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Reviewers' Report, with responses from Beneris

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National Public Health Institute (KTL), Jouni Tuomisto

REVIEW REPORT OF FP6 PROJECTS

Individual report / **Consolidated report**

- Name(s) of reviewer(s): Luca Bucchini - Marta Schuhmacher
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Introduction

A general outline of the review process is given in a separate document on ‘Project reviews in FP6 for project coordinators and external reviewers’ (downloadable from <http://www.cordis.lu/fp6/project-management.htm>)

The reports and deliverables of the project were prepared according to the Guidance notes on Project reporting in FP6 (downloadable from <http://www.cordis.lu/fp6/find-doc.htm#reporting>)

Questions to be answered by the reviewer(s)

1. OVERALL ASSESSMENT

a. Executive summary Please follow the order of the individual sections of this report

Comments:

Most of the objectives and technical goals have been achieved by BENERIS in the first 19 months, in area of science as challenging and innovative as risk benefit assessment, with approaches that, although not mainstream, appear promising. Anyhow, methodological advances in the specific area of

risk-benefit, which is distinct from risk assessment where a consensus on many issues now exists, are much needed. However, some adjustments seem necessary to achieve the objectives as stated in the Technical Annex.

Specifically, it's necessary that the final results reflect exactly the risk-benefit from food consumption. To that, all the partners should be actively involved in the objective of this project.

The information obtained from other projects developed by the different partners of the project should be specified very clearly in the report.

Technical cooperation with QALIBRA should be improved on a variety of issues.

While the project may provide a significant contribution to the field, extreme caution should be exercised in implying that the risk-benefit assessments in case studies can be used for policy-making, especially given the likely uncertainty in the underlying biological assumptions; the limitations of the developed methodology should always be stressed. This will not detract from the value of the project

- Good to excellent project (The project has fully achieved its objectives and technical goals for the period and has even exceeded expectations)
- **X Acceptable project (The project has achieved most of its objectives and technical goals for the period with relatively minor deviations)**
- Unsatisfactory project (The project has failed to achieve critical objectives and/or is not at all on schedule)

Response

Responses to the general comments will be given below together with the responses to the detailed comments.

b. Recommendations

Collaboration between both projects (Qalibra and Beneris) should be strengthened. Both project should work together and to use a single repository of surveillance.

Response

During the first half of the projects, there was major collaboration between CSL and TUDelft, who are the responsible partners of the mathematical method development. This collaboration will continue.

Already before the projects started, we realised that the approaches of the two projects were different. Therefore, we think that it was useful to have a period where both projects were allowed to develop their approaches into a more practical phase. Now, it has become possible to evaluate and compare the methods and approaches in practice, and learn from the experiences of the other project.

The data repository has been in the objectives of Beneris, and good progress has been performed there. The information structure has been developed, and the internet tools to work on small amounts of data have been established^[1]. The repository is available for Qalibra project to test and use, but practical steps have not yet been taken. Some examples of data can already be found from the data repository^[2] However, the current software solution is not optimal for large pieces of data, and a relational database solution is being developed. This is currently under test use, and it will be ready for production during spring 2008.

The Qalibra consortium agrees to explore the possibilities of a common Qalibra-Beneris data repository. A major question is whether the solutions developed by Beneris are suitable for Qalibra. To this extent Qalibra and Beneris will investigate options for creating a single repository or access point for data from the 2 projects, and decide on the best option by the end of Sept 2008. This work will for example include discussions and evaluations on the kind and format of data

and the way data will be entered and accessed.

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

Response

The Qalibra and Beneris consortiums agree that it would be highly desirable to perform cross validation of methods using the other project's oily fish data. The Beneris fish case study is currently being built using the data repository, so a large part of the information is available also for Qalibra or other interested parties. (Some unpublished data is still confidential, and the distribution of that data will be done case by case, but in such a way that enough information will be available for Qalibra for cross-validation.)

