Project no: **022936**
Project acronym: **Beneris**
Project title: **Benefit-risk assessment for food:**
                      an iterative value-of-information approach

Instrument: STP – Specific Targeted Project

Periodic Activity Report

Third project report (D41)

<u>Revision 2</u>

(Without comments and replies)

Due date of deliverable: **1 April, 2009**
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Duration: **3,5 years**

Organisation name of the lead contractor for this deliverable:
National Institute for Health and Welfare – THL (Jouni Tuomisto)

CONTENTS

Publishable Executive Summary

Beneris

Project acronym: Beneris

Project full title: Benefit-risk assessment for food: an iterative value-of-information approach

Contract no: 022936

Related to other Contract no: 022957/QALIBRA

Project duration: 1 April 2006 - 30 September 2009

Reporting period: **1 April 2008 - 31 March 2009**

Project objectives

The general objective of this project is to **create a framework for handling complicated benefit-risk situations**, and apply it for analysis of the benefits and risks of certain foods. The first food commodity to be used in the development of the methodology is fish. Some of the detailed objectives that are relevant for the second year are listed below.

Objectives in developing benefit-risk analysis methods

- To develop Bayesian belief networks (BBN) to handle complicated benefit-risk situations, and to develop a decision support system (DSS) based on BBN.

- To develop improved methods for dose-response assessment, combining epidemiological and toxicological data, and apply them in combining epidemiological and toxicological information on fish contaminants (esp. dioxins and PCBs).

- To develop an integrated repository of surveillance, nutrient and food consumption data that is capable of receiving, analyzing, and disseminating the accumulated data for benefit-risk analysis and to key stakeholders.

Scientific objectives in food risks and benefits

- To estimate average nutrient intakes and food consumption in various subgroups based on national registries in three countries and to explore the use of the data in benefit-risk analysis.

- To estimate the health benefits of fish, and understand the effect of fish on different population subgroups (age, health, pregnancy etc.)

- To establish the association between external dose (intake) and internal dose (concentrations in the body) by analysing contaminants (PCDD/Fs, PCBs, PBDEs, organotin compounds, PCNs and Hg/methyl-Hg) from 100-200 placentas.

- To find out the effects of certain policy options on dietary habits and on intake of important nutrients and contaminants (e.g. vitamin D, n-3 fatty acids, dioxins, PCBs).

As an example, does a restrictive recommendation on fish eating increase meat consumption?

Objectives in dissemination

- To integrate results into updated benefit-risk assessments, and evaluate the remaining uncertainties and their importance for decision-making.

- To develop an internet interface for publishing risk assessment results.

- To develop a method to publish entire benefit-risk models over the Internet using XML.

- To disseminate the results and to evaluate the relevance and usefulness of the work done in the project from the perspective of an end-user / authority.

Participants

Participant role	Partic. no.	Participant name	Participant short name	Country
Coordinator	1	National Institute for Health and Welfare (formerly: National Public Health Institute)	THL (formerly: KTL)	FI
Contractor	2	Delft University of Technology	TUDelft	NL
Contractor	3	Oy Foodfiles Ltd	FFiles	FI
Contractor	4	Food Safety Authority of Ireland	FSAI	IE
Contractor	5	National Food Institute / Technical University of Denmark	DTU	DK
Contractor	6	Food Safety Authority of Denmark	FVST	DK
Contractor	7	Lendac Ltd	Lendac	IE
Contractor	8	Fundación Privada para la Investigación Nutricional	FIN	ES

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Public website for the project: http://www.beneris.eu
See also: http://en.opasnet.org

Work performed

The work with benefit-risk analysis methods has taken a very challenging task: to develop completely new approach to benefit-risk assessment. This work has been done in close collaboration with Intarese and some other projects about environmental health risk assessment. The new approach is based on three principles: openness during all phases of the assessment work; strict application of scientific criticism in all parts of the assessment; and an information structure enabling reusability of information directly in other assessments. These principles affect the work performed, the structure and content of the report produced, and the mere philosophy of doing assessments.

Beneris has developed and applied Bayesian belief networks (BBNs) in describing the benefits and risks. There are also issues about proper tools of calculating and presenting the results of a BBN. Beneris has also actively worked on developing BBN software that assists decision-making, handles any continuous variables and allows for functional relations between BBN nodes.

Results achieved so far and expected end results

The core of a new benefit-risk assessment method has been developed and is now being published. A website (http://en.opasnet.org) for performing benefit-risk assessments is up and running, and several assessment case studies are under way, also outside Beneris. The website is designed for assessments that are performed openly, allowing also for stakeholder participation. There is a database to be used as an integrated repository for assessment information. The work has produced practical experience on this kind of collaborative work and, and this experience has been used to develop the benefit-risk assessment methods further.

Intentions for use and impact

The methods and tools developed in Beneris are offered to other projects, or real-life benefit-risk assessments. The website is available for this purpose. Several projects have already started to use the website for their own work: Intarese, Heimtsa, and Hiwate (funded by EU); Claih, Bioher, and Hitea (funded by the Academy of Finland); and a few current applications or projects that will start soon have adopted the use of the website: Plantibra (EU application about risks and benefits of plant extracts) and Bepraribean (risks and benefits of food). We hope that it will become a place where several assessors are able to share their information and work collaboratively, thus producing better assessments.

The main elements of the publishable results and the plan for using and disseminating the knowledge

The main products of Beneris are the improved methodology for benefit-risk assessments, the website (called Opasnet) for performing them in a collaborative way, and the integrated repository (called Opasnet Base) containing ready-to-use information needed in assessments. Interested assessors will be identified and recruited for working with their own assessments using the website. These practical real-life examples will be a major method for disseminating the results of Beneris.

An example of a benefit-risk analysis performed in the project website with the Internet tools: Benefit-risk assessment of methyl mercury and omega-3 fatty acids in fish.

Section 1 - Project objectives and major achievements during the reporting period

The general objective of this project is to create a framework for handling complicated benefit-risk situations, and apply it for analysis of the benefits and risks of certain foods. The first food commodity to be used in the development of the methodology is fish.

The specific objectives of this project, and the progress related to them are described below.

Objectives in developing benefit-risk analysis methods

The exact objectives in the Description of work are:

- To develop Bayesian belief networks (BBN) to handle complicated benefit-risk situations, and to develop a decision support system (DSS) based on BBN.

- To develop improved methods for dose-response assessment, combining epidemiological and toxicological data, and apply them in combining epidemiological and toxicological information on fish contaminants (esp. dioxins and PCBs).

- To develop an integrated repository of surveillance, nutrient and food consumption data that is capable of receiving, analyzing, and disseminating the accumulated data for benefit-risk analysis and to key stakeholders.

The progress during the reporting period is described under these three bullet points. In addition, general progress with a new benefit-risk approach is described first.

Progress during the reporting period

New approach

The work with benefit-risk analysis (BRA) methods has taken a very challenging task: to develop completely new approach to risk assessment. This work has been done in close collaboration with Intarese project, which is about environmental health risk assessment. Together, Beneris and Intarese have identified several new areas that should be developed on top of the traditional risk assessment, to make it better tackle with the new challenges of benefit-risk assessment of food. These areas deal with fundamental properties of benefit-risk assessment, and its basic content. The areas are 1) purpose and properties of a benefit-risk assessment; 2) causality; 3) collective structured learning; 4) value judgements; 5) variable structure; 6) collaborative work; and 7) dealing with disputes.

During this reporting period, we understood a fundamental property of assessments. Our original idea was that the assessments should consist of two kinds of objects: one kind describing scientific issues, and the other kind describing value judgements. We thought that these two kinds need to be kept strictly separately. Now we understand that also value judgements are scientific issues with research questions like this: "What are the true values of the society S about the issue X?" This has major implications on the work, because now all the rules and practices that used to apply only to scientific issues, also apply to value judgements. This makes the whole system easier, more transparent, and subject to scientific criticism.

BBN methods

Beneris has further developed statistical methods that are useful in benefit-risk assessment. This work has been about using Bayesian belief networks (BBNs) in describing the benefits and risks. There are also issues about proper tools of calculating and presenting the results of a BBN. Beneris has also actively worked on developing BBN software that assists decision-making, handles any continuous variables and allows for functional relations between BBN nodes. The BBN work has been lead by TUDelft in collaboration with other partners.

During this reporting period, TU Delft has been working on improving the Bayesian belief network (BBN) software UNINET including among others software performance and graphical interface. Beneris has also further developed practices for describing Uninet models in Opasnet.

Improved dose-responses

One methodological aim was to develop improved methods for dose-response assessment. During this reporting period, the Taylor's expansion as the dose-response method was applied in the fish case study.

TU Delft has continued its work on methodological issues regarding case-control studies raised during the second year of the project. One of the regression models used to estimate the relative risk based on epidemiological data is the Cox proportional hazard model. It is known that the omission of pertinent covariates from the Cox model causes biased estimates of the model parameters. This implies that the estimates of the relative risk are biased as well. During past few months TU Delft has developed a new approach for estimating regression coefficients of the Cox model. In contrast to the maximum partial likelihood method this approach allows to express the bias in the estimates of the coefficients caused by omission of covariates in a closed analytical form. This gives an opportunity to study and explore the properties of the omission bias analytically.

Intergrated repository (Opasnet Base)

The major development during this reporting period has been on the integrated data repository, which is now called the Opasnet Base. The idea of an integrated repository of data has been under active development. The overall structure for the repositoroy has been developed. The structure has been developed in close collaboration with Intarese project, and there has been remarkable improvement since the start of Beneris. The main findings are described on the Opasnet website (http://en.opasnet.org/w/Opasnet_base and http://en.opasnet.org/w/Opasnet_Base_structure). The most notable developments are 1) Interfaces for the website and the modelling software (Uninet, Analytica); and 2) Interfaces for data exchange between Opasnet Base and the modelling software.

The second version (with an improved and more flexible structure) of Opasnet Base (data repository) was launched. This clearly improved the usability of the database, making its structure very flexible for all kinds of data. This was a specific objective of the development.

The interface for downloading data from the new version was developed. The interface development was a major effort during the third year and took longer than expected. Therefore, a lot of the actual data uploading is still waiting to happen. However, the first data

were uploaded to the repository, and the functionality of the database was demonstrated in several meetings.

Methods to link assessments in Opasnet and data in Opasnet Base were developed. This makes it possible to save effort in the user interface of the Opasnet Base, as it will mainly be used through the Opasnet website anyway. This is a more natural structuring of the information, and Opasnet already has a user interface with many useful functionalities.

Scientific objectives in food risks and benefits

The exact objectives in the Description of work are:

- To review the existing databases and their availability for chemical contaminant data in Europe, and integrate available data.

- To estimate average nutrient intakes and food consumption in various subgroups based on national registries in three countries and to explore the use of the data in benefit-risk analysis.

- To estimate the health benefits of fish, and understand the effect of fish on different population subgroups (age, health, pregnancy etc.)

- To establish the association between external dose (intake) and internal dose (concentrations in the body) by analysing contaminants (PCDD/Fs, PCBs, PBDEs, organotin compounds, PCNs and Hg/methyl-Hg) from 100-200 placentas.

- To combine existing and new data from food consumption databases with data on levels of contaminants in fish. The special emphasis is on children and the developing foetus.

- To estimate distributions of nutrient intake and food consumption relevant to benefit-risk analysis in a number of populations, and also the variability in exposure among various subgroups in the population.

- To identify food consumption patterns and food choices that determine the intake of those nutrients and contaminants that are related to benefit/risk-balance of a food item.

- To explore the usability of these patterns in another country than in which they were developed.

- To find out the effects of certain policy options on dietary habits and on intake of important nutrients and contaminants (e.g. vitamin D, n-3 fatty acids, dioxins, PCBs). As an example, does a restrictive recommendation on fish eating increase meat consumption?

Progress during the reporting period

Existing databases

As described in previous reports, the SafeFoods and other experience lead to the conclusions that the collection of data for benefit-risk analyses should be designed so that there is special emphasis on the applicability and simplicity of the data. This has been put into action in the structure of the integrated repository (see above). We have identified the key information that

is needed in the repository. This includes the list of food items and fish species the consumption of which will be collected into the repository. The data has been obtained from all participating Beneris countries as planned. The data processing and the upload of the data to the database is ongoing.This work has waited for the updates of the structure of the Opasnet Base.

