ACCESSIBLE REPORT

TO COMMISSION STAFF RESPONSIBLE FOR REPORTING TO THE PARLIAMENT AND TO THE COUNCIL UNDER ARTICLE 14 OF THE BATHING WATER DIRECTIVE OF 15TH FEBRUARY 2006

EU FRAMEWORK 6
SPECIFIC TARGETTED RESEARCH PROJECT

EPIBATHE

PROJECT REFERENCE 022618

MAY 2009

This Activity Report covers the period
1st June 2007 to 31st March 2009

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Contents

1 Context of this report

This Supplement[1] to the Epibathe project final report (see Workpackage 9 of the Description of Work) is designed to distil the central lessons of the Epibathe project to inform Commission Officers in drafting their report to the Parliament and the Council as required under Article 14 of Directive 2006/7/EC[2].

A concise report, accessible to the interested 'lay' reader, has been requested. To this end, we highlight and illustrate the main findings of the Epibathe project in this report. Readers wishing to explore the detailed scientific findings, and statistical analyses undertaken to derive the conclusions, can access reports, presentations and meeting minutes at

http://www.epibathe.eu/

2 Structure of this report

This report provides a brief description of the Epibathe project (Sections 3-5) and outlines the main findings (Sections 6-7) as well as guiding the reader to the principal data which underpins this assessment.

3 Project rationale

Epibathe was funded under EU Framework programme 6 to produce 'science support for policy'. It was commenced in December 2005 and was completed in March 2009. The imperative for this research effort was the relative paucity of EU data describing the health effects of bathing in EU freshwaters and Mediterranean marine waters. Both environments provide important recreational resources throughout the Community. In formulating the water quality criteria, defined in the 2006 Bathing Water Directive[2], it was felt prudent that the Commission should seek to initiate research into this aspect of bathing water regulation and this aim was drafted into Article 14 of the Directive.

4 Project Partners

The consortium which undertook the Epibathe project is outlined in Table 1. The coordinating institution was UWA. Field investigations in Hungary and Spain were undertaken by NIEH and URV respectively. The principal responsibility for epidemiological data analysis was with NPHS. UEA provided training materials and advice on ethical clearance and WHO undertook literature evaluations and ensured the Epibathe outcomes were effectively assimilated within WHO policy developments

[1] See *Project Reporting in FP6* (2004), Section 6.9, Page 17

[2] Anon (2006) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC. *Official Journal of the European Union L 64*, 37-51.

and updating of the WHO *Guidelines for Safe Recreational Water Environments* (2003)[3] which was undertaken in 2009.

Participant name	Short name	Country	Leader
University of Wales, Aberystwyth.	UWA	UK	David Kay
Fodor Joszef Orszagos Kozegeszsegugyi Kozpont. (Now named the 'National Institute for Environmental Health'), Budapest.	FJOKK (NIEH)	Hungary	Kádár Mihály
University of Rovira and Virgili, Reus.	URV	Spain	Maria Figueras
National Public Health Service, Cardiff.	NPHS	UK	Roland Salmon
University of East Anglia, Norwich.	UEA	UK	Paul Hunter
World Health Organisation, Geneva.	WHO (UN)	Switzerland	Jamie Bartram

Table 1 Partners in the Epibathe project team

5 Methodology

5.1 Fieldwork

A randomised controlled trial (RCT) protocol, as developed during earlier UK[4] and German[5] investigations, was implemented which mirrors the approach used in developing the scientific basis of current WHO (2003)[6] 'Guideline' values. This protocol required a volunteer group which was taken to a bathing water, randomised into bather and non-bathers, then exposed through 'normal' bathing activity, during which time, water quality was closely monitored through detailed spatial and temporal measurement of a suite of faecal indicator organisms used to regulate bathing waters. Before, during and after the exposure period, the volunteers were interviewed and the resultant data analysed to investigate any relationships between water quality and health outcomes reported by the volunteers. The experimental protocol required approval by appropriate local ethics panels. Eight separate trials were completed, four

[3] WHO (2003) *Guidelines for safe recreational water environments Volume I*. WHO, Geneva. 219p available from http://www.euro.who.int/watsan/Publications/20031021_1.

