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QALIBRA-Heilsuvogin
Third Annual Report

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Öryggi og umhverfi

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Titill / Title	**QALIBRA-Heilsuvogin. Third Annual Report**		
Höfundar / Authors	Helga Gunnlaugsdottir, Nynke de Jong, Matthew Atkinson, Heleen van Dijk, Meike Wentholt, Lynn Frewer, Bjorn Thorgilsson, Heida Palmadottir, Andy Hart		
Skýrsla / Report no.	30-09	*Útgáfudagur / Date:*	Október 2009
Verknr. / project no.	1681		
Styrktaraðilar / funding:	*ESB*		
Ágrip á íslensku:	Þessi skýrsla er þriðja ársskýrsla í Evrópuverkefninu QALIBRA og nær yfir tímabilið 1.04.2008 til 31.03.2009. QALIBRA, eða "Quality of Life – Integarted Benefit and Risk Analysis. Webbased tool for assessing food safety and health benefits," skammstafað QALIBRA (Heilsuvogin á íslensku), er heiti Evrópuverkefnis, sem heyrir undir Priority 5, Food Quality & Safety í 6. rannsóknaráætlun ESB. Um er að ræða þriggja og hálfs árs verkefni sem Rannsóknastofnun fiskiðnaðarins (nú Matís ohf) stýrir. Verkefnistjóri er Helga Gunnlaugsdóttir, deildarstjóri á Matís. Markmið QALIBRA- verkefnisins er að þróa magnbundnar aðferðir til að meta bæði jákvæð og neikvæð áhrif innihaldsefna í matvælum á heilsu manna. Þessar aðferðir verða settar fram í tölvuforriti sem verður opið og aðgengilegt öllum hagsmunaaðilum á veraldarvefnum. Þátttakendur í verkefninu eru frá Íslandi, Bretlandi, Hollandi, Grikklandi, Portúgal og Ungverjalandi		
Lykilorð á íslensku:	*Árskýrsla, QALIBRA, áhættu og ávinningsgreining, innihaldsefni matvæla, magnbundnar matsaðferðir, feitur fiskur, markfæði*		
ummary in English:	"QALIBRA - Quality of life – integrated benefit and risk analysis. Web – based tool for assessing food safety and health benefits" is a project funded by the EC's Sixth Framework Programme, Priority 5, Food Quality & Safety. It started in April 2006 and will end in 2009. To assess the balance between the risks and benefits associated with a particular food, they must be converted into a common measure of net health impact. Uncertainties affecting the risks and benefits cause uncertainty about the magnitude and even the direction of the net health impact. QALIBRA will develop methods that can take account of multiple risks, benefits and uncertainties and implement them in web-based software for assessing and communicating net health impacts. The objectives of QALIBRA are to develop a suite of quantitative methods for assessing and integrating beneficial and adverse effects of foods, and make them available to all stakeholders as web-based software for assessing and communicating net health impacts. The participants in the project are: Matís, Iceland, coordinator, Central Science Laboratory, United Kingdom, National Institute of Public Health and The Environment, The Netherlands, Wageningen University, The Netherlands, University of Patras, Greece, Altagra Business Service, Hungary, National Institute for Agriculture and Fisheries Research, Portugal.		
English keywords:	*Periodic report, QALIBRA, risk-benefit analysis, quantitative methods, oily fish, functional food*		

Quality of Life – Integrated Benefit and Risk Analysis.
Web-based tool for assessing food safety and health benefit
(N° 022957)

May 2009

Deliverable D27

Third periodic activity and management report

Helga Gunnlaugsdottir, Nynke de Jong, Matthew Atkinson, Heleen van Dijk, Meike Wentholt, Lynn Frewer, Bjorn Thorgilsson, Heida Palmadottir and Andy Hart

Lead participant: Matís

Specific Targeted Research Project

Thematic Priority 5: Food Quality & Safety

Due date of deliverable: 31.03.2008
Actual submission date: 28.05.2009
Start date of project: 01.04. 2006
Duration: 2006 – 2009
Revised: 24.08.2009

Project co-funded by the European Commission within the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	**X**
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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1. EXECUTIVE SUMMARY

National and European food policy, including regulations and advice to consumers, should take account of the risks and benefits of different foods, i.e. their positive and negative effects on human health. Information on risks and benefits should also be available to other interested parties, including food producers, retailers and consumers.

Usually, information on risks and benefits is presented separately. This is unsatisfactory, because it leaves the recipient uncertain as to the balance of risk and benefit. Ideally, information on risks and benefits should be combined to indicate the overall effects of particular dietary choices, i.e. the net health impact.

The central goals of QALIBRA are therefore to develop improved approaches for the assessment and communication of net health impact of dietary choices. To maximise dissemination and uptake of the project outputs, they will be implemented as web-enabled software.

Uncertainties affecting risks and benefits cause uncertainty about the magnitude and even the direction of the net health impact, as illustrated in Figure 1. Therefore, the approaches developed by QALIBRA aims to take account of uncertainties and communicate them effectively to both technical users and consumers.

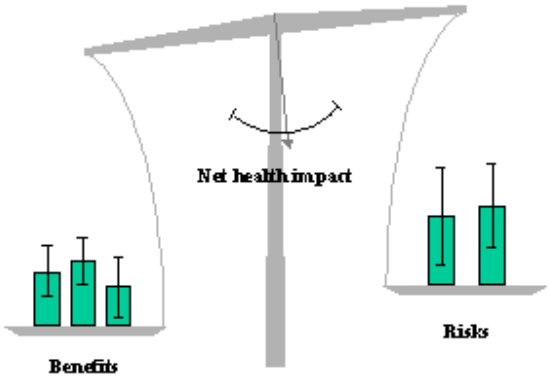

Figure 1. Net health impact depends on the balance of benefits and risks and their associated uncertainties.

The new tools developed by QALIBRA will be tested and evaluated in detailed case studies including the important and topical examples of seafood and functional foods.

The specific objectives of QALIBRA are therefore as follows:

1. Develop a generalised modular approach to risk-benefit analysis,
2. Implement the approaches in web-enabled software, with different components adapted to different user groups,
3. Develop targeted risk communication strategies for integrated risk-benefit analysis, adapted to the needs of different stakeholders,
4. Use the methods and software developed by QALIBRA to carry out detailed case studies on the risks and benefits of oily fish and functional foods,
5. Establish information-sharing and joint activities with BENERIS, another EU-funded project undertaking complementary research,
6. Project management.

The work in the project is organized under 7 work packages, one for each of objectives 1-3 and 5-6 and 2 for the two case studies under objective 4. Progress and results achieved in each work package is summarized below.

Work package 1 has continued to work on the development of the overall framework for risk-benefit analysis. This reporting period the framework has been updated to allow inclusion of variability and uncertainty for every model input. Further development will be ongoing until month 42. In addition, this work package has concentrated on development of dose-response models and algorithms for specific beneficial and detrimental effects that are relevant for consumption of oily fish (Case study 1) and phytosterol enriched functional foods (case study 2), and on advanced methods for quantifying expert knowledge and uncertainty in the choice of dose-response models. This work is presently advancing beyond traditional approaches to dose-response modelling.

Work package 2 will implement the QALIBRA methods as web-enabled software. During the third year, versions 4.3 and 5 of the system design have been developed and finalised. Version 3 of the system was delivered and implemented in September 2008 and a formal usability evaluation of this version of the system was conducted in January 2009. The outcome of this usability evaluation was presented in deliverable D23. In light of the results from the usability evaluation of Version 3 of the system further development of the website and web-tool will be carried out in the next period.

Work package 3 is developing strategies for communicating and disseminating risk benefit information. This period a paper with the results from the first focus group study was submitted to a scientific journal. Further, the second round of stakeholder analysis (Delphi study) was carried out, the analysis of the data finalised and presented at consortium meetings. In addition, this work package developed dissemination material for the *pilot* end-user workshop, the outcome of this work is presented in Revision 1 of deliverable D22. This work package also compiled a revised plan for using and dissemination the knowledge for the QALIBRA project as a whole.

Work package 4 is developing case study 1, on oily fish. A preliminary analysis comprising one positive and one negative health effect was completed earlier in the project, as a starting point for a more comprehensive analysis including a wider range of effects. During the third year the selection of the most important positive and negative health effects for oily fish to include in the comprehensive version of case study 1 has been completed. Data for the selected health effects has been evaluated in detail, and used in advanced modelling of dose/response relationships for positive and negative health impacts. In addition, work has begun on scientific papers on several technical issues encountered in case study 1.

Work package 5 is developing case study 2, on functional foods. The work this period has involved translation of the health effects into DALY and description of the uncertainties as well as extrapolations encountered in case study 2. This work package has also provided dose-response models for the most important positive and negative health endpoints in case study 2, defined the final intake scenario's for habitual

phytosterol/-stanol intake, and completed modelling of net health impacts in terms of DALYs using the Qalibra framework and software from Work Packages 1 and 2. Work on a report on case study 2 and outputs for use as examples in WP3 end-user workshop is currently ongoing.

Work package 6 comprises cluster activities between QALIBRA and the Beneris project, which is conducting complementary research on risk-benefit analysis. 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. The planning of the third and final Cluster meeting, to be held 10-11 June 2009, is also well under way. Partners from both projects continued to liaise about ideas and possibilities for a shared QALIBRA- Beneris data repository. During this reporting period, Beneris has developed the first draft of a cluster dissemination plan.

Work package 7 is responsible for coordination and management of the QALIBRA project. In the third project year this work package has fine-tuned, monitored and coordinated the work in the project. The second annual reports for the project were delivered to the Commission and three overall project meetings was held during this reporting period.

The main elements of the publishable result of the plan for using and dissemination the knowledge are: project website, posters, brochures, presentations at scientific conferences and scientific publications. Furthermore, the QALIBRA web tool system website will become public at the end of the project, and training materials will be produced and tested for use in continuing dissemination after the end of the project.

The expected end result of the project is the completion of advanced tools and approaches for analyzing and communicating the risks, benefits and net health effects of dietary choices, implemented as web-enabled software. This is intended for use by a range of stakeholders, including policy-makers, the food industry and consumers, providing them with better information on the overall health impacts of different foods, or of foods produced by different methods. This will enable decision-makers and consumers to make well-informed choices between different foods, or between different production practices, and thereby improve the safety and health benefits of the food chain.

