similar uses and purposes. Furthermore, the mapping of the interaction models in Table 4 shows that in general the approaches are more prone to disengagement than engagement.

Perspectives to evaluating assessment performance also vary. The biggest source of differences appears to be whether the goodness of assessment is considered in terms of conforming to a rigorous assessment procedure, the quality of assessment results, or the outcomes of using those results. Some differences also exist in whether performance is predominantly evaluated in qualitative or quantitative terms. Characterizations of establishment indicate that there are traditional, well-recognized, and broadly applied, but also emergent, novel, and less known approaches included in the overview. For the purpose of this analysis, such diversity is valuable in order to get a grasp of the contemporary conventions, but also to identify the directions where the field of environmental health is shifting.

By considering characterizations of different approaches across the attributes of the analysis framework, further interesting observations can be made. One is that of how the approaches vary in their consideration of risks and benefits (Table 6). Differences exist in several dimensions: (i) if only single or multiple phenomena are considered (ii) if benefits or positive impacts are considered in addition to risks and negative impacts, (iii) how estimates of positive and negative impacts are compared and/or aggregated, and (iv) which domains and respective phenomena are included (cf. Fig. 1) in scrutiny. Again, the range spans from very strict and narrow definitions of estimating risks of single substances to overarching, nearly all-embracing, approaches where health risks are considered as factors in a broader context of multiple direct and indirect risks, benefits, and impacts.

Unfortunately, this analysis does not have the power to reveal very much of the details within the dimensions of scope and aggregation of outcomes of interest. It rather aims to identify and explicate their nature. However, it may be noted that the means for aggregating multiple risks and benefits in environmental health assessment are mostly the same as in any other field concerned with health, for example DALYs, QALYs (quality adjusted life years) and monetizing.

Certain patterns are also identified among the analyzed approaches, for example by considering the novelty of approaches and whether they are developed and applied in a regulatory or an academic setting. In the more regulatory approaches, particularly YVA and REACH, the problem framing, question setting and consequently the assessment process are relatively predetermined according to the specific regulatory uses of risk prevention. The more academic approaches, e.g. IRGC risk governance framework and Open assessment, allow for much more flexibility in adapting the question setting and the assessment process according to changing contexts and situations. On the other hand, the flexibility could also be interpreted as vagueness of the approach.

A somewhat similar pattern exists in terms of novelty or traditionalism of the theory bases of the approaches. Traditionalism seems to be more strongly linked with disengaging and novelty with engaging perspectives towards the relationships between assessment and decision making as well as stakeholders and public. There also seems to be a correlation between regulatory approaches and traditionalism as well as academic approaches and novelty. Furthermore, it appears that the more traditional or regulatory an approach is, the more established it is, although this can not be considered a universal rule.

Table 6. Risks and benefits considered in different approaches.

Approach	Consideration of risks and benefits
Red Book risk assessment	Health risk estimates for single substances
Understanding risk	Health risk estimates from risk assessment combined with any other information brought up in deliberation
IRGC risk governance framework	Risk–benefit and risk–risk comparisons regarding risks related to physical impacts affecting human health and safety, economy, environment, and/or the fabric of society at large. If risk is negligible or very significant, benefits are not assessed
Chemical safety assessment: REACH	Health and environmental risks for single substances. In case of authorization or restriction of a chemical/product, wider impacts of the action can also be evaluated in terms of direct and indirect health, economic, and social impacts and societal distribution of these impacts (ECHA, 2008b)
Environmental impact assessment: YVA	Risks, impacts and benefits to environment, society, and human health according to the characteristics of the assessed project. Different aspects are emphasized in different uses
Health impact assessment	Direct and indirect risks, impacts and benefits to human health. Aggregation of health impacts to a single measure advocated
Integrated environmental health impact assessment	Multiple benefits, risks, and impacts to human health in the broader context of environment, society, economy, and technology. Indicators for presenting assessment results differ according to the type of assessment and the stakeholders and users involved
Open assessment	Any impacts considered relevant in relation to the assessment question. Presentation, aggregation, and comparison according to the intended use(s)

All in all, the most distinctive overall characteristic of contemporary environmental health assessment is plurality, although the weight of establishment seems to be mostly on relatively traditional risk assessment as well as regulatory assessment. However, the characterizations of different approaches to environmental health assessment raise a question whether and to what extent the stated aims of the approaches, the conceptualizations of the approaches, and their practical applications actually meet? In other words, are the assessment purposes fulfilled, and do the approaches provide sufficient means to achieve that, even in theory? For example, in several approaches the evaluation of performance does not seem to consider aspects of using the results of the assessment at all, indicating that these approaches may not try to maximize what is stated as their aims, but possibly something else instead. Somewhat similarly, one may well ask if the approaches which do not explicitly consider intended use in their process descriptions, and which apply models of interaction that do not provide much power for the user side, even seriously strive for their stated purposes. Then again, the more engaging approaches often provide little practical means for achieving the interest, attention and involvement of the user side, and, thereby, for reaching the desired level of engagement. One may also well ask if environmental health assessment professionals truly consider the engagement of users and stakeholders as essential and desired, or whether it is rather seen as an obligatory add-onto a fundamentally expert-driven assessment process? Also, little guidance is usually provided on how to manage assessments with broad scopes and high levels of aggregation across domains, outcomes of interest, and types of phenomena considered in practice.

The overview of the eight approaches above can be considered sufficiently representative to reveal the essential aspects of the complex field of environmental health assessment. However, it could well be reasoned that, for example, nuclear safety assessment as described by the International Atomic Energy Agency (IAEA, 2010), life cycle assessment (LCA) as described by the Scientific Applications International Corporation (SAIC, 2006) for the United States Environmental Protection Agency (U.S. EPA), or the NRC's risk-based decision-making framework (NRC, 2009) that builds on the Red Book risk assessment and Understanding risk approaches, should have been included in the overview. Their inclusion would have added to the plurality of approaches, probably in terms of all of the attributes of analysis. However, according to the authors' understanding, it would not have affected the main conclusions, as described below, remarkably.

3.5 Conclusions

In several aspects, the theoretical ideals, conceptual means and common practices seem to be quite far from each other in the field of environmental health assessment. This is also acknowledged by Knol (2010) in her characterization of the current status of integrated assessment approaches in environmental health: ''inte-

grated environmental health impact assessment might seem too complex and extensive to carry out [...but] integrated environmental health impact assessment is not extensive and complex enough.'' The emerging assessment approaches are more complex than the currently established ones. While pursuing for more flexibility, engagement, and wide-ranging integration, the novel and academic approaches may lose the power of detailed guidance that the more narrowly scoped and rigorous regulatory and traditional approaches have. Then again, it appears that even the new integrated approaches are still too simple to effectively analyze and solve many of the current problems.

Despite the challenges in practical application, there are clear tendencies towards (a) increasing engagement between assessment and management as well as stakeholders, (b) pragmatic framing of assessments according to specific and practical policy needs, (c) integration of multiple benefits and risks from multiple domains, and (d) explicit incorporation of both scientific facts and value statements in assessments. These tendencies can be considered as a response to the inherent challenges brought about by the complexity of environmental health assessment, as well as an indication of the incapability of the traditional and established approaches to sufficiently serve the whole range of needs in policy making.

How to address the above issues in assessments in practice is a clear development need for the novel approaches and the field of environmental health assessment as a whole. For example, many means and tools already exist for stakeholder engagement and aggregation of multiple risks and benefits to support decision making. However, they need to be developed as feasible and essential aspects of functional assessment and policy processes. Therefore, an important question in further development is whether an approach is flexible enough to incorporate current and future means and tools required to fulfill the declared aims.

From an outsider's perspective, the most interesting aspects of environmental health assessment are likely to be found among the emerging approaches. While the traditional and regulatory assessment approaches resemble those common also in other fields of assessment, the above stated aspects of engagement, pragmatism, integration, and explicit inclusion of values can be considered as interesting and innovative particularities of assessment in the field of environmental health.

Acknowledgments

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4 Looking beyond borders: Integrating best practices in benefit-risk analysis into the field of food and nutrition

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Abstract

An integrated benefit–risk analysis aims to give guidance in decision situations where benefits do not clearly prevail over risks, and explicit weighing of benefits and risks is thus indicated. The BEPRARIBEAN project aims to advance benefit–risk analysis in the area of food and nutrition by learning from other fields. This paper constitutes the final stage of the project, in which commonalities and differences in benefit–risk analysis are identified between the Food and Nutrition field and other fields, namely Medicines, Food Microbiology, Environmental Health, Economics and Marketing–Finance, and Consumer Perception. From this, ways forward are characterized for benefit–risk analysis in Food and Nutrition. Integrated benefit–risk analysis in Food and Nutrition may advance in the following ways: Increased engagement and communication between assessors, managers, and stakeholders; more pragmatic problem-oriented framing of assessment; accepting some risk; pre- and post-market analysis; explicit communication of the assessment purpose, input and output; more human (dose–response) data and more efficient use of human data; segmenting populations based on physiology; explicit consideration of value judgments in assessment; integration of multiple benefits and risks from multiple domains; explicit recognition of the impact of consumer beliefs, opinions, views, perceptions, and attitudes on behaviour; and segmenting populations based on behaviour; the opportunities proposed here do not provide ultimate solutions; rather, they define a collection of issues to be taken account of in developing methods, tools, practices and policies, as well as refining the regulatory context, for benefit–risk analysis in Food and Nutrition and other fields. Thus, these opportunities will now need to be explored further and incorporated into benefit–risk practice and policy. If accepted, incorporation of these opportunities will also involve a paradigm shift in Food and Nutrition benefit–risk analysis towards conceiving the analysis as a process of creating shared knowledge among all stakeholders.

4.1 Introduction

Benefit–risk analysis of Food and Nutrition is developing fast. Benefit–risk analysis aims to give guidance in decision situations where both benefits and risks have been identified; when the benefits do not clearly prevail over the risks, explicit weighing of benefits and risks is indicated. Benefit–risk analysis can be seen as a triad of the (1) assessment, (2) management and (3) communication of integrated benefits and risks, analogous to the common contemporary risk analysis paradigm (Fig. 1) (WHO/FAO, 1995).

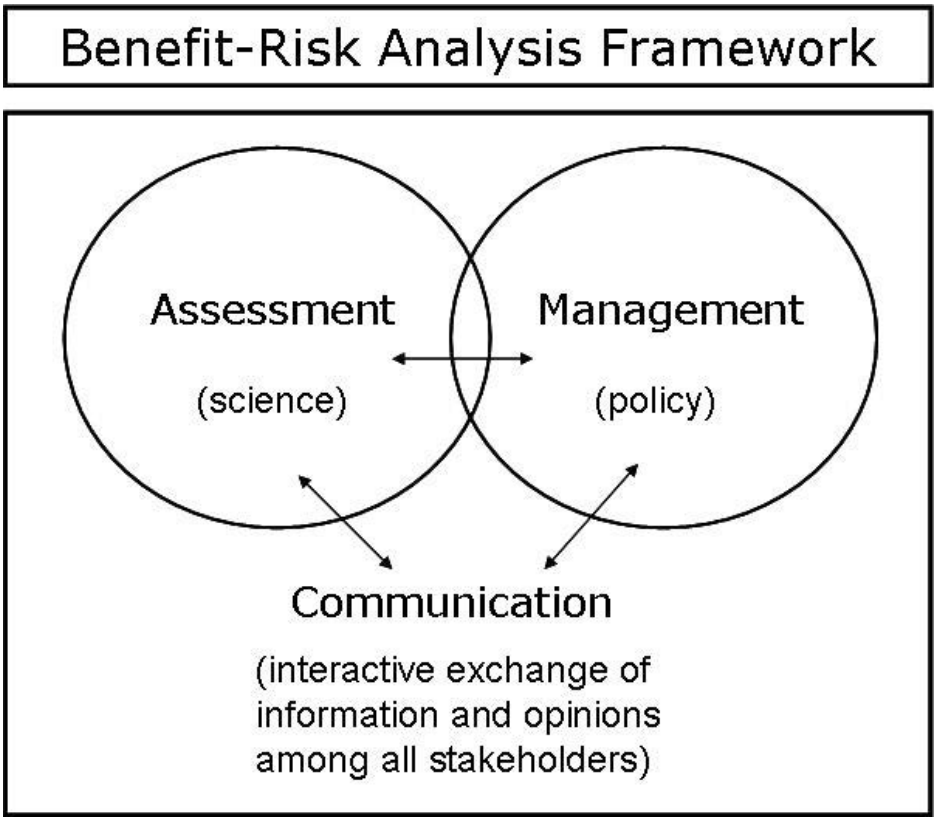

Figure 1. Contemporary benefit–risk analysis framework. Based on the risk analysis framework by WHO/FAO (1995).

Benefit–risk *assessment* of Food and Nutrition comprises a science-based process intended to qualitatively or quantitatively estimate the benefits and risks for humans following exposure (or lack of exposure) to a particular food or food component and includes the potential to integrate them into comparable measures.

Benefit–risk *management* entails the process of weighing policy alternatives in light of the results of benefit–risk assessment and other relevant information. Benefit–risk *communication* covers the interactive exchange of information and science-based opinions concerning benefits and risks among assessors, managers, consumers and other stakeholders.

The scope of Food and Nutrition risk assessment is fairly well established (Renwick et al., 2003); it deals with the assessment of adverse health effects caused by physical or chemical agents, occurring naturally in foods or as environmental contaminants, or resulting from food preparation or manufacturing processes. However, in the benefit–risk context, the scope of benefit-assessment is a point of discussion. A beneficial effect can be looked at as the reverse of an adverse effect (WHO, 1994), i.e. a physical or other change within a person that improves functional capacity or the capacity to deal with stress or that decreases susceptibility to harmful effects. This can be measured as prevention of disease, i.e. reduction of risk, but currently it is difficult to measure benefits directly, at an early stage or as an 'above-normal' capacity. Cases where the benefit is obvious but where different risks are involved (in severity and mechanism) could also be taken under the wing of benefit–risk analysis. Benefit–risk analysis presents up-to-date knowledge in a dynamic public health process, aimed at optimization, i.e. looking for ways to maximize benefits while minimizing risk.

In recent years, many projects have done significant work to identify the possibilities and difficulties of benefit–risk analysis in the Food and Nutrition field (Tijhuis et al., 2011). Much progress has already been made, but benefit–risk thinking and practise have not yet become commonly established. Therefore, for further development, the field of Food and Nutrition could benefit from looking beyond its borders and learning from other fields of research (and possibly also *vice versa*) and this is the explicit goal of BEPRARIBEAN project (http://en.opasnet.org/w/Bepraribean) (Verhagen et al., 2011). To serve this goal, we recently compiled reviews covering the state of the art in benefit–risk analysis for Food and Nutrition (Tijhuis et al., 2011) and five other fields: Medicines (Luteijn et al., 2011), Food Microbiology (Magnússon et al., 2011), Environmental Health (Pohjola et al., 2011a), Economics and Marketing–Finance (Kalogeras et al., 2011) and Consumer Perception (Ueland et al., 2011). The individual reviews were led by the researchers from within the respective fields and were contributed to by the researchers from the other fields. Summaries of the key issues from the reviews and a summary of the contemporary regulatory context for Food and Nutrition management and assessment are presented in Section 2.

In Section 3, the focus is on identifying how the benefit–risk approaches in the different areas compare to and differ from the benefit–risk approaches in the area of food and nutrition. In order to exemplify the (combined) perspectives and approaches from within the different areas, we include an example of a case: the

effects of replacing current animal protein sources by more sustainable dietary protein sources. This topic was considered suitable because it is inherently multidisciplinary and currently of global interest. This example is meant as an illustration and does not aim to be a conclusive analysis.

From this, in Section 4, we aim to identify opportunities for further development of benefit–risk analysis in food and nutrition.

In Section 5, we sum up the main points of this paper, and the whole BEPRARIBEAN project, and indicate some implications that these points will or may have for Food and Nutrition benefit–risk analysis in the future.

4.2 Summaries of key issues by focus area and EU regulatory context for Food and Nutrition

In 2.1–2.6 we summarize the key issues from the 6 state of the art reviews: Food and Nutrition (Tijhuis et al., 2011), Medicines (Luteijn et al., 2011), Food Microbiology (Magnússon et al., 2011), Environmental Health (Pohjola et al., 2011a), Economics and Marketing–Finance (Kalogeras et al., 2011) and Consumer Perception (Ueland et al., 2011). They are complemented in 2.7 with a short overview of the contemporary regulatory context for Food and Nutrition management and assessment in the European Union.

4.2.1 Benefit-risk analysis in Food and Nutrition (Tijhuis et al. 2012)

This paper addresses the three components of benefit–risk *analysis*, but focuses on *assessment*. Benefit–risk assessment in Food and Nutrition is geared to weigh the beneficial and adverse effects a food or food component may have, in an integrated measure, in order to make better-informed policy decisions regarding public health issues.

Historically, the assessments of risks and benefits have been separate processes. In risk assessment, toxicology is the main contributor as the toxicological approach is demanded by regulation. It traditionally assumes that a maximum safe dose can be determined from studies in experimental animals or sometimes humans and that division of this dose by appropriate safety factors defines the ‘safe’ intake for the human population. Epidemiology plays a minor role in risk assessment. Epidemiology describes associations between risk (or beneficial) factors and disease endpoints in humans. It has traditionally focussed more on relative than on absolute risks. Nutrition, as a science, uses a mixture of methodologies and is involved in estimating risks specifically for nutrients and other dietary factors. Benefit assessment for Food and Nutrition is newly developing in regulatory terms, but has been the subject of nutritional epidemiological research for a long time. Benefit assessment is working on concepts such as whether reduction of risk of disease should be termed a benefit, whether a benefit can be measured as a state rising above the average health and in which time frame (short or long term), and

how broad its scope should be. In nutrition, current interest is in 'optimal' food and nutrient intake, implying knowledge of both intakes where risks occur and intakes where benefits occur. In this, there is a scientific development away from general population intakes towards an intake based on subgroups. In summary, the goal of risk assessment in food and nutrition is to reasonably guarantee absence of an effect (risk) whereas the goal of benefit assessment is to reasonably guarantee the presence of an effect (benefit). This distinction affects the assessment approach, the evaluation of the generated data and the way these can be used. In both risk and benefit assessment, good dose–response data, i.e. with relevant intake levels and suitable for the target population, are scarce. Better integration of all underlying disciplines and an approach focussed more on humans and continuous data is indicated.

Current approaches to bring benefit and risk assessment together mirror the traditional risk assessment paradigm of hazard identification, hazard characterization, exposure assessment and risk characterization. A tiered approach is advocated, as this allows for transparency, in-between consultancy with the benefit–risk manager and the possibility of an early stop in the assessment and thus increased efficiency. There is agreement about the importance of a good description of the benefit–risk question and the uncertainties in its assessment. Benefit–risk comparison can be qualitative and quantitative, with increasing data requirements. In a quantitative comparison, benefits and risks are expressed in a common currency. Severity of disease can be taken into account by attributing weights, e.g. using disability adjusted life years (DALY's). These integrated measures need to be accompanied by at least (1) a description of the unintegrated benefits and risks on subgroups and (2) data uncertainties. In the quantification process, deterministic input may be substituted by probabilistic input; well-accepted methodology for probabilistic assessment is available.

Close communication, between and within benefit–risk assessors and managers, requires attention. In benefit–risk management some risk will have to be considered acceptable in order to achieve more benefits. Thus, current risk management will also need to consider a shift from striving for zero risk towards explicit weighing of risks and benefits in order to achieve an optimal outcome. The communication of benefits and risks to the public used to be separate, but the impact of combined benefit–risk messages is being explored.

In conclusion, benefit–risk assessment is developing steadily in the field of food and nutrition. General point of attention is the communication between fellow scientists, managers and the general public. General strengths are the ability to systematically and transparently show the current knowledge and its gaps and to provide what is likely the best answer to a question with a large potential impact on public health.

4.2.2 Benefit-risk analysis in Medicines (Luteijn et al. 2012)

Medicines can lead to significant health benefits. The health benefits come at the risk of potential adverse drug reactions. Since the thalidomide disaster in the early 1960s, increased regulatory attention has been placed in the benefit–risk profiles of medicines. This key-event has lead to not only demands on safety demonstration before registration of a medicine, but also to demands in regard to demonstration of efficacy, i.e. the effectiveness of a medicine under controlled conditions.

Benefit–risk assessment in medicine is highly regulated and has been developed for decennia. Benefit–risk assessment (and monitoring) takes place both in the pre-registration and the post-registration phase of a medicine. In the pre-registration phase, the candidate medicine goes through a process of phase I–III trials, involving populations of increasing size and different aims and designs as discussed in the state of the art paper. These clinical trials are conducted by the manufacturer and involve a considerable financial investment. Trials will only be continued if the manufacturer feels the drug stands a chance to successfully gain marketing authorization by sufficient proof of efficacy and safety. Data gathered by these clinical trials, reinforced by animal model data and possible post-marketing experience with similar compounds, will provide the safety and efficacy data for the marketing authorization procedure. The pre-marketing clinical trials have been criticized for being designed for fast approval instead of the generation of scientific knowledge. A number of mainly quantitative benefit–risk methods are employed during the pre marketing phase, including ‘number needed to treat’ and ‘number needed to harm’. Expert opinions play a big role in benefit–risk assessment of medicines, both pre-registration and post-registration. There is no standard protocol for analyzing the benefit–risk profile of a drug, after the manufacturer submits the clinical trial data, responsible authorities will take the evidence into account and form an expert opinion on the registration submission. Both the benefits (efficacy) and the risk (adverse drug reactions, ADRs) play a role in this expert opinion: larger benefits can justify larger risks. No consensus has been reached on a standardized methodology for benefit–risk assessment in medicine registration. The European Committee for Medicinal Products for Human Use recommends the use of multiple types of mainly qualitative, benefit–risk methodology and argues that use of quantitative methodology can lead to a misleading feeling of precision.

4.2.2.1 Pre-registration

The pre-registration clinical trials themselves suffer from a number of practical limitations; these include the small number of subjects in clinical trials, a restricted population in terms of age, gender and ethnicity, restricted co-medication and co-morbidity, a short duration of exposure and follow up and statistical problems with assessing multiple outcomes. These problems are acknowledged by the responsible authorities. Because the clinical trials take place in a controlled environment, situations of off-label use, drug–drug interactions and non-compliance will be

limited to theoretical consideration. Therefore, clinical trials will provide information on the efficacy of a medicine, rather than effectiveness of a medicine. Despite the differences between efficacy and effectiveness, efficacy will provide an indication of effectiveness of a drug. It should be realized there is no solution for the majority of these problems. For example; it would be ethically unacceptable to conduct safety experiments in pregnant women. Experience in this population will be limited to animal models and post-registration data.

During the application process, a risk management program will be submitted along with the clinical trial data, outlining risk minimization and post marketing surveillance activities.

4.2.2.2 Post-registration

After registration, the benefit–risk profile of medicines will be monitored by post-marketing surveillance. Pre-marketing knowledge on the benefit–risk profile of a medicine will be limited for reasons mentioned above. Post-marketing surveillance is conducted by responsible authorities, marketing authorization holders and independent researchers in order to collect data on ADRs and monitor the effectiveness of existing risk management activities. In case a new ADR is discovered, responsible authorities can reassess the benefit risk profile forming a new expert opinion. Information discovered during post-marketing surveillance can lead to modification of marketing authorizations, risk management programs or even suspension of marketing authorizations in the case of serious ADRs. Many recent developments and initiatives are currently ongoing in post-marketing surveillance, many of them involving large databases to collect information on ADRs. The more statistical power, the better the investigators are able to detect ADRs. For this reason, an increasing amount of international cooperation is taking place in Europe. Other problems include different legislation between European countries.

A different type of benefit–risk assessment in the post-registration phase is Health Technology Assessment (HTA). In HTA, the health impact and economic impact of a new health technology are assessed using (economic) modelling techniques, usually in order to be included in public formularies. The main challenge of HTA is to assess the trade-offs between financial investment and health benefits. For this purpose, indexes such as QALY and DALY have been developed. The trade-off between financial investment and health benefits is perceived as controversial by many. Marketing authorizations have become less meaningful without reimbursement (after a positive HTA assessment) in many countries. The mandate and methodology of HTA agencies differ between countries.

The state of the art paper concluded that no ‘one size fits all’ approach is available for benefit–risk assessment in medicines. Choice of methodology depends on the context of the benefit–risk assessment, including indication, patient groups and the stage of the regulatory process. Also, use of multiple methodologies is encouraged due to each having its own specific strengths and weakness. Furthermore,

improved cooperation between responsible authorities and HTA agencies can be of value in benefit–risk assessment.

4.2.3 Benefit-risk analysis in Food Microbiology (Magnússon et al. 2012)

Microorganisms, i.e. bacteria, fungi and viruses, are all constituents of our natural environment. The field of food microbiology concerns the multitude of microorganisms that inhabit and contaminate our foods. Food and nutrition are essential for sustaining human life. However, no food carries zero risk for microbiological hazards. The risk varies considerably depending on food types and matrices. Some foods have a higher risk than others of containing microbiological contaminants and pathogenic microorganisms that can be hazardous to our health and well being. Furthermore, consumer sub-groups can be variably susceptible to foodborne infections and intoxications; the elderly, young children and individuals with underlying diseases being more at risk.

Food microbiology is largely focused on food safety and limiting public exposure to harmful food borne pathogens. However, the great majority of microorganisms are harmless to our health and many microorganisms are even important to various food production processes e.g. the making of cheese, wine, beer and bread. Microorganisms are used in various ways for the benefits of humans e.g. through advances in medical technology, biotechnology, agriculture and in food processing, to name a few. Although microorganisms can be seen as indirectly beneficial to human health through the above-mentioned activities, the human health consequences of microorganisms in foods are often either neutral or adverse. In food microbiology the reduction in human exposure to food borne pathogens can commonly be regarded as the main public health benefit. Probiotic microorganisms and the activities of the gut microflora can be mentioned as an exception to this – the effect of probiotics can be seen as *directly* beneficial to human health. It must be noted, however, that to date all such probiotic health claims have been refuted by EFSA, the European Food Safety Authority, (http://www.efsa.europa.eu/en/topics/topic/article13.htm); currently, there is lack of evidence for the direct beneficial effects as judged by EFSA's criteria, but at the same time there is lack of evidence that beneficial effects do *not* exist.

Benefit–risk analysis is a relatively new and to-date largely undefined field of research within food microbiology. The benefit–risk analysis approach is concerned with issues affecting public health and improving public health management based on the balanced weighing of risks and benefits. From a food microbiological standpoint studies using methods that balance risks and/or risks and benefits using composite metrics are scarce. Published studies to date have mainly been intervention assessments or risk comparison studies that apply risk assessment criteria for comparing the level of two individual risk factors – with the purpose of

identifying the most important health risks – commonly a chemical risk and the benefits of reduced microbiological risk. The criteria for the assessment of risks are well established within food microbiology (and are based on risk assessment criteria developed within toxicology), but at present the criteria for assessing positive health effects are not well defined.

A key issue in food microbiological benefit–risk analysis is how to address the assessment of benefits and the multidisciplinary discussion of how to aggregate risk and benefit estimates. The most straightforward approach to be used for benefit–risk analysis in food microbiology could be envisioned to follow the tiered approach for benefit–risk analysis formulated in the field of food and nutrition. Food microbiological benefit–risk analysis converges largely with that of food and nutrition. In addition, it often involves the evaluation of chemical as well as microbiological risks and benefits.

A key issue in food microbiological benefit–risk analysis is how to address the assessment of benefits and the multidisciplinary discussion of how to aggregate risk and benefit estimates. The most straightforward approach to be used for benefit–risk analysis in food microbiology could be envisioned to follow the tiered approach for benefit–risk analysis formulated in the field of food and nutrition. Food microbiological benefit–risk analysis converges largely with that of food and nutrition. In addition, it often involves the evaluation of chemical as well as microbiological risks and benefits.

In conclusion, the field of benefit–risk analysis in food microbiology is in its infancy and the assessment criteria for benefits are not well defined. Reduced pathogen risk can be seen as the principal benefit regarding food microbiology while scientific data on direct microbial benefits are lacking.

4.2.4 Benefit-risk analysis in Environmental Health (Pohjola et al. 2012)

The field of environmental health is very broad and involves significant physico-chemical, biological, technological and social complexity. Consequently there is no single state-of-the-art approach, but a multitude of approaches to assess environmental health risks and benefits have been developed for different purposes and contexts within the field. These approaches can be characterized e.g. as either regulatory or academic, depending on the context of development and application for the approach, or rather traditional or novel, depending on how strictly and narrowly the assessment scope and procedure are determined by the approach.

In comparison to the traditional and regulatory approaches the emphasis among the more novel and academic approaches is on (a) increased engagement between assessors, decision makers, and stakeholders, (b) more pragmatic problem-oriented framing of assessments, (c) integration of multiple benefits and risks from multiple domains, and (d) inclusion of values, alongside scientific facts, in explicit

consideration in assessment. These tendencies can be considered as responses to the challenge of complexity within the field, but also as indications of the incapability of the currently established approaches to adequately address all aspects of this complexity. On the other hand, the all-embracing aims of the novel academic approaches may also lead to lack of clarity in comparison to the regulatory and traditional approaches, unless duly designed and implemented.

The key issues in benefit–risk analysis in environmental health are not so much related to the technical details of performing the analysis, but rather to (i) the level of integration, and (ii) the perspective to consider the relationship between assessment and the use of its outcomes. The level of integration can range from producing health risk estimates for single substances to aggregation, weighing, and comparison of multiple benefits, risks, impacts, and costs alongside explicit account of values of those concerned. Significant differences are also brought about by whether an "assessment push" or an "information need pull" perspective is adopted. The perspective largely defines what, how and why, issues are considered in an assessment.

In the "assessment push" perspective, the issue to be assessed is defined by those responsible for the assessment, and the focus of assessment is to produce an objective estimate of the risks, benefits, etc. according to certain defined principles and means, whatever the estimate may be used for. Approaches taking an assessment push perspective thus also predetermine the possible levels of integration in terms of e.g. what phenomena are considered, whether also benefits or costs are considered in addition to risks, and what means of aggregation or comparison are used. In the "information need pull" perspective the issue to be assessed, as well as the principles and means for its assessment, is formulated according to a specified practical need. The need thus determines the suitable format of the assessment outcome, which further determines how the assessment should be made. Therefore inclusion of all relevant issues, all levels of integration, and all means of aggregation and comparison are, at least in principle, available for use as required to serve the need. Naturally, most of the approaches to environmental health assessment fall somewhere in between these extremes by incorporating aspects of both push and pull. However it can be identified that the regulatory and the most traditional, simultaneously the currently most established, approaches clearly position themselves closer to the assessment push end of the continuum.

Challenges lie in the aggregation, weighing, and/or comparison of multiple benefits and risks. For example: the use of DALY's, QALYs or euro's as general aggregate measures, incommensurability of benefit estimates aiming for avoidance of false positives and risk estimates aiming for avoidance of false negatives, and taking account of perceived risks and benefits together with "scientifically assessed" risk and benefit estimates.

In conclusion, probably most of all commonly known methods for benefit–risk analysis are applied among the various different approaches to environmental health assessment, but there is no single view to dominate the whole broad field.