[4] Kay, D., Fleisher, J.M., Salmon, R.L., Jones, F., Wyer, M.D., Godfree, A.F., Zelenauch-Jacquotte, Z. and Shore, R. (1994) Predicting the likelihood of gastroenteritis from sea bathing - Results from randomized exposure. *The Lancet 344(8927*), 905-909.

[5] Wiedenmann, A., Krüger, P., Dietz, K., López-Pila, J., Regine Szewzyk and Botzenhart, K. (2006) A randomized controlled trial assessing infectious disease risks from bathing in fresh recreational waters in relation to the concentration of Escherichia coli, intestinal enterococci, Clostridium perfringens and somatic coliphages. *Environmental Health Perspectives 8115*, 1-41.

[6] Kay, D., Bartram, J., Pruss, A., Ashbolt, N., Wyer, M.D., Fleisher, J.M., Fewtrell, L., Rogers, A. and Rees, G. (2004) Derivation of numerical values for the World Health Organization guidelines for recreational waters. *Water Research 38(5*), 1296-1304.

in Hungary and four in Spain. Volunteer numbers exceeded targets in all field campaigns which were completed successfully in 2006 and 2007.

5.2 Data available for analysis

The new information generated by the Epibathe research: i.e. on EU fresh and Mediterranean waters, has been analysed separately and also combined with existing data acquired using the same research methods in Germany and the United Kingdom. This meta-analysis of the larger data set includes data on over 7,000 volunteers who participated in these randomised controlled trials between 1989 and 2007.

6 Results

6.1 Summary of principal findings

Water quality encountered during the new Hungarian and Spanish investigations was relatively 'clean' as would be expected from the choice of sites which were in compliance with the *Imperative* standard of the EU bathing Water Directive (1976). However, elevations in symptom reporting in the bather group(s), i.e. when compared to the non-bather group(s), were observed. It was also notable that the background rates of most symptoms, principally gastrointestinal (GI) symptoms, was lower in the Epibathe studies than in previous studies in the UK and Germany. These temporal differences could be due to improvements in effluent treatment and the general health status of the European population over the 20 year period spanned by these investigations.

The analysis of the combined data set, specifically that component focused on GI symptoms, suggests that enterococci are best predictor of illness in bathers using marine waters and *Escherichia coli* is a better index of GI symptoms in bathers using freshwater. The evidence-base created by this analysis suggests that exposure to marine recreational waters presents approximately twice the risk associated with fresh waters containing similar faecal indicator organism densities. Furthermore, the new combined analysis suggests similar risk levels to those assumed in derivation of the original Guidelines for Safe Recreational Water Environments by WHO in 2003 and the revised Bathing Water Directive in 2006. Thus, the Epibathe empirical field studies and combined data analysis does not suggest that a change in the water quality standards suggested by either the WHO or the European Union are in need of revision.

However, the Epibathe project has produced data suggesting significant limitations in the microbiological methods defined in the revised Bathing Water Directive (2006). For example, the 'most probable number' (MPN) method for *E. coli* (ISO 9308-3) produced false positive results which could have classified a Mediterranean bathing area as having 'poor' quality when the same site would be characterised as of 'excellent' water quality if measured by the 'membrane filtration' (MF) method (ISO 9308-1). However, the MF method also produced significant problematical results generally attributable to its poor selectivity when applied at both the Hungarian freshwater bathing sites and at one Mediterranean bathing site influenced by freshwater contamination.

6.2 Field sites

Figure 1 shows the 4 Hungarian sites examined and Figure 2 shows the sites in Spain.