The public website for the project may be examined at www.qalibra.eu
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Other contractors:

Central Science Laboratory	CSL	United Kingdom
National Institute of Public Health and The Environment	RIVM	The Netherlands
Wageningen University	WU	The Netherlands
University of Patras	UPATRAS	Greece
Altagra Business Service	ALTAGRA	Hungary
National Institute for Agriculture and Fisheries Research	INIAP/IPIMAR	Portugal

2. PROJECT OBJECTIVES & MAJOR ACHIEVEMENTS-YEAR 3

Overview of general project objectives

The strategic goals of QALIBRA are to develop a suite of quantitative methods for assessing and integrating beneficial and adverse effects of foods, apply them to selected food groups, and make them available to all stakeholders as web-based software for assessing and communicating net health impacts.

The general objectives of QALIBRA are:

1. Develop a generalised modular approach to risk-benefit analysis using menus of dose-response and valuation functions. The dose-response functions will cover different types of positive and negative health effects that are commonly encountered in food safety assessment. The valuation functions will integrate positive and negative health effects using common measures of net health impact (e.g. quality-adjusted life years, QALYs). The framework will also include methods for comprehensive risk ranking, methods for characterising data quality and methods for separating uncertainty and variability (Workpackage WP1).
2. Implement the risk-benefit analysis methods developed in QALIBRA in web-enabled software that is available for use by all stakeholders via an integrated website, with different components adapted to different user groups using appropriate interaction styles, terminology and information presentation techniques (WP2).
3. Develop targeted risk communication strategies for integrated risk-benefit analysis, adapted to the needs of different stakeholders, and develop and test programs and materials for dissemination of the practical use of the QALIBRA software by technical end-users (WP3).
4. Use the methods and software developed by QALIBRA to carry out comprehensive risk-benefit analyses for selected food groups including oily fish (with input from Beneris for salmon & herring) and functional foods, for selected EU populations, and use the results to evaluate and improve the QALIBRA approaches (WP4 & 5).

5. Establish a platform for cluster activities between QALIBRA and BENERIS projects and report about them to the Commission (WP6).
6. Manage and coordinate the QALIBRA project to ensure the activities are properly focussed on the Commission's objectives and achieve high standards of scientific and technological excellence, ensure the quality of the consortium personnel and the mobilisation of resources, to monitor and evaluate progress against the project milestones and to make timely and appropriate adjustments when necessary (WP7).

Approaches for risk-benefit analysis with respect to food safety are currently at a relatively early stage of development. In recent years attempts have increasingly been made to quantify the risks and benefits of dietary choices, but usually they are considered separately or integrated only in a qualitative way. Although general frameworks for risk-benefit analysis have been proposed in the literature, the few studies that have quantified net health impacts have been specific to particular problems. Uncertainties affecting risks and benefits are often given only fleeting consideration and are very rarely quantified in any formal way. The few research studies, which have quantified net health impacts, have not attempted to quantify the uncertainties associated with them. Finally, while there has been a rapid growth in social sciences addressing risk perception and risk communication, only limited attention has so far been given to approaches for communicating net health impacts, or to approaches for communicating uncertainty.

QALIBRA will advance this state of the art by:

- further developing the concept of a general framework for risk-benefit analysis, and optimising it for ranking, assessing and integrating beneficial and adverse effects of foods and their environmental contaminants
- evaluating dose-response models and functions for integrating and valuing health impacts, selecting those most relevant to food safety questions and refining them if necessary for use in the general framework
- identifying suitable methods for characterising the main types of uncertainty affecting food risk-benefit assessments, and incorporating them in the framework
- investigating the risk-benefit information needs and reactions of technical users and consumers, and developing effective risk-benefit communication strategies
- implementing the approaches as web-based software for assessing and communicating net health impacts, with appropriate functions for both technical users and consumers
- intensive testing and evaluating the approaches in detailed case studies, including the important and topical example of seafood and functional food.

Summary of recommendations from previous reviews

QALIBRA was reviewed by the Commission's evaluators at the mid-term review meeting. The main points of the recommendations are summarised below:

- QALIBRA should focus on developing methodology (including exploration of case studies) rather than on producing risk-benefit analyses suitable for regulation.
- Assessment of user needs should concentrate mostly on technical users and risk managers.
- QALIBRA and Beneris should develop a single repository of datasets and use them for cross-validation of methods.
- Risks and benefits should be explored for different age groups.
- QALIBRA and Beneris should develop a joint glossary of key terms for risk-benefit analysis.
- Targeting the QALIBRA tool and its outputs at all stakeholders may be premature.

The QALIBRA consortium responded to the Commission on these recommendations and is taking account of them, and of further feedback from the Scientific Advisory Panel, in the continuing work program.

Summary of the objectives, work performed, contractors involved and main achievements YEAR 3 for different workpackages (WP)

WP1. Development of generalised modular approach to risk-benefit analysis using menus of dose-response and valuation/integration functions

Contractors involved: RIVM, CSL, Matis

Objectives, work performed and main achievements YEAR 3

- Find solutions for the dose-modelling and the translations into DALY of the positive and the negative health effects as the data is prone to serious uncertainties. The status of this work is that the dose-response modelling is advancing beyond traditional approaches to dose-response modelling.
- Provide dose-response models for the most important positive and negative health end-points related to the fish case study 1B, the outcome of this work has been implemented in the QALIBRA framework
- Update the QALIBRA framework to allow inclusion of variability and uncertainty for every model input, the outcome of this work has been implemented in the QALIBRA framework
- Initialize work on scientific articles on the dose-response modelling, intake scenario's, the framework and integration method, this work is currently ongoing

WP2. Implementation of methods as web-enabled software for all stakeholders

Contractors involved: CSL, UPATRAS, Matis, RIVM, WU

Objectives, work performed and main achievements YEAR 3

- Finalise Version 3 of system, the outcome of this work was described in deliverable D21
- Finalise Version 5 of system design, the outcome of this work was a version that contains details of functions to allow sharing of risk-benefit assessments and potential to publicize these assessments
- Finalise intermediate versions of the system design and on the system itself, the outcome of this work was: Version 4.3 of the system design, Version 2.1 of the system and version 1 of the user documentation were finalised
- Carry out usability evaluation of Version 3 of the system, the outcome of this usability evaluation was presented in deliverable D23
- Continue work on Version 4 of the system, this work is currently ongoing

WP3. Development of strategies for communicating and disseminating risk benefit information and dissemination

Contractors involved: WU, Matis, UPATRAS, CSL, RIVM, IPIMAR, Altagra

Objectives, work performed and main achievements YEAR 3

- Finalise and submit paper with results from focus groups to a scientific journal.
- Develop a draft protocol for the second round of consumer studies and conduct a pilot study for the second round of consumer studies, this work has been finalised. The collection of data for the second round of consumer studies is currently ongoing.
- Develop and carry out the second round of stakeholder analysis (Delphi study), finalise the data analysis of the Delphi study, present and the results at overall project meetings. The outcome of this work was presented at the 6th and 7th overall project meetings for QALIBRA and a draft report has been written.
- Finalise a report with the dissemination material for *pilot* end-user workshop, the outcome of this work was presented in deliverable D22.
- Develop material for the *final* end-user workshop to be held in Budapest, September 2009, this work is currently ongoing.
- Finalise the QALIBRA brochure, the published brochure has been disseminated at conferences and workshops related to food and food safety
- Dissemination of the QALIBRA project. This reporting period the QALIBRA project has been presented on 9 different occasions at national and international conferences/lectures i.e. 8 oral presentations and 1 poster. Further, one scientific article based on results from the project has been published.

WP4. Case study 1 on seafood

Contractors involved: Matis, IPIMAR, RIVM, CSL

Objectives, work performed and main achievements YEAR 3

- Finalise the identification of most important endpoints and studies for case study 1b, this work has been completed
- Select the positive and negative health effects for oily fish to include in case study 1 on oily fish. The status of this work is that data for the selected health effects has been evaluated in detail, and used in advanced modelling of dose/response relationships for positive and negative health impacts.
- Finalise data collection for phase B of case study 1, this milestone has been reached and the outcome of this work will be used as input into the development of generalized modular approach to risk-benefit analysis in WP1
- To start work on scientific papers on several issues related to case study 1, this work has been initialized

WP5. Case study 2 on functional foods

Contractors involved: RIVM, CSL, Matis,

Objectives, work performed and main achievements YEAR 3

- Provide dose-response models for the most important positive and negative health endpoints in case study 2, define the final intake scenario's for habitual phytosterol/-stanol intake, complete the modelling of net health impacts in terms of DALYs using the Qalibra framework and the web-enabled software, this work has been finalised and the outcome of this work has been applied in WP1 and WP2
- Translation of the health effects into DALY and description of the uncertainties as well as extrapolations encountered in case study 2, the outcome of this work was applied in the modelling work
- Prepare report on case study 2 on a functional food and outputs for use as examples in WP3 end-user workshop, this work is currently ongoing and a draft report has been finalised

WP6. Cluster activities between the QALIBRA and Beneris projects

Contractors involved: Matis, CSL, RIVM, WU, UPATRAS, Altagra, IPIMAR

Objectives, work performed and main achievements YEAR 3

- Optimize the interaction and the cluster activities between the QALIBRA and Beneris projects. 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. The planning of the third and final Cluster meeting, to be held 10-11 June 2009, is also well under way.

- Partners from both projects continued to liaise about ideas and possibilities for a shared QALIBRA- Beneris data repository. BENERIS has granted QALIBRA access to their data repository (called the Opasnet Base http://base.opasnet.org).
- Beneris has developed the first draft of a cluster dissemination plan

WP7. Project coordination and management

Contractors involved: Matis, CSL, RIVM, WU, UPATRAS, Altagra, IPIMAR

Objectives, work performed and main achievements YEAR 3

- The objective during the third project year has been to fine tune, monitor and coordinate the work in the QALIBRA project
- Finalise the second periodic reports (i.e. annual progress report and annual financial report) , the outcome of this work was submitted to the Commission (Deliverable D20)
- Organize & plan project meetings and ensure that minutes were prepared for all meetings. Three overall project meeting have been held in the project during the third year and reports that describe the outcome of each meeting are enclosed with this report (Annex 2, 3 and 4)
- Organize & plan Project Steering Group (PSG) meetings and write minutes from these meetings

3. WORKPACKAGE PROGRESS OF THE PERIOD

Overview of the actions carried out in WP1-WP7 in the reporting period

WP1. Development of generalised modular approach to risk-benefit analysis using menus of dose-response and valuation/integration functions

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point of this period was that the work in WP1 was delayed 3-4 months as the construction of the framework and the delivery of data on positive and negative health effects turned out to be more complicated than originally foreseen
- Find solutions for the dose-modelling and the translations into DALY of the positive and the negative health effects as the data is prone to serious uncertainties
- Provide dose-response models for the most important positive and negative health end-points related to the fish case study 1B
- Construct final habitual oily fish intake scenario's
- Update the QALIBRA framework, including uncertainties and variations, together with partner CSL
- Initialize work on scientific articles on the dose-response modelling, intake scenario's, the framework and integration method

