

Vinnsla og vöruþróun
Processing and Product
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Biotechnology



Matvælaöryggi
Food Safety



QALIBRA – Heilsuvogin

Second Annual Report

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Skýrsla Matís 13-08
Júní 2008

ISSN 1670-7192



<i>Titill / Title</i>	QALIBRA-Heilsuvogin. Second Annual Report		
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<i>Skýrsla / Report no.</i>	13-08	<i>Útgáfudagur / Date:</i>	Júní 2008
<i>Verknr. / project no.</i>	1681		
<i>Styrktaraðilar / funding:</i>	ESB		
<i>Ágrip á íslensku:</i>	<p>Þessi skýrsla er önnur ársskýrsla í Evrópuverkefninu QALIBRA og nær yfir tímabilið 1.04. 2007 til 31.03. 2008.</p> <p>QALIBRA, eða “Quality of Life – Integrated Benefit and Risk Analysis. Web-based 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 og hálfis árs verkefni sem Rannsóknastofnun fiskiðnaðarins (nú Matís ohf) stýrir. Verkefnistjóri 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 munu verða settar fram í tölvuforriti sem verður opið og aðgengilegt öllum hagsmunaaðilum á veraldarvefnum.</p> <p>Þátttakendur í verkefninu eru frá Íslandi, Bretlandi, Hollandi, Grikklandi, Portúgal og Ungverjalandi.</p>		
<i>Lykilorð á íslensku:</i>	<i>Ársskýrsla, QALIBRA, áhættu- og heilnæmismat, innihaldsefni matvæla, magnbundnar aðferðir, feitur fiskur, markfæði</i>		
<i>Summary in English:</i>	<p>“QALIBRA - Quality of life – integrated benefit and risk analysis. Web – based tool for assessing food safety and health benefits” is a project funded by the EC's Sixth Framework Programme, Priority 5, Food Quality & Safety. It began in April 2006 and will end in 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 will develop methods that can take account of multiple risks, benefits and uncertainties and implement them in web-based software for assessing and communicating net health impacts.</p> <p>The objectives of QALIBRA are to develop a suite of quantitative methods for assessing and integrating beneficial and adverse effects of foods, and make them available to all stakeholders as web-based software for assessing and communicating net health impacts.</p> <p>The participants in the project are:</p> <p>Matís, Iceland, coordinator, Central Science Laboratory, United Kingdom, National Institute of Public Health and The Environment, The Netherlands, Wageningen University, The Netherlands, University of Patras, Greece, Altagra Business Service, Hungary, National Institute for Agriculture and Fisheries Research, Portugal.</p>		
<i>English keywords:</i>	<i>Periodic report, QALIBRA, risk-benefit analysis, quantitative methods,, oily fish, functional food</i>		

Skýrsluágrip Matis ohf
Matis Food Research, Innovation & Safety
Report Summary



ISSN: 1670-7192

Skýrsluágrip Matis ohf
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ISSN: 1670-7192

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1. EXECUTIVE SUMMARY

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

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

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

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

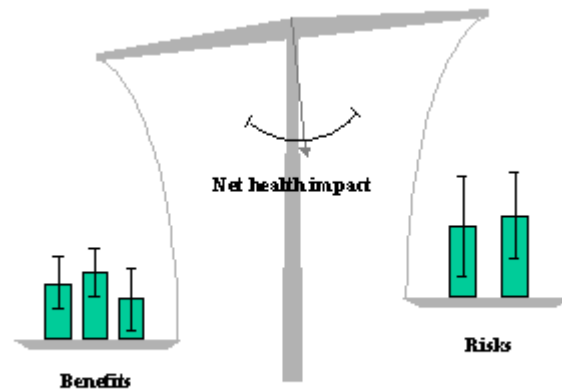


Figure 1. Net health impact depends on the balance of benefits and risks and their associated uncertainties.

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

The specific objectives of QALIBRA are therefore as follows:

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



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

Work package 1 has continued to work on the development of the overall framework for risk-benefit analysis and two new version of the framework have been delivered this period (i.e. deliverables D8 & D13), further development will be ongoing until month 42. In addition, this work package has concentrated on development of dose-response models and algorithms for specific beneficial and detrimental effects that are relevant for consumption of oily fish and phytosterol enriched functional foods, and on advanced methods for quantifying expert knowledge and uncertainty in the choice of dose-response models.

Work package 2 will implement the QALIBRA methods as web-enabled software. During the second year, versions 2 and 3 of the system design have been developed and reviewed by project partners. Two versions of the system have been implemented during this reporting period, version 1 was delivered and presented at the mid-term meeting in November 2007 and version 2 was delivered at the end of March 2008. Technical advances during this period include provision for provision of input data in matrix form, which allows the user total flexibility in the choice of methods for quantifying uncertainty and variability. This also facilitates use of outputs from risk assessment software developed in other EU projects (e.g. Monte Carlo, Safe Foods). A formal usability evaluation of version 1 of the system was conducted, producing extensive recommendations for its improvement.

Work package 3 is developing strategies for communicating and disseminating risk benefit information. This period the first focus group study on communication of risk benefit analysis outputs was conducted and the findings were presented in deliverable D15. Further, the protocol for the stakeholder analysis (Delphi study) and the Delphi questionnaire were finalised and the outcome of this work used in the initial round of stakeholder analysis (Delphi study). In addition, this work package developed a revised plan for using and dissemination the knowledge for the QALIBRA project as a whole.

Work package 4 is developing case study 1, on oily fish. The case study is proceeding in two stages, first a preliminary analysis comprising one positive and one negative health effect, and then a more comprehensive analysis including a wider range of effects. During the second year the first a preliminary analysis was finalised and presented in deliverables D11 and D19. Valuable feedback was received from the EU evaluators and Scientific Advisory Panel, and this is being used to improve the methodology for the second, comprehensive analysis. The collection of data is ongoing for the second analysis, and systematic procedures were devised and implemented for selecting the most important positive and negative effects for analysis.

Work package 5 is developing case study 2, on functional foods. The work this period has involved construction of a database containing information on positive and negative health effects of phytosterols/-stanols and selection of most relevant positive and negative health effects, ready for analysis in the next period.



Work package 6 comprises cluster activities between QALIBRA and the Beneris project, which is conducting complementary research on risk-benefit analysis. The second Cluster meeting was held this reporting period at the same time as the midterm review of the two projects and the outcome was reported in deliverable D16. A Gordon conference was organised and planned by Beneris in cooperation with QALIBRA. The conference theme was Environment and health - approaches to benefit-risk analysis and it was held in Valamo in Finland December 3-5, 2007. In addition, individual partners from both projects continued to liaise on methods for uncertainty analysis.

Work package 7 is responsible for coordination and management of the QALIBRA project. In the second project year this work package has fine-tuned, monitored and coordinated the work in the project. The first annual reports for the project were delivered to the Commission and one overall meeting was held at the midterm of the project.

