Project no: 022936
Project acronym: Beneris
Project title: Benefit-risk assessment for food: an iterative value-of-information approach

Instrument: STP-Specific Targeted Project

Deliverable 45:

Application of benefit:risk assessment to a food safety agency

Due date of deliverable:	**Aug 1, 2009**
Actual submission date:	**Nov 15, 2009**
Dissemination level:	**PU**
Start date of project:	**April, 1st 2006**
Duration:	**3,5 years**

Organisation name of the lead contractor for this deliverable: **FSAI**

Application of benefit:risk assessment to a food safety agency (D45)

Preliminary explanatory note

Deliverable D45 in the Beneris project was to evaluate the methodology for benefit:risk assessment (BRA) developed under WP 1 from the perspective of a food safety authority involved in risk assessment, and this was a key task for the Food Safety Authority of Ireland, as one of the Beneris partners. However, in WP 5, dissemination, an objective was to carry out end-user evaluations of the methodological and substantive work packages emerging from Beneris, in particular the methodology for BRA. FSAI is one such end-user. FSAI identifies that there is an overlap between the evaluations to be carried out for each of these work packages. The report that follows relates to the deliverable D45, but much of the information provided can also be regarded as appropriate for the end-user evaluation and can contribute to the deliverable D46.

Introduction

The key objective of the Beneris project has been "*to create a framework for handling complicated benefit:risk situations, and apply it for analysis of the benefits and risks of certain foods"* Achievement of this objective was of considerable interest to the Food Safety Authority of Ireland, who on a daily basis is faced with the dilemma of providing advice on the benefits of healthy eating on the one hand and providing advice regarding potentially harmful contaminants in food on the other, together with the challenge of putting potential risks in perspective (risk communication). In particular, the first food commodity selected for the development of the methodology was fish. FSAI had already been involved in BRA and provision of appropriate dietary advice in relation to fish consumption, and had extensive data on levels of contaminants in fish. These data have been provided for the Beneris database (WP 2).

The contributions of FSAI to WP1, development of methods to facilitate "a benefit-risk approach with an iterative top-down approach to explore risks of food and its contaminants" were seen as falling into two main areas:

1. evaluation of the framework for its value to FSAI in carrying out its own risk:benefit analyses and as a tool to develop enhanced risk communication.

2. ongoing contribution by staff of the FSAI to the method development including active participation in the emerging approach of open risk assessment;

While the former is a core component of the evaluation by a FSA of the methodology for BRA developed under WP1, it is also part of end-user evaluation, as already indicated. Both aspects will be reported on, as follows.

Evaluation of the ORA/BRA framework of Beneris and OPASNET for its value to FSAI in carrying out risk:benefit analyses and as a tool to develop enhanced risk communication

This evaluation has been carried out by Dr Iona Pratt, consultant and risk assessor, on behalf of FSAI.

In reporting on the outcome of this evaluation, the starting point is that, as stated above, FSAI is actively involved in BRA on an ongoing basis, and is committed to and interested in any approach that makes BRA easier to carry out, more transparent, more comparable from assessment to assessment, which is founded on common principles and understanding and which provides possibilities for stakeholder involvement. These are all objectives under the ORA/BRA framework of Beneris and OPASNET. It can be taken, therefore, that BRA is applicable to a food safety agency. The question is. therefore, how useful would the particular methodology of ORA be to FSAI in taking forward its work in this area.

In carrying out the evaluation, FSAI (Dr Pratt) has spent an extensive period working with the information available on the OPASNET and Beneris websites and also with the guidance developed on the methodology, namely pyrkilo guides 1 and 2, now entitled "Open Risk Assessment: a new way of providing scientific information for decision-making", or, shortly "Open Assessment". A particular objective was to see how the case study on BRA of fish consumption was supported by the ORA methodology in terms of transparency, dispute resolution and possibilities for stakeholder involvement.

The outcome of the evaluation indicates that Open Assessment:

- has potential in terms of transparency
- opens up innovative ideas and lateral thinking during the process of problem definition and dispute resolution
- represents a new way of thinking about and approach to (risk) assessment
- for BRA of particular (fundamental) importance for decision-making, represents a unique opportunity to obtain input from all stakeholders and to take into account viewpoints that would not normally be heard during "traditional" BRA,
- ergo, has the potential to bring assessors, researchers and decision makers (e.g. risk managers) together, which is not normally the case in traditional (risk) assessment.