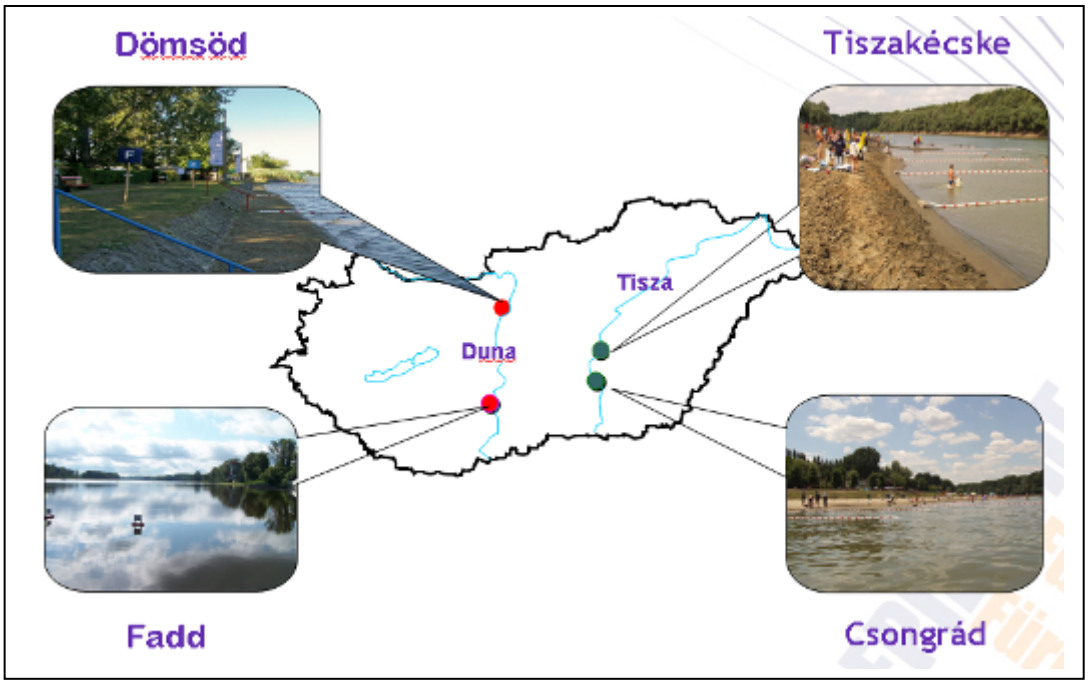

Figure 1 Hungarian sites examined in 2006 and 2007

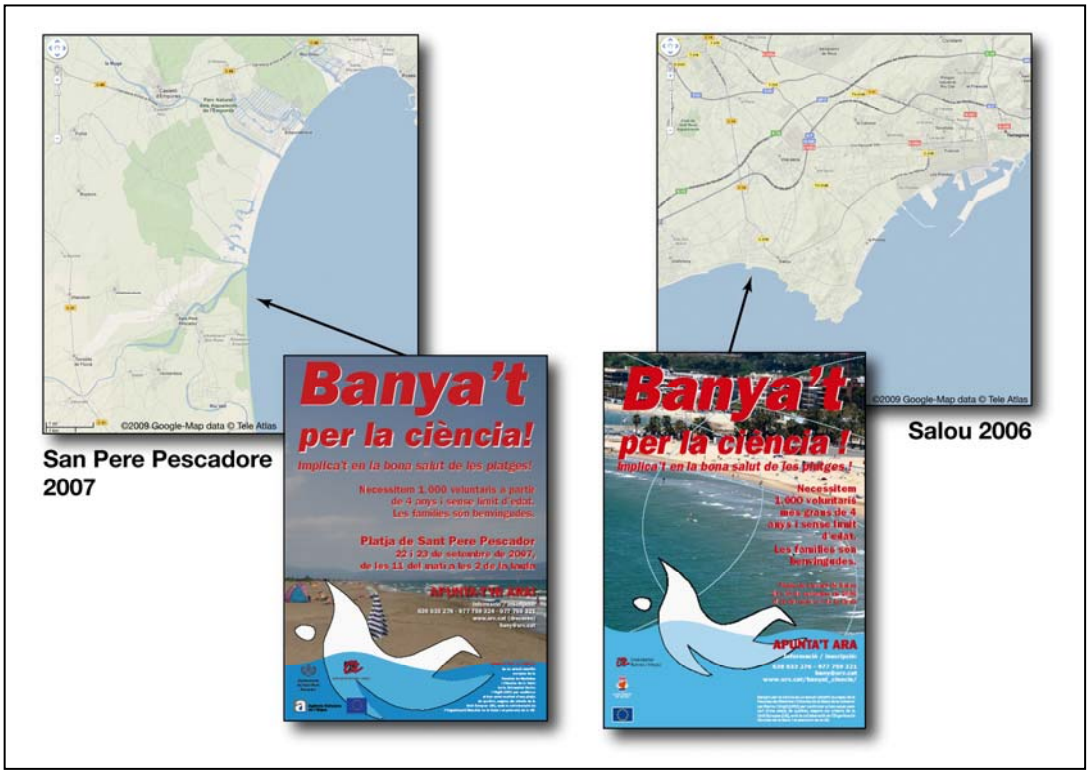

Figure 2 Spanish sites examined in 2006 and 2007

Water quality, at each field site, was measured in each of six marked swim zones at 20 minute intervals. Bathers were asked to remain in the water for a minimum of ten