4.2.5 Benefit-risk analysis in Economics and Marketing-Finance (kalogeras et al. 2012)

Risk is a key component of economic behaviour. All market participants (e.g. investors, producers, consumers) accept a certain level of risk as necessary to achieve certain benefits. There are many types of risk including price, production, financial, institutional, and individual human (e.g. health-related) risks. All these risks should be effectively managed in order to derive the utmost of benefits and avoid disruption and/or catastrophic economic consequences for the food industry and market participants' wellbeing.

In (food) economics, finance and marketing-management literature, the *utility* concept (total satisfaction received from consuming a product/service) plays a crucial role in determining market participants' benefit–risk trade-offs that drive economic phenomena. This utility is often derived from outcomes such as wealth, income, profit, selling price, among others. That is, the outcome domain is a monetary one. Yet, in behavioural economics, behavioural finance, economic psychology, marketing and consumer behaviour literature, market participants may also derive utility from non-monetary outcomes by exposing a combination of cognitive and affective behaviour.

The dominant paradigm in business economics on which decision makers (e.g. farmer, food manufacturer, retailer, consumer) rely in their benefit–risk trade-offs is the expected utility model. This model is concerned with choices among risky prospects. The goal of a decision maker is the maximization of his/her expected utility. In the expected utility framework, the shape of the utility function is assumed to reflect a decision maker's risk preference. Therefore, the expected subjective utility function of any prospect reveals the individuals' attitudes towards risk. There is a continuous stream of research on decision makers' risk preferences in the fields of food economics and marketing–finance that employs expected utility models that are objective or normative, i.e. assumption and establishment of norms implying the rationality principle in economic behaviour of market-participants: maximization of their utility, by using time series and/or panel data for production, consumption, pricing levels of food products; and subjective, i.e. relaxing the rationality assumptions inherent in the normative models by using survey- and experimental-based data gathering instruments involving psychometric constructs or lotteries. Both theoretical and empirical research accounts show that decision makers can be simultaneously risk-seeking and risk-averse in different domains, implying that risk preference is context-specific.

In the context of agribusiness and food markets, concerns about food safety, quality, and nutrition have persistently been present at all levels of decision making (operational, tactical and strategic) by food producers, manufacturers, commodity traders, retailers, and consumers. However, business economic scholars are often confronted with conceptual and methodological challenges due to the unobserved and multidimensional nature of human decision making process. That is, the actual behaviour of market participants is not always consisted with the "true" level of risk that they face.

Recent research in management sciences and decision analysis argued that by decoupling the benefit–risk trade-offs of decision makers into separate dimensions a more robust conceptualization and prediction may be achieved. Specifically, market participants have two kinds of evaluation systems on which perceived and/or actual benefits of an investment or consumption object cognitively rely on: (a) *utilitarian* dimension of instrumentality and (b) a *hedonic* dimension. The first dimension refers to how useful or beneficial the investment or consumption action is. The second dimension of benefits refers to the experiential affect associated with the investment and consumption. These two dimensions are neither mutually exclusive nor need to be evaluative consistent. Similarly, risk behaviour may be decoupled into the separate dimension of *risk attitude* and *risk perception*. Risk *attitude* is formed by one's predisposition to the content of the risk in a specific market situation and reflects a decision-maker's interpretation of this risk content in a specific way, whereas risk *perception* refers to the likelihood of one's exposure to the risk content. This decoupling approach may serve as the basis for studying the decision-making process of market participants regarding food safety- and nutrition-related issues, in the light of benefit–risk trade-offs. Yet, one may recognize the challenges for operationalising such a framework, adapt it to specific decision contexts, and accounting for its dynamics.

In conclusion, the study of market participants' benefit–risk trade-offs in business economics rely on the utility concept. Although the dominant paradigm in economics is the expected utility model that has a normative nature, the behavioural study of market participants' benefit–risk trade-offs emerges. Nowadays, there are various and different approaches and techniques to businesses economics to identify and evaluate the benefit–risk trade-offs on institutional or individual market participants. Yet, there is no single view to dominate the whole discipline. The decoupling of benefit–risk behaviour into separate components that deal with both the utilitarian as well as hedonic aspects of benefits and risks may offer more robust conceptualizations and predictions for studying benefit–risk trade-offs in various highly uncertain decision contexts entailed in the agribusiness and food markets.

4.2.6 Benefit-risk analysis in Consumer Perception (Ueland et al. 2012)

Food and nutrition are central to the survival of human beings as well as to their well-being and quality of life. However, a "nutritionally perfect life" is not necessarily consistent with consumers' feelings of how a perfect life should be which again has implications for what motivates consumers' food choice. The inconsistencies are partly the result of consumers' perceptions of benefits and risks with regard to food and nutrition and of the way consumers trade off between benefits and risks in order to maximize the outcome they prefer. Thus, by incorporating the study of consumers' perception of benefits and risks in a food and nutrition context, possible outcomes of food and nutrition measures can be better understood.

For consumers, benefit perception of food is usually more important than risk perception. The benefits are particularly related to the hedonic perspective; food should taste good, be pleasurable and fulfil expectations to an enjoyable experience. Risks, on the other hand, are more often subject to conscious deliberations and external factors, such as available information, media coverage and personal interest that contribute to consumers' risk perception.

Consumers' perception of risks is associated with mortality and morbidity and goes along two main dimensions related to; the extent that the risk is unknown, and what are the consequences of the risk. Food risks are not perceived to be as severe as are for instance risks associated with firearms or airplanes. However, some foods, particularly those that score high on the unknown dimension, are perceived with trepidation by consumers. Conversely, foods that are perceived as risky are often foods that are unfamiliar or produced by novel technologies. Furthermore, foods that are (perceived to be) highly processed are considered to be less desirable and more risky, than foods perceived to have a low level of processing. The possibility to discern what the food product is made of, or what it is derived from, contributes to a feeling of safety and to lower risk perception among consumers.

There are ways to reduce perceived risk of foods for instance through familiarising the consumer with the food, or by adding characteristics that may be seen as benefits to the food product. Increasing healthiness and enhancing taste are factors that make consumers more willing to accept the product. Adding benefits to a product does not reduce the risk itself but reduces the consumers' perception of the risk. Benefit and risk perception of foods are in many cases inversely correlated: when something is perceived as being highly beneficial, it is correspondingly perceived as having low risk. However, slightly different paths are used in the formation of these perceptions; benefit perception is based on heuristics and experience, while risk perception is largely the result of cognitive information processing.

Nutrition is one aspect belonging to food products that is normally not associated with hedonic benefits of foods. However, nutrition is accepted as an essential

part of consumers' life, and health attributes of foods are perceived as benefits when diet considerations are important for the consumers. Consumers easily perceive risks belonging to malnutrition, both related to over- and under-consumption of nutrients, but consumers' may choose not to pay attention to these risks.

In conclusion, in a food and nutrition setting it is important to understand which food attributes related to perceived and real benefits and risks that influence food choice, in order to provide for an optimal diet from both a health perspective as well as from a hedonic perspective.

4.2.7 Contemporary regulation context for Food and Nutrition assessment and management

The European Union (EU) Food Safety legislation (http://ec.europa.eu/food/food/foodlaw/index_en.htm, EU, 2000) is built around high food safety standards, of which the final aim is to protect the health of the consumers and to reduce the risks connected to unsafe food (van der Meulen and van der Velde, 2008).

The development of the requirements is the result of stratified legislative measures, often approved by incidents (food safety crises consequent to foodborne diseases) rather than by a systematic legislative plan. Regulation EC/178/2002 is the General Food Law, containing general provisions useful to orientate the interpreter in understanding the mechanisms and procedures to be followed in order to reduce risks related to unsafe food. The general principles of food law may be considered the top of the ideal pyramid of a regulatory food control systems. Regulations and directives have been formulated within this frame.

The aim of EU food policy is to assure a high level of food safety, animal health, animal welfare and plant health within the European market. In this sense, the General Food Law constitutes the main reference point of the EU food legislation. It applies to all stages of the production, processing and distribution of food and also to feed produced for, or fed to, food producing animals. More in detail, the General Food Law establishes the principles of risk analysis in relation to food and establishes the structures and mechanisms for the scientific and technical evaluations which are undertaken by the European Food Safety Authority (EFSA). As an exception of the general tendency to regulate risks rather than benefits, it is worth mentioning the EFSA health claims procedure under Regulation (EC) No 1924/2006, which plays a relevant role in the regulation of the benefits. Nevertheless, also in this case, we may see that the final objective of regulating benefits turns into the legislative intention to prevent risks, both connected to the functioning of the market and to the consumers' protection, if we consider that the general objective of the Regulation is to ensure the effective functioning of the internal market as regards nutrition and health claims whilst providing a high level of consumer protection (EC, 2006).

Food law, and in particular measures relating to food safety have to be based on scientific expertise. The EU has developed its own risk analysis principles in conformity with the International standards. Regulation EC/178/2002 establishes in EU law that the three phases of risk analysis (risk assessment, risk management and risk communication) provide the basis for food law as appropriate to the measure under consideration. Therefore, the General Food Law states that scientific assessment of risk must be undertaken in an independent, objective and transparent manner based on the best available science. Risk management is the process of weighing policy alternatives in the light of results of a risk assessment and, if required, selecting the appropriate actions necessary to prevent, reduce or eliminate the risk to ensure the high level of health protection determined as appropriate in the EU. In the risk management phase, the decision makers need to consider a range of information in addition to the scientific risk assessment. These include, for example, the feasibility of controlling a risk, the most effective risk reduction actions depending on the part of the food supply chain where the problem occurs, the practical arrangements needed, the socio-economic effects and the environmental impact. Regulation EC/178/2002 establishes the principle that risk management actions are not just based on a scientific assessment of risk but also take into consideration a wide range of other factors legitimate to the matter under consideration (http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm).

In sum, at a legislative level we may observe that the main objective is to regulate risks connected to unsafe food, rather than benefits and the balance between risks and benefits. Risk management is a procedure which involves legislative tools together with scientific expertise. The choice to regulate risks rather than benefits is deeply linked to the necessity to reduce the risks on the market by defining the tasks of the European Commission, the European Food Safety Authority (http://www.efsa.europa.eu) and the national competent authorities in charge to implement at local level the European provisions.

4.3 Commonalities and differences, and illustration in a case study

This section contains some of the characteristics that the different fields, described in the previous section, share in common and in which they differ with respect to benefit–risk analysis.

The general settings in which benefit–risk analyses within the different fields currently may take place are described in Table 2. The general characteristics of integrated *assessment* of benefits and risks within different fields are described in Table 3. In order to illustrate the commonalities and differences, a conceptual case example of replacing animal protein with environmentally more sustainable dietary protein is presented in Table 4. The case example described here is meant as an aid, to illustrate and characterize the different fields that form this paper. The

attributes in the tables, according to which benefit–risk analysis within the different fields are described, are adapted from the framework applied for characterizing approaches to benefit–risk analysis in the field of environmental health in Pohjola et al. (2011a) and explained in Table 1.

In Section 3.1, general commonalities and differences are described, taking the main points from Table 2 and Table 3. Issues arising from the illustrative case study in Table 4 are discussed in Section 3.2.

Table 1. Explanation of the attributes applied in Tables 2–4.

Attribute	Explanation
Management question	The public issue that is to be addressed
Main problem owners and stakeholders	Those responsible for or involved in the analysis
Assessment-management interaction	The nature of the relationship between management and assessment
Assessment question	The issue that is to be addressed and requires an answer
Measurements of risk	The types of exposure and effect measurements used to characterize the risks
Measurements of benefit	The types of exposure and effect measurements used to characterize the benefits
Answer	The kind of information produced to answer the question
Approach	The main characteristics of the way the assessment is executed

Table 2. Current general setting for benefit–risk analysis within different fields.

Attribute[a]	Food and Nutrition	Medicines	Food Microbiology	Environmental Health	Economics and Marketing–Finance	Consumer Perception
Management question	What is the optimal decision for public health, where and how can the largest net population health gains be realised, with respect to food-related questions, e.g. - recommendation of nutrients or foods - policy for fortification - food processing methods - introduction of novel foods	What is the optimal decision for public health, with respect to - drug safety - drug efficacy - drug safety monitoring and management - drug benefit–risk balance - eligible patient populations	What is the optimal decision for public health, with respect to microbial food safety and (to a lesser extent) microbiologically mediated health benefits?	What is the optimal decision for public health when focusing on environmentally mediated direct and indirect health impacts? Can be considered in the context of other issues such as - economic impacts - equity and social well-being impacts - impacts to the environment	What is the optimal utility that market participants derive from outcomes based on benefit–risk trade-offs such as production, costs, sales, or consumption of a food product? Other issues to be considered: - cognitive vs. affective decision making - risk attitudes (RA) and risk perceptions (RP) formation - drivers of RA and RP (e.g. trust, knowledge) - utilitarian vs. hedonic benefits/gains	What is the optimal decision from an acceptance perspective (as well as from a health perspective)? Who will benefit (identification)? How can target groups be reached (communication/marketing)? Food production (taste and health optimisation)
Main problem owners and stakeholders	Policy makers (decisions), scientists (assessment)	Policy makers (decisions), scientists (evaluation), pharmaceutical companies (assessment, evalua-	Policy makers (decisions), Scientists (assessment)	Policy makers, industry, citizens (decisions), scientists, industry, commerce, in some approach-	Producers, marketers, policy makers, consumers (decisions), financial analysts (assessment of technical feasibility), marketers	Consumers (decisions, ad hoc assessment), Risk managers, marketers (com-

		tion), agencies (evaluation, supervision), general practitioners (advice on patient level), patients (decisions)		esb,NGOs, citizens, in some approaches[b] anyone (assessment), industry, commerce, NGOs, citizens (evaluation)	(assessment of economic feasibility), industry managers and lobby representatives (managerial feasibility)	munication), Policy makers (decisions)
Assessment-management interaction	Separate (physically and intellectually), but becoming more interactive	Ranges from separate to intertwined. Also depends on the stage in the marketing process	Functionally separate approaches, increasing consultation and interaction between the two	Approaches[b] range from strictly separate to deeply intertwined	Approaches range from aggregate to disaggregate. They involve ad hoc self-assessment in decision situations by consumers. More systematic assessment, often by external assessors regarding policy decisions, marketing decisions, investment decisions	Ad hoc self-assessments by consumers in decision situations, communication of both scientific and marketing information to identified target groups

[a] Attributes are explained in Table 1 and adapted from the framework applied for characterizing approaches to benefit–risk analysis in the field of environmental health in Pohjola et al. (2011a).

[b] Approach refers to different approaches to making benefit–risk assessments within the field of environmental health, e.g. health impact assessment, REACH, open assessment, etc. (Pohjola et al., 2011a).

Table 3. General characteristics of integrated assessment of benefits and risks within different fields.

Attribute[a]	Food and Nutrition	Medicines	Food Microbiology	Environmental Health	Economics and Marketing–Finance	Consumer Perception
Assessment question	- What are the integrated health benefits and risks of (a change in) consumption of a food or food component in a particular population? - What is the current state of knowledge regarding a health issue?	- What is the pre-registration risk–benefit profile of a medicine? - What is the post-registration risk–benefit profile of a marketed medicine? - What is the cost-effectiveness of a health technology in a specific population?	What are the qualitative or quantitative microbiologically mediated health risks (and benefits) associated with food borne microorganisms and food consumption in particular populations?	What are the direct and indirect environmentally mediated health impacts of e.g. - chemicals or chemical products - policies - industrial activity - other activities - in principle anything Approaches vary significantly in terms of their inclusiveness/ exclusiveness	- What drives market participants' decision making process and hence their actual behaviour under risk? - What drives food producers'/ farmers' risk–benefits trade-offs, e.g. regarding the use of optimal level of pesticides? - What drives consumers' risk–benefit trade-offs, e.g. regarding acceptance of unfamiliar technologies?	- What are the characteristics of food items that influence consumers' perceptions of benefits and risks, attitudes and reactions? - What is/are the target population(s)?
Measurements of risk	Increased disease risk from food or food component	Adverse drug reactions, drug–drug interactions. misuse, non-compliance	Increased disease risk from food borne pathogens. Introduction of new and emerg-	Risk of compromised health due to something. Non-health risks caused by the same something	Cognitive and affective information processing regarding market participants risk attitudes and risk perceptions	Consumers' cognitive and affective information processing regarding perceived

			ing pathogens			risks measured by qualitative and quantitative techniques
Measurements of benefit	Reduced disease risk or improved health state from food or food component	Disease treated, disease progression stopped or slowed by medicines or lowering of risk factor, or increased benefit/cost ratio	Reduced risk from food borne pathogenic microorganisms. ‘‘True’’ benefit from beneficial microorganisms. Benefit of microorganisms as human food source	Expected health benefits due to something. Non-health benefits caused by the same something	Effective and efficient handling of risk-bearing activities in which market participants may be engaged at the different channels of the food supply chain	Consumers’ cognitive and affective information processing regarding perceived benefits such as liking, and feeling good about doing the right thing, measured by qualitative and quantitative techniques
Answer	- Quantified benefits and risks - Comparison with guidance level or risk threshold - Quantitative comparison, Inte-	- Quantified benefit and risk - Integrated measures (QALY, DALY, cost, mainly in HTA)	- Qualitative comparison of benefits and risk - Quantitative comparison using integrated measures	- Estimates of risks and benefits - Comparisons and/or aggregated measures. Mostly quantitative, but qualitative also possible. Approaches vary greatly	- Combination of qualitative and quantitative analyses of the dynamics of decision making process. - Comparison of actual vs. perceived behavioural outcomes	- Description of consumer segments - Strategies for communication

	grated measures (QALY[b], DALY[b])	- Qualitative judgment	(QALY, DALY)	in breadth of inclusion as well means of weighing and/or integration. - Mostly health risk(s) considered in the context of other factors: e.g. other risks, benefits. - Comparison of impacts of different policy options or scenarios	- Accounting for the influence of the unobserved heterogeneity on market participants' behaviour of the decision context characteristics and dynamics, and behavioural anomalies that may explain several patterns/paradoxes in economic behaviours	
Approach	Tiered approach. When needed to answer the question, and possible: quantification of benefits and risks and quantitative comparison. Software is available to support this	Highly standardized and regulated. - Qualitative assessment of benefit and risk - Delphi procedure - Modelling studies	Tiered approach has been advocated for analysing benefits and risks. - Qualitative assessment - Quantitative assessment	- Traditional: assessment is an exclusive expert process. - Regulatory: assessment requirements are determined by legislation - Novel: assessment is an inclusive social process - Academic: assessments aim for right answers and optimal solutions	- Positive approach (study on what is the real economic behaviour), using both qualitative and quantitative empirical approaches - Normative research approach (study on what ought to be the economic behaviour), using mainly quantitative analytical frameworks. - Triangulated research approaches, using a combination of qualitative and quantitative research approaches	Identification of relevant consumer segments, using a combination of qualitative and quantitative research approaches

[a] Attributes are explained in Table 1 and adapted from the framework applied for characterizing approaches to benefit–risk analysis in the field of environmental health in Pohjola et al. (2011a).

[b] Should include separate presentation for all benefits and risks and for population subgroups, and address uncertainties.

4.3.1 General commonalities and differences

The purpose of benefit–risk *management* is to arrive at the optimal decision, while accounting for all relevant issues. The purpose of benefit–risk *assessment* is to provide the science-based information on the integrated benefits and the risks to support in answering the benefit–risk management question, i.e. to contribute to evidence-based decision making. The focus of benefit–risk *analysis* in the different fields is

- *Food and Nutrition:* improving public health/preventing disease by better food and nutrition and generating knowledge for food improvement or innovation and general understanding.
- *Medicines:* curing, slowing or preventing disease by means of medication and monitoring benefit–risk profiles of marketed medicinal products with or without its impact on budget.
- *Food Microbiology:* preventing food borne disease caused by micro-organisms and generating knowledge for microbiological product innovation.
- *Environmental Health:* preventing damage to health mediated through the environment, possibly also reducing impact on economy, society and environment.
- *Economics and Marketing–Finance:* optimising public economic policies, corporate investment and marketing strategies.
- *Consumer Perception:* stimulating good food choice by using insights in consumers' perceptions, attitudes and behaviour relating to a particular case and by increasing acceptance through information, increasing familiarity, reducing uncertainty, and product optimization.

The challenges of aggregating and weighing benefits and risks are shared by the different fields. Two issues coming up in this connection are the inclusion of multiple benefits and risks with different scopes, and the explicit inclusion of subjective information. Among the fields that are considered, assessments in Food and Nutrition, Food Microbiology, Medicines and Environmental Health focus predominantly at health/disease, mostly physical health/disease (though several approaches in Environmental Health are open to also include other domains). Quantitative weighing of benefits and risks via DALYs or QALYs has been performed in Food and Nutrition, Food Microbiology, Environmental Health and in post-marketing modelling studies for Medicines. Mostly this is done within strict and relatively narrow bounds, e.g. focusing on the health effects of food compounds. In Economics and Marketing–Finance as well as Consumer Perception, health is not the centre of attention. In the latter two, human perception and behaviour is an important topic of investigation, whereas the former four strive for more 'objective' health information. However, also there, the influence of perception

and behaviour is acknowledged, at least to some degree, e.g. in the form of the placebo effect and compliance to prescriptions or advice. Qualitative comparison and use of expert judgment are part of all fields, but in differing degrees. For example, expert opinions/judgments in different phases have an important role in the progress of medicine benefit–risk analysis along the early stages of drug development. In Food and Nutrition, (expert) value statements are explicitly named only in comparison or combination of benefits and risks (e.g. qualitative comparison, and disability weights). Non-expert value judgments are increasingly taken into account particularly in Environmental Health.

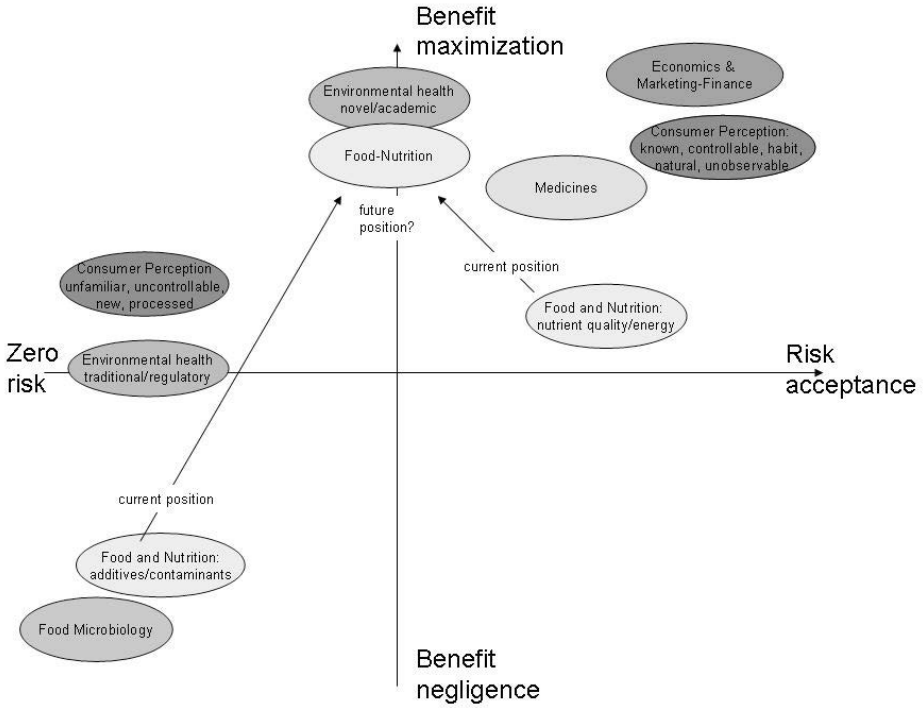

Figure 2. Acceptance of risk and valuation of benefit within the different fields. Location of each node represents a stereotypical approach to benefit–risk analysis within a field. Fields with great variation regarding acceptance of risks and valuation of benefits are described as two stereotypical approaches representing two extremes within the field.

Another notable issue relates to differences in the valuation of benefits and the acceptability of risks, both by consumers and managers. In Food and Nutrition and Food Microbiology, chemical, biochemical and microbiological risks are not accepted, i.e. food safety issues are minimised to such a low level that risks are virtually absent (see also Section 2.7). Especially Food Microbiology is illustrative of

the important role of 'risk' in public health. In contrast, in many approaches to Environmental Health and in Medicines, some risk is accepted for a greater benefit. In Medicines, risk, in the form of adverse drug reactions, is accepted for the greater benefit of recovery or of alleviation of symptoms. Also, by observing the common everyday practices, some degree of risk coming from the environment in the form of traffic, energy production, radiation, disinfection, etc. can be considered as accepted in order to meet the needs of modern society. However, the perceptions of such risks may vary significantly among policy makers and the public, and the differing perceptions may not always be backed up with well-reasoned knowledge. Moreover, in Economics and Marketing–Finance and Consumer Perception, (high) risks can be accepted if the expected benefits are higher and at least some degree of risk is accepted as necessary to bring about benefits in general. Some differences with respect to the degree in which risk is accepted and benefit is valued are illustrated in Fig. 2. With respect to Food and Nutrition, there appears to be a discrepancy: risks brought about by unfavourable nutritional quality and/or quantity of the diet (i.e. unbalanced intake of nutrients and foods resulting in deficiencies and/or chronic disease), are more readily accepted (as voluntary, right to choose) both by consumers and policy makers.

The field of Medicines stands out by being aimed at a single product or technology, which is tested within a controlled environment (pre-registration); the situation in 'real life' (e.g. interference from other medication or from food, low compliance) can be observed only after market approval. In all phases of the life of a medicine, the benefit–risk balance can be different. The benefit–risk balance can also change during the life of an individual. Within Medicines, as well as Consumer Perception, there is a stronger individual basis than in the other areas.

Notable in Environmental Health is the development towards more interaction between all those who are in some way related to the process (assessors, managers, industry, NGO's, and citizens) and to let actual problems drive analyses. In Food and Nutrition, increasing engagement between assessors and managers is recognized to be valuable, but presently there is virtually no role for stakeholders in assessment.

Table 4. Illustration of the commonalities and differences between fields by means of a conceptual case example – replacing animal protein sources with more environmentally sustainable protein sources.*

Attribute[a]	Food and Nutrition	Medicines	Food Microbiology	Environmental Health	Economics and Marketing–Finance	Consumer Perception
Management question	- What is the net public health consequence of promoting and facilitating the consumption of sustainable protein sources? - Do certain subgroups require special attention?	- What impact on medical treatment does promoting and facilitating the consumption of sustainable protein sources have? - Do certain subgroups require special attention?	- What is the net public health consequence of promoting and facilitating the consumption of sustainable protein sources? - Do certain subgroups require special attention?	- What is the optimal way of reducing the environmental burden of animal protein containing food item production, in combination with optimal nutrition? - Do certain subgroups require special attention	- How can an effective and efficient economic decision be made regarding the shift of food production focusing on plant protein methods? - How can such food items be marketed effectively?	- How can food industry managers and policy makers assess, predict, and explain the impact of consumers benefit–risk perception on implementation and success of a shift in focus from animal to plant protein?
Assessment question	What are the weighted effects on nutrient adequacy and population health when changing to: - Higher dietary contribution of old and new plant foods and lower dietary contribu-	- What impact on medical treatment does promoting and facilitating the consumption of sustainable protein sources have?	What is/are - the weighted effects when substituting animal proteins with alternative protein sources, with respect to - microbiological health	What is the health impact of changing animal protein to other protein sources? Both direct (via food) and indirect (via	- What drives consumers' willingness-to-pay for sustainable food products? - Evaluation of knowledge, experience, attitudes and	In what way may a shift in focus from animal to plant protein be acceptable and for whom? How is the topic

	tion of meat and dairy. - ‘‘new’’ dietary source, e.g. insects; In differing degrees (scenarios)?Special attention for those with special needs, such as children	- Do certain subgroups require special attention?	risks/benefits of alternative protein sources? - increased/reduced exposure to foodborne pathogens? - food safety of protein from microorganisms (single cell protein) for human consumption? - risk of new and emerging pathogens from new food production processes and/or	e.g. environment and societal change) health impacts are considered. Ecological and other impacts should be known for overall conclusions, but they may be assessed elsewhere. Options may also be assessed according to their environmental (ecological) impacts in order to weigh and compare their overall net benefits	perceptions concerning advantages/benefits and disadvantages/risks, and socioeconomic and demographic information	understood? What are preferable options, and why are these options preferred?
Measurements of risk	- Nutritional status, e.g. reduced iron, vitamin B12, calcium; - Morbidity and mortality, e.g. increase in allergy; e.g. soy, lupin, other new protein; insect poisons	Morbidity and mortality; e.g. increase in allergy, interaction between phytonutrients and medication	- Morbidity, and mortality. - Increased exposure to pathogens during storage of plant foods/ insects e.g. mycotoxins, grain molds, spoilage	Health impacts of diet change, actual vs anticipated diet changes, pollutants in diet, possible health impacts of ecological changes	Consumers’ rejection, perceived unnaturalness, alternative choices, buying behaviour, measured by qualitative and quantitative tech-	Consumers’ rejection, perceived unnaturalness, alternative choices, buying behaviour, measured

			organisms, foodborne pathogens. - Increased exposure or introduction of new pathogens		niques	by qualitative and quantitative techniques
Measurements of benefit	- Nutritional status, e.g. reduced saturated fatty acids, increased vitamin C, folate, phytonutrients - Morbidity and mortality, e.g. reduced obesity, CVD	Morbidity and mortality, e.g. reduced obesity, reduced CVD; influence of reduced protein load, indirect influence on antibiotics resistance	- Reduced morbidity and mortality due to decreased exposure to food borne pathogens - Microorganisms as an alternative source of protein/food	- Health impacts of diet change. - Also non-health benefits such as use of land, water, energy; emission of greenhouse gasses; biodiversity	Ethical, environmental and health matters measured by qualitative and quantitative techniques	Ethical, environmental and health matters measured by qualitative and quantitative techniques
Answer	- Incidence of nutritional deficiencies and improved nutritional status - (net) incidence of CVD, cancer - DALY[b], QALY[b]	- Predicted preventions of CVD and other benefits, Number needed to treat to achieve a single beneficial outcome - Predicted risks. Number needed to harm to achieve a single adverse health outcome. - Weighting of bene-	- Incidence and morbidity of food borne disease e.g. using DALY. - Health benefits of increased access to alternative source of protein (‘‘single cell proteins’’, SCP)	- Incidences of health impacts, possibly summarised as e.g. DALYs. - Ecological and other impacts presented and discussed. Comparison of health and other impacts is done possibly qualitatively or	- Predictions of consumer reactions - Description of agribusinesses’ risk–benefit trade-offs with respect to their corporate socially responsible behaviour: sacrificing monetary benefits with the aim to promote/produce socially, economically, and environmen-	- Predictions of impacts of benefit–risk perceptions on consumer behaviour. - Identification of drivers for acceptance and how they should be presented

		fits and risks and assessment of needs of risk management and/or risk minimization		quantitatively, using e.g. monetarisation	tally sustainable and healthy products/services that benefit society as a whole	
Approach	Tiered; - identification of benefits and risks of change to more plant foods and/or insects - exposure scenarios: substitute meat and dairy based meals in actual food consumption data - comparison of nutrient intakes with guidance values - quantification of benefits and risks, e.g. using literature for dose–response relations on animal and plant protein - integration of benefits and risks into common measure	Tiered approach.Identification of benefits, risks and risk groups. Assessment of need for risk management and/or risk minimization	- Identification of microbiological risks of alternative protein sources e.g. insects, plants, SCP. - Comparison with microbiological risk of conventional protein sources e.g. meat, dairy products. - Integration of risks and benefits	Traditional and regulatory approaches do not suit well in this complex case. Instead, novel, inclusive approaches could be used. This would mean e.g. an open participatory process using quantitative models that are developed, shared, and discussed in the Internet	- Normative Approach: Maximization of farmers' benefits e.g. when using biological pest controls, hedging strategies, insurance products, based on axioms and norms; - Positive Approach: Predict and explain consumer preference structures for intrinsic versus extrinsic quality cues of sustainable food products	- Increase availability and information about best product alternatives - Increase knowledge of best choices for different target groups - Enhance visibility and knowledge of benefits - Reduce impact of perceived risk through information

[a] Attributes explained in Table 1 Adapted from the framework for characterizing approaches to benefit–risk analysis in environmental health in Pohjola et al. (2011a).
[b] Include separate presentation for all benefits and risks and for population subgroups, and address uncertainties.
* This case example is meant to illustrate more tangibly what is described in Tables 2 and 3; the topic was considered suitable because it is inherently multidisciplinary and currently of global interest.

