



Project no: **022936**Project acronym: **Beneris**

Project title: Benefit-risk assessment for food:

an iterative value-of-information approach

Instrument: STP – Specific Targeted Project

Publishable final activity report Final report (D48b)

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Dissemination level: PU

Start date of project: April, 1st 2006

Duration: 3,5 years

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



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

Contract no: 022936

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Project duration: 1 April 2006 - 30 September 2009

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Project websites: http://en.opasnet.org (in English) http://en.opasnet.org (in Finnish),

http://www.beneris.eu

1. Project execution

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 are listed below.

1.1.1 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.

1.1.2 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?

1.1.3 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

Role	No.	Name	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	TU Delft	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 Data Systems 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 assessment report produced, and the mere philosophy of doing assessments. This has resulted in a benefit-risk assessment method that is now called *open asssessment*.

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 performance of a benefit-risk assessment; 2) causality in structuring an assessment; 3) collective structured learning; 4) value judgements within assessments; 5) variable and information structure; 6) collaborative work; and 7) dealing with disputes. All of these challenges have been solved in at least a tentative way such that the solution is both consistent with other parts of the method and possible to implement in practice. Detailed descriptions can be read from Opasnet from the following pages: 1) Performance, 2) Causality, 3) Trialogue, 4) Value judgement, 5) Variable structure, 6) Mass collaboration, and 7) Discussion, respectively.

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.

The work related to combining existing databases into an integrated repository has lead to several important conclusions that have affected the plans of further work. First, it is very difficult and time consuming to integrate food consumption data between the countries. Therefore, 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 structure. This applies both to existing databases, and the data produced within Beneris. Second, the new benefit-risk analysis method created new requirements for the database to be developed. These considerations were taken into account when the Beneris data repository was designed. This work resulted in Opasnet Base, which is described below.

Collaboration with QALIBRA

Beneris has established a collaboration effort through clustering with QALIBRA, and these two consortia have been collaborating from the start of both projects. QALIBRA and Beneris have also collaborated with the BRAFO project, which is developing tiered framework for risk-benefit assessment.

Below we shortly highlight the events and activities resulting from the related to these cluster activities between Beneris and QALIBRA.

Progress during the first year:

• The first Cluster meeting of the Qalibra and the Beneris projects was organized and planned by IFL/Matis in cooperation with KTL/THL, RIVM and CSL/FERA. The

- meeting was held at RIVM, Netherlands May 23rd-24th 2006 at the same time as both projects conducted their separate kick-off meetings. A report containing the output from the Cluster meeting was submitted to the Commission in July, 2006.
- The cluster website (www.qalibra-beneris.eu) was developed by CSL/FERA (QALIBRA) in collaboration with Beneris in July, 2006.
- The membership of the Scientific Advisory Panel (SAP) for QALIBRA and Beneris was been finalized.
- QALIBRAliaised with Beneris about methods for quantifying uncertainty. To progress this, a CSL scientist visited TU Delft to learn about the methods for dealing with uncertainty in expert opinion in Beneris.

Progress during the second year:

- The second Cluster meeting (i.e. the midterm meeting) of the sister projects QALIBRA and Beneris was organised and planned in cooperation between Matis, KTL/THL and CSL/FERA. The meeting was held in Helsinki, Finland, 7–9 November 2007. This meeting focused on the review of activities and sharing information between the two projects as well as the consultation of the Scientific Advisory Panel (SAP). A report containing the output from the Cluster meeting was written and submitted to the European Commission by QALIBRA.
- Roger Cooke visited Central Science Laboratory (CSL) on 26, 27 Nov. 2007, where he
 conferred with researchers in the Qalibra project and gave a presentation. This was
 followed by a visit of CSL scientist Alistair Murray to Delft (4 Dec. 2007) during
 which further collaboration was discussed. This collaboration has spun of into further
 expert elicitation activities with Dr. W. Aspinall.
- A Gordon conference was organised and planned by the KTL/Beneris in co-operation with QALIBRA, ERAC and Sytyke. The conference theme was Environment and health - approaches to benefit-risk analysis and it was held in Valamo in Finland December 3-5, 2007, partners from both Beneris and QALIBRA attended this meeting.
- KTL/THL launched an open website for BRA (http://heande.pyrkilo.fi).QALIBRA was granted access to data and discussion pages at the open websites