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved - YEAR 3

- RIVM has developed dose-response functions for stroke, fatal heart disease, developmental IQ (methylmercury vs. n-3 fatty acids) and TCDD (dioxins, with three disease endpoints)
- RIVM has transferred data from case 1B and 2 to CSL in order to incorporate in the web-based tool
- RIVM has provided additional data in order to calculate DALY's like population life expectancies, incidence of disease rates, disability weights for CSL.
- RIVM has explored the possibility to include non-fatal heart disease in the framework in collaboration with CSL but dismissed this endpoint as it would mean considerable adjustment of the web-tool which cannot be implemented in the time-frame of the project. Furthermore, there is very little data to base the dose-response functions on. In effect this means that the beneficial effect is underestimated
- Matis continued the data collection and evaluation for case study B and reported to RIVM on the remaining endpoints and studies to be included in the modelling

- RIVM has explored the possibility to include health effects of vitamin D (based on data supplied by Matis) in the framework but dismissed this endpoint as it would be time consuming to find suitable dose-response data for which cannot be finalised within the time frame of the project. As the external reviewers have stated that the development and justification of the methodology should be the main focus of QALIBRA rather than the completion of a comprehensive policy-applicable risk-benefit assessment RIVM has decided to focus on the main health effects and not to include vitamin D
- RIVM has started to draft the TCDD scientific article including the challenges encountered.
- RIVM performed a final check on the data interpretation in the TCDD topic
- RIVM performed a final check on the data interpretation of the methylmercury topic
- RIVM drafted a first version of the methylmercury paper
- RIVM wrote a first draft of the dose-response discussion paper
- RIVM submitted an abstract on risk-benefit analysis on neurodevelopment to ICN, Bangkok, October 2009
- RIVM continued the work on the QALIBRA framework in collaboration with CSL.
- RIVM developed further the oily fish intake scenario's based on realistic data.
- Matis and CSL participated in discussions on progress and definition of next steps of action in WP1 at project meetings
- RIVM prepared and attended the 6th project meeting in Reykjavik, September 2008 as well as the 7th project meeting in Wageningen, January 2009

Deviations from the project workprogramme & corrective actions taken/suggested:
The consortium has agreed not to work on developing methods to provide personalised risk-benefit estimates for individuals. This decision is based on the concerns raised by the EU reviewers and on the need to give priority to solving the primary technical problems of risk-benefit analysis

As reported in the 2nd annual activity report the dose response modelling is expert work and turns out to very case sensitive and laborious. The DALY method has been implemented in the QALIBRA framework as this method is likely to be the most relevant for experts. The construction and the data delivery on positive and negative health effects turned out to be time consuming. It has been decided to work on case 2 (functional foods) in parallel to case study 1B (seafood) as case study 2 appears to be less complex than case study1 and to learn parallel from both case studies. It was also foreseen that this action would expedite the development of the QALIBRA framework. Further, it was decided to limit case study 1B to two important negative compounds i.e. TCDD (with several health endpoints) and methylmercury as well as three important positive health

effects (neurodevelopment, stroke, fatal heart disease). Since the project reviewers had mentioned in their midterm review that the focus of Qalibra should be on the development of the framework and not on the production of comprehensive policy-applicable risk-benefit assessments it has been decided to focus on the previously mentioned main health effects in the QALIBRA project.

Table 1: Deliverables List for WP1

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D3	Catalogue and ranking of existing integration methods	1	Month 4	Month 8	10,5	11 **Completed**	RIVM
D5	Catalogue and ranking of dose response models	1	Month 8	Month 8	7,25	8 **Completed**	RIVM
D7	Set of dose-response models and algorithms for some specific effects that are relevant for consumption of selected foods	1	Month 12-42	Month 12-42	18	Ongoing	RIVM
D8	Version 3 of QALIBRA framework for Risk-Benefit assessment	1	Month 12	Month 15	15	15 **Completed**	RIVM
D13	Version 4 of framework taking account for Risk-Benefit assessment	1	Month 18	Month 23	12,25	12,3 **Completed**	RIVM
D28	Scientific papers on dose-response and uncertainty models	1	Month 42	Month 42	6,5		RIVM
D29	Scientific papers on framework and integration methods	1	Month 42	Month 42	5		RIVM

Table 2: Milestones List for WP1

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M1.1	Inventory of types of dose-response models and endpoints potentially relevant for risk-benefit in selected foods	1	Month 8	Month 8 **Completed**	RIVM
M1.2	Partners review of dose-response and uncertainty algorithms	1	Month 12	Month 18 **Completed**	RIVM
M1.3	Criteria for data quality of each type of dose response relationship	1	Month 42	Month 42	RIVM
M1.4	Inventory of types of dose-response models useful for risk-benefit measures and ranking their information content	1	Month 42	Month 42	RIVM
M1.5	Catalogue and ranking of integration methods and selected primary method accepted by partners	1	Month 4	Month 8 **Completed**	RIVM
M1.6	Partners review of proposed framework	1	Month 12	Month 12-18 **Completed**	RIVM
M1.7	Adapted framework based on experience in case studies WP4 and 5	1	Month 18	Month 41	RIVM

WP2. Implementation of methods as web-enabled software for all stakeholders

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point for this period was that the work in WP2 was on schedule
- Finalise Version 4.3 of the system design
- Finalise Version 2.1 of the system
- Finalise Version 3 of the system (deliverable D21)
- Finalise Version 5 of system design
- Continue work on Version 4 of the system
- Finalise Version 1 of the user documentation within the web-enabled software
- Carry out usability evaluation of Version 3 of the system
- Write a report with the results from the usability evaluation of Version 3 of the system (Deliverable D23)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 3

- CSL finalised Version 4.3 of the system design, this was an extra version of the system design which was created in order to quickly include the findings in Report 2 on usability evaluation of the system (i.e. Deliverable D17 finalised month 24)

- CSL finalised Version 2.1 of the system, this was an extra version of the system which was introduced to include recommendations from the usability study, detailed in version 4.3 of the system design

- CSL also finalised the work on Version 5 of the system design. This version of the system design was intended to include consumer functions. At the time of writing this version of the system design it was unclear whether the science will be adequately developed to make consumer functions justifiable. Therefore, version 5 of the system design contains details of functions to allow sharing of assessments, and potential to publicize these assessments if the science justifies this. The decision on whether to implement these functions will be taken at the end of the project

- CSL finalised and delivered Version 3 of the system (Deliverable D21). This version of the system did not include consumer functions (as described above), but did include a significant redevelopment of the user interface, allowing a much simpler way of selecting parameters of the model and also allowing a greater number of parameters to be included to allow other case studies to be implemented.

- CSL finalised Version 1 of the user documentation. It was decided that the best place to put the user documentation was within the website. Accordingly, the guideline text and the user help was considerably developed during the reporting period.

- During this reporting period CSL made changes to the modelling framework and code to:
  - Allow user to make any inputs dependent on age and other attributes (e.g. gender)
  - Allow deterministic (single value) inputs as an alternative to matrices, and allow any combination of deterministic, variable and uncertain inputs, thus enabling the user to start with a completely deterministic assessment and then progressively refine it by making more inputs probabilistic
  - Represent recovery from disease as a one-off DALY loss

- CSL continued to work on Version 4 of system e.g. implement additional dose-response and integration algorithms

- CSL provided technical support for the Usability Evaluation of Version 3 of the system
- UPATRAS performed user testing evaluation studies regarding Version 3 of the system i.e. the QALIBRA web-tool
- UPATRAS designed, implemented and analyzed the results of user testing evaluations in order to study various aspects of version 3 of the QALIBRA web-tool
- UPATRAS organized and performed a usability evaluation in order to evaluate the QALIBRA web-tool site against usability heuristics
- UPATRAS wrote a report with the results from the usability evaluation of Version 3 of the system (Deliverable D23)
- UPATRAS assisted CSL in further development of the website and web-tool in light of the usability evaluation of Version 3 of the system
- CSL, RIVM and Matis participated in a telephone conference held the 22nd of July 2008 regarding the Qalibra publishing process and the user documentation in the QALIBRA web-tool and commented on minutes from the meeting
- Matis, RIVM and WU participated in the Usability Evaluation of Version 3 of system
- Matis participated in discussions on progress and definition of next steps of action in WP2 at overall project meetings

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

Version 4 of the system, and the corresponding System Design Version 6 have been slightly delayed, in order to await scientific input. These tasks will be finished during the first part of the next reporting period.

Table 1: Deliverables List WP2

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D9	System design v3: basic & framework functions and 1st algorithms from WP1.	2	Month 12	Month 13	22	22 **Completed**	CSL
D10	Report 1 on usability evaluation.	2	Month 12	Month 12	2.5	2.5 **Completed**	UPATRAS

D14	Version 1 of system with functions for basic operations, framework and Case Study 1-A on seafood.	2	Month 18	Month 18	9	9 **Completed**	CSL
D17	Report 2 on usability evaluation of the system	2	Month 24	Month 24	2.5	2.5 **Completed**	UPAT RAS
D18	Version 2 of system including functions for Case Studies 1-B on seafood	2	Month 24	Month 24	12	12 **Completed**	CSL
D21	Version 3 of system including consumer information functions	2	Month 30	Month 30	7	7 **Completed**	CSL
D23	Report 3 on usability evaluation of the system	2	Month 36	Month 36	16	16 **Completed**	UPAT RAS
D32	Final system, system design, user documentation & arrangements for long-term support	2	Moth 42	Month 42	8		CSL

Table 2: Milestones List WP2

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M2.1	Version 3 of system design reviewed and accepted by partners as basis for implementation.	2	Month 12	Month 13 **Completed**	CSL
M2.2	Decide improvements to system, based on case study 1-A on seafood and usability evaluation.	2	Month 24	Month 24 **Completed**	CSL
M2.3	Decide final improvements, based on case studies 1 and 2, usability evaluation & end-user workshop.	2	Month 36	Month 36	CSL

WP3. Development of strategies for communicating and disseminating risk benefit information and dissemination

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point of work was that WP3 was on schedule
- Finish and submit paper with results from focus groups to a scientific journal
- Develop a draft protocol for the second round of consumer studies, conduct a pilot study for the second round of consumer studies, and collect data for the second round of consumer studies
- Develop and carry out the second round of stakeholder analysis (Delphi study), present preliminary results at the consortium meeting in Iceland, finalise the Delphi study and present the final results at the 7th Consortium meeting in Wageningen
- Develop material for the *pilot* end-user workshop and finalise a report with the dissemination material for pilot end-user workshop (deliverable D22)
- Develop material for the end-user workshop to be held in Budapest, September 2009
- Finalize a brochure about the QALIBRA project
- To size opportunities to disseminate the QALIBRA project

