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QALIBRA – Heilsuvogin Fourth Annual Report

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<i>Ágrip á íslensku:</i>	<p>Þessi skýrsla er fjórða og síðasta ársskýrsla í Evrópuverkefninu QALIBRA og nær yfir tímabilið 1.04. 2009 til 31.12. 2010. QALIBRA, eða "Quality of Life – Integrated 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 að ræða þriggja ára og 9 mán verkefni sem Matís ohf stýrir. Verkefnistjóri fyrir verkefnið í heild er Helga Gunnlaugsdóttir, deildarstjóri á Matís.</p> <p>Markmið QALIBRA- verkefnisins er að þróa magnbundar aðferðir til að meta bæði jákvæð og neikvæð áhrif innihaldsefna í matvæum á heilsu manna. Þessar aðferðir hafa verið settar fram í tölvuforriti sem er opið og aðgengilegt öllum hagsmunaaðilum á heimasíðuverkefnisins http://www.galibra.eu. Aðferðirnar sem þróaðar voru prófar á tvenns konar matvælum þ.e.a.s. fisk og markfæði. Þátttakendur í verkefninu eru frá Íslandi, Bretlandi, Hollandi, Grikklandi; Portúgal og Ungverjalandi</p>		
<i>Lykilorð á íslensku:</i>	<i>Árskýrsla, QALIBRA, áhættu og ávinningsmat, innihaldsefni matvæla, magnbundnar matsaðferðir, tölvuforrit, fiskur, markfæði</i>		
<i>Summary in English:</i>	<p>This is the forth and last annual report from the "QALIBRA - Quality of life – integrated benefit and risk analysis. Web – based tool for assessing food safety and health benefits" project funded by the EC's Sixth Framework Programme, Priority 5, Food Quality & Safety. It began in April 2006 and ended December 2009.</p> <p>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 has developed methods that can take account of multiple risks, benefits and uncertainties and implemented them in a web-based software for assessing and communicating net health impacts. The methods and software developed by QALIBRA were used to carry out detailed case studies on the benefits and risks of oily fish and functional foods. The software developed in the project to assess and integrate beneficial and adverse effects of foods is available at the website of the project http://www.galibra.eu.</p> <p>Participants in the project: Matís, Iceland, coordinator, The Food and Environment Research Agency United Kingdom, National Institute of Public Health and The Environment, The Netherlands, Wageningen University, The Netherlands, University of Patras, Greece, Altagra Business Service</p>		
<i>English keywords:</i>	<i>Periodic report, QALIBRA, risk-benefit assessment, quantitative methods, web-based software, oily fish, functional foods.</i>		

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

November 2010

Deliverable D34

Fourth periodic activity and management report

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Lead participant: Matis

Specific Targeted Research Project

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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.

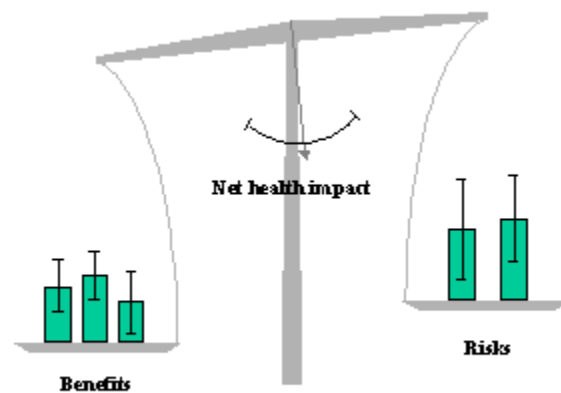


Figure 1. Net health impact depends on the balance of benefits and risks and their associated uncertainties.

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 and finalised the development of the overall framework for risk-benefit analysis. This reporting period alternative calculation methods have been evaluated and the most suitable approach implemented within the QALIBRA framework. Further, work has been performed to increase the flexibility of the QALIBRA framework to enable it to accommodate both QALIBRA case studies and also other risk-benefit assessment problems to enhance its wider usefulness. The work on dose-response models and algorithms for effects that are relevant for the foods in the selected case studies has been finalised and the outcome of this work implemented within the QALIBRA framework and tool as well as described in deliverable D7. In addition, two manuscripts of scientific articles (deliverables D28 and D29c) have been finalised as part of WP1.

Work package 2 will implement the QALIBRA methods as web-enabled software for risk-benefit assessments of foods (called the QALIBRA tool). During the fourth year, the code has been modified as necessary to accommodate the results of case study 1B and case study 2 and implemented in the QALIBRA tool. In addition, other final refinements have been carried out to ensure that QALIBRA tool is flexible and user friendly. The work in WP2 this reporting period has also included design and application of complementary techniques like expert based evaluation and user testing approaches. Version 8 of system design and the final documentation of the web system have been developed and finalised, the outcome of this work is described in deliverable D32 and accessible at the QALIBRA website.

Work package 3 is developing strategies for communicating and disseminating risk benefit information. During the fourth year a report with the results from the second round of consumer study has been finalised and presented in deliverable D26. Further, a report that describes the outcome of stakeholder analysis (Delphi study) was finalised. In addition, this work package developed dissemination material for the *final* end-user workshop (deliverable D22) and organised, planned and carried out the *final* end-user workshop held 9-10th of September 2009 in Budapest. This work package also compiled plans for using and dissemination the knowledge for the QALIBRA project as a whole.

Work package 4 is developing case study 1, on oily fish. During the fourth year the data collection and data evaluations on the positive health effects of seafood for case study 1 was completed. The modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework has been refined and the outcome tested using the web-based QALIBRA. Further, the final report on Case Study 1B on seafood has been completed and presented in deliverable D24. In addition, two manuscripts of scientific articles (deliverables D29b and D30) have been finalised as part of WP4.

Work package 5 is developing case study 2, on functional foods. The work this period has involved adaption of the dose-response models for the most important positive and negative health end-points related to case study 2 on functional foods. Further, the



modelling of net health impacts in case study 2 using the Qalibra framework has been refined and the outcome tested using the web-based software developed in QALIBRA. In addition, a report (deliverable D25) and scientific article (deliverable D3) based on case study 2 on functional foods have been finalised as part of WP5.

Work package 6 comprises cluster activities between QALIBRA and the Beneris project, which is conducting complementary research on risk-benefit analysis. The final Beneris and QALIBRA cluster meeting was held 10-11 June 2009 and a report describing the outcome of this meeting has been completed (deliverable D35). Further, Beneris has prepared and submitted the final version of the cluster dissemination plan.

Work package 7 is responsible for coordination and management of the QALIBRA project. In the fourth project year this work package has fine-tuned, monitored and coordinated the work in the project. The third and the fourth annual reports for the project were delivered to the Commission as well as the publishable final report.

The main elements of the publishable result from the QALIBRA include: project website, the QALIBRA web-based software for benefit-risk assessment of food (i.e. the QALIBRA tool), posters, brochures, scientific publications and presentations to stakeholders in general i.e. at scientific conferences, to food authority personnel, to food industry representatives and the general public.

The main products of the project is the development of a flexible, general framework for quantitative benefit-risk assessment of foods, including probabilistic approaches for quantifying variability and uncertainty; implementing the framework as user-friendly web-based software; conducting case studies with selected foods (oily fish and phytosterol-enriched margarines); and developing new strategies for risk-benefit communication.