However, the main issue with cross-validation is not the data exchange. It is the work needed to transform the data into a form that can be used in the other modelling system. This work would require significant resource that was not included in the budgets for Qalibra and Beneris. Further, this work could not be carried out until the final year of the project (i.e. when the original analyses are complete). Therefore, Qalibra will consult with Beneris at month 31 (end of October 2008) to assess the feasibility of undertaking these additional analyses.

The link of BBN to the rest of project is crucial. All the partners should really be involved all in the activities of the project.

Response

We agree that the linkage between Bayesian Belief Network (BBN) modeling and the rest of the project is crucial. Therefore, TU Delft is in continual communication with KTL with regard to building and quantifying the BBN. Up to now, KTL has been in charge of the communication with the rest of the project participants, except insofar as others browse the BENERIS website. This is to prevent loss of baseline integrity in the project management. Now however, partially as a result of the mid-term meeting, TU Delft has also established direct links to various participants, copying the correspondence to KTL.

The coordination of the activities should be improved in order to achieve the proposed objectives.

Response

This was a very strong comment from the reviewers, and it was also heard from the partners. The coordinator takes it seriously and is currently restructuring the tasks of the personnel involved in the coordination. This process and discussions are likely to continue until February 2008. At least one new meeting is likely to be added to the Beneris time plan. The new practices and plans will be written into a document and distributed to the partners and the Commission.

The coordinator should make sure that all the partners will effectively participate in the evaluation of the integration methodology.

Response

Many partners have already participated in the evaluation. The most important such event was the Berlin meeting in September. The evaluation work will get emphasis during the spring 2008. This is because many parts of the methodology and tools have until now been under development, but more and more functionalities and contents are being materialised. Thus, the evaluation becomes easier as the content becomes practical. A major way for evaluation is a website which explains the integration methodology in such a way, that any part of it can be evaluated and commented directly on the web page.

The deliverables and reports should be improved and better organized in order to reflect the activity performed.

Response

The deliverables have indeed been rather technical, often with little explanation of the background, objectives, and the activity performed. This has partly been due to the fact that this project, although not a large one, has a large number of deliverables with short time intervals. This has left us a shorter period of time than anticipated for writing the documentation of the work done. Guidance on this will be given to partners about this, and more emphasis will be paid on this by the coordinator before the deliverables are sent to the Commission.

Each report should include in great detail which methodology has been followed to identify the risks and benefits with sufficient evidence.

Response

The identification of risks and benefits follows different methodologies in the two case studies. For the fish case study, a detailed literature search has been performed about the health effects of fish.^[3] These searches have been used to select the effects to be estimated in the case study. In addition, detailed discussions among the whole Beneris project group have been undertaken to come up with a feasible, relevant and scientifically interesting set of health risks and benefits. For the vegetable case study, the scoping period is still ongoing and the outcomes have not yet been decided. The open participation approach will be applied: the discussion on the benefits and risk to be included will be performed on the project website. In both cases, the process of defining the scope, including the argumentation, will be a part of the final assessment.

We recommend adapting the terminology used in the report to the standard terminology used in risk assessment in order to facilitate the communication with the scientific community.

Response

We agree on the necessity of harmonizing terminology. Where the terminology may have been idiosyncratic until now, appropriate changes will be made under the supervision of KTL. In this matter, TU Delft is supplying input to KTL.

To clarify how the results of the deliverable D19 (Contaminants in placenta) will be used in the risk-benefit model from food consumption.

Response

The fish case model contains an age group 0-2 years. The contaminant exposure estimation for them is problematic, as a large part of it comes from mother during pregnancy or via lactation. Some effects considered, notably the teeth defects due to dioxin, occur during this period. It is therefore important to evaluate the exposure of the child using the information about the mother's diet and the pollutant concentrations in the placenta. A regression analysis will be performed, and the results of this analysis will be used in the case study for estimating children's exposures.

Efforts should be made to get information and results from other European projects (EUROFIR, etc..) in order avoid duplication of work and to maximise the results of the project.

Response

Many of the participants in BENERIS participate in other EU funded projects and these contacts

will be used to avoid duplicate work and to maximise the synergy between these projects.