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

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

The public website for the project may be examined at www.qalibra.eu
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Central Science Laboratory	CSL	United Kingdom
National Institute of Public Health and The Environment	RIVM	The Netherlands
Wageningen University	WU	The Netherlands
University of Patras	UPATRAS	Greece
Altagra Business Service	ALTAGRA	Hungary
National Institute for Agriculture and Fisheries Research	INIAP/IPIMAR	Portugal

2. PROJECT OBJECTIVES & MAJOR ACHIEVEMENTS-YEAR 1

Overview of general project objectives

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

The general objectives of QALIBRA are:

1. Develop a generalised modular approach to risk-benefit analysis using menus of dose-response and valuation functions. The dose-response functions will cover different types of positive and negative health effects that are commonly encountered in food safety assessment. The valuation functions will integrate positive and negative health effects using common measures of net health impact (e.g. quality-adjusted life years, QALYs). The framework will also include methods for comprehensive risk ranking, methods for characterising data quality and methods for separating uncertainty and variability (Workpackage WP1).
2. Implement the risk-benefit analysis methods developed in QALIBRA in web-enabled software that is available for use by all stakeholders via an integrated website, with different components adapted to different user groups using appropriate interaction styles, terminology and information presentation techniques (WP2).
3. Develop targeted risk communication strategies for integrated risk-benefit analysis, adapted to the needs of different stakeholders, and develop and test programs and materials for dissemination of the practical use of the QALIBRA software by technical end-users (WP3).
4. Use the methods and software developed by QALIBRA to carry out comprehensive risk-benefit analyses for selected food groups including oily fish (with input from Beneris for salmon & herring) and functional foods, for selected EU populations, and use the results to evaluate and improve the QALIBRA approaches (WP4 & 5).
5. Establish a platform for cluster activities between QALIBRA and BENERIS projects and report about them to the Commission (WP6).
6. Manage and coordinate the QALIBRA project to ensure the activities are properly focussed on the Commission's objectives and achieve high standards of scientific and technological excellence, ensure the quality of the consortium personnel and the mobilisation of resources, to monitor and evaluate progress against the project milestones and to make timely and appropriate adjustments when necessary (WP7).

Approaches for risk-benefit analysis with respect to food safety are currently at a relatively early stage of development. In recent years attempts have increasingly been made to quantify the risks and benefits of dietary choices, but usually they are considered separately or integrated only in a qualitative way. Although general frameworks for risk-benefit analysis have been proposed in the literature, the few studies that have quantified net health impacts have been specific to particular problems. Uncertainties affecting risks and benefits are often given only fleeting consideration and are very rarely quantified in

any formal way. The few research studies, which have quantified net health impacts, have not attempted to quantify the uncertainties associated with them. Finally, while there has been a rapid growth in social sciences addressing risk perception and risk communication, only limited attention has so far been given to approaches for communicating net health impacts, or to approaches for communicating uncertainty.

QALIBRA will advance this state of the art by:

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

Summary of recommendations from previous reviews

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

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

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

Summary of the objectives, work performed, contractors involved and main achievements YEAR 2 for different workpackages (WP)

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

Contractors involved: RIVM, CSL, Matis

Objectives, work performed and main achievements YEAR 2

- Development of version 3 of QALIBRA framework for Risk-Benefit assessment, the outcome of this work was presented in deliverable D8
- Development of version 4 of framework for Risk-Benefit assessment, the outcome of this work was presented in Deliverable D13
- Continue development of dose-response models & algorithms as well as the framework and quantification of uncertainty, this work is currently ongoing

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

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

Objectives, work performed and main achievements YEAR 2

- Finalise implementation of Version 1 of system with functions for basic operations, framework and Case Study 1A, the outcome of this work was deliverable D14
- Finalise Version 2 of system including functions for Case Study 1B, the outcome of this work was deliverable D18
- Continue work on Version 3 of system design: detailed plan for basic & framework functions and first algorithms from WP1, this work is currently ongoing
- Usability evaluation of Version 1 of system, the outcome of the usability evaluation was presented in deliverable D17

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

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

Objectives, work performed and main achievements YEAR 2

- Conduct the first focus group study on communication of risk benefit analysis outputs, the outcome of this work was presented in deliverable D15
- Finalise the protocol for the stakeholder analysis (Delphi study), develop the questionnaire and pilot the Delphi questionnaire on project partners. The outcome of this work was then used in the initial round of stakeholder analysis (Delphi study)

- Develop a list of potential participants in the stakeholder analysis
- Dissemination of the QALIBRA project. This reporting period the QALIBRA project has been disseminated on 17 different occasions at national and international conferences/lectures i.e. 15 oral presentations and 2 posters

WP4. Case study 1 on seafood

Contractors involved: Matis, IPIMAR, RIVM, CSL

Objectives, work performed and main achievements YEAR 2

- Finalise the preliminary report on Case study 1-A, the outcome of this work is deliverable D11
- Collect data for phase B of Case study 1 (oily fish), the outcome of this work is a table of the collected data consisting of 582 records at the end of this reporting period, this work is currently ongoing
- Provide data for modelling of dose/response relationships for positive and negative health impacts, the outcome of this work was then applied in WP1
- Finalise the report on Case study 1-A (deliverable D19), the outcome of this work is deliverable D19

WP5. Case study 2 on functional foods

Contractors involved: RIVM

Objectives, work performed and main achievements YEAR 2

- Finalisation of a database containing information on positive and negative health effects of phytosterols/-stanols, this work has been completed
- Selection of most relevant positive and negative health effects of phytosterols/-stanols and description of selection criteria, this work has been completed
- Search for available dose-response functions, the outcome of this work has been collected in a table

WP6. Cluster activities between the QALIBRA and Beneris projects

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

Objectives, work performed and main achievements YEAR 2

- Optimize the interaction and the cluster activities between the QALIBRA and Beneris projects. The 2nd Cluster meeting was held at the same time as the midterm review of the two projects. This meeting was held in Helsinki, Finland, 7-9 November 2007 and focused on the review of activities and sharing information between the two projects as well as the consultation of the Scientific Advisory Panel (SAP). A report containing the output from the 2nd Cluster meeting has been delivered (Deliverable D16).

- A Gordon conference was organised and planned by the KTL/Beneris in co-operation with QALIBRA. The conference theme was Environment and health - approaches to benefit-risk analysis and it was held in Valamo in Finland December 3-5, 2007.
- Individual partners from both projects continued to liaise on methods for uncertainty analysis.

WP7. Project coordination and management

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

Objectives, work performed and main achievements YEAR 2

- The objective during the second project year has been to fine tune, monitor and coordinate the work in the QALIBRA project
- Finalise the first periodic reports (i.e. annual progress report and annual financial report) , the outcome of this work was submitted to the Commission (Deliverable D12)
- Finalise “The interim science and society reporting questionnaire” for QALIBRA and submit it online to the Commission
- Organize & plan project meetings and ensure that minutes were prepared for all meetings. A report that describes the outcome of the overall meeting held in Helsinki November 2007 is enclosed with this report (Annex 2)

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 2

- 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
- Internal and external review of dose-response models and contents of the overall framework
- Development of version 3 of QALIBRA framework for Risk-Benefit assessment (Deliverable D8)

- Development of version 4 of framework for Risk-Benefit assessment (Deliverable D13)
- Continue development of dose-response models and algorithms for specific beneficial and detrimental effects that are relevant for consumption of oily fish and phytosterol enriched functional foods (Deliverable D7 in collaboration with WP4 and WP5)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved - YEAR 2