The QALIBRA tools and approaches for analyzing and communicating the risks, benefits and net health effects of dietary choices is intended for use by a range of stakeholders, including policy-makers, the food industry and public health professionals 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 better-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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Wageningen University	WU	The Netherlands
University of Patras	UPATRAS	Greece
Altagra Business Service	ALTAGRA	Hungary
Instituto Nacional de Recursos Biológicos I.P./IPIMAR	INRB IP/ IPIMAR	Portugal

2. PROJECT OBJECTIVES & MAJOR ACHIEVEMENTS-YEAR 4

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. disability-adjusted life years (DALYs) and quality-adjusted life years (QALYs)) (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 4 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, FERA, Matis

Objectives, work performed and main achievements YEAR 4

- Evaluate alternative calculation methods and implement the most suitable approach within the QALIBRA framework and tool, this work has been completed.
- Increase the flexibility of the QALIBRA framework to enable it to accommodate both QALIBRA case studies and also other risk-benefit assessment problems to enhance its wider usefulness. The status of this work is that QALIBRA has now succeeded in the development of a flexible framework and approach.
- Finalise the refinements and improvements of the QALIBRA framework, this work has been completed.
- Finalise the work on dose-response models and algorithms for effects that are relevant for the foods in the selected case studies. The outcome of this work was implemented within the QALIBRA framework and tool as well as described in deliverable D7.

- Finalise work on scientific articles on the dose-response modelling as well as the framework and integration method. The outcome of this work is that two manuscripts of scientific articles (deliverables D28 and D29c) have been finalised.

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

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

Objectives, work performed and main achievements YEAR 4

- Modify the code as necessary to accommodate the results of case study 1B and case study 2, the outcome of this was implemented in the web-based QALIBRA tool
- Provide the website and web-based QALIBRA tool in an appropriate state to facilitate the final end-user workshop in September 2009, the outcome of this work was a successful completion of the external end-user workshop
- Design and apply complementary techniques like expert based evaluation and user testing approaches, the outcome of this work was then implemented in the modification and refinement of the QALIBRA tool
- Make final refinements to ensure that QALIBRA tool is flexible and user friendly, the outcome of this work is accessible at the QALIBRA website
- Finalise Version 8 of system design and the final documentation of the web system, the outcome of this work was described in deliverable D32 and is accessible at the QALIBRA website

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

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

Objectives, work performed and main achievements YEAR 4

- Collect data for the second round of consumer study and finalise a report on this consumer study. The outcome of this work was presented in deliverable D26 and submitted as a scientific article to a peer reviewed scientific journal.
- Organisation, planning and carry out the *final* end-user workshop held 9-10th of September 2009 in Budapest, this work has been completed.
- Develop material for the *final* end-user workshop held September 2009 in Budapest and finalise a revised report with the dissemination material for the workshop. The outcome of this work was presented in deliverable D22
- Finalise a report on stakeholder analysis (Delphi study). A report that describe the outcome of this stakeholder analysis is enclosed with this activity report (Annex 3)

- Analyse the feedback questionnaires of the *final* end-user workshop in September 2009. A report that describe the outcome of this analysis is enclosed with this activity report (Annex 4)
- Dissemination of the QALIBRA project. This reporting period the QALIBRA project has been presented on at least 15 different occasions at national and international conferences/workshops were partners of the consortium presented the project with 25 oral presentations and 8 poster. Further, one popular publication with an overview of the QALIBRA project and what it has achieved has been published and two scientific articles have been accepted. In addition, nine manuscripts of scientific articles based on the results from QALIBRA have been prepared and will be submitted to peer reviewed scientific journals.

WP4. Case study 1 on seafood

Contractors involved: Matis, IPIMAR, RIVM, FERA

Objectives, work performed and main achievements YEAR 4

- Finalise the data collection and data evaluations on the positive health effects of seafood for case study 1, this work has been completed.
- Refine and adapt the dose-response models for the most important positive and negative health end-points related to case study 1 on seafood, this work has been completed.
- Refine the modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework and test the outcome using the web-based software developed in QALIBRA, this work has been completed.
- Finalise the final report on Case Study 1B on seafood. The outcome of this work was described in Deliverable D24
- Finalise scientific articles based on case study 1. The outcome of this work is presented in Deliverable D29b and Deliverable D30

WP5. Case study 2 on functional foods

Contractors involved: RIVM, FERA, Matis,

Objectives, work performed and main achievements YEAR 4

- Refine and adapt the dose-response models for the most important positive and negative health end-points related to case study 2 on functional foods, this work has been completed
- Refine the modelling of net health impacts in case study 2 using the Qalibra framework and extensive testing of the outcome using the web-based software developed in QALIBRA, this work has been completed
- Finalise work on a report and scientific article based on case study 2 on functional foods. The outcome of this work is presented in Deliverables D25 and D31

WP6. Cluster activities between the QALIBRA and Beneris projects

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

Objectives, work performed and main achievements YEAR 4

- Optimize the interaction and the cluster activities between the QALIBRA and Beneris projects. The final Beneris and Qalibra cluster meeting was held 10-11 June 2009 and a report describing the outcome of this meeting was submitted to the Commission as deliverable D35 from QALIBRA
- Beneris has prepared and submitted the final version of the cluster dissemination plan

WP7. Project coordination and management

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

Objectives, work performed and main achievements YEAR 4

- The objective during the fourth project year has been to fine tune, monitor and coordinate the work in the QALIBRA project
- Finalise the third and the fourth periodic reports (i.e. annual progress report and annual financial report) , the outcome of this work was submitted to the Commission (Deliverables D27 and D34)
- Finalise the final report for the QALIBRA project, the outcome of this work is presented in deliverable D36
- Organize & plan project meetings and ensure that minutes were prepared for all meetings. One overall project meeting was held in the project during the fourth year and a report that describe the outcome of this meeting is enclosed with this report (Annex 2)
- 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 4

- 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
- Evaluation of alternative calculation methods and implementation of the most suitable approach within the Qalibra framework and tool.
- Increase the flexibility of the Qalibra framework to enable it to accommodate both QALIBRA case studies and also other risk-benefit assessment problems to enhance its wider usefulness.
- Finalise the work on dose-response models and algorithms for effects that are relevant for the foods in the selected case studies (deliverable D7).
- Finalise the refinements and improvements of the QALIBRA framework
- Finalise work on scientific articles on dose-response modelling as well as the framework and integration method (deliverables D28 and D29c).

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved - YEAR 4

- RIVM continued the work on the QALIBRA framework in collaboration with FERA. During this period a fundamental change to the method of calculation used within the Qalibra framework was introduced. Earlier work in the project had involved simulating whole lifetimes of a large sample of individuals, including interactions between different health effects of dietary change. It was agreed to adopt instead a simpler approach that was already present in the scientific literature and is partly based on previous work by RIVM, estimating the potential annual impact of the dietary change rather than simulating whole lifetimes. FERA carried out substantial work to evaluate the alternatives and implement the new approach within the Qalibra framework and tool.
- FERA also completed extensions to the framework and code to enable it to accommodate continuous (as well as quantal) dose-response functions; effects on the next generation; QALY (as well as DALY) calculations; and dependency of more parameters (e.g. disability weights) on intake. All of these were needs that had become apparent from case studies in Qalibra and in the related project BRAFO.

- RIVM has refined and adapted dose-response functions for stroke, fatal heart disease, developmental IQ (methylmercury vs. n-3 fatty acids) and TCDD (with three disease endpoints)
- RIVM has transferred additional data for case study 1B and case study 2 to FERA in order to incorporate in the web-based tool to make the calculations more accurate
- RIVM also provided additional data to calculate DALY's like population life expectancies, incidence of disease rates, disability weights, intake estimates etc. to improve the datasets for these parameters of the assessment in the QALIBRA framework
- Matis and IPIMAR finalised 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
- FERA received inputs for the case study 1B from RIVM, Matis and IPIMAR and implemented them in the Qalibra tool, in consultation with RIVM. Results were fed back to partners for interpretation and use in case study presentations, reports and papers.
- RIVM finalised a report on the application of animal toxicity data in risk-benefit analysis using 2,3,7,8-TCDD as an example (Deliverable D29a)
- RIVM finalised deliverable D28 "Scientific paper on dose-response models", which is an appeal for the presentation of detailed human derived data for dose-response calculations in nutritional science
- RIVM, FERA and Matis finalised deliverable D7 on dose-response models and algorithms for effects that are relevant for the foods in the selected case studies
- FERA, RIVM and Matis contributed to Deliverable D29c on the final QALIBRA framework for Risk-Benefit assessment
- Matis and FERA participated in discussions on progress and definition of next steps of action in WP1 at project meetings

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 and content wise problems of risk-benefit analysis

As reported in the 2nd and 3rd annual activity report the dose response modelling is expert work and turned 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. It was decided to limit case study 1B to two important negative compounds i.e. dioxin related (TCDD with several health endpoints) and methylmercury (with neurodevelopment as endpoint) 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 was been decided to focus on the previously mentioned main health effects in the QALIBRA project. Qalibra has now succeeded in the development of a flexible framework and approach.