minutes and the water quality experienced at the time and place of bathing was attributed to each bather. This provided a range of 'exposures', i.e. over time and space, both between sites and within each three hour exposure period. Figure 3 shows the range in water quality as measured by enterococci concentrations for all sites examined. (For a full analysis see Appendix 6 Epibathe Final Activity Report).

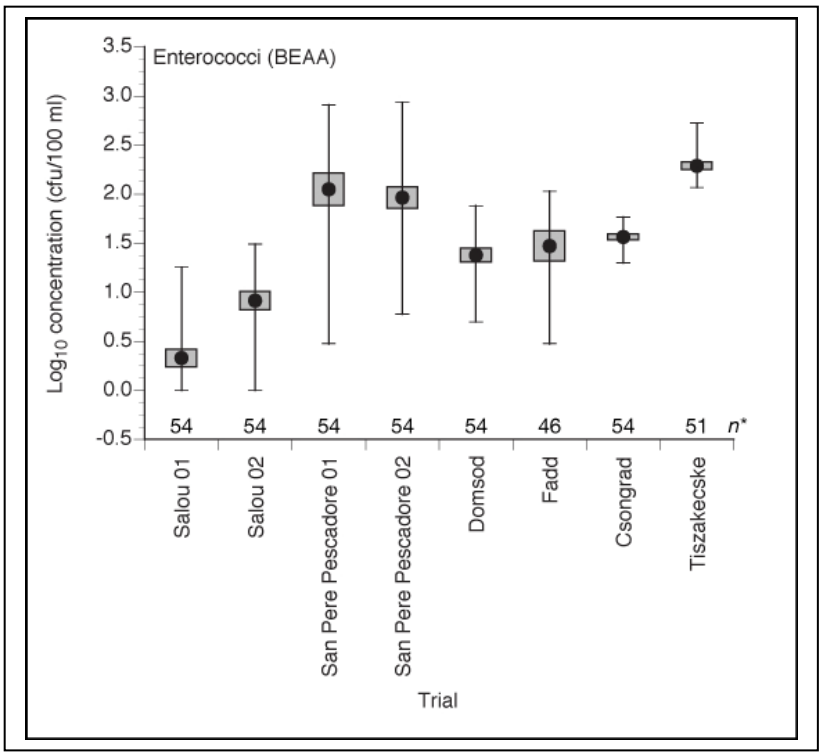

Figure 3 Enterococci concentration measured at each of the Epibathe trial sites in 2006 and 2007

6.3 Results of the Epidemiological data analysis relating water quality to health outcomes

Five separate analyses have been completed to examine the following relationships and associations:

i. risk of gastroenteritis from recreational bathing water: analysis of Epibathe data from Hungary and Spain;

ii. risk of gastroenteritis from recreational bathing water: a meta-analysis of randomised exposure trials in four European countries;

iii. estimating the risk of gastroenteritis in European fresh bathing waters using *E. coli* as indicator organism;

iv. risks of non-enteric diseases from European recreational bathing water; and

v. the effects of non-water related risk factors on gastroenteritis.

For a full analysis, see Appendix 2 of the Epibathe Final Activity Report. A total of 17 randomised controlled trial experiments were available for this analysis, eight of which were funded under the Epibathe project. The populations of bathing and non-bathing volunteers who participated in these trials and provided usable data are outlined in Table 2 below.

Classification	**GI**	**AFRI**	**Ear**	**Eye**	**Skin**
Non-bathers (n)	3,780	3,953	3,943	3,939	3,590
Bathers (n)	3,432	3,580	3,563	3,557	3,246

Table 2 Population numbers available for the epidemiological analyses using the combined EU data set.