Progress during the third year:

- Beneris developed a joint glossary with Intarese and gave 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 developed the first draft of a cluster dissemination plan

Progress during the fourth year

- The final Beneris and Qalibra cluster meeting was organised and planned in cooperation between Matis, THL, Altagra and FERA. The meeting was held in Budapest 10-11 June 2009. The objective of the final meeting was dissemination of activities and sharing of information between the two projects as well as the consultation with the Scientific Advisory Panel (SAP).
- At the final Beneris and QALIBRA cluster meeting the draft cluster dissemination plan was discussed and a revised final version accepted.

- The final report on the cluster activities was written and submitted to the European Commission by QALIBRA in September 2009
- In order to promote post-project activities of the two consortia Beneris and QALIBRA aim to publish several scientific articles together in a special issue. The tentative journalfor this joint dissemination is Food and Chemical Toxicology.
- Beneris participated in a final end-user workshop held by QALIBRA 9-10th September 2009 in Budapest. This end-user workshop included practical hands-on training with the risk-benefit software produced by QALIBRA, using case studies developed in the project.

Intentions for use and impact

The methods and tools developed in Beneris were and are being offered to other projects, or real-life benefit-risk assessments. Opasnet workspace is available for this purpose. Several projects have already started to use the website for their own work: Intarese, Heimtsa, Hiwate, and Plantlibra (funded by EU); Claih, Bioher, and Hitea (funded by the Academy of Finland); and Bepraribean (European project on 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 than alone.

Openness, scientific criticism, and an efficient information structure are the three guiding principles of open assessment. We believe that the improved methods are able to serve policy-making in a better way than the previous methods. It is easier to produce credible assessments. They are more likely to tackle questions that are of real interest to stakeholders or decision-makers. They are likely to produce decisions that better informed.

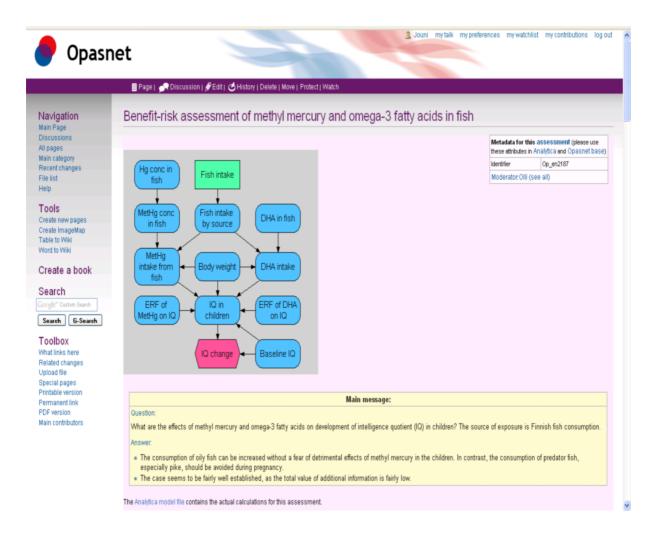
Of course, this does not happen by itself. There must be a real need to apply the new methods, and authorities must do their homework in learning to use them. Open assessment has high potential, but it has not yet shown in a real-life decision-making that it is able to outperform traditional assessments. If it succeeds in this critical test, it may lead to a quantum leap in reducing the gap between science and policy.

2. Publishable results

The main products of Beneris are the improved methodology (open assessment) for benefit-risk assessments, the web workspace Opasnet for performing them in a collaborative way, and the Opasnet Base database containing ready-to-use information needed in assessments. Interested assessors have been identified and contacted 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.