There was a discussion about which data should be uploaded into the Opasnet Base. The conclusion was that the database will be as open as possible, not limiting to fish data or even food. Any data relevant for assessments related to environment, health, or other issues can be uploaded. In addition, the database has now been opened for both modelled results of assessments and original data from studies. This approach hopefully encourages researchers to join forces and gradually make the data sharing the default.

<u>Nutrient intake data and comparison</u>

Based on the food data received, the analyses are ongoing to transform the data into a format suitable for uploading in the Opasnet Base. This work will last until the end of the project. The comparative analyses of nutrient intake patterns will begin after the data has been uploaded to the database.

Specific tasks related to food and nutrient intake data include collection of data from Spain (related to WP4) , mercury and fatty acid data from Ireland, and analysis of food intake patterns in Finland. Intake estimate methods for contaminants were developed and applied (D29, D30).

<u>Contamination research</u>

The large task of chemical analysis of 130 placenta samples were finalised and statistical analyses started during this reporting period. However, the preliminary results showed no correlation between mother's diet and pollutant concentration in placenta (which was used as the marker for fetal exposure). Therefore, further chemical analyses were started, and they will be finalised during the fourth year. A manuscript about these issues has been produced during this reporting period, and it will be finalised and submitted during the fourth year.

In addition, statistical analyses based on the pollutant concentration studies were performed, and intakes of contaminants per age and sex were analysed.

<u>Risk-benefit analyses</u>

The full Bayesian belief network (BBN) model has been developed, and the data collection for the model has practically come to an end by the end of the reporting period.

Objectives in dissemination

The exact objectives in the Description of work are:

- To integrate results into updated benefit-risk assessments, and evaluate the remaining uncertainties and their importance for decision-making.

- To evaluate the integration methodology by all partners and develop it further.

- To develop an internet interface for publishing risk assessment results.

- To develop a method to publish entire benefit-risk models over the Internet using XML.

- To develop methods to collect feedback from end-users about benefit-risk analyses.

- To enhance the availability of existing databases through this interface.

- To disseminate the results and to evaluate the relevance and usefulness of the work done in the project from the perspective of an end-user / authority.

Progress during the reporting period

Overall, the dissemination activities are scheduled in the mid-term and end of the project. There has been four streams of activities here:

- The Beneris wesite and an open assessment Opasnet website were utilised.

- Open assessment workshop

- Tools to publish models in the Internet have been developed.

- A full benefit-risk analysis (case 1: fish) has been started in the Internet.

The Beneris website

There are three websites that are used in Beneris. First, the Beneris website (www.beneris.eu) provides public access to the Beneris project. The importance of this website has decreased during the project. Therefore, a decision was made to move all the contents to the newer website Opasnet, which is used by several projects. Second, a closed project website has been used for benefit-risk assessment work. Model details have beed described and discussed there, and proprietary data have been uploaded and analysed there. The different model versions can be downloaded from there. This way, all partners in Beneris have access to the most up-to-date information within the project. During the Final project meeting it was decided to merge this website with the password-protected area of Opasnet. This way, it is possible to share information with other projects before the information is published in scientific journals. Third, some parts of the work had been opened to an openly available website Opasnet (http://en.opasnet.org) during the second year.. More material has been produced there during this reporting period. In addition, many methods have been described there, making it easier to start new assessments on the website.

Open assessment workshop

The methods and tools developed in Beneris were disseminated in a workshop organised in Kuopio, Finland, February 16-20, 2009. This was a joint event together with Intarese, and it was open to anyone interested.

Tools to publish models

The tools to publish models are directly linked to the overall method development (Workpackage 1). The main achievements are described there, and here we only focus on the dissemination aspects. We have developed an Internet interface in collaboration with Intarese project. The system to publish models has three major parts. First, the interface makes it possible to describe the contents and results of benefit-risk analyses, and enable stakeholders to bring up related issues and concerns. This interface looks and feels like Wikipedia. Second, the detailed assessment models can be downloaded from the file managemen system and run on user's own computer. In addition, it is possible to upload models to the server in such a way that anyone can run the models simply by using a web browser. The beneris assessments

will be uploaded there for public use during the last reporting period. Third, the Opasnet Base offers a possibility to upload model results. These can then be directly used by policy-makers, stakeholders, or researchers. All of the functionalities described are now functional and they have been tested during the reportin period. Practical experience from endusers will occur during the last period.

<u>Dissemination of benefit-risk analysis of fish</u>

The fish case study has been used as an example for dissemination activities and methods. There is a published article on this (Leino et al., 2008). The results of the study have been disseminated in a press conference in Helsinki (Seminar on the environment and health of the Baltic Sea, April 1st, 2009).

Recommendations from the Mid-term Review relevant for this period, and actions taken by Beneris

"Methodological advances in the specific area of risk-benefit are much needed. Particular attention is deserved by aspects that are unique to risk-benefit assessments."

> Disability-adjusted life years is a major method to combine risks and benefits. BENERIS will apply and develop DALYs (disability-adjusted life years) and develop tools for practical use. The work has continued in collaboration with INTARESE, and the DALY model is ready for pilot use in the projects. Beneris has actively sought users for the model also outside the developer group, e.g. from Harvard University.

"Technical cooperation with QALIBRA should be improved."

> BENERIS has developed the open assessment website, and it is available for other projects – including QALIBRA – to be used. Beneris participated in a Qalibra meeting, describing the new functionalities.

"QALIBRA and BENERIS should work together and use a single repository of surveillance."

> The single repository was developed and tested. It is now in small-scale production use. This work was done in collaboration with HEIMTSA.

"The share data base should be used for cross validation of methods."

> Based on the discussions with QALIBRA and BENERIS, the cross validation was abandoned because it would have caused remarkable additional technical work (e.g. adjusting data formatting) without a clear benefit.

"The partners should interact more with the Science Advisory Panel (SAP). They should be informed on the progress of the work, and the outputs of the project."

> The SAP interaction works best when there are some practical results to be shown and clear questions related to the progress. Beneris has only recently come to a phase where all the tools are functional and show some real-life assessments and data. The continued development of the Opasnet Base has postponed the interaction. Now that the database exists with a fair amount of data, the SAP will be asked for comments about the tools and results obtained so far. This will be done before the final meeting in June 2009, and the discussion will continue there.

"Potential users and other stakeholders (outside the consortium) are not suitably involved."

Dissemination plan contains a detailed plan about how to involve stakeholders and potential users. The potential users of the Opasnet website include now much more groups than previously anticipated, also outside the food sector. Therefore, also the dissemination has been targeted to many different groups. The main groups contacted are researchers in other projects. This is because they might adopt the tools in their own work and assessments. If assessments are not performed using the tools, there is no interest by the endusers on the website. Another target group have been decision-makers who might utilise the assessments.

Section 2 - Workpackage progress over the period

This section describes the progress of work by workpackage.

WP1: "Method (top-down approach to risk-benefit analysis)"

WP leader	KTL/THL / Jouni Tuomisto
Partners involved	KTL/THL, TUDelft, FFiles, FSAI, DTU, FVST, Lendac, FIN
Workpackage objectives	- To introduce all partners to the common methods to be used: integrated modelling and Bayesian belief networks. (partners: all; D1, D15; year 2) - To develop Bayesian belief networks (BBN) to handle complicated benefit-risk situations. (partners: THL, TUDelft; D8, D22; year 3) - To develop a decision support system (DSS) based on BBN. (partners: TUDelft, THL; D25, D46, D48; year 4) - To develop improved methods for dose-response assessment, combining epidemiological and toxicological data. (partners: THL, TUDelft; D8; year 1) - Apply the dose-response methods in combining epidemiological and toxicological information on fish contaminants (esp. dioxins and PCBs). (partners: THL, TUDelft; D38; year 4 M42) - To integrate results from the previous workpackages into an updated assessment. (partners: all; D38, D40; year 4 M42) - To evaluate the remaining uncertainties and their importance for decision-making. (partners: TUDelft, THL, FIN; D38, D40; year 4 M42) - To evaluate the integration methodology by all partners and develop it further. (partners: all; D15, D35; year 4 M41) - To produce risk assessments that will be used for Internet interface and Dissemination Workpackages. (partners: all; D22, D38, D40; year 4 M42)

An overview main achievements of the 3rd reporting period

- The development of Opasnet website continued by launching assessments and adding new methods.

- The Opasnet Base (data repository) its functional state, and first data were uploaded.

- Improved dose-responses methods were developed for Cox proportional hazards model; the work for combining toxicological and epidemiological data was delayed.

- Interfaces for the website and the modelling software (Uninet, Analytica) were developed.

- Interfaces for data exchange between Opasnet Base and the modelling software were developed.

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Major new developmental areas for BRA method were identified and solutions suggested

- Work done in collaboration with Intarese

- A functional BBN was developed and tested with pilot data

- A draft method for combining epidemiological and toxicological data was developed in collaboration with Intarese

Main achievements of the 2nd reporting period:

- Improved the BBN model for benefit-risk assessments (model calibration)

- Improved the BBN software (especially its data mining capabilities)

- Data provided on contaminants intake from fish by Irish consumers

- Designed and developed Internet based tools to facilitate conversion and dissemination of benefit-risk assessment models and data to e.g. Mediawiki format.

The work in this workpackage was organized under three main themes: **pyrkilo method**, **Bayesian belief networks** (BBN), and **improved dose-response** (combining epidemiological and toxicological information). The three themes were described in detail in the 1st-year report.

Progress towards objectives

FoodFiles:
The main objective of WP1 is to develop comprehensive risk analysis methods which integrate both adverse and beneficial health effects of food products. Foodfiles has been assisting THL in selection of quantitative estimates for the benefit-risk analysis.

Lendac:
Lendac involvement in WP1 was in the area of developing tools to facilitate conversion of benefit risk assessment data to a format suitable for web dissemination. It was later decided to focus on Mediawiki as the platform for data dissemination and Lendac await clarification of requirements.

THL:
The method development has had several phases. In 2007, the information structures were developed for the decision support system (DSS). These were then operationalised as a website for making benefit-risk assessments. The major phase for website development occurred in the first part of 2008. Since spring 2008, more emphasis has been on developing the data repository and its structure. The last period of Beneris (after spring 2009) will be about uploading the data collected into the repository, and to describe the methods and case studies in the website. There is also work about improving the user interfaces.

Bayesian belief networks (BBN) have been selected as a major tool in developing decision support systems. There are specific software for BBN, notably Uninet. However, there are several functionalities that are needed in benefit-risk assessments, such as handling of multidimensional arrays. Uninet is not a good software for this, but Analytica is designed for just that purpose. On the other hand, Analytica is not very strong in handling correlated probability distributions.

Therefore, THL together with TUDelft have been developing a platform for benefit-risk assessment BBNs that is software-independent. It is based on the same basic idea as Uninet and BBNs. It is closely connected to the development of the Opasnet Base (see WP2.4). The platform makes it possible to develop and run BBNs with any relevant software, store the results, and open them in any other relevant software. During the current reporting period, THL developed the concept and basic database structures needed for the platform. The interfaces between software exist for uploading models from Analytica and Uninet, and downloading for Analytica. The last reporting period will be used to finalise the interfaces for

Analytica and Uninet, and start developing interfaces for other software, the first one being probably the statistical software R. The interface is very generic, and therefore new user can easily develop their own interfaces for their own software, if they find the models developed in Opasnet by Beneris and subsequent projects useful.

TU Delft:

During the reporting period TU Delft has continued its work on methodological issues regarding case-control studies raised during the second year of the project. One of the regression models used to estimate the relative risk based on epidemiologic data is the Cox proportional hazard model. It is known that the omission of pertinent covariates from the Cox model causes biased estimates of the model parameters. This implies that the estimates of the relative risk are biased as well. During past few months TU Delft has developed a new approach for estimating regression coefficients of the Cox model. In contrast to the maximum partial likelihood method this approach allows to express the bias in the estimates of the coefficients caused by omission of covariates in a closed analytical form. This gives an opportunity to study and explore the properties of the omission bias analytically.

During the third year of the project TU Delft has been also working on improving the Bayesian belief network (BBN) software UNINET including among others software performance and graphical interface. Moreover, TU Delft participated in the Open Assessment Workshop organized by THL in February 2009 during which the concept of BBNs was presented to workshop participants including project partner THL. TU Delft was also invited to the workshop on 'Methodology' organized by BRAFO project in September 2008 in Rome. This workshop allowed to compare and exchange opinions about benefit-risk assessment methodologies that have been developed in BENERIS and BRAFO projects.

