

Andy Hart and Helga Gunnlaugsdottir, of the QALIBRA project, explain the route to improved communication around the food industry

Risk-benefit assessment for better food safety

Can you explain a little about the background of your project, its aim and where the concept came from?

Many foods and food ingredients have both benefits and risks. However, common food labelling methods means that either benefits or risks are presented, not usually both.

The central goal of QALIBRA is therefore to develop improved approaches for the assessment and communication of net health impacts of food policies and dietary choices. As part of this, QALIBRA aims to identify and potentially characterise the uncertainties affecting risks and benefits, as these may cause uncertainty about the magnitude and even the direction of the net health impact. The tools developed by QALIBRA will be tested and evaluated in detailed case studies.

How did you first become involved with the programme and what has your input been thus far?

The call text of the activity (T.5.4.8.3 - Assessing health benefits against potential effects of environmental contaminants in selected food groups) which fell under the thematic priority Food Quality and Safety in the EU Framework 6 Programme, was of great interest and very relevant for the research carried out at the institutes we work for. Researchers at Matis had been in contact with researchers at FERA regarding another project that did not materialise. These institutes decided to join forces again when this call text came out in the fall of 2004 and build a consortium that would send in an application for this call text.

What are the expectations and objectives of the project?

QALIBRA aims to develop methods that can take account of multiple risks, benefits and uncertainties and implement them in a web-based software for assessing and communicating net health impacts.

How it has progressed thus far?

The overall progress of the project has been good, however, we had a slow start that was

largely due to the complexity of the issues involved in risk-benefit assessment, and the ambitious methodology that QALIBRA set out to develop.

Are there any 'partners' involved in your research? If so, can you explain their expertise, what they contribute and what they will gain from their involvement?

- Matis, Iceland, coordinator and leads work for case studies on seafood
- The Food and Environment Research Agency (FERA), United Kingdom, leads work on the web-enabled software, expertise in uncertainty analysis and statistics
- National Institute of Public Health and The Environment (RIVM), the Netherlands, leads the development of the general framework for risk-benefit analysis & functional food case study, expertise in toxicology and epidemiology
- Wageningen University, the Netherlands, leads work on risk communication and dissemination
- University of Patras, Greece, expertise in web interface design, and evaluation of usability of prototypes of the web-enabled software
- Altagra, Hungary, expertise in planning and organising end-user testing workshops
- IPIMAR, Portugal, relevant expertise for case studies on seafood

Furthermore, has your organisation collaborated with international partners – has the collaborative approach worked?

The main strength of the QALIBRA project is that it is based on a co-operation between leading institutions in Europe with complementary expertise in risk-benefit assessment methodologies, uncertainty analysis, risk communication and the selected case studies i.e. oily fish and functional foods. This collaborative approach has worked very well in this project.

In addition, QALIBRA has formed close and productive collaborations with two other

EU projects on risk-benefit assessment: the BENERIS project, which takes a complementary approach to risk-benefit methodology, and the BRAFO project, which is developing tiered framework for risk-benefit assessment. The tools developed by QALIBRA fit very well into the upper (quantitative) tiers of the BRAFO framework.

Can you tell us if you have faced any major challenges so far?

The biggest challenges have been the complexity of the problem, limitations in available data, and developing a general framework and software that are applicable to a wide range of risk-benefit problems. The complexities include the need to take account of aspects of health effects (such as the duration and severity of effects, and the possibility of recovery) that are not normally considered in risk assessment. Data to estimate these are often lacking or indirect, especially when the effects have been identified from animal testing. Developing general tools requires a very flexible design for both the model and the software, so that they can deal with different types of effects (e.g. quantal and continuous effects; and effects on the current or next generation).

What is the expected output of the project?