- SAFEFood: From DTU, there are several participants in this project. Annette Petersen, Ole Ladefoged and Tue Christensen participate in SAFEFood as well as BENERIS. In SAFEFood, consumption data from Sweden, Czech Republic, Italy, the Netherlands and Denmark are collected for fruit, vegetables and cereals. For the moment, we are using the same Danish consumption data in both of these projects. We are aware of the risk of duplicate work in BENERIS and we are at the moment using some of the experience from SAFEFood in BENERIS.
- EUROFIR: In DTU there are more than one person working in both EUROFIR and BENERIS, but we also have several near colleagues working in EUROFIR only. We are going to contact them in order to avoid duplicate work and to see if there are possibilities for synergy between these projects. However, we do not consider this as very likely. Nevertheless, we are at least going to have Dr. Anders Møller as a private consultant. Dr. Møller has been participating in SAFEFood and BENERIS, but now he works for EUROFIR.
- BRAFO: This project also addresses risk-benefit assessments of food. Dr. Ole Ladefoged participates in this project and will ensure that no duplicate work will be made in BRAFO and BENERIS.
- QALIBRA: The collaboration between QALIBRA and BENERIS will be increased. This should make it possible to avoid duplicate work between these projects.
- INTARESE: This project is about method development for environmental health risk assessment. Close collaboration between Intarese and Beneris have been going on since the start, as KTL is a partner in both. The method development has been synergistic, and no duplication of work has occurred.

In addition to the above European projects, DG Sanco (Dr. Frans Verstraete) has been contacted by BENERIS with a request for food occurrence data of PCDD/Fs and PCBs. However, although Dr. Verstraete has been positive to provide the data requested, unfortunately after several repeated appeals for the data we are still waiting for a delivery. Thus, it seems at the moment that obtaining the data from DG SANCO will not come true, and therefore the occurrence data for data repository will be based on the data provided by the BENERIS partners.

The second case study (vegetables, against food supplements) should be well defined.

Response

Planning the second case study was deliberately postponed to gather experience from the first case study, and to find out possibilities to get hold of necessary data. The current proposal is that two groups of population are selected, one eating plenty of fruit and vegetables, one very little. A nutritionist will be recruited for 2 – 3 months to evaluate data availability, to assess the impact on the low-vegetable group, if they start using fortified foods and/or vitamin supplements, and to plan the benefit-risk approach including selection of reasonable endpoints for assessments. There are three obvious uncertainties, one is the limitation of adding only some missing nutrients by fortification or use of supplements while fruits and vegetables might be important sources of a variety of micronutrients (a good example is the beta-carotene interventions to prevent cancer), the other is the possibility that using supplements in fact gives the consumer an excuse not to improve their eating habits, and the third one is the indirect effect of vegetables replacing something else (e.g. saturated fats). Therefore the gross effect of benefit-risk assessment of supplements might, on a population basis, be either negative or positive.

The project should clarify who will be involved in the decisions of the validation of the model and who exactly will be the end-user of the model.

Response

The validation of the work was an important issue in the discussions during the mid-term meeting. This issue had clearly been under-represented in the project planning. After the meeting, we also acknowledge the need for a formal peer review of the most critical methods developed in Beneris, as well as benefit-risk assessment results. To achieve this, we have written a draft paper about quality control and quality assurance in open risk assessment^[4]. It will be written into a full document by the end of 2008.

The end-users of a benefit-risk assessment are defined as an important part of the scoping of the assessment.^[1] For the fish case study, the primary users are public health authorities and decision-makers involved in giving food recommendations. The secondary user group is the general public: quantitative estimates are offered to increase understanding of the magnitudes of the related issues. For the vegetable case study, the scoping is still ongoing, but the end-users will be defined during that process during spring 2008.