Deviations from the project workprogramme, and corrective actions taken/suggested

FSAI:

FSAI was not able to become involved in evaluation of the risk assessments developed under WP1 due to lack of resources and the retirement of Iona Pratt.

THL:

The work about combining toxicological and epidemiological information has not progressed as planned. The reason is that the PhD student who was working on this task has been on maternity leave since summer 2008. THL will take actions to make sure that the work will be finalised. At the moment, it has not been decided whether the work should still be postponed a little and wait for her return, or to reallocate the task to someone else, which takes an extra effort for someone to get familiarised in the topic. Probably it is better to postpone the work a little, because the work is in good phase, the basic model and tools have been developed, and the effort to actually finalise the work is not very large.

Lendac:

As outline above – switch to Mediawiki.

Deliverables

No.	Name	WP no.	Due (project month)	Actual	Foreseen	Reasons for deviation and recuperative measures	Estim.	Used	Lead contractor(s)
				Date of submission			Indicative person-months		
D33	Consumer info on case results	1	24		September 2009	Consumer info will be about the final case study and reported with D38	1	0	THL
D35	Pyrkilo guide 3	1	26	Aug 6, 2009		Was delivered after the final adjustments to the data repository sections had been made.	3	1	THL

Milestones

None in this reporting period.

WP2: "Database"

The work done in WP2 is described in detail below, under the sub-workpackage titles.

Deliverables

No.	Name	WP no.	Due (project month)	Actual	Foreseen	Reasons for deviation and recuperative measures	Estim.	Used	Lead contractor(s)
				Date of submission			**Indicative person-months**		
D7	Database review: contaminant food intake	2	8	24 April, 2008		Difficulties in the distribution of work within DTU and the reorganization needed.	2	2	DTU
D19	Contaminants in placenta	2	17	May 15, 2009 (first version)	September 2009 (resubmission)	In addition to the original study plan, some further analyses of placentas were undertaken. The statistical analyses are under way and will be finalised by September.	17	19	THL
D21	Intake of contaminants: natl registries	2	18		September 2009	The deliverable has been adjusted to include only Finnish data, because the PCDD/F concentration data that has been requested from the Commission during P2 has still not been delivered.	1	0	THL (FVST)
D26	Evaluation of patterns	2	20		September 2009	Delayed due to data delays from DG Sanco	2	2	THL
D27	Intakes based on patterns and average	2	20	2 July, 2008		Work completed late due to a key person's (Tero Hirvonen) part-time absence	3	3	THL
D32	Critical dietary patterns	2	22	2 July, 2008		Work completed late due to a key person's (Tero Hirvonen) part-time absence	3	3	THL
D36	Fetus contaminants from mother's diet	2	27		September 2009	Delivery delayed because new chemical analyses had to be performed.	2	2	THL
D39	Combined database	2	33		1 Sept 2009	The database exists but delay is due to database interface and data management.	2	2	DTU

Milestones

(Presented by sub-workpackage below.)

WP2.1: "Food intake studies"

WP leader	FSAI / Iona Pratt
Partners involved	KTL/THL, FSAI, DTU, FVST, FIN
Workpackage objectives	- To review the existing databases and their availability for chemical contaminant data in Europe, and integrate available data. (partners DTU; D7; year 3) - To estimate average nutrient intakes and food consumption in various subgroups based on national registries in three countries and to explore the use of the data in benefit-risk analysis. (partners FSAI, THL, DTU, FIN; D7, D10, D11, D14; year 2) - To estimate distributions of nutrient intake and food consumption relevant to benefit-risk analysis in a number of populations, and also the variability in exposure among various subgroups in the population. (partners FSAI, THL, DTU, FIN; D7, D10, D11, D14; year 2) - To identify food consumption patterns and food choices that determine the intake of those nutrients and contaminants that are related to benefit/risk-balance of a food item. (partner THL; D27; year 3) - To explore the usability of these patterns in another country than in which they were developed. (partner THL; D26; year 4 M41) - To find out the effects of certain policy options on dietary habits and on intake of important nutrients and contaminants (e.g. vitamin D, n-3 fatty acids, dioxins, PCBs). As an example, we will test the hypothesis whether a recommendation to restrict fish eating would increase meat consumption. (partners THL, TUDelft; D38; year 4 M42)

An overview main achievements of the 3rd reporting period

- Food intake data from Spain (related to WP4) was collected.

- Mercury and fatty acid data from Ireland was collected.

- Food intake patterns in Finland were analysed.

- Food intake data from Ireland (related to WP4) were evaluated but dropped.

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Data collecting and computation completed on food consumption data for Finnish, Spanish and Irish populations, as classified by gender, age classes, various food stuffs and fish species. In addition, some nutrient intakes from Finnish and Spanish populations were classified as above.

Main achievements of the 2nd reporting period:

- Provision of detailed data on contaminant concentrations in fish and on pollutant intakes by Irish consumers

- Food consumption data for different age groups of the Irish population made available

- Distributions of food consumption and nutrient intakes in adults, children, and pregnant women have been calculated and reported

- Food consumption patterns and food choices identified for Finnish adults

- Acquired survey-based food consumption data and fish species-specific intake data for Spain

Progress towards objectives

FIN:
FIN has contributed to WP2 in 2008-2009 with consumption data on food groups, nutrients, and specific data on vegetables. This was done with the objective of conducting a descriptive analysis of consumption patterns in children that will be utilised in WP.4. Data analysed were drawn from the EnKid Study that was conducted in a representative sample of Spanish children and youth.

FSAI:
FSAI contributed updated data on mercury levels and fatty acid profiles in Irish fish species, and dialogued with DTU regarding probabilistic modelling of intakes using Irish data and Danish fish consumption data. We also investigated the availability of consumption data for vegetables by young children in Ireland, together with intake data for key nutrients (from vegetables) for the same population group, for the 2nd case study, and discussed this with THL.

THL:
Low and high scores of food consumption patterns were studied and the nutrients that are crucial in benefit/risk-analysis of fish were found out (Findiet 2002 –study) (D27). The critical dietary patterns i.e. associations of foods, nutrients and contaminants crucial for benefit/risk assessment of fish were studied and reported (Findiet 2002 –study) (D32).

Deviations from the project workprogramme, and corrective actions taken/suggested

FSAI:
While FSAI was nominally leader for WP2.1, Food intake studies, in practice the main responsibility for this has transferred to THL, with a focus on detailed consumption data for Finnish and Spanish adults and children. This is considered appropriate since THL have the necessary expertise and overall vision of the Beneris strategy and are in a position to coordinate the work on food intake studies in the most effective manner.

Although the data required for the 2nd case study (on vegetables) is available in Ireland, FSAI does not own the individual data (on an individual child basis) and would have to obtain these data from the Irish Universities Nutritional Alliance (IUNA). By the time we began to discuss this with THL (January 2009), there was insufficient time available to provide the necessary input into the project.

THL:
D27 (Intakes based on patterns and average) and D32 (Critical dietary patterns) were completed late due to a key-person's (Dr. Tero Hirvonen) absence.

Milestones

None in this reporting period.

WP2.2: "Contaminant concentration"

WP leader	KTL/THL / Terttu Vartainen
Partners involved	KTL/THL, DTU
Workpackage objectives	• The general objective is to find out association between external dose (intake) and internal dose (concentrations in the body). The immediate objectives are (partners THL, DTU; D19, D20, D36; year 4 M42) • To analyse contaminants (PCDD/Fs, PCBs, PBDEs, organotin compounds, PCNs and Hg/methyl-Hg) from 50-200 placentas. (partners THL, DTU; D19; year 4 M38)

An overview main achievements of the 3rd reporting period

- Statistical analyses based on the pollutant concentration studies were performed.

- The need for new chemical analyses (fat concentrations) was identified. (These analyses started on the fourth year.)

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- The preparation and chemical analysis of 130 placenta samples for methyl mercury (DTU) and other pollutants including PCDD/Fs, PCBs, PBDEs, organotin compounds, and PCNs (KTL/THL) has started.

Main achievements of the 2nd reporting period:

- Placental contaminants analyzed by KTL/THL for seven groups of persistent organic pollutants (PCDD/F, PCB, PBDE, PBB, PCN, DDE, OT)

- Started studies of association between intake and internal dose

- Placentas also analyzed for the concentrations of Hg, Se, As, Cd, and Pb (DTU)

- Analysis of 130 placentas for methyl mercury finalized (DTU)

Progress towards objectives

THL:
D19 Contaminants in placenta delivered; Data on concentrations of 130 placenta samples for several groups of persistent organic pollutants (PCDD/F, PCB, PBDE, PBB, PCN, p,p'-DDE, OT) and metals Hg, Se, As, Cd, Pb, and methylHg provided for the BENERIS data repository.

Studies of association between calculated/estimated intake and internal dose started on winter 2009.

Deviations from the project workprogramme, and corrective actions taken/suggested

THL:
D19 was delayed but in spring 2009 the data was made available for data repository.

Association studies were started a little bit delayed due to matters which were independent on BENERIS –project. That is that not all basic data for the association study was obtained in time.

Milestones

None in this reporting period.

WP2.3: "Contaminant intake studies"

WP leader	KTL/THL / Tero Hirvonen
Partners involved	KTL/THL, FSAI, DTU, FIN
Workpackage objectives	• To combine existing and new data of food diary data with data of contaminants. The special emphasis is on children and the developing foetus. (partners THL, DTU, FIN, FSAI; D20, D29, D30; year 3)

An overview main achievements of the 3rd reporting period

- Intakes of contaminants (D29, D30) per age and sex were analysed.

- Intakes of contaminants by the fetus from mother's diet were analysed but not finalised, because a need for further chemical analyses was identified.

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- A probabilistic intake estimation method (Monte Carlo simulation) has been developed and tested, using data from WP2.1 and WP2.2.

Main achievements of the 2nd reporting period:

- Calculated and reported the food intake of subpopulations (D18), intake of contaminants in children (D20), and the food intake of pregnant women (D18 and 29-30)

- Calculations of contaminants during pregnancy

- Detailed data made available on contaminant concentrations in, and their intakes from fish by Irish adults.

- A review on toxicity data of methylmercury in progress

- Database for intake of and critical contaminants (PCDD/F, PCB, Hg) in fish was derived from published data

Progress towards objectives

FIN:
FIN contributed to finalising the analysis of the intake of fish contaminants in the adult (aged 25-74 years n=1530, 706 men and 824 women from the ENCAT study) and children and young (aged.4-24 years n=3337, 1527 men and 1810 women from the EnKid Study) populations in Spain. Contaminant data was obtained from a large variety of informations from different toxicological studies conducted in different Spanish regions.

THL:
Contaminant intakes among Finnish adults aged 25-64 years by sex and age groups were studied and reported (D29 and D30). The work to study fetus contaminants from mother's diets is nearly done (D36).

Deviations from the project workprogramme, and corrective actions taken/suggested

FSAI:
As outlined for WP 2.1, while Ireland has food diary data for children, and was interested to become involved in case study 2 on vegetables, the time available and the proprietorial ownership of the data prevented us from providing the necessary data at the individual level

THL:
D29 and D30 (Contaminant intakes among Finnish adults, by sex and age group) were completed late due to lack of working time of the statistician.

D36 (Fetus contaminants from mother's diets) is still under work due to lack of working time of the statistician and due to the unification of National Public Health Institute (THL) with another governmental institution which has brought unexpected work tasks to the personnel. The work was completed by the end of May, 2009. However, a new data need was identified, related to aft content of placentas (see above). This requires further work.

Milestones

Name	WP no.	Due (project month*)	Actual achiev. date	Foreseen achiev. date	Reasons for deviation and recuperative measures	Lead contractor(s)
Intake of different contaminants in different subpopulations is compared with the TDI values of EC and WHO.	**2.3**	not determined		August 2009		THL
Food consumption advice is given for relevant subpopulations.	**2.3**	not determined		August 2009		THL

WP2.4: "Database work"

WP leader	DTU / Ole Ladefoged
Partners involved	KTL/THL, DTU, Lendac
Workpackage objectives	• To develop an integrated repository of surveillance, nutrient and food consumption data, (DTU, THL; D39; year 4 M41) • To develop a robust system capable of receiving datasets from multiple sources on an ongoing basis, (THL; D39; year 4 M41) • To develop a rapid analytical tool for deriving intake estimates for key contaminants and essential nutrients to address the overall aims of the project. (TUDelft, THL; D29, D30; year 3) • To develop tools for making the accumulated data readily available to key stakeholders involved in risk analysis including the European Food Safety Authority and national authorities. (THL; D39; year 4 M41)

An overview main achievements of the 3rd reporting period

- The concentrations of methyl mercury, cadmium, lead, arsenic, total mercury and selenium in 130 human placentas were analysed.
- The second version (with an improved and more flexible structure) of Opasnet Base (data repository) was launched.
- The interface for downloading data from the new version was developed.
- The first interface version for uploading data to the repository was developed.
- The first data were uploaded to the repository.
- Methods to link assessments in Opasnet and data in Opasnet Base were developed.
- Intake estimate methods for contaminants were developed and applied (D29, D30).