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 48	18	26 Completed	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 45	Month 48	6,5	8 Completed	RIVM
D29	Scientific papers on framework and integration methods	1	Month 45	Month 48	5	10 Completed	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 45	Month 45 Completed	RIVM
M1.4	Inventory of types of dose-response models useful for risk-benefit measures and ranking their information content	1	Month 45	Month 45 Completed	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 45 Completed	RIVM

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

Workpackage objectives and starting point of work at the beginning of YEAR 4

- The starting point for this period was that there was a slight delay in the work in WP2
- Implement additional dose-response & integration algorithms and finalise Version 4 of the system
- Modify the code as necessary to accommodate the results of case study 1B and case study 2
- Provide the website and web-based QALIBRA tool in an appropriate state to facilitate the *final* end-user workshop in September 2009.
- Design and apply complementary techniques like expert based evaluation and user testing approaches
- Make final refinements to ensure that web-based QALIBRA tool is flexible and user friendly



- Finalise Version 8 of system design and the final documentation of the web system (Deliverable D32)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 4

- FERA worked on a significant re-write of the QALIBRA web-based software for risk-benefit assessments of foods (i.e. the QALIBRA tool). This was necessary in order to accommodate the changes in the QALIBRA framework (for details see WPI work tasks described above). There were a number of extra parameters which were required to be input, and also some simplifications in the internal code. This necessitated a change to the internal code of the tool as well as making a change to the user interface needed.
- FERA directed considerable effort towards getting the change of the web-based QALIBRA software finished before the *final* end-user workshop in September 2009. The final end-user workshop in September 2009 proved to be a very useful test of the QALIBRA tool as it was demonstrated live and there was also an interactive practical hands-on training session using the QALIBRA web-tool. This ensured that the system was capable of handling large numbers of people (> 40) using it at one time, and properly queuing the requests in an appropriate way.
- The feedback from the *final* end-user workshop told us that the system as it was presented was a very interesting piece of scientific work, which presented Risk – Benefit assessment in a novel quantitative way. However, the feedback also informed us that the participants did not completely understand some of the new concepts introduced in the QALIBRA tool and that the system contained inadequate help and explanations. Accordingly, FERA has worked to enhance and refine the assistance given to users of the QALIBRA tool, in order to ensure that the system is well enough described, and simple enough for users to be able to effectively use it without requiring extensive training.
- FERA developed interactive graphical outputs from the Qalibra tool, finalized the results from Case Studies 1B and 2, added functionality to allow users to specify single value inputs for each of the parameters in the Qalibra framework
- FERA implemented ‘sharing’ and ‘grouping’ actions for assessments, and added functionality to allow the tool to handle both single-step (quantal) functions and multi-step (continuous) dose-response functions. This was a response to the requirements in the case studies.
- FERA provided ‘User Friendly’ error messages to inform the user why the tool has failed to calculate, implemented ‘QALY’ as well as ‘DALY’ output information, and improved and added to the online support text.
- FERA created a ‘Wizard’ to train and register new users of the Qalibra tool.



- FERA finalised Version 8 of system design and the final documentation of the web system (Deliverable D32)
- UPATRAS performed usability evaluation studies for assessing the usability and the development of the final version of QALIBRA tool.
- UPATRAS assisted FERA in further development of the website and QALIBRA tool in light of the expert based evaluation and user testing approaches
- UPATRAS have designed and applied complementary techniques like expert based evaluation and user testing approaches. These studies have been analyzed and proposals made to FERA to enhance the usability of the QALIBRA tool.
- UPATRAS developed a user questionnaire that was given to participants to report their feedback after the *final* end-user workshop in September 2009.
- Matis and RIVM participated in the expert based evaluation and user testing approaches
- Matis contributed to discussions regarding the graphical outputs from the QALIBRA web-tool as well as registration, access and the user documentation in the QALIBRA tool
- Matis participated in discussions on progress and definition of next steps of action in WP2

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

Version 4 of the system, and the corresponding System Design Version 8 have been delayed, as it was necessary to modify the web tool to cope with scientific findings in the case studies, and it was decided to ensure the version presented to participants of the *final* end-user workshop was as complete as possible. The feedback from the end-user workshop also revealed that it was necessary to enhance and refine the assistance given to users of the QALIBRA tool, in order to ensure that the system is well enough described, and simple enough for users to be able to effectively use it without requiring extensive training.

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	FERA

D10	Report 1 on usability evaluation.	2	Month 12	Month 12	2.5	2.5 Completed	UPAT RAS
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	FERA
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	FERA
D21	Version 3 of system including consumer information functions	2	Month 30	Month 30	7	7 Completed	FERA
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	Month 42	Month 42	8	16 Completed	FERA

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	FERA
M2.2	Decide improvements to system, based on case study 1-A on seafood and usability evaluation.	2	Month 24	Month 24 Completed	FERA
M2.3	Decide final improvements, based on case studies 1 and 2, usability evaluation & end-user workshop.	2	Month 36	Month 42 Completed	FERA

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 4

- The starting point of work was that WP3 was on schedule, except that the end-user workshop delayed to allow external users to evaluate a more developed version of the QALIBRA software (i.e. the Web-based QALIBRA tool)
- Collect data for the second round of consumer study and finalise the report on this consumer study (deliverable D26)
- Organisation, planning and implementation of the *final* end-user workshop held 9-10th of September 2009 in Budapest
- Develop material for the *final* end-user workshop held in September 2009 in Budapest
- Finalise a revised report with the dissemination material for the *final* end-user workshop (deliverable D22)
- Finalise a report on stakeholder analysis (Delphi study)
- Use the project website to disseminate the result of the project and as a webgate and support for the community of users of the final QALIBRA web-based software for risk-benefit assessments of foods (i.e. the QALIBRA tool) produced by QALIBRA
- 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 4

- WU has collected data for the second round of consumer study
- WU has written the report on the second consumer study and submitted this as deliverable D26
- WU has submitted a scientific article discussing the results from the consumer studies conducted in the QALIBRA project to a peer reviewed scientific journal.
- WU finalised a report with the results from the stakeholder analysis (Delphi study)
- WU and Matis organised and co-ordinated the development of Deliverable D33: Final dissemination plan for post–project activities, and submitted this as a deliverable
- All partners contributed to the development of Deliverable D33
- Altagra, Matis, FERA, RIVM, and WU participated in the organisation and planning of the *final* end-user workshop held 9-10th of September 2009 in Budapest