- RIVM has internally reviewed the work in progress regarding the development of dose-response models and the final framework (August 29th 2007)
- RIVM discussed the internal review process and next steps of action in WP1 with partners CSL and Matis at a meeting in Leeds, UK September 5th 2007
- RIVM, in collaboration with CSL and Matis has delivered D8: Version 3 of the QALIBRA framework. The overall framework is analogue to the quantitative risk-benefit analysis described in Hoekstra et al. (2007), but included additional modelling of variability within the population and aims to quantify uncertainties at each stage of the process.
- RIVM, in collaboration with CSL and Matis has delivered D13: Version 4 of the framework. This is the second version of the description of the risk-benefit framework used in the QALIBRA project. It is an update of deliverable D8 and addresses from the comments of the Scientific Advisory Panel (SAP) and the EU-reviewers on deliverable D8.
- RIVM is continuing the work on the framework in collaboration with CSL, among others:
 - CSL developed and implemented an approach for enabling the framework to accept matrix inputs of data representing variability and uncertainty for all input parameters, including for example dose response models and disease weights. This has the important advantage of providing complete flexibility for the user in how these inputs are generated and to allow the use of other existing software for that purpose (e.g. PROAST for dose-response modeling).
 - CSL explored the suitability of Bayesian model averaging as a technique for quantifying uncertainty about the choice of alternative models for the same input, and produced a demonstration of this approach showing how it could be applied to three alternative dose-response models for a single dataset, for discussion at the project meeting in April 2008.
 - CSL explored formal methods for eliciting expert opinion that could potentially be applicable for obtaining some types of framework inputs, e.g. expert judgements on the relative likelihood of alternative dose response models, disability weights, or other inputs for which objective data are limited. A demonstration example is currently being prepared.
 - CSL began exploring practical methods for conducting sensitivity analysis by conducting multiple model runs with contrasting assumptions/inputs to test their impact on the results. This work will be continued in the next period.

- CSL proposed an alternative graphical format for presenting probabilistic estimates of the net health impact of dietary changes, designed for easier interpretation by non-specialists.
- RIVM, in collaboration with CSL is developing oily fish intake scenario's based on realistic data.
- Matis continued the data collection and evaluation for case study B and reported to RIVM on the most important end-points and studies to be included in the modelling

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

It was planned to develop algorithms for a menu of dose-response functions. Instead CSL has designed the framework to accept output from dose-response modeling done outside the framework as dose response modeling is expert work and turns out to very case sensitive. It was also planned to develop algorithms for a menu of valuation/integration functions. Currently only the DALY method is implemented. This method is likely to be the most relevant for experts. Based on recommendations from the EU reviewers to focus the Qalibra tool on expert stakeholders, the DALY method is the preferred approach. The construction but also the data delivery on positive and negative health effects is laborious. As described in last years periodic report there was a delay in the delivery of Deliverables 8 and 13 due to the delay in delivery of data. To avoid further delays in WP1 it has been decided to focus on Case study 2 in parallel to Case study 1B as Case study 2 appears to be less complex and to learn in parallel from both case studies.

Table 1: Deliverables List for WP1

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

Table 2: Milestones List for WP1

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M1.1	Inventory of types of dose-response models and endpoints potentially relevant for risk-benefit in selected foods	1	Month 8	Month 8 Completed	RIVM
M1.2	Partners review of dose-response and uncertainty algorithms	1	Month 12	Month 18 Completed	RIVM
M1.3	Criteria for data quality of each type of dose response relationship	1	Month 42	Month 42	RIVM
M1.4	Inventory of types of dose-response models useful for risk-benefit measures and ranking their information content	1	Month 42	Month 42	RIVM
M1.5	Catalogue and ranking of integration methods and selected primary method accepted by partners	1	Month 4	Month 8 Completed	RIVM
M1.6	Partners review of proposed framework	1	Month 12	Month 12-18 Completed	RIVM
M1.7	Adapted framework based on experience in case studies WP4 and 5	1	Month 18	Month 18-24	RIVM

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

Workpackage objectives and starting point of work at the beginning of YEAR 2

- The starting point for this period was that the work in WP2 was on schedule, except for the decision to delay system design v3 in order to include work done in other work packages (particularly WP1).
- Finalise implementation of Version 1 of system with functions for basic operations, framework and Case Study 1A
- Finalise Version 2 of system including functions for Case Study 1B
- Continue work on Version 3 of system design: detailed plan for basic & framework functions and first algorithms from WP1
- Work on Version 2 of dummy web-pages for basic functions and framework functions
- Start work on Version 4 of system design (update to include extra functions from WP1).

- Usability evaluation of Version 1 of system.
- Start work on Version 5 of system design: add functions for consumer information.

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 2

- CSL worked on the various versions of the system design and on the system itself e.g. CSL has implemented two versions of the system during this reporting period, version 1 was delivered at the mid-term meeting in November 2007 (based upon the work in Case Study 1A - Deliverable D14), and version 2 was delivered at the end of March 2008, although not yet including all the functions from Deliverable D18, because of timing constraints
- UPATRAS produced a Usability Evaluation of Version 1 of system and assisted CSL in further development of the website and web tool in light of this evaluation. UPATRAS finalised a report on the usability evaluation of the system (Deliverable D17)
- Matis, RIVM and IPIMAR assisted in the Usability Evaluation of Version 1 of system

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

As described in the last year Deliverable D9 was delivered in Month 13 instead of 12. However, this did not affect any other deliverables, and D14, D17 and D18 were all delivered to time during this reporting period.

Table 1: Deliverables List WP2

Del. no.	Deliverable name	Work-package no.	Date due	Actual/Forecast delivery date	Estimated indicative person-months *)	Used indicative person-months *)	Lead contractor
D9	System design v3: basic & framework functions and 1st algorithms from WP1.	2	Month 12	Month 13	22	22 Completed	CSL
D10	Report 1 on usability evaluation.	2	Month 12	Month 12	2.5	2.5 Completed	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	CSL
D17	Report 2 on usability evaluation of the system	2	Month 24	Month 24	2.5	2.5 Completed	UPAT RAS
D18	Version 2 of system including functions for Case Studies 1-B on seafood	2	Month 24	Month 24	12	12 Completed	CSL
D21	Version 3 of system including consumer information functions	2	Month 30	Month 30	7		CSL
D23	Report 3 on usability evaluation of the system	2	Month 36	Month 36	16		UPAT RAS
D32	Final system, system design, user documentation & arrangements for long-term support	2	Month 42	Month 42	8		CSL

Table 2: Milestones List WP2

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

M2.3	Decide final improvements, based on case studies 1 and 2, usability evaluation & end-user workshop.	2	Month 36	Month 36	CSL
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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 2

- The starting point of work was that WP3 was on schedule
- Conduct the first focus group study on communication of risk benefit analysis outputs.
- Report on first focus group study on communication of risk benefit analysis outputs (Deliverable D15 and Milestone M3.2).
- Paper with results from focus groups written and submitted.
- Finalise the protocol for the stakeholder analysis (Delphi study), develop the questionnaire and pilot the Delphi questionnaire on project partners.
- Develop a list of potential participants in the stakeholder analysis.
- Conduct stakeholder analysis (Delphi study).
- Report on stakeholder analysis with recommendations for the QALIBRA project.
- Develop version 2 of QALIBRA dissemination plan.
- To size opportunities to disseminate the QALIBRA project.