For EU marine waters (Spain and the UK), the clearest trend in increasing risk of illness with decreasing water quality was evident using enterococci as indicator of water quality. Table 3 shows a meta-analysis used to calculate the Odds Ratio (OR) of gastroenteritis associated with ascending quartile exposures to enterococci.

Quartile cut-points (enterococci/100ml)	**Subjects**		**Meta-analysis**	
	N	**% ill**	**Adjusted OR**	**95% CI**
Non-bathers	1,598	6.7	1.00	N/A
0-8	340	7.1	1.35	0.75-2.45
9-27	360	9.7	1.44	0.87-2.36
28-88	357	13.2	1.47	0.94-2.31
≥89	357	6.7	2.06	0.84-5.04
Overall	**3,012**	**7.9**	**1.39**	**1.03-1.87**

Table 3 Meta-analysis used to explore the relationship between reported gastroenteritis in the bather cohort and enterococci concentration in EU marine bathing waters.

The meta-analysis forest plot for all marine sites is presented in Figure 4 below.

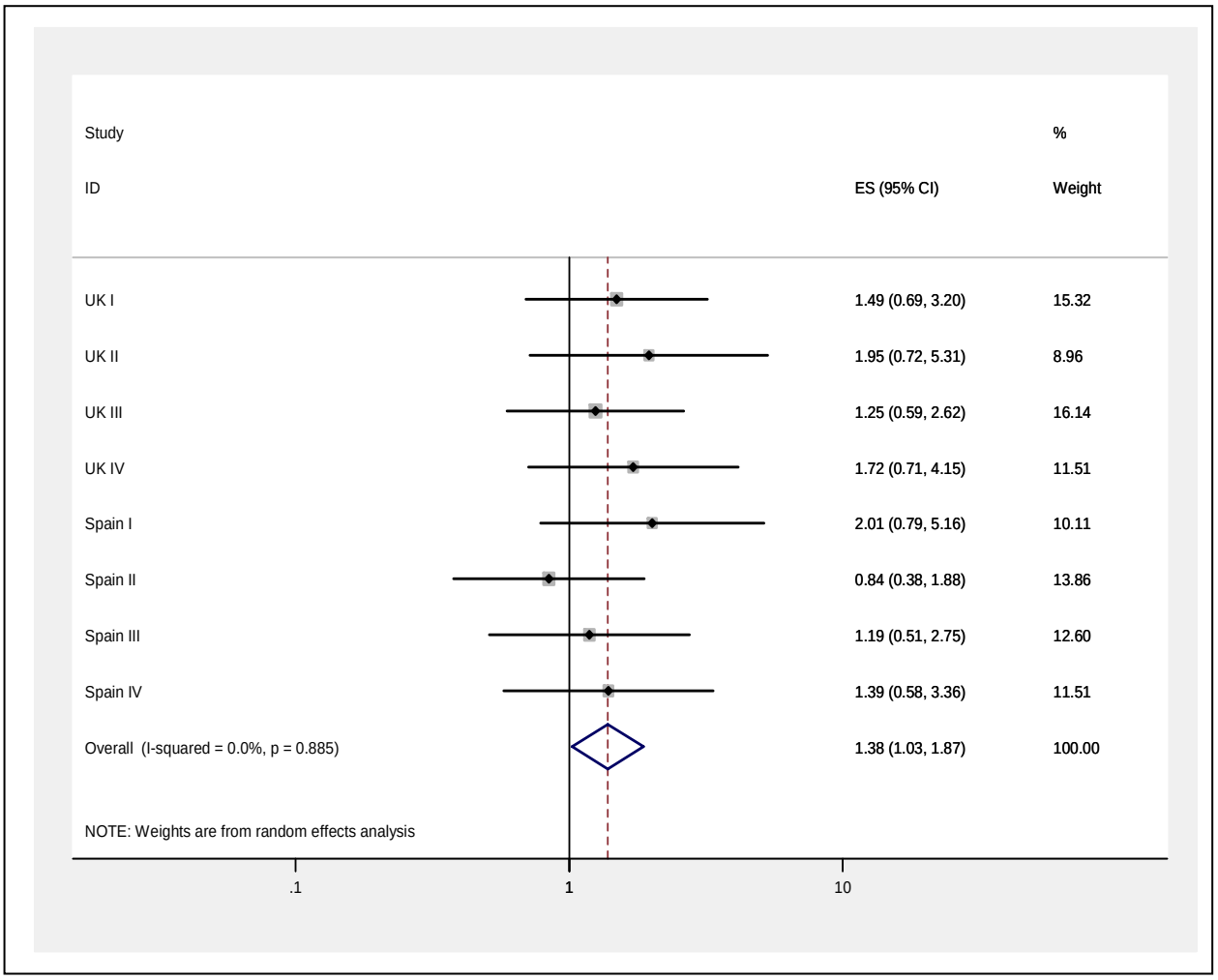

Figure 4 Forest plots representing the OR (ES (95%CI)) of gastroenteritis in each marine water site (i.e. bather *vs* non-bather) at different enterococci concentrations. The dotted line is the mean OR for all sites.

For fresh waters (German and Hungary), the clearest dose-response relationship between gastrointestinal symptoms and water quality was seen with *E. coli* concentration. Table 4 shows the freshwater analysis.