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved- YEAR 3

- WU, in collaboration with CSL, has finished the paper on the first focus group study on communication of risk benefit analysis outputs and submitted the paper to a scientific journal on the 11th of July 2008.
- WU has developed a draft protocol for the second round of consumer studies.
- WU has conducted the first pilot study for the consumer study.
- WU has carried out additional surveys to increase the response rate for the first Delphi round.
- WU has developed and carried out the second round of the Delphi survey.
- WU has given a presentation of the preliminary results of the Delphi study at the 6th Consortium meeting in Iceland.
- WU has presented the final results of the Delphi to the consortium at the 7th Consortium meeting in Wageningen.
- WU has started to draft a report based on the final results of the Delphi study

- CSL, Matis, RIVM, UPATRAS, and WU have organized and developed the *pilot* end-user workshop. This *pilot* end-user workshop was held in coherence with the 7th Consortium meeting in Wageningen.
- CSL, Matis, RIVM, UPATRAS, and WU have developed and adapted the dissemination material from the *pilot* end-user workshop for the final end-user workshop.
- CSL, Matis, UPATRAS, WU, and RIVM have participated in the pilot end-user workshop.
- Altagra, Matis, CSL, RIVM and WU have started the organisation and planning of the *final* end-user workshop, which will be held 9-10th of September 2009 in Budapest.
- Matis organised and co-ordinated the development of Revision 1 of Deliverable D22; Dissemination material for first end-user workshop.
- Matis wrote version 3 of QALIBRA dissemination plan i.e.'Plan for using and disseminating the knowledge'.
- CSL, UPATRAS, Matis and WU finalized the QALIBRA Brochure
- All partners participated in discussions on progress and definition of next steps of action in WP3 at project meetings

Dissemination activities YEAR 3

One scientific article was published this reporting period and a brochure with information about the QALIBRA project was finalised and has been disseminated at various national and international conferences.
The QALIBRA project was also presented /disseminated at the following national and international conferences from 1 April 2008 -31 March 2009:

- Poster at the UK Food Standards Agency annual risk assessment research workshop, UK, 1-2 May 2008. (Dr. Andy Hart, CSL)
- Oral presentation entitled "Seafood and consumers health" at the first International Congress of Seafood Technology that took place from 18-21 May 2008 in ÇEŞME – İZMİR, Turkey (Dr Leonor Nunes, IPIMAR)
- Oral presentation entitled "Emerging consumer trends - challenges for food safety" at International association for Food protection, Latin America, Campinas, Brazil. 26th of May 2008 (Dr. Lynn Frewer, WU)
- Oral presentation entitled "Overview of the Qalibra project" at the ILSI Europe BRAFO Workshop on 'Methodology', 25th of September 2008, Rome, Italy. (Dr. Andy Hart, CSL)
- Oral presentation entitled "Benefits and risks associated to fish products: Strategies for a responsible utilization" 8-9 November 2008, at the Annual Conferences of the Faculty of Veterinary of Lisbon. (Dr Leonor Nunes, IPIMAR)

- Oral presentation entitled "Consumer risk perception and communication. Implications for food choice" at a Seminar hosted by the Norwegian Committee for risk perception, Oslo, Norway, 9th of January 2009 (Dr. Lynn Frewer, WU)
- Oral presentation entitled "Consumers, risk-benefit perception and food choices" at the University of Manchester, UK, 29th of January 2009 (Dr. Lynn Frewer, WU)
- Oral presentation entitled "Trust, risk and food choice. Implications for communication" at the Annual meeting of the Swedish Toxicology association. Stockholm, Sweden. 20th of March 2009 (Dr. Lynn Frewer, WU)
- Oral presentation entitled "Fish products and human health" held 27.03.09 at Conference Cycles organized by the Faculty of Science for Master of Science students on Human Biology and Environment, University of Lisbon, Portugal (Dr Leonor Nunes, IPIMAR)

In addition to these the following interaction with another EU projects working on risk-benefit analysis were carried out YEAR 3;

Dr Andy Hart and Dr Jeljer Hoekstra participated in the ILSI Europe BRAFO Workshop on 'Methodology', 25-26 September 2008, Rome, Italy. At this workshop they suggested to the BRAFO members to join the end-user workshop organised by QALIBRA September 2009 in Budapest. A formal arrangement and invitation about this has been sent to the BRAFO steering committee and accepted.

Furthermore, Dr Andy Hart participated in a series of meetings and teleconferences with Work Package 6- Heat processing of the BRAFO project. The aim of this activity is to learn about different risk-benefit problems, identify additional functionality that may make the Qalibra tool useful for a wider range of problems, and ultimately encourage and assist the BRAFO team in using the Qalibra tool in their work. Activities in this period included:

- Meetings of Brafo WP6 in Brussels, 23 October 2008 and 20 March 2009
- Teleconferences of Brafo WP6 on 17 December 2008 and 20 April 2009.

In addition to this a meeting was held 31st of March 2009 with team members from QALIBRA at RIVM and active members of the EFSA working group on Risk/Benefit procedures

Deviations from the project work program, and corrective actions taken/suggested:
In month 34 (January 2009) the first *pilot* end-user workshop has been held. Based on this *pilot* workshop a final end-user workshop will be given in September 2009 (month 42) together with a dissemination activity to present the outcomes of the QALIBRA project. As a result, milestone 3.4 is expected to be completed in month 42 instead of month 36 as originally planned. This delay was considered necessary in order to be able to allow external users (e.g. from food authorities and specialist from Member States) to evaluate a more developed version of the software (i.e. the Web-based QALIBRA tool).

The contents and the finalisation of deliverable D26 (report on 2nd focus group study, on interactive provision of personal risk-benefit information) has been changed. The reason for

this deviation is the decision of the consortium to give priority to solving primary technical problems of risk-benefit analysis rather than developing methods to provide personalized risk-benefit information to consumers, a change in deliverable D26 (report on 2nd focus group study, on interactive provision of personal risk-benefit information) is required.
The present aim is to further develop insights into consumer reactions and information needs regarding the output of risk-benefit analyses by examining consumer reactions to QALYs, in addition to consumer reactions to DALYs, which were studied in the first consumer study (D15). It is foreseen that a more quantitative study will be conducted in order to facilitate hypothesis testing regarding information interventional and policy recommendations regarding communication of risk-benefits. Due to budget constraints, data are expected to be collected in one country. Because of the more fundamental processes under study, and the application of a controlled experimental design to the study, this is not expected to have a large effect on results and implications, as the results will be generic. We would like to use the case studies from the other WP's in this quantitative consumer study, and therefore D26 is expected to be delayed until month 40.

Table 1: Deliverables List WP3

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative personmonths	Used indicative personmonths*)	Lead contractor
D6	Report on stakeholder analysis, identifying potential end-users and their information needs.	3	Month 10	Month 11	9	9 **Completed**	WU
D15	Report on first focus group study, on communication of risk-benefit analysis outputs.	3	Month 18	Month 20	11,5	11,5 **Completed**	WU
D22	Dissemination materials for first end-user workshop	3	Month 34	Month 35	9	9 **Completed**	WU
D26	Report on second focus group study, on interactive provision of personal risk-benefit information.	3	Month 36	Month 40	8		WU
D33	Final dissemination plan for post-project activities.	3	Month 42	Month 42	5		Matis

Table 2: Milestones List WP3

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M3.1	Potential end-users and their information needs identified.	3	Month 10	Month 10 **Completed**	WU
M3.2	Appropriate communication methods identified for risk-benefit analysis identified.	3	Month 18	Month 20 **Completed**	WU
M3.3	Methods identified for interactive provision of personal risk-benefit information.	3	Month 36	Month 40	WU
M3.4	End-user workshop completed.	3	Month 36	Month 42	Altagra
M3.5	Long-term dissemination plan finalised.	3	Month 42	Month 42	Matis

WP4. Case study 1 on seafood

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point of the work in WP4 was that the work was approximately 3 months delayed
- Finalize identification of the most important endpoints and studies to include in modelling
- Compile data on different nutrients (compounds) in oily fish and on how they positively affect various human health endpoints
- Select the most important positive and negative health effects for oily fish to include in the comprehensive version of case study 1 on oily fish
- Compile data on contaminants in oily fish and on how they negatively affect various human health endpoints
- Evaluate the selected data for health effects in detail and used in advanced modelling of dose/response relationships for positive and negative health impacts
- Initialise work on scientific papers based on case study 1
- Use opportunities to disseminate the Qalibra project

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved – YEAR 3

- Strategies on data searching and data collation for case study 1b on the positive health effects of oily fish were developed jointly by Matis, IPIMAR and RIVM.
- Matis has continued working according to a strategy developed April 2008. The strategy is based on the identification of the most important factors in fatty fish potentially having positive health impact on humans. During the last period the most important human health endpoints associated with each of these fish factors, were identified and strength of evidence for the association evaluated using expert opinions and conclusions from relevant reports, overview articles and other sources containing relevant expert opinions. The most important fish factors identified include fish oil, selenium and vitamin D. The selected positive health effects related to oily fish are being tested in the modelling studies for case study 1.
- Matis finished the data collection and data evaluations with regard to vitamin D and human bone health.
- IPIMAR carried on the search in several scientific web-sites in order to get recent information concerning the effect of fish products and fish oils on cardiovascular health and on cancer diseases.
- Matis has liaised with RIVM on the progress of the data sampling and on the strength of the association between the various endpoints and factors.
- Matis sent results for fish oil to RIVM in June and then worked on health factors associated with Se and vitamin D. Considerable work was spent on evaluation of strength of evidence with regard to Se and vitamin D, this data was sent to RIVM in October and November and also presented at the 7th project meeting in Wageningen
- IPIMAR has searched the literature for the main contaminants in fish and health effects and send the data to RIVM and CSL
- CSL collected concentration data for relevant chemicals in seafood from FSA and other UK sources for use in case study 1B.
- RIVM has developed dose-response functions for stroke, fatal heart disease, and developmental IQ (methylmercury vs. n-3 fatty acids).
- RIVM has gathered data on TCDD effects (with three disease endpoints). RIVM has transferred data to CSL in order to incorporate in the web-based tool.
- RIVM has provided CSL with additional data in order to calculate DALY's like population life expectancies, incidence of disease rates, disability weights etc.
- Matis, CSL RIVM and IPIMAR participated in discussions on progress and definition of next steps of action in WP4 at project meetings
- RIVM has started work on a paper focusing on TCDD including the challenges encountered as well as on a paper with regard to methylmercury.