4.3.2 Illustrative case example

The case example presented here (Table 4) to illustrate Section 3.1 from a practical viewpoint deals with dietary protein sources, in particular the effect of replacing less sustainable sources with more sustainable sources. Protein and the amino acids that build protein are important, as they form the body's system of structural and functional elements that exchange nitrogen with the environment and have many other functions (Millward et al., 2008 and WHO, 2007). Converting plant protein sources into animal protein sources is relatively inefficient and negatively affects the ecosystem when applied on a large scale (FAO, 2006). With the increasing world population and the net increased affluence, the consumption of animal protein is increasing. Without policy action, the ecosystem is overly pressured and food security is endangered. Alternative protein sources, with less impact on the ecosystem, are known. They include plant sources, algae, insects and cultured meat. The aim of the benefit–risk assessment is to support well-informed policy making with respect to a protein transition by providing the best available science.

From Table 4 it can be seen that the fields of Food and Nutrition, Medicines and Food Microbiology have a rather tight focus, whereas the fields of Environmental Health, Economics and Marketing–Finance and Consumer Perception apply broader scopes in their assessments. Especially in the latter two the effect on health/disease is only one of many considerations in the broader implications that a shift in focus from animal to plant protein has. Table 4 also shows the different types of measurements and approaches used to answer the assessment question.

Furthermore, the case study shows that a successful protein transition, even when a net benefit is supported in terms of health and sustainability, co-depends on consumer perceptions and actions in terms of its actual realization. Sustainability and health are, for a large segment of consumers, less important drivers of food choice than e.g. the liking of animal protein rich products. For alternatives to be accepted, some criteria will have to be considered, among others: taste, expense, use of technology/naturalness, and trust. Marketing and communication strategies will be essential in creating acceptance. However, if long-term net benefit is to be achieved, there is also an essential role for the authorities in actively 'making the healthy and sustainable choice the easy choice' and implementing necessary regulations towards food industry.

From the regulatory point of view, the eventual choice to shift to dietary protein sources that are more sustainable than the current animal products should not constitute a further burden for the legislator. In case new products are being introduced, the general framework to regulate risks connected to these products remains the General Food Law and in particular the Novel Foods Regulation (EC 258/97).

4.4 Opportunities for Food and Nutrition benefit-risk analysis

In this section we discuss how benefit–risk analysis for food and nutrition may improve from looking at other research areas. A number of issues that require further attention in Food and Nutrition have been identified (Tijhuis et al., 2011). To name some key issues:

Paradigm. In the contemporary benefit–risk analysis paradigm (Fig. 1), assessment and management are marked entities. Communication and some degree of interaction, though acknowledged, may not currently receive the attention they deserve, both within and between the analysis components. In addition, management of public health in Food and Nutrition is currently still very much focused on risk and aimed at identifying numbers below which intake is presumed to be safe.

Data. The arms of the benefit–risk assessment paradigm are not symmetric; they currently serve different goals (i.e. to demonstrate presence of benefit and absence of risk), they are built on different methodologies, they are rooted in different research traditions, etc. For a benefit–risk analysis in Food and Nutrition it is essential that quantitative data on beneficial and adverse effects are available, covering the relevant exposure and target population. For many foods and ingredients this is currently not available. A fundamental difficulty in this is the translation of dose and effect found in animal studies to the human situation. Apart from this species issue, lack of dose–response data is also a problem for human studies. There are several possible reasons for this, not always easily solvable: performance of studies in humans is expensive, is ethically not acceptable or scientists are not used to quantifying or presenting dose–response information; also, in benefit assessment the legal situation is new.

Context and implementation. Besides issues relating to assessment and comparison of benefits and risks, there is currently often no explicit consideration of which benefits and risks should be considered in different contexts and why; and whether only health risks and benefits induced by foods and food ingredients are sufficient in light of the practical uses of the benefit–risk analysis results. With respect to outcomes in the form of advice, there is a discrepancy between results from assessment of benefits and risks in the form of advice, and consumers' behaviour. Input of the public and other more specified stakeholders into assessment and management, to drive the analysis or to find solutions, is currently not common.

Below, these issues are addressed further in the form of concepts and practices from other fields that may be incorporated (more) in Food and Nutrition benefit–risk analysis.

4.4.1 Paradigm

4.4.1.1 Increased engagement and communication between assessors, managers, and stakeholders

Thus far, benefit–risk analysis in Food and Nutrition has been building on (the clearly demarcated) assessment and management, and virtually no role has been provided for stakeholders in these processes. However, the experiences from other fields indicate that more intimate interaction between assessors, managers, and stakeholders is essential for effective implementation of existing and available knowledge. This would take form in assessors, managers, and stakeholders in the field of Food and Nutrition each having their specific roles and responsibilities while engaging in the shared process of developing and applying knowledge (Fig. 3). Increased engagement can enhance e.g. clarity of the relevance of assessment questions and applicability of assessment results as well as acceptance of the outcomes of their practical implementation.

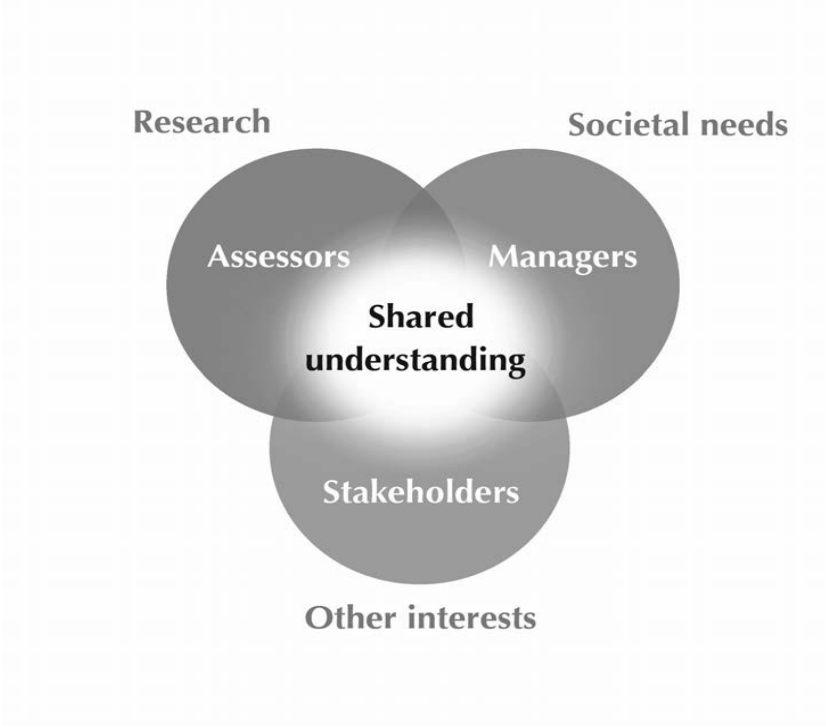

Figure 3. A new framework for benefit–risk analysis emphasizing increased communication and engagement. Creation of shared understanding based on both science and values is at the core of the joint knowledge process. Communication is essential during the whole process of benefit–risk analysis. Stakeholders are explicitly acknowledged as participants in the process.

Communication is (increasingly more) important between all those involved in the analysis: next to a role for professional communication specialists to address the stakeholders/general public, the assessors and managers could benefit from increased communicational skills between and amongst them, to result in a shared understanding of science and values (Fig. 3). Standardized forms, formats, practices, and procedures can be helpful in facilitating communication e.g. by allowing participants in the analysis to focus on the content instead of the format or by making the general public more familiar with risk and benefit information. However, the standardized formats and practices should not be made too strict and coercive, yet be flexible enough so that they can adapt to changing needs and contexts. For example, the information structure of Opasnet, a web-workspace for conducting open assessments, provides a universal information structure that is applicable for describing any kinds of phenomena, but allows quite free formatting of the actual substance of the descriptions (Pohjola et al., 2011b). Another example is the web-based QALIBRA software for quantitative benefit–risk assessment in foods. The software is web-based and free to users after completing a short online training session (www.qalibra.eu). It provides a consistent conceptual framework to help think about, organise and execute benefit–risk assessment, and optional sharing and discussion of assessments and data with other users.

4.4.1.2 More pragmatic problem-oriented framing of assessment

One of the aspects that can be enhanced by increased engagement, as also mentioned above, is framing of assessments and formulation of assessment questions to better serve the practical needs of those who (are intended to) use the assessment results in practice. Although purely curiosity-driven question setting is defendable in traditional science, assessments may better be considered as processes of applying scientific means and knowledge for practical problem solving, and thus adopting a demand-driven pragmatic approach. In order to achieve this, incorporation of decision makers as well as stakeholders, e.g. consumers and industry, in analysis is necessary.

Along this line, in most cases food products that consumers actually ingest (whole foods) may be more relevant objects of benefit–risk than mere isolated food ingredients or substances in food. Also, in addition to looking at only the health risks or benefits of the food itself, the rest of the food pattern should receive some attention to be practically useful.

4.4.1.3 Accepting some risk: inevitable interlinkage of risk and benefit

Risk is omnipresent, but it should be realised that so is benefit. Risk and benefit go together. Policy aimed at the combination of minimizing risk and maximizing benefit may result in a net higher benefit for public health than policy aimed at minimizing risk only (van Kreijl et al., 2006). This approach implies accepting some level of risk. Or, from a positive perspective, it means acceptance of taking

benefit into explicit consideration. This will not only result in more informed public health decisions, but also create more public support and understanding of the broader picture within which decisions are made. Where the optimum for health lies needs to be assessed on a case by case basis, addressing also the needs and context of each specific case (see Section 4.3).

4.4.1.4 Pre- and post-marketing analysis of benefits and risk of food products

Based on the experiences from the medical area, both pre- and post-market analyses could be required for certain food products. A pre-market assessment may be conducted by the producer of relevant foods or food ingredients (and evaluated by independent authorities), prior to market introduction, to address benefits and risks according to the current knowledge level. A post-market analysis (also termed 'postlaunch monitoring' (de Jong et al., 2007) and 'post-market monitoring' (Hepburn et al., 2008)) would engage all stakeholders, in particular authorities, with inputs from consumer organisations, science and industry. Post-market analyses may be triggered whenever new important evidence is gained, thus resulting in a follow-up over years. (Passive) surveillance systems can form the first step in identifying signals of potentially unknown risks. In addition, surveillance systems can also follow up on beneficial physiological effects of food or food ingredients (de Jong et al., 2007) and can be used for evaluation purposes: did a benefit–risk advice or decision have effect? Such post-market effectiveness monitoring may form an elegant and desirable addition to the health claims area (de Jong et al., 2007 and Hepburn et al., 2008). This post market effectiveness monitoring could be part of a dynamic and pro-active management plan where there is feedback between public health efficacy, management and manufacturers.

4.4.2 Data

4.4.2.1 Explicit communication of the assessment purpose, input and output

If benefit–risk analysis intends to achieve its goals of improving public health through the realized net benefits of consuming food products, it needs to produce explicit messages of their benefits and risks as well as the factors that influence them. There is ongoing discussion regarding the common currencies being developed and applied for aggregating and communicating multifaceted health and other outcomes (Tijhuis et al., 2011). One area of research that is still open is how to better take account of above average health states within the aggregated measures, e.g. quality weights. Also, the long-accepted definition of health (WHO, 1948) is now increasingly being debated to include the ability to adapt (Anonymous, 2009 and Huber et al., 2011).

Often it is advisable, if possible, to use more than one outcome measure, for example DALY and cost effectiveness. This will also show the broader perspective that surrounds each case, and may prevent or lower a false sense of security that quantification of complex issues in one measure may give. Finding optimal (combinations of) aggregated measures is important, however, it may be even more important to consider how to best explicate the essential aspects of the information produced in the analysis in different situations and contexts.

It needs to be realized that all models are inherently false if the goal is to 100% reflect reality; they can be useful, however, when used and interpreted in the right way. Some input into the models is surrounded by more uncertainty than other. This can be at least evaluated by sensitivity analyses or value of information analysis (Saltelli and Annoni, 2010 and Tuomisto et al., 2004). The uncertainties can be made explicit. Some uncertainties may not be very important for the outcome. Uncertainty is more important for the parameters that drive the outcome, or in other words: that form the basis for the ultimate decision. It also needs to be realized that different expertises are involved and required in creating the output, such as mathematicians, nutritionists, toxicologists, medical doctors, etc. Increased interaction between disciplines and domains will optimize the modelling, the input the models require and their interpretation.

4.4.2.2 More human (dose-response) data and more efficient use of human data

Human data are more valuable than animal data for assessing both benefits and risks, as there is no need to extrapolate/translate dose, effects and physiological differences. Human data, however, are also less available: they are often more expensive and more difficult (sometimes impossible) to obtain than animal data. On two accounts, however, benefit–risk analysis could benefit relatively easily from data that already exists or is conveniently available.

Firstly, researchers often can present more quantitative data in their publications. For example, when presenting a group risk covering a range of exposures (e.g. a quartile), information on exposure and its variation can be included.

Secondly, human data can also be obtained in the post-market phase for products for human use (see also Section 4.1). Obtaining data in the post-market phase has advantages. It allows real-life information to be incorporated into the assessment, such as compliance, compensation behaviour and real-life effect size. Also, it benefits from high numbers compared to pre-market data. Experience in Medicines has also shown limitations of post-marketing surveillance, however, such as reporting bias and selection bias. In the social sciences, there is a new trend to actively let consumers participate in data generation, in the form of creating panels to obtain research data. It may be informative to follow this development.

As the availability of applicable data is hampering the use of benefit–risk analysis in Food and Nutrition, it may be relevant to establish a database on benefit

and risk data and research to promote and coordinate its further development. However, selective reporting should be prevented and thus a system of registration before execution of the assessment (as required in the clinical trial database) would have to be considered.

4.4.2.3 Distinguishing physiologically different populations within the customer population

As in Medicines, where the dynamics of the benefit–risk profile throughout the life cycle is recognized, some researchers in Food and Nutrition are also developing towards a more inter- and intra-individualised approach. For example, in the window of benefit approach, inter- and intra-individual variation is explicitly taken into account (Tijhuis et al., 2011). One disadvantage of population health measures is that its effects are not always visible for individuals (prevention paradox). This could be overcome by a more individualised approach, which may have an additional psychological advantage of increased compliance. Difficulty is that the more a subgroup approaches the individual (i.e., $n = 1$), the more difficult it becomes to show the effectiveness of a measure, using traditional statistical methods.

In some cases, benefits and risks apply to different population segments. For example, by fortifying a staple food with folic acid, the children of women in the 1st trimester of pregnancy (the target group) will benefit from the risk reduction of neural tube defects, but other groups may also be affected (and not always favorably) (Hoekstra et al., 2008). Both an opportunity and a challenge lie in specifically targeting the population groups that benefit most from the food product.

4.4.2.4 Explicit consideration of value judgments in assessment

Value judgments, based e.g. on opinions, interpretations and perceptions, have an important influence on decision making and behaviour e.g. by food safety managers, food producers, marketers and consumers. Therefore, identification and understanding of the values that drive e.g. decisions of managers and behaviour of consumers need to be explicitly taken into account in systematic assessment alongside scientific facts. This is essential for the assessments to serve the practical needs of decision making. This is not to say that subjective value judgment could replace systematically obtained research-based data and information in assessment (though assumptions, choices and interpretations are actually already an integral part of obtaining the objective quantitative data, and the use of assessment results is subsequently guided by subjective opinions in policy making). But it can complement scientific knowledge by making it more coherent, relevant, and applicable. For example, in the context of the case study (Table 4), a good benefit–risk assessment must systematically consider the differing value judgments regarding e.g. the importance of environmental protection, biodiversity, human health, personal preferences about different foods, and cultural traditions that relate to the

issue of replacing animal protein with protein from other sources in the diet. Failing to do so would likely result in assessment outputs that are of little value in practical decision making. Value judgments are thus relevant and valuable input to the science-based assessments as parts of effective benefit–risk analysis.

4.4.3 Context

4.4.3.1 Integration of multiple benefits and risks from multiple domains

Integration of multiple benefits and risks from multiple domains is an essential means for achieving enhanced applicability of assessment results. Most often, a reductionist approach to benefit–risk analysis, focusing on narrowly bound problems, is not adequate for serving practical real needs that do not obey disciplinary boundaries. Therefore, assessment and management should allow for broad integration of both benefits and risks from multiple domains, according to needs. By taking a holistic view of benefit–risk analysis at an early stage, decisions on which scientific areas should be included in the benefit–risk analysis will focus the assessments. Not all other factors can be integrated into a common measure and aspects of health may remain in the focus of the process. However, they can be placed within a reasonable context, or bigger picture, provided by the other aspects to be considered. For example, benefit–risk assessment on fish consumption can show that benefits prevail over risks, but consideration of sustainability issues or consumer preferences may steer the analysis towards inclusion of farmed fish raised on sustainable feed or alternative non-fish sources.

The importance of integration and contextualization is also illustrated by the case study in Section 3.2. In the field of Food and Nutrition, dealing mostly with health, it can be quite relevant to consider also consumer perception and behaviour, ethics, environment, industry interests, etc. It should be noted that the relevance of context is already part of the principles of Food Law as "other legitimate factors" http://ec.europa.eu/food/food/foodlaw/principles/index_en.htm, making room for consideration also of benefits. However, good documenting of the factors and practices to incorporate them are still lacking.

4.4.3.2 Explicit recognition of the impact of consumer beliefs, opinions, views, perceptions, and attitudes on behaviour

Consumers are an essential stakeholder group regarding food and nutrition. In the process of benefit–risk analysis of Food and Nutrition, it needs to be taken into account in what direction and to what extent food and nutrition aspects may influence consumer behaviour. This includes studies on human decision making, on behaviour of market segments and on benefit–risk tradeoffs in these groups. Alongside benefit–risk assessment on a physiological level, consumer characteristics such as perceptions or values can be measured in order to correct for differences between consumers or target groups in how they behave with respect to the

problem. For example, in the case of monosodium glutamate (MSG), concerns by consumers and consumer groups about MSG consumption (Freeman, 2006 and Williams and Woessner, 2009), influenced by commonly available non-scientific information, override scientific knowledge (Singh, 2011) to the extent that food industry has begun reducing or removing MSG from their products (http://www.toro.no/index.php?mapping=344; http://www.unilever.com.vn/brands/foodbrands/knorr/index.aspx). Whether or not the consumer behaviour in this case can be backed up by Food and Nutrition research results, recognition of its existence and understanding of its basis and impacts is important in assessment as well as decision making by food safety managers, consumers, producers, marketers and other stakeholders. Consumer studies can qualitatively and quantitatively assess consumers' compliance with advice and why benefits and risks are acted upon in different ways, both cognitively and unconsciously. The data thus provided can be used as feedback in the benefit–risk analysis, to overcome the difficulties associated with the traditional science-decision-communication approach. Just as *a hazard is not a risk until there is exposure*, *a food is not healthy until it's eaten*. An important contribution of consumer research to benefit–risk analysis in food and nutrition is particularly related to how to implement measures to achieve the best effects. Identification of relevant target groups and formulating communication strategies that work, are major aspects that could benefit the goals of benefit–risk analysis in food and nutrition. From a management perspective, taking consumers' view-points into account is relevant in the implementation phase when the aim of the benefit–risk analysis is to provide advice, directions or action plans. Specifically: in case consumer's viewpoints are not in conformity with current scientific insights, risk managers should strive for means of an appropriate consumer information and education.

4.4.3.3 Segmenting market participants behaviour

Differentiation of sub-groups can take place in terms of physiological characteristics, as addressed before, but also in terms of their cultural, cognitive and behavioural characteristics.

The segmentation criteria for grouping the behaviour of market participants depending on whether the food offering is aiming to reach the end-user (e.g. consumer) or another business are different. The more typical criteria for segmenting prospects at a corporate business level usually entail the industry type, the size of the corporation, e.g. in terms of revenues or employees, time-related factors, access to competitive offerings, and the need for customization, among others. The criteria that are often used to group the behaviour of individual market participants (e.g. consumers) may include demographics, cultural-, economic-, religion-related, social-status, accessibility to food offerings, and avocation-related interests, among others. Yet, once the identification of specific segments has been achieved, there is a series of subtle influences on the buying behaviour such as the beliefs,

views, concerns, attitudes, perceptions, information needs, brand awareness, and commitment to specific values and business operations of market participants. That is, a series of unobservable (e.g. latent) factors may influence the purchasing behaviour and/or decisions of different segments of food producers, wholesalers, retailers, managers, and consumers. Moreover, the differing preferences of market participants that are attributable to their heterogeneous desires and varying wants may be driven by several unobservable factors often referred in the academic literature as *behavioural anomalies*, such as humans' *personality traits* (e.g. need for cognition, ambiguity, need for certainty, risk-aversion, loss-aversion, myopia, overconfidence) or *heuristics* (i.e., rules of thumb) that lead people to find things out for themselves, usually by trial and error.

The consideration of a heterogeneous food market as a number of smaller homogenous food markets, highlights the diversity in market participants attitudes, perceptions and preferences and their driving forces. This view reflects the market-orientation of the food industry. Such an orientation is essential if segmentation of market participants' behaviour in the agribusiness and food markets may be used as one of building blocks of effective food and nutrition policy-making and marketing-management planning.

4.5 Conclusions

The BEPRARIBEAN project has looked into benefit–risk analysis within six different, but somewhat interrelated, scientific fields. The main findings of the project are described in the previous sections, particularly in the form of the key messages in the section 'Opportunities for food and nutrition benefit–risk analysis'.

While looking into benefit–risk analysis from different scientific perspectives we realized that different fields are facing similar problems. All fields struggle with the challenges of aggregation, weighing, and comparison of multiple benefits and risks. This stresses the need for an interdisciplinary approach and mutual learning. We identified some differences with respect to the degree in which risk is accepted (Fig. 2). Consumer and marketing sciences could give useful insight in the psychological mechanisms behind this and give advice in how to target specific groups or how to put risk perceptions into perspective. Stakeholder participation is increasingly valued as important, thereby granting it a position in the benefit–risk analysis-triad next to assessment and management (Fig. 3). Increasing interaction between the three is essential for making policy decisions addressing real public health issues, using the best available scientific data on diet-health relations. We want to emphasize again that interaction can and should take place without each losing its own responsibilities, roles and interests. The tiered approach and transparency in assessment proposed for the Food and Nutrition field (Tijhuis et al., 2011) is one way to support this.

Altogether, the key messages suggest that benefit–risk analysis in Food and Nutrition should be considered as a joint process where the experts, professional decision makers, as well as consumers and other stakeholders come together to create shared understanding (Fig. 3). In this, different domains of benefits and risks are explicitly considered, as are their greatest net benefits (taking subgroups into account). Focusing on food safety and not addressing food benefits is a risk management decision just as much as accepting some risk in order to achieve more benefits. Either way, both policy makers and consumers should let go of the artificial line between risk coming from chemicals and micro-organisms in the diet (captured in regulation for consumer protection) and risk coming from a bad quality and quantity of the diet (captured in dietary advice for consumer protection). In the end, for both situations, the result is disease and burden to society; as the former is currently relatively well taken care of, the latter currently has much larger impact on public health and resources (Tijhuis et al., 2011, UN, 2011 and van Kreijl et al., 2006).

The identification of several key messages that describe how Food and Nutrition benefit–risk analysis, as well as benefit–risk analysis in general, should be practiced is not an end in itself. Rather, it gives guidance for developing and implementing such practices in order to make this vision a reality. This work will require further development of the systems and tools started in previous projects and adoption of new methods, tools, and data sources to support the improved benefit–risk analysis practices. Contributions are required from all relevant actors in the analysis in order to promote the realization of improved benefit–risk analysis. Regulatory frameworks may need to be adjusted to allow and support the new contexts and practices of analysis. Managers may need to adopt a more active role as participants in knowledge creation and allow for broader involvement of other participants in the analysis. Assessors also need to adapt their attitudes towards considering themselves in the role of facilitating the development of shared understanding, not only among experts, but also among managers and stakeholders.

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5 Openness in participation, assessment, and policy making upon issues of environment and environmental health: a review of literature and recent project results

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Abstract

Issues of environment and environmental health involve multiple interests regarding e.g. political, societal, economical, and public concerns represented by different kinds of organizations and individuals. Not surprisingly, stakeholder and public participation has become a major issue in environmental and environmental health policy and assessment. The need for participation has been discussed and reasoned by many, including environmental legislators around the world. In principle, participation is generally considered as desirable and the focus of most scholars and practitioners is on carrying out participation, and making participation more effective. In practice also doubts regarding the effectiveness and importance of participation exist among policy makers, assessors, and public, leading even to undermining participatory practices in policy making and assessment. There are many possible purposes for participation, and different possible models of interaction between assessment and policy. A solid conceptual understanding of the interrelations between participation, assessment, and policy making is necessary in order to design and implement effective participatory practices. In this paper we ask, do current common conceptions of assessment, policy making and participation provide a sufficient framework for achieving effective participation? This question is addresses by reviewing the range of approaches to participation in assessment and policy making upon issues of environment and environmental health and some related insights from recent research projects, INTARESE and BENERIS. Openness, considered e.g. in terms of a) scope of participation, b) access to information, c) scope of contribution, d) timing of openness, and e) impact of contribution, provides a new perspective to the relationships between participation, assessment and policy making. Participation, assessment, and policy making form an inherently intertwined complex with interrelated objectives and outcomes. Based on experiences from implementing openness, we suggest complete openness as the new default, deviation from which should be explicitly argued, in assessment and policy making upon issues of environment and environmental health. Openness does not undermine the existing participatory models and techniques, but provides conceptual means for their more effective application, and opens up avenues for developing new kinds of effective participatory practices that aim for societal development through collaborative creation of knowledge.

5.1 Introduction

Stakeholder and public participation is undoubtedly one of the most central topics in contemporary discourse regarding environmental and environmental health policy and assessment. Environmental issues typically involve multiple interests regarding e.g. political, societal, economical, and public concerns and particularly in cases where they are known or perceived to relate either directly or indirectly to human health and well-being, the concerns often also become very personal. In such a setting of physical, chemical, biological, and societal complexity, it is widely accepted as important to include plural perspectives, particularly from the "affected parties", in the processes of policy making as well as the processes of producing information to guide and support policy making. As the idea of participation mainly builds on the theories and practices of democracy [1,2], this is particularly the case in the so called Western democracies, but increasingly also in countries not generally considered as democratic by their constitution, such as the People's Republic of China [3,4].

In addition to being founded on the principles of democracy, public participation is addressed in several intergovernmental agreements, e.g. the Principle 10 of the Rio Declaration [5], and the Aarhus Convention on Access to Information, Public Participation in Decision- Making and Access to Justice in Environmental Matters [6]. Also several laws on different levels of governance around the world, e.g. the EU Strategic Environmental Assessment Directive (2001/42/EC), the EU Public Participation Directive (2003/35/EC), The Law of the People's Republic of China on Environmental Impact Assessment [4], and the Finnish Environmental Impact Assessment (EIA) Act (468/94) and corresponding EIA Decree (713/2006), explicitly consider public participation and describe legal frameworks for its application. The legal requirements provide, however, only one perspective to participation. Importance of participation is also argued for example based on ethical, political, pragmatic, and epistemological [7] as well as substantive, normative, and instrumental reasons [1], and participation is seen to have the potential to deliver e.g. substantive, procedural, and contextual effects [8,9]. Participation in assessment and policy making upon issues of environment and environmental health has become commonplace.

This paper explores the following question: do current common conceptions of assessment, policy making and participation provide a sufficient framework for achieving effective participation? By effectiveness we mean influence on the outcomes, i.e. changes in values, attitudes, and behaviour in the society (cf. [10]), of the processes that the participation relates to, e.g. participatory assessments or policy making.

Policy making is here understood as decision making upon issues of societal importance and assessments are considered as systematic science-based endeav-

ours of producing information to support policy making. Public participation and stakeholder involvement are here seen as instances of the same issue which is mostly referred to as participation, meaning contributions from the parties, organizations or individuals that do not have formal roles as decision makers or experts in the assessment or policy processes in question.

These broad definitions allow inclusion of various types of participation, assessment, and policy making, practiced in and designed for several societal, institutional and geographical contexts by many different actors. For example, risk assessment, environmental impact assessment, and health impact assessment, whether practiced by consultants, federal agencies, or academic researchers, in Europe, USA, or China, are considered as just different manifestations of the fundamentally same process of science-based policy support. They are, however, clearly distinguishable from curiosity- driven research, ad hoc assessments, or assessments made to justify predetermined decisions. Here we focus on issues relevant to environment and environmental health, but the implications can be extended also to many other substantive contexts.

Answers to the question are sought for by discussing recent literature relevant to the question. That knowledge is complemented with some insights from recent research projects, INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe) [11] and BENERIS (Benefit-Risk Assessment of Food: an Iterative Value-of-Information Approach) [12].

INTARESE was an EU-funded research project running from 2005 to 2011, developing methodology and tools for integrated environmental health impact assessment (IEHIA), and testing them in case studies. BENERIS was also an EU-funded research project running from 2006 to 2009, developing a framework and tools for complicated benefit-risk situations, and applying them for analyzing benefits and risk of certain foods.

The review starts from purposes of participation and ends in consideration of openness. Overall, it presents a new perspective to the relationships between participation, assessment, and policy making.

5.2 Review

5.2.1 Purpose of participation

The discourse on participation, involving both scholars and practitioners has primarily focused on implementation of participation while the multiple objectives and purposes of participation, particularly in relation to the objectives and purposes of the processes they relate to, have received much less attention [13]. This discourse has resulted for example in various guidance documents for stakeholder involvement [8,14,15], detailed presentation and discussion of various models for public participation, [16-21], and analysis of the applicability of participation

techniques [22-24]. Although they are all important contributions to developing understanding about participation and its implementation, it is not always easy to identify how they link to the "outcome effectiveness of participatory processes in their societal context", as Newig [25] put it in developing his analytical framework for evaluating the impact of participation to improved environmental quality. Many means for public participation exist, but the ends they serve may not always be explicitly identified (for more on the theory of means-ends relationships, see e.g. [26]).