The new benefit-risk assessment method (open assessment) was described on the web workspace Opasnet (http://en.opasnet.org). This work will also continue after Beneris. The Beneris fish case study was described in Opasnet in two parts: a separate sub-assessment was performed about methylmercury and omega-3 fatty acids in children(http://en.opasnet.org/w/Benefit-risk_assessment_of_methyl_mercury_and_omega-3_fatty_acids_in_fish), and the full assessment (http://en.opasnet.org/w/Benefit-risk_assessment_of_fish_consumption_for_Beneris) contained also other pollutants and endpoints. However, some details of the full assessment are being published in scientific journals, and they will appear on Opasnet after publication.

Several assessment case studies are under way outside Beneris. The website is designed for assessments that are performed openly, allowing also for stakeholder participation. A database called Opasnet Base (http://en.opasnet.org/w/Opasnet_Base) was used to upload model results and nutrition studies performed in Beneris. The work has produced practical experience on this kind of collaborative work, and this experience has been used to develop the benefit-risk assessment methods further.



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. This sub-assessment graph is shown as an example only, because the full fish case graph has more than a thousand nodes and would not fit on the page.

Opasnet is a website to collect, organise, and distribute information on issues relevant for benefit-risk analyses (BRA) of food (http://en.opasnet.org). It also contains material about many other topics than food, e.g. climate change policies and health, health risks of air pollution, and emissions of metal industry. Current size: 980 web pages, 450 files, 176 users, 270000 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 a proper copyright. Opasnet uses *attribute – share alike* copyright of Creative Commons. It means that information in Opasnet can be freely used for any purpose on two conditions. First, the original source must be acknowledged. Second,

the derivative works must also have similar open copyright, i.e. they must also be freely usable.

Opasnet also has a feedback and discussion functionality to facilitate contribution. Although most people who are contributing to the website are probably researchers, it is also important to have functionalities for asking questions, make value judgements about the topics covered, and give feedback about the content. An example of feedback collection is http://en.opasnet.org/w/End_user_evaluation.

Opasnet Base is a database to collect, organise, and distribute quantitative model results and input data (http://base.opasnet.org). Its current size is 66 data tables, and 2 million rows. The content is open and freely available to all. The website was recently opened after structural improvements. Data from several assessments are being uploaded to the database.

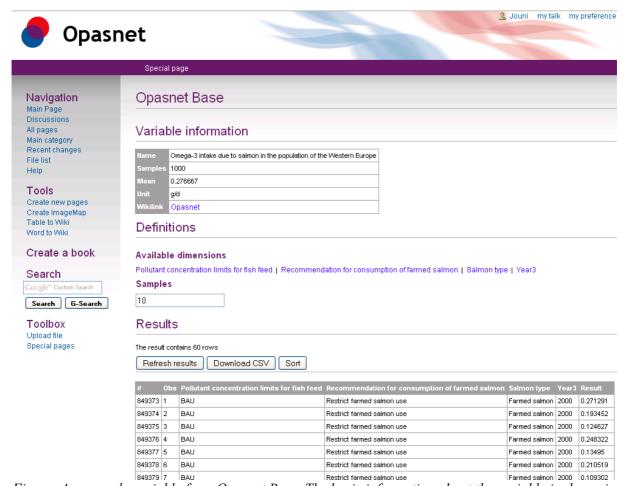


Figure. An example variable from Opasnet Base. The basic information about the variable is shown in the box on the top of the page. In the middle section, it is possible to select the details and samplesize to be shown. Finally, the bottom part shows the result values and indices.

D33 Consumer info about benefits and risks of fish is a dissemination material about the main results of Beneris. http://en.opasnet.org/w/file:Beneris_dissemination_material.pdf. It was published in November 2009.

D46 End-user evaluation of Opasnet, open assessment, and the fish case study was performed in September-November 2009. http://en.opasnet.org/w/End_user_evaluation.

D38 Final fish benefit-risk assessment was published in Semptember 2009. http://en.opasnet.org/w/Benefit-risk assessment of fish consumption for Beneris