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved- YEAR 2

- WU has conducted a pilot focus group in the Netherlands to identify potential problems with the protocol for the first round of consumer focus groups.
- WU has conducted the focus groups discussion in the Netherlands and subsequently transcribed and translated this discussion.
- CSL, IPIMAR and Matis searched for suitable subcontractors for conducting the focus groups in each country.
- CSL, IPIMAR and Matis liaised with WU and the subcontractors of each country about the execution of the focus groups discussions in the participating countries.
- Matis translated the protocol for the first round of consumer focus groups from English to Icelandic.
- Matis attended the focus groups discussions in Iceland and assisted in it's execution.

- Matis translated the results of the first round of consumer focus groups discussions from Icelandic to English.
- CSL, IPIMAR, Matis and RIVM provided data on average national consumption level of fatty fish and on the recommended amounts of fatty fish consumption in each country.
- WU has developed a coding scheme and coded the (translated) transcripts from the focus groups held in all participating countries.
- WU, in collaboration with CSL, IPIMAR, Matis, RIVM and UPATRAS, has delivered the report on the first focus group study on communication of risk benefit analysis outputs (D15 and M3.2).
- WU is finalising the writing of the article on the results of the focus groups to be submitted to a scientific journal.
- WU has in collaboration with Matis, CSL, RIVM, and UPATRAS set up a pilot questionnaire for the Delphi study.
- WU has undertaken the pilot work for the Delphi questionnaire and adapted the questionnaire accordingly.
- WU has in collaboration with Matis, CSL, RIVM, UPATRAS, Altagra and IPIMAR selected a list of participants for the Delphi study.
- WU has conducted initial round of Delphi questionnaire.
- WU has conducted a telephone conference with partners from Altagra, CSL, IPIMAR, Matis, RIVM and UPATRAS developing plans for the end-user workshop.
- UPATRAS produced a draft agenda regarding the end-user workshop.
- Matis wrote version 2 of QALIBRA dissemination plan

Dissemination activities YEAR 2

The QALIBRA project was presented /disseminated at the following national and international conferences from 1 April 2007 -31 March 2008:

- Oral presentation as well as poster and handout at The ILSI-Europe conference on Functional Foods held in Malta 9-11 May 2007 (Dr. Nynke de Jong, RIVM)
- Presentation to UK Food Standards Agency's Probabilistic Modelling Working Group, London, UK. 18th of May 2007.(Dr. Andy Hart, CSL)
- Lecture at the UK Food Standards Agency Workshop on Risk Assessment Research, Hexham, UK. 7-8 of June 2007. Dr. Andy Hart, CSL)
- Oral presentations at Dutch National workshop entitled 'Risk-Benefit: applications and needs' with several stakeholders held in Utrecht, the Netherlands, June 11th 2007 (Dr Jeljer Hoekstra, Heidi Fransen, Janneke Kloosterman and Dr Nynke de Jong, RIVM)
- Poster and handout at the Royal Statistical Society annual conference in York UK. 17-19 July 2007. (Helen Owen, CSL)

- Seminar at the Center for Food Safety and Nutrition (CFSAN, part of the US FDA) 24th of July 2007. (Dr Villie Flari, CSL)
- Lecture at the Risk Assessment of Chemicals in Food Task Force. BRAFO Project- Joint Meeting. Held 13th of September 2007 in ILSI Europe offices, Brussels, Belgium. (Bjorn Thorgilsson, Matis)
- Oral presentation at II Iberian Congress on Food, Nutrition and Dietetic entitled 'Nutritional value of seafood products' held in Santa maria da feira, Portugal. 27th September 2007. (N. Bandarra & M.L.Nunes, IPIMAR)
- Presentation to UK Food Standards Agency's Probabilistic Modelling Working Group, London, UK. 29th of November 2007.(Dr. Andy Hart, CSL)
- Presentation on risk communication to the Japanese Food safety Commission Tokyo, Japan, January 2008. (Dr. Lynn Frewer, WU)
- Lecture on "Risk communication and risk governance" at the University of Osaka, Japan, January 2008. (Dr. Lynn Frewer, WU)
- Oral presentation about Qalibra at a workshop within the SAFEFOODERA Health-Risk Network. Held 25th of January 2008 at Schiphol, Netherland (Dr Nynke de Jong, RIVM)
- Oral presentation about the QALIBRA project at the kick-off meeting of BRAFO held 11-12 February 2008 in Brussels, Belgium. (Dr Helga Gunnlaugsdottir, Matis)
- Oral presentation on Qalibra methodologies at the kick-off meeting of BRAFO, a complementary 6th Framework EU project. Held 11-12 February 2008, Brussels, Belgium. Dr Jeljer Hoekstra (RIVM)
- Lecture given to M.Sc. students at Birmingham University, UK. February 2008 (Dr Villie Flari, CSL)
- Poster at CSL/Durham University seminar day, Durham, UK. 19th of March 2008 (Drs A Hart & M Kennedy, CSL)
- Oral presentation entitled "Seafood benefits" at Sea Exhibition Conferences, Olhão, Portugal. 20th of March 2008 (N. Bandarra & M.L. Nunes, IPIMAR)

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

The delivery of the report on the first round of focus groups was delayed 2 months due to delays in international data collection. The submission of an article on the first round of focus groups to a scientific journal is delayed until month 30 due to pregnancy leave of the first author. The finalisation of the Delphi study and the report will be delayed until January 2009 due to problems with the development of the survey topics and questions, which have now been overcome. In addition, the data collection takes longer than expected due to a low response rate, which we attempt to overcome by inviting additional participants to the survey. In total, the survey and subsequently its report is delayed for about 10 months (i.e. until month 34). Further, it is foreseen that due to the outcomes of consumer study 1 (D15) that a more quantitative study for deliverable D26 will be carried out than originally planned.

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 34	9		UPATRAS
D26	Report on second focus group study, on interactive provision of personal risk-benefit information.	3	Month 36	Month 36	8		WU
D33	Final dissemination plan for post-project activities.	3	Month 42	Month 42	5		Matis

Table 2: Milestones List WP3

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

WP4. Case study 1 on seafood

Workpackage objectives and starting point of work at the beginning of YEAR 2

- The starting point of the work in WP4 was that the work was approximately 3 months delayed due to delay in the data collection for Case study 1A and delay in WP1
- Finalise the preliminary report on Case study 1-A (deliverable D11)
- Collect data for phase B of Case study 1 (oily fish).
- Provide data for input into WP1 (modelling of dose/response relationships for positive and negative health impacts).
- Finalise the report on Case study 1-A (deliverable D19)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identification of contractors involved – YEAR 2

- Matis continued the literature search for the endpoint: 'stroke' in this period, using the Icelandic countrywide access portal to electronic databases and e-journals (<http://www.hvar.is/>). All of the 86 stroke records became part of the case 1B data table (see below).
- RIVM, CSL, Matis and IPIMAR worked on and contributed to the finalization of Deliverable D11 “Qalibra Framework for Risk-Benefit assessment: Case study 1A: preliminary analysis for oily fish”. Matis and CSL worked on and contributed to D19, a final report on case study 1A.
- Strategies in data searching and data collation for case study 1B on oily fish was developed jointly by Matis, IPIMAR and RIVM on various phone and physical meetings during this period.
- Data collection for phase B continued this period (Matis, IPIMAR), i.e. the case study on the whole spectrum of risks and benefits in relation to oily fish consumption. An ovid medline database (<http://www.ovid.com>) continued to be the main search tool in this period. Articles were identified either directly through the search of the database, using relevant keywords or in referenced material of articles already obtained. Data was extracted into a table in a similar fashion as for case 1a. The table format is based on suggestions and discussions at the third partner meeting in Lisbon 15.-16 March 2007. Each record (row) in the table presents the effect of a particular fish-factor (e.g. omega-3 fish oil) on a certain health endpoint, relevant to humans (e.g. stroke). Where possible, the effect was presented as dose response values. Additional fields (columns) shed light on the available data (e.g. study design, study population, confounding factors and strength of evidence). Each record also keeps information on the scientific article from which it originates. 582 records at the end of this period.
- Matis discussed with RIVM the table of collected data. These discussions resulted in change of approach:

- Matis & IPIMAR will concentrate on positive effects of fish consumption on human health endpoints, while RIVM will concentrate on the negative effects.
- Search for information in reviews, reports and meta-analysis studies will be emphasised.
- Causal relationship between fish consumption and human health endpoint will be weighed using criteria developed by the World Health Organization (i.e. WHO criteria).
- All relevant information on the human health endpoints that meet the set criteria will be collected.
- Among positive health effects under consideration are coronary heart disease (CHD), stroke, depression and sudden cardiac death (SCD).
- RIVM is working on dose-response models of coronary heart diseases (CHD).
- RIVM has constructed dose-response models of the selected positive health effects.
- RIVM has constructed an overview of the contaminants in oily fish.
- RIVM has constructed a table of the 10 most important contaminants in oily fish based on the toxicological tolerable daily intake (TDI) information
- RIVM has selected relevant contaminants to be included in the risk-benefit equation based on potential intake levels
- RIVM has tried to translate effects into relevant endpoints for humans

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

Deliverable D19 (Matis; Report on Case Study 1-A) will be delayed by 1 month to month 25 because the final discussion regarding content was postponed until the 5th project meeting held in April 2008 (month 25).

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 36	Month 36	17		Matis
D30	Scientific paper(s) on case studies A and B	4	Month 42	Month 42	2		Matis

Table 2: Milestones List WP4

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

WP5. Case study 2 on functional foods

WP objectives, starting point of work at the beginning of YEAR 2

- The starting point for this period was that WP5 was on schedule
- Finalisation of a database containing information on positive and negative health effects of phytosterols/-stanols
- Selection of most relevant positive and negative health effects and description of selection criteria
- Extract dose-response functions from the literature and the constructed table or construct the functions by the scattered information in the literature
- Description of the uncertainties and extrapolations
- Propose initial ideas on habitual intake scenario's

Progress towards objectives, tasks worked on and achievements made with reference to planned objectives, identify contractors involved- YEAR 2

- RIVM has constructed the final database on positive and negative health endpoints of phytosterols/-stanols
- RIVM has decided on which health effects are to be taken into the risk-benefit equation
- RIVM has consulted experts to evaluate the decided health effects
- RIVM has tabulated the available dose-reponse functions from the literature
- RIVM has launched ideas on habitual intake scenario's and will present them to partners during the next overall QALIBRA meeting in Patras.

Deviations and corrective actions

No deviations

Table 1: Deliverables List WP5

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

Table 2: Milestones List WP5

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

WP6. Cluster activities between the QALIBRA and BENERIS projects

Workpackage objectives and starting point of work at the beginning of YEAR 2

- The starting point for this period was that the work in WP6 was on schedule
- Optimize the interaction and the cluster activities between the QALIBRA and Beneris projects
- Organise and plan the second Cluster meeting and write a report containing the output from the Cluster meeting (deliverable D16)

Progress towards objectives – tasks worked on and achievements made with reference to planned objectives, identify contractors involved – YEAR 2

- The second Cluster meeting (i.e. the midterm meeting) of the sister projects QALIBRA and Beneris was organised and planned in cooperation between Matis, KTL and CSL. The meeting was held in Helsinki, Finland, 7–9 November 2007. This meeting focused on the review of activities and sharing information between the two projects as well as the consultation of the Scientific Advisory Panel (SAP)

- Report containing the output from the Cluster meeting was written and submitted to the European Commission (Deliverable D16)
- The Cluster agreement between QALIBRA and Beneris has been signed by both parties
- Beneris partner Prof Roger Cooke (Delft University) visited CSL in Nov 2007, to exchange information on approaches to modeling and uncertainty used in the two projects and to give a seminar for CSL staff on “Bayesian Belief Networks to Model the Combined Effects of Multiple Risks and Benefits on Human Health”.
- A Gordon conference was organised and planned by the KTL/Beneris in cooperation with QALIBRA. The conference theme was Environment and health - approaches to benefit-risk analysis and it was held in Valamo in Finland December 3-5, 2007 and partners from both QALIBRA and Beneris attended this meeting.
- The final meeting of the QALIBRA and Beneris projects is in its planning phase in cooperation between Matis, Altagra and KTL. The final meeting will be held in Budapest 10-11 June, 2009
- QALIBRA (Matis) has been granted access to data and discussion pages at websites used by Beneris partners for this purpose (www.pyrkilo.fi)

Deviations and corrective actions

The delivery of the report from the Cluster meeting (deliverable D16) was delayed 1.5 months because the Cluster meeting was held 3 weeks later than originally planned.

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
D16	Report from the cluster activities related to the midterm meeting	6	Month 20	Month 22	2	2 Completed	Matis
D35	Final report from the cluster activities	6	Month 42	Month 42	2		Matis

Table 2: Milestones List WP6

Milestone no.	Milestone name	Workpackage no.	Date due	Actual/Forecast delivery date	Lead contractor
M6.1	Project kick-off meeting	6	Month 2	Month 2 Completed	IFL/Matis
M6.2	Sharing data on concentrations (exposure assessment)	6	Month 12	Month 30	IFL/Matis
M6.3	Midterm meeting	6	Month 19	Month 20 Completed	Matis
M6.3	SAP Meetings	6	Month 39	Month 39	Matis

WP7. Project coordination and management

Workpackage objectives and starting point of work at the beginning of YEAR 2

- The starting point for this period was that the work in WP7 was on schedule
- The objective during the second project year has been to fine tune, monitor and coordinate the work in the QALIBRA project
- Finalise the first periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission (Deliverable D12)
- Finalise “The interim science and society reporting questionnaire” for QALIBRA and submit to the Commission
- Ensure that all partners prepared both the interim socio-economic reporting questionnaire and the interim reporting questionnaire on workforce statistics
- 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 2

- Matis in collaboration with the QALIBRA consortium worked on and contributed to the finalisation of the first periodic reports (i.e. annual progress report and annual financial report) and submitted them to the Commission (Deliverable D12)
- Matis finalised “The interim science and society reporting questionnaire” for QALIBRA and submitted to the Commission