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Based on the evaluation of existing work on food databases, it was concluded that the collection of data for benefit-risk analyses should be designed so that there is a special emphasis on the applicability and simplicity of the data.

Main achievements of the 2nd reporting period:

- Report on available data for fish consumption and concentrations in Denmark, Finland and Ireland (D7)

- The overall structure of an integrated repository of data has been outlined, developed, and implemented in close collaboration with Intarese project. The database has been set up for testing and further development.

Progress towards objectives

DTU:
DTU has analyzed the concentrations of methyl mercury, cadmium, lead, arsenic, total mercury and selenium in 130 human placentas.

THL:
In the beginning of the reporting period, the first draft of the data repository (http://base.opasnet.org) was available. However, there were problems with the structure, which had to be streamlined. This was mainly done in THL, with consultation from TUDelft. THL built a new structure during summer and fall 2008. Then the major developmental effort changed into developing the interface between the repository and the user website Opasnet

(http://en.opasnet.org). During the reporting period, THL developed an interface for project researchers to upload their data into the repository, and a simple interface for all users of the website to view the data.

The basic idea is that Opasnet is a wiki-type website that describes any issues related to benefits and risks of food. This includes whole assessments, and also detailed data about e.g. food intake. Opasnet is for organising, synthesising, and discussing the information. On the other hand, the data repository (now called the Opasnet Base) is a storage for detailed numerical data that is used either as input for models, or as outcomes of assessments. Each piece of data in the Opasnet Base is linked to a description page in Opasnet. The data can be easily and directly accessed by clicking a link on the description page.

At the end of the reporting period, the Opasnet Base is up and running. The new structure has proved to be useful, and anyone can download data from there. At the very end of the reporting period, THL opened a web interface that can be used by anyone for uploading data into the Base. So far, there is no practical experience about this interface, and it is expected to be a major target for further development during the last period of Beneris. In addition, the project has produced or collected a lot of information that has not been uploaded into the Base but will be uploaded before the end of the project. A third area of development related to the Opasnet Base is to develop an interface for downloading and viewing data in formats that are more user-friendly. We need formats for data that is directly used in further modelling and benefit-risk analyses, and we need formats for data that are simple to read and understand by interested citizens who seek information from the Opasnet website and Opasnet Base.

There is a more detailed description of the functionalities of the Opasnet Base below.

Deviations from the project workprogramme, and corrective actions taken/suggested

None.

Milestones

None in this reporting period.

Opasnet Base

Opasnet Base is a part of Opasnet and a storage and retrieval system for results of variable and data from studies. It is designed to be flexible enough to store information in almost any format: probability distributions or deterministic point estimates; spatially or temporally distributed data; or data with multiple dimensions. It can be used as a direct source of model input data, thus making it possible to use shared input information sources such as population data, climate scenarios, or dose-responses of pollutants. Opasnet Base can be accessed via links from Opasnet variable and study pages (e.g. the meta data box), via a web interface and via the model Opasnet base connection.ANA.

In the near future (summer 2009) it will also be possible to upload own study and model results into the Opasnet Base. This way, all researchers can participate in collecting and distributing scientific information for open use. Openly available data is a prerequisite for effective policy assessments.

The Base view and the Opasnet view

The Opasnet Base can be accessed view two different views. The Base view shows a list of data items that can be looked at (Figures 1-2). The Opasnet view looks like Wikipedia with a large number of descriptive web pages. These description pages may have links to a particular piece of data (Figures 3-5).
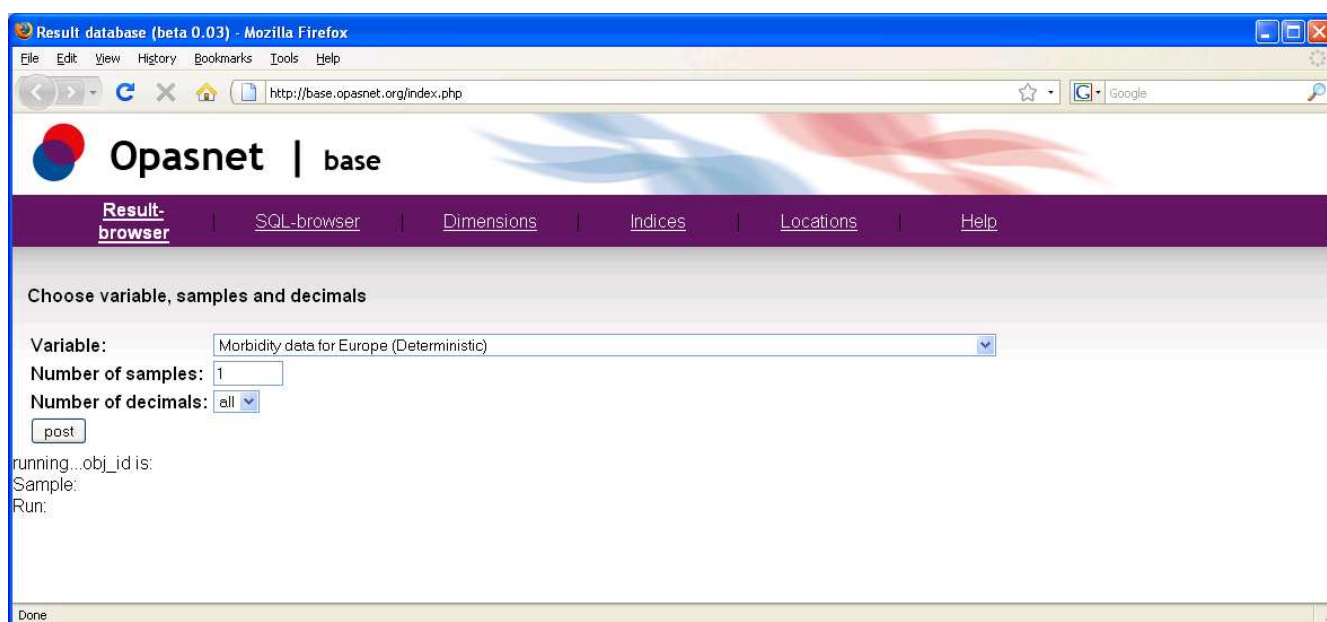
Figure 1. A view of the Opasnet Base where you can select the variable you want to explore. By selecting options and clicking the post button the result will be downloaded.
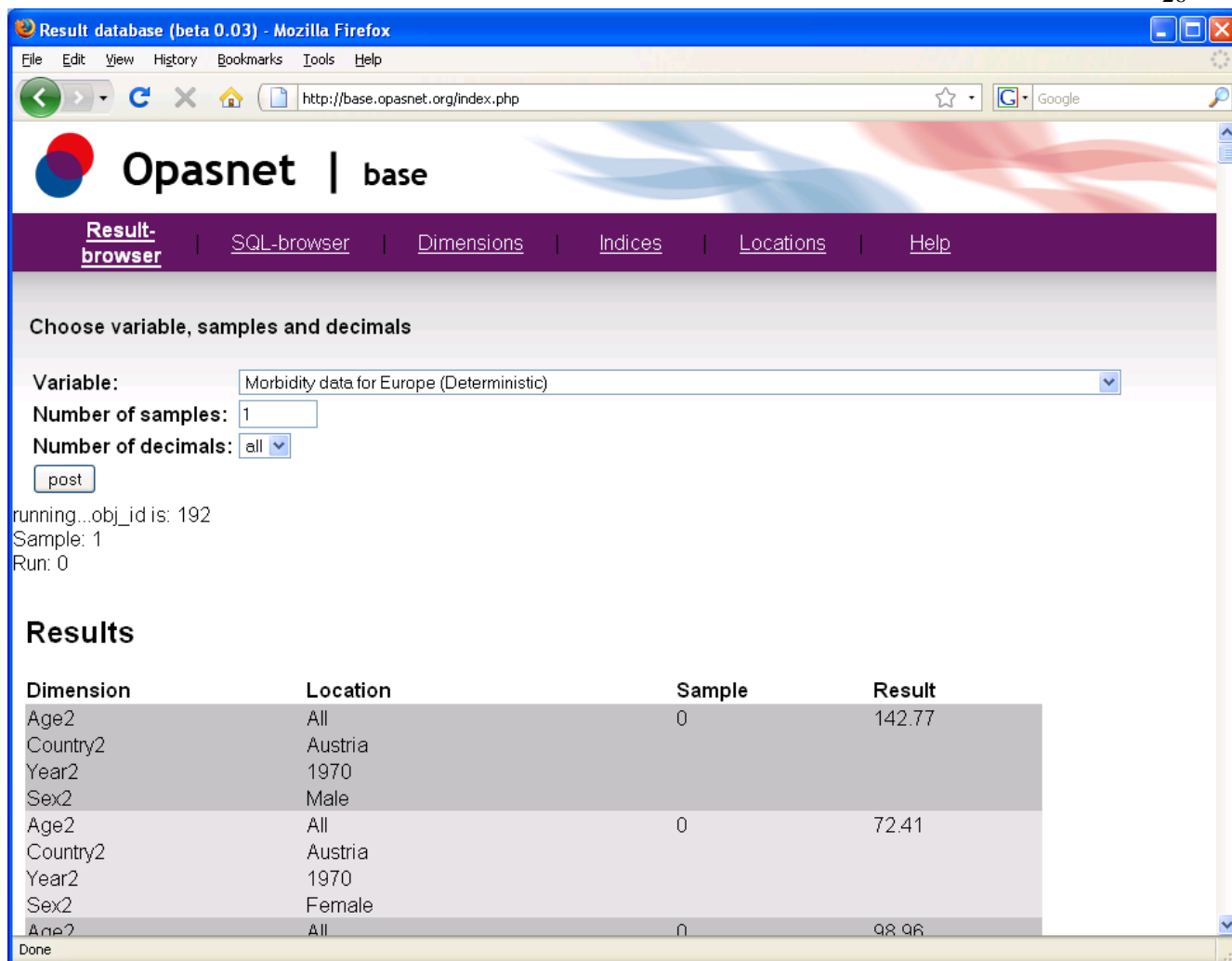
Figure 2. The results are shown for each subgroup (in this case, indexed by age, sex, country, and year).

The subgroups of a data are defined when the data is uploaded. There are no restrictions to the indices and subgroups used. For practical reasons, it is recommended that the data producers use standardised indices when possible. For example, diagnoses or causes of death should be based on ICD-10 codes whenever possible. This makes it much easier to combine the data with other related data, and to utilise the data in new assessments. Each result may be indexed to any number of relevant indices. The example in Figure 2 has four indices.

Figure 3. An example of a description page of a study. The results of the study are stored in the Opasnet Base.

The studies and variables are described in detail in Opasnet, which is a Wikipedia-like website. Figure 3 shows an example of morbidity data description. Also, discussions about the data are possible on this page and the related discussion page (link at the top panel). This makes it possible to evaluate and review the quality of the data in an open way. The evaluations will be valuable information for the users of the data. They will help to understand the limitations and possible uses of the data.

On the top right corner, there is an info box about the data. By clicking the links, the user can directly open detailed information about the data. For example, the user can list the different runs (versions) of the data, or the means of each subgroup (age group, sex and so on). It is also possible to download the whole data with all observations in the Opasnet Base.

Figure 4. An example of model description. The lower part of the page is in Figure 5.