The question about the end-users of the models developed is another matter. We are developing a website where all models and procedures developed in Beneris are freely available to everyone. They are also open for criticism. We therefore expect that those models that will become actively used, will also be actively evaluated and criticized by the users and peer researchers. An assessment is a one-time event, and it will stay unchanged after it has been finished. In contrast, the methods and models on the website will be continuously edited and improved by researchers and other participants in benefit-risk assessments based on their own needs. It is therefore more difficult to predict who will actually be the main user groups for the models in the long run. We are developing the website in collaboration with several research projects, and we hope that there will be several large user groups, including food authorities in Europe, environmental health researchers, and policy-makers interested in environmental health or food issues.

More oversight of what underlies the model (how potentially it works, interactions, et.) need to be explained.

Response

There have been multiple reports explaining the model. However, the model exposition report will be upgraded into a paper suitable for publication. In addition, TU Delft is planning to write a tutorial on using the BBN software to create new models or to modify existing models according to national or regional prerogatives. This will be done within the first months of 2008.

Information about how the BBN propagate the uncertainty of the different nodes (nutritional effectors, personal effectors and health endpoints) is needed.

Response

To provide this information on the BENERIS website, we will add links to some of the many papers explaining the technical features of BBNs.

A sensitivity analysis of the model should be done.

Response

A sensitivity analysis will be done as soon as the adequate model has been built and properly quantified.

2. OBJECTIVES

a. Have the objectives for the period been achieved?

- Yes
- **X Partially**
- No

Comments:

The revision of the existing data base for chemical contaminants in Europe has been only partially achieved.

Response

There were unfortunately some difficulties in the distribution of work within DTU, the partner responsible for this deliverable. After an unsuccessful attempt to subcontract an external consultant, it was therefore decided to transfer the work for this deliverable to another department of DTU. Thus, we have agreed with Annette Petersen from the Chemical Department in the National Food Institute (part of DTU) that the final report on this deliverable will be delivered at the latest on 1 April, 2008.

The report will contain compiled information about consumption surveys and data, as well as information on the content of relevant substances (e.g. mercury, iodine, dioxin) in fish. The starting point is the data already collected in the participating countries.

To improve the dose-response model, it would be necessary to clarify how the toxicology and epidemiological data are combined.

Response

For combining the toxicological and epidemiological information, we are currently using the following approaches: 1) A checklist of correction factors for the dose-response relationship, 2) a causal diagram describing the phenomenon of dose-response as real-world objects and their causal links (implemented using Analytica and MediaWiki software), 3) a case study of TCDD-induced developmental dental defects: human vs. rat.

The approaches #1 and #2 are basically two viewpoints on the same topic, except that by means of the latter one it will hopefully be possible to directly calculate the best estimate of the true dose-response given the current data.

The correction factors are needed due to the various uncertainties involved, classified as those internal in each study (e.g. measurement errors, confounding factors), extrapolation uncertainties (e.g. high-to-low-dose and endpoint extrapolation), and uncertainties in pooling of the studies (e.g. publication bias).

In the case study (approach #3), the checklist of correction factors was applied. We systematically compared one epidemiological and one toxicological study on a same health effect, i.e. the developmental dental aberrations induced by 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD). The aim is to create a combined best-estimate dose response of TCDD-induced dental aberrations, including the identification of the most important uncertainties and their size.

The development of the approach should be even more precisely detailed, particularly as to the reasoning behind choices made, implications, limitations, assumptions of each step of the model, extending the use of available standard approaches (e.g., WHO criteria, EFSA documents).

Response

We completely agree that this is very important. This work is now getting speed, as we are finalising the information structures that are needed to describe these issues. In practice, this means that the structure of our website is practically finished, and we have started to write the contents online^[5]: the methods, their motivations, assumptions, and comparisons to other existing methods.

Developing, testing and proposing methodology seems and should be the primary underlying goal of the project. Particular attention is deserved by aspects that are unique to risk-benefit assessments (identification of multiple endpoints, measures of integration, their acceptability and ethical implications, combination of epidemiological and toxicological evidence, etc.). For example, the level of evidence for negative effects required by most regulations is lower than that for benefits and this may be relevant for risk-benefit assessments as well. The identification of the valid human health endpoint is a major task per se and should be well argued and based on uniform criteria, which may include relevant EC regulations.