- Matis has started to work on a critical review paper on the evidence for the health effects of fish and the challenges encountered

Deviations from the project workprogramme & corrective actions taken/suggested:

The consortium has agreed to work on case 2 (functional foods) in parallel to case study 1 (seafood) as case study 2 appears to be less complex than case study 1 and to learn parallel from both case studies. This decision has caused approximately 3-4 months delay in the work on case study 1.

Further, it has been decided to limit case study 1B to two important negative compounds i.e. TCDD (with several health endpoints) and methylmercury as well as three important positive health effects (neurodevelopment, stroke, fatal heart disease). Since the project reviewers had mentioned in their midterm review that the focus of Qalibra should be on the development of the framework and not on the production of comprehensive policy-applicable risk-benefit assessments it has been decided to focus on the previously mentioned main health effects in the QALIBRA project.

Table 1: Deliverables List WP4

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D11	Preliminary outputs from Case study 1-A , for use as examples in WP3 focus groups.	4	Month 12	Month 16	16,5	16,5 **Completed**	IFL/Matis
D19	Report on case study 1A	4	Month 24	Month 25	17	17 **Completed**	Matis
D24	Report on case study 1 B	4	Month 36	Month 39	17		Matis
D30	Scientific paper(s) on case studies A and B	4	Month 42	Month 42	2		Matis

Table 2: Milestones List WP4

Milestone no.	Milestone name	Workpackage no.	Date due	Actual/Forecast delivery date	Lead contractor
M4.1	Performance of version 1 software evaluated in case study 1 A, decide on improvements	4	Month 24	Month 24 **Completed**	Matis
M4.2	Performance of version 1 software evaluated in case study 1 A, decide on improvements	4	Month 36	Month 36	Matis

WP5. Case study 2 on functional foods

WP objectives, starting point of work at the beginning of YEAR 3

- The starting point for this period was that WP5 was on schedule
- Define the final intake scenario's for habitual phytosterol/-stanol intake
- Provide CSL with dose-response models for the most important positive and negative health endpoints in case study 2
- Translation of the health effects into DALY in collaboration with CSL
- Complete modelling of net health impacts in terms of DALYs using the Qalibra framework and software from Work Packages 1 and 2
- Prepare a report on case study 2 on a functional food and outputs for use as examples in WP3 end-user workshop

Progress towards objectives, tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 3

- RIVM has developed of dose-response models for phytosterol intake and the selected positive (IHD) effects and negative (night-blindness) effect
- RIVM has defined several intake scenario's based on comments from Matis and CSL
- RIVM has provided additional data in order to calculate DALY's like population life expectancies, incidence of disease rates, disability weights to CSL
- RIVM and CSL have calculated the net health effects with the Qalibra framework
- RIVM has written a first draft of the phytosterol paper (deliverable D30) including background material on uncertainties and extrapolations for the report on case study 2 (deliverable D25).
- RIVM has submitted an abstract on risk-benefit analysis on phytosterols intake to ICN, Bangkok, October 2009 (RIVM)
- Matis and CSL participated in discussions on progress and definition of next steps of action in WP5 at overall project meetings
- Matis participated in the preparation of dissemination material from WP5 that was used as input into deliverable D22

Deviations and corrective actions

Deliverable D25 is approximately 1-2 month delayed, working is on-going on this deliverable and a draft report has been finalised.

Table 1: Deliverables List WP5

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D25	Report on case study 2 on functional food and outputs for use as examples in WP3 end-user workshop	5	Month 36	Month 38	18		RIVM
D30	Scientific paper on case study 2	5	Month 42	Month 42	2,5		RIVM

Table 2: Milestones List WP5

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M5.1	Performance of version 4 software evaluated in case study 2, decide on improvements	5	Month 36	Month 37	RIVM

WP6. Cluster activities between the QALIBRA and BENERIS projects

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point for this period was that the work in WP6 was on schedule
- Organise and plan meetings regarding cluster activities and write minutes from the meeting
- Optimize the interaction and the cluster activities between the QALIBRA and Beneris projects

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identify contractors involved – YEAR 3

- 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. Matis wrote minutes from this meeting.
- 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 shared 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.
- CSL has started to organise and plan the final SAP meeting, which will be held during the final cluster meeting 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.
- QALIBRA will also invite Beneris to participate in a final 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 http://en.opasnet.org/w/Dissemination_plan_for_benefit-risk_assessment_of_food

Deviations and corrective actions

No deviations from the project workprogramme have occurred in W6

Table 1: Deliverables List WP6

Del. no.	Deliverable name	Work package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *	Lead contractor
D2	Report from the cluster activities	6	Month 3	Month 3	2	2 **Completed**	IFL/Matis
D4	Establishment of a cluster web-page	6	Month 4	Month 4	1	1 **Completed**	CLS
D16	Report from the cluster activities related to the midterm meeting	6	Month 20	Month 22	2	2 **Completed**	Matis
D35	Final report from the cluster activities	6	Month 42	Month 42	2		Matis

Table 2: Milestones List WP6

Milestone no.	Milestone name	Workpackage no.	Date due	Actual/Forecast delivery date	Lead contractor
M6.1	Project kick-off meeting	6	Month 2	Month 2 **Completed**	IFL/Matis
M6.2	Sharing data on concentrations (exposure assessment)	6	Month 12	Month 39	IFL/Matis
M6.3	Midterm meeting	6	Month 19	Month 20 **Completed**	Matis
M6.3	SAP Meetings	6	Month 39	Month 39	Matis

WP7. Project coordination and management

Workpackage objectives and starting point of work at the beginning of YEAR 3

- The starting point for this period was that WP7 was on schedule
- The objective during the third project year has been to fine tune, monitor and coordinate the work in the Qalibra project
- Finalise the second periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission (Deliverable D20)
- Organize & plan project meetings and ensure that minutes were prepared for all meetings
- Update the project website as needed

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved - YEAR 3

- Matis in collaboration with the QALIBRA consortium worked on and contributed to the finalisation of the second periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission (Deliverable D20)
- Matis and CSL organised, planned and chaired the 5th overall project meeting of QALIBRA in cooperation with UPATRAS. The meeting was held at University of Patras, Greece, the 9-10th of April 2008
- Matis wrote a report describing the outcome of the 5th overall project meeting in Patras in cooperation with CSL. (Annex 2 to this report)
- Matis organised and chaired a Project Steering Group (PSG) telephone meeting held the 25th of April 2008 and wrote minutes from meeting
- Matis in collaboration with the QALIBRA consortium finalised the publication policy for QALIBRA

- Matis and CSL organised, planned and chaired the 6th overall project meeting for QALIBRA. It was held at Matis in Reykjavík, Iceland, the 3-4th of September 2008. Matis and CSL also wrote a report describing the outcome of the meeting. (Annex 3 to this report)
- Matis organised a Project Steering Group meeting held in Reykjavík, Iceland, the 4th of September 2008 and wrote the minutes from the meeting.
- Matis and CSL organised, planned and chaired the 7th overall project meeting for QALIBRA in cooperation with WU. The meeting was held in Wageningen, Netherlands, 20-22th of January, 2009.
- Matis wrote a report describing the outcome of the 7th overall project meeting in Wageningen in cooperation with CSL (Annex 4 to this report)
- One member of the scientific advisory panel (SAP) participated in the first end-user workshop held 20th of January 2009, Wageningen, Netherlands. This workshop was intended to trial the usability of training materials in its readiness for a final end-user workshop to be held later in the project, it was carried out with project partners, non-involved staff from organisations in the Qalibra project and a member of the SAP
- Matis has started to organise and plan the final overall project meeting for QALIBRA in cooperation with CSL and Altagra, it will be held in Budapest 11 June, 2009
- Matis and CSL have updated the project website as needed (www.qalibra.eu)
- All partners have prepared running activity reports from each partner to WP leaders, these reports are intended for internal monitoring of the progress of project work etc
- The overall project workplan and timetable were updated at the 5th, 6th and 7th overall project meetings for QALIBRA
- Matis has liaised with the European Commission scientific officer and informed her about the progress of the project as well as submitted project deliverables to the Commission.
- Advanced payments were distributed to partners in September 2008

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Deviations from the project workprogramme & corrective actions taken/suggested:

No deviations from the project workprogramme have occurred in WP7

Table 1: Deliverables List WP7

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D1	Poster-project presentation	7	Month 3	Month 3	0,5	0,5 **Completed**	IFL/Matis
D12	First periodic reports – activity report and periodic management (financial) report	7	Month 12	Month 14	1,5	2,0 **Completed**	IFL/Matis
D20	Second periodic report– activity report and periodic management (financial) report	7	Month 24	Month 26	1	1,5 **Completed**	Matis
D27	Third periodic report– activity report and periodic management (financial) report	7	Month 36	Month 38	1		Matis
D34	Fourth periodic reports – activity report and periodic management (financial) report	7	Month 42	Month 44	2		Matis
D36	Final Report to the Commission	7	Month 42	Month 44	2		Matis

Table 2: Milestones List

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M7.1	Project kick-off meeting	7	Month 2	Month 2 **Completed**	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 8	Month 8 **Completed**	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 12	Month 12 **Completed**	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 19	Month 20 **Completed**	Matis
M7.2	Overall project meetings of the partners	7	Month 24	Month 25 **Completed**	Matis
M7.2	Overall project meetings of the partners	7	Month 30	Month 30 **Completed**	Matis
M7.2	Overall project meetings of the partners	7	Month 36	Month 34 **Completed**	Matis
M7.2	Overall project meetings of the partners	7	Month 39	Month 39	Matis
M7.3	Scientific Advisory Panel Meetings	7	Month 19	Month 20 **Completed**	Matis
M7.3	Scientific Advisory Panel Meetings	7	Month 39	Month 39	Matis

4. CONSORTIUM MANAGEMENT

Consortium management

The main decision body for the project consortium is the Project Steering Group and Scientific Committee (PSG/SC), which consists of the WP leaders, project coordinator and the chair of scientific committee. The main responsibility of the PSG/SC is to set the overall strategic course of the project. During this reporting period the PSG/SC held one separate telephone meeting as well as a brief meetings in connection with the 6th and 7th overall project meeting. The management role of the WP Leaders requires them to take

stock of the progress regularly against the plans during the life of the project, and bring deviations to the attention of the other partners.

A Scientific Advisory Panel (SAP) has been formed in cooperation with the project Beneris (see WP6 for details) and is composed of four permanent members and additional experts will be invited to join on *Ad hoc* basis to compliment the expertise within the panel, depending on the issues being addressed. Four members of the SAP joined the midterm cluster meeting held in Helsinki 7-9 Nov 2007 and reviewed the progress of the work, and gave advice regarding the scientific outputs from the project. Prior to the meeting some documents from both Beneris and QALIBRA were sent to the SAP for review.