- Altagra managed and carried out the *final* end-user workshop held 9-10th of September 2009 in Budapest with external end-users including participants from food authorities, food industry, public health professionals and academia from 15 countries in Europe.
- Matis, FERA, Altagra , RIVM, and WU contributed to the development and revision of the dissemination material from the *pilot* end-user workshop for the *final* end-user workshop. These materials were written to be sufficiently generic such that they can be used for further training courses.
- FERA, RIVM, Matis, Altagra, IPIMAR and WU participated in the final end-user workshop held 9-10th of September 2009 in Budapest
- FERA provided technical expertise on the web-enabled QALIBRA tool at the *final* end-user workshop in Budapest
- Matis, Altagra, FERA and RIVM participated in the organisation and planning of a workshop for BRAFO held 10-11 September 2009 that was carried out as a follow up of the QALIBRA end-user workshop to understand and explore the applicability of the QALIBRA web-tool for the BRAFO case studies
- Altagra managed and executed the special workshop for BRAFO held 10-11 September 2009 that was carried out as a follow up of the QALIBRA end-user workshop
- Matis organised and co-ordinated the development of final version of Deliverable D22; Dissemination material for first end-user workshop. FERA, RIVM, Altagra, UPATRAS and WU contributed to the preparation of deliverable D22. These materials were written to be sufficiently generic such that they can be used for further training courses.
- WU has analysed the feedback questionnaires of the final end-user workshop and collated the results in the report: “Analysis post-questionnaire for QALIBRA tool, End-user workshop 9-10 September 2009”
- Matis co-ordinated the completion of version 4 of QALIBRA dissemination plan i.e. ‘Plan for using and disseminating the knowledge’ and all partners contributed to this report.
- Matis led the writing and development of an overview article about the QALIBRA project and what it has achieved that was published December 2009 in International Innovation by Research Media (www.researchmedia.eu)
- All partners participated in discussions on progress and definition of next steps of action in WP3 at project meetings

Dissemination activities YEAR4

The main dissemination activities in year 4 organised by the QALIBRA consortium in year 4 were:

- i. The final cluster meeting i.e. the final joint meeting of the sister projects Qalibra and Beneris held in Budapest June 10-11th 2009 (for details refer to deliverable D35)
- ii. The final end-user workshop held 9-10th of September 2009 in Budapest with external end-users including participants from food authorities, food industry, public health professionals and academia, altogether 31 external participants from 15 countries in Europe
- iii. Popular publication in International Innovation published by Research Media Ltd (www.researchmedia.eu) in December 2009. This article provides an overview of the QALIBRA project and what it has achieved. Research Media will disseminate this output to 29'000 delegates across the whole of Europe and the INCO countries in the research, government and food sector.
- iv. To use the project website to disseminate the result of the project as well as a webgate and support for the community of users of the final QALIBRA web-based software for risk-benefit assessments of foods (i.e. the QALIBRA tool)
- v. A total of 25 oral presentations and 8 posters were presented by QALIBRA partners to a wide range of audience worldwide (for details refer to Annex 1-Final plan for using and disseminating the knowledge).

To promote end-user uptake of the web-based software developed in QALIBRA a special effort was made to attract food safety experts with a direct interest in risk-benefit analysis of food, and give them a detailed introduction to the risk-benefit modelling approaches developed in the project and practical hands-on training with the risk-benefit software produced by QALIBRA. Therefore, the QALIBRA consortium made contact with the organisation board of two other ongoing EU-projects dealing with risks and benefits of food, Beneris and BRAFO, in ample time prior to the workshop to invite them to participate in the final end-user workshop. As a result of this productive relationship, twelve experts from BRAFO and two experts from Beneris attended the *final* end-user workshop organised by QALIBRA in Budapest 9-10th of September 2009. In addition, seventeen food safety experts from various European member states attended the workshop. The end-user workshop proved to be a very successful event, the QALIBRA web-based tool was demonstrated live and there was also an interactive practical hands-on training session using the QALIBRA web-tool. This ensured that the system was capable of handling large numbers of people (> 40) using it at one time, and properly queuing the requests in an appropriate way.

In addition, BRAFO and QALIBRA organised a special joint follow up workshop to explore the applicability of the QALIBRA web-tool to a range of case studies being undertaken by BRAFO. This joint workshop was held 10-11 September 2009, immediately after the finalisation of the QALIBRA end-user workshop. The aim of this activity was 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.

The QALIBRA end-user workshop was also attended by two active members of the EFSA working group on Risk/Benefit procedures (Dr A. Knaap, chair of the working group, and Dr B. Bottex, secretary of the working group). Both BRAFO and EFSA have recognised and mentioned the additional value of the Qalibra tool in the quantitative stages of benefit-risk assessments.

In addition to this Dr Andy Hart, Dr Helga Gunnlaugsdottir and Dr Jeljer Hoekstra participated in the ILSI Europe BRAFO Workshop on 'Case Studies', 29-30 October 2009, Brussels, Belgium. There, the applicability of the QALIBRA web-tool to the case studies being undertaken by BRAFO was discussed in each working group.

Jeljer Hoekstra (RIVM) has been accepted as an expert in collaboration effort between FAO/WHO to bring forward experts and data on risk-benefit assessment of fish consumption. He will actively participate in this group in 2010 on behalf of RIVM and disseminate about risk-benefit assessment of fish consumption based on his Qalibra experience.

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

The final end-user workshop was held in September 2009 (month 42) instead of month 34 (January 2009). 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).

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	12 Completed	Matis
D26	Report on second focus group study, on interactive provision of personal risk-benefit information.	3	Month 45	Month 44	8	8 Completed	WU
D33	Final	3	Month 45	Month 48	5	5	WU

	dissemination plan for post-project activities.					Completed	
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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 Completed	WU
M3.4	End-user workshop completed.	3	Month 36	Month 42 Completed	Altagra
M3.5	Long-term dissemination plan finalised.	3	Month 45	Month 48 Completed	WU

WP4. Case study 1 on seafood

Workpackage objectives and starting point of work at the beginning of YEAR 4

- The starting point of the work in WP4 was that the work was approximately 3 months delayed
- Finalise the data collection and data evaluations on the positive health effects of fish for case study 1
- Refine and improve the dose-response models for the most important positive and negative health end-points related to case study 1 on seafood
- Refine the modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework and test the outcome using the web-based software developed in QALIBRA
- Finalise the final report on Case Study 1B on seafood (Deliverable D24)
- Finalised scientific articles based on case study 1 (Deliverable D29b and Deliverable D30)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved – YEAR 4

- Matis and IPIMAR finalised the data collection and data evaluations on the positive health effects of oily fish for case study 1B and sent their results to RIVM and FERA
- IPIMAR worked together with Matis and RIVM on the development of the case study 1 on seafood. The selection of the relevant constituents and main effects on health and the attainment of information concerning the dose-response functions were the main focus of activity.
- FERA and RIVM have refined the modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework and tested the outcome of the risk-benefit assessment for seafood using the web-based software developed in QALIBRA
- RIVM refined and improved the dose-response models for the most important positive and negative health end-points related to case study 1 on seafood
- FERA received inputs for the case study 1B from RIVM, Matis and IPIMAR and implemented them in the Qalibra tool, in consultation with RIVM. Results were fed back to partners for interpretation and use in case study presentations, reports and papers.
- Matis, RIVM, IPIMAR and FERA contributed to the final report on Case Study 1B on seafood (Deliverable D24). The selection of the endpoints and relevant fish ingredients is based on expert knowledge possessed by Qalibra partners, or retrieved through literature search and/or personal communication. The work in case study 1 is based on preparation, selection and evaluation of data by Qalibra partners, this data is then implemented in the Qalibra tool and the results fed back to partners for interpretation and use in reports and papers regarding case study 1 on seafood.
- RIVM, FERA and Matis finalised Deliverable D29b, a scientific article entitled “Fish consumption during child bearing age: A quantitative risk-benefit analysis on neurodevelopment”
- Matis has prepared a review paper on the evidence for the beneficial health effects of fish. This scientific paper (Deliverable D30) aims to give an overview of the positive health effects of fish consumption to food policy makers.
- Matis, FERA, RIVM and IPIMAR participated in discussions on progress and definition of next steps of action in WP4 at project meeting

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

The selection of the endpoints and relevant fish ingredients is based on expert knowledge possessed by QALIBRA partners, or retrieved through literature search and/or personal communication. The work in case study 1 is based on data preparation, selection and evaluation by QALIBRA partners, this data is then implemented in the QALIBRA tool and the results fed back to partners for interpretation and use in reports and papers regarding case study 1 on seafood. Due to continuous efforts of refining and improving the QALIBRA web-based software

the calculations necessary for finishing D24 were not been possible until very recently and this has resulted in a 3 month delay of D24. The refinements required included evaluation of alternative calculation methods and implementation of the most suitable approach within the QALIBRA framework and the web-based QALIBRA tool.