Opasnet pages also contain direct links to model results. The page in Figure 4 describes a model about cardiovascular effects of salmon consumption. The page contains both detailed information about how the effects are estimated (i.e., the details of the model), and also the summary of the model results (see Figure 5).
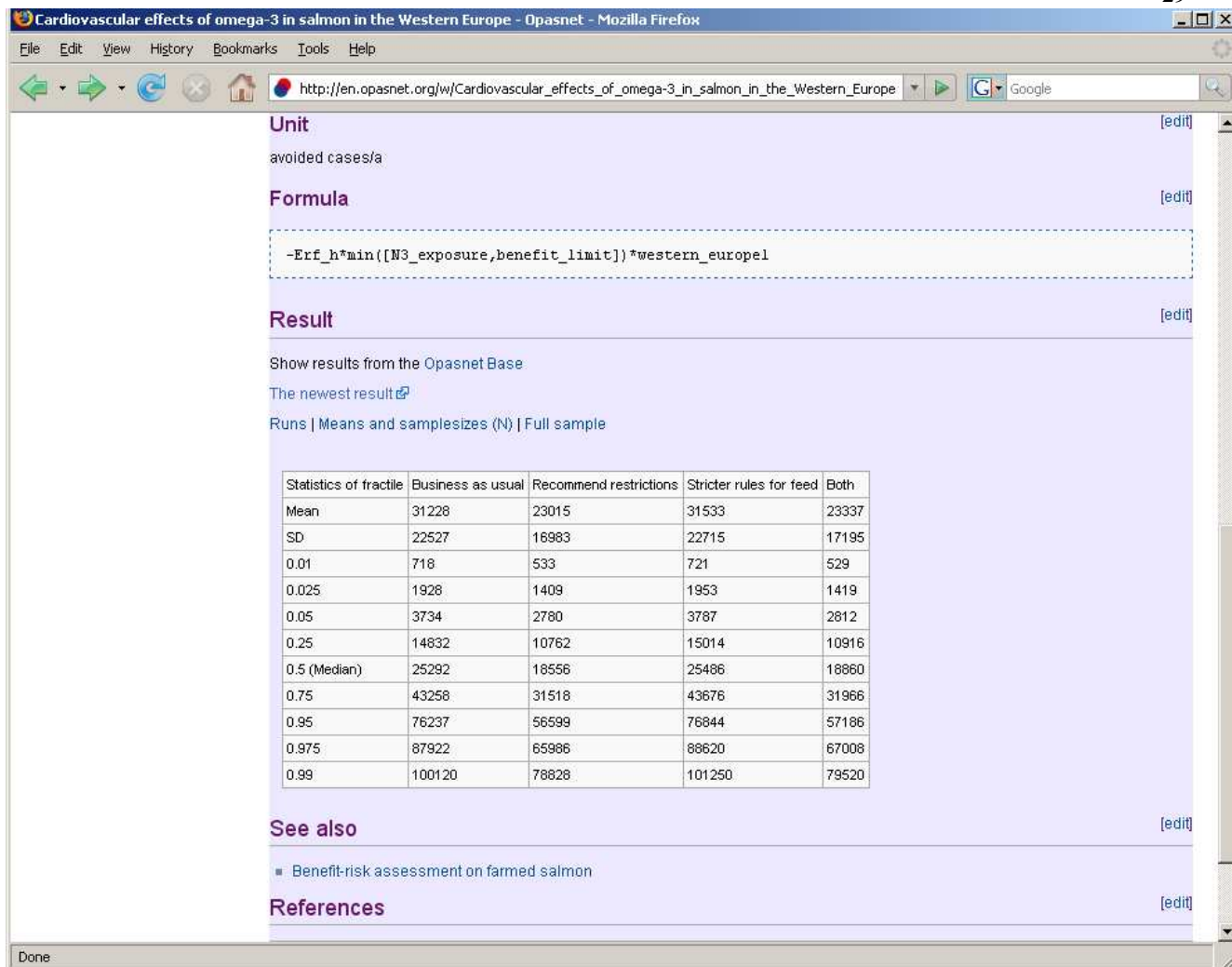
Figure 5. The lower part of the page shown in Figure 4.

Some uses of Opasnet Base

Storage of interpreted model results

Originally, **Opasnet base** was designed to be the storage for interpreted model results, i.e. variable results. Variables attempt to answer specific real-world questions, and their results are the current best attempts to answer these questions. This is different than with studies that report the observations from a single study. Variable results are expected to improve in time eternally, while data from a study is fixed after the study has been done and observations made.

Storage of study results

Opasnet Base can be used to collect observation data from studies. A study can be a traditional research study, which is documented in Opasnet Data afterwards, or it can be an Opasnet study where the data is collected on a particular page of Opasnet using a web form. (The web form functionality is under development and will be available in fall 2009.) There are several purposes:

- To collect observation data to be directly usable in interpretations of variables and other objects.

- To collectively collect information about specific cases, and based on these data conditionalise a generalised assessment model with data specific to a particular case.

However, there are some things about variables and studies that should be understood:

- The object for a collection of observations is called a study, while the object of interpretations is called a variable. As an example, a study can collect information about a population group by a questionnaire and by taking a blood sample.
- Each study may be multidimensional just like a variable and have indices along e.g. space, time, or sex.
- If the data is collected using an Opasnet web form, then the timestamp and username or IP will be recorded for each entry. This is not needed, if the data comes from a previously performed study (which is static data in the eyes of Opasnet).
- In some cases, it might be useful to restrict the number of entries per user to one. However, this is done only at the interpretation phase where only the last entry is counted. There are no restrictions to enter new data, and therefore a user may change his/her previous entry by simply making a new entry.

Making value-of-information analyses in Opasnet base

Value of information (VOI) is a decision analysis tool for estimating the importance of remaining uncertainty for decision-making. Result database can be used to perform a large number of VOI analyses, because all variables are in the right format for that: as random samples from uncertain variables. The analysis is done by optimising an indicator variable by adjusting a decision variable so that the variable under analysis is conditionalised to different values. All this can in theory be done in the result database by just listing the indicator, the decision variable, and the variable of interest. Practical tools should be developed for this. After that, systematic VOI analyses can be made over a wide range of environmental health issues.

Analysing the change in the quality of a variable result in Opasnet base

All results that have once been stored in the result database remain there. Old results can be very interesting for some purposes:

- The time trend of informativeness and calibration (see performance) can be evaluated for a single variable against the newest information.
- Critical pieces of information that had a major impact on the informativeness and calibration can be identified afterwards.
- Large number of variables can be assessed and e.g. following questions can be asked:
  - How much work is needed to make a variable with reasonable performance for practical applications?
  - What are the critical steps after which the variable performance is saturated, i.e., does not improve much despite additional effort?

See also pages in the Opasnet website:

- Opasnet Base structure
- Opasnet
- Open assessment
- Opasnet base connection.ANA
- Benefit-risk assessment on farmed salmon
- Morbidity data for Europe

WP3: "Case 1: Fish"

WP leader	FFiles / Henna Karvonen
Partners involved	KTL/THL, TUDelft, FFiles, DTU, FIN
Workpackage objectives	The general objective is to perform risk-benefit analysis on fish based on the methods developed in WP1; nutrition and contaminant information collected in WP2; and benefit dose-responses derived in this WP. We will estimate the dose-response slopes for different health benefits of fish including uncertainty around these estimates. A key task is to quantify the cardiovascular benefits of fish on different population subgroups, like cardiovascular patients vs. healthy adults, using the large body of published literature. Other potential benefits of fish include beneficial effects during pregnancy and early childhood on childhood development, allergies, and osteoporosis. All of these effects will be reviewed, prioritized and the most important effects and their uncertainties will also be quantified. (THL, TUDelft, FFiles; D38; year 4 M42)

In general, WP3 aims at performing benefit-risk analysis on fish consumption based on methods developed in WP1 and data on consumption and contaminants collected in WP2. TU Delft has had the main responsibility of developing the Bayesian belief network, while KTL/THL, together with FFiles, has prepared the preliminary case study.

The different threads of work were described in more detail in the 1st-year report.

An overview main achievements of the 3rd reporting period

- Health impact review about fish-related endpoints was performed (D28).

- Parts of the fish case study were described and published in Opasnet website.

- Data collection for completing the case study continued.

- The interface tools for combining models (in Uninet) and Opasnet website were tested.

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- A BBN developed for the full BRA of fish.

- Literature review on health effects of fish was completed. Evaluation of the most relevant health effect indicators of fish is under way.

- The preliminary BRA on fish was finalised and published.

Main achievements of the 2nd reporting period:

- Reviews on quantifiable cardiovascular health benefits of fish and omega-3 fatty acids (D16) and other health benefits of fish (D28) completed

- An improved, more sophisticated version of the BBN model for the case study (TU Delft)

- Collection of data needed for the new BBN model has been started (FSAI, FIN)

Progress towards objectives

FIN:

FIN has participated in the fish-case by providing consumption data on fish and the analysis of contaminant intake in Spanish representative samples of children and youth.

FoodFiles:

Foodfiles has reviewed the existing data from clinical trials and epidemiological studies on the various health effects of fish in children. During this period Foodfiles has been writing a review on health effects of fish among children in developed countries for the further development of the benefit-risk analysis. The draft of the report is already available and the finalizing will be done by June, 2009.

FSAI:

FSAI was not involved in WP3 other than contribution of data on levels of POPs and mercury in fish

THL:

More detailed input data for the BBN has been delivered. Demographies and dose-response relationships provide more specific information for variables in the BBN. Also, shape of the outcome product(s) of the BBN model have been under discussion.

TU Delft:

The contents of the general Bayesian belief network (BBN) model for the fish case study have been defined during second year of the project. During the current reporting period the quantification of the model has progressed. TU Delft has actively participated in the process of collecting data for the BBN and has been working on analyzing and merging this data into a single consistent model. As a result of joint effort of TU Delft and THL one part of the general BBN model has been quantified and described in the Opasnet website. This part of the model refers to the impact of prenatal exposure to omega-3 fatty acids and methyl mercury via fish intake on the IQ of children. The work on other parts of the model continues.

Deviations from the project workprogramme, and corrective actions taken/suggested

FoodFiles:

Since several meta-analyses on the cardiovascular health and the effects of fish consumption or intake of fish oils in adults have been published during the recent years, we felt that another perspective was needed for the meta-analysis of health benefits. Consequently, we included the effect of age on the health benefit assessment.

Deliverables

| No. | Name | WP no. | Due (project month) | Date of submission | | Reasons for deviation and recuperative measures | Indicative person-months | | Lead contractor(s) |
				Actual	Foreseen		Estim.	Used	
D22	Preliminary benefit-risk analysis of fish	3	18	15 May, 2008		Deliverable was delayed due to parallel activities	1	5	THL
D38	Full benefit risk analysis of fish	3	32		September 2009	Reasons for the delay relate to tool interfaces and data gathering.	3	6	THL

Milestones

Name	WP no.	Due (project month*)	Actual achiev. date	Foreseen achiev. date	Reasons for deviation and recuperative measures	Lead contractor(s)
Quantification of the effect of fish on cardiovascular disease and mortality. Identification of the need for further expert elicitation and other work. Feedback from of benefit-risk analysis.	3	18	April 2009		The expert needs have been identified. The information was collected using in-house experts during 2008-2009.	THL/TUDeflt
Recommendations for further research specifying the areas considered most important for the public health	3	24		Sept 2009	Will be based on the value-of-information analysis from the case study.	

WP4: "Case 2: Vegetables"

WP leader	FIN Lluis Serra-Majem
Partners involved	KTL/THL, FSAI, DTU, FIN
Workpackage objectives	• To perform a preliminary benefit-risk analysis for vegetables in diet. A special focus will be on alternative sources of nutrients, such as supplements and food fortification. (THL, FIN; D40; year 4 M38) • To perform an updated benefit-risk analysis based on the preliminary analysis, the new intake data from several countries, and the redefined scope based on discussions among Beneris researchers. (THL, FIN; D40; year 4 M42)

An overview main achievements of the 3rd reporting period

- The study protocol for the vegetable case study was finalised.

- The analyses were performed for the Finnish data (the work was finalised in the beginning of the year 4).

- The Spanish data were prepared for the analysis (to be done during year 4).

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- None (needed further development and application of methods in WP3).

Main achievements of the 2nd reporting period:

- Four exhaustive reviews to generate summary tables on the risk-benefit relationship of vegetable consumption, with focus on 1) health risk associated with vegetable intake due to contaminant contents 2) health effect [+ or –] of vegetable consumption 3) health benefits of supplements and fortified foods containing key vegetable nutrients 4) general health effects [+ or –] of vegetable consumption in adults.

- Case study 2 was scoped in the mid-term meeting in Helsinki.