Changes in responsibilities and to the consortium itself

No change within the QALIBRA consortium.

However, the Terveyden ja hyvinvoinnin laitos (THL) - National Institute for Health and Welfare, Kuopio, Finland has taken over all responsibilities of Kansanterveyslaitos (KTL) - National Public Health Institute, Kuopio, Finland, as of January 1st 2009.

Project timetable and status

The updated workplan and project timetable can be observed in the enclosed barchart.

Changes and impacts on planned milestones

In the second reporting period some deliverables and work in work packages were delayed by one to four months, as WP1, WP2, WP3 and WP4 have dependences on each others outputs this delay has caused changes for some tasks in the project timetable. The delay in deliverables has also resulted in comparable delays in planned milestones. It is envisaged that this discrepancy will be addressed by the end of the next period.

		Work planning and time table - Full duration of project (months)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42
Research, technological development and innovation related activities	**1.**	**WP1. Development of generalised modular approach to risk-benefit analysis using menus of dose-response and valuation/interagtion functions (WP Leader RIVM)**																																									
	1.1	**Subtask 1. Assessment of positive and negative health effects**																																									
	1.1.1	Catalogue and prioritise endpoints and dose response models.																																									
	1.1.2	Dose-response & uncertainty algorithms for one adverse and one beneficial effects																																								
	1.1.3	Dose-response & uncertainty algorithms for additional adverse and beneficial effects.																																								
	1.1.4	Scientific paper(s) on dose-response & uncertainty algorithms.																																								
	1.2	**Subtask 2. Integration of positive and negative health effects**																																								
	1.2.1	Catalogue and prioritise integration methods. Version 1 of framework for integration & outputs																																								
	1.2.2	Version 2 of framework for integration & outputs. Algorithm for first integration method.																																								
	1.2.3	Version 3 of framework taking account of Advisory Panel review. Algorithms for additional integration methods.																																								
	1.2.4	Version 4 of framework taking account of lessons from Case Study A.Algorithms for additional integration methods.																																								
	1.2.5	Scientific papers on framework and integration methods.																																								
	2.	**WP2. Implementation of methods as web-enabled software for all stakeholders (WP Leader CSL)**																																								
	2.1	Agree detailed development procedures. Version 1 of system design: overall structure & basic functions.																																								
	2.2	Version 2 of system design: add outline design for framework functions.Plan for evaluation of system usability (link with stakeholder analysis in WP3).																																								
	2.3	Usability evaluation of vers.1 of~~dummy web pages~~ website.																																								
	2.3	Vers.3 of system design: detailed plan for basic & framework functions and first algorithms from WP1																																								
	2.3	Version 1 of dummy web-pages for basic functions and framework functions.																																								
	2.3	Vers.2 of dummy web-pages.Start implementation of system.																																								
	2.4	Implement Version 1 of system with functions for basic operations, framework and Case Study A. Version 4 of system design (update to include extra functions from WP1).																																								
	2.5	Usability evaluation of Version 1 of system. Version 2 of system including functions for Case Studies B																																								
	2.6	Version 4.3 of system design																																								
	2.6	Version 2.1 of system - include rest of actions following on from Usability Evaluation of version 1 of system																																								
	2.6	Create and Agree Publishing Process																																								
	2.6	Version 5 of system design: add functions for consumer information.																																								
	2.6	Version 3 of system: add consumer information functions.																																								
	2.7	Usability evaluation of Version 3 of system focussing on added functions & consumer interface. Version 4 of system: implement additional dose-response and integration algorithms.Version 6 of system design. Version 1 of user documentation.																																								
	2.8	Version 5 of system (final): implement final dose-response and integration algorithms and improvements to interface.Finalise user documentation & arrangements for long-term support.Version 7 of system design (final documentation).																																								
	3.	**WP3. Develoment of strategies for communicating and disseminating risk-benefit information (WP Leader WU)**																																								
	3.1	Identify end-users & stakeholders. Outline plan for stakeholder analysis.																																								
	3.2	Conduct stakeholder analysis, identify technical user needs for outputs (& usability for WP2). Version 1 of QALIBRA dissemination plan (to be reviewed at every project meeting)																																								
	3.3	Detailed plan for focus group study on consumer needs for risk-benefit information.																																								
	3.4	Conduct focus groups, identify consumer needs.Version 1 (outline) plan for end-user workshop.																																								
	3.5	Version 2 (detailed) plan end-user workshop. Start preparation of workshop materials and identify participants. Detailed plan for 2nd set of focus groups.																																								
	3.6	Vers.3 of dissemination plan. Vers.1 of dissemination materials. Trial run of end-user workshop at project meeting 6.																																								
	3.7	Conduct second set of focus group. Version 2 of dissemination materials.Hold end-user workshop .																																							W	
	3.8	Final dissemination plan (for post project activities). Version 3 (final) of dissemination materials.Scientific papers on results of stakeholder analysis and consumer focus groups.																																								
	4.	**WP4. Case study 1, seafood (oily fish) (WP Leader IFL)**																																								
	4.1	Collate and evaluate key dose-response studies and exposure data for Case Study A (oily fish). Collate data required for integration method.Draft priorities for additional dose-responses and integration methods.																																								
	4.2	Implement Case Study A using existing general software (e.g.Crystal Ball) & draft paper.																																								
	4.3	Revise Case Study A taking account of Advisory Panel review. Collate and evaluate data for Case Studies B.																																								
	4.4	Repeat Case Study A using Vers.1 of system, compare results. Complete preparation of data for Case Studies B.																																								
	4.5	Conduct Case Study B with Version 4 of system.																																								
	4.6	Scientific paper(s) on Case Studies A and B																																								
	5.	**WP5. Case study 2, functional food (WP Leader RIVM)**																																								
	5.1	Initial definition and scoping including priorities for dose-response and integration methods																																								
	5.2	Collate and evaluate data for Case Study 2, functional food																																								
	5.3	Conduct Case Study 2 using Version 4 of system																																								
	5.4	Scientific paper on Case Studies 2																																								
	6.	**WP6. Cluster activities between QALIBRA and BENERIS (WP Leader IFL)**																																								
	6.1	Cluster web-page. Confirm Advisory Panel members																																								
	6.2	Version 1 (outline) plan for cluster dissemination.																																								
	6.3	Final dissemination plan (for post project activies)																																								
	6.4	Cluster meetings		M																			M																		M		
	6.5	Scientific advisory Panel meetings																					M																		M		
	6.6	Cluster coordination																																								
Management activities	**7.**	**WP7. Project coordination and management (WP Leader IFL)**																																								
	7.1	Establish project website.Confirm Advisory Panel members.																																								
	7.2	Advisory Panel peer review version 1 of framework.																																								
	7.3	Advisory Panel peer review Case Study A.																																								
	7.4	Advisory Panel peer review Case Studies B and case study 2.																																								
	7.5	Project meetings and PSG/SC meetings		M								M			M								M																		M		
	7.6	Project management and administration, coordination of reports to Commission, interactions with Commission																																								

Coordination activities

The Coordinating Partner (Matis) has the overall responsibility and executes the overall management of the project. The main coordination activities during this reporting period have included finalization of the first periodic reports (i.e. annual progress report and annual financial report) and finalization of the "The interim science and society reporting questionnaire" for QALIBRA, organization & planning of project meetings and ensuring that minutes were prepared for all meetings. Matis has also distributed advance payment from the Commission to the other partners, communicated with the Commission and sent deliverables from the project to the Commission. The project progress has been monitored by deliverables, updated overall workplan and project meetings. The project website has been used for maintaining the project document archive. Communication between partners has mainly been with electronic communications (Email, telephone etc.) as well as overall project meetings and work-package meetings. Possible co-operation with other projects/programmes have been identified and there is active interaction between other EU projects, e.g. BRAFO and Beneris, working on Risk-Benefit analysis of food.

5. OTHER ISSUES RELATED TO PERIODIC ATIVITY REPORT

The 'Plan for using and disseminating the knowledge-Version 3' is presented in Annex 1 to this report.

6. PERIODIC MANAGEMENT REPORT FOR QALIBRA

Justification of major cost items and resources for each workpackage (WP)

WP1. Development of generalised modular approach to risk-benefit analysis using menus of dose-response and valuation/integration functions

A brief description of the work performed in WP1 by each contractor:

Partner 1 (Matis):

- Data collection and evaluation for case study B regarding the most important end-points and studies to be included in the modelling
- Participated in discussions on progress and definition of next steps of action in WP1 at project meetings

Partner 2 (CSL):

- Continuation of the work on the framework in collaboration with RIVM

Partner 3 (RIVM):

- Development of dose-response functions for stroke, fatal heart disease, developmental IQ (methylmercury vs. n-3 fatty acids) and TCDD (dioxins, with three disease endpoints)
- Data (case 1B and 2) transfer to CSL in order to incorporate in the web-based tool
- Provided additional data in order to calculate DALY's like population life expectancies, incidence of disease rates, disability weights
- Discussion and dismissing the end point non-fatal heart disease
- Work has started on a TCDD paper including discussions on the challenges encountered
- Final check on the data interpretation in the TCDD and methylmercury topics
- Wrote a first draft of the methylmercury paper
- Wrote a first draft of the dose-response paper has been written
- Continuation of the work on the framework in collaboration with CSL

Explanatory note on any major cost items

Partner 1 (Matis):

Matis is the coordinator for the project and WP leader for 3 workpackages in the Qalibra project which increases the number of meeting that Matis has to attend. Further, a larger proportion of the work for Matis has been carried out by senior scientist than junior scientist than originally planned, hence personnel cost/man month was higher than planned.

Partner 3 (RIVM):

The majority of personmonths have been spent on the development of the risk-benefit model, the finding of adequate data to construct dose-response models, the finding of solutions for the different case studies to fit in the risk-benefit model and the web-based tool. Especially for the toxicological effects (determined in animals) of oily fish, tailor-made solutions and worst-case – best-case approaches had to be constructed in order to get a step further than the traditional toxicological approaches. For most health effects no adequate (human) data are available, therefore assumptions have to be made. The decision process with respect to this is time-consuming as this should be done carefully and in consultation with the consortium and internal and external

experts. The RIVM work for WP1 and WP4 is strongly intermingled. As a consequence the same explanation accounts for WP4.

A summary explanation of the impact of major deviations for WP1

The development of the risk-benefit models, the general framework and the data search for the selection of positive and negative health effects in the risk-benefit analysis as well as the search for adequate data to build the dose-response relationship has turned out to be more laborious than originally foreseen. As a consequence more man-months have been spent on this work than originally planned. Furthermore, there was a delay in the development of the general framework and Deliverables D8 and D13 were delayed. To avoid further delays in WP1 it has been decided to focus on Case study 2 in parallel to Case study 1B as Case study 2 appears to be less complex and to learn in parallel from both case studies.