Table 1: Deliverables List WP4

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Fo recast 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 45	Month 48	17	25 Completed	Matis
D30	Scientific paper(s) on case studies A and B	4	Month 45	Month 48	2	7 Completed	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 B, decide on improvements	4	Month 36	Month 42 Completed	Matis

WP5. Case study 2 on functional foods

WP objectives, starting point of work at the beginning of YEAR 4

- The starting point for this period was that WP5 was on schedule
- Refine and adapt the dose-response models for the most important positive and negative health end-points related to case study 2 on functional foods
- Refine the modelling of net health impacts in case study 2 using the Qalibra framework and extensive testing of the outcome using the web-based software developed in QALIBRA

- Finalise work on a report and a scientific article based on case study 2 on functional foods

Progress towards objectives, tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 4

- RIVM has refined and adapted the dose-response models for phytosterol intake and the selected positive (IHD) effects and negative (night-blindness) effect
- RIVM has provided additional data on sterol intakes, incidences of heart diseases in relation to cholesterol, night blindness and disability weights to improve the datasets for these parameters of the assessment in the QALIBRA framework
- RIVM and FERA have refined the modelling of net health impacts in case study 2 using the Qalibra framework and tested of the outcome of the risk-benefit assessment using the QALIBRA web-based software for phytosterol the case study
- RIVM and FERA worked on and finalised a report on case study 2 (deliverable D25).
- RIVM and FERA worked on and finalised a scientific article entitled “Benefit-risk assessment of phytosterols in margarine; a QALIBRA case study” (deliverable D31).
- Matis and FERA participated in discussions on progress and definition of next steps of action in WP5 at overall project meetings

Deviations

No deviations from the project workprogramme have occurred in WP5

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 41	Month 42	18	18 Completed	RIVM

D30	Scientific paper on case study 2	5	Month 45	Month 48	2,5	2,5 Completed	RIVM
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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 39 Completed	RIVM

WP6. Cluster activities between the QALIBRA and BENERIS projects

Workpackage objectives and starting point of work at the beginning of YEAR 4

- 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
- Optimise 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 4

- The final Beneris and QALIBRA cluster meeting was organised and planned in cooperation between Matis, THL, Altagra and FERA. The meeting was held in Budapest 10-11 June 2009. The objective of the final meeting was dissemination of activities and sharing of information between the two projects as well as the consultation with the Scientific Advisory Panel (SAP).
- Altagra managed and executed the final Beneris and QALIBRA cluster meeting held in Budapest 10-11 June 2009
- FERA and Matis organised and planned the final SAP meeting that was held during the final cluster meeting in Budapest 10-11 June, 2009
- At the final Beneris and QALIBRA cluster meeting the draft cluster dissemination plan was discussed and a revised final version accepted. The practical actions in the plan relate mostly to Opasnet, and therefore mostly guides applies to Beneris - and especially THL after the project has ended. The dissemination strategy is also available on Opasnet:
http://en.opasnet.org/w/Dissemination_plan_for_benefit-risk_assessment_of_food

- Matis organised and wrote the final report on the cluster activities and submitted it to the European Commission (Deliverable D35).
- Matis liaised with Beneris regarding cluster activities and collaboration
- Beneris participated in a final end-user workshop held by QALIBRA 9-10th September 2009 in Budapest. This end-user workshop included practical hands-on training with the risk-benefit software produced by QALIBRA, using case studies developed in the project.
- In order to promote post-project activities of the two consortia Beneris and QALIBRA aim to publish several scientific articles together in a special journal issue. The tentative journal for this joint dissemination is Food and Chemical Toxicology. Drafts of the majority of these articles are ready and contact has been made with the editor of this journal.

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/Fo recast 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/FERA
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	3,5 Completed	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 Postponed due to changes in the development of data repository.	IFL/Matis
M6.3	Midterm meeting	6	Month 19	Month 20 Completed	Matis
M6.3	SAP Meetings	6	Month 39	Month 39 Completed	Matis

WP7. Project coordination and management

Workpackage objectives and starting point of work at the beginning of YEAR 4

- The starting point for this period was that WP7 was on schedule
- The objective during the fourth project year has been to fine tune, monitor and coordinate the work in the Qalibra project
- Finalise the fourth periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission
- Finalise the final report for the project and submit to the Commission
- Finalise the “Interim science and society reporting questionnaire” for QALIBRA online
- 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 4

- Matis in collaboration with the QALIBRA consortium worked on and contributed to the finalisation of the third and fourth periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission (Deliverables D27 and D34)
- Matis in collaboration with the QALIBRA consortium worked on and contributed to the finalisation of the final report to the commission (Deliverable D36)

- Matis and FERA organised, planned and chaired the 8th overall project meeting of QALIBRA in cooperation with Altagra. The meeting was held in Budapest June 11th 2009
- Matis and FERA wrote a report describing the outcome of the 8th overall project meeting in Budapest in cooperation with FERA. (Annex 2 to this report)
- Matis organised and chaired a Project Steering Group (PSG) telephone meeting held the 24th of April 2009 and wrote minutes from meeting
- Matis finalised the “Interim science and society reporting questionnaire” for QALIBRA online
- Matis and FERA 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 8th 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 April 2009

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/Fo recast 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	1,5 Completed	Matis
D34	Fourth periodic reports – activity report and periodic management (financial) report	7	Month 45	Month 49	2	2,5 Completed	Matis
D36	Final Report to the Commission	7	Month 45	Month 49	2	2,5 Completed	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 Completed	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 Completed	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 meeting in connection with the 8th 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. Further, two members of the SAP joined the final cluster meeting of QALIBRA and Beneris held in Budapest 10-11 June 2009. QALIBRA and Beneris partners gave the SAP a detailed introduction to the risk-benefit modelling approaches developed in the two projects and the risk-benefit software developed. The SAP members reviewed the progress of the work, and gave advice regarding the scientific outputs from the two projects. 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

The operation of the Instituto Nacional de Investigaçao Agraria e das Pescas/National Institute for Agriculture and Fisheries Research in Portugal was discontinued on October 31st 2007. As of November 1st 2007 the Instituto Nacional de Recursos Biológicos I.P./IPIMAR has taken over all the responsibilities of the National Institute for Agriculture and Fisheries Research in the QALIBRA project and a corresponding amendment has been accepted by the European commission to the project contract. Due to changes at the Department of Food and Rural Affairs (DEFRA), Central Science Laboratory (CSL) has merged with some other DEFRA agencies to become The Food and Environment Research Agency (FERA). This change at DEFRA is only related to change of legal name and a corresponding amendment has been accepted by the European commission to the project contract.

Project timetable and status

There are no major changes in the project timetable from the third annual report and the current workplan and project timetable can be observed in the bar-chart below.

Changes and impacts on planned milestones

In the third 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. All deliverables have now been finalised.

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 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 and cooperation between other EU projects, e.g. BRAFO and Beneris, working on Risk-Benefit analysis of food.

5. OTHER ISSUES RELATED TO PERIODIC ACTIVITY REPORT

The ‘Final plan for using and disseminating the knowledge-Version 4’ is presented in Annex 1.