Response

Many of the critical issues mentioned have been discussed earlier. The criteria for including issues to or excluding them from an assessment is indeed crucial. In general, our approach says that these decisions must be made during the issue framing phase of the assessment by the group of participating assessors. Of course, a particular kind of an assessment may require a more strict rule for endpoint selection, such as an EC regulation. The guidance about this will be added as a part of the methodology documentation.

b. Are the overall objectives (i) still relevant and (ii) still achievable within the time and resources available to the project?

(i)

- X Yes
- Partially
- No

(ii)

- Yes
- X Partially
- No

Comments:

In order to fulfil the objectives, the project should be focused on the achievement of a relative simplified model (fewer contaminants, fewer endpoints and fewer interactions) for both case studies, been focus in the risk-benefit from food consumption.

Response

"Things should be as simple as possible, but not simpler" (Einstein, folklore). To find which variables or dependencies are unimportant, we must first build an adequate model that includes all plausible influences. An abridged model can then be made, after performing a sensitivity analysis of this larger model. This is what the "iterative top-down approach" in the name of the project means: things are first looked at with a wider view, and the work and resources are focussed on the critical parts when they are identified.

c. Do you recommend changes in objectives in order to keep up with the current state-of-the-art?

- Yes
- X Partially
- No

Comments:

Finalization for potential regulatory or policy use, or individual level use, does not seem possible or desirable within the current scientific and regulatory state-of-the-art.

Response

It is true that the results of this project are unlikely to have any impact on the regulatory practices during its lifetime, or that the case studies would follow the current regulatory state-of-the-art. However, we are developing scientifically defensible methods for benefit-risk assessment that can be used and further developed for years. In other words, we aim to develop the state-of-the-art for future assessments. This impact can only be evaluated after several years.

3. WORKPLAN AND RESOURCES

a. Has the project as a whole been making satisfactory progress in relation to the Description of Work (Annex I to the contract)?

- Yes
- **X Partially**
- No

Comments:

The integration of the different partners has been deficient. The progress of the whole project has not been focus in the main objective (risk-benefit from food consumption) but in different individual objectives. Among others, the methods of ORA appear suitable for BENERIS and their adaptation to risk-benefit assessment to fall within the scope of the Technical Annex, to the extent and within the limits agreed by all partners. On the other hand, development of ORA per se, as an instrument for risk assessment in general, does not appear to fall within the scope of the Technical Annex. This may include developing and disseminating material devoted to ORA per se or courses devoted to ORA in general, and not specifically to risk benefit assessment and to the specific objectives of BENERIS. This cannot be solved by a mere reference to BENERIS in the material and seems to detract from the project's objectives.

Response

It is true that our current emphasis is very much on open risk assessment. This is not only because we find the openness as an important feature of an improved benefit-risk assessment. A major part of open risk assessment work is basic research on about doing assessments, and it is actually the ontology of an assessment. We see all benefit-risk assessments as a large information structure. The applicability and usability of the assessments are heavily dependent on whether the information structure is a good one. Now that the information structure has taken its shape, we will be better able to focus on the specific needs of benefit-risk assessment for foods. This work could not have been done in the opposite order.

The distinction of BENERIS from other projects should be clearly reflected at all times. Lack of distinction from other projects in which individual partners of the project are involved may affect negatively the objectives of BENERIS.

Response

We will emphasise the roles of each partner and the Beneris project in the reporting of future products. We have found the collaboration with other projects (especially Intarese, but also others like Hiwate or Heimtsa) very useful for the objectives of Beneris. The collaboration has resulted in great synergy, and it has actually made it easier to achieve specific goals of the different projects. The fruits of this collaboration have started to materialise more clearly during 2008.

The currently available model which involves BBN and ORA should be developed with constant oversight from qualified toxicologists, epidemiologists and biologists as available in the project, to ensure at least to some extent biological validity. Great attention should be devoted to model uncertainty as opposed to parameter uncertainty.