Despite the theoretical stance that participation is generally viewed as highly desirable and its benefits are often assumed to be obvious and substantial [13], the practices of policy making and assessment do not always represent this view. For instance, in a Finnish environmental permit case on a waste treatment activity the decision-maker, the permit applicant, as well as the stakeholders all questioned the meaningfulness of participation in the process, although in principle participation was seen as important by all [27]. The inconsistent utilization of public's contributions has also been seen as a general weakness in the Finnish environmental impact assessment system due to being strongly dependent on the developer's attitudes towards participation as well as the weak links between the assessment and related decision making processes [28]. This can be assumed representative of many other environmental impact assessment systems conducted under the EU Environmental Impact Assessment Directive (85/337/EEC) as well. Also in Canada the record of project-based environmental assessment in delivering on the promise of meaningful public participation has been identified as less than promising [29].

A major source of the problem with participation is that it has been more focused on process and access, rather than on outcomes [29]. It appears that the issue of effective participation needs to be considered in terms of the different possible purposes of both participation and assessment as well as their roles in the related policy making processes. O'Faircheallaigh [13] has presented a nice characterization of ten specific purposes and activities, categorised under three broad purposes, for public participation in environmental impact assessment. The characterization is made in such a generic way, i.e. not bound to any specifics of contemporary environmental impact assessment practices, that we here assume it generalisable to all policy making and assessment regarding environmental and environmental health issues. According to O'Faircheallaigh [13] the three broad purposes for participation are:

- Obtain public input into decisions taken elsewhere
- Share decision making with public
- Alter distribution of power and structures of decision making

These categories roughly correspond to 1) participation influencing assessments and (potentially) their outputs, 2) participation influencing policy making and (potentially) policy decisions, and 3) participation as a means for influencing policy making from outside the existing institutional policy making structures. Within the broad purposes there can be several more specific sub-purposes, many of which are identified and discussed by O'Faircheallaigh [13], e.g. according to the kinds of expected, desired or allowed participant contributions. It is important to note that the purposes for participation are not exclusive, but can, and in fact often do, co-exist and interact. Advancing of different purposes of participation is strongly dependent on the attitudes towards participation among those who control the policy making and assessment processes, but also the types of interaction between assessment and policy making. Particularly this becomes apparent when attempting to advance several specific purposes of participation across categories, for example simultaneously filling information gaps with local knowledge, inviting public to decision making, and especially empowering marginalized groups (cf. [13]).

The relationships between participation, assessment, policy making, and their outcomes are outlined in Figure 1 and discussed in following sections.

5.2.2 Role of participation in assessment

There are multiple kinds of assessment that serve different purposes and address different kinds of questions, and thereby provide different contexts for participation. For example, Pope et al. [30] have differentiated between a) ex-post, project-based assessments (a typical kind for environmental impact assessment), b) ex-ante, objectives- led assessment (a typical kind for strategic environmental assessment), and c) (a more theoretical) assessment for sustainability. Briggs [31], on the other hand has differentiated between i) diagnostic assessment (does a problem exist, is policy action needed?), ii) prognostic assessment (implications of potential policy options, which option to choose?), and iii) summative assessments (effectiveness of existing policies). Assessment approaches may also be characterized according to their contexts of development and application as more regulatory or academic in their nature [32].

Many other classifications exist and new ones could be made, but what is important from the point of view of participation in assessments is the possible influence that is allowed for participation in different assessment settings. For example, does the assessment structure allow for rethinking a project at the time the public is engaged in a project-based environmental assessment (cf. [29])?, can the stakeholders influence the choice of policy options to be considered in a prognostic integrated environmental health impact assessment (cf. [31])?, or does a downstream user of a chemical product have any other role besides providing assessors with information on specific chemical use contexts in a REACH (Registration,

Evaluation, Authorisation and Restriction of Chemical Substances (EU)) chemical safety assessment [33]? The framing of an assessment approach can be a significant constraining factor for potential effectiveness of participation.

Quite often stakeholder involvement and public participation are seen as specific steps or stages in the assessment process (e.g. [31,34,35], Finnish EIA Act (468/94)), which may limit the possible influence of participation to only certain questions topical at that particular stage. Also according to the study on the state-of-the-art in benefit-risk analysis conducted in the BEPRARIBEAN (Best Practices for Risk-Benefit Analysis of Foods) project [36], the commonly applied, contemporarily well established approaches to environmental health assessment treat stakeholder involvement and public participation rather as an add-on, often brought about by legal requirements, than as an essential aspect of assessment or decision making processes [32].

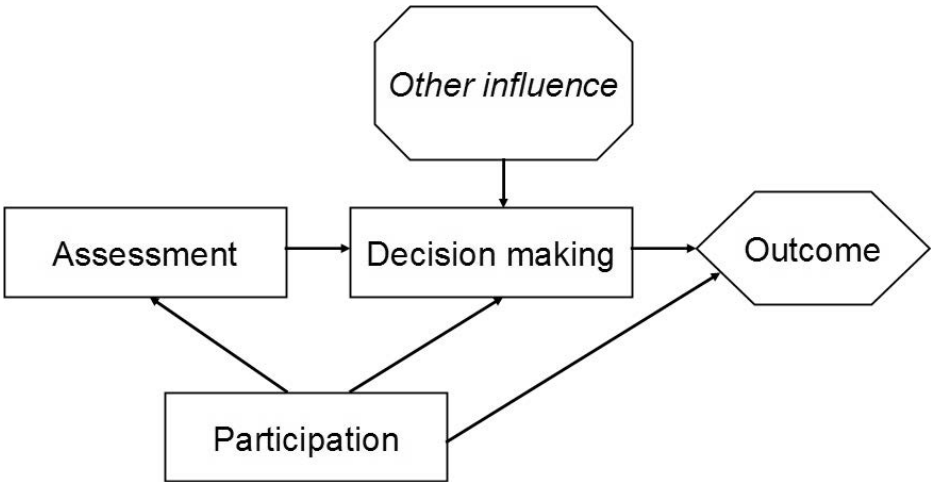

Figure 1. Relationships between participation, assessment, policy making, and their outcomes. Arrows depict alternative routes for potential influence from participation to outcomes.

5.2.3 Role of participation in policy making

On the other hand, in many aspects the level of influence that participation in assessments can have is not directly in control of the assessors. For example, in the aforementioned Finnish environmental impact assessment system, where participation is legally enforced as a part of the assessment process, the decision making structures outside the assessment may induce that certain aspects of assessment results, e.g. in particular public concerns regarding social impacts, cannot be given weight in the decision making [28]. Also the Finnish land use planning system, in which there are legal requirements for impact assessment including public partici-

pation, treats planning (zoning) and development as separate processes, which means that the details of planned development, issues of great public interest, are outside the scope of assessment and stakeholder involvement [37]. Both of these examples describe national implementations of EU directives, and are thereby somewhat representative of the whole target area of the corresponding EU legislation.

The influence of assessment, participation, as well as all other potential inputs to policy making is much determined by the setting in which policy decisions are being made. As an example from another kind of societal context, the Chinese authorities may welcome public participation if it improves the quality of information available to government decision makers, but may not at all be willing to give public the power to contribute to and influence decision making by participating in the formulation of a proposal, the whole assessment process, the implementation, and the evaluation of a proposal [4,13].

5.2.4 Indirect participatory influence

If no satisfactory roles are provided for public, or even expert, input directly in decision making or indirectly through assessment, alternative options for influencing policy need to be looked for outside the institutionalized decision making structures, as pointed out also by O'Faircheallaigh [13]. In fact, quite many, particularly the more academic, assessment approaches, although explicitly aiming to support policy making, do not explicitly describe their linkages to any particular specific policy uses [32]. This may be interpreted indicative of their, more or less implicit, intentions to activate also other channels than only direct influence to policy making. An alternative way to advance the societal purposes of assessments is e.g. to promote social learning among public officials, market players, and citizens. Also in the recent evaluation of the existing EIA legislation in Finland the indirect influence of the information and knowledge obtained in the participatory assessment, which does not directly serve the formal sectoral permit decision processes related to the assessed project, was interpreted as an important aspect of the Finnish EIA system by contributing to the general awareness among the society upon the environmental and health impacts of on-going developments [38].

5.2.5 Assessment-policy interaction

As has been pointed out above, the interaction between assessment and policy making can be crucial for effective participation. Another question then is what influences the assessment results, potentially influenced by participation, have in the related decision making processes. Although often quite credulously assumed by assessors and assessment scholars that assessments have significant impacts to the decision making processes they aim to serve (cf. [13]), few approaches to assessment actually even explicitly consider assessment performance in terms of the

outcomes of using the assessment results in their intended contexts of use [32,39]. Concerns have also been expressed that the emphasis in environmental impact assessment has been more on process and procedure, rather than on purpose and effects [40,41].

Assessment-policy, as well as related science-policy and research-practice, relationships have recently been subjects of intense discussion and several characterizations of the interfaces or boundaries in between them have been presented from different viewpoints. For example Sterk et al. [42] have characterized five boundary arrangements of varying levels of engagement between science and policy, van Kerkhoff and Lebel [43] have presented six categories of relationships between research-based knowledge and action, a continuum of increasing engagement and power sharing, and Cashmore [40] has described a spectrum of five models representing varying conceptions of the role of science, and participation, in environmental impact assessment. In addition, the relationships have been considered in multiple other discourses, e.g. on trans- and interdisciplinary research [44-47], regulatory science [48], Integration and implementation sciences [49], post-normal science [50], integrated research [51], informing science [52], knowledge brokerage [53,54], science integrators [55], boundary organizations, objects and systems [56-58], science-policy interfaces [59], participatory integrated assessment [60,61], environmental health assessment [32], making use of science in policy [62-64], adaptive governance [65-67], policy integration [68], policy practice [69], and policy analysis [70].

Although the viewpoints, bases and contexts in the above mentioned discourses vary, in aggregate they seem to be pointing to the direction of increased openness. According to our interpretations in the context of this paper, of the main lessons from these discourses regarding assessment-policy interaction and participation are as follows:

- The traditional model of disengaged scientific assessment and policy making is increasingly considered both by policy makers and researchers as inadequate to address existing policy needs sufficiently
- There is a need for more pragmatic needs-oriented question setting in assessments
- Deeper engagement between assessment and policy making is essential for policy effectiveness
- Stakeholder and public participation is essential for relevance both in assessment and policy making
- Values are an important aspect of the needed knowledge input for both assessment and policy making.

This broad gradual movement could be characterized as a shifting of both assessment and participation from the lower degrees of involvement, e.g. informing or information collection, towards the higher degrees of involvement, e.g. co-deciding, delegated power, joint planning, or partnering, in relation to policy making (cf. [8,15,20,40]). The shift can also be identified e.g. by observing the development in the perspectives to the relationship between risk assessment and risk management adopted in the publications of the NRC (National Research Council (USA)): from strict disengagement in the so called Red Book [71] to binding through deliberative characterization in the so called Orange Book [72], and on to an intertwined process of risk-based decision making in the recent so called Silver Book [73]. Also the role of stakeholder involvement has grown alongside the development of assessment-policy interaction.

Participation, assessment, and policy making are becoming to be perceived as an intertwined complex that needs to be considered as a whole, not as separate independent entities. The question of effective participation is thus meaningful only in the broader context that also concerns the purposes and effects of policy making and the processes of producing the knowledge that it is based on. However, as has been pointed out above, the common current practices of participation, assessment, and policy making are not necessarily always in line with the latest discourses in the literature.

5.2.6 Dimensions of openness

One obstacle for effectively addressing the issue of effective participation may be the concept of participation itself. As long as the discourse focuses on participation, one is easily misled to considering it as an independent entity with purposes, goals and values in itself, without explicitly relating it to the broader context of the processes whose purposes it is intended to serve. The conceptual framework we call the dimensions of openness attempts to overcome this obstacle by considering the issue of effective participation in terms of openness in the processes of assessment and decision making. The framework was developed as a part of the assessment methodology development in the INTARESE project, and it is intended as guidance for designing and managing participatory assessment and decision making practices. In the project, the development work was originally motivated by a notion of a simultaneous need to improve effectiveness of assessments in environmental health policy making as well as to improve effectiveness and meaningfulness of stakeholder involvement in environmental health assessments.

As the name implies, the framework consists of five essential dimensions of openness in assessment and decision making, or more generally, creation and use of collective knowledge. The dimensions of openness does not attempt to provide an exhaustive and mutually exclusive list of all aspects of openness, but to explicate and emphasize those that are seen as the most essential ones in the context of

environment and health assessment and policy. The five dimensions of openness are:

- **Scope of participation,** referring to who are allowed to participate in the process.
- **Access to information,** referring to what information regarding the issue at hand is made available to participants.
- **Timing of openness,** referring to when participants are invited or allowed to participate.
- **Scope of contribution,** referring to which aspects of the issue at hand participants are invited or allowed to contribute to.
- **Impact of contribution,** referring to what extent are participant contributions allowed to have influence on the outcomes, i.e. how much weight is given to participant contributions.

The dimensions of openness compile the main issues of participation in one solid framework. In the framework, the more commonly addressed questions of access (to process and to information) and timing of participation are complemented with less commonly addressed questions of extent and influence of participation on the outcomes of the process. The five dimensions can be considered as the determinants of the possibilities and limitations provided by the context for the effectiveness of participation. As such, the framework explicates the aspects of openness that need to be taken account of in order to match the processes and procedures of collective knowledge creation and use, e.g. environmental health assessment and related policy making, with their aims and purposes. Thereby it also provides a means for identifying the relationships between participation, assessment, and decision making.

The framework bears resemblance e.g. to the criteria for evaluating implementation of the Aarhus Convention principles by Hartley and Wood [23], the categories to distinguish a discrete set of public and stakeholder engagement options by Burgess and Clark [74], and particularly the seven categories of principles of public participation by Webler and Tuler [75]. However, whereas they were constructed for the use of evaluating or describing existing participatory practices or designs, the dimensions of openness framework is explicitly and particularly intended to be used as a checklist type guidance to support design and management of participatory assessment and decision making processes.

The perspective adopted in the framework can be characterized as contentual because it primarily focuses on the issue in consideration and describing the prerequisites to influencing it, instead of being confined to only considering techniques and manoeuvres to execute participation events. Thereby it helps in participatory assessment and decision making processes to achieve their objectives, and

on the other hand in providing possibilities for meaningful and effective participation. The framework does not, however, tell how participation should be arranged, but rests on the existing and continually developing knowledge base on participatory models and techniques. Although a contentual perspective to participation, dimensions of openness does not contradict with the procedural perspectives to participation, but rather provides a backdrop for their effective application.

The contentual perspective makes the framework applicable in design and management of both assessment and policy making processes. Although assessment and decision making may appear as very different kinds of processes, the choice of point of view is actually only a question of adjusting the scope of application of the framework; whether decision makers are included in an assessment or not? After all, assessment and related decision making should ideally only be alternative perspectives to the same issue, the former emphasizing the development of knowledge, the latter emphasizing the use of knowledge. Within the contentual perspective, everyone, including also e.g. authorities, project managers, and experts, not only public, stakeholders, NGO's (non-governmental organizations) etc., are considered as participants to development and implementation of knowledge. They are all considered as, at least potentially, relevant contributors to either creating knowledge or deciding about an issue of interest. The different kinds of participants naturally take different roles according to their interests, capabilities, professions, as well as formal and legal positions in relation to the issue.

The degree of openness can be managed in terms of the dimensions of openness according to specific purposes and goals. The situational, contextual, and practical issues, for example legal requirements, public perceptions, available resources, time constraints, complexity of the case, confidentiality etc. also need to be taken account of in deciding upon suitable degree of openness. The degree of openness can be adjusted separately for different groups of participants, or even on an individual basis, and varying from a case to another, as needed. The overall openness of the process can be considered as a function of all five dimensions across all roles, although it should be noted that the dimensions are not independent, but rather interrelated.

For example, the first dimension, scope of contribution, determines the participant groups among which questions regarding e.g. access to information or scope of contribution are only even relevant. In addition, while all dimensions contribute to the overall openness, it is the fifth dimension, the impact of contribution, which ultimately determines the effect on the outcome. Accordingly, it is recommended that aspects of openness in assessment and decision making processes are considered step-by-step, following the order as presented above.

The greatest power of the framework is that it puts the issue at hand in focus and does not build on any preconceptions about possible or acceptable inputs to its development. It allows to first ask what are the inputs needed to develop the issue

to achieve its purpose, and then consider the arrangement for its realization, without being preconfined to existing conventions and institutions of participation, assessment and decision making, which, as argued above, are in many cases known to be inadequate. The framework i) provides a context for evaluation and constructive criticism of existing conventions and institutions, ii) facilitates innovative application of existing means for participatory processes within and alongside the existing conventions and institutions, and iii) promotes development of new means, conventions and institutions for participatory practice. Thinking in terms of openness provides a new perspective to participation in assessment and policy making.

5.2.7 Implementation of openness

The first version of the dimensions of openness framework was developed already in the early phases of the INTARESE project. At the same time also an alternative, procedural, assessment approach was developed within the project, eventually leading to the formulation of the IEHIA method [31]. Although in retrospect it can be seen that the dimensions of openness framework and the IEHIA method are complementary rather than fundamentally contradictory, some practical difficulties in merging these views led into their development side by side rather than together within the project. Consequently, the dimensions of openness framework was eventually taken for further development and application also outside the project. In practice, this meant that the authors, also the initiators of the framework development, began to develop and apply the dimensions of openness framework in their work for developing a new, more holistic approach for environmental health risk analysis within one of the partnering institutions, the National Institute for Health and Welfare (THL) from Finland. The approach was first known as Pyrkilö (originating from the Finnish word pyrkiä, to strive for), and later as open risk assessment [76]. Eventually the method became named open assessment and the web-workspace for conducting open assessments became named Opasnet [32,77-79]. A major part of the early development of the Opasnet web-workspace was particularly carried out in the BENERIS project.

The method development work took account of several of the aspects of policy making, assessment, and participation discussed above, and was influenced by the research results and experiences e.g. on collective knowledge creation in fields of education, psychology, and philosophy [80], computer-supported collaborative learning [81,82], mass collaboration [83] as well as crowd-sourcing [84,85]. Application of the framework in this setting led into a somewhat extreme interpretation of participatory practice in the context of environmental health: the assessments should be made completely open by default and limitations in degree of any dimension of openness should be done only based on cogent and explicitly argued reasons! The framework also illuminated that assessments, the knowledge creation

processes, need to be deeply intertwined with the decision making processes, the knowledge use, if they seriously attempt to achieve their purposes of influencing policy. This makes decision makers a particularly essential kind of active assessment participants. These ideas, quite contrary to the currently common conceptions of assessment and participation, became two of the fundamental principles guiding open assessment method and Opasnet web-workspace development. The idea of open assessment is illustrated in Figure 2.

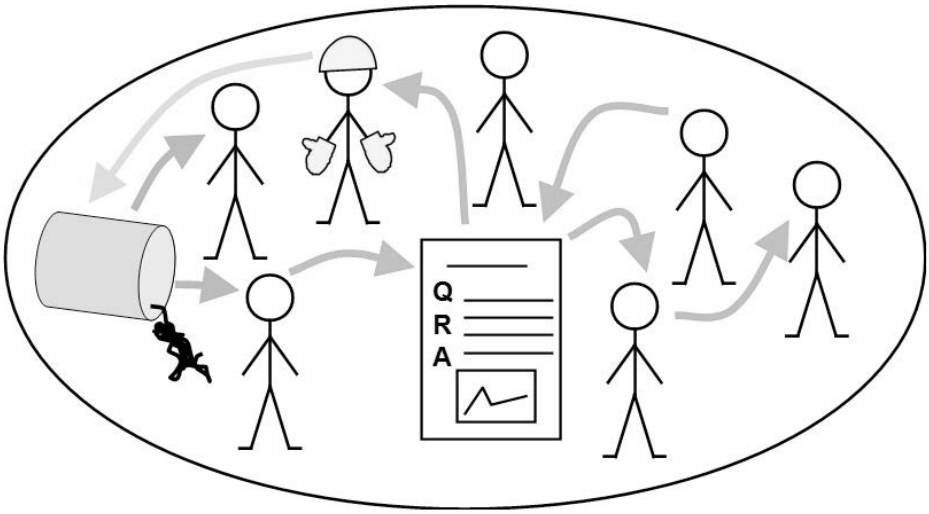

Figure 2. Open assessment as a collaborative social knowledge process. The straw men depict the members of a society. The paper sheet depicts an assessment in Opasnet (Q = question, R = rationale, A = answer). Arrows depict observation (here of an undesired event, a toxic liquid spill), information flow (from members of society to an assessment in Opasnet, from the assessment to members of society, or directly between members of society), and knowledge-based action (correctly taking care of the spill).

The unconventionality of the principle of complete openness, and how it relates to the interrelations between participation, assessment, and decision making, is illustrated by the comparison, in terms of the dimensions of openness, of five assessment approaches relevant in the field of environment and environmental health in table 1. The comparison also demonstrates the application of the framework in evaluating existing practices. For the sake of clarity the focus of comparison is here on "external participation" in the assessment processes, e.g. by decision makers, stakeholders or public. The possible differences in the roles of the expert assessors nominated for the assessment task are thus not explicitly considered. The five assessment approaches included in the comparison are 1) Open

assessment [32,76-79] (State of the art in benefit-risk analysis: Environmental health. Unpublished manuscript developed in the BEPRARIBEAN project), IEHIA [31], YVA - the Finnish environmental impact assessment system (Finnish EIA Act 468/94) [28], the so called "Red Book" risk assessment [71], and its recent update, the "Silver Book" risk-based decision making framework [73].

In addition to describing varying degrees of openness, the comparison illustrates striking differences in how the approaches see the interrelations between participation, assessment, and decision making. Open assessment and the Red Book risk assessment represent the two extremes. Whereas the former sees participation, assessment, and policy making as aspects of the same collaborative process, the latter does not even consider participation and explicitly recognizes interaction between assessment and the external world only in distribution of assessment results to decision making. The three other examples, IEHIA, YVA, and Silver Book fall in between these extremes by allowing some degrees of openness, although in somewhat different ways, and identifying linkages between participation, assessment, and decision making. However, as was mentioned earlier, the linkage from YVA assessments, and participation organized within them, is known to be weak. Also for IEHIA, the description of the relationship between assessment and decision making remains quite implicit. The Silver Book perspective makes a radical update to the Red Book perspective, yet it still retains the risk assessment as a fundamentally independent and exclusive expert process.

The scrutiny of openness according to the dimensions of openness framework can, as exemplified above, reveal interesting aspects of participation, assessment, and policy making practices, and their potential to deliver what they intend to. Although in many discourses participation seems to be assumed to have "value in itself", or plainly seen to "belong to democracy", from a contentual point of view this kind of reasoning misses the main point of openness. Openness is not an end in itself, but rather a means for advancing societal development through creation and use of broadly distributed collective knowledge. Openness calls into question the assumptions behind the institutional practices that we have accustomed ourselves to take for granted.

Table 1. Perspectives to openness in "external participation" for five example assessment approaches considered according to the dimensions of openness framework.

Dimension / Approach	Scope of participation	Access to information	Timing of openness	Scope of contribution	Impact of contribution
Open assessment	Everyone, e.g. decision makers, NGO's, citizens, external experts, allowed to participate. User participation particularly important.	All information should be made available to all participants.	Continuous.	All aspects of the issue can be addressed by everyone.	Based on relevance and reasoning, not source. All relevant contributions must be taken into account. Conclusions from collaboration intended to turn into action through collective knowledge creation among participants in a shared web-workspace.
IEHIA	Specified users (e.g. policy makers), and stakeholders (preferably by proxy) invited to participate.	?[1]	User and stakeholder participation during issue framing, design and appraisal phases (not during execution phase).	Users and stakeholders can participate in scoping and design of assessment and interpretation of results.	Participant views influence the construction of the assessment framework. Appraisal phase discourse regarding the assessment results, their implications for action, and their linkage to the goals defined in issue framing assumed to ensure that those involved accept the outcomes
YVA	Public, liaison authority (e.g. regional environmental centre), other authorities.	Assessment plan and assessment report provided to the public by the project developer. Liaison authority also has access to	Participation in two phases. Public hearing periods, possible authority statements regarding both assessment plan and assessment report.	Any public representative can give any statements, and the liaison authority may ask specific statements from other authorities in both phases. Liaison authori-	Public statements filed along with the liaison authority statements. Ultimately up to the project developers and the decision makers to decide if and how public statements are taken account of in project design or decision making. The liaison authority, also taking account of public and other

		information regarding e.g. other plans, projects and operations relevant to the project.	Liaison authority gives its statements after the public and the other authority statements.	ty gives an overall statement on both the assessment plan and the assessment report.	authority statements, can also demand e.g. certain issues to be considered in the assessment or other additional information to be provided by the project developer.
Red Book	N/A[2] (Assessment for nominated scientific experts only).	N/A	N/A	N/A	Assessment results provided for decision makers and intended to be taken into account, alongside options evaluation, in decision making and action by federal agencies.
Silver Book	Decision-makers, technical specialists, and other stakeholders.	Formal provisions for internal and external stakeholders at all stages.	At all stages: problem formulation and scoping, planning and conduct of risk assessment, and risk management.	Problem formulation and scoping, confirmation of utility of risk assessment, and risk management.	Stakeholders as active participants. However, participation should in no way compromise the technical assessment of risk, which is carried out under its own standards and guidelines.

[1] ? = could not be determined based on the information source
[2] N/A = not applicable.

For example, complete openness, as adopted in open assessment, actually applies an inverse interpretation of the dimensions of openness, i.e. who should not be allowed to participate, what information should not be made available to participants etc. From this perspective it often becomes difficult to argue e.g. for exclusion of any specific groups or individuals from assessments, or withholding important information, especially if also the arguments are exposed to open critique. Particularly this is the case in the context of environment and environmental health, where the issues addressed are often relevant to virtually everyone and every organization or individual is a potential source of relevant contributions. As an example, issues regarding global climate change involve a nearly infinite amount of actors in different roles e.g. as contributors to climate change, its mitigation and adaptation, or parties affected by impacts of climate change or its mitigation and adaptation actions.

Openness necessarily also requires a more inclusive view to assessment than what the conventional conceptions of assessment provide. Assessment should not only be confined to mean the expert-driven, natural science influenced, fact-based, sometimes strictly quantitative, so called scientific assessments aiming to find objective answers. It should also extend to explicit inclusion of values and all kinds of knowledge from all sources, qualitative treatment of information, and creation of contextual, situational, and pragmatic knowledge among assessment participants. Such a conception of assessment actually ideally also includes decision making, and other possible uses of knowledge created by assessment. Although confronted with "scientific assessment" above, the open conception of assessment is actually not any less scientific. After all, the heart of science is in development of shared belief systems based on open critique, evidence, interpretation, and argumentation, which necessitates openness. Creation of new fora for scientific discourse, and invitation of new participants and new topics to enter these fora does not in itself guarantee scientifically valid outputs, but it provides possibilities for overcoming the identified limitations to effectiveness in policy making, assessment, and participation in the conventional approaches that build on exclusivity and disengagement rather than openness.

5.3 Conclusions

In conclusion, based on the review of literature and insights from recent research projects, we state that:

- Inclusion of stakeholders and public to participate in assessments and policy making upon issues of environment and environmental health is an issue of both great interest and importance.
- The discourses on both assessments and participation in the contexts of environment and environmental health have been too much focused on processes and procedures, and too little attention has been given to their purposes and outcome effectiveness in policy making.
- Consideration of effective participation is meaningful only in the context of purposes and effects of the assessment and policy making processes that participation relates to.
- The dimensions of openness framework provides a conceptual means for identifying and managing the interrelations between the purposes and outcomes of participation, assessment, and policy making, and thereby also for effective application of existing participatory models and techniques.
- The dimensions of openness framework also provides a context for evaluation and constructive criticism of contemporary conventions and institutions of participation, assessment, and policy making, and a basis for developing new conventions and institutions.
- From a contentual point of view, it can be argued that participation, assessment, and policy making upon environmental and environmental health issues should be considered as completely open rather than exclusive processes by default.
- Openness should not, however, be considered as an end in itself, but rather a means for advancing societal development through creation and use of broadly distributed collective knowledge upon issues of great societal relevance.
- Openness brings about challenges, but they are mostly practical, rather than fundamental in their nature.

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6 Societal impacts of environment and health assessments and models – from outputs to outcomes?

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Abstract

The calls for knowledge-based policy and policy-relevant research, invoke a need to evaluate and manage environment and health assessments and models according to their societal outcomes. This review explores how well the existing approaches to assessment and model performance serve this need. The perspectives to assessment and model performance in the scientific literature can be called 1) quality assurance/control, 2) uncertainty analysis, 3) technical assessment of models, 4) effectiveness and 5) other perspectives, according to what is primarily seen to constitute the goodness of assessments and models. The categorization is not strict and methods, frameworks and tools in different perspectives may overlap. However, altogether it seems that most approaches to assessment and model performance are relatively narrow in their scope. The focus in most approaches on the outputs and making of assessments and models. Practical application of the outputs and the consequential outcomes are often left unaddressed. It appears that more comprehensive approaches that combine the essential characteristics of different perspectives are needed. This necessitates a better account of the mechanisms of collective knowledge creation and the relations between knowledge and action. Some new approaches to assessment, modelling and their evaluation and management span the chain from knowledge creation to societal outcomes, but the complexity of evaluating societal outcomes remains a challenge.

6.1 Introduction

In a time when knowledge base of policies and policy-relevance of research is called for probably more than ever before, there is an increasing need to evaluate the success of environment and health assessments and models according to their societal effectiveness. In a recent thematic issue on the assessment and evaluation of environmental models and software [1], Matthews et al. [2] suggested that the success of environmental modelling and software projects should be evaluated in terms of their outcomes, i.e. changes to values, attitudes, and behaviour outside the walls of the research organization, not just their outputs. However, until now, there has been limited appreciation within the environmental modelling and software community regarding the challenges of shifting the focus of evaluation from outputs to outcomes [2].

The situation in the domain of environment and health related assessments, such as integrated assessment [3], health impact assessment [4], risk assessment [5-7], chemical safety assessment [8], environmental impact assessment [9], and integrated environmental health impact assessment [10] appears to be similar. A recent study on the state of the art in environmental health assessment revealed that although most assessment approaches aim to influence the society, this is rarely manifested in the principles and practices of evaluating assessment performance [11].

The emphasis in the scientific discourses on evaluating assessments and models has been on rather scientific and technical aspects of evaluation within the research domain, and perspectives that address the impacts of assessments and models in broader societal contexts have emerged only quite recently and are still relatively rare (cf. [12]). Such evaluations are qualitatively different [2], which indicates a need to reconsider the criteria and frameworks for evaluating assessment and model performance.

Furthermore, evaluation of assessments and models is not only a matter of judging how good an assessment or a model is, but it also guides their making and the use of their outputs (cf. what you measure is what you get (WYMIWYG) in [13]).

In evaluation of societal effectiveness, assessments and models are considered as instances of science-based support to decision making upon issues relevant to environment and health. Assessments always involve modelling of some kind, at least implicit conceptual models. Conversely, modelling is also often identified with assessment [14]. In addition, decision support systems, information support tools, integrated modelling frameworks and other software tools and information systems to assist in developing, running, and analyzing models are here perceived as integral parts of assessment and modelling (cf. [15]).

Assessments and models can be considered e.g. as diagnostic, prognostic, or summative according to the kinds of questions they address [10], ex-ante or ex-post according to their timing in relation to the activities being assessed [16], and regulatory or academic according to the contexts of their development and application [11]. They can also be developed, executed, and applied by many kinds of actors, e.g. consultants, federal agencies or academic researchers. However, assessments and models, as perceived here, should be clearly distinguished from purely curiosity-driven research, ad hoc assessments, and assessments or models made only to justify predetermined decisions.