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):

- Finalised data collection and evaluation for case study B and reported to RIVM on the remaining endpoints and studies to be included in the modelling
- Contributed to the finalisation of deliverable D7 on dose response models
- Contributed to Deliverable D29c on the final QALIBRA framework for Risk-Benefit assessment

- Participated in discussions on progress and definition of next steps of action in WP1 at project meetings

Partner 2 (FERA):

- Continuation of the work on the framework in collaboration with RIVM
- Completed extensions to the framework and code to enable it to accommodate continuous (as well as quantal) dose-response functions; effects on the next generation; QALY (as well as DALY) calculations; and dependency of more parameters (e.g. disability weights) on intake.
- Received inputs for the case study 1B from other partners and implemented them in the Qalibra tool. Results were fed back to partners for interpretation and use in case study presentations, reports and papers.
- Finalised deliverable D29c on the final QALIBRA framework for Risk-Benefit assessment
- Participated in discussions on progress and definition of next steps of action in WP1 at project meetings

Partner 3 (RIVM):

- Refined and adapted dose-response functions for stroke, fatal heart disease, developmental IQ (methylmercury vs. n-3 fatty acids) and TCDD (with three disease endpoints)
- Continuation of the work on the framework in collaboration with FERA e.g. contributed to Deliverable D29c on the final QALIBRA framework for Risk-Benefit assessment
- Data (for case studies 1B and 2) transfer to FERA 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
- Finalised a report on the application of animal toxicity data in risk-benefit analysis using 2,3,7,8-TCDD as an example (Deliverable D29a)
- Finalised deliverable D7 on dose-response models and algorithms for effects that are relevant for the foods in the selected case studies
- Finalised deliverable D28 "Scientific paper on dose-response models"

Explanatory note on any major cost items:

None

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 and information on the diseases related to the intake of the nutrient, as well as the ‘disability weights’ to quantify the relative severity of health effects associated with intake of the nutrient under study 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, the complexity and novelty of the science and mathematics behind the framework was challenge that required more man-months than originally planned.

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: 31.12.09		
Participants	Type of expenditure (as defined by participants)	Budget	Actual Costs (EUR)					Pct. Spent	Remaining Budget (EUR)
			Period 1	Period 2	Period 3	Period 4	Total		
		e	a1	b1	c1	d1	e1	((a+b+c+d)/e)*	e-e1
Part. 1, Matis	Total Person-month	55,50	14,68	20,55	10,61	50,11	95,95	172,88	-40,45
	Personnel costs	288.750,00	67.297,42	78.954,00	38.276,90	171.348,92	355.877,24	123,25	-67.127,24
	Subcontracting		0,00	0,00	0,00	500,00	500,00		-500,00
	Consumable cost		2.979,49	490,00	1.259,85	8.107,29	12.836,63		-12.836,63
	Travel cost,		14.591,59	6.835,00	6.805,71	5.518,68	33.750,98		-33.750,98
	Indirect cost		102.362,00	78.954,00	38.276,90	171.348,92	390.941,82		-390.941,82
	Other costs (The rest)	441.515,00	0,00	0,00	0,00	0,00	0,00	0,00	441.515,00
	Total Costs	730.265,00	187.230,50	165.233,00	84.619,36	356.823,81	793.906,67	108,71	-63.641,67
Part. 2, CSL/FERA	Total Person-month	84,00	13,18	41,62	23,50	23,15	101,45	120,77	-17,45
	Personnel costs	426.934,00	71.847,00	181.743,86	94.760,47	110.056,86	458.408,19	107,37	-31.474,19
	Equipment (Computer server etc)	10.000,00	0,00	1.010,14	1.731,04	9.360,11	12.101,29	121,01	-2.101,29
	Consumable cost		677,03	420,78	1.825,42	205,86	3.129,09		-3.129,09
	Travel cost,		3.475,49	3.358,00	5.615,50	4.985,97	17.434,96		-17.434,96
	Indirect cost		55.898,34	137.611,84	72.952,71	76.674,19	343.137,08		-343.137,08
	Other costs (The rest)	416.894,00	0,00	0,00	0,00	0,00	0,00	0,00	416.894,00
	Total Costs	853.828,00	131.897,86	324.144,62	176.885,14	201.282,99	834.210,61	97,70	19.617,39
Part. 3, RIVM	Total Person-month	63,00	28,00	23,13	21,83	7,70	80,66	128,03	-17,66
	Personnel costs	678.912,00	254.099,00	223.849,00	218.860,00	90.830,00	787.638,00	116,01	-108.726,00
	Other costs (The rest)	68.000,00	9.745,00	5.937,00	4.117,00	10.039,68	29.838,68	43,88	38.161,32
	Total Costs	746.912,00	263.844,00	229.786,00	222.977,00	100.869,68	817.476,68	109,45	-70.564,68
Part. 4, WU	Total Person-month	24,50	6,52	11,54	13,11	8,92	40,09	163,63	-15,59
	Personnel costs	204.329,00	20.299,63	40.742,54	48.394,60	38.020,94	147.457,71	72,17	56.871,29
	Subcontracting	18.000,00	0,00	9.350,00	0,00	21.255,00	30.605,00	170,03	-12.605,00
	Consumable cost		410,21	175,60	3.114,32	108,74	3.808,87		-3.808,87
	Travel cost,		4.322,52	3.336,04	3.298,60	4.504,56	15.461,72		-15.461,72
	Indirect cost		5.006,47	8.850,84	10.961,50	8.526,85	33.345,66		-33.345,66
	Other costs (The rest)	35.866,00					0,00	0,00	35.866,00
	Total Costs	258.195,00	30.038,83	62.455,02	65.769,02	72.416,09	230.678,96	89,34	27.516,04
Part. 5, UPATRAS	Total Person-month	36,00	4,86	8,49	16,74	10,51	40,60	112,78	-4,60
	Personnel costs	165.000,00	21.433,00	39.200,00	77.357,45	48.680,00	186.670,45	113,13	-21.670,45
	Subcontracting		0,00	0,00	0,00	2.200,00	2.200,00		-2.200,00
	Consumable cost		0,00	883,04	1.302,67	0,00	2.185,71		-2.185,71
	Travel cost,		4.339,74	2.176,14	3.592,92	986,46	11.095,26		-11.095,26
	Indirect cost		5.154,55	8.451,84	16.450,60	9.933,29	39.990,28		-39.990,28
	Other costs (The rest)	67.800,00					0,00	0,00	67.800,00
	Total Costs	232.800,00	30.927,29	50.711,02	98.703,64	61.799,75	242.141,70	104,01	-9.341,70
Part. 6, ALTAGRA	Total Person-month	2,00	0,50	0,20	1,00	2,50	4,20	210,00	-2,20
	Personnel costs	14.000,00	800,00	160,00	800,00	20.000,00	21.760,00	155,43	-7.760,00
	Subcontracting		0,00	0,00	0,00	2.000,00	2.000,00		-2.000,00
	Consumable cost		0,00	0,00	0,00	7.033,40	7.033,40		-7.033,40
	Travel cost,		777,96	0,00	895,56	0,00	1.673,52		-1.673,52
	Indirect cost		156,91	0,00	181,03	5.406,68	5.744,62		-5.744,62
	Other costs (The rest)	41.200,00	6,60	0,00	9,58	332,58	348,76	0,00	-348,76
	Total Costs	55.200,00	1.741,47	160,00	1.886,17	34.772,66	38.560,30	69,86	16.639,70
Part. 7, IPIMAR	Total Person-month	19,00	9,00	8,50	10,50	3,90	31,90	167,89	-12,90
	Personnel costs	85.960,00	21.606,05	23.485,49	27.416,59	16.480,51	88.988,64	103,52	-3.028,64
	Subcontracting		0,00	0,00	0,00	2.500,00	2.500,00		-2.500,00
	Consumable cost		0,00	1.544,30	62,14	2.620,61	4.227,05		-4.227,05
	Travel cost		3.904,60	3.252,45	6.391,19	6.122,76	19.671,00		-19.671,00
	Indirect cost		5.230,11	5.656,45	6.866,93	5.243,05	22.996,54		-22.996,54
	Other costs (The rest)	53.192,00	639,90		464,70	991,35	2.095,95	3,94	51.096,05
	Total Costs	139.152,00	31.380,66	33.938,69	41.201,55	33.958,28	140.479,18	100,95	-1.327,18