A tabular overview of budgeted costs and actual costs

Table 3: Budget vs Actual Costs

Cost Budget Follow-up Table									*) total budget figures-not EC funding
Contract N°: FOOD-CT-2006-022957		**Acronym: QALIBRA**						**Date: 01.04.07**	
Participants	**Type of ecpenditure (as defined by participants**	**Budget**	**Actual Costs (EUR)**					**Pct. Spent**	**Remaining Budget (EUR)**
			Period 1	**Period 2**	**Period 3**	**Period 4**	**Total**	**Total**	
		e	a1	b1	c1	d1	e1	((a1+b1+c1+d1)/e)*100	e-e1
Part. 1, Matis	**Total Person-month**								
	Personnel costs	288.750,00	84.869,00	78.954,00	38.276,90		202.099,90	69,99	86.650,10
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	441.515,00	102.361,50	86.279,00	46.342,46		234.982,96	53,22	206.532,04
	Total Costs	730.265,00	187.230,50	165.233,00	84.619,36		437.082,86	59,85	293.182,14
Part. 2, CSL	**Total Person-month**								
	Personnel costs	426.934,00	75.971,26	185.522,64	102.201,39		363.695,29	85,19	63.238,71
	Server	10.000,00	0,00	1.010,14	1.731,04		2.741,18	27,41	7.258,82
	Major cost item 'Y'								0,00
	Other costs (The rest)	416.894,00	55.926,60	137.611,84	72.952,71		266.491,15	63,92	150.402,85
	Total Costs	853.828,00	131.897,86	324.144,62	176.885,14		632.927,62	74,13	220.900,38
Part. 3, RIVM	**Total Person-month**						0,00		
	Personnel costs	678.912,00	254.099,00	223.849,00	218.860,00		696.808,00	102,64	-17.896,00
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	68.000,00	9.745,00	5.937,00	4.117,00		19.799,00	29,12	48.201,00
	Total Costs	746.912,00	263.844,00	229.786,00	222.977,00		716.607,00	95,94	30.305,00
Part. 4, WU	**Total Person-month**								
	Personnel costs	204.329,00	20.299,63	40.742,54	48.394,60		109.436,77	53,56	94.892,23
	Subcontracting	18.000,00		9.350,00			9.350,00	51,94	8.650,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	35.866,00	9.739,20	12.362,48	17.374,42		39.476,10	110,07	-3.610,10
	Total Costs	258.195,00	30.038,83	62.455,02	65.769,02		158.262,87	61,30	99.932,13
Part. 5, UPATRAS	**Total Person-month**								
	Personnel costs	165.000,00	21.433,00	39.200,00	77.357,45		137.990,45	83,63	27.009,55
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	67.800,00	9.494,29	11.511,02	21.346,19		42.351,50	62,47	25.448,50
	Total Costs	232.800,00	30.927,29	50.711,02	98.703,64		180.341,95	77,47	52.458,05
Part. 6, ALTAGRA	**Total Person-month**						0,00		
	Personnel costs	14.000,00	800,00	160,00	800,00		1.760,00	12,57	12.240,00
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	41.200,00	941,47	0,00	1.086,17		2.027,64	4,92	39.172,36
	Total Costs	55.200,00	1.741,47	160,00	1.886,17		3.787,64	6,86	51.412,36
Part. 7, IPIMAR	**Total Person-month**								
	Personnel costs	85.960,00	21.220,48	23.809,79	27.416,59		72.446,86	84,28	13.513,14
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	53.192,00	10.361,97	10.585,52	13.784,95		34.732,44	65,30	18.459,56
	Total Costs	139.152,00	31.582,45	34.395,31	41.201,54		107.179,30	77,02	31.972,70

A tabular overview of budgeted person-months and actual person-months

Table 4: Person-Months Status table[†]

Person-Month Status Table														
Contract N°: 22957		Partner - Person-month per Workpackage									AC-own staff			
Acronum: Qalibra														
Period: 3, 1st April 2008 - 31st March 2009		TOTALS	Coordinator	Part. 1 Matis	Part. 2 CSL	Part. 3, RIVM	Part. 4, WU	Part. 5, UPATRAS	Part. 6, ALTAGRA	Part. 7, IPIMAR	AC TOTALS	AC participant 4	AC participant 5	AC participant 7
Workpackage 1: Development of generalised modular approach to risk-benefit analysis using menur of dose-response and	Actual WP total:	7,75		1,47	0	6,28	0	0	0	0	0			
	Planned WP total*:	74,5		5,5	22	44	3	0	0	0	0			
Workpackage 2: Implementation of methods as web-enabled software for all stakeholders	Actual WP total :	37,37		1,18	24	0,45	0	11,74	0	0	0			
	Planned WP total*:	79		2	51	1	3	22	0	0	0			
Workpackage 3: Development of stragetis for communicating and disseminting risk-benefit information and dissemination	Actual WP total:	21,6		0,94	0	0,25	13,11	4,5	0,8	2	2,4	0,4		2
	Planned WP total*:	42,5		4	1	3	17	13	1,5	3	0			
Workpackage 4: Case study 1 on seafood	Actual WP total:	21,99		4,09	0	9,9	0	0	0	8	3,5			3,5
	Planned WP total*:	52,5		30	3,5	4	0	0	0	15	0			
Workpackage 5: Case study 2 on functional food	Actual WP total:	5,23		0,76	0	4,47	0	0	0	0	0			
	Planned WP total*:	20,5		7	4,5	9	0	0	0	0	0			
Workpackage 6: Cluster activities	Actual WP total:	1,4		0,2	0	0	0	0,5	0,2	0,5	0,5			0,5
	Planned WP total*:	7		1,5	1	1	1	1	0,5	1	0			
Workpackage 7: project coordination and management	Actual WP total:	2,45	1,57	0,4	0	0,48	0	0	0	0	0			
	Planned WP total*:	8	4,5	1	1	1	0,5	0	0	0	0			
Toral Project Person-month	Actual total:	97,79	1,57	9,04	24	21,83	13,11	16,74	1	10,5	6,4	0,4	0	6
	Planned WP total*:	284	4,5	51	84	63	24,5	36	2	19	0	0	0	0

* Planned person months for the full duration of project (42 months)

[†] For AC contractors, a tabular overview of all resources employd on the project and a global estimate of all costs

WP2. Implementation of methods as web-enabled software for all stakeholders

A brief description of the work performed in WP2 by each contractor:

Partner 2 (CSL):

- Finalised Version 4.3 of the system design
- Finalised Version 2.1 of the system
- Finalised and delivered Version 3 of the system (deliverable D21)
- Finalised Version 5 of system design
- Continued to work on Version 4 of the system
- Finalised version 1 of the user documentation within the web-enabled software
- During this period CSL made changes to the modelling framework and code to:

- Allow user to make any inputs dependent on age and other attributes (e.g. gender)
- Allow deterministic (single value) inputs as an alternative to matrices, and allow any combination of deterministic, variable and uncertain inputs, thus enabling the user to start with a completely deterministic assessment and then progressively refine it by making more inputs probabilistic
- Represent recovery from disease as a one-off DALY loss

- CSL provided technical support for the usability evaluation of Version 3 of the system

Partner 5 (UPATRAS):

- Performed user testing evaluation studies regarding Version 3 of the system i.e. the QALIBRA web-tool
- Designed, implemented and analyzed the results of user testing evaluations in order to study various aspects of version 3 of the QALIBRA web-tool
- Organized and performed a usability evaluation in order to evaluate the QALIBRA web-tool site against usability heuristics
- Wrote a report with the results from the usability evaluation of Version 3 of the system (Deliverable D23)

Partner 1 (Matis):

- Participated in discussions regarding the Qalibra publishing process and the user documentation in the QALIBRA web-tool
- Participated in the usability evaluation of Version 3 of system
- Participated in discussions on progress and definition of next steps of action in WP2 in reports from overall project meetings

Partner 3 (RIVM):

- Participated in discussions regarding the Qalibra publishing process and the user documentation in the QALIBRA web-tool
- Participated in the usability evaluation of Version 3 of system

Partner 4 (WU):

- Participated in the usability evaluation of Version 3 of system

Explanatory note on any major cost items

None

A tabular overview of budgeted costs and actual costs

See table 3

A tabular overview of budgeted person-months and actual person-months

See table 4

A summary explanation of the impact of major deviations for WP2

None

WP3. Development of strategies for communicating and disseminating risk benefit information and dissemination

A brief description of the work performed in WP3 by each contractor:

Partner 4 (WU):

- WU, in collaboration with CSL, has finished the paper on the first focus group study on communication of risk benefit analysis outputs and submitted the paper to a scientific journal on the 11th of July 2008.
- Developed a draft protocol for the second round of consumer studies.
- Conducted the first pilot study for the consumer study.
- Developed and carried out the second round of the Delphi survey.
- WU has given a presentation of the preliminary results of the Delphi study at the 6th overall project meeting and the final results of the Delphi survey at the 7th overall project meeting
- Wrote a draft report based on the final results of the Delphi survey
- Organized in collaboration with partners the *pilot* end-user workshop, held in coherence with the 7th overall project meeting in Wageningen. WU also participated in the pilot end-user workshop
- Participated in the development of dissemination materials from the *pilot* end-user workshop for the final end-user workshop in collaboration with other partners (Deliverable D22)
- Participated in the organisation of the *final* end-user workshop (9-10th of September 2009 in Budapest) together with Matis, Altagra and CSL
- Worked on and finalized the QALIBRA brochure in collaboration with CSL, UPATRAS and Matis

Partner 1 (Matis):

- Wrote revision 3 of the 'Plan for using and disseminating the knowledge' for the Qalibra project.
- Organised and co-ordinated the development of Revision 1 of Deliverable D22; Dissemination material for first end-user workshop
- Contributed to the organisation and development of the *pilot* end-user workshop in close collaboration with the other partners (WU, CSL, UPATRAS). Matis also participated in the *pilot* end-user workshop held 20th of January 2009
- Worked on the organisation and planning of the *final* end-user workshop in co-operation with CSL, Altagra, WU and RIVM, it will be held 9-10th of September 2009 in Budapest.
- Contributed to the finalisation of the QALIBRA brochure

Partner 2 (CSL):

- Contributed to the planning and implementation of the pilot end-user workshop, including drafting the agenda, developing and giving presentations, demonstrations and practical sessions, and assisting in identifying participants.
- Participated in the development of Revision 1 of Deliverable D22; Dissemination material for first end-user workshop
- Worked on the QALIBRA brochure in collaboration with WU, UPATRAS and Matis

Partner 3 (RIVM):

- Participated in the pilot end-user workshop
- Participated in the development of dissemination materials from the *pilot* end-user workshop for the final end-user workshop in collaboration with other partners (Deliverable D22)

Partner 5 (UPATRAS):

- UPATRAS finalized the description on methodologies for development training material for the pilot and the end user workshop
- Participated in the development of Revision 1 of Deliverable D22; Dissemination material for first end-user workshop
- UPATRAS designed and finalized the QALIBRA brochure in collaboration with CSL and WU

Partner 6 (Altagra):

- Contributed to the organisation and development of the *pilot* end-user workshop
- Worked on the organisation and planning of the *final* end-user workshop in co-operation with Matis, CSL, WU and RIVM, it will be held 9-10th of September 2009 in Budapest.