- New approaches for assessing, integrating and communicating food benefits & risks
- Web-enabled software which implements the risk-benefit analysis methods developed in the project
- Project website with general information about the project as well as access to the QALIBRA risk-benefit software
- Scientific and popular publications
- Presentations at national and international meetings (e.g. scientific conferences, university lectures)
- Brochure about the QALIBRA project
- International technical end-users workshop for disseminating processes and results to stakeholders



Ironing out uncertainty when making food choices

The QALIBRA project is addressing the difficulties caused by the practice of presenting the risks and benefits of certain foods separately

DECIDING TO TAKE a step into the unknown, particularly when it involves a decision that might have implications for health, almost invariably involves the weighing up of risks and benefits. A person with a heart condition, for example, may think carefully before travelling to an exotic destination, if it involves a long and potentially stressful flight. Food contains many beneficial ingredients, but can also contain potentially harmful substances. Potential benefit and harm can be present even in the same ingredient. For example, vitamins and minerals are necessary micronutrients but excessive levels could result in adverse effects. Many other examples can be mentioned e.g. fatty fish may reduce the risk of heart disease but can contain contaminants, fruits and vegetables are good for health but can contain pesticides, phytosterols lower blood cholesterol but a potential negative effect of the lowering of blood beta-carotene levels is still debated. Therefore, food and food ingredients can be both beneficial and adverse

In the case of food, it is usually the case in Europe that information on risks and benefits is presented separately. This approach can be unhelpful, because it leaves consumers, and those responsible for advising consumers, uncertain as to where the balance lies between potentially positive and negative effects. At worst, it could lead to dietary choices or recommendations with unexpected and unwanted consequences.



This is the issue that the QALIBRA project ('Quality of Life - Integrated Benefit and Risk Analysis') is aiming to address. Ideally, information on risks and benefits need to be combined to indicate the overall effects of particular dietary choices, and provide an assessment of the resulting impact on health. With this in mind, the key aim of QALIBRA, which began in 2006, is to develop improved approaches for the assessment and communication of the impact of dietary choices on health, and to present the methodology as web-enabled software (www.qalibra.eu).

QALIBRA coordinator Helga Gunnlaugsdottir says: "In retrospect, the objectives we set for the project were very challenging". They included:

- Developing a generalised modular approach to risk-benefit analysis using menus of dose-response and valuation functions
- Implementing the risk-benefit analysis methods developed in web-enabled software that is available for use by all stakeholders via an integrated website, with different components adapted to different user groups
- Developing targeted risk communication strategies for integrated risk-benefit analysis, adapted to the needs of different stakeholders, and developing and testing programmes and materials for dissemination
- Using the methods and software developed to carry out comprehensive risk-benefit analyses for selected food groups including oily fish and functional foods, for selected EU populations, and using the results to evaluate and improve the QALIBRA approaches

"As the project developed", explains Helga, "it became clear that making the QALIBRA software available to non-specialists could generate misleading results and cause unnecessary alarm, because risk-benefit modelling requires high levels of expertise and very careful interpretation. Both our own advisory panel and the European Commission's reviewers advised us to modify this part of the project, and focus instead on generating reliable information that could subsequently be communicated to consumers." In another change, the consortium decided that as other software packages (e.g. Proast) already

INTELLIGENCE

The QALIBRA project focuses on developing methods to quantify the net health impacts of foods and provide better information for decision makers and consumers. The project includes case studies on seafood and functional foods, and aims to make models available as web-based software.

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PROJECT PARTNERS

**Matis – Food Research
Innovation and Safety**
www.matis.is

**The Food and Environment Research
Agency, UK**
www.defra.gov.uk/fera

**National Institute for Public Health
and the Environment, Netherlands**
www.rivm.nl

Wageningen University, Netherlands
www.wur.nl

University of Patras, Greece
www.upatras.gr

Altagra Business Service, Hungary
www.altagra.hu

**Instituto Nacional de Recursos
Biológicos I.P/IPIMAR, Portugal**
www.iniap.pt

COLLABORATIONS

QALIBRA has established a collaboration through clustering with EU project BENERIS: For more information visit www.qalibra.beneris.eu

QALIBRA is cooperating with the BRAFO (Benefit-Risk Analysis of Foods) project. For more information visit <http://europe.ilsa.org/activities/ecprojects/BRAFO>

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provide menus of dose-response models, it would be more efficient to equip the QALIBRA tool with a flexible interface to accept input from any model, rather than duplicate the existing functions.