50 unit cut-points	**Subjects**		**Meta-analysis**	
(*E. coli* /100ml)	**N**	**% ill**	**Adjusted OR**	**95% CI**
Non-bathers	2,182	4.7	1.00	N/A
0-49	451	3.3	0.70	0.35-1.39
50-99	565	5.0	1.39	0.82-2.35
100-49	239	5.0	1.23	0.56-2.69
150-199	116	6.0	1.59	0.52-4.88
200-249	65	10.8	1.77	0.65-4.86
≥250	582	8.1	1.67	1.04-2.67
Overall	**4,200**	**5.2**	**1.20**	**0.88-1.62**

Table 4 Meta-analysis used to explore the relationship between reported gastroenteritis in the bather cohort and *E. coli* concentration in EU fresh bathing waters.

The meta-analysis forest plot for all freshwater sites is presented in Figure 5 below.

Both analyses (i.e. of fresh and marine waters) suggest elevations in illness in the bather cohorts. However, results from fresh water studies do not display a consistent incremental elevation in odds ratio (OR) as the exposure increase.

It should be noted also that the values presented in Tables 3 and 4 are of single exposure concentrations and they are, therefore, not directly related to a calculated percentile compliance concentration as is specified in the Bathing Water Directive (2006) and the WHO Guidelines for Safe Recreational Water Environments (2003).