Response

Toxicologists at KTL and elsewhere are closely involved with the model development. Epistemic, aleatory, and volitional uncertainty are all important. Model uncertainty falls under epistemic uncertainty, and of course receives proper attention. Closely related is the issue of model calibration which is also receiving attention. The latter requires separate data capture efforts.

Also, the process should be driven by available scientific evidence, and not by expert judgment, which appears to be crucial especially on evaluating interactions, a key feature of the model. Sensitivity analysis could be applied to identify the variables where the contribution of expert judgment has been essential.

Response

It is a pillar of this project that experimental and field data will be used to the maximal extent. The availability of such data strongly drives the model development. However, expert judgment is used to fill gaps in the data, so as to enable the completion of the model, and to guide further data gathering efforts.

The specific work on placenta (D19) should be clarified with great detail in terms of scientific rationale and working hypotheses, taking into account feedback from the SAP, the most recent state-of-the-art in the field, timing of exposure and also statistical power.

Response

In risk assessments in general, one of the key elements is exposure assessment. In BENERIS, we will make intake estimates based on food frequency questionnaires of both children and adults, in order to assess the intake of pollutants through diet. Children are a special target group in BENERIS, and since the exposure to pollutants does not start only after birth but already in uterus, it is crucial to obtain information on the exposure during the fetal stage.

Since mothers can act as biofilters of pollutants transported through the placenta into the fetus, we cannot fully assess fetal exposure by solely assessing the mothers' intake from food frequency questionnaires. Therefore, placental specimens are the best means to acquire the necessary information. Placental measurements, together with food frequency intake estimates of pollutants, will hopefully give us information about the quantity and quality of the pollutants that fetuses are exposed to. The pollutant compounds examined in BENERIS are relatively stable in humans, and therefore we can estimate that fetuses are fairly constantly exposed to the pollutants in question.

The statistical power of 130 placentas might not be too strong, but the funding in BENERIS does not allow more placenta samples to be analysed.

The insufficient collaboration between QALIBRA-BENERIS projects has caused a loss of advantage of their resources.

Response

This problem has been identified, and some solutions have been discussed above. As the case study models have now taken a physical form, it is a good time to start collaboration and

comparison of the two approaches. We hope that the development of two different approaches will teach something that would not have been otherwise identified.

Invitation/participation in workshops related to the methods developed in the projects is valuable but does not seem to be sufficient to ensure the functioning of the cluster.

Response

Although it is not sufficient, we are going to continue this practice. In addition, the case studies of Beneris will be built on a website so that Qalibra researchers will be able to see the development and also participate if they want. We are going to explore the tools developed by Qalibra and apply their functionalities on the Beneris work when possible.

A common web-based repository with QALIBRA of input data that are to be made publicly available should be designed and implemented, including data formats that can then be used for QALIBRA and BENERIS tools.

Response

The design and implementation of the data repository is well on the way. A draft design of the repository was completed in the autumn^[6] and the pilot version of it, utilising SQL database, is currently in test use. The content of the data repository will consist of summary data, not the original datasets, being therefore available for public access without data ownership conflicts. The data repository will be made available for Qalibra to use for storing and querying data as soon as its functionalities have been developed to include a convenient web-based user interface.

Development of different methodologies in BENERIS and QALIBRA may be valuable, but policy (and, as far as possible, methodological) implications, if any, should be coherent and the need for eventual convergence to a standard method to conduct risk-benefit assessments should be borne in mind.

Response

Creating a standard method to conduct risk-benefit assessments within single research projects is a very challenging task indeed. It is more than likely that two different approaches produce somewhat different results and recommendations, and this is in fact the strength of a scientific process. The differences will challenge both projects, this gives food for further thought, and the end result might well be different from either one. It is obvious that convergence is sought for during the contract period, but it may well happen that the final methodology will develop during the scientific discussion that follows between all scientists, in scientific literature and international meetings (organized e.g. by EFSA) after the contract period. It is also highly likely that the methods developed during the contract period are suitable only in certain frameworks (e.g. concerning nutritional benefits of fish compared with risks of contaminants) but not others (e.g. GMO). The most important aspect initially is to show the difficulties of the present risk assessment practices, and to indicate what would be the first steps to improve them.

b. Has each work package (WP) been making satisfactory progress in relation to the Description of Work (Annex I to the contract)?