Progress towards objectives

FIN:
During the 2008-2009 period, FIN's contribution has consisted in the provision of consumption data on foods and nutrients with a special emphasis on vegetables in the target population of Spanish children and youth. The different consumption patterns of individuals consuming lower quantities of vegetables and those with greater consumption were analysed with the aim of evaluating how influenced the intake of vitamins and certain nutrients, as well as other foods. This data will be of use for conducting the benefit-risk study on vegetables and possibility of substituting beneficial nutrients they provide with vitamin supplements or fortified foods.

FSAI:
As already indicated, FSAI investigated the availability of consumption data for vegetables by young children in Ireland, together with intake data for key nutrients (from vegetables) for the same population group, for the 2nd case study, and discussed this with THL.

THL:

The work of a preliminary benefit-risk analysis for vegetables in diet has started with discussions which members of the Beneris-project could participate. Individual food consumption and nutrient intake data will be used from 3- and 6-year-old Finnish and Spanish children. The nutrient intakes from supplements will not be taken into account. The objective is to find a level of fortification where all children's intakes of folate and vitamins A and C are between average needs and biggest acceptable levels of intake (UL). The work is still continuing.

Deviations from the project workprogramme, and corrective actions taken/suggested

FSAI:

Although the data required for the 2nd case study (on vegetables) is available in Ireland, FSAI does not own the individual data (on an individual child basis) and would have to obtain these data from the Irish Universities Nutritional Alliance (IUNA). By the time we began to discuss this with THL (January 2009), there was insufficient time available to provide the necessary input into the project.

THL:

D40 (Full benefit-risk analysis: vegetables) is still under work due to lack of working time of the statistician. The work has also been delayed by the unification of National Public Health Institute (KTL) with another governmental institution which has brought unexpected work tasks for the personnel. The work related to Finland was completed by the end of May, 2009, and the work related to Spain will be completed in September, 2009.

Deliverables

No.	Name	WP no.	Due (project month)	Actual	Foreseen	Reasons for deviation and recuperative measures	Estim.	Used	Lead contractor(s)
				Date of submission			**Indicative person-months**		
D40	Full benefit-risk analysis: vegetables	4	34		September 2009	The Finnish part is finished, work will be repeated in Spain.	2		THL

Milestones

None in this reporting period.

WP5: "Dissemination"

WP leader	FSAI / Iona Pratt
Partners involved	THL, TUDelft, FSAI, DTU, FVST, Lendac, FIN
Workpackage objectives	• To develop an internet interface for publishing risk assessment results. Specifically, (Lendac, THL; D17; year 2) • to develop a method to publish entire benefit-risk models over the Internet using XML; (Lendac, THL; D17; year 2) • to develop methods to collect feedback from end-users about benefit-risk analyses; (Lendac, THL, FSAI; D17, D46; year 4 M42) • to enhance the availability of existing databases through this interface. (THL D39; year 4 M41) • To disseminate the results and to evaluate the relevance and usefulness of the work done in the project from the perspective of an end-user / authority. (FSAI, THL, TUDelft; D31, D43, D46; year 4 M42)

An overview main achievements of the 3rd reporting period

- Open Assessment Workshop 2009 was organised in February 2009.

- End-user evaluation (D31) was performed in spring 2009.

- The Beneris tools were made available to other projects. EU-wide Intarese, Heimtsa, and Hiwate and several Finnish projects are actively using them.

- Draft dissemination plan (D5) was written (and subsequently accepted in June 2009).

- Feedback tools were developed for the www.beneris.eu website.

- Guidance for model publishing in Opasnet was improved.

- Guidance for commenting and peer review in Opasnet (based on the mid-term review) was created.

- A model publisher (website that runs model without a need to install anything) was set up and first models made available.

- Background data (useful for several assessments) was made available via Opasnet Base.

- Collaboration with Brafo was continued by providing Beneris data to Brafo and commenting Brafo work.

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Beneris website was opened.
- A tool for transforming BRA models into web pages was developed.
- The planning of a Gordon conference was started.

Main achievements of the 2nd reporting period:

- Development of the Pyrkilo method towards the more sophisticated Open Assessment methodology

- Development of a website to outline project objectives, progress reports, news, events etc.

- Development of Internet based tools to facilitate conversion and dissemination of results of benefit-risk models (Lendac)

- Conversion of benefit-risk model data to Mediawiki format was completed

- Development and opening of the open assessment website (http://en.opasnet.org) in collaboration with the Intarese project.

- Conference about environmental health in the Valamo monastery (December 3-5, 2007) organized in collaboration with Qalibra project.

- Preliminary benefit-risk assessment on fish published in a peer reviewed journal (Leino et al. 2008)

- Workshop on evaluation of the methodologies arranged (Berlin, September 2007), with two participants from Qalibra

- Kuopio Open Assessment workshop in February 2008, with participants from Beneris, Intarese, Envirisk, Hiwate, and Heimtsa

The streams of dissemination activities and future plans of dissemination were discussed in detail in the 1st-year report.

Progress towards objectives

FSAI:
As indicated in the mid-term and 2nd year reports, the ongoing development of the Pyrkilo method for risk:benefit analysis and the increasing focus of the Beneris project on Open Risk Assessment (ORA) has reduced FSAI's input to WP5 in a major way, and leadership and responsibility for dissemination was taken over by THL (KTL) in year 2, although FSAI was nominally the workpackage leader for WP5

Lendac:
The dissemination strategy planned revolved around development and support of the Beneris website (www.beneris.eu) and the consequent development of tools/interfaces to facilitate dissemination of information via this website. This involved the development of a website with facilities to outline various project objectives, partner information, news events, reports etc together with a comprehensive search interface. It was developed to provide secure multi level authoring options to allow various project partners to publish reports and research results under control of an editorial group. The development included the capability to issue polls, feedback reports etc on aspects of benefit risk analysis. Lendac continue to support and host the Beneris website. This aspect of the work programme was to include the development of Internet based tools to facilitate conversion and dissemination of benefit risk model results via the Beneris website. Lendac were involved in the initial conversion of XML output from benefit risk models but at a later stage it was decided to focus on Mediawiki/Pyrkilo as the focus of the open risk assessment within Beneris. Lendac await clarification of dissemination requirements.

THL:
During the mid-term meeting, the responsibility of dissemination was transferred from FSAI to THL. The main objective for an Internet interface for publishing risk assessment results

was achieved already during the previous period. The Opasnet website (http://en.opasnet.org) serves this purpose. The work during this reporting period has been about improving the interface in general, and to tackle a few specific issues. The achievements about specific objectives are described below:

The basic method about publishing models is twofold. The model is described in detail in Opasnet, so that a user can see the outline and functionalities of a model simply by reading the website. In addition, whole models can be uploaded to the website, so that anyone can run the model and test its assumptions. This requires that the user first downloads a free model player for Analytica models. A recent development was that THL bought a license for Analytica Web Player (AWP). Using this player, a user can run uploaded models with just a web browser, without a need to install anything.

Based on the comments from the Scientific Advisory Panel in the midterm meeting, THL launched a task to improve feedback methods and quality assurance. A major part of this work occurred during this reporting period. The work divides into three parts. First, functionalities and instructions were developed so that users can comment on assessment contents (http://en.opasnet/w/Discussion), thus pointing out work-to-be-done or bringing in new information. Second, instructions for formal peer review (http://en.opasnet.org/w/Peer_review) within the Opasnet website were also developed. This work is still ongoing, and experience will be collected to improve the peer review process. Third, a functionality for making polls in Opasnet is being developed. Polls can be used for several purposes, e.g. user evaluation of content or collection of value judgements about issues in an assessment. The poll functionality will become available during the last reporting period.

Work was done to collect such information into the data repository that is useful for several benefit-risk assessments. Such information includes WHO mortality and morbidity data, which can be used as background risk information in assessments that use relative risks. The data upload will increase in the near future, as the new upload interface has recently become available.

The work done in Beneris has been actively disseminated to other EU-funded projects (and also many things have been learned from them in Beneris). Foodfiles and THL have provided dose-response information related to the fish case study to the Brafo project. In addition, the benefit-risk assessment methods developed in Beneris have been actively provided for Brafo in form of the methodology report (Deliverable 15) and by commenting the tiered benefit-risk approach developed in Brafo.

Beneris has actively collaborated with Intarese project in developing a website for collaborative assessments. The Opasnet website is a joint effort. In addition, the data repository (Opasnet Base) has been developed in Beneris but is now being increasingly used by Heimtsa project. Heimtsa is also producing data that could not be collected with Beneris resources.

TU Delft:
TU Delft has contributed to the objectives of this work package by describing variables of the Bayesian belief network model developed within WP3 in Opasnet website which is an open internet platform for performing benefit-risk assessments and collecting information needed for these assessments. Moreover, TU Delft participated in the Open Risk Assessment workshop held in February 2009 in Kuopio during which the usefulness of methods and tools developed within BENERIS was discussed.

Dissemination activities are planned for the spring of 2009, Cooke will visit Argonne National Labs and Univ. of Wisconsin and present BENERIS results.

Deviations from the project workprogramme, and corrective actions taken/suggested

FSAI:
While FSAI was willing to support THL as required, the necessary interaction between the two organisations did not occur and FSAI did not have an understanding of what was to be disseminated. Thus, achievement one of the objectives of the project: evaluation of the relevance and usefulness of the work done in the project from the perspective of an end-user/food safety (deliverables 31 and 46, scheduled for months 21 and 40) has not been possible. This has been compounded by lack of resources at FSAI and the retirement of Iona Pratt.

Lendac:
As outlined above.

Deliverables

No.	Name	WP no.	Due (project month)	Actual	Foreseen	Reasons for deviation and recuperative measures	Estim.	Used	Lead contractor(s)
				Date of submission			**Indicative person-months**		
D31	Enduser evaluation	**5**	21	May 15, 2009		The main evaluation will be done not until the last reporting period (D46). However, a preliminary evaluation has been performed based on the experience collected until now.	2	2	THL (FSAI)
D37	Internet update	**5**	27	Aug 6, 2009		The Internet update has been a continuously ongoing process without a clear finalisation date. The deliverable was written after some larger updates.	3	3	Lendac

Milestones

None in this reporting period.

WP6: "Cluster activities"

WP leader	KTL/THL / Anna Karjalainen
Partners involved	KTL/THL, TUDelft, FSAI
Workpackage objectives	The objective is to establish a platform for cluster activities between Qalibra and Beneris projects and report about them to the Commission. (THL; D17, D5; year 4 M40)

An overview main achievements of the 3rd reporting period

- Beneris developed a Glossary of benefit-risk assessment terms and provided that to Qalibra.

- Beneris developed Opasnet Base that can be used also by Qalibra to store data.

- Beneris joined a Qalibra meeting to explain the use of Opasnet Base. Possible ways to utilise it in Qalibra were discussed.

- Beneris participated in the planning of the joint meeting in June 2009 (Qalibra was responsible for organising the meeting).

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Beneris kick-off meeting on May 2006.

- The first Cluster meeting and a report containing the output from the Cluster meeting (deliverable D3)

- Joint web page opened.

- Collaboration with TU Delft and CSL about modeling.

- Cluster coordination.

- Joint project meetings planned/organized.

- Gordon conference in preparation.

- Scientific advisory panel appointed.

Main achievements of the 2nd reporting period:

- Roger Cooke visited Central Science Laboratory (CSL) on November 26-27, 2007.

- Visit by Alistair Murray to Delft on December, 2007.

- Patrycja Gradowska presented the Bayesian Belief Network approach in the "Valamo conference" on environmental health risk assessment

- Expert elicitation activities with Dr. W. Aspinall.

- Recognized the need for more collaborative work in order to develop of an integrated dissemination strategy for Qalibra and Beneris

- Open website for BRA (http://en.opasnet.org)

Main achievements of the 3rd reporting period

- A telephone meeting of the sister projects QALIBRA and Beneris was held the 4th of September 2008 during the sixth overall project meeting for Qalibra were Jouni Tuomisto and Olli Leino participated in the part of the meeting dedicated to cluster activities

- Beneris has developed a joint glossary with Intarese and have given QALIBRA partners access to this glossary (http://en.opasnet.org/w/Glossary). The glossary will be maintained by THL also after the end of the Beneris project.

- Beneris and QALIBRA have discussed ideas and possibilities for a QALIBRA-Beneris data repository. BENERIS has granted QALIBRA access to their data repository (called the Opasnet Base http://base.opasnet.org).

- Matis has started to organise and plan the third and final Cluster meeting of the sister projects QALIBRA and Beneris in cooperation with CSL, Altagra and THL. The meeting will be held in Budapest 10-11 June, 2009.