The QALIBRA project was organised in seven work packages. The first worked on the development of an overall framework for risk-benefit analysis, using common currencies such as Disability-Adjusted Life Years (DALYs) to quantify the balance of risk and benefit, and providing the option to quantify uncertainty in every element of the calculation.

Work package two focussed on implementing the QALIBRA methods as web-enabled software, and conducting detailed testing with end-users to make it as user-friendly as possible. Work package three investigated challenges and solutions for communicating and disseminating risk benefit information. The fourth and fifth work packages developed food-related case studies to test the applicability of the QALIBRA methodology and software. The first case study was about oily fish, while the second concentrated on a functional food, i.e. margarine enriched with phytosterolesters.

To start with the second case study, the literature search revealed a convincing serum cholesterol lowering effect of margarines enriched with phytosterolesters. As we know from drug trials that the lowering of cholesterol levels is associated with a lower incidence rate for heart diseases we assumed that this would also account for the enriched margarines. For the negative effect, the literature was less pronounced. We decided to take the lowering of beta-carotene levels as an example. This meant that we had to work with many uncertainties and assumptions in order to calculate a potential negative health effect i.e. an increase in the incidence of night blindness. The results show that the positive effect outweighs by far the negative effect.

The first case study on oily fish also included an extensive literature search on positive and negative health effects. Many studies have described health effects of oily fish but for many effects there is still no absolute proof. The results show the positive effects taken on board (fatal heart diseases and stroke) again outweigh the effects of the contaminants included in QALIBRA (dioxins, methylmercury).

The case studies helped us to build the tool but should be expanded more deliberately in new projects.

The sixth and seventh work packages provided management and coordinated interactions with other EU projects. As part of this, QALIBRA has been cooperating with another EU project in the same call, BENERIS (www.beneris.eu).

Both projects deal with risks and benefits of food, using complementary methods and approaches. QALIBRA and BENERIS held joint meetings to share ideas, approaches and results, and developed a common dissemination strategy. In addition, QALIBRA formed a very productive relationship with another EU project, BRAFO, which is coordinated by ILSI-Europe (www.ilsa.org/Europe/Pages/BRAFO.aspx). Helga says: "BRAFO is developing a tiered framework for risk-benefit assessment, and the QALIBRA methods and software fit very well with the higher tiers". A joint workshop was held in September 2009 to explore the applicability of the QALIBRA tool to a range of case studies being undertaken by BRAFO. At a subsequent BRAFO meeting in October, Ib Knudsen President of ILSI-Europe reported back on the joint workshop, saying "The QALIBRA model and software was very impressive in practical use when demonstrated at the workshop." further he said "It will be important to run educational courses to make scientists in the field familiar with and confident with the use of the QALIBRA model on practical cases in order to ensure that the QALIBRA model will become commonly used, further development and attract refinements as it deserves."

As the project draws to a close the QALIBRA software will be made available for wider use. It is intended for use primarily by health assessors in food authorities and the food industry, providing them, their decision-makers and the public with better information on the overall health impacts of different foods, or of foods produced by different methods. It is expected that this will:

- Provide decision-makers with a better basis for policy and regulatory decisions and contribute to improving the safety and health benefits of the food chain
- Help consumers to make better-informed dietary choices
- Contribute to reinforcing competitiveness of European food industries by providing companies with better information on the overall health impacts of different foods and production practices. This will help them to compete more effectively by meeting consumer demands for healthy foods.