- Yes
- **X Partially**
- No

Comments:

Workpackage 3 has suffered some retard in obtaining results in the first case-study.

Response

Unfortunately, some delay was caused in this WP by the delayed provision of information by DTU on a few input variables for the model. However, we plan to complete this work in January 2008.

c. Have planned milestones and deliverables been achieved for the reporting period?

- Yes
- **X Partially**
- No

Comments:

Deliverable 16: Cardiovascular health benefit of fish and omega-3 fatty acids, has not been presented.

Response

Foodfiles has completed a review on quantifiable cardiovascular health benefits of fish and omega-3 fatty acids for the further development of the benefit-risk analysis (D16). The original timetable of the deliverable was month 14, but additional time was requested from the Commission until 15 October, 2007. The report was completed by 15 October and was placed on the Beneris web-site and attached to the midterm report after that.

Deliverable D22 : Preliminary benefit-risk analysis of fish has not been finished.

Response

Unfortunately, the results of the whole case study are not yet available, since the collection of input data for the model is still in progress. However, a preliminary case study with a large part of the final analysis is well under way, and KTL and TU Delft intend to complete this work in January 2008.

d. Have resources been deployed as foreseen in Annex I, overall and for each participant?

- Yes
- Partially
- No

Comments:

No information about this issue has been obtained

e. Have costs incurred (personnel costs and other major cost items) been 1) necessary for the implementation of the project and 2) economic. Note that both aspects (1 and 2) have to be covered in the answer.

- Yes
- Partially
- No

Comments:

5. CONSORTIUM PARTNERSHIP

a. Has the collaboration between the participants been effective?

- Yes
- **X Partially**
- No

Comments:

More collaboration between the different partners is necessary to achieve the proposed objectives.

Response

We agree on this, and refer to previous discussions on the topic.

b. Have the partners contributed as planned to the project and tasks assigned to them?

- **X Yes**
- Partially
- No

Comments:

c. Do you identify any conflicts or evidence of underperforming partners, lack of commitment or change of interest of any partners? Do you recommend any changes in responsibilities?

- Yes
- Partially
- **X No**

Comments:

6. MANAGEMENT

a. Has the scientific/technical management been performed as required?

- Yes
- **X Partially**
- No

Comments:

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

Response

The communication with the SAP is likely to be clearly enhanced. Getting to know the SAP personally since the mid-term meeting is a great advantage. More and more of the material and products of the project are going to be available on the web, available to the SAP to read and comment. In addition, advice from the SAP will be asked for a limited number of specified questions during the second half of the project.

b. Has the administrative and financial management been performed as required (including proper handling of contractual matters, maintenance of the consortium agreement, intellectual property rights, technical collective responsibility, sub-contracting, competitive calls)?

- Yes
- Partially
- No

Comments:

c. Have (electronic) information and communication networks been established as required to support interactive working between the teams involved (if relevant)?

- Yes
- Partially
- No

Comments:

d. Is the consortium interacting in a satisfactory manner with other related 5th and 6th Framework projects or other R&D national/international programmes (if relevant)?

- Yes
- Partially
- No

Comments:

7. USE AND DISSEMINATION OF KNOWLEDGE

a. Does the project have significant use potential (if applicable)?

- **X Yes**
- Partially
- No

Comments:

b. Is the Plan for the Use and Dissemination of Knowledge developing in a satisfactory manner?

- Yes
- **X Partially**
- No

Comments:

The aim of the project will not be to give information of the risk-benefit of the food consumption to consumers. The model and obtained results will be disseminating between scientific, policymakers, and risk managers.