- All partners prepared both the interim socio-economic reporting questionnaire and the interim reporting questionnaire on workforce statistics and submitted them to the Commission
- Matis and CSL organised, planned and chaired the 4th overall QALIBRA project meeting in cooperation with Beneris. The meeting was held in Helsinki, Finland, 7–9 November 2007. Representatives from all QALIBRA partners, except ALTAGRA, attended the meeting. Matis and CSL wrote a report that contains the main results of the discussions, main conclusions and actions (Annex 2 to this report)
- One major output, i.e. deliverable D11 – Draft report from case study 1A, was sent to the SAP for review during this reporting period
- Matis and CSL are planning the 5th overall project meeting of QALIBRA in cooperation with UPATRAS. The meeting will be held in Patras, Greece 9-10 April 2008
- Matis organised and chaired a project steering group (PSG) telephone meeting, wrote Minutes from meeting and worked on draft documents regarding publication policy
- Matis liaised with QALIBRA partners regarding the QALIBRA consortium response to the EC reviewers report after the midterm review of the project and contributed to finalisation of the QALIBRA response letter to the European Commission scientific officer in cooperation with QALIBRA & Beneris partners
- A new design and layout of the QALIBRA website was developed by CSL based on the usability evaluation of the website performed by UPATRAS (www.qalibra.eu). Matis and CSL have updated the website as needed.
- 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
- CSL has been responsible for updating the overall project workplan.
- 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 December 2007

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

No deviations from the project workprogramme have occurred in WP7

Table 1: Deliverables List WP7

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

Table 2: Milestones List

Milestone no.	Milestone name	Work-package no.	Date due	Actual/Forecast delivery date	Lead contractor
M7.1	Project kick-off meeting	7	Month 2	Month 2 Completed	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 8	Month 8 Completed	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 12	Month 12 Completed	IFL/Matis
M7.2	Overall project meetings of the partners	7	Month 19	Month 20 Completed	Matis
M7.2	Overall project meetings of the partners	7	Month 24	Month 25 Completed	Matis
M7.2	Overall project meetings of the partners	7	Month 30	Month 30	Matis
M7.2	Overall project meetings of the partners	7	Month 36	Month 35	Matis
M7.2	Overall project meetings of the partners	7	Month 39	Month 39	Matis
M7.3	Scientific Advisory Panel Meetings	7	Month 19	Month 20	Matis
M7.3	Scientific Advisory Panel Meetings	7	Month 39	Month 39	Matis

4. CONSORTIUM MANAGEMENT

Consortium management

The main decision body for the project consortium is the Project Steering Group and Scientific Committee (PSG/SC), which consists of the WP leaders, project coordinator and the chair of scientific committee. The main responsibility of the PSG/SC is to set the overall strategic course of the project. During this reporting period the PSG/SC held one separate telephone meeting as well as a brief meeting in connection with the 4th overall project meeting. The management role of the WP Leaders requires them to take stock of



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

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

Changes in responsibilities and to the consortium itself

An amendment to QALIBRA Contract No. FOOD-CT-2006-022957 was accepted by the European Commission August 21st 2007. According to this amendment the contract has been modified so that Matis ohf has taken over the rights and obligations of Icelandic Fisheries Laboratories (IFL) as of January 1st 2007.

Project timetable and status

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

Changes and impacts on planned milestones

In the second reporting period some deliverables and work in work packages were delayed by one to four months, as WP1, WP2, and WP4 have dependences on each others outputs this delay has caused changes for some tasks in the project timetable. The delay in deliverables has also resulted in comparable delays in planned milestones. It is envisaged that this discrepancy will be largely addressed by the end of month 36.

Coordination activities

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

5. OTHER ISSUES RELATED TO PERIODIC ATIVITY REPORT

The ‘Plan for using and disseminating the knowledge-Version 2’ is presented in Annex 1 to this report.

6. PERIODIC MANAGEMENT REPORT FOR QALIBRA

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

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

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

Partner 3 (RIVM):

- Internal RIVM review of the work in progress regarding the development of dose-response models and the final framework (August 29th 2007)
- Discussion of the internal review process and next steps of action with partners CSL and Matis at a meeting held in Leeds 5th of September 2007
- Produced deliverable D8 (Version 3 of the framework) in collaboration with CSL and Matis

- Produced deliverable D13 (Version 4 of the framework) in collaboration with CSL and Matis. This is an update of deliverable D8 and addressed the comments from the Scientific Advisory Committee (SAP) and the EU-reviewers at the midterm meeting of the project
- Continuation of the work on the framework in collaboration with CSL.
- Development of oily fish intake scenario's based on realistic data

Partner 1 (Matis):

- Worked on and contributed to the finalisation of Deliverables D8 & D13
- Data collection and evaluation for case study B regarding the most important end-points and studies to be included in the modelling
- Chaired and participated in a meeting held in Leeds 5th of September 2007 on the progress and next steps of action in WP1. Contributed to writing minutes from the meeting.

Partner 2 (CSL):

- Worked on and contributed to deliverables D8 & D13
- Development of the general framework algorithms for QALIBRA from a preliminary case study (Case Study 1A)
- Development and implementation of an approach for enabling the framework to accept matrix inputs of data
- Explored the suitability of Bayesian model averaging
- Explored formal methods for eliciting expert opinion
- Explored practical methods for conducting sensitivity analysis
- Proposal of an alternative graphical format for presenting probabilistic estimates

Explanatory note on any major cost items

Partner 1 (Matis):

Matis attended five meetings during the reporting period. One overall project & cluster meeting, Gordon conference & cluster meeting, one workpackage meeting (on WP1) and two interaction meetings with another EU-project working on Risk and Benefit analysis (BRAFO). Matis is the coordinator for the project and WP leader for 3 workpackages in the Qalibra project which increases the number of meeting that Matis has to attend.

Partner 3 (RIVM):

The majority of personmonths have been spent on the development of the risk-benefit model, the data search for the selection of positive and negative health effects and the data search for adequate data to build the dose-response relationship. For some health effects no adequate data are available, therefore assumptions have to be made. This work has been very time-consuming as it needs to be done carefully. The RIVM contingent involves co-operation between four distinct RIVM centres: Centre for Nutrition and Health, Centre for Substances and Integrated Risk Assessment, Centre for Public Health Forecasting, and the Centre for Prevention and Health Care Research, which increases the number of meeting delegates required for each overall project meeting in the QALIBRA project.