In our opinion, however, it also has considerable disadvantages, including:

- robustness – the method is only as good as the quality of the information that contributors bring to it
- slowness; the method requires constant active input,
- reluctance of contributors to expose themselves in "print" by articulating points that they are not certain about (the need for courage to engage in the dispute process),

- the possibility that the process can be derailed by mavericks
- the difficulty of persuading researchers that this represents a viable alternative to traditional publication in demonstrating career achievements.
- the difficulty of persuading conservative risk managers that this is an adequate basis for decision-making
- Etc, etc.

Most of the disadvantages listed are also shared by more traditional methods of (risk) assessment, in particular the first, robustness – the outcome is only as good as the quality of the information that contributors bring to it (put garbage in, get garbage out). Closed fora assessment groups such as scientific expert groups are hampered by the particular dynamic and expertise of the group, while ORA in theory provides the opportunity with anybody with a valid view point and expertise to offer to contribute to the assessment process. On the one hand, this can make the process more credible and strengthen the ultimate outcome, on the other hand the transparency of the process can make the process less credible because opposing arguments are clearly articulated for all to see during dispute resolution. If not intelligently managed by the moderator there may be no outcome at all. It is of interest to speculate whether the current impasse regarding Genetically Modified Food in Europe could be resolved by ORA such as that offered by OPASNET

FSAI has considered whether the particular methodology of ORA would have been useful in taking forward its work folic acid on fortification of food in Ireland. In 2004, the Minister for Health and Children set up a National Committee on Folic Acid Food Fortification, tasked with reviewing options for the fortification of foods with folic acid in view of the relatively high level of Neural Tube Defects (NTDs) in Ireland. In carrying out this work the Committee addressed the broader aspects of implementing this policy including the technical issues regarding fortification, addressing risk and examining other reported health benefits that are linked to fortification. As part of the work of this Committee, a public consultation was conducted on possible options for the fortification of foods with folic acid. Following analysis of risks and benefits and comments made during the public consultation, the Committee recommended in its report (http://www.fsai.ie/uploadedFiles/folic_acid.pdf) the mandatory fortification with folic acid of most white, brown and wholemeal breads on sale in Ireland.

However, the Implementation Group entrusted with translating this recommendation into national working practice has recently reported that at the current time there would no benefits to public health to introduce mandatory folic acid fortification (http://www.fsai.ie/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=7602). This new advice follows scientific assessment and a number of factors which negate the need for a mandatory policy. These factors include the fact that women of childbearing age now receive 30% more folate in their diet as compared to three years ago, due to voluntary fortification across the food sector; a reduction in the incidence of neural tube defects to 0.93 per 1,000 births has occurred since 2005 and finally, preliminary and inconclusive data indicate some potential for adverse effects to excessive high levels of folic acid.

The FSAI/National Committee assessment of the benefits and risks of folic acid fortification has been a lengthy (5 year) process, and even at this time is not fully resolved, in parallel with

a comparable process in the United Kingdom. While an assessment carried out using the methods and approaches of OPASNET would not have provided a viable, more speedy alternative, indeed in our opinion it would have prolonged the whole process considerably (see 2nd bullet point under "disadvantages" above), it would have enhanced the consultation aspects of the assessment. It could conceivably also have brought forward more information on risks and benefits on which to base the assessment.

This example, together with that of Genetically Modified Food, highlights some of FSAI's main concerns regarding the application of benefit:risk assessment to a food safety agency, namely the potential slowness of the process and the risk of "hijacking" of the process by particular stakeholders. The majority of our BRAs and the ensuing decision-making have to be executed in "real time". i.e. a decision has to be made on the basis of credible science in the shortest possible time to a Government Minister who is almost certainly being pressed for an anwer. We do not see that the ORA/BRA framework of Beneris and OPASNET can readily deliver this.

It has to be said, however, that our potentially positive evaluation of OPASNET has been hampered (or shaded towards the negative) by the slow development of the methodology and the late publication of the case study on BRA of fish consumption. In relation to the latter, we have evaluated the model, but find that the current report is difficult to follow due to lack of explanation of the methodology. We also find the conclusions to be drawn, after 3 years work, relatively limited and predictable. It is difficult to assess the impact of the ORA methodology on the outcome of the case study from the discussions on this topic on OPASNET, particularly in the light of the currently "multifunctional" nature of the website, with many discussions relating to topics other than that of specific interest.