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

Table 4: Person-Months Status table[†]

Person-Month Status Table		Partner - Person-month per Workpackage									AC-own staff			
Contract N°: 22957														
Acronym: Qalibra														
Period: 4, 1st April 2009 - 31st December 2009														
		TOTALS	Coordinator	Part. 1 Matis	Part. 2 FERA	Part. 3 RIVM	Part. 4 WU	Part. 5 UPATRAS	Part. 6 ALTAGRA	Part. 7 IPM/MAR	ACTOTALS	AC participant 4	AC participant 5	AC participant 7
Workpackage 1: Development of generalised modular approach to risk-benefit analysis using menu of dose-response and valuation/integration functions	Actual WP total:	10,93	6,93	0,00	4,00	0,00	0,00	0,00	0,00	0,00	0,00			
	Planned WP total*:	74,50	5,50	22,00	44,00	3,00	0,00	0,00	0,00	0,00	0,00			
Workpackage 2: Implementation of methods as web-enabled software for all stakeholders	Actual WP total :	30,24	4,18	23,15	0,00	0,00	2,41	0,00	0,50	1,50	1,50	1,00	0,50	
	Planned WP total*:	79,00	2,00	51,00	1,00	3,00	22,00	0,00	0,00	0,00	0,00			
Workpackage 3: Development of strategies for communicating and disseminating risk-benefit information and dissemination	Actual WP total:	28,72	8,96	0,00	0,00	8,76	8,00	2,00	1,00	1,34	0,34	1,00		
	Planned WP total*:	42,50	4,00	1,00	3,00	17,00	13,00	1,50	3,00	0,00				
Workpackage 4: Case study 1 on seafood	Actual WP total:	25,91	20,71	0,00	3,20	0,00	0,00	0,00	2,00	2,50	0,50	2,00		
	Planned WP total*:	52,50	30,00	3,50	4,00	0,00	0,00	0,00	15,00	0,00				
Workpackage 5: Case study 2 on functional food	Actual WP total:	2,84	2,54	0,00	0,30	0,00	0,00	0,00	0,00	0,00				
	Planned WP total*:	20,50	7,00	4,50	9,00	0,00	0,00	0,00	0,00	0,00				
Workpackage 6: Cluster activities	Actual WP total:	2,60	1,52	0,00	0,00	0,08	0,10	0,50	0,40	0,40			0,40	
	Planned WP total*:	7,00	1,50	1,00	1,00	1,00	1,00	0,50	1,00	0,00				
Workpackage 7: project coordination and management	Actual WP total:	5,55	4,36	0,91	0,00	0,20	0,08	0,00	0,00	0,00				
	Planned WP total*:	8,00	4,50	1,00	1,00	0,50	0,00	0,00	0,00	0,00				
Total Project Person-month	Actual total:	106,79	4,36	45,75	23,15	7,70	8,92	10,51	2,50	3,90	5,74	0,34	1,50	3,90
	Planned WP total*:	284,00	4,50	51,00	84,00	63,00	24,50	36,00	2,00	19,00	0,00	0,00	0,00	0,00

* Planned person months for the full duration of project (45 months)

[†] For AC contractors, a tabular overview of all resources employed 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 (FERA):

- Implemented additional dose-response & integration algorithms and finalise Version 4 of the system
- Modified the code as necessary to accommodate the results of case study 1B and case study 2
- Worked on improving the web-enabled software this included: developing interactive graphical outputs from the Qalibra tool, finalized the results from Case Studies 1B and 2, added functionality to allow users to specify single value inputs for each of the parameters in the Qalibra framework, implemented ‘sharing’ and ‘grouping’ actions for assessments, and added functionality to allow the tool to handle both single-step (quantal) functions and multi-step (continuous) dose-response functions
- Provided the website and web-based QALIBRA tool in an appropriate state to facilitate the final end-user workshop in September 2009.
- Made final refinements to ensure that web-based QALIBRA tool is flexible and user friendly
- Finalised Version 8 of system design and the final documentation of the web system (Deliverable D32)

Partner 5 (UPATRAS):

- Designed and applied complementary techniques like expert based evaluation and user testing approaches. These studies were analyzed and proposals made to enhance the usability of the QALIBRA web-based tool.
- Assisted in further development of the website and web-tool in light of the expert based evaluation and user testing approaches
- Developed a user questionnaire that was given to participants to report their feedback after the *final* end-user workshop in September 2009.

Partner 1 (Matis):

- Contributed to in discussions regarding the graphical outputs from the Qalibra web-tool as well as registration, access and the user documentation in the QALIBRA web-tool

- Participated in expert based evaluation and user testing approaches
- 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 expert based evaluation and user testing approaches

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

It was significant and demanding task to ensure that the staff developing the software for WP2, who were mainly IT professionals, understood the science and mathematics behind the framework enough to ensure that the tool did the job required of it. The complexity and novelty of the science made this a challenge and thus this work required more man-months than originally planned.

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):

- Collected data for the second round of consumer study and finalised a report based on the results from this study (deliverable D26)
- Submitted a scientific article discussing the results from the consumer studies conducted in the QALIBRA project
- Finalised a report with the results from the stakeholder analysis (Delphi study)
- WU organised and co-ordinated the development of Deliverable D33 i.e. the final dissemination plan for post-project activities
- Contributed to the development of dissemination materials for the *final* end-user workshop in collaboration with other partners (deliverable D22- revision 2)

- Participated in the organisation and development of the *final* end-user workshop together with Matis, Altagra, RIVM and FERA. WU also participated in the *final* end-user workshop held 9-10th of September 2009 in Budapest
- Analysed the feedback questionnaires of the final end-user workshop and collated the results in a report

Partner 1 (Matis):

- Wrote and coordinated revision 4 of the ‘Plan for using and disseminating the knowledge’ for the Qalibra project.
- Organised, co-ordinated and contributed to the development of Revision 2 of Deliverable D22; Dissemination material for first end-user workshop
- Contributed to the organisation and development of the *final* end-user workshop in collaboration with the other partners (Altagra, FERA, RIVM and WU). Matis also participated in the *final* end-user workshop held 9-10th of September 2009 in Budapest
- Matis participated in the organisation and planning of a workshop for BRAFO held 10-11th of September 2009 that was carried out as a follow up of the QALIBRA end-user workshop to understand and explore the applicability of the QALIBRA web-tool for the BRAFO case studies
- Matis led the writing and development of an overview article about the QALIBRA project and what it has achieved that was published December 2009 in International Innovation by Research Media (www.researchmedia.eu)
- Matis organised and contributed to the development of Deliverable D33 i.e. the final dissemination plan for post–project activities

Partner 2 (FERA):

- Contributed to the development of dissemination materials for the *final* end-user workshop in collaboration with other partners (Deliverable D22- revision 2)
- Participated in the organisation and development of the *final* end-user workshop together with Matis, Altagra, RIVM and WU. FERA also participated in the *final* end-user workshop held 9-10th of September 2009 in Budapest
- FERA provided technical expertise on the web-enabled QALIBRA tool at the *final* end-user workshop
- FERA participated in the organisation and contributed to technical and scientific aspects of a workshop for BRAFO held 10-11th of September 2009 and carried out as a follow up of the QALIBRA end-user workshop
- FERA contributed to the writing and development of an overview article about the QALIBRA project

Partner 3 (RIVM):

- Contributed to the development of dissemination materials for the *final* end-user workshop in collaboration with other partners (deliverable D22- revision 2)
- Participated in the organisation and development of the *final* end-user workshop together with Matis, Altagra, FERA and WU. RIVM also participated in the *final* end-user workshop held 9-10th of September 2009 in Budapest
- RIVM participated in the organisation and contributed to technical and scientific aspects of a workshop for BRAFO held 10-11th of September 2009 and carried out as a follow up of the QALIBRA end-user workshop