A summary explanation of the impact of major deviations for WP1

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

A tabular overview of budgeted costs and actual costs

Table 3: Budget vs Actual Costs

Cost Budget Follow-up Table		*) total budget figures-not EC funding							
Contract N°: FOOD-CT-2006-022957		Acronym: QALIBRA				Date: 01.04.07			
Participants	Type of expenditure (as defined by participants)	Budget	Actual Costs (EUR)					Pct. Spent	Remaining Budget (EUR)
			Period 1	Period 2	Period 3	Period 4	Total	Total	
			e	a1	b1	c1	d1	e1	
Part. 1, Matis	Total Person-month								
	Personnel costs	288.750	84.869	78.954			163.823	56,7	124.927,00
	Major cost item 'X'						0		0,00
	Major cost item 'Y'						0		0,00
	Other costs (The rest)	441.515	102.362	86.279			188.641	42,7	252.874,50
	Total Costs	730.265	187.231	165.233			352.464	48,3	377.801,50
Part. 2, CSL	Total Person-month								
	Personnel costs	426.934	75.971	185522,6			261.494	61,2	165.440,10
	Major cost item 'X'	10.000	0	1010,14			1.010	10,1	8.989,86
	Major cost item 'Y'								0,00
	Other costs (The rest)	416.894	55.927	137611,8			193.538	46,4	223.355,56
	Total Costs	853.828	131.898	324144,6			456.042	53,4	397.785,52
Part. 3, RIVM	Total Person-month						0		
	Personnel costs	678.912	254.099	223849			477.948	70,4	200.964,00
	Major cost item 'X'						0		0,00
	Major cost item 'Y'						0		0,00
	Other costs (The rest)	68.000	9.745	5937			15.682	23,1	52.318,00
	Total Costs	746.912	263.844	229.786			493.630	66,1	253.282,00
Part. 4, WU	Total Person-month								
	Personnel costs	204.329,00	20.299,63	40.742,54			61.042,17	29,9	143.286,83
	Subcontracting	18.000,00		9.350,00			9.350,00	51,9	8.650,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	35.866,00	9.739,20	12.362,48			22.101,68	61,6	13.764,32
	Total Costs	258.195,00	30.038,83	62.455,02			92.493,85	35,8	165.701,15
Part. 5, UPATRAS	Total Person-month								
	Personnel costs	165.000	21.433	39200			60.633,00	36,7	104.367,00
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	67.800	9.494,29	11511,02			21.005,31	31,0	46.794,69
	Total Costs	232.800	30.927	50.711			81.638,31	35,1	151.161,69
Part. 6, ALTAGRA	Total Person-month						0		
	Personnel costs	14.000	800	160			960	6,9	13.040,00
	Major cost item 'X'						0		0,00
	Major cost item 'Y'						0		0,00
	Other costs (The rest)	41.200	941	0			941	2,3	40.258,53
	Total Costs	55.200	1.741	160			1.901	3,4	53.298,53
Part. 7, IPIMAR	Total Person-month								
	Personnel costs	85.960,00	21.220,48	23.809,79			45.030,27	52,4	40.929,73
	Major cost item 'X'						0,00		0,00
	Major cost item 'Y'						0,00		0,00
	Other costs (The rest)	53.192,00	10.361,97	10.585,52			20.947,49	39,4	32.244,51
	Total Costs	139.152,00	31.582,45	34.395,31			65.977,76	47,4	73.174,24

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: 2, 1st April 2007 - 31st March 2008														
		TOTALS	Coordinator	Part. 1 Matis	Part. 2 CSL	Part. 3 RIVM	Part. 4, WU	Part. 5, UPATRAS	Part. 6, ALTAGRA	Part. 7, IPIMAR	AC TOTALS	AC participant 4	AC participant 5	AC participant 7
Workpackage 1: Development of generalised modular approach to risk-benefit analysis using menu of dose-response and valuation/integration functions	Actual WP total:	37,33	2,62	23,84	10,87	0	0	0	0	0	0			
	Planned WP total*:	74,5	5,5	22	44	3	0	0	0	0	0			
Workpackage 2: Implementation of methods as web-enabled software for all stakeholders	Actual WP total :	19,21	0,23	12,52	0,46	0	6	0	0	0	2,08	0,38	1,7	
	Planned WP total*:	79	2	51	1	3	22	0	0	0	0			
Workpackage 3: Development of strategies for communicating and disseminating risk-benefit information and dissemination	Actual WP total:	17,11	1,82	0	0,16	11,04	2,49	0,1	1,5	3	2		1	
	Planned WP total*:	42,5	4	1	3	17	13	1,5	3	0				
Workpackage 4: Case study 1 on seafood	Actual WP total:	32,86	13,71	4,2	8,45	0	0	0	6,5	3			3	
	Planned WP total*:	52,5	30	3,5	4	0	0	0	15	0				
Workpackage 5: Case study 2 on functional food	Actual WP total:	2,93	0	0	2,93	0	0	0	0	0				
	Planned WP total*:	20,5	7	4,5	9	0	0	0	0	0				
Workpackage 6: Cluster activities	Actual WP total:	1,5	0,4	0	0	0,5	0	0,1	0,5	1,08	0,38	0,2	0,5	
	Planned WP total*:	7	1,5	1	1	1	1	0,5	1	0				
Workpackage 7: project coordination and management	Actual WP total:	3,09	1,57	0,2	1,06	0,26	0	0	0	0				
	Planned WP total*:	8	4,5	1	1	1	0,5	0	0	0				
Total Project Person-month	Actual total:	114	1,57	18,98	41,62	23,13	11,54	8,49	0,2	8,5	9,17	2,77	1,9	4,5
	Planned WP total*:	284	4,5	51	84	63	24,5	36	2	19	0	0	0	0

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

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

- Continued work on Version 3 of system design: detailed plan for basic & framework functions and first algorithms from WP1.
- Implementation of Version 1 of system with functions for basic operations, framework and Case Study 1A
- Worked on version 2 of dummy web-pages
- Finalised Version 2 of system including functions for Case Study 1B

- Worked on Version 4 of system design (update to include extra functions from WP1) as well as Version 4.1 & Version 4.2 of system design

Partner 5 (UPATRAS):

- Carried out usability evaluation of version 1 of the system and wrote a report with the outcome of the evaluation (Deliverable D17)

Partner 1 (Matis):

- Assisted with Usability evaluation of Version 1 of system

Partner 3 (RIVM):

- Assisted with Usability evaluation of Version 1 of system

Explanatory note on any major cost items

Partner 2 (CSL):

A computer server has been purchased to run the QALIBRA models on. At the time of writing, this has been purchased with room for expansion, as the full computational load is not yet known. Should it be necessary, the server will be expanded internally. This will not exceed the budgeted figure.

A tabular overview of budgeted costs and actual costs

See table 3

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

See table 4

A summary explanation of the impact of major deviations for WP2

None

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

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

Partner 4 (WU):

- Conducted focus groups discussion in the Netherlands and subsequently transcribed and translated this discussion.
- Developed a coding scheme and coded the (translated) transcripts from the focus groups held in participating countries.

- Produced the report on the first focus group study on communication of risk benefit analysis outputs (deliverable D15).
- Set up a pilot questionnaire for the Delphi study, carried out the pilot Delphi survey and adapted the questionnaire accordingly.
- Selected a list of participants for the Delphi study and conducted the initial round of Delphi questionnaire.
- Started organising and planning the end-user workshop

Partner 1 (Matis):

- Wrote revision 2 for the 'Plan for using and disseminating the knowledge' for the QALIBRA project.
- Participated in the preparation and execution of the focus group studies in Iceland
- Translated the protocol & the results of the first round of consumer focus groups in Iceland and contributed to the report of the study (deliverable D15)
- Assistance with developing the list of participants for Delphi study
- Participated in the design and development of the Delphi study
- Contributed to development of plans for the end-user workshop
- Presented the QALIBRA project internationally on two different occasions

Partner 2 (CSL):

- Contributed to development of plans for the end-user workshop

Partner 3 (RIVM):

- Assistance with developing the list of participants for Delphi study.
- Contributed to the design and reporting of the first focus group study on communication of risk benefit analysis outputs
- Contributed to the design and development of the Delphi study
- Contributed to development of plans for the end-user workshop

Partner 5 (UPATRAS):

- Contributed to the development of the protocol for the stakeholder analysis.
- Contributed to the development of the questionnaires that were used in the focus groups studies
- Contributed to the report on the first focus group study

- Contributed to the design and development of the Delphi study
- Contributed to development of plans for the end-user workshop
- Contributed to development of plans for the end-user workshop and produced a draft agenda for this event.