However we do find the information generally available on OPASNET potentially a useful resource (though does it offer more than a Google or Wikipedia search?). OPASNET does offer a scientifically based resource for assessment where links can be made to the results of other assessments, or indeed the relevant part of other assessments can be "posted" on the OPASNET. This is not possible in a "traditional" (risk) assessment.

In conclusion we consider that OPASNET and the tool of Open Assessment are of potential value in BRA, and could be useful in the work of a food safety agency. However the delays in method development and in the fish case study have resulted in a situation where it is difficult to assess full potential at this time.

Contribution by staff of the FSAI to the methods for benefit:risk assessment (WP 1)

The initial methodological approach to development of a robust and plausible approach to BRA was termed the pyrkilo method, which was founded on the principles of open assessment. The approach was to be directed initially to BRA of fish consumption, the specific analysis being developed in WP 3, case study 1: fish. An early objective in WP 1 was to reach a common understanding among all partners of the aims of the work and the scientific and practical methods that would be applied during the project and a draft guidance document (D1) was developed for this purpose. As described in the guidance, the intended outcome of the pyrkilo method was to provide a "cumulative source of assessments, insights, and data, a collection of links to data sources, databases, and literature, a system to publish

risk benefit analyses over the internet and a system to collect feedback related to risk benefit analyses."

At this stage in the project, the FSAI's aim was to become familiar with the approach and to contribute to the open dialogue (Discussion) on the Beneris website on the fish case study. However, the discussions on the website on the method were rather limited:

- December 2006: Food Risk-Benefit BBN, Trace element intake in Finnish mothers
- February 2007:Dose-response functions of various endpoints due to fish exposure
- August 2007: Pyrkilo Guide 2
- October 2007: Scoping fish case study boundaries

While FSAI could (and should) have become involved in the discussions on dose-response functions of various endpoints due to fish exposure and scoping fish case study boundaries, FSAI was having difficulty in understanding the approach and the usefulness of these discussions at this stage in the project.

In September 2007, two members of FSAI staff, Edel Conway and Iona Pratt, attended the Beneris training workshop in Berlin, which provided further insight into the developing methodology including the application of Bayesian Belief Networks in the fish case study. At this meeting, the pyrkilo guide 2 was presented, and FSAI contributed actively to the discussions on the method, now entitled "Open Risk Assessment: a new way of providing scientific information for decision-making". Further opportunity (limited because of lack of time) to provide input into the methodology was afforded by the mid-term meeting of Beneris in November 2007, again attended by Edel Conway and Iona Pratt. We were unfortunately unable to attend the 7th Valamo Conference on "Environment and Health – approaches to benefit-risk analysis" in December 2007 due to conflict with other meetings, nor the Kuopio risk assessment workshop in February 2008. Attendance at these meetings might have afforded us with more opportunity to understand the scientific basis and value of open risk assessment (ORA)

While the mid-term meeting of Beneris in November 2007 emphasised the need for Beneris partners such as FSAI to become more involved in the ORA methodology and in its use for the case study in fish, this was made more complex by the migration of the assessment work under Beneris to the OPASNET and HEANDE websites. OPASNET reflected the needs and input of several EU-funded research projects, notably Beneris, Intarese and Heimtsa, and the Discussions on the OPASNET website reflect that varied input. Relatively few of them related to the BRA under Beneris and those that did were not well-developed in terms of an active ORA-type dialogue that FSAI felt it could usefully contribute to. In addition, the detailed outcome of the BRA on fish consumption was not available on OPASNET until 3 October 2009.

In conclusion, therefore, FSAI has not contributed actively to the method development in WP 1 although it had intended to do so, and had attempted to "get to grips" with the methodology under development. The reasons for this were multifaceted and included:

- Delays in the development of the methodology

- Delays in the completion of the fish study
- The complexity of the OPASNET input
- The lack of resources and commitment at FSAI to become more actively involved in WP 1
- The lack of motivational leadership from the project coordinator

During the course of the Beneris project, for the above reasons, FSAI considered very seriously withdrawing from the project following the mid-term meeting in 2007, and communicated this to the project coordinator. We agreed eventually that FSAI would remain in the project, but primarily for the purposes of providing data for the database aspects of the project.