- QALIBRA has invited Beneris to participate in a short trial end-user workshop held by QALIBRA 11th of June during the final cluster meeting of the projects in Budapest The participation of Beneris in this workshop will be used to evaluate the feasibility for cross validation of methods used by QALIBRA and Beneris.

- QALIBRAwill also invite Beneris to participate in a f inal end-user workshop held by QALIBRA 9-10th of September 2009 in Budapest. The participation of Beneris in this workshop will be used to promote post-project activities of the two consortiums.

- Beneris has developed the first draft of a cluster dissemination plan

Progress towards objectives

FSAI:
FSAI has not contributed to the objectives of this WP, as the main responsibility was taken by THL

TU Delft:
Cooke has had ongoing contact with a member of the QALIBRA team, Villie Flari. These contacts support prioritization activities with regard to degraded health states. Although this work is not directly related to QALIBRA, it has grown out of contacts between QALIBRA and BENERIS.

Deviations from the project workprogramme, and corrective actions taken/suggested

None.

Deliverables

| No. | Name | WP no. | Due (project month) | Date of submission | | | Reasons for deviation and recuperative measures | Indicative person-months | | Lead contractor(s) |
				Actual	Foreseen			Estim.	Used	
D5	Beneris&Qalibra dissemination strategy	6	4	Aug 6, 2009			The deliverable was finally approved in the project meeting in June 2009	1	1	THL

Milestones

Name	WP no.	Due (project month*)	Actual achiev. date	Foreseen achiev. date	Reasons for deviation and recuperative measures	Lead contractor(s)
Sharing data on concentrations (exposure assessment) for different fish species (Salmon & herring from BENERIS and other oily fish from QALIBRA)	6	12		September 2009	Postponed due to changes in the development of data repository.	THL

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The work undertaken in WP7 is described below under Section 3 (Consortium management).

Section 3 - Consortium management

WP leader	KTL/THL / Jouni Tuomisto
Partners involved	KTL/THL, TUDelft, FFiles, FSAI, DTU, FVST, Lendac, FIN
Workpackage objectives	The objective of this activity is to guarantee a smooth and effective collaboration between partners, and an organised processing of different activities so that all partners are working in concert, and at the end of each year and at the end to take lead in reporting activities. (THL+all; D13, D24, D34, D41, D48; Year 4 M43)

An overview main achievements of the 3rd reporting period

- Project was managed according to the new time line.

- Ethical reports were updated as requested.

- Opasnet was utilised in managing the case studies.

- Adjustments to the time line were made as a response to delays (these are explained in detail in the relevant Workpackages).

Starting point at beginning of reporting period

Main achievements of the 1st reporting period:

- Kick-off meeting organised.

- Steering committee elected.

- Framework development agreed upon.

- Project deliverables prepared.

- Upcoming Gordon conference and 2nd project meeting prepared.

- Partners informed via email on relevant issues.

Main achievements of the 2nd reporting period:

- Tasks reorganized and redistributed (due to sick leaves of key researchers) by the coordinator for improving project coordination and management.

- Updateing the project timetable.

Progress towards objectives

FSAI:
FSAI has responded to the project leader as required and has contributed to all necessary reports.

Lendac:
Lendac has been involved in group discussions and meetings regarding project development.

THL:

Contact has been kept to other members of Beneris within THL regarding overall timetable of deliverables and how to proceed with WP2. Ethical documentation was provided for all the dietary data.

As the Opasnet website and the Opasnet Base database were developed into the production stage, the emphasis of the work started to shift to actual implementation of the methods and tools developed. The tools were designed to take the focus from administration to the actual substance and execution. This revealed the management pressures.

TU Delft:

During the reporting period TU Delft has been is a continuous contact with the THL partner regarding the Bayesian belief network to be developed for the fish case study within WP3. In addition to an ongoing e-mail correspondence two meetings between TU Delft and THL took place, first one in September 2008 in Rome during the ILSI Europe BRAFO workshop on 'Methodology', and second (initiated by TU Delft) in October 2008 in Kuopio. The main aim of these meetings was to discuss the current contents of the BBN model (i.e. variables included, data and data analysis methods used to quantify the model) and also other parts of the model that are still under development.

Changes in personnel. Consortium management problems and corrective actions.

The assistant of the project coordinator was on sick leave for a lengthy period, and finally quit THL. Because of this, there was a need to reorganise the coordination work, which was done within the existing personnel in THL. In addition, some deliverables were deliberately postponed to the last reporting period.

Due to the shifts in responsibilities, the role of FSAI has diminished from the original plan; this has been reported also in the previous resports. On the other hand, the responsibilities of THL and TU Delft have increased. The impact of this shift is 80 912.82 € during the whole project period. This funding will be redistributed for the last reporting period to the partners with new tasks. This will ensure that the whole project will be successfully completed. The decision will be made in the project meeting in June, 2009.

In the Form C financial statements, an adjustment (–23 167.64 €) to the reported costs of previous periods was made by partner 5 (DTU), since by mistake they had claimed too much costs (~100 000 DKK) in reporting period 2. A final adjustment will be made by DTU in the 4th periodic report. (E-mail information from KPMG Net Source consultant Helle Sejten, Økonomicenter Syd; email: hesej@vet.dtu.dk, mob. +45 2529 5967.)

Project timetable and status

There are no major changes in the project timetable. The completion of the full benefit-risk analysis of fish has been postponed by six months.

The current timetable is shown below.
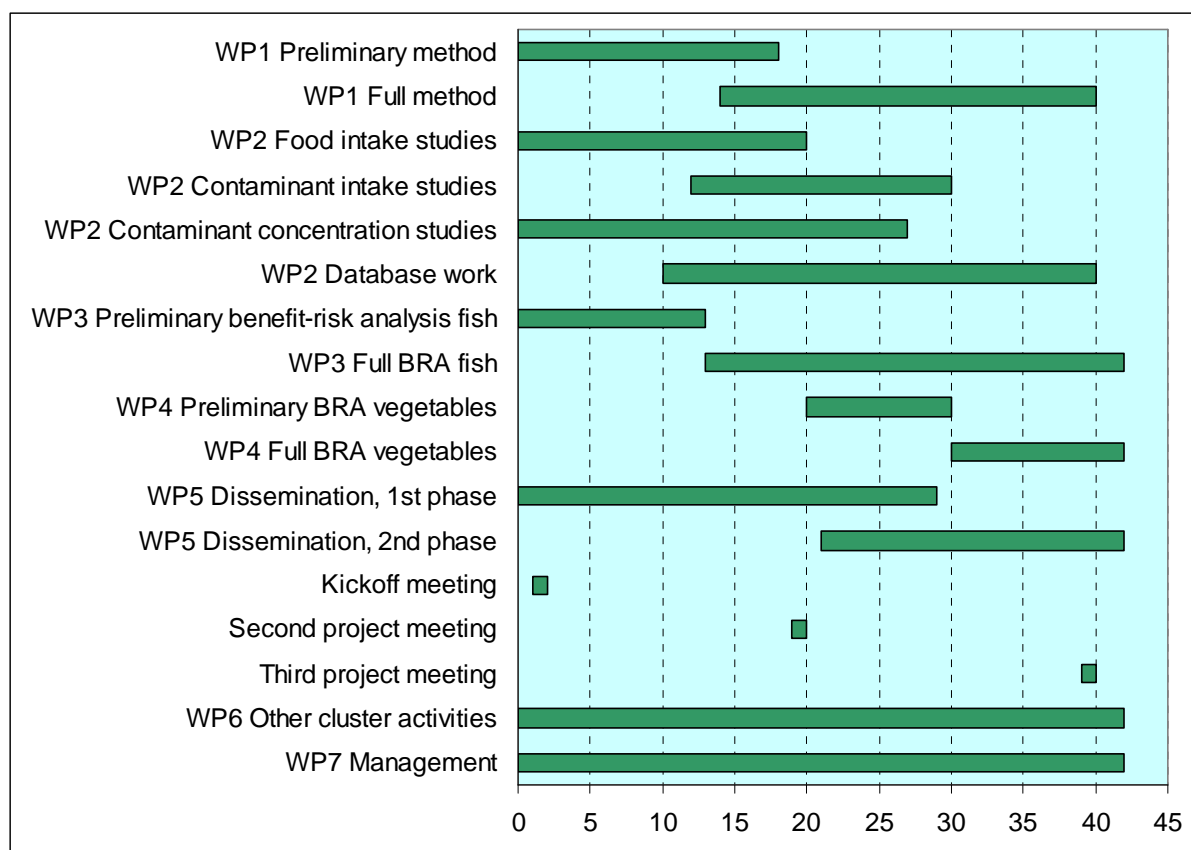
Deliverables

No.	Name	WP no.	Due (project month)	Actual	Foreseen	Reasons for deviation and recuperative measures	Estim.	Used	Lead contractor(s)
D34	Second year report	7	24	15 May, 2008			0.5	1	THL
D41	Third project report	7	36	15 May, 2009			0.2	1	THL

Milestones

None in this reporting period.

Section 4 - Other issues

None.

Appendix I - Plan for using and disseminating the knowledge

Section 1 – Exploitable knowledge and its use

Beneris, with others, has produced a website for working on and disseminating benefit-risk analyses of food. The website is a collaborative effort between several research projects, especially Beneris, Intarese, Heimtsa, Erac, and Hiwate. The results of the analyses have potentially high economic interest and hopefully will result also in commercial use. However, the website itself and its contents are open and distributed freely on a non-profit basis. The website is open (http://en.opasnet.org; previously heande.pyrkilo.fi), and it already contains several benefit-risk and other analyses on food and other topics..

Table 1. Exploitable Knowledge and its Use

Exploitable Knowledge (Description)	Exploitable Product(s) or Measure(s)	Sector(s) of Application	Timetable for Commercial Use	Patents or Other IPR Protection	Owner & Other Partner(s) Involved
Benefit-risk assessments (BRA) of food issues. The content is open and freely available to all.	A website to collect, organise, and distribute BRA information. http://en.opasnet.org	Food safety. Environmental health.	Products are available for commercial use as soon as they appear on Opasnet website.	Based on Creative Commons license Attribution – Share alike.	Owner: KTL/THL and all partners involved in developing the website and/or producing information.
Background information for assessments, such as population, mortality, morbidity, and food intake data..	Data available on Opasnet Base. (http://base.opasnet.org)	As above	As above	As above	As above
Method descriptions for making benefit-risk assessments. E.g models to compute health summary measures such as DALYs.	Descriptions available on Opasnet (http://en.opasnet.org), possibly accompanied by actual models to apply the methods.	As above.	As above.	As above.	As above.

Section 2 – Dissemination of knowledge

Table 2. Dissemination of Knowledge - Overview.

Planned/Actual Dates	Type +	Type of Audience ++	Countries Addressed	Size of Audience	Partner Responsible
1 April, 2009	Press conference about Baltic fish consumption and health. Presentation of risks and benefits of fish by Jouni Tuomisto.	Journalists, authorities from food administration, researchers.	Finland	ca. 50	Hannu Kiviranta, Jouni Tuomisto (THL)
25 September, 2008	Brafo meeting, Rome	Food authorities and researchers	Several EU countries	ca. 50	Jouni Tuomisto / THL, Patrycja Gradowska / TUDelft (participants)
16-20 February, 2009	Open assessment workshop	Researchers from several EU-funded projects	Several EU countries	15	THL, Jouni Tuomisto; TUDelft, Patrycja Gradowska
September, 2009	TAPAS project meeting	Researchers from several fields	Several EU countries	20?	THL, Jouni Tuomisto
June 16-17, 2009	Bepraribean project meeting, Bilthoven NL	Researchers from several fields incl. food.	Several EU countries	10	THL, Jouni Tuomisto
Fall 2009	Plantlibra project kickoff	Researchers from several fields incl. food.	Several EU countries.	ca. 20?	THL, Jouni Tuomisto
June 12-13, 2009	AGORA project meeting, Cambridge, UK	Researchers civil engineering, geology, earthquake sciences	Several EU countries, US	30	THL, Jouni Tuomisto

+ Includes press releases (press/radio/TV), media briefings, conferences, exhibitions, publications, project website, posters, flyers, direct e-mailing, film and video

++ General public, higher education, research, industry (sector x)

Dissemination plan

Purpose

The **dissemination plan for benefit-risk assessment of food** aims to spread information about methods and tools for making better assessments about benefits and risks that relate to food consumption. Typically, these assessments are performed by or for food authorities or companies in the food sector. However, some assessments may be directed to general consumers to promote a healthy diet. The dissemination should be targeted to both those who make these assessments, and those who read the assessments.