Partner 6 (Altagra):

- Contributed to development of plans for the end-user workshop

Partner 7 (IPIMAR):

- Participated in the preparation and execution of the focus group studies in Portugal
- Translated the protocol for the first round of consumer focus groups
- Assistance with developing the list of participants for Delphi study
- Participated in the design and development of the Delphi study
- Contributed to development of plans for the end-user workshop

Dissemination activities:

This reporting period the QALIBRA project has been disseminated on 17 different occasions at national and international conferences/lectures i.e. 15 oral presentations and 2 posters. For details regarding these activities please refer to the overview of WP3 in Chapter 3 and version 2 of the 'Plan for using and disseminating the knowledge' (Annex 1)

Explanatory note on any major cost items.

Partner 1 (Matis):

Matis attended the Gordon conference held in co-operation with Beneris in Finland as well as two other interaction meetings for dissemination of the project held in Brussels with another EU-project (BRAFO) working on Risk and Benefit analysis

A tabular overview of budgeted costs and actual costs

See table 3

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

See table 4

Summary explanation of the impact of major deviations for WP3

None

WP4. Case study 1 on seafood

Description of the work performed in WP4 by each contractor

Partner 1 (Matis):

- Worked on and contributed to the finalisation of Deliverables D11 & D19.
- Constructed a database on the mapping of the positive health effects of oily fish in cooperation with RIVM.
- Data collection and evaluation for case study 1B regarding the most important positive health effects to be taken into account in the case study for oily fish in cooperation with RIVM & IPIMAR.
- Worked on a procedure for identifying positive health points in cooperation with RIVM.
- Searched for dose-response relationships of the selected positive health effects.

Partner 2 (CSL):

- Worked on and contributed to the finalisation of Deliverables D11 & D19.
- Carried out preliminary work to identify relevant alternative dietary scenarios
- Carried out preliminary investigations of advanced statistical methods for modeling long-term consumption of multiple foods using data from short-term surveys.

Partner 3 (RIVM):

- Worked on and contributed to the finalisation of Deliverables D11 & D19.
- Development of oily fish intake scenario's based on realistic data
- Contributed to the construction of the databases on the mapping of the positive health effects of oily fish
- Worked on a procedure for identifying positive health points in cooperation with Matis
- Searched for dose-response relationships and additional data of the selected positive health effects and constructed dose-response models of the selected positive health effects
- Selection of relevant contaminants to be included in the risk-benefit equation based on levels in fish, concentrations, types of fish and potential intake levels.
- Development of strategies to translate (animal trial) effects into relevant endpoints for humans

Partner 7 (IPIMAR):

- Data collection for case study 1A and data collection for case study 1B in collaboration with Matis
- Worked on and contributed to the finalisation of Deliverables D11 & D19.
- Contributed to the construction of the databases on the mapping of the positive health effects of oily fish
- Searched and collected data about fish consumption in Portugal
- Searched for dose-response relationships of the selected positive health effects.

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 WP4

Due to delay in recruitment a larger proportion of the work for Matis has been carried out by senior scientist than junior scientist than originally planned, hence personnel cost/man month was higher than planned.

WP5. Case study 2 on functional foods

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

In this reporting period only RIVM has performed work in WP5:

- Constructed a database on positive and negative health endpoints of phytosterols/-stanols
- Decided which health effects are to be taken into the risk-benefit equation
- Searched for dose-response relationships and constructed a table with the available dose-response functions from the literature
- Worked on habitual intake scenario's

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

None

WP6. Cluster activities between the QALIBRA and BENERIS projects

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

All partners except ALTAGRA participated in the following work:

- The second Cluster meeting (the midterm meeting) of the sister projects QALIBRA and Beneris. The meeting was held in Helsinki 7-9 November 2007

Partner 1 (Matis):

- Planned the second Cluster meeting in cooperation with KTL and CSL.
- Responsible for writing a report containing the output from the Cluster meeting, Deliverable D16
- Attended a Gordon conference organised by Beneris partners with the theme Environment and health-approaches to benefit-risk analysis in Valamo in Finland December 3-5, 2007
- Started planning the final meeting of the QALIBRA and Beneris projects in Budapest 10-11 June 2009 in cooperation with Altagra and KTL

Partner 2 (CSL):

- Planned the second Cluster meeting in cooperation with KTL and Matis
- Liaised with the Scientific Advisory Panel regarding review of documents from Beneris and QALIBRA prior to the second Cluster meeting

Partner 6 (Altagra):

- Started planning the final meeting of the QALIBRA and Beneris projects in Budapest 10-11 June 2009

Explanatory note on any major cost items

All partners except Altagra attended the second cluster meeting which was held in Helsinki 7-9 November 2007.

A tabular overview of budgeted costs and actual costs

See table 3

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

See table 4

Summary explanation of the impact of major deviations for WP6

None

WP7. Project coordination and management

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

All partners participated in the following work:

- Finalization of the first annual periodic report (Deliverable D12)
- Finalization of the interim socio-economic reporting questionnaire and the interim reporting questionnaire on workforce statistics
- Contributed to the QALIBRA consortium response to the EC reviewers report after the midterm review of the project
- Contributed to interim progress reports (used for internal monitoring of progress)

All partners except ALTAGRA participated in the midterm project meeting held in Helsinki 7-9 November 2007

Partner 1 (Matis):

- Finalized the first annual periodic report (Deliverable D12)
- Finalized the “Interim science and society reporting questionnaire” for QALIBRA
- Organized and chaired one overall project meeting in cooperation with CSL and KTL/Beneris

- Contributed to reports that describe the outcome of the meetings in cooperation with CSL
- Contributed to planning of the 5th overall project meeting of QALIBRA in cooperation with UPATRAS. The meeting will be held in Patras, Greece 9-10 April 2008
- Organised and chaired a project steering group (PSG) telephone meeting, wrote Minutes from meeting and worked on draft documents regarding publication policy
- Monitored and coordinated the activities in the QALIBRA project
- Monitored and coordinated the activities for WP4 and WP6 (WP leader for WP4 & WP6)
- Distributed advanced payments to other QALIBRA consortium participants

Partner 2 (CSL):

- Developed a new design and layout of the QALIBRA website (www.qalibra.eu) based on the usability evaluation of the website performed by UPATRAS
- Organized and chaired one overall project meeting in cooperation with Matis
- Contributed to reports that describe the outcome of the meetings
- Chaired QALIBRA scientific committee.
- Monitored and coordinated the activities for WP2 (WP leader for WP2)

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)

Partner 5 (UPATRAS):

- Planning of the fifth overall project meeting in cooperation with Matis and CSL

Explanatory note on any major cost items

All Partners except ALTAGRA attended the midterm meeting which was held in Helsinki 7-9 November 2007.

Partner 1 (Matis):

Matis attended five meetings during the reporting period. One overall project & cluster meeting, Gordon conference & cluster meeting, one workpackage meeting and two

interaction meetings with another EU-project working on Risk and Benefit analysis (BRAFO). Matis is the coordinator for the project and WP leader for 3 workpackages in the Qalibra project which increases the number of meeting that Matis has to attend.

A tabular overview of budgeted costs and actual costs

See table 3

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

See table 4

Summary explanation of the impact of major deviations for WP7

None

Form C Financial Statement per activity for the contractual reporting period

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

Summary financial report

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

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

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