Altogether, assessments and models can be considered as fundamentally having two purposes: i) describing reality, and ii) serving the needs of practical decision-making. Accordingly, the structure of the interaction between assessments and models and their societal context can be described as in Figure 1.

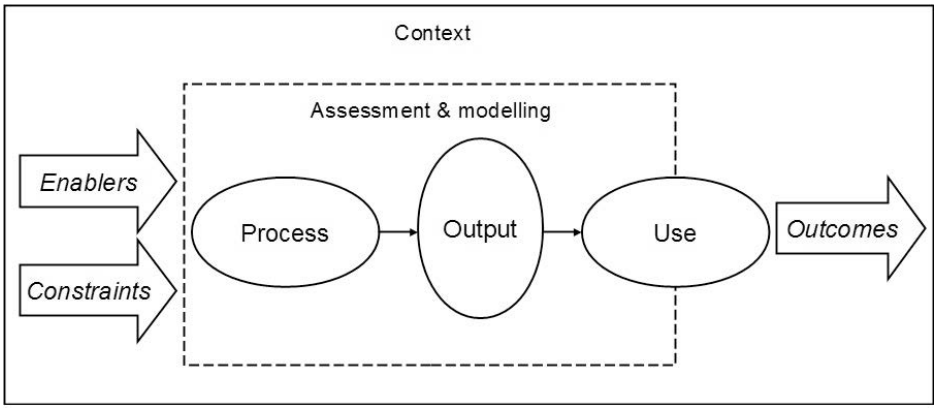

Figure 1. Assessment and modelling in interaction with their societal context (influenced e.g. by [2,17-20]).

The endeavours of assessment and modelling are here broken down into:

- Process, the procedures and practices of their assessment and modelling
- Output, the assessment and model results and products, and
- Use, the application of the assessment and model outputs

The surrounding context enables, and on the other hand also constrains, assessment and modelling e.g. in the form of funding, facilities and education, but also as acceptance of or demand for assessments and models. The societal context is also the medium where the outcomes of assessments and models are realized. Use is located on the boundary between the assessment/modelling domain and the context, which indicates that the application of assessment and model outputs is

the primary point of interaction between assessments or models and their societal context.

In following, the approaches to environment and health assessment and model performance in the scientific literature are reviewed and categorized according to which aspects are primarily seen to constitute the goodness of assessments and models. The perspectives identified are called i) quality assurance/control, ii) uncertainty analysis, iii) technical assessment of models, iv) effectiveness, and v) other perspectives. The question underlying this review is how much and how is the interaction with the societal context reflected upon in the approaches to environment and health assessment and model performance in contemporary scientific literature? The purpose is thus not to discuss the details of different methods, tools and frameworks, but instead map how the approaches relate to the aspects of assessments and models in interaction with their societal context, as illustrated in Figure 1. Recent contributions in the literature are emphasized, but some important or illustrative examples that were published before 2000 have been included as well. After the review, the approaches and perspectives are discussed in terms of their capability to serve the needs of outcome oriented evaluation and management of assessments and models. In addition, a framework for developing more comprehensive outcome oriented approaches is proposed.

6.2 Perspectives to model and assessment performance

6.2.1 Quality assurance/control

One of the major themes in assessment and model performance related literature can be referred to as quality assurance/control (QA/QC) perspective. The focus in this perspective is primarily on determining how the processes of assessment and modelling, sometimes also decision making, are to be conducted in order to assure the quality of the output.

There are multiple alternative definitions for quality (see e.g. [21]). However, as regards assessment and models, the interpretation is mostly analogous with the perception in the ISO-9000 framework, i.e. as the organizational structures, responsibilities, procedures, processes, and resources to assure and improve quality [22]. Also the hierarchy of evidence in medical science, ranking types of evidence strictly according to the procedure by which they were obtained [23], is an example of the quality assurance/control perspective. However, as pointed out by Cartwright [24] with regard to randomized controlled trials, the procedure alone cannot guarantee delivery of useful information in practical contexts.

One common variation of this perspective is stepwise procedural guidance (Table 1). Such guidance provides relatively strict and detailed descriptions of the steps or phases of an assessment or modelling process that are to be executed in a more or less defined order. Faithful execution of the procedure is assumed to lead

to good outputs. A similar, but often less rigorous, variation of the QA/QC perspective is checklist guidance emphasizing issues that need to be taken account of in the assessment or modelling process or their evaluation. The checklists can be more or less detailed and they usually do not strictly define the order or sequence of execution.

Table 1. Examples of quality assurance/control perspective to assessment and model performance.

Type	Description
Stepwise procedural guidance	Ten iterative steps in development and evaluation of environmental models [25]
	HarmoniQuA guidance for quality assurance in multidisciplinary model-based water management [26]
	Methodology for design and development of integrated models for policy support [27]
	Framework for integrated environmental health impact assessment [10]
	BRAFO tiered approach for benefit-risk assessment of foods [28]
	Generic framework for effective decision support through integrated modelling and scenario analysis [29]
	Formal framework for scenario development in support of environmental decision making [30]
Checklist guidance	Seven attributes of good integrated assessment of climate change [31]
	List of end use independent process based considerations for integrated assessment [32]
	QA/QC performance measurement scheme for risk assessment in Canada [33]
	Checklist for quality assistance in environmental modelling [34]
Evaluation of input quality	Pedigree analysis in model-based environmental assessment [35]
	Methodology for recording uncertainties about environmental data [36]
	Method for analyzing assumptions in model-based environmental assessments [37]

In addition, the accounts that address evaluation of input quality can be considered as manifestations of the QA/QC perspective (Table 1). However, the primary focus in QA/QC is often on the outputs, and the input quality evaluations typically complement uncertainty analysis or technical assessments of models (see below). For example, model parameter uncertainty analysis can be considered as an example of evaluation of input quality, but in practice, it is most often considered as an aspect of either uncertainty analysis or technical assessment of models.

Characteristic for stepwise guidance is that it attempts to predetermine a procedure in order to guarantee good quality of outputs. As such, it takes a proactive

approach to managing performance. Checklist guidance and evaluation of input quality can also be applied proactively, but the examples found in literature mostly represent a reactive approach of evaluating already completed assessments and models.

6.2.2 Uncertainty analysis

Another major theme in the assessment and model performance literature is the uncertainty analysis perspective. The contributions within this perspective vary significantly, ranging from descriptions of single methods to overarching frameworks, but the common idea is characterization of certain properties of the assessment and model outputs. Fundamentally, the perspective builds on quantitative statistical methods based on probability calculus [38], but also other than probability-based approaches to uncertainty have been presented [39]. Many manifestations of this perspective in the context of environment and health assessment and models also extend to consider qualitative properties of the outputs.

One variation of the uncertainty analysis perspective is identification of the kinds and sources of uncertainty in assessment and model outputs (Table 2). Some uncertainties are often considered as being primarily expressible in quantitative, while others in qualitative terms. The sources of uncertainty may include aspects of the assessment and modelling processes, and in some cases also intended or possible uses and use contexts of the outputs are acknowledged.

Table 2. Examples of uncertainty analysis perspective to assessment and model performance.

Type	Description
Identification of kinds of uncertainty	Conceptual basis for uncertainty management in model-based decision support [40]
	Uncertainty in epidemiology and health risk and impact assessment [41]
	Uncertainty in integrated assessment modelling [42]
Guidance on dealing with uncertainties	Knowledge quality assessment for complex policy decisions [43]
	Operationalising uncertainty in integrated water resource management [44]
	Framework for dealing with uncertainty in environmental modelling [45]
Methods for uncertainty analysis	Approaches for performing uncertainty analysis in large-scale energy/economic policy models [46]
	Modelling of risk and uncertainty underlying the cost and effectiveness of water quality measures [47]
	Addressing uncertainty in decision making supported by Life Cycle Assessment [48]
	Sensitivity analysis of model outputs with input constraints [49]

Also guidance on how to assess or deal with different kinds of uncertainties exist (Table 2). Such frameworks usually combine qualitative and quantitative aspects of uncertainty deriving from various sources. Consequently, aspects of the assessment and modelling processes, e.g. input quality and user acceptance, are often also included in the frameworks. The primary focus still remains in the characteristics of the assessment and model.

In addition, also numerous more or less explicit methods, means and practices to analyse uncertainties of assessment and model outputs exist (Table 2). In addition to the standard statistical characterization, for example sensitivity, importance, and value of information analysis and Bayesian modelling are essential in the context of environment and health assessment and models. Such methods are dominantly quantitative.

In the uncertainty analysis perspective, it appears typical that the issue of uncertainty is approached from an external observer's point of view. The evaluation of performance is thus mainly considered as a separate, often ex-post, activity taking place in addition to the actual assessment or modelling process, not as its integral proactive part.

6.2.3 technical assessment of models

This perspective focusing on characteristics of models is particularly present in the modelling literature. In addition, also different kinds of software tools that are applied in developing, running, and analyzing models can be evaluated similarly as models.

Particularly the object of interest in technical assessment of models is development and application of formal methods for testing and evaluating models within defined domains of application (Table 3). Generally, model evaluation and performance is considered to cover structural features of models, representativeness of model results in relation to a certain part of reality, as well as usefulness with regard to a designated task (cf. [50]). However, usefulness mainly refers to expert use of models, corresponding mostly to the so-called process effects, i.e. changes in the capacity of those engaged in the modelling and assessment endeavours, rather than outcomes (cf. [2]). Most commonly, technical assessment of models takes place in terms of validation and verification by comparing models and their results against each other or measurement data.

A variation of this perspective, more common for the discourses in assessment literature, is analysis of model uncertainty (Table 3). Here the aim typically is to characterize the properties of a model in order to be able to correctly interpret or evaluate its outputs. Model uncertainty is often considered as one aspect of a broader uncertainty analysis concept.

Table 3. Examples of technical assessment of models perspective to assessment and model performance.

Type	Description
Means for model and software evaluation	Criteria for environmental model and software evaluation [51] Terminology and methodological framework for modelling and model evaluation [52] Evaluation methods of environmental modelling and software in a comprehensive conceptual framework [53] Top-down framework for watershed model evaluation and selection [53] Overview of atmospheric model evaluation tool (AMET) [54] Appropriateness framework for the Dutch Meuse decision support system [55] Empirical evaluation of decision support systems [56] Numerical and visual evaluation of hydrological and environmental models [57]
Evaluation of models	Evaluation of an ecosystem model for wheat-maize cropping system in North China [58] Parameterisation and evaluation of a Bayesian network for use in an ecological risk assessment [59] Evaluation of quantitative and qualitative models for water erosion assessment in Ethiopia [60] Evaluation of modelling techniques for forest site productivity prediction using SMAA [61]
Analysis of model uncertainty	Model uncertainty in the context of risk analysis [62] Scenario, model and parameter uncertainty in risk assessment [63] Framework for dealing with uncertainty due to model structure error [64]

The technical assessment of models is predominantly a reactive perspective to, as it requires an existing model or software system that can be tested and analyzed. The evaluation, however, is usually perceived as an integral part of the model development, not a separate entity, enabling application of technical assessment of models in different developmental stages within the modelling or assessment process. On the other hand, the common practice of self-evaluation of models may also lead e.g. to limited usability, credibility and acceptability due to lack of interaction with the context.

6.2.4 Effectiveness

Whereas the three former perspectives can be considered conventional, emphasizing of assessment and model effectiveness has become a major topic only recently in assessment and model performance related literature.

Table 4. Examples of effectiveness perspective to assessment and model performance.

Type	Description
Frameworks and criteria for effectiveness	Framework for the effectiveness of prospective human impact assessment [67]
	Process, impact and outcome indicators for evaluating health impact assessment [68]
	Criteria for appraisal of scientific inquiries with policy implications [69]
	Necessary conditions and facilitating factors for effectiveness in strategic environmental assessment [70]
	Policy effectiveness in participatory environmental assessment [71]
	Dimensions of openness for analyzing the potential for effectiveness in participatory policy support [72]
	Properties of good assessment in evaluating effectiveness of assessments [73]
Effectiveness evaluations	Several cases of evaluating effectiveness of health impact assessment in Europe [74]
	General effectiveness criteria for strategic environmental assessment and their adaptation for Italy [75]
	Environmental impact assessment evaluation model and its application in Taiwan [76]
	Effectiveness of the Finnish environmental impact assessment system [77]
	Example of outcome evaluation for environmental modelling and software [2]
Use of models, tools and outputs	Framework to assist decision makers using of ecosystem model predictions [78]
	Analysis of contribution of land-use modelling to societal problem solving [79]
	Use of decision and information support tools in desertification policy and management [80]
	Developing tools to support environmental management and policy [81]
	Role of computer modelling in participatory integrated assessments [82]
	Usage and perceived effectiveness of decision support systems in participatory planning [83]
	Credible uses of the distributed interactive simulation (DIS) system [84]
	Analysing interaction between environmental health assessment and policy [10]

In the effectiveness perspective, the aim of assessments and models is perceived as promotion of changes in values, attitudes, and behaviour outside the walls of the research community (cf. [2]) by maximizing the likelihood of an assessment process to achieve the desired results and the goals set for it [65]. In principle, here performance of assessments and models is thus determined by the impacts delivered into the broader societal context. However, due to the complexity of reality, evaluation of outcomes is often perceived as very difficult, if not impossible [66], and possibly even leading to incorrect conclusions regarding effectiveness (cf. [67]). Consequently, the effectiveness criteria and frameworks (Table 4) often address aspects of process and output, as well as contextual ena-

blers and constraints, rather than outcomes, as determinants of effectiveness. Some contributions also make a distinction between (immediate) impacts and (indirect) outcomes. As a result, although the aim is to address the outcomes, some approaches to effectiveness in the end turn out quite similar to checklist guidance in quality assurance/control (see Table 1).

The approaches emphasizing the use of models, tools and their outputs can also be considered as a manifestation of the effectiveness perspective (Table 4). They can generally be characterized as attempts to operationalise the interaction between assessments or models and the practical uses of their outputs. Most of the contributions are, however, relatively tool-centred, and most often little attention is given to the cognitive processes involved in the delivery and reception of information produced by assessments and models.

The approaches to effectiveness range from external ex-post evaluations to supporting of development and management of assessments as well as decision processes. All approaches, however, explicitly acknowledge the role of use in delivering the effects of knowledge provided by assessments and models, although the criteria for evaluating effectiveness may vary.

6.2.5 Other perspectives

Many contributions to assessment and model performance in relevant literature can be quite comfortably located within the four perspectives above. However, also some other aspects addressing credibility and acceptability, information quality, and communication (Table 5) that deserve a mention.

Table 5. Examples of other perspectives to assessment and model performance.

Type	Description
Acceptance and credibility	Obtaining model credibility through peer-reviewed publication process [51]
	Model credibility in the context of policy appraisal [87]
Information quality	A conceptual framework of data quality [88]
	An asset valuation approach to value of information [89]
	Ten aspects that add value to information [90]
	Knowledge quality in knowledge management systems [91]
Communication	Uncertainty communication in environmental assessments [92]
	Checklist for assessing and communicating uncertainties [93]
	Communication challenges from a release of a pathogen in urban setting [94]
	Clarity in knowledge communication [95]

Credibility is often considered necessary for acceptance of assessment and modelling endeavours and their outputs. It can be obtained more or less formally

or informally e.g. through peer review, extended peer-review [85] or reputation. Credibility and acceptability are often considered as aspects of broader performance concepts.

Assessment and modelling are essentially processes of producing structured information. Therefore, the contributions regarding information quality, even outside the fields of assessment and modelling, are of relevance here. Like the uncertainty analysis perspective also information quality looks into certain properties of an information product. Similarly, the variation among contributions addressing information quality is big.

In addition, communication of results, e.g. in terms of communicating uncertainties and risk information, relates to performance of assessments and models. However, the issues of communication are often not considered as integral parts of modelling and assessments endeavours. For example, risk assessment, risk management and risk communication are traditionally considered as separate, yet interrelated, entities, each having their own aims, practices, and practitioners (e.g. [86]).

6.3 Discussion

6.3.1 Overview of approaches and perspectives

It seems that none of the perspectives nor any individual approaches alone sufficiently serve the needs of outcome oriented evaluation and management of assessment and model performance. In most approaches, the main emphasis is on the processes and outputs of assessment and modelling while use, outcomes and other contextual aspects are addressed to a lesser extent, although more frequently in recent literature. Although the approaches focusing on processes and outputs may be robust, they tend to miss important aspects of interaction with the societal context. On the other hand, the approaches focusing on the interaction may be more vague and still provide only partial solutions to considering how and why assessments and models influence their societal contexts.

Many approaches to performance seem to perceive evaluation as a separate entity, often taking place only after the making of an assessment or model. In many cases evaluation is considered as a responsibility of others than assessors and modellers, but for example in the essentially proactive stepwise guidance in the quality assurance/control perspective, and the technical assessment of models perspective, the evaluation is usually integrated in the model development. In addition, some of the effectiveness frameworks explicitly aim to support design and execution, not only evaluation, of models and assessments.

The emphasis on processes and outputs in evaluation and management of assessment and model performance is in line with the fact that the issues of effectiveness and policy-relevance of assessments and models have become major top-

ics only during the last decades. As assessors, modellers and researchers more generally, have been lacking requirements and incentives for effectiveness and policy-relevance (cf. [96]), correspondingly the practices, principles and methods of performance management and evaluation have not developed to address these issues. Instead, the impacts of assessments and models have mostly been considered mainly in terms of their process effects (cf. [2]) within the communities of assessors and modellers. However, virtually all assessment and modelling endeavours in the fields of environment and health are motivated, at least nominally, by the aim to influence societal decisions and actions and the need to evaluate and manage them according to their societal outcomes seems justified.

6.3.2 Towards new approaches

It appears that more comprehensive approaches that provide a better coverage of the different aspects of assessments and models in their societal context, are needed to support evaluation and management of assessments and models. In practice, this requires taking account of the making of assessments and models, their use in decision making and implementation as well as their consequential outcomes (Figure 2). Such approaches would combine the essential characteristics of the different perspectives into one framework, methodology or combination of tools and provide both rigour and better linkage to the outcomes.

However, a mere compilation of features taken from different perspectives would probably not be sufficient. A more thorough account of the mechanisms of collective knowledge creation and the relations between knowledge and action in a societal context is needed in order to bridge assessments and models with their outcomes [97] (Pohjola et al., 2011). Unfortunately these aspects are barely even recognized in most current approaches to model and assessment performance.

The need to span the whole chain from knowledge creation to outcomes and bringing the producers and users of knowledge to a more intimate interaction is recognized in some new approaches to assessment, modelling and their evaluation and management (e.g. [2, 98-99] Koivisto and Pohjola 2012; Matthews et al., 2011; Tijhuis et al., 2012). However, the complexity of evaluating the outcomes remains a challenge. In the eyes of an evaluator, the relative simplicity of considering only processes, outputs or direct impacts in tightly bound settings of expert activities may still appear inviting in comparison to attempting to account for complex indirect impacts within the broader social context. However, this would not be adequate for serving the purposes of assessment, models and their evaluation.

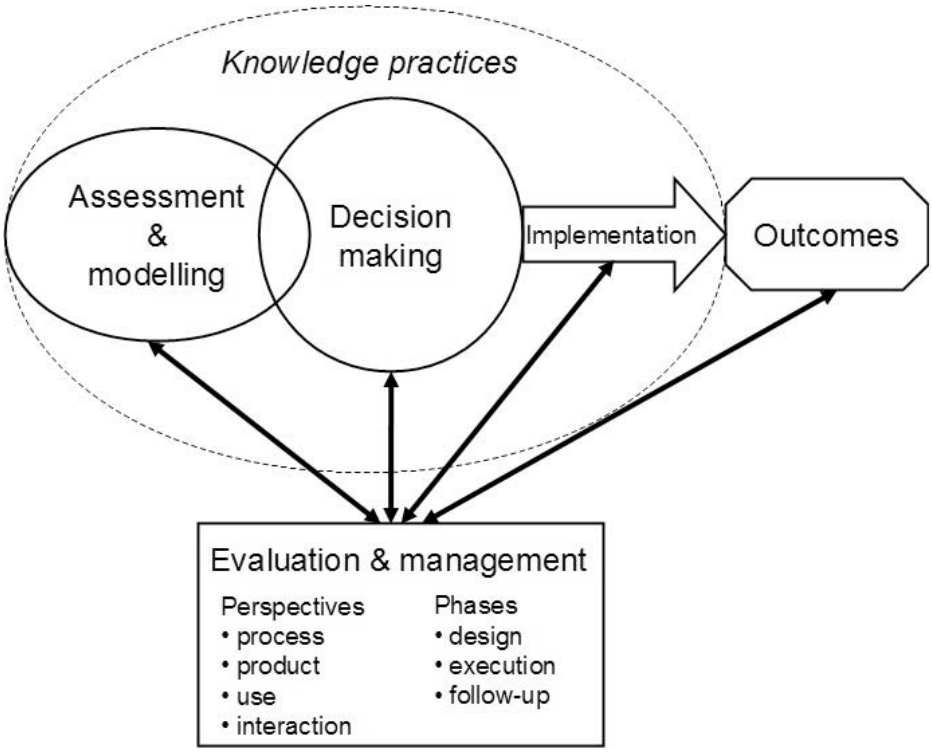

Figure 2. A framework for comprehensive evaluation and management of assessment and model performance. The chain from assessment and modelling to outcomes mostly consists of production, communication and application of knowledge in a societal context.

In order to overcome this challenge, the new comprehensive approaches should not only focus on either processes, outputs, uses or outcomes of assessments and models, but particularly consider and address the knowledge that is created, transferred and applied within the intertwined processes of modelling, assessment and decision-making (see Figure 2). In practice this also means that the evaluation and management should be a continuous counterpart of designing and making assessments and models and applying their outputs in practice. After all, models can only be evaluated in relative terms, and their primary value is heuristic [100].

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7 Pragmatic Knowledge Services

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Abstract

Knowledge, innovations and their implementation in effective practices are essential for development in all fields of societal action, e.g. policy, business, health, education, and everyday life. However, managing the interrelations between knowledge, innovation and practice is complicated. Facilitation by suitable knowledge services is needed. This paper explores the theory of converging knowledge, innovation, and practice, discusses some advances in information systems development, and identifies general requirements for pragmatic knowledge services. A trialogical approach to knowledge creation and learning is adopted as a viable theoretical basis. Also three examples of novel knowledge services Opasnet, Innovillage, and Knowledge Practices Environment (KPE), are presented. Eventually, it is concluded that pragmatic knowledge services, as hybrid systems of information technology and its users, are not only means for creation of practical knowledge, but vehicles of a cultural change from individualistic perceptions of knowledge work towards mediated collaboration.

7.1 Introduction

Knowledge and innovations are essential for the guidance and development of virtually all fields of practice, e.g. policy, business, health, education, and everyday life. The development of current knowledge societies has changed the ways of working with knowledge towards producing and cultivating knowledge in collaboration with different stakeholders and transfer of practices in relation to the advances in knowledge and innovations [Knorr-Cetina, 07]. This societal change also generates challenges to which the ways of conducting knowledge work and the related knowledge services need to answer. A pervasive example of challenges in converging knowledge, innovation and practice is climate change, where advances in climate science and efforts invested in international climate policy fail to result in effective mitigation and adaptation actions [Brunner, 06], [IARU, 09], [IPCC, 07], [Mickwitz, 09]. An example discourse from a scientific Climate Congress (Copenhagen, March 2009) illustrates the reality of contemporary climate science-policy interaction. While the IPCC chair re-stated in his keynote speech that "we in the Intergovernmental Panel on Climate Change do not prescribe any specific action, but action is a must", the keynote speeches by the policy representatives urged the scientific community to "use their expertise to guide policy" [Hedegaard, 09], "provide the necessary knowledge needed to make the necessary decisions" [Sander, 09], and "express the knowledge in a way that has an intended effect" [Ashton, 09]. The conventional models of linking knowledge and action with chain-like mechanistic relationships between two distinct communities do not suffice in addressing the complexity of sustainable development [van Kerkhoff, 06].

As alternative models for knowledge-practice interaction, for example van Kerkhoff and Lebel [van Kerkhoff, 06] suggest regarding knowledge-action relationships as arenas where research-based knowledge and practice interact, but not necessarily in a simple or straightforward manner, and Brunner [Brunner, 06] calls for a pragmatic paradigm for policy practice that i) considers knowledge as intertwined with action, ii) develops context-sensitive practical knowledge, and iii) evaluates knowledge and actions according to their purposes. The relationships between science and policy, research and practice, or assessment and decisions are subjects of intense discussion in current research [Pohjola MV, manuscripta]. These discourses highlight the main points of improvement, but provide only marginal guidance on practical implementation (see also [van Kerkhoff, 06]). For example, while the academic discourse on assessments in environment and health emphasizes the importance of dialogue with stakeholders and public, the assessment practices often remain a monologue of experts, where contact with users, other experts and public is taken only when obligatory [Pohjola MV, manu-

scriptb]. Research to date has fallen short on what it means to manage the boundary between science and policy [McNie, 07].

It appears that the importance of converging knowledge, innovation, and practice as well as its main challenges are identified, but the conceptual and practical means for its implementation are lacking. Suitable knowledge services are needed. It is here argued that such knowledge services must: i) build on solid conceptual understanding about the interrelations between knowledge, innovation, and practice, and ii) possess corresponding functionalities to activate effective interaction between knowledge, innovation and practice. It is fundamental that these two issues are considered as intertwined aspects of the same whole. In the following, we briefly present a trialogical framework as a potential foundation for explicating what is required for such knowledge services. By presenting and discussing three novel knowledge services that implement the trialogical approach, we aim to explicate the practical implications of these requirements for what we call pragmatic knowledge services.

7.2 Knowledge, innovation and practice

Shaping of human activity and practices requires innovations and cultivation and creation of knowledge in collaboration. Integration of plural interests and perspectives is an essential part of these processes. Development of shared practices also requires innovative development and use of technologies as well as creation of new kinds of modes of action. These issues are considered below, particularly in terms of their implications for the development of supporting knowledge services.

7.2.1 Collective knowledge creation

Creation of new knowledge is rarely a cognitive process of a single individual. Typically, cognitive tasks are physically, socially and temporally distributed and the new ideas and hypotheses are often materialized as external artefacts [Paavola, 06]. Approaches to distributed cognition have for long emphasized that inquirers in a search of knowledge are not usually processing things only in their heads, but use various resources from their environment to guide the search for new ideas (see [Hutchins, 95], [Salomon, 93]). Also argumentative processes of producing new hypotheses and ideas, i.e. abductive search for hypotheses, can be considered collaborative rather than happening only in individuals' heads [Paavola, 06]. Abductive inference produces tentative solutions to be worked collaboratively. They can be either applied in practice until better solutions are formulated or as intermediate steps that guide and promote the search for better solutions. In pragmatic knowledge creation process the search for novel ideas can be supported by, and often necessitates, abductive argumentation [Paavola, 09a]. By means of argumentation it is possible to reason why one tentative solution should be considered as superior to others or argue about the types of a preferred solution even before such

solutions are found. Argumentation also functions as a mediator between collaborators.

The central idea deriving from pragmatism, aiming to integrate the issues of knowledge, innovation and practice, is that people through participation "continuously construct and re-construct the social meanings that shape our thoughts and actions" [Simpson, 09, 1333]. This means that knowledge creation is fundamentally a social process and this process is essentially linked with the ways we act and the kinds of practices we create and maintain. Knowledge becomes intertwined with action and especially with social action [Simpson, 09, 1334-6]. Also the tools and artefacts we use as the means of our action are a part of this continuous process of construction and re-construction. Although the idea of the social aspect of knowledge is not new, in current knowledge societies it extends from socially maintained and explicated knowledge also to the means of knowledge construction.

7.2.2 Innovation

In innovations knowledge becomes integrated into action as systematically developed means for practice. The process of innovation relies on application and generation of knowledge aiming to develop something that can be grounded in practice. The outcomes of innovation can be realized in many ways, not only in terms of economical benefits, and the common definition of innovations as commercialized inventions is too narrow and technology-centred. In recent literature, innovation has been described as the multifocal development of social practice [Tuomi, 03]. It has also been argued that the criterion for successful technical innovations is that they become social institutions, i.e. their use becomes rooted in the common everyday practice [Pohjola P, 09]. The ideas concerning systemic innovations [Andersen, 08], open innovations [Chesbrough, 03], and democratized innovations [von Hippel, 05] point out additional challenges for knowledge services to support innovation by highlighting both the importance and complexity of networked innovation activity.

Contemporary investigations on innovation processes imply that they cannot be understood as linear sequences of independent sub-processes, but rather as multidirectional [Pinch, 84] and multifocal [Tuomi, 03]. They are not merely processes carried out by product developers and R&D departments, but require the participation of various groups of stakeholders, from users to different kinds of professionals. For example, innovation in health care, such as new drug treatment for some disease, requires expertise and involvement of various parties: from patients, nurses and doctors to drug developers, directors of health care organizations, legislation etc. It is only in these systems or networks of multiple actors where the innovations become existent. Involvement of these actors in the early stages of multifaceted innovation processes is essential and knowledge services

need to provide support for collective knowledge creation and innovation throughout the whole process, from idea generation to normalization of practices [May, 09].

7.2.3 Trialogical approach to knowledge creation and learning

The "trialogical" approach has been suggested and applied especially in the context of computer-supported collaborative learning (CSCL) as a novel framework for considering the issues of knowledge creation and innovation (see [Hakkarainen, 09], [Lakkala, 09], [Paavola, 09b]. It emphasizes the role of collaborative development and reconstruction of concrete, shared artefacts in mediating knowledge creation, as well as reflecting and transforming knowledge practices, the ways of collaboratively working with knowledge, with supporting processes, and executing knowledge tasks.

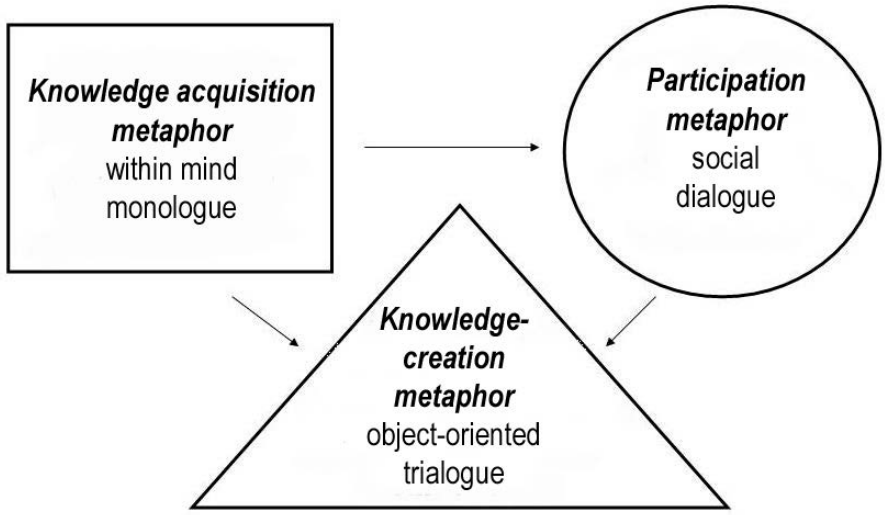

Figure 2. The three metaphors of learning.