Partner 5 (UPATRAS):

- Contributed to the development of dissemination materials for the final end-user workshop in collaboration with other partners (deliverable D22- revision 2)

Partner 6 (Altagra):

- Led the organisation and development of the *final* end-user workshop held 9-10th of September 2009 in Budapest.
- Managed and carried out the *final* end-user workshop held 9-10th of September 2009 in Budapest with external end-users including participants from food authorities, food industry, public health professionals and academia from many countries in Europe.
- Contributed to the development of dissemination materials for the *final* end-user workshop in collaboration with other partners (deliverable D22- revision 2)
- Participated in the organisation and planning of a workshop for BRAFO held 10-11th of September 2009 that was carried out as a follow up of the QALIBRA end-user workshop
- Managed and executed the special workshop for BRAFO held 10-11th of September 2009 in Budapest

Dissemination activities:

A total of 25 oral presentations and 8 posters were presented by QALIBRA partners to a wide range of audience worldwide (for details refer to Annex 1-Plan for using and disseminating the knowledge)

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

The organisation, development and implementation of the *final* end-user workshop as well as the development of material used for dissemination at the workshop was very demanding, thus this work required more required more man-months than originally planned.

WP4. Case study 1 on seafood

Description of the work performed in WP4 by each contractor

Partner 1 (Matis):

- Finalised the data collection and data evaluations on the positive health effects of oily fish for case study 1B
- Worked on and contributed to the finalisation of the final report on Case Study 1B on seafood (Deliverable D24)
- Worked on and contributed to the finalisation of Deliverable D29b, a manuscript for a scientific article entitled “Fish consumption during child bearing age: A quantitative risk-benefit analysis on neurodevelopment”
- Worked on and contributed to the finalisation of a manuscript for review paper of the positive health effects of fish consumption (Deliverable D30)

Partner 2 (FERA):

- Refined the modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework and tested the outcome of the risk-benefit assessment for seafood using the web-based QALIBRA tool
- Contributed to the finalisation of the final report on Case Study 1B on seafood (Deliverable D24)
- Worked on and contributed to the finalisation of Deliverable D29b, a manuscript for a scientific article entitled “Fish consumption during child bearing age: A quantitative risk-benefit analysis on neurodevelopment”

Partner 3 (RIVM):

- Refined the modelling for quantitative risk-benefit assessment of net health impacts in case study 1 with the QALIBRA framework and tested the outcome of the risk-benefit assessment for seafood using the web-based QALIBRA tool
- RIVM refined and improved the dose-response models for the most important positive and negative health end-points related to case study 1 on seafood

- Worked on and contributed to the finalisation of the final report on Case Study 1B on seafood (Deliverable D24)
- Worked on and contributed to the finalisation of Deliverable D29b, a manuscript for a scientific article entitled “Fish consumption during child bearing age: A quantitative risk-benefit analysis on neurodevelopment”
- Contributed to the finalisation of a manuscript for review paper of the positive health effects of fish consumption (Deliverable D30)

Partner 7 (IPIMAR):

- Finalised the data collection and data evaluations on the positive health effects of oily fish for case study 1B
- Worked on and contributed to the finalisation of the final report on Case Study 1B on seafood (Deliverable D24)

- Contributed to the finalisation of a manuscript for review paper of the positive health effects of fish consumption (Deliverable D30)

Explanatory note on any major cost items

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

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 and information on the diseases related to the intake of the nutrient, as well as the ‘disability weights’ to quantify the relative severity of health effects associated with intake of the nutrient under study 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.

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 (FERA):

- Refined the modelling of net health impacts in case study 2 using the Qalibra framework and tested of the outcome of the risk-benefit assessment using the QALIBRA web-based software for case study 2 on functional food
- Worked on and contributed to the finalised a report on case study 2 (deliverable D25).
- Worked on and contributed to a scientific article entitled “Benefit-risk assessment of phytosterols in margarine; a QALIBRA case study” (deliverable D31).

Partner 3 (RIVM):

- Refined and adapted the dose-response models for phytosterol intake and the selected positive (IHD) and negative (night-blindness) effect
- Provided additional data on sterol intakes, incidences of heart diseases in relation to cholesterol, night blindness and disability weights to improve the datasets for these parameters of the assessment in the QALIBRA framework
- Worked on and contributed to the finalised a report on case study 2 (deliverable D25).
- Worked on and contributed to a scientific article entitled “Benefit-risk assessment of phytosterols in margarine; a QALIBRA case study” (deliverable D31).

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 WP5

The majority of man-months 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.

WP6. Cluster activities between the QALIBRA and BENERIS projects

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

All QALIBRA partners participated in the following work:

- The final Beneris and QALIBRA cluster meeting that was held in Budapest 10-11th of June 2009

Partner 1 (Matis):

- Organised and planned the final cluster meeting of the QALIBRA and Beneris projects held in Budapest 10-11th of June 2009
- Organised and planned the final SAP meeting that was held during the final cluster meeting
- Organised and wrote the final report on the cluster activities (Deliverable D35).
- Contributed to the final cluster dissemination plan
- Liaised with Beneris regarding cluster activities and collaboration

Partner 2 (FERA):

- Organised and planned the final cluster meeting of the QALIBRA and Beneris projects held in Budapest 10-11th of June 2009
- Organised and planned the final SAP meeting that was held during the final cluster meeting
- Contributed to the final cluster dissemination plan

Partner 6 (Altagra):

- Organised and planned the final cluster meeting of the QALIBRA and Beneris projects held in Budapest 10-11th of June 2009
- Altagra managed and executed the final Beneris and QALIBRA cluster meeting held in Budapest 10-11 June 2009

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 contributed to the following work:

- Finalization of the third and the fourth annual periodic report (Deliverables D27 and D34)
- Contributed to interim progress reports (used for internal monitoring of progress)
- The 8th overall project meeting of QALIBRA held 11th of June in Budapest, Hungary
- Finalization of the final report to the commission (Deliverable D36)

Partner 1 (Matis):

- Coordinated and finalized the third and fourth annual periodic report (Deliverables D27 and D34)
- Coordinated and finalized the final report to the commission (Deliverable D36)
- Contributed to planning of the 8th overall project meeting of QALIBRA in cooperation with Altagra and FERA
- Organized and chaired the overall project meeting in cooperation with FERA
- Contributed to a report that describes the outcome of the 8th overall project meeting (Annex 2 to this report)
- Organized and chaired project steering group (PSG) meetings and wrote minutes from meetings
- Updated the project website as needed
- Monitored and coordinated the activities in the QALIBRA project
- Monitored and coordinated the activities for WP4 and WP6 (WP leader for WP4 & WP6)
- Finalised the “Interim science and society reporting questionnaire” for QALIBRA online
- Distributed advanced payments to other QALIBRA consortium participants

Partner 2 (FERA):

- Contributed to planning of the 8th overall project meeting of QALIBRA in cooperation with Altagra and Matis
- Organized and chaired the overall project meeting in cooperation with Matis

- Contributed to a report that describes the outcome of the 8th overall project meeting
- 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)

Explanatory note on any major cost items

The following explanations have been provided by partners making to adjustment to previous periods in their Form C for period 4:

FERA: The adjustment relates to a calculation that we applied retrospectively to previous periods following recommendations from Internal Audit. The calculation is an overhead adjustment from an EU Absorption calculation which is calculated by Finance at the end of each Financial year. This calculation arose following an audit from the EU Commission but had not been appropriately applied to the Qalibra project for previous periods.

Altagra: The adjustment is due to error in calculation of indirect costs in previous periods where the flat rate of 20% was only applied to cost related to consumables and travel and not personnel cost.

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 partner of the QALIBRA project the Form C Financial Statement, signed and stamped by the participants, are enclosed as separate documents to the periodic report. In addition, an audit certificate is included for each partner of the QALIBRA project.

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 different reporting periods.