Response

It is true that policy-makers and researchers are our primary target group. However, the results will also be available for the consumers and general public.

The cluster website should be expanded to include the single repository and shared resources.

Response

The access to the shared data repository will be included on the cluster website when the data repository has been made functional. This will aid in cross validating the methods used in each of these projects.

c. Have the contractors disseminated project results and information as foreseen by the contract and the plan for dissemination and use of knowledge (publications, conferences...)?

- X Yes
- Partially
- No

Comments:

d. Are potential users and other stakeholders (outside the consortium) suitably involved (if applicable)?

- Yes
- Partially
- X No

Response

We have seen the involvement of potential users very important, as can be seen from our ideas about open risk assessment. The first half of the Beneris project has been method development, and development of case studies. Therefore, there has not been much where users might have been able to participate. The second half will be very different, as the methods for stakeholder involvement have been developed, and the case studies are becoming detailed enough to interest users. We are considering of organising stakeholder meetings related to the case study results, to get feedback for the finalisation of the case studies.

Comments:

8. OTHER ISSUES

a. Have policy-related and/or regulatory issues been properly handled (if applicable)?

- X Yes
- Partially
- No

Comments:

b. Have ethical issues been appropriately handled (if applicable)?

- Yes
- Partially
- **X No**

Comments:

Response

We are slightly puzzled about this feedback, since we have obtained a routine approval of the studies from our Ethical Review Board. Without more specific information as to the type of ethical issue(s) pertained to by the Reviewers, we unfortunately can not address this item in more detail.

c. Have safety issues been properly handled (if applicable)?

- Yes
- Partially
- No

Comments:

d. Has progress on the Gender Action Plan been satisfactory (if applicable for this reporting period)?

- **X Yes**
- Partially
- No

Comments:

Name (s) of the reviewer(s): Bucchini Luca - Marta Schuhmacher

Date: 12-november-2007

Signature(s):

APPENDICES (optional)

a. Status of project reports and deliverables

b. Visibility Actions (to be completed by the Project Officer)

Mark which actions would be appropriate for follow-up by EC programme policy units:

- Exploitation Strategy Seminar
- Contact the Innovation Relay Centres
- Promote / highlight as a success/case story

Flag this project for in case the programme looks for projects with certain characteristics:

- high visibility/media attractive project;
- project with an impact on EU policies;
- project with a major role for women;
- project with a significant impact on health, safety, environment;
- project with ethical issues associated.
- substantial breakthrough character
- significant impact on employment
- significant participation from outside EU
- involvement of the top researchers in the field
- involvement of the top economic actors in the field

References

1. ↑ ^{1.0} ^{1.1} Deliverable 15: Open Risk Assessment: A New Way of Providing Scientific Information for Decision-making. Publications of the National Public Health Institute B18/2007, Helsinki.
2. ↑ Persistent pollutant concentrations in salmon
(http://heande.pyrkilo.fi/heande/index.php/Variable:Persistent_pollutant_concentrations_in_salmon). Heande website, accessed 7 Jan, 2008. Salmon intake in the population of the Western Europe
(http://heande.pyrkilo.fi/heande/index.php/Variable:Salmon_intake_in_the_population_of_the_Western_Europe). Heande website, accessed 7 Jan, 2008.
3. ↑ Henna Karvonen: Deliverable 6 [1]
(http://www.pyrkilo.fi/beneris/index.php/Health_effects_of_fish) ; Henna Karvonen: Deliverable 16 [2] (http://www.pyrkilo.fi/beneris/images/9/9e/Deliverable_16.pdf) .
4. ↑ Quality control and quality assurance in open risk assessment: a draft [3]
(http://heande.pyrkilo.fi/heande/index.php/Heande:Quality_control) . Website accessed 7 Jan 2008.
5. ↑ The Heande website. Accessed Jan 7, 2008 (<http://heande.pyrkilo.fi>)
6. ↑ Result database (http://heande.pyrkilo.fi/heande/index.php/Help:Result_database)

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