Dissemination activities:

This reporting period the QALIBRA project has been disseminated on 9 different occasions at national and international conferences/lectures i.e. 8 oral presentations and 1 poster. One scientic article has been published and the QALIBRA Brochure has been printed and disseminated at national and international conference etc. For details regarding these activities please refer to the overview of WP3 in Chapter 3 and version 3 of the 'Plan for using and disseminating the knowledge' (Annex 1)

Explanatory note on any major cost items.
None

A tabular overview of budgeted costs and actual costs
See table 3

A tabular overview of budgeted person-months and actual person-months
See table 4

Summary explanation of the impact of major deviations for WP3
None

WP4. Case study 1 on seafood

Description of the work performed in WP4 by each contractor

Partner 1 (Matis):

- Developed strategies in data searching and data collation for case study 1b on the positive health effects of oily fish
- Worked according to the strategy developed for collection of data. In period 3 the most important human health endpoints associated with each factor in case study 1b, on oily fish, were identified and strength of evidence for the association evaluated using expert opinions and conclusions from relevant reports, overview articles and other sources containing relevant expert opinions.

- Finalized the data sampling and data evaluations with regard to vitamin D and human bone health.
- Matis has been communicating with RIVM on the progress of the data sampling and on the strength of the association between the various endpoints and factors.
- Sent results to RIVM for fish oil in June, before working on health factors associated with Se and vitamin D. The rest of the data was sent to RIVM in emails in October and November and also presented on the 7th project meeting in Wageningen January 2009.
- Started to work on a critical review paper on the evidence for the health effects of fish.

Partner 2 (CSL):

- Collected concentration data for relevant chemicals in seafood from FSA and other UK sources for use in case study 1b

Partner 3 (RIVM):

- Developed strategies in data searching and data collation for case study 1b on the positive health effects of oily fish
- Worked on final decisions about what effects to include in the case studies based on the databases and the mapping of the negative health effects of oily fish
- Discussed and dismissed the inclusion of vitamin D.
- Continued the search for dose-response relationships and required additional data of the selected positive and negative health effects
- Constructed dose-response models of the selected positive health effects, e.g. stroke, fatal heart disease, and developmental IQ (methylmercury vs. n-3 fatty acids)
- Constructed solutions for negative (toxicological) health effects where dose-response models where lacking

Partner 7 (IPIMAR):

- Developed strategies data searching and data collation for case study 1b on the positive health effects of oily fish
- Carried on the search in several scientific web-sites in order to get recent information concerning the effect of fish products and fish oils on cardiovascular health and on cancer diseases
- Searched the literature for the main heavy metal contaminants in fish
- Collected data from scientific papers concerning the risks of chemical contaminants on cardiovascular health

Explanatory note on any major cost items

Partner 1 (Matis):
Matis is the coordinator for the project and WP leader for 3 workpackages in the Qalibra project which increases the number of meeting that Matis has to attend. Further, a larger proportion of the work for Matis has been carried out by senior scientist than junior scientist than originally planned, hence personnel cost/man month was higher than planned.

Partner 3 (RIVM):
The majority of personmonths have been spent on the development of the risk-benefit model, the finding of adequate data to construct dose-response models, the finding of solutions for the different case studies to fit in the risk-benefit model and the web-based tool. Especially for the toxicological effects (determined in animals) of oily fish, tailor-made solutions and worst-case – best-case approaches had to be constructed in order to get a step further than the traditional toxicological approaches. For most health effects no adequate (human) data are available, therefore assumptions have to be made. The decision process with respect to this is time-consuming as this should be done carefully and in consultation with the consortium and internal and external experts.

Partner 7 (IPIMAR):
Due to problems with in recruitment of suitable people, a larger proportion of the work for IPIMAR has been carried out by senior scientist than originally planned, hence personnel cost/man month was higher than planned.

A tabular overview of budgeted costs and actual costs

See table 3

A tabular overview of budgeted person-months and actual person-months

See table 4

Summary explanation of the impact of major deviations for WP4

WP5. Case study 2 on functional foods

A brief description of the work performed in WP5 by each contractor

Partner 1 (Matis):

- Participated in discussions on progress and definition of next steps of action in WP5 at project meetings

- Participated in the preparation of dissemination material from WP5 in deliverable D22

Partner 2 (CSL):

- CSL received draft inputs for case study 2 from RIVM and modified them in consultation with RIVM to make them compatible with the Qalibra tool, then ran the model and generated results, which were presented at *pilot* end-workshop in January 2009
- Participated in discussions on progress and definition of next steps of action in WP5 at project meetings

Partner 3 (RIVM):

- Development of dose-response models for phytosterol intake and the selected positive (IHD) effects and negative (nightblindness) effect
- Definition of the intake scenario's
- Provision of additional data in order to calculate DALY's like population life expectancies, incidence of disease rates, disability weights for CSL
- First draft of the phytosterol paper has been written

Explanatory note on any major cost items

Partner 3 (RIVM):

The majority of personmonths have been spent on the development of the risk-benefit model, the finding of adequate data to construct dose-response models, the finding of solutions for the different case studies to fit in the risk-benefit model and the webbased tool. Tailor-made solutions and worst-case – best-case approaches had to be constructed in order to get a step further than the traditional approaches. For especially the negative health effects no adequate (human) data are available, therefore assumptions have to be made. The decision process with respect to this is time-consuming as this should be done carefully and in consultation with the consortium and internal and external experts.

A tabular overview of budgeted costs and actual costs

See table 3

A tabular overview of budgeted person-months and actual person-months

See table 4

Summary explanation of the impact of major deviations for WP5

None

WP6. Cluster activities between the QALIBRA and BENERIS projects

A brief description of the work performed in WP6 by each contractor:

All partners participated in the following work:

- Telephone meeting of the cluster projects QALIBRA and Beneris that was held the 4th of September 2008 during the sixth overall project meeting for Qalibra

Partner 1 (Matis):

- Planned the telephone meeting held 4th of September regarding the cluster activities in cooperation with KTL/THL and CSL and wrote minutes from the meeting
- Organised and planned the third and final Cluster meeting of the QALIBRA and Beneris projects in Budapest 10-11 June 2009

Partner 2 (CSL):

- Organised and planned the third and final Cluster meeting of the QALIBRA and Beneris projects in Budapest 10-11 June 2009
- Organised and planned the final SAP meeting

Partner 6 (Altagra):

- Planned the final Cluster meeting of the QALIBRA and Beneris projects in Budapest 10-11 June 2009 in cooperation with Matis, CSL and KTL/THL

Explanatory note on any major cost items

None

A tabular overview of budgeted costs and actual costs

See table 3

A tabular overview of budgeted person-months and actual person-months

See table 4

Summary explanation of the impact of major deviations for WP6

None

WP7. Project coordination and management

A brief description of the work performed in WP7 by each contractor:

All partners participated in the following work:

- Finalization of the second annual periodic report (Deliverable D20)
- Contributed to interim progress reports (used for internal monitoring of progress)
- The 5th overall project meeting of QALIBRA in Patras, Greece
- Contributed to the publication policy for QALIBRA

All partners except ALTAGRA participated in the 6th overall project meeting in Reykjavik

All partners except ALTAGRA and IPIMAR participated in the 7th overall project meeting in Wageningen

Partner 1 (Matis):

- Finalized the second annual periodic report (Deliverable D20)
- Organized and chaired three overall project meeting in cooperation with CSL
- Contributed to planning of the 5th overall project meeting of QALIBRA in cooperation with UPATRAS.
- Planned the 6th overall project meeting of QALIBRA held at Matis n Reykjavik
- Contributed to planning of the 7th overall project meeting of QALIBRA in cooperation with WU
- Contributed to reports that describe the outcome of all project meetings in cooperation with CSL
- Organized and chaired project steering group (PSG) meetings, wrote Minutes from meetings and worked on draft documents regarding publication policy
- Updated the project website as needed
- Started to organise and plan the final overall project meeting to be held in June 2009
- Monitored and coordinated the activities in the QALIBRA project
- Monitored and coordinated the activities for WP4 and WP6 (WP leader for WP4 & WP6)
- Distributed advanced payments to other QALIBRA consortium participants

Partner 2 (CSL):

- Organized and chaired three overall project meeting in cooperation with Matis
- Contributed to reports that describe the outcome of the meetings
- Chaired QALIBRA scientific committee.
- Monitored and coordinated the activities for WP2 (WP leader for WP2)
- Updated the project website as needed

Partner 3 (RIVM):

- Monitored and coordinated the activities for WP1 and WP5 (WP leader for WP1 & WP5)

Partner 4 (WU):

- Monitored and coordinated the activities for WP3 (WP leader for WP3)
- Organized and planned the 7th overall project meeting in cooperation with Matis and CSL.

Partner 5 (UPATRAS):

- Organized and planned the 5th overall project meeting in cooperation with Matis and CSL.

Explanatory note on any major cost items

All partners attended the 5th overall project meeting which was held at UPATRAS in Greece April 2008. All partners except ALTAGRA participated in an overall project meeting held at Matis in Reykjavík September 2008. All partners except ALTAGRA and IPIMAR participated in an overall project meeting held at WU in the Netherlands January 2009.

A tabular overview of budgeted costs and actual costs

See table 3

A tabular overview of budgeted person-months and actual person-months

See table 4

Summary explanation of the impact of major deviations for WP7

None

Form C Financial Statement per activity for the contractual reporting period

For each participant of the QALIBRA project the Form C Financial Statement, signed and stamped by the participants, are enclosed as separate documents to the periodic report.

Summary financial report

A summary report of total (direct + indirect cost) costs in euros as claimed by each participant of QALIBRA and activity type for the reporting period is enclosed as a separate document to the periodic report.

Summary of periodic report on the distribution of the Community's contribution

The periodic report on the distribution of the Community's contribution records the distribution of funding to each contractor during that period is enclosed as a separate document to the periodic report. It shows the distribution (in euros) of funds made by the coordinator to contractors during the reporting period.