A basis for the trialogical approach is an epistemological distinction between three basic metaphors of learning and human cognition associated with monologues, dialogues, and trialogues (figure 1). The monological processes of information sharing and knowledge acquisition, and dialogical processes of learning through communication and participation, are supplemented with knowledge creation as a trialogical process of collaborative development of epistemic artefacts and practices.

Innovative activity from the trialogical perspective means that all relevant parties should become involved in the processes of learning and production of knowledge artefacts. There are various unsuccessful examples of attempts to routinise new technology without appropriate inclusion of relevant users into the development and learning processes (for an example in health technology assessment, see [Edmondson, 01]). The trialogical processes extend to the organization of work around concrete artefacts and practices in addition to mere information sharing or communication.

The trialogical approach has been developed in the context of collaborative learning. We maintain, however, that the explicit linking of knowledge creation with practices (e.g. [Hakkarainen, 09]) and with cognitive processes and artefacts as their products and mediators, the trialogical approach is a viable foundation for the convergence of knowledge, innovation and practice also more generally.

7.2.4 Facilitation of converging knowledge, innovation, and practice

The development of information systems has been dominated by two general approaches: technology-centred development and research, and user-oriented development and research. The former has focused on the systems, applications, and technology for representing, organizing, and manipulating information (and knowledge), while the latter has put its emphasis on the ways of interaction between the users and the system [Pohjola P, 10]. These conventional views are currently challenged e.g. by mass collaboration and the Pragmatic Web.

In the early phases of the web (Web 1.0) the emphasis was on presenting existing information in a syntactically structured way (syntactic web) provided by the HTML markup for representing information in the web for users to browse and search. In the Web 2.0 era, the Semantic Web initiative promoted meaningful description of data by means of ontologies that were intended to provide taxonomies of concepts where meanings and relations between concepts could be defined in a unifying way. The increasing interest towards the Pragmatic Web relates to the limitations of the Syntactic Web and the Semantic Web, for example the limited possibility of describing meanings of signs and symbols. Like in any other use of signs and symbols, their meanings become defined and changed in use and interaction between people (and knowledge systems). Meaning is a social phenomenon.

Investigations regarding the Pragmatic Web have been directed for example to examining how communicative actions within a pragmatic context are performed via Web media. These investigations have analyzed how mutual understanding and commitments to actions can evolve in conversation in knowledge systems that support pragmatic aspects of knowledge [de Moor, 10]. Some Pragmatic Web investigators have also proposed extensions to the Semantic Web, such as enhancing human collaboration with techniques for ontology negotiations and pragmatic

ontology building in communities of practice [Schoop, 06]. It has also been argued that the Pragmatic Web is not merely a knowledge exchange medium; it should be an active knowledge system that supports human interaction and accomplishment of knowledge tasks [Delugach, 06]. Accordingly the Pragmatic Web, as well as any other information system, should be conceived as a hybrid network constituted by both the users and the technology [Pohjola P, 10].

The emergence of wikis and other web-based collaborative software have enabled the development of new kinds of practices for co-producing knowledge in virtual workspaces where masses of people can engage in collaborative work (e.g. [Tapscott, 06], [Noveck, 09]). These means of collaboration and the artefacts they produce have also become interesting objects of research and development [Cress, 08], [von Krogh, 09]. The rise of social media is said to have brought conversation back into the heart of the Internet, but now, in contrast to the early stages of Internet, intricately interlinked with content [de Moor, 10]. Building on what has been discussed above, certain general requirements for knowledge services to facilitate convergence of knowledge, innovation, and practice can be identified. A pragmatic knowledge service should:

- Enable collaborative knowledge creation
- Support development and application of collaborative knowledge practices
- Support practical implementation of knowledge
- Adapt to changing contexts, situations, and purposes

The first requirement is centred on the technical properties of the system that constitute the workspace by which the users engage in collaboration. This may mean e.g. tools and functions for managing shared artefacts and collaboration among plural participants with heterogeneous capabilities, as well as organization of contributions.

The second and third requirements extend more to address also the content of the system in guiding the dynamics of the user collective. The technical properties can also provide support e.g. by re-use of shared artefacts, and tools for discussing, developing, and sharing practices. Relying solely on tools and information provided by the workspace may not, however, be sufficient and also social practices outside or besides the workspace may be relevant.

In a pragmatic setting the issues in creation and use of collective knowledge are contextual and situational and vary from a case to another. Consequently, the technical properties and contents of the workspace, the practices of its use, and the practices of knowledge implementation need to be allowed to adapt through the interactions between the workspace, the user collective and the societal context.

7.3 Three examples of novel knowledge services

The examples, Opasnet, Innovillage, and Knowledge Practice Environment (KPE), represent different perspectives to implementing the trialogical approach in a knowledge service. Opasnet and Innovillage are developed by the National Institute for Health and Welfare (THL) in Finland in collaboration with multiple partners in Finland and Europe. KPE is a development of a multi-partner project where the research work has been coordinated by the University of Helsinki, and the technical development of KPE by Metropolia University of Applied Sciences, Helsinki.

All the examples are described in terms of their a) purpose, b) method, c) system, d) use, and e) contextual fit. Of the three examples, Opasnet and KPE are already existing and functioning knowledge services and described in terms of their current manifestations, while Innovillage is still in its early development and mainly considered according to planned designs.

7.3.1 Opasnet

Opasnet is a web-workspace for producing and providing science-based support for policy making in the field of environment and health. It provides a virtual arena for open collaboration on generating practical solutions to problems of societal relevance. Opasnet aims to improve increased awareness and understanding among both those who make decisions and those who are affected by those decisions. It welcomes decision makers in public policy, industry and commerce, experts of different kinds, as well as civil society organization representatives, consumers, and citizens as active participants in open assessments. Opasnet is developed in the context of environmental health, but its scope of application is intended as extensible in principle to all systematic practice-driven endeavours of collective knowledge creation.

The main principles in organizing open assessments are:

- Assessments create collective knowledge by searching solutions to practical problems by means of science and account of plural values.
- Assessments are endeavours of describing reality as causal networks of interrelated phenomena. Conclusions to guide decisions and actions are drawn based on analyses made over the network. No intentional distortion of information (e.g. going for the worst-case scenario) is accepted.
- Participation in assessments is unlimited. Limiting of openness is allowed only based on well argued cogent reasons. [Pohjola MV, manuscripta]
- Information objects produced in assessments should be freely available for anyone to use and develop further.

- Assessment performance comprises of i) quality of information in relation to the problem addressed, ii) applicability of produced information in its intended use, and iii) efficiency of its production process [Pohjola MV, 10].
- Also methods and tools of open assessment are subject to open critique.

The most distinctive aspect in open assessments is openness. As the issues of environmental health are relevant to virtually anyone, anyone can be a relevant contributor to an environmental health assessment, and the knowledge created in environmental health assessments can be of relevance to anyone. Openness is also seen as an essential aspect of scientific inquiry and to enhance the relevance and applicability of the knowledge created in assessments. On the other hand, it brings about practical challenges for managing assessments.

Opasnet is a collaborative workspace for conducting open assessments. It provides the assessment participants a) the virtual location of and access to the workspace, b) the information available in the workspace, c) a structure for organizing information, and d) tools to aid and guide collaborative production of information within the workspace. Opasnet is located in the open internet (http://en.opasnet.org).

Technically Opasnet consists of a wiki, a database, and a modelling and simulation environment. The main interface between Opasnet and its users is the wiki. It is built on the Mediawiki platform, and many of its basic functions resemble those e.g. in Wikipedia (http://en.wikipedia.org). The database stores numerical information for and from the modelling and simulation environment used for mathematical operations and analysis. They are also essential, as quantitative data and models often form the core of the information produced in environmental health assessments. Collaboration, however, mainly takes place through textual and graphical communication that a wiki supports well. Thereby it is most often adequate that the models, their application, and their results are described and discussed as parts of the assessment, although those actually participating in modelling and analysis would only constitute a small fraction of the collaborators in the assessment as a whole.

The main information content of Opasnet consists of past and on-going assessments and their parts, i.e. variables. In addition there are descriptions of the methods and tools needed in open assessments and other supporting information e.g. about research projects, studies, terminology, lectures etc. The supporting information aims to guide and aid in using the system effectively according to its purpose. The information is structured as wiki pages (figure 2), and related data (in the database) and models (e.g. files for external applications) can also be read or launched from or linked to the wiki pages. Every wiki page also has a related discussion page.

Certain information objects, e.g. assessment and variable have a predefined formal structure; name, scope, definition, and result. The sub-attributes under each attribute vary depending on the object (table 1.). A simple unified information structure is cognitively ergonomic and aids in targeting contributions to relevant locations within the system, and enhances the re-use of previously produced objects.

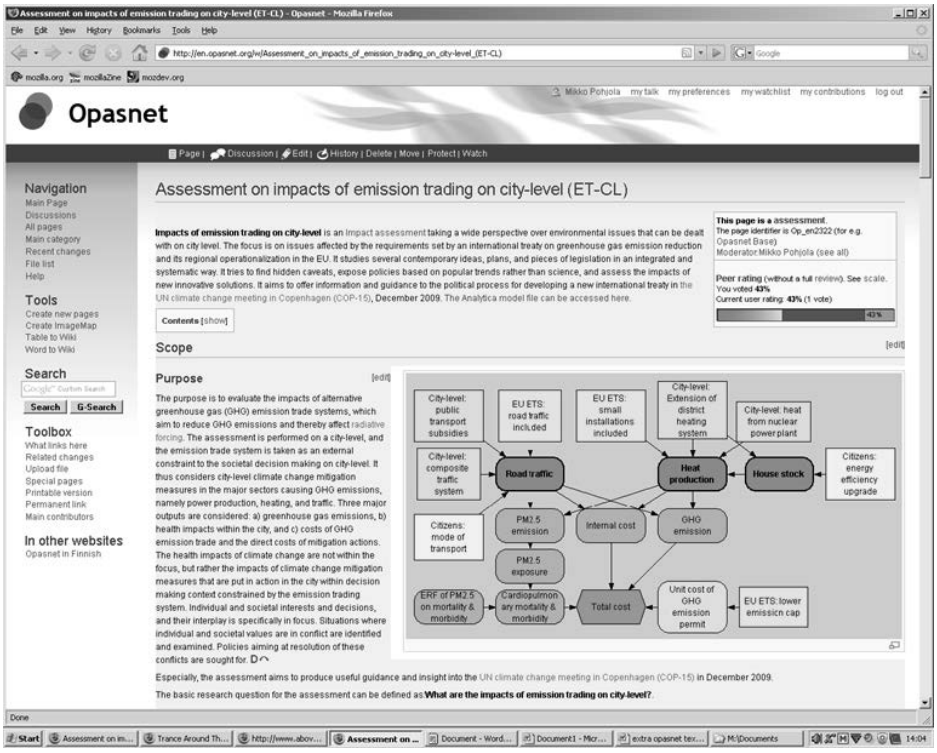

Figure 2. An assessment page in Opasnet.

Most contributions to Opasnet take place in textual or graphical form in the wiki. The ways of contributing are: a) reading existing content, b) commenting of existing content with a page-specific comment box, c) participating to or starting a free discussion on a discussion page, d) participating to or starting a formal argumentation on a discussion page, e) structuring comments and freely formatted discussion fragments into formal argumentation structure on a discussion page, and f) editing contents of a page or creating a new page.

The two first kinds of contribution are possible without logging into the system, but the latter require creating a user account and logging in. Anyone can create an account. Contributions by multiple discussants can be organized on discus-

sion pages according to pragma-dialectical argumentation [van Eemeren, 02]. Argumentation consists of a statement regarding the actual content describing the issue of interest, a hierarchy of arguments either attacking or defending the statement or other arguments, and a resolution. Corresponding templates for discussion structure, attacking argument, defending argument, and (neutral) comment have been implemented as buttons in the edit window of Opasnet. Once a stable resolution has been found, it should be implemented on the content page accordingly. If no single solution can be found, the resolution consists of all views that are still considered valid after the argumentation. Also other comments and discussions should be taken account of when editing the pages.

Table 1. The attributes and sub-attributes of assessment and variable objects.

Attribute	Explanation	Assessment sub-attributes	Variable sub-attributes
Name	A descriptive identifier		
Scope	A question describing the issue(s) of interest	Purpose Boundaries Scenarios Intended use Participants	
Definition	Explains how the question is answered and provides rationale for the answer	Decision variables Indicators Value variables Other variables Analyses Indices	Dependencies Data Unit Formula
Result	The current answer to the question	Results Conclusions	

Opasnet users can also contribute by rating Opasnet pages according to their i) scientific quality and ii) usefulness (see figure 2). The user evaluation provides feedback the contributors to the page and guides other users in perceiving and interpreting the content. Opasnet also has some project managerial functions, e.g. task lists for nominating/suggesting tasks to different users. The users can also volunteer as moderators of wiki pages and the user community is assumed to self-organize to adopt different housekeeping roles as happens e.g. in Wikipedia.

The development of Opasnet started in 2006, and it has been piloted in several assessments in research projects, e.g. a benefit-risk assessment on farmed salmon (http://en.opasnet.org/w/Benefit-risk_assessment_on_farmed_salmon). It begins to be ready for full-scale use, but experiences on broad participation are still limited.

In addition to the main Opasnet site in English, there is a Finnish language version of Opasnet focusing on issues of domestic interest (http://fi.opasnet.org), and a limited access site Heande for use e.g. in research projects or other situations where complete openness of all content is not possible due to different reasons. In the main Opasnet in English there have been more than 300000 visits since Opasnet was opened, and there were more than 2000 individual visitors during 2009. The number of active editors is currently between 20 and 50, and there are nearly 1500 content pages. At the Assessment and Modelling Unit of National Institute of Health and Welfare, the primary developer of the system, Opasnet has gradually become one of the main tools for carrying out everyday work tasks.

Mostly Opasnet has been used by a relatively limited group of scientific experts in environmental health in roles of developing content in the system. Certain assessments, e.g. on a plan to build a municipal solid waste incineration plant in a town in south-west Finland, (http://fi.opasnet.org/fi/Poltto, in Finnish), have also attracted considerable attention by public, mainly as readers, but also as discussants. Serious attempts to involve professional decision makers and other intended users of assessment results into using Opasnet have been rare and results thus far are scarce. Thereby the effectiveness of the approach has not yet been sufficiently demonstrated. However, there are several new research projects that have adopted Opasnet as their collaborative workspace. For future development it will be necessary to attract more practitioners and public to participate in creation, and particularly use, of knowledge.

The most common challenges in using Opasnet appear to relate to: a) finding information, or whether it exists, within the system, b) knowing what one is "allowed" to do within the system, c) overcoming the fear of making mistakes in an open system, d) using the edit-window to make contributions to Opasnet-wiki, e) applying the argumentation format to organize discussions, f) deciding upon the object type and name when creating a new object, g) applying the attribute structures, i) managing relations between related and/or similar objects, j) managing the relations between wiki pages and external models addressing same phenomena, k) uploading data to Opasnet Base, l) creating a real linkage between assessments and their intended use, and m) invoking active collaboration among more than 2-3 individual users on a shared object or set of objects. It appears that the threshold to adopt Opasnet should be lowered and the benefits of using the system need to be better demonstrated. Some of the technical barriers can also be expected to be gradually overcome through the technical development of the Mediawiki platform as well the increasing familiarity among the potential users with collaborative software.

Participation has become a central issue in public policy making upon environmental issues during the last few decades. Participation is addressed e.g. in the Rio Declaration on Environment and Development [UNEP, 92] and the Aarhus

Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters [UNECE, 98], as well as in environmental legislation on different levels. Also the public has become more accustomed to use open information sources to obtain knowledge upon issues of their interests and also to use that knowledge to influence decisions regarding those issues. However, the currently common approaches to environmental health assessment are still relatively conservative and in practice assessments mostly tend to be exclusive rather than open [Pohjola MV, manuscriptb]. Among researchers openness is often met with concerns regarding e.g. reduced quality, loss of credibility, vandalism, and intentional bias.

In this setting Opasnet has been received with apparent interest, but also quite persistent reluctance to adopt it into everyday use. This is probably partly due to underdevelopment of the method and incomplete or complicated properties of the workspace as well as the effort required to become acquainted with the system. Partly it also derives from the conflicts between the principle of open collaboration and the prevailing practices in research as well as policy making. Researchers often fear that operating in an open system hinders, or completely prevents, scientific publications, and thus accumulation of scientific merit. It may also be perceived to lead to the erosion of the traditional expert status. Also professional decision makers may be unwilling in practice to share their power, and the meaningfulness of participation in decision making processes is sometimes questioned by decision makers, stakeholders, and problem owners alike (see e.g. [Inkinen, 07]).

All in all, it still appears that the society at large is gradually moving towards broader acceptance of systems and practices that build on openness and collaboration. One example is the first prize recently awarded to Opasnet in the World Summit Awards Finland competition in the e-government & institutions category (http://www.mindtrek.org/2010/wsa), opening up a chance for Opasnet to participate in the global World Summit Awards in 2011 (http://www.wsis-award.org/).

7.3.2 Innovillage

Innovillage is an environment for the development, assimilation and evaluation of technology and services in the social and health sector. Its central idea is to support open participation in the development processes of social and health care services and to provide a method for evaluating the effectiveness and outcomes of these development processes. It promotes a multifaceted perspective to innovations where all the relevant participants should have a possibility to engage in the innovation process. This means that the participants in a service innovation process can include patients, health or social care professionals, developers, researchers and management. Innovillage provides an approach and tools for innovations

that can overcome the shortcomings of existing approaches, for example, in addressing the local and contextual dependencies of social and health services.

The theoretical background of Innovillage is in multi-perspective view of systemic innovations, founded on the Actor-Network Theory (ANT). Initially, ANT has been developed in science and technology studies (Latour, Callon) and is here extended with the trialogical approach. ANT sees innovations and technology as embedded in a network of both human and non-human actors [Latour, 05], in which the technology and innovations become defined. This nature of innovations (both social and technical) requires that the knowledge service needs to provide support for extracting information about the relevant aspects of development and implementation of a practice. From the trialogial perspective, it is crucial that all relevant members of the network can contribute to a shared object of work and provide their perspectives for the innovation process. Ignoring issues of usability, practical know-how or ethical aspects, not to mention legal or economic issues, can lead to the failure of the innovation process.

For conceptualizing the services and assessing the effectiveness of the services, the developers of Innovillage have developed a Relational Evaluation Approach (REA), a framework for the development and assessment of technology and services in social and health care. The REA is at the heart of Innovillage and it is applied in Innovillage for i) describing the essential components of the service innovation, and ii) assessment of its outcomes in relation to the purposes that the service has been developed for. REA is applied in three stages:

- As a conceptual tool for developing ideas in the early stages of the innovation process, and developing an Implementation Model (IM) for the service.
- Assessment of the implementation process of the service in a certain context (according to the IM).
- Assessment of the longer term effects of the service in relation to the purpose and expected outcomes of the service described in the IM.

When constructing the IM of the service, the REA is applied in describing its central and essential elements as a hypothesis of what is required in order to produce the intended outcomes and to fulfil its defined purpose. The aspects of the REA framework are i) definition of purpose and expected outcomes, ii) a description matrix for more specific characterisation (table 2), and iii) a process-like summary.

In its general form, the description matrix consists of six topics which are described from three perspectives (if necessary): clients', professionals', and organisational perspective. The required level of detail in descriptions depends on the purpose and outcomes of the service. For example, the purpose of a new kind of service for the home care of elderly people could be specified as providing more

quality life years at home, and the outcomes e.g. as maintaining a good quality of life, reducing mental problems from institutionalization, and cost-effectiveness in terms of reduced amount of labour. The characteristic features of the service are detailed in the description matrix e.g. in terms of what kind of professionals are required, what kinds of clients there are, what education is needed, what use of tools is required from the professionals and the clients, and what of organisational prerequisites does the service have. Eventually, the summary describes the processes (actions) that the service is made of, such as daily food delivery, medical examinations etc.

The Implementation Model is used as a conceptual tool or an artefact for communicating the features of the service. It is also the model for implementing the service in different contexts. Each implementation in a certain context naturally has its specific independent features, as the resources and skills of professionals vary between organizations, the clients are not a homogeneous mass, and organizational structures are different. The implementation of the service thus requires tailoring of the general model according to the specifics of the context. Innovillage also provides tools and concepts for specifying the implementation processes and for evaluating both the implementation and the outcomes of the service.

The development work and innovation processes are carried out in a collaborative web-workspace. The REA is built into the system and the collaboration in the web-workspace is structured by its concepts. It provides an environment for the participants to collaborate on specifying the general features as an IM of services in relation to their specified purposes and expected outcomes and assessing existing services according to an IM. These processes are conducted in the system by enabling the users to create projects, create networks with other projects and other tasks to support and enhance collaboration. The IM's and the assessments are shared knowledge artefacts that coordinate the collaborative work. The work carried out within the system is supported with a library of methods for the development and evaluation of health and social services. The workspace also consists of a database of (descriptions of) existing services which can be exploited as templates in the development of a new service. The Innovillage workspace actually has much in common with Opasnet: a collaborative working environment, emphasis on open participation and involvement, aim to combine the expertise of various stakeholders into the development process, and shared objects of development.

The main functionalities for facilitating collaboration are 1) management of projects in which the innovation or assessment processes are conducted, 2) collaborative workspace where the service and its assessment are conceptualized, 3) a network manager for enhanced interprofessional collaboration between different people from different professions, and 4) a search interface, which provides both a professional-type systematic search with specific keywords and a more natural-type of interface for searches (see [Hearst, 09]). The main user group is profes-

sionals who conduct development projects and work in the social and health sector. Other relevant user groups are clients participating in the development of services, managers responsible for the projects, as well as project funders.

Table 2. REA description matrix with some example questions.

Topic of description / perspective	Clients' perspective	Professionals' perspective	Organisational perspective
Tasks and division of labour	What kind of tasks is required from the clients?	What kind of tasks the professionals are required to take? What kind of division of labour is required among the professionals?	What kind of organisational tasks does the service require?
Actors/Agents	What kind of actors do the clients consist of?	What kind of professionals is required in the service?	What kind of organisational actors does the service require?
Tools, skills, knowledge	What kind of knowledge, skills and use of tools does the service presuppose from the clients?	What kind of knowledge, skills and use of tools are required from the professionals?	What kind of knowledge, skills and use of tools are required from the organisational actors?
Rules and principles	What kind of ethical and other rules and norms relate to the clients' activity?	What kind of ethical and other rules regulate the professionals' work?	What kind of ethical and other rules regulate the organisation?
Laws and regulations	How do laws and regulations relate to clients' activities?	What kind of influence do laws and regulations have for professional work?	How do laws and regulations affect the organisational activities?
Economics	What kind of economical resources does the service require from clients?	What kind of effects do the activities of the professionals have on economical resources?	What kind of economical resources are required from the organisation?

In addition to a web-workspace for collaborative development and assessment, the knowledge service also entails support for collaboration and transfer of knowledge and skills within and between networks, such as face-to-face meetings, consultation thematic workshops, and tutoring. Their function is to promote interprofessional working practices and democratic participation by different stake-

holders. It is not presumed that mere technology (as a knowledge service) with its functionalities and affordances could facilitate open and interprofessional innovation processes in an effective way. Instead, the knowledge service should be a combination of technology and other facilitating services and practices.

The Innovillage knowledge service is a combination of open participation and more structured and managed types of work. Rather than relying on the assumption of self-organizing communities as the users of the system [Pohjola P, 10], the system aims at supporting the development of effective working practices that enhance the multifaceted approach to developing novel services. This can be done in the service e.g. by inviting different professional networks into co-development and co-creation of services, the ways of creating an interprofessional network by inviting various stakeholders into a development process or by interacting with other projects and developers.

An example of interprofessional collaboration is the ongoing pilot project within Innovillage where more than ten municipalities in Finland implement a developed and piloted set of five services in social and health care. The services are first described as an Implementation Model by local service development professionals together with a group of forthcoming users and other social and health care professionals. At the second stage, the municipalities create an implementation plan according to the IM's and specific needs of their organisation. During the course of implementation they conduct an assessment of the service and its implementation within their individual contexts. The individual projects involve various stakeholders ranging from managerial level to social workers, nurses as well as health and social service clients. The central participants from different municipalities that work with similar services also come to form a wider interprofessional network within Innovillage.

One central aim in developing Innovillage is to provide support for development and management of working practices. Experiences from the use of knowledge services show that even services with the best functionalities and affordances do not generate collaborative development and innovation activity without motivated and committed practitioners. It has also been noted that the practitioners need to be engaged into knowledge creating processes and be motivated to work for the outcomes of the process (see [Engeström, 08]). Successful collaboration also requires the creation of the ways of working with knowledge, i.e., creating knowledge practices [Hakkarainen, 09]. By providing the support for managing work roles and work tasks, the system aims at supporting the development of effective working practices that can become normalized in the practicing community [May, 09]. This means that the service should enable the practitioners to construct the ways and practices of collaboration both within and outside the system. Facilitation of the socio-technical innovation process of Innovillage requires con-

sideration of the supporting knowledge service as a hybrid system of both technology and its users.

Innovillage has been developed according to the acknowledged need for enhancing the creation and assessment of services in social and health care. Although there is much pep talk for creating more customer-oriented ways of service development, much of existing practices and social structures (funding, organizations, etc.) support project-oriented and professional-driven development processes. An increasing amount of work where clients and client perspectives are more involved is, however, being made. As Innovillage is in a developmental phase, the experiences of contextual fit are still limited. The workspace and the REA are currently being piloted and tutoring and workshops based on REA are only just starting. However, Innovillage builds on an existing system for describing services in social care, so there already are professionals who are familiar with the approach and have previous experiences that support the kind of work that Innovillage promotes. Generally the professionals are also eager to get involved with the new extended approach to describing and assessing services.

The challenges of the Innovillage knowledge service in a national scale relate to a required cultural change in social and health care service innovation. Much development work in the social and health sector is done in individual projects and there is a lot of overlapping work being done. In many cases also the outcome effectiveness of these projects is not properly evaluated. What is required is a change towards increasing and more open distribution of the services developed in the projects and more efforts on the implementation and assessment of these services. Innovillage aims to facilitate this kind of cultural change, but also participation of the multiple stakeholders is required to make it happen.

7.3.3 KPE

Knowledge Practices Environment (KPE) is a virtual environment with a set of integrated tools and functionalities for working with knowledge artefacts, and for planning, organizing and reflecting on related tasks, artefacts and user networks [Markkanen 08], [Lakkala 09]. It is developed in a large, five-year (2006-2011) EU-funded Knowledge-Practices laboratory (KP-Lab) project (see http://www.kp-lab.org/ and http://www.knowledgepractices.info). An explicit goal of the KP-Lab project has been to develop and investigate tools, practices, and models that support collaborative knowledge creation processes and trialogical learning. A basic starting point for the project has been to develop tools to support flexible work and learning with knowledge artefacts and related practices and processes both in educational and working contexts. The focus has been especially in higher education courses where students and teachers collaborate with outside organizations and learn “authentic” project work and knowledge practices. These more regularly

take place in universities of applied sciences, but similar practices have been also investigated in universities.

In the KP-Lab project following design principles have been formulated to characterize the general features of trialogical learning (cf. [Paavola 09b]):

- Organizing activities around shared objects: A central idea of trialogical learning is that work and learning are organized around developing shared, concrete objects, that is, conceptual artefacts (e.g., ideas, plans, models) through concrete, material products (e.g., prototypes, design artefacts) and/or practices (e.g., ways of working in higher education).
- Supporting integration of personal and collective agency and work: People integrate their own personal work and group's practices and resources for developing shared objects, combining participants' expertise and contribution into the shared achievement.
- Emphasizing development and creativity on shared objects through transformations and reflection: Interaction and transformations between tacit knowledge, knowledge practices, and conceptualizations are seen as a driving force in processes of knowledge creation.
- Fostering long-term processes of knowledge advancement with shared objects (artefacts and practices): Trialogical learning requires sustained, long-standing work for the advancement of the objects of inquiry.
- Promoting cross fertilization of various knowledge practices and artefacts across communities and institutions: Knowledge work in KP-Lab engages people in solving complex, authentic problems and producing objects also for purposes outside the educational institution. An essential aspect of the KP-Lab project is hybridization between schooling/studying and research cultures as promoted in various investigative learning practices.
- Providing flexible tools for developing artefacts and practices: Trialogical learning cannot easily be pursued without appropriate technologies that help the participants to create, share and elaborate, reflect and transform knowledge artefacts and practices. Collaborative technologies should provide affordances for trialogical learning processes.

These design principles are quite general, meaning that they could not be implemented straightforwardly to guide the practices and technology development. They have, however, provided broad outlines for characteristics of learning and for the needs required from the mediating tools developed in the KP-Lab project.

KPE is a web-based application providing tools, functionalities and features for sustained collaborative working with shared artefacts, processes, and practices. KPE provides virtual working spaces, called shared spaces, for the collaborative work, enables viewing the knowledge objects and their relations from different perspectives and supports object-bound development of all items in a shared

space. Basic tools and functionalities include, in addition to the common upload, versioning etc. functions, the following: integrated wiki, note editor, commenting, context-based chat, semantic tagging, linking of items allowing also spatial organisation, real-time and history based awareness features, and various analytic tools, among others. The tools and functionalities are highly integrated into the basic views to enable versatile and flexible connection, organization and reflection of all information related to the knowledge objects, processes and people concerned. The role of technology for enhancing trialogical practices is framed by four types of mediation which specify the above mentioned design principles to the general aims of the technology development. These types of mediation are reformulations of the ones introduced by Rabardel and Bourmaud [Rabardel 03], see [Hakkarainen 08], i.e., epistemic, pragmatic, collaborative, and reflective mediation (table 3).

Table 3. Short descriptions of the types of mediation supported by KPE.

Type of mediation	Description
Epistemic mediation	Creating and working with knowledge artefacts. The aim is to give support for users to create, transform and organize shared knowledge artefacts, to support commenting on shared artefacts (object-bound commenting and chat), and development of shared artefacts (drafting and versioning iteratively), as well as sustained use of knowledge artefacts and conceptualizations.
Pragmatic mediation	Organizing and coordinating knowledge-creation processes. The aim is to provide flexible possibilities and support for planning work processes, support for updating and revising the plans, as well as coordinating the collaborative knowledge processes with other practices.
Collaborative mediation	Building and managing networked communities and social relations required for carrying out knowledge-advancement efforts. The aim is to support networking, community building and interaction around shared processes and artefacts as well as interaction across different groups and communities allowing users to lean, learn, share and combine on each others' competencies, expertise and experience.
Reflective mediation	Making visible, reflecting on, and transforming knowledge practices. The aim is to enable users to reflect on their practices (processes), and jointly analyze and developed the practices and processes.

The system is designed to support multimediation by providing a shared knowledge space that facilitates all four modes of mediation and their flexible use. A shared space in KPE can be either a personal space or a collective space. A collective space is created for the knowledge community involved in a trialogical process. Each shared space includes three main views: a Process View, a Content

View and a Community View. The Process View supports time based chronological way of organizing tasks. It is mainly used for projects with explicit tasks and deadlines. The Content View includes all the items that the users have produced, e.g. content-based chat, notes, uploaded files, web-links, wiki-links or Google documents, as well as the tasks (figure 3). The items can be commented, discussed, tagged and linked. The Community View provides a visual presentation of all members of the shared space and textual description of the members contact information, items, action and assigned responsibilities they have. The members can create groups and assign roles to themselves as well as create specific e-mail lists for groups or shared space. The views can also be tailored by users according to their specific needs (Tailored View).