A special focus in this plan is on web-based tools and methods that are applicable in Europe.

The key objective of dissemination is to ensure that the methods and tools developed in research projects will become widely known and used, and that they will be further developed by new research after the original projects have ended.

Background

There are several European projects that are developing methods for benefit-risk assessment of food. Beneris, Qalibra, and Brafo are jointly collaborating in this area. In addition, there are several other projects that are closely related although their focus is not on food but on environmental health in general. These projects include Intarese, Heimtsa, and 2-Fun. These projects are producing useful information and methods that can be used also in the food sector. For example, Intarese is developing a toolbox for making environmental health impact assessments on the Internet. Heimtsa is collecting a background incidence database for essential background information used in assessments.

Tasks in the Dissemination plan

The dissemination about methods and tools developed for benefit-risk assessment divides into several parts that mutually strengthen each other towards the key objective. We will work so that the tools will

- be maintained, updated, and kept available to the users for several years after the original projects,
- be utilised in new projects as the basis for new development,
- be utilised for collecting existing useful information related to benefit-risk assessments and food,
- be utilised in real policy situations in the food sector to produce guidance for decision-making,
- be utilised in real policy situations outside the food sector, thus increasing the critical mass of users and developers,
- be utilised for publishing peer-reviewed scientific articles with a novel principle "publish first, review later."
- gain awareness among the potential users so that they can use the tools in new situations,
- gain awareness among stakeholders so that they can demand the use of the tools in new situations,
- provide better interfaces for the end-users of the modelling software.

Sustained maintenance

There is a threat that methods and tools developed by a research project are not maintained after the end of the project. Clear actions should be taken to prevent this. One way to do this is to find new projects that utilise the methods and tools (see below). Other actions are considered here.

Policy guidance and risk assessment are priorities of THL. Currently, there is a research group of nine people dedicated in maintaining and developing Opasnet. However, only one position is permanent and all others are on temporary project funding. Without any new funding, the functionalities of Opasnet can be maintained until the end of 2012.

There is a need for discussion to identify an ecological niche for each tool, so that each tool has good prospects of surviving in the future with some new funding. If there is no foreseen funding, it should be considered whether some tools should be merged to ensure and the know-how is inherited into the new systems.

Actions and suggestions are needed to ensure that a more sustained funding can be achieved. Roles of different institutes in the maintenance should be discussed. Different tools can be maintained by different institutes, but then cooperation is needed to keep the tools coherent. Systematic and established forms of cooperation in the benefit-risk assessment of foods are still missing.

New projects

Bepraribean, Intarese, Heimtsa, Hiwate, and Brafo are all ongoing projects with European Union funding. They are all related to open assessment in one way or another. The use of open assessment is encouraged in all of these projects. Now that the Opasnet Base is entering the phase of practical use, it offers real utility to the projects and their data management and modelling efforts. Partially, the projects are working on similar topics, and the information produced in one project is useful in another. This is a way to avoid duplication of work and save resources to more important things.

These projects will be informed about the new development, and possible collaboration is developed together with a contact person. The contact person for the projects are Jouni Tuomisto (Bepraribean, Brafo), Mikko Pohjola (Intarese, Heimtsa), and Päivi Meriläinen (Hiwate). New projects and contact persons will be added to the list when they are identified.

Collection of existing information

Most of the resources of Beneris and Qalibra have been used in developing methods and tools for benefit-risk assessment and testing them with case studies. Less emphasis has been in producing new information or collecting existing information outside the projects. Beneris has produced food intake and contaminant information, but otherwise it has not systematically searched for food or other data for Opasnet Base (previously Beneris data repository).

Beneris should put much more effort in collecting existing data into Opasnet Base, and existing methodological information into Opasnet during the last months of the project. The dissemination budget of Beneris has been underspent, and this resource can be redirected to data and information collection. A website with useful information is only useful if it is larger than a critical mass. Users will go to the website only if it contains enough information, i.e. if the expected balance of the benefit of the information and the cost of finding it is favourable to a user.

The collection of data and information can be effectively decentralised. It is based on a web page about information that is wanted to the website. Anyone can read the list, search for the information, organise it into a proper format and upload it to the website. THL can organise this work and pay for the workers. The only requirements for the payment are that 1) the person registers him/herself to the THL system for payments, 2) the task and the amount of compensation for the work is agreed beforehand with the contact person, 3) and the contact person controls that the agreed work has actually been done.

- See Information collection tasks for Opasnet

Real policy situations in the food sector

EFSA is a potential key user of the methods developed in Qalibra and Beneris. EFSA experts and staff are involved in the Scientific advisory panel of the two projects. During the rest of the projects, a plan should be developed about how to utilise the methods and tools developed in the projects in a small practical case study arising from the needs of EFSA. The case should be performed in the near future, preferably starting before the end of the projects in September 2009. In practice, this should relate to the work and case studies already performed in the projects. This is probably the only way to do the case study without extensive new research and funding for it. The advice of the scientific advisory panel is needed in identifying a relevant and feasible question.

Real policy situations outside the food sector

The open assessment methods developed in Beneris are not dependent on the actual sector in which they are applied. The use of the methods in any sector will spread the word and also help their usage in the food sector. Therefore, the dissemination plan includes actions that promote the methods in other potential sectors. The most important of these is currently climate change, and this is described in more detail.

In December 2009, the politicians of the world will gather to Copenhagen to decide about future actions to tackle climate change. There is an opportunity to make assessments about some of the open issues before the Copenhagen meeting, thus offering guidance for the actual decision-making. There is an ongoing assessment about climate change mitigation policies on city-level (the case city is Helsinki) in Opasnet. Health impacts of fine particles from heat production and traffic are estimated together with climate change effects and direct costs.

The policy process of climate change mitigation has a very high profile. Any good development related to policy-making in this area may also bring awareness to the methods used to achieve the development. Therefore, the case study related to climate change should also be used to promote the methods. The first task here is, of course, to make a good assessment that actually is of interest to the policy-makers. The researchers of Beneris are closely involved in the Helsinki case study.

Peer-reviewed scientific articles

With benefit-risk assessment of food, there is a constant need of new published peer-reviewed information. A critical problem typically is that although the information exists, it has not yet been published in a peer-reviewed journal or series. The process of peer review is often lengthy, typically several months. In addition, the authors aim to publish in good journals, and there is a high risk of rejection so that the submitting process starts over again in another journal.

In physics, where the speed of scientific innovation is high, researchers cannot afford the delay in publishing, because someone else may publish the same innovation. Therefore, physicists typically publish their manuscripts without any peer review in a website called Arxiv.org. A manuscript may subsequently be criticised and edited, until the author thinks it is ready for publication in an "official" scientific journal. Although this approach has been applied in physics for more than 15 years, it is still a novel idea in other scientific disciplines.

This system speeds up the publishing process, gives the new information available to the users earlier, and is more fair in the competition about the first publisher of an innovation.

A similar system is needed in the food sector. The current idea is to launch Opasnet Journal, which would have the same principle as Arxiv: **publish first, review later.** Opasnet offers a natural workspace for writing manuscripts of this kind, and the peer-reviewed and accepted manuscripts can also be published as articles in Opasnet.

As the work needed to found a new scientific peer-review journal is large, this objective is probably going to take a long time to materialise. In the meantime, we explore the possibility to launch a report series, Opasnet Reports, which can publish also non-peer-reviewed material. However, it makes it possible to publish assessments and other material in Opasnet so that it is given a permanent reference, an archived electronic version that is permanently available, and also a printed version that is stored in libraries.

Awareness among users

The potential users of the methods developed include EFSA, national food authorities such as Evira in Finland, and food industry. The awareness among these users is promoted by personal contacts (e.g. some Beneris staff is now working in Evira, thus bringing information directly to the user organisations). However, also a systematic campaign to raise awareness is needed. A newsletter is produced, briefly describing the methodological results of Qalibra and Beneris, and providing links to the websites where these methods and tools can actually be utilised and where more detailed information can be found. This newsletter is spread to national and international food authorities and to organisations representing food industry in Europe. The newsletter is sent in fall 2009, before the end of the two projects.

Awareness among stakeholders: Continuous contacts to new people who are interested in the topic or open assessments.

Open assessment is a method that only works if there is a critical mass of people actively involved. It can be used in the traditional way with only a small group of experts involved, but then it does not produce any added value compared with the traditional methods. New people should be continuously recruited to use open assessment and Opasnet. Signals from people interested in food safety or promoting openness can frequently be found from the societal discussion from television, newspapers, and magazines. Therefore, one part of the dissemination plan is to keep eye on this discussion, and make contacts to people who might be interested in food safety or open assessment.

The experience so far has shown that many people who are used to the traditional assessment methods are not interested in using openness as the key property in assessments. Therefore, the group of people who are likely to promote open assessments is partially different than the group currently involved in assessments. We cannot restrict the recruitment to the current risk assessors.

There is a need to identify and find these new people. Because this group does not exist yet as a group, it is a challenging task to identify the potential new users. Often people have a strong opinion about the openness of information, as has been seen with the discussion on the electronic (free) distribution of music. Some people emphasize the benefits of openness, while others are concerned about the intellectual property rights of the person who originally produced the information (or music, which is also information), while still others are concerned about the profit from the investments to music marketing. A recent example of this is the trial of the founders of the PirateBay, a music distribution system, and the subsequent increase in popularity of Piratpartiet in Sweden. Users who find open assessments as a good idea are more likely to be found among Piratpartiet than among their opponents.

As a part of the dissemination plan, we will make contacts to people who show interest in open distribution of information, and inform them about our open assessment project. If their agenda is related to food risks and benefits, or otherwise a topic with potential synergism, possibilities for practical collaboration are sought for.

Improved user interface of modelling software

There is a need to facilitate the use of software that are suitable for modelling benefit-risk assessments. Uninet is a key software for disseminating the details of a benefit-risk assessment. However, Uninet deals with BBNs (or dependency diagrams) that are often very complex. Therefore, the dissemination of the results are inherently difficult. We have noticed that the user-friendliness of Uninet must be improved from specific points to make it suitable for its dissemination task. Therefore, the June 2009 meeting of Beneris decided to allocate resources for two tasks on Uninet. First, to improve readability of the output by a) adding a report generator, b) adding possibility of exporting conditional samples, and c) by graphical improvements of the output window. Second, to facilitate the compatibility with other software the user is using, we will extend the import/export model feature to data-mined models.

There is also a need to facilitate the dissemination of Analytica models. This will be done mainly by utilising and enhancing the use of Analytica Web Publisher (AWP). AWP is a server-based version of Analytica, which can be used and models can be run simply with a web browser.

Section 3 – Publishable results

Table 3. Publishable Results.

Result Description	Possible Market Applications	Stage of Development	Collaboration Sought or Offered	Collaborator Details	IPR Granted or Published	Contact Details
Opasnet: A website to collect, organise, and distribute information on issues relevant for benefit-risk analyses (BRA) of food. http://en.opasnet.org Current size: 900 web pages, 450 files, 168 users, 250000 page views.	The content is open and freely available to all.	The website has been intensively utilised. Several assessments are being worked on at the website.	Interested parties are welcome to contribute to the case studies with their own information, as long as it is offered under IPR rules.	Main developer: THL	Based on Creative Commons Attribute – Share alike copyright license	Jouni Tuomisto, KTL/THL, P.O.Box 95, FI-70701 Kuopio, Finland. email: jouni.tuomisto @thl.fi
Opasnet Base: A database to collect, organise, and distribute quantitative model results and input data http://base.opasnet.org Current size: 66 data tables, 2 million rows.	The content is open and freely available to all.	The website was recently opened. Data from several assessments are being uploaded to the database.	As above.	Main developer: THL	As above.	Jouni Tuomisto, KTL/THL, P.O.Box 95, FI-70701 Kuopio, Finland. email: jouni.tuomisto @thl.fi
D33 Consumer info about benefits and risks of fish.	As above.	To be published with D38 in September 2009	The product has a feedback and discussion functionality to facilitate contribution.	THL	As above	As above
D46 End-user evaluation.	As above.	To be published in September 2009.	As above.	FSAI, THL	As above	As above
D38 Final fish benefit-risk assessment.	As above.	As above	As above	TUDelft, THL	As above	As above