All of the views provide synchronous awareness features, e.g. a lock if someone works on an item, a hand if someone is moving an item, colour-based coding of on-line information, etc. In addition, asynchronous awareness information is provided by means of recent changes, notifications and histories (version lists) of items.

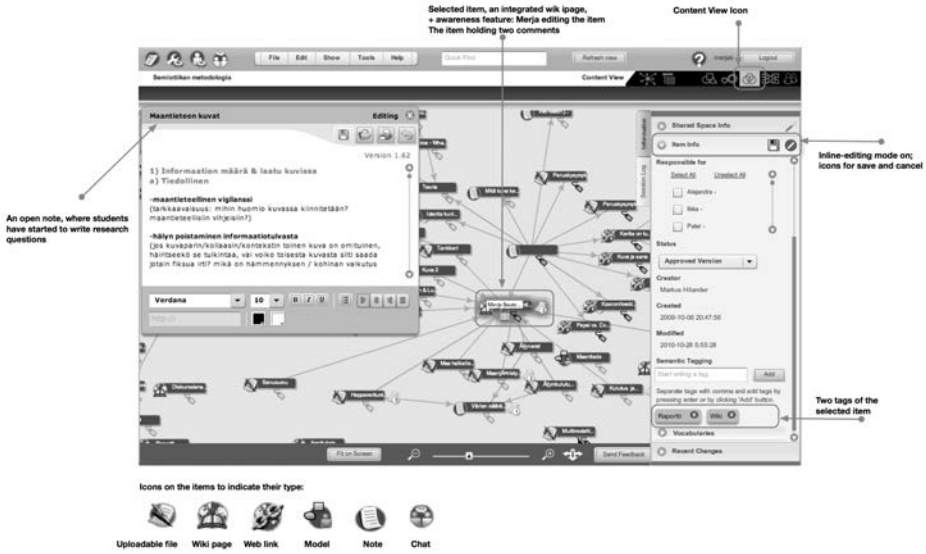

Figure 3. Content View: Items and tasks of a student pair in an example course.

KPE has been developed and investigated in large research cases in higher education courses and projects especially in Finland, Netherlands, Austria, Germany, and Sweden. It has also been used in various smaller courses all over Europe. In the production version of the environment there are 105 shared spaces and in total the amount of registered users is around 1200. At the moment of writing this, the

project is still ongoing, meaning that the system, following the agile development method ideas, is a beta version and has some usability issues to be settled. KPE has provided a test bed, which has amounted to such requirements, that it has not turned out as useful as was expected in the design process. Therefore, some of the functionalities and features need to be simplified and the core functions need to be brought to the front of the user experience. Strong points of KPE have been the possibility to structure and organize the group work in a flexible manner, for example visually and/or non-linearly, to use one platform for various tasks and processes, and to use different tools for various purposes. Some restrictions have been experienced with some tools, e.g. for producing text documents, conferencing, etc., which are not integrated, but users would like to be integrated with KPE. Multimediation, e.g. combining epistemic and pragmatic activities together, is, however, seen as a clear advantage of KPE.

The KP-Lab project challenges existing practices in the higher education. Existing knowledge practices in regular university courses are still more oriented towards individualistic learning. More widely used virtual learning environments, such as Moodle or Blackboard, provide only limited support for collaborative knowledge creation practices, and support more information sharing or work with ready-made tasks provided by teachers. Furthermore, none of the current learning environments combine the spatial, semantic and filtered categorization and organization of knowledge artefacts and practices/tasks in similar holistic manner as KPE does. Courses in universities of applied sciences are more often oriented to learn project work done collaboratively but also there the challenge is to learn more in-depth practices of collaboration. There is a clear need for developing courses and projects aiming to develop tools and practices needed in the modern knowledge work.

7.4 Summary and comparison of examples

The main characteristics of the three example knowledge services are summarized and compared in table 4 according to the general requirements for pragmatic knowledge services identified above. Much of the differences in the approaches can be considered to derive from the different use purposes in their contexts. Despite some differences, all of the examples hold properties related to each of the requirements. Conceptually they also address the essence of the trialogical approach, collaborative development of shared artefacts, in a similar fashion, although the technical implementations vary from one to another.

Table 4. Summary and comparison of the main characteristics of the three example knowledge services.

	Opasnet	Innovillage	KPE
Collaboration	A unified information structure on a Mediawiki platform Method and tool guidance and other information in addition to assessments and variables Assessments described as causal networks of variables A range of contribution options: reading, commenting, discussion, argumentation, and content editing Complete openness as a default	Three structured forms of knowledge objects: Implementation Model (IM), assessment of implementation, assessment of effectiveness Relationships between objects either hierarchical (e.g. belonging to an IM) or other links (e.g. functional similarity indicated by a user) Various ways of creating knowledge objects (e.g. individually, by a group, in open collaboration) All objects can be commented by all users	Content View (knowledge objects), Process view (structuring the process), Community view (group formation), Tailored view (re-arrangement of items) Wiki pages, short text notes, comments, links, object-bound chat histories, or up loadable files Relationships between items as 1) visual or conceptual links, 2) spatial arrangement, or 3) semantic tags Awareness features and recent changes help organising the work flow Brainstorming by light textual note tool and the sketch pad for drawing ideas.
Knowledge practices	Also methods and tools described and developed within Opasnet Previously developed objects reusable as such, as templates, or as examples	Tutoring and workshops to support collaborative ways of working Library of methods for organizing innovation and development projects	Analytic tools for analyzing and visualizing knowledge practices Shared spaces can be used as examples of tool sets, of spatial or semantic organization, or of different tasks structures

	Wiki-practices resemble those in other Mediawiki applications		Previous works of users as examples for new-comers and for re-use
Knowledge implementation	Assessment questions formulated according to practical knowledge needs Intended knowledge users (explicitly intended to be) involved in assessments Recommended decisions or actions described in assessment conclusions	Structured assessment of implementation of new service practices Implementation Model as one of the central elements Professional tutoring for implementation	Participants from different organizations preferred and easily added A space can be all open or restricted depending on the need of the project
Adaptivity	All content subject to change as new knowledge emerges An environment for sharing and integrating information produced either within or outside the system Generic design allows application in collective knowledge creation for all purposes	Knowledge objects are iteratively evaluated; assessments should affect the implementation models Change of experiences and information between different networks working on similar issues User-experiences provides feedback to assessment and models	All knowledge artefacts are changeable Virtual spaces can be re-used or copied The sets of tools can be selected by the users to fit their needs Users can share and adopt-adapt best practices in an integrated collective forum

KPE is a collaborative learning environment making it primarily a service for creating knowledge for its own sake, although not indifferent to the uses of knowledge. The approach in KPE more or less assumes a specified group of users, such as a class or participants of a course, although in principle it does not pose any restrictions to the size of the group. The KPE workspace provides a multitude of tools for flexible use by its users for a broad range of specific purposes.

Opasnet is a knowledge service for creating knowledge to support societal decision making. As such it explicitly includes the intended use of knowledge in its method as well as the workspace implementation. Also the descriptions of methods and tools are explicit objects of collaborative development. Opasnet adopts an extreme approach to openness by allowing unlimited participation, and provides a general structure to guide collaboration, which leaves space for improvised use in collaborative knowledge creation for virtually any purpose.

Innovillage is an innovation environment, which inherently brings the practical implementation of knowledge into the core of the knowledge service. This also results in explicit inclusion of activities of supporting knowledge practices and knowledge implementation outside or besides the workspace in the knowledge service concept. The approach can be characterized as semi-open, as it opens some aspects of the process for unlimited participation, but leaves certain aspects for professional collaboration. Innovillage provides the most rigorous structure for the service, which also makes it most bound to the specific purpose it is primarily developed for. This does not, however, prevent its flexible use within its intended context of use.

All of the examples challenge the prevailing paradigms in their contexts. The basis of the challenge is the same for all; the trialogical approach. The individualistic perceptions of learning and knowledge creation appear as deeply rooted in common practices of all knowledge work, not only education. This appears as resistance to adopt collaborative trialogical knowledge processes, even if their purposes, methods, and practical implementations were in principle welcomed and accepted. It does not, however, undermine the needs to develop the current methods and implementations, but does indicate a need for a simultaneous cultural change.

7.5 Conclusions

The trialogical approach to knowledge creation and learning provides a good framework for considering convergence of knowledge, innovation, and practice, and developing pragmatic knowledge services. Such knowledge services are required to enable collaborative knowledge creation, support development of knowledge practices and practical implementation of knowledge, and adapt to changing needs. They can not be considered as mere information systems, but as

socio-technical hybrids, including also the human actors engaging in creation and use of knowledge.

The theories of knowledge creation and learning, the advances in information systems development, and the three examples of novel knowledge services indicate that the conception of pragmatic knowledge services is feasible. Although experiences from the three examples highlight needs for conceptual and technical improvement in developing effective pragmatic knowledge services, also broader cultural changes regarding knowledge work is needed. The change from individualistic learning and knowledge creation towards trialogical collaboration can be considered as representing the shift from an information society towards a knowledge society. The current and future pragmatic knowledge services are not only means for creation of practical knowledge in their specific contexts of use, but also vehicles of this broader cultural change.

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8 Evaluating effectiveness of open assessments on alternative biofuel sources

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Abstract

Biofuels have raised controversial debate regarding environmental, social and economical aspects and sustainability. The complexity of biofuel decisions and investments by the industry and the society necessitates inclusion of knowledge, information, and opinions from a diversity of sources. Environmental assessments estimate environmental and other impacts of the options before a decision. Open, collaborative knowledge creation can support decisions in two ways: by building trust and credibility, and by developing a more sound knowledge base. Open assessment is a decision support method that allows open participation in assessments with a transparent and freely accessible process. In this paper, we evaluate two open assessment case studies about biodiesel production decisions. The evaluation compiles the views of the participants regarding the potential of the assessments to influence the decisions in terms of quality of content, applicability, and efficiency as well as openness. According to the evaluation, openness can be feasibly implemented and it was much appreciated by the participants. More experiences on broad and active participation are still needed for further development of methods and tools. However, the currently common practices and attitudes for closed and disengaged processes seem to limit open decision support the most. In addition, open collaboration needs to be facilitated by suitable tools and practices as well as participants with sufficient skills for their application for the issues being assessed.

8.1 Introduction

Growing energy demand and greenhouse gas emissions from fossil fuels have increased the interest in the production of renewable energy. Within these biofuels, i.e. liquid or gaseous fuels for transport produced from biomass (EU, 2009), are of special interest. Biofuel production is a fast growing industry and it has received a lot of attention as it is considered e.g. to aid in reducing greenhouse gas (GHG) emissions from the transport sector, decrease the dependence on fossil fuels and contribute to the economic growth of the developing countries (Ryan et al. 2005; Mathews, 2008; Cassman & Liska, 2007). To help to reach the GHG emission reduction goals European Union has set a target to cover at least 10 % of the energy demand of the transport sector with renewable energy resources by 2020 (EU, 2009).

However, the sustainability of the production has been criticized and whether biofuels offer carbon savings depends on how they are produced. Converting native ecosystems to biofuel production can create so called "biofuel carbon debt" and release many times more CO2 comparing with the annual GHG reductions that these biofuels would provide by replacing fossil fuels (Fargione et al. 2008). The use of nitrogen fertilizers in the crop production of commonly used biofuels such as biodiesel from rapeseed and bioethanol from corn, can contribute as much or more to global warming as the combustion of fossil fuels (Crutzen et al. 2008). Additionally the production itself can require more energy input from fossil fuels than can be created (Pimentel & Patzek 2005). Furthermore, many other ethical and environmental issues have been addressed, such as the conflict between biofuel production and the global food security, the use of limited water resources, land ownership and the conflicts between land owners and indigenous territories, competition with grazing wild and domesticated animals and the possible threats to biodiversity and soil fertility (Gomiero et al. 2010, Tilman et al. 2009, Giampetro & Mayumi 2009). Due to the many controversial issues associated with the biofuel production, the sustainability of the production can vary significantly and their use may not be such an easy, and trouble-free solution to climate change as at first might have appeared.

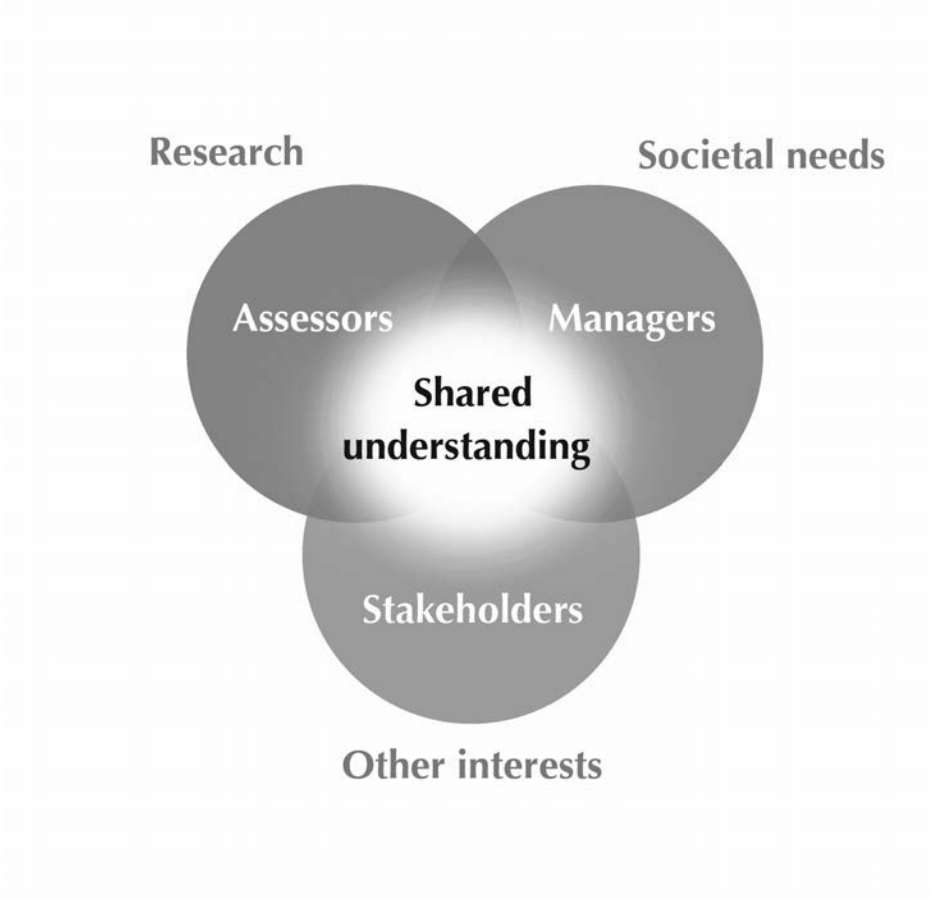

Figure 1. Complex decisions need to take account of multiple needs, interests and sources of knowledge (reproduced from Tijhuis et al. 2012 with permission).

When deciding about new investments in biofuel production and supply, industrial decision makers have to consider a wide range of scientific and non-scientific information that has to do with financial, environmental and social aspects of the production chain. For example, the GHG-emissions as well as other impacts and costs of the production can vary considerably between different raw materials and production sites. In addition, the policies and the views of stakeholders and the public on local, regional and global level pose significant constraints on the biofuel investment decisions.

Public participation and stakeholder involvement in assessment and policy making is built on the ideas of democracy (Fiorino, 1990), and it is seen to enhance acceptance, integrate local knowledge to the scientific information and produce more flexible and transparent decisions (Reed, 2008; van den Hove, 2000).

However, the emphasis of environmental assessment is claimed to often be more on process and procedure, rather than its purpose and effects (Cashmore, 2004; Jay et al. 2007) and only few approaches to assessment actually even explicitly consider assessment performance in terms of the outcomes of using the assessment results in their intended contexts of use (Pohjola et al. 2012, Pohjola et al. manuscript). Correspondingly, although participation is increasingly appreciated as a part of environmental assessment and decision making, its implementations have often concentrated in process and access rather than outcomes (Doelle & Sinclair, 2006).

Open assessment method was created to provide a means for more purpose-driven and effective support to decision making in open collaboration (Pohjola & Tuomisto 2011, Pohjola et al. 2012). It aims to support decision making by means of systematic analysis of different decision options and providing a forum for all involved parties to collect and integrate knowledge and views and thereby influence the decisions. As its name implies, open assessment differs from most common assessment approaches in terms of openness. In principle, everyone is allowed to participate in and contribute to open assessments (Pohjola & Tuomisto 2011). In addition, tight linkage between assessments and the use of their results is seen as a necessity for effectiveness (Pohjola et al. 2012, Pohjola et al. manuscript). Ideally, everything in the process should be transparent and all content subject to open scientific criticism. The method emphasizes substantive content over participatory procedures. This means that the assessors seek all relevant views rather than a set of views expressed by a balanced representative group, and that arguments are evaluated based on how they hold against criticism rather than how many participants support them. In this thinking, there is no need to discriminate participants with vested interests as long as there is a large enough a pool of participants and information sources. As long as the above mentioned fundamental principles (for more detailed list of principles, see Pohjola et al. 2011) are not violated, open assessments can address almost any topics and apply many kinds of methods for assessing impacts, risks, benefits etc. and analyzing decision options. The open collaboration, however, needs to be facilitated by sufficient tools and practices as well as assessment coordinators, which help in converging the knowledge and views of different participants into shared descriptions of the issues being assessed. One essential means for avoiding divergence and vandalism in open assessment is the application of structured discussion (http://en.opasnet.org/w/Discussion) for sorting out irrelevant, unreasoned, or repeated statements when compiling participant contributions.

Open assessments are usually conducted in the Opasnet web-workspace (http://www.opasnet.org, Pohjola et al. 2011), which is particularly designed to host open assessments and contains functionalities that are useful for open assessment. The Opasnet web-workspace is discussed more in the next section. Open

assessment and Opasnet have been developed in several research projects involving both national and international collaboration, e.g. EU-funded INTARESE-, HEIMTSA and BENERIS-projects involving partners from more than 30 European countries. They are currently applied as one of the central assessment tools in Department of Environmental Health of the National Institute for Health and Welfare in Finland (THL). Application examples include EU-funded research project URGENCHE (http://www.urgenche.eu) for developing healthy city-level climate policies in eight cities in Europe and China, Vesiopas (http://fi.opasnet.org/fi/Vesiopas, currently in Finnish only) for online modelling of health effects of microbiological hazards in drinking water in support of the water safety planning in waterworks according to the EU legislation, and Tekaisu-project (http://en.opasnet.org/w/Tekaisu) for developing the use of environmental and health knowledge in municipal policy making in Finland. Currently the Opasnet in English contains in total 2600 pages and more than 30 open assessments with a wide variety of topics (see http://en.opasnet.org/w/Category:Assessments). Most open assessments up to date have addressed issues of environment and health, but the methods and tools are applicable to all practical knowledge support in open collaboration. Correspondingly, most open assessments have thus far been coordinated by THL, but open assessments can be initiated, as well as coordinated, by anyone. Opasnet is located in the open internet and is available for use by anyone.

In this paper we evaluate two open assessment case studies that assessed the feasibility of two alternative biodiesel feedstock, *Jatropha curcas* oil plant (later referred to as Jatropha) and the oil extracted from fish waste by-products from fish farming. The cases were limited to only assessing biodiesel production, not bioalcohol or other forms of bioenergy. The assessments were requested and financed by Neste Oil Corporation and they were performed by THL in the open Opasnet workspace (http://en.opasnet.org). The information produced in the assessment was primarily collected and analyzed in order to support the decision making processes of the primary user (Neste Oil), but at the same time it was also intended to be applicable in societal decision making processes in other situations.

This paper aims to contribute to the development of improved assessment and policy making methods, tools and practices by evaluating the effectiveness of two open assessment cases in terms of their quality of content, applicability, efficiency and openness (Pohjola & Tuomisto 2011, Pohjola et al. manuscript). By effectiveness we fundamentally mean influence of assessment on the outcomes, i.e. changes in values, attitudes, and behaviour in the society (Matthews et al. 2011), but in practice what is possible to evaluate rather reflects the likelihood of an assessment to achieve the desired results and goals set for it (Hokkanen & Kojo, 2003). Open assessment has been developed and argued as a means for overcoming the limitations of effectiveness in science-based decision support (cf. Matthews et al. 2011,

Pohjola & Tuomisto 2011, Pohjola et al. manuscript). Therefore, evaluation of its application is important both to the development of open assessment and Opasnet, but also to the development of science-based decision support in general. Correspondingly, the research questions we sought answers for were:

1. Was open assessment method and the Opasnet workspace feasible means for the assessments?
2. Did they provide means for all participants to influence the assessments?
3. Did the assessments influence the knowledge of the primary users and other participants?
4. Was the applied evaluation approach feasible for evaluating assessment effectiveness?

First, we present the two open assessment case studies, discuss the theory behind our evaluation approach, and describe the implementation of the evaluation. Then we present and discuss the results of evaluation, and ultimately draw conclusions upon their implications to assessment theory and practice.

8.2 Material and methods

8.2.1 Open assessment case studies

Environmental health assessments are typically rather limited in openness (Pohjola et al. 2012), and therefore there is a need for a proof of concept for more open approaches. Many of the previous open assessments by THL had been motivated by scientific rather than practical interests. Therefore, THL was interested in performing this kind of assessments in order to test open assessment in a real-life situation with a clear customer need.

The basic idea behind open assessments is to collect information and create knowledge that is needed for decision making in broad collaboration among participants (Figure 2). The information is organized as an assessment that predicts the impacts of different decision options on some outcomes of interest. Decisions, outcomes, and other issues are modeled as distinct parts that are, in practice, web pages in Opasnet, an open web-workspace dedicated for making these assessments.

In Opasnet, users can collect, synthesize, describe, discuss, and distribute information using a wiki; upload data to a database; upload files; and build and run computational models. The main interface between Opasnet and its users is the wiki. It is built on the Mediawiki platform, and many of its basic functions resemble those e.g. in Wikipedia (http://en.wikipedia.org), but many additional functionalities e.g. for modelling and organization of information have been developed. The wiki provides a forum for the participants to collaborate upon finding

well-founded solutions to practical problems (see Figure 2). Opasnet is located in the open internet. Anyone can read its contents and post comments on its pages. Editing of the pages, however, requires logging into the system. Anyone can create a user account.

Both assessment cases were performed in Opasnet and each part of the assessments (e.g. cultivation of Jatropha, amounts of oil produced from the harvest, or social impacts) were described, discussed and estimated on a separate page in the workspace. Both assessments were done and published in Opasnet in Finnish, but a summary is provided in English (http://en.opasnet.org/w/Biofuel_assessments).

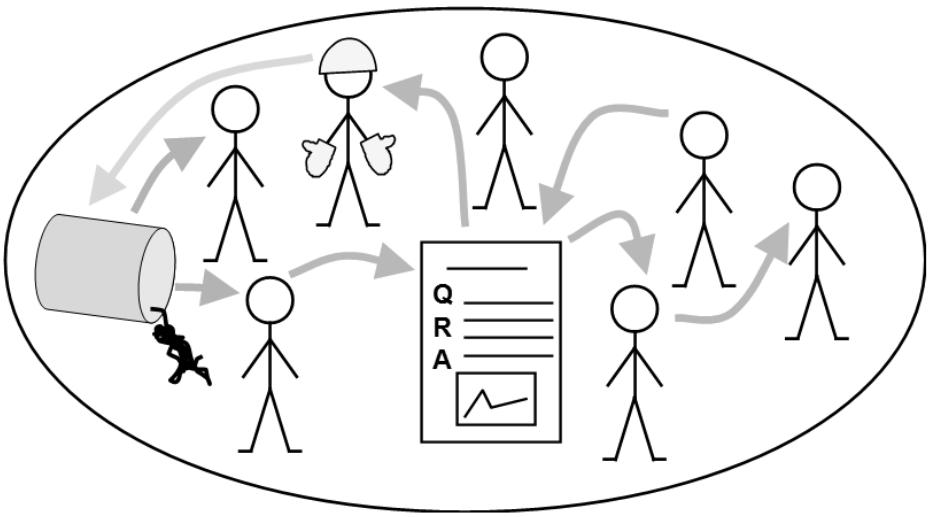

Figure 2. In open assessment, members of a society adopt different roles in relation to identifying needs, making assessments, making decisions, and taking actions. An assessment page in Opasnet has a central role in collecting observations (here of an undesired event, a toxic liquid spill) and spreading information to and from members. Knowledge-based actions are taken to clear up the spill. Reproduced from Pohjola & Tuomisto 2011 with permission.

The two biofuel assessments in question were requested and financed by Neste Oil Corporation (a Finnish refining and marketing company focusing on advanced, cleaner traffic fuels, http://www.nesteoil.com) and they were performed by THL between June 2011 and February 2012. The primary aim of the assessments was to investigate the feasibility of the two potentially interesting alternative raw materials in biodiesel production, Jatropha and waste oil from fish industry. The focus was on the environmental, climate, and social impacts and the acceptance of the production by Finnish stakeholders. The production of biodiesel from waste oil from fish industry was considered to take place in Southeast Asia using local or

regional raw material sources. The location for biodiesel production from Jatropha and origin of raw material was not specified.

Previously, Neste Oil had assessed that palm oil is an ecological and economical alternative to fossil fuels. To their surprise, there was a major outrage and anti-Neste Oil campaign after Neste Oil started fuel production based on palm oil in Singapore in 2010 (http://www.greenpeace.org/finland/en/media/Press-releases/Protest-against-Neste-Oils-palm-oil-diesel/). Therefore, Neste Oil had an interest in understanding how open, participatory assessments would work in practice and seeing whether open assessments could explore the attitudes about certain topics in the society. Jatropha and waste oil from fish industry had already been identified as potential economically and technically feasible raw materials for biodiesel production. As a Finland-based company, Neste Oil was primarily interested in the views of the Finnish stakeholders. However, participants were invited to discuss the issue from a global or local point of view. In addition to producing supporting information to Neste Oil and societal decision makers, the assessments aimed to increase the awareness and knowledge of stakeholders and public on the two new potential alternatives for biofuel sources.

The work started in June 2011. The topics of interest and underlying motivation were clarified in discussions with THL and Neste Oil. Assessments started as exploratory, because no exact assessment questions were given in the beginning. A key interest was to identify potential reasons for not using Jatropha or waste oil from fish industry in biofuel production. In the beginning, more attention was paid to Jatropha, because the first information sources found in the beginning of the work were optimistic about Jatropha cultivation on poor lands. The scoping of the fish oil case was not clarified in the beginning, and the assessment team started by looking at ocean fishing; the current megatrend of depletion of ocean fishery stocks (e.g. Myers & Worm, 2003) was seen as a major obstacle of using waste oil from fish industry in large quantities at least for long periods of time. Only later, the scope was redirected by Neste Oil to South East fish farming.

The assessments were performed by a group of assessment coordinators (a group of four of environmental scientists, open assessment experts, and modellers). In addition seven university or high school students worked as summer trainees doing most of the practical work in the assessments. The coordinators were not experts in Jatropha, fish industry, or fuel distillation, but the focus was on environmental issues and attitudes. Neste Oil participated in the assessments as the primary user of their results and contributed mostly in assessment scoping. In addition, a group of stakeholders was invited to contribute to any parts of the assessments. As the assessments were conducted as open assessments, it was possible for also anyone else to participate.

Most of the assessment work was done between June and August 2011. The information sources included both scientific and non-scientific journal articles and

web pages. The results were summarised on wiki pages of the Opasnet assessment workspace (numerically when possible) and used as parts of the computational models built for the assessments. Uncertainties were described as probabilities handled by Monte Carlo simulation algorithms. The models, coded in an open source R language, were built in the same web workspace as all the text content, and they can be read and run by anyone directly from the web pages.

In September 2011, THL and Neste Oil organised a meeting where the draft results were presented and discussed. It had been found out that Jatropha is actually not a very productive plant unless cultivated on rich land, possibly leading to land use competition with food crops. In contrast, waste oil from fish industry turned out to be more interesting, especially when Neste Oil wanted to focus on large fish farming industry in Southeast Asia. This stimulated a period of new data collection. Key findings are presented in http://en.opasnet.org/w/Biofuel_assessments.

Assessment coordinators contacted stakeholder groups in October and November 2011 and invited them to participate. Participation intended i) to inform stakeholders about the assessments and their results, ii) to help in collecting further information and iii) to get a comprehensive picture of different stakeholder's views. Altogether 18 stakeholders including 3 energy companies, a human rights organization, 5 environmental organizations, 10 researchers, research centres or expert organisations (detailed list at http://en.opasnet.org/w/Biofuel_assessments) were invited to collaborate by commenting on the existing assessment and introducing possible lacking information. Feedback was received from six groups or individuals. All the process took place in a wiki-based internet page where anyone could comment.

The stakeholders were asked to comment on the assessments and to argue whether from their point of view it was feasible to invest in Jatropha or waste oil from fish industry as feedstock for biodiesel production. All feedback was included in the assessments in the form of formal argumentation and relevant page contents. Conclusions were updated when warranted. A few new aspects were raised (e.g. about the role of EU climate policies), but the main conclusions of the study did not change due to the feedback.

The main conclusion about Jatropha was that it might be useful in small-scale fuel oil production, especially if the plant has other simultaneous uses such as prevention of erosion, but not in large-scale industry. The main conclusion about waste oil from fish industry was that it is a promising source and seems to be available in large enough quantities at least in Southeast Asia, but ecologically it has dual impacts and the balance is uncertain: it reduces the side stream of fish industry waste, but it may stimulate the primary process of fish farming and its potentially harmful impacts.

In February 2012, the assessments had reached a sufficient degree of maturity. The website and a small seminar were the final products for Neste Oil. Finally, all

participants (Neste Oil, stakeholders, summer trainees, and coordinators) were asked to evaluate the final output and the making of the assessments. The evaluation is described in more detail below.

8.3 Assessment effectiveness

While the assessments were conducted according to an approach allowing open participation via a web-based assessment workspace throughout the assessments, also a novel approach to evaluating effectiveness of assessment was adopted. This approach is based on the frameworks *Properties of good assessment* and *Dimensions of openness* recently developed in the EU-funded INTARESE (Integrated Assessment of Health Risks of Environmental Stressors in Europe) and BENERIS (Benefit–Risk Asessment of Food: An iterative Value- of-Information approach) projects, and it considers assessment effectiveness in terms of quality of content, applicability, efficiency and openness (Pohjola & Tuomisto 2011, Tuomisto & Pohjola 2007). The actual objects of interest in evaluating effectiveness of assessments are the changes they provoke (Matthews et al. 2011), but as it would require follow-up and post-hoc analysis, such evaluation would provide little guidance on the assessment in question. Therefore the evaluation approach adopted here focuses on identifying the potential of the assessment to serve its explicated purposes (cf. Hokkanen & Kojo 2003), and thereby providing guidance already to the design and execution phases of the assessment. Simultaneously it also creates a basis for possible post-hoc analyses effectiveness that address the realization of that potential. It should be noted, however, that in the case study assessments discussed in this paper the evaluation of assessment effectiveness was done only after the delivery of results, not so much as an intrinsic part of conducting the assessment.

In this study, two separate frameworks were utilized for the evaluation of the effectiveness and performance of the assessment. The first framework, called *dimensions of openness* (Pohjola & Tuomisto, 2011) was designed as a tool for characterizing the approaches and settings of supporting decision making by means of science-based analysis and participation. It considers the possibilities and constraints for assessors and participants to influence the decisions and consequent actions in terms of:

- **Scope of participation**, Who are allowed to participate in the process?
- **Access to information**, What information about the issue is made available to participants?
- **Timing of openness**, When are participants invited or allowed to participate?
- **Scope of contribution**, To which aspects of the issue are participants invited or allowed to contribute?
- **Impact of contribution**, How much are participant contributions allowed to have influence on the outcomes? In other words, how much weight is given to participant contributions?

In this study, the framework "dimensions of openness" was primarily applied to evaluate the effectiveness of participation by characterizing the possibilities of the invited stakeholders to influence the assessment as well as the decisions and actions of the primary user (Neste Oil) through the assessment. It should be noted, however, that the framework itself is not limited to considering only external participation, but all activities in assessment-policy interaction.

The second framework (*the properties of good assessment* -framework) was designed as a tool for evaluating and managing performance of models and assessments, particularly in the context of environment and health (Tuomisto & Pohjola 2007) considers the potential of the processes and outputs of assessments to meet their explicated purposes and influence the decision processes and consequential actions that they address in terms of their i) quality of content, ii) applicability, and iii) efficiency (Table 1). The first version of the framework was published in 2007 (Tuomisto & Pohjola 2007) and it has recently been updated (http://en.opasnet.org/w/Properties_of_good_assessment). In this study we applied a slightly simplified version (Table 1.), particularly emphasizing the properties characterizing applicability, as the basis for the participant evaluation questionnaires.

In Table 1, the description column provides a general explanation of the meaning of each category or property. The question column then attempts to explicate what is intended by the description by providing sample questions that could be asked in evaluating a model or assessment in terms of that category or property. The category quality of content characterizes the information content in the assessment output. The properties under applicability characterize both the output and the process according to their capability of delivering the information content to the intended use. Attributes under efficiency characterize how much output is delivered with the spent effort.

The two above described frameworks, dimensions of openness and properties of good assessment, overlap most apparently in relation to the properties under the applicability category. For example, have the needs of different participants been taken account of in scoping and question setting of the assessment (relevance), to

what extent is it possible for different participants to contribute to assessment (availability), is assessment content comprehensible to all participants (usability), and are there possibilities to participate to an acceptable degree (acceptability). The focus in this study are, however, in evaluating the potential of participatory influence to assessment and the potential of the assessment to influence its primary users as well as other participants.

Table 1. A simplified version of the properties of good assessment as applied as a basis for the evaluation questionnaire for the participants of the biofuel assessment.

Category	Description	Questions
Quality of content	Specificity, exactness and correctness of information. Correspondence between questions and answers.	How many possible worlds does the answer rule out? How few possible interpretations are there for the answer? How close is the answer to reality or real value? How completely does the answer address the assessment question? Is everything addressed? Is something unnecessary?
Applicability	*Relevance*: Correspondence between output and its intended use	How well does the information provided by the assessment serve the needs of the users? Is the assessment question good in relation to the purpose of the assessment?
	Availability: Accessibility of the output to users in terms of e.g. time, location, extent of information, extent of users.	Is the information provided by the assessment available when, where and to who is needed?
	Usability: Potential of the information in the output to generate understanding among its user(s) about the topic of assessment.	Can the users perceive and comprehend the information provided by the assessment? Does users' understanding increase about the assessed issue?
	Acceptability: Potential of the output being accepted by its users. Fundamentally a matter of its making	Are the assessment result (output), and the way it is obtained and delivered for use, perceived as acceptable by the users?
Efficiency	Resource expenditure of producing the assessment output either in one assessment or in a series of assessments.	How much effort is spent in the making of an assessment? If another (somewhat similar) assessment were made, how much (less) effort would be needed?

8.3.1 Evaluation of assessment effectiveness

After completion of the assessments and delivery of results to the primary user, all participants were contacted again and asked to evaluate the performance of the assessments by completing evaluation questionnaires based on the properties of good assessment and dimensions of openness -frameworks described above (see http://en.opasnet.org/w/Talk:Biofuel_assessments for the questionnaires). To get a comprehensive feedback of the assessments, the questionnaires were sent to the representatives of the primary user (3), invited stakeholders (19) and summer trainees (7) as well as the assessment coordinators at THL (4).

Due to different roles and perspectives adopted, the questionnaires were slightly modified for each participating group (see also Table 2). The question 1 on inclusion of stakeholder contributions was targeted only to stakeholder representatives, questions 2-6, addressing quality of content and applicability of assessment, were targeted to all groups, and question 7 on assessment efficiency only to the primary users (see http://en.opasnet.org/w/Talk:Biofuel_assessments for questionnaire). Respondents were free to choose which questions they provided their answers to, and some respondents left some questions unanswered e.g. due to not feeling capable or willing to evaluate those aspects of the assessments. Both assessments (Jatropha and the fish oil cases) were evaluated together, but so that the respondents were allowed to provide differing numerical values or comments on each assessment if needed. For each question, the respondents were asked to provide a numerical integer value between the range 1-5 (1 meaning bad and 5 meaning good). In addition, textual comments were asked to accompany the numerical values.

We received in total 12 responses (38 % response rate). Three of these were from primary users, four from stakeholders (one with only textual comments), two from summer trainees, and three from assessment coordinators. Although the number of responses was low, the group of respondents can be considered as representative of those participants who were actively involved in and contributed to the assessments. With such a small data set it was not, however, meaningfully possible to conduct proper statistical analyses for the numerical data. Therefore, only the characteristics, including number of respondents (N), range from lowest to highest score, as well as arithmetic mean (Mean), of the numerical data for each question are presented in this article. In addition, the averages for questions 3-6 (applicability) and questions 1-7 (effectiveness) were calculated using all existing values and omitting missing values. For those interested, the results of some statistical tests are at http://en.opasnet.org/w/Talk:Biofuel_assessments#Analyses.

The characteristics of the numerical data can only be considered as providing some indication of possible variation between evaluations of different properties and by different respondents. Instead, the focus of evaluation is on the textual comments provided with the numerical responses. These are scrutinized along

with informal communications during the assessments, subjective experiences among the assessment coordinators, as well as the indications based on numerical results in the next section as an overall evaluation of the assessment effectiveness in these two cases.

8.4 Results

The characteristics of the numerical results of the evaluations asked from all participants provide some indication of possible variation between evaluations of different properties and by different respondents. The characteristics of the numerical data are presented in Table 2.

Table 2. Characteristics of the numerical data from the evaluation questionnaires.

Question type	Question	N	Mean (Range)
Influence of participation (stakeholders only)	1. Are stakeholder comments included well in assessment?	2	3 (3-3)
Quality of content	2. Is assessment question answered accurately, truthlikely and comprehensively?	10	3.7 (3-4)
Applicability	3. Relevance: Does assessment serve well your (organization's) knowledge needs?	9	3.44 (1-4)
	4. Availability: Has assessment content reached you (your organization)?	7	3.29 (1-5)
	5. Usability: Has assessment influenced your understanding on the assessed issues?	11	3.55 (1-5)
	6. Acceptability: Was assessment made in a good and acceptable way?	9	4.22 (3-5)
	Questions 3-6 average	11	3.59 (1.00-5.00)
Efficiency (Primary users only)	7. How good is assessment output given the resources used?	3	4.67 (4-5)
Effectiveness	Questions 1-7 average	11	3.72 (1.80-4.70)

On a general level, the numerical results can be interpreted to indicate that the participants evaluated the assessments at least moderately effective across all questions. Looking at the data it seems that the external participants, i.e. users and stakeholders, would be slightly more critical in their evaluation than the internal participants, i.e. summer trainees and assessment coordinators, regarding some questions. The data is, however too small for reliably testing this with statistical

analysis (see http://en.opasnet.org/w/Talk:Biofuel_assessments#Analyses). These findings are applied as complementary to the analysis of textual comments from respondents discussed below in terms of openness, quality of content, applicability and efficiency.

8.4.1 Openness

In theory, everyone was allowed to participate in the biofuel assessments. In practice the active participation was mainly reduced to the three representatives of the user (from Neste Oil) initiating and following the assessment, the seven summer trainees doing most of the assessment work, the four coordinators guiding the assessment work, and the eighteen stakeholders that were invited to participate and out of which six actually contributed to the assessment. The webpage statistics, however, show that there was also some passive participation in the assessment, meaning that outside of the group of the active participants some people were reading the wiki pages of the assessment, but not contributing to the content of the pages.

The web pages of the two assessments were downloaded 9403 times in total between June 2011 and June 2012. This made the biofuel assessments one of the most popular assessments in Opasnet. A download was counted every time someone loaded a page for reading, and when someone saved contributions on a page. Most of the downloads were made by the coordinators and the summer trainees, as implied by the 5673 downloads already during the active work period in June - August 2011. There are no detailed statistics about who was actually downloading the pages, but time-wise statistics imply that there was also a lot of activity from outside the contributor group during the commenting period in November - February (2422 downloads). The number was clearly lower earlier, during the updating period (730 downloads) and after the commenting period (578 downloads).

The number of downloads suggest that there was clear activity related to the assessments, and the information produced was indeed absorbed by a fair group of interested people. On the other hand, biofuels are a hot topic that is of interest to a much larger group than what was reached. In a sense, the potential of informing people was larger than what actually was realised, probably because marketing of the results was not set as a high priority and the related activities were modest.

The assessments were performed in the Opasnet website and all the information in the assessment pages was available not only to all active participants, but also to anyone interested throughout the assessment. All contributions were added on the assessment pages even if they had been provided via other means of communication than the Opasnet wiki. However, along the course of assessments it became apparent that the users did not openly reveal all the information they had regarding the assessed topics nor their interests, which had effects both on the process and the output of the assessments. It is also difficult to estimate how much

relevant knowledge possessed by the invited persons may have been left out of the assessments due to unwillingness to participate, technical difficulties of contribution and other reasons.

In principle it was possible to follow and contribute to the progress of the assessments continuously via the assessment pages in the Opasnet workspace. The assessments developed rapidly between June and August 2011 as a result of the work by the summer trainees, and at a slower rate until February 2012 mainly as a result of the work by the assessment coordinators. The stakeholders were contacted only after some months of assessment work, when the assessments were already in quite comprehensive form, and most of the stakeholder contributions were given in reaction to this request. The contributions of the users were mostly given via meetings or discussions between them and the assessment coordinators regarding initiation, intermediate checkpoint and delivery of assessment results. Only a few *spontaneous* contributions were made by the stakeholders and users outside these somewhat formal contribution periods.

All participants, and in fact anyone, were allowed to comment and contribute to all parts of the assessment, except for the assessment questions that were discussed between the users and coordinators. All contributions were compiled in Opasnet and integrated in the assessment. Stakeholder comments were listed on corresponding assessment pages in the form of formal argumentation (see http://en.opasnet.org/w/Talk:Biofuel_assessments for examples) and relevant page contents and conclusions were updated accordingly when needed. Because most stakeholder participants were unfamiliar with working with wikis, many contributions were provided by more conventional means, e.g. by e-mail or through discussion, and added to corresponding Opasnet pages by the assessment coordinators. However, this probably did not limit the contents of the contributions or which aspects they addressed.

Altogether, all types of contributions were allowed to influence the assessment content. However, one stakeholder representative expressed her slight dissatisfaction in the evaluation about the fact that her point regarding use of fish waste in biogas production did not result in updating of the assessment scope, although the point was agreed to be relevant. The discussion was, however, included in the assessment.

At this point it is not easy to estimate what impact that the assessment, and all contributions to it, has on the decisions and actions of the user. However, the assessments did not link directly to any on-going decision process. In addition, the evaluation comments indicate that the assessments confirmed rather than changed the understanding about the assessed topics among the users. The influence on practical decisions and actions most likely remained at best moderate.

8.4.2 Quality of content

The quality of the assessment outputs were considered relatively good by the participants. Particularly, the inclusion of various aspects of the production chain in the assessment was appreciated. In addition, the comments provided by stakeholders had only little impact on the output of the assessment as most of the provided information was already found in the assessments, which can be seen as an indication of their comprehensiveness. However, the assessment questions were originally formulated as too vague and thereby difficult to be answered accurately. The questions were clarified during the assessment, but eventually also many issues that were out of the scope of the final questions were addressed. In addition, the reliability of the information produced was criticized by some of the participants due to the information sources used, as not all the data of accurate, up-to-date information was available.

8.4.3 Applicability

The applicability in general was evaluated as relatively good by the participants, but some variation between questions as well as respondents can be seen.

As regards relevance, the phrasing of the original research questions was too vague to provide users with the information they were looking for. That was partly because the used approach was new for the users and they did not succeed in expressing their needs very clearly from the beginning. Eventually, after the research questions were specified, both of the assessments succeeded relatively well in fulfilling the users' needs in terms of describing the feasibility of Jatropha and waste oil from fish farming as biofuel feedstock. Also learning about the open assessment methodology was appreciated both by the users and the stakeholders.

Although the assessments were performed in the Opasnet environment and were freely accessible to anyone interested throughout the assessments, the users did not evaluate them as having reached their target participants very well. This is probably mainly due to the limited active participation in the assessments. However, as mentioned above, the web page statistics indicate that the assessments did reach some people (readers) also outside the group of active participants.

Aspects of usability seemed to split the opinions among participants most clearly. While the users and the stakeholders mostly saw that the assessments had little or no influence on their understanding of the topics, those mostly involved in making the assessment, i.e. summer trainees and coordinators, saw them as very enlightening. This could be interpreted so that the users and the active stakeholders were already very familiar with the topics that were assessed, while the summer trainees and coordinators were not. In addition, some of the stakeholders found the Opasnet workspace difficult to use, which limited or even prevented their active participation.

Acceptability of the assessments and the way they were performed was considered good by the participants. The openness of the process was especially appreciated, as was also mentioned above. Within the questions on applicability the greatest agreement between respondents was about acceptability.

8.4.4 Efficiency

The efficiency was considered good according to the users, although it must be noted that the number of respondents was only three. In addition, it was interesting to see that the work by a relatively small group of non-experts, the seven summer trainees, could result in such good quality assessments in a reasonably short time. However, as pointed out by one of the user representatives, efficiency also depends on how much active participants can be attracted in assessments. Due to the similarity of the two assessments, they both benefited from each other because there were many variables that were possible to develop simultaneously for both assessments. Even though the assessments are not active anymore, their information remains in the Opasnet workspace, and it can be easily accessed and used by anyone, e.g. in future assessments on related topics.

8.4.5 Effectiveness

The questionnaire results and other feedback indicate moderate success of the assessments in the eyes of the participants. Indeed, when considering the assessments only as processes of answer seeking and information producing, this is probably a correct interpretation. In addition, it probably gives a fair characterization of the potential of the assessments and the methods they applied in delivering that information to use. However, as was discussed already above in relation to openness, in practice the assessment effectiveness in terms of practical decision support did not achieve much of its potential.

If we consider the effects as changes in the knowledge in the members of the society and the decisions and actions influenced by this knowledge, it is hard to see that these assessments have changed or will change the world much, even if their contents were of good quality and their making efficient and credible. Based on the evaluation, two specific aspects behind the gap between potential and realization can be pointed out. First, the mere possibility for unlimited continuous participation did not result in broad and active collaboration. Second, the active and open involvement of the users is crucial for obtaining meaningful assessment outputs and creating a true linkage between the assessment and use of its results. Both of these aspects are relevant for the development of assessment methods and tools, but particularly for the development of collaborative practices for creation and use of knowledge. It is not enough that the methods and tools allow for openness and deep engagement, if the assessment participants choose to act according to the

traditional closed and disengaged models of participation, assessment and decision making (cf. Pohjola & Tuomisto 2011, Pohjola et al. 2011).

The more or less positive evaluation in these example cases of limited participation is not a sufficient proof for the goodness of open assessment method and the usefulness of the Opasnet workspace. Experiences with broader collaboration and deeper engagement are needed. However, neither does the evaluation indicate that the method and the workspace would not be functional. Despite some difficulties, the approach enabled the assessments to fulfill the objectives set for them, and the openness of the process was particularly appreciated. Although some participants faced some difficulties in using the Opasnet workspace, inclusion of all contributions worked well because of the technical assistance given by the coordinators. Also the transparency and the possibility to criticize all the steps of the assessment process make open assessment a method worth consideration. After all, the effectiveness of typical assessments and models is usually not any better (Pohjola et al. 2011, Matthews et al. 2011, Pohjola et al. manuscript). By means of open assessment and Opasnet, all the assessment information at least remains openly accessible for anyone in the internet for free possible further use. This increases the potential for effectiveness.

The open assessment method and Opasnet workspace provided functional means and tools to work openly and transparently and to involve various stakeholders in the assessment process. However, the realization of broad, active and continuous collaboration among plural participants remained far from its potential in the two biofuel assessment cases. This was mainly due to the active involvement of both users and stakeholders remaining relatively low.

8.4.6 Evaluation approach

Also the applied evaluation approach, based on the dimensions of openness and properties of good assessment frameworks, was shown to be usable for evaluating assessment effectiveness. Despite the recognized limitation that it emphasizes the potential for effectiveness rather than actual changes influenced by assessments, it still provides a more comprehensive and meaningful characterization of the aspects that contribute to assessment effectiveness (cf. Pohjola et al. 2011, Matthews et al. 2011, Pohjola et al. manuscript). It also helps to illuminate the strengths, weaknesses and points of improvement, and provides support to conveying the assessment information to its intended use. However, this evaluation exercise was done only after the assessments were completed, and the capabilities of this approach to aid design and execution of assessments was not sufficiently tested here.

8.5 Conclusions

The possibility to participate and to influence the decision-making processes regarding environmental and health issues is an important matter for stakeholders and the public in general. In this paper we presented two environmental open assessment cases, where openness was implemented as a principal characteristic of the procedure. Based on the evaluation it can be concluded that:

1. Open assessment method and the Opasnet workspace are feasible means for performing assessments and providing decision support, at least regarding topics such as those considered in the two case studies. Experiences on broader and more active participation are needed to guide their further development.
2. Participants in the two case studies considered that they had good possibilities to contribute to the assessments. In fact, open assessment and the Opasnet workspace provided all assessment participants more means for contributing to assessments than they were willing, capable, or ready to make use of. Contradictingly this may have prevented some participants from contributing.
3. The assessment cases did not have a great influence on the users and other participants, except for the learning about the assessed topics among the summer trainees and coordinators, who were the people mostly involved in making the assessment. This was mostly due to a weak link between the assessment and its use, in other words weak involvement of the users. More active engagement of the users would have been needed to realize the potential of the assessments in terms of effectively supporting practical decision making.
4. The evaluation approach applied in evaluating the two assessment cases was shown to be feasible for evaluating effectiveness of assessments and decision support in general. However, the small number of responses to the evaluation questionnaires did not allow for proper application of statistical analysis within the evaluation framework..

On a general level, it can be said that functional methods and tools allowing for openness and effectiveness in assessment already exist. It seems that an open approach is also much appreciated. The currently common practices and attitudes adapted for closed and disengaged processes, however, still seem to limit the effective application of open collaboration in practical science-based decision support. In addition, room still exists for improving the user-friendliness of Opasnet and other tools for collaborative assessment. Also existence of sufficient skills and knowledge for coordination, particularly compiling participant contributions into clear shared descriptions, is important for the success of open assessments.

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9 Discussion

The previous chapters have explored the traditions of and future insights in environmental health assessment as well as other fields of assessment relevant to environment and health. The considerations have addressed several aspects of environmental health assessment including assessment-policy relationship as well as the roles of participation, modelling and information systems in serving the purpose of assessments, i.e. producing and providing scientifically sound knowledge support to societal decision making. The aim of this work has been to identify the essential characteristics that either enable or delimit environmental health assessments in serving their purpose, i.e. being effective. The main findings are summarized and discussed here.

9.1 Environmental health assessment as collaborative learning

By considering the contents of previous chapters from an epistemological point of view, environmental health assessments can be characterized as means to ends (von Wright, 1963) and their information outputs as intentional artefacts (Hughes 2009), where the intention is to influence the end of health and well-being through societal decisions and actions. As such, assessments can take the form of ex ante, ex tempore, ex nunc as well as ex post evaluation of policies (cf. Hänninen and Junnila 2012, Pope et al. 2004). The knowledge about environment-health relationships and the actions to influence them are thus tightly interconnected in the idea of environmental health assessment. However, as was shown in previous chapters, surprisingly often this idea is all but missing in the currently common practice of environmental health assessment. In some approaches, such as the so-called Red Book risk assessment (NRC 1983), the disengagement is even considered as one of the cornerstones of assessment.

The interconnectedness of knowledge and action also means that the intended uses and use plans of assessment results and communication thereof are essential in the design and making as well as the application of environmental health assessments (cf. Vermaas and Houkes 2006, Houkes 2006, Franssen 2006). Environmental health assessment cannot be considered only as communication of results from environmental health research to policy making or the public. Identification of purpose and meaningful contextualization according to a practical assessment problem is required.

However, considering environmental health assessment as mere information production about environment-health relationships is not sufficient either. It should rather be perceived as an endeavour of collective learning regarding desir-

able actions that influence the environment-health relationships in order to help dealing with them. In essence, environmental health assessment is intentional development of shared belief systems (cf. Hilpinen 1995) among those to whom these environmental health-relationships are of relevance. Effective environmental health assessment thus necessitates collaboration between environmental health experts and relevant decision makers, but also those affected by or otherwise interested in the issues at hand. In addition, an arena for such a collaboration to take place, as well as means to guide the collaboration towards practical solutions, is needed.

The idea of social learning has been brought up also previously in discourses on public participation in assessment and policy. It has, however, been often considered mostly in the sense of educating stakeholders and the public to better understand the recommendations by experts and decisions by policy makers (e.g. Steyart et al. 2007, Webler 1995), than in terms of equipping policy makers with knowledge to be applied in decisions and actions (cf. Sanderson 2002). Altogether, the idea of learning has had little effect on the methods, tools, and practices of assessment and policy making, as well as the assessment-policy-public interaction in practice.

If aiming for effective science-based support to practical decision making in environmental health, the principles of scientific knowledge creation should be applied also in the exploration of problems and the search for solutions to them, not only in the underlying analysis of environment-health relationships. This calls for openness, transparency and broad collaboration in environmental health assessment.

Altogether, the essence of environmental health assessment can be described by means of an analogy with the pragmatic children's logic presented in the introduction: The scientific characterizations of the relationships between environment and health by environmental health experts get their meaning from their practical application in the decisions and actions that influence health and well-being in the society. In short, assessments are to change the world. The fundamental and practical purposes cannot be neglected in the practice and development of environmental health assessment. Instead, they should be explicitly recognized and implemented along the whole chain from scientific research to societal outcomes in order for the knowledge obtained through research to effectively influence the world. Assessments and their interactions with policy need to be designed starting from the purposes and knowledge needs of decision making and managed so that they become satisfied (see figure 2 in chapter 6).

9.2 Implications to science-policy interaction in general

The above considerations are not specific only to assessment and decision making regarding environmental health, but are generalizable and applicable to virtually

all application of knowledge in policy as well as other practical decision making. Similar characteristics and challenges as discussed in previous chapters can easily be identified e.g. in the discourses on science-policy interfaces as well as evidence-based policy.

On global scale, the science-policy interaction has traditionally been based on the idea of producing scientific assessments in expert bodies such as the Intergovernmental Panel on Climate Change (IPCC) and pushing the knowledge to policy and public. In order to overcome the limitations identified in the effectiveness of such efforts, improved policy relevance of scientific assessments as well as the underlying research has been called for (Perrings et al. 2011). However, this alone has been claimed as insufficient as it overlooks the reality and needs of policy making and neglects often important non-scientific local knowledge (Briggs & Knight 2012, Hulme et al. 2011). Altogether, the progress of the discourse resembles closely what was discussed in previous chapters regarding environmental health assessment.

Evidence-based policy has been a subject of remarkable interest for more than a decade, but it has recently become a hot topic in Finland. In evaluations of policy effectiveness, it has been identified that the demand and supply of information do not meet optimally, and both the policy relevance of research and the use of research results in policy making need to be improved (Lankinen et al. 2012, Junnila 2012). Correspondingly, it has been investigated that the municipalities in Finland can be characterized at best only modestly active in applying impact assessments to support municipality-level decision making (Kauppinen 2012). Interestingly, however, the main mechanisms recently suggested to promote the strengthening of the evidence-base of policies are a comprehensive reform of sectoral state research institutes and state research funding (Lankinen et al. 2012, Junnila 2012) as well as enhanced education of science communication within doctoral programs (Treuthardt and Nuutinen 2012). Similar indirect efforts attempting to address the challenges in the use of science-based knowledge in decision making have been common also in the context of environmental health assessment as was discussed in the previous chapters. However, as the history of environmental health assessment shows, such attempts alone have not been sufficient for resolving the challenges in effective provision and use of knowledge in policy making.

Generally it is desired that policies are based on sound knowledge and reasoning, but it may be questioned whether the applied means and the attempts to improve them really serve their purposes. In the end the most of the discourses addressing interaction between science and policy on different levels and within different contexts seem to boil down to calling for "better knowledge input" to policy as well as different kinds of bodies or arrangements to provide such input. Little emphasis is put on the practices of making use of the knowledge inputs in

the policy processes. Correspondingly, much of the work dealing with knowledge and policy focus on the production of knowledge (Jones 2009), and the role of policy making is typically delimited to at most creating a demand to drive the so called policy relevant assessments and research.

On the other hand, it is also often reminded that science-based knowledge is only one (minor?) input among all other inputs to societal decision making (e.g. Briggs & Knight, 2012, Krohn & Wilskman 2012). Altogether, science and policy remain perceived as distinct entities (van Egmond et al. 2011) and the effective practices of obtaining and using knowledge in policy making are not paid any more attention than in the discourses on environmental health assessment (cf. Potter and Harries 2006, Almeida and Báscolo 2006). In fact, it appears that environmental health assessment could be considered as a forerunner in developing methods and tools for science-based support to policy making. The emphasis in the development of environmental health assessment is shifting towards design, management and facilitation of effective practices in intertwined production and use of knowledge as an essential part of policy making, and it looks like the other branches of science-policy interaction should follow.

9.3 Implementation in practice?

How can such assessment-policy interaction be realized? After all, environmental health assessment, as suggested above, may sound very idealistic. However, its implementation is for the most part already possible in practice, as has been indicated by the development and application of open assessment and Opasnet (see also http://en.opasnet.org/w/Category:Assessments for more assessment examples in Opasnet). On the other hand, it must be noted that the experiences from practical implementation of these ideas, methods, and tools in intimate interaction with policy making and broad public participation are still limited. It should also be reminded that open assessment and Opasnet are only examples attempting to apply the ideas of effective environmental health assessment discussed above. Their functionalities and practices are thus inevitably imperfect, yet developing, manifestations of the ideas. Correspondingly, this thesis presents a conceptual basis for effective environmental health assessment, as well as science-policy interaction in general, rather than a ready solution for its implementation.

Despite the limitations in the currently common methods and practices of environmental health assessment, there already exists a lot of potential in the emerging assessment approaches. In addition, the development of digital networks and the rise of the social media have prepared the society for open production and sharing of knowledge during the last decades. Consequently, the knowledge supply side of the assessment-policy interaction can be considered to be in a relatively good order as regards practical implementation. Correspondingly, it appears that the greatest bottleneck for effectiveness of environmental health assessment is in poli-

cy making, the knowledge demand side. Particularly the commonly adopted practices of obtaining and using existing and available knowledge in decision making do not seem to make use of the knowledge supply by experts as well as non-experts. As a result, the best available knowledge does not become properly embedded in decisions, their implementations, and outcomes.

However, also encouraging examples exist, indicating that effective science-policy interaction is possible. For example, in the context of evidence-based health policy in the Netherlands, it has been possible to demonstrate productive interaction between researchers and policy makers in co-production of research and health policy (van Egmond et al. 2011, Bekker et al. 2010). This has required learning and adapting to each other's needs from both policy makers as users of knowledge and researchers as suppliers of knowledge (van Egmond et al. 2011) as well as intentional blurring of the boundary between science and policy. In addition, such co-production of research and policy does not just happen, but explicit coordination as well as mediating infrastructures is needed for its realization (Bekker et al. 2010). However, knowledge can only effectively contribute to the policy making process, if policy makers and researchers together negotiate available evidence and interpret its value for policy making (Bekker et al. 2010).

The characteristics of effective practices in the Dutch science-policy interaction are close to what is proposed for environmental health assessment in this thesis. They also resemble the conceptual basis of the on-going Tekaisu-project (http://en.opasnet.org/w/Tekaisu, Pohjola et al. 2012) for developing knowledge-based municipality-level decision making in Finland, particularly addressing impacts to environment and health. From a theoretical perspective, the main aims of the Tekaisu-project are to design and implement effective and sustainable practices for collaborative needs-driven decision support as well as evaluation and management of decision making over the whole chain from knowledge creation to societal outcomes.

What is necessary to realize in implementation of such practices for effective environmental health assessment and policy, is that they necessitate acceptance and involvement of not only environmental health and other experts in charge of assessments, but also policy makers on different levels of governance as well as the members of society at large. In fact, a broad cultural change is needed. Fundamentally the question is only about ensuring the existence of well-reasoned and applicable knowledge where and when practical decisions and actions take place. However, in the current situation, where many common practices and attitudes are based on separation of experts, lay-people, and policy makers as well as withholding of knowledge, there are many practical limitations to implementing practices that build on openness, transparency and collaboration. If, and when, these ideas become implemented in everyday assessment-policy interaction, it can be considered a comprehensive reform of knowledge practices in policy making.

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10 Conclusions

As answers to the research questions in chapter 2, it can be concluded that:

1. In principle, environmental health assessment is development and delivery of knowledge, not mere information, to the processes where decisions and actions that have influence on environment and health are made. The purpose is to enhance health and well-being in the society.
2. There are many approaches to environmental health assessment, but they share the idea of providing support to decision making on societally relevant issues. The common practices based on physical, organizational or intellectual separation of assessment and policy are insufficient for serving the needs of practical decision making. Consequently, societal decisions on issues of environment and health are often unoptimal and not based on best existing and available knowledge.
3. Environmental health policy making based on best available knowledge requires tight and transparent linkage of assessment and decision making, inclusion of all relevant stakeholders, practical problem framing, and application of the scientific methods of knowledge creation also in exploration of problems and development of solutions, not only in analysis of the underlying environmental health phenomena. Effectiveness of assessments and policy making must be evaluated and managed across the whole chain from obtaining knowledge to the outcomes of decisions and their implementation.
4. An outcome-oriented turn is already taking place in the development and practice of environmental health assessment. The methods and tools of collaborative knowledge creation already enable pragmatic openness in environmental health assessment. The development of digital networks and the social media have prepared the society for open production and sharing of knowledge. What is still needed is a broad cultural change from disengagement and withholding of knowledge towards openness, transparency and collaboration for effective environmental health assessment and policy. The focus of future development shall be set particularly on developing practices of effective use of knowledge in policy making. Also the knowledge and experience available in social and political sciences shall be incorporated in this development more profoundly.

These conclusions apply primarily to environmental health assessment, but are also generalizable to the interaction between science and policy in general.