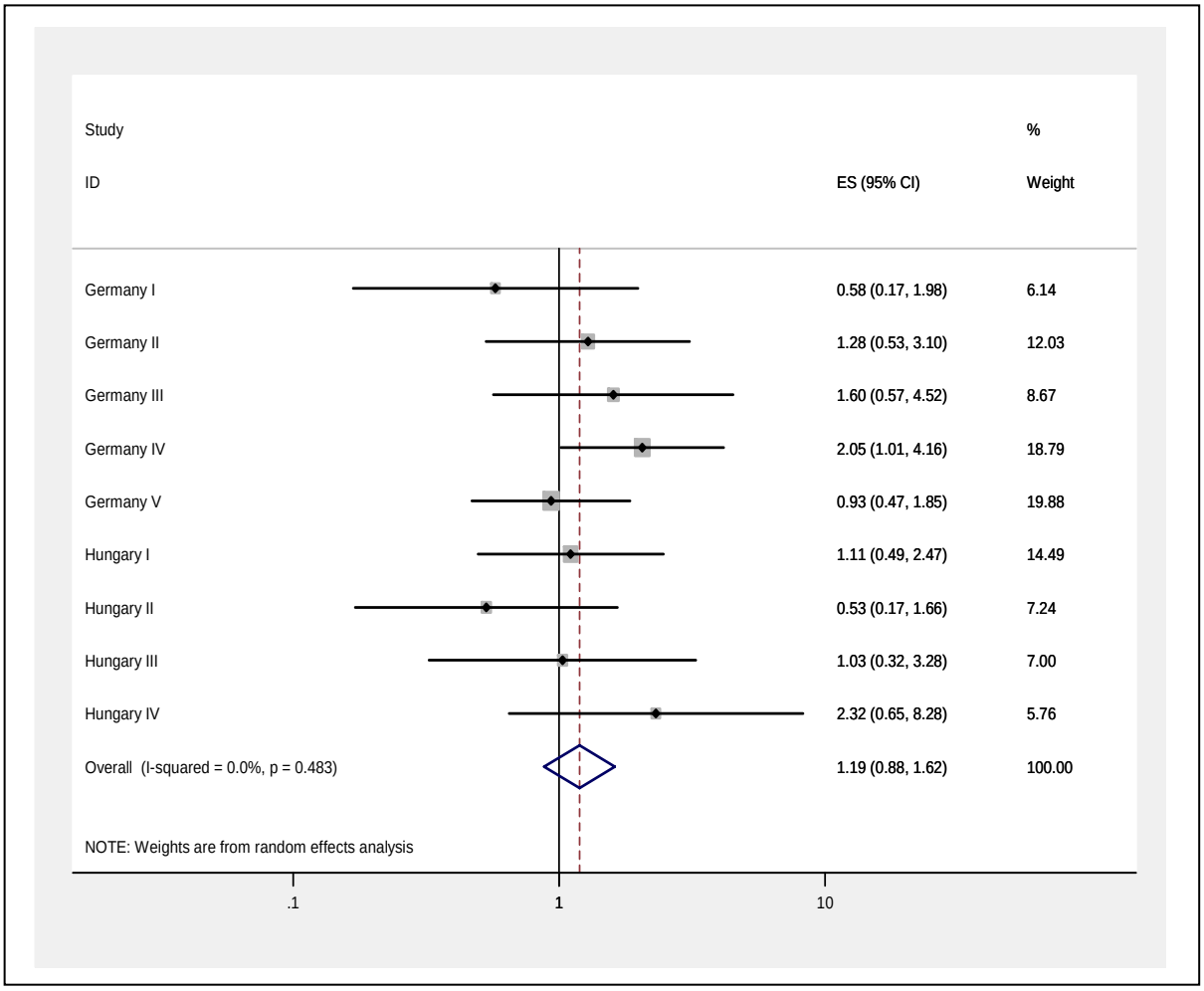

Figure 5 Forest plots representing the OR (ES (95%CI)) of gastroenteritis in each fresh water site (i.e. bather *vs* non-bather) at different *E. coli* concentrations. The dotted line is the mean OR for all sites.

6.4 Risk assessment

The original risk assessment which underpinned the WHO Guidelines[7] was derived from the UK studies. This assumed a simple linear relationship between enterococci concentration in marine waters and rates of gastroenteritis in bathers. However, the assumption of a single linear relationship becomes questionable where several individual studies are combined spanning different regions and time periods. This may result in the rates of illness in the non-bather groups exhibiting variability between sites and times, which is normal for gastroenteritis in the community. It was for this reason that the epidemiological analysis summarised above adopted a 'meta-analysis' approach, rather than reporting a linear modelling analysis. Furthermore,

[7] Kay, D., Bartram, J., Pruss, A., Ashbolt, N., Wyer, M.D., Fleisher, J.M., Fewtrell, L., Rogers, A. and Rees, G. (2004) Derivation of numerical values for the World Health Organization guidelines for recreational waters. *Water Research 38(5*), 1296-1304.

risk assessment in the period since the WHO analysis was completed as advanced. In particular, assumptions of simple linear relationships have been replaced by approaches which assume that the 'drivers' (e.g. enterococci in marine waters) of an outcome (e.g. gastroenteritis rates in a bather group) are better described as statistical distributions, rather than individual values. Expressed in risk assessment terminology, linear modelling has been replaced by stochastic modelling in many areas of health risk assessment.

The concluding International Workshop of the Epibathe project was conducted at the WHO head quarters in Geneva in January 2009 and the choice of risk assessment approaches was addressed. The participating expert group agreed that a stochastic approach to risk assessment was most appropriate and this was applied to the Epibathe data by Professor Paul Hunter (Epibathe partner UEA). The advantages of this approach are that the modelling of risk can be accomplished without the need to make certain, potentially over-simplistic, assumptions in the underlying data[8]. Instead, the input 'drivers' can be expressed as statistical distributions, which is generally a more realistic representation of reality.

Using this approach, the risk of gastroenteritis attributable to bathing in EU marine waters (i.e. using the UK and Spanish data sets combined; see Figure 4) which have a 95th percentile water quality of 200 enterococci per 100ml was calculated at 4.5% (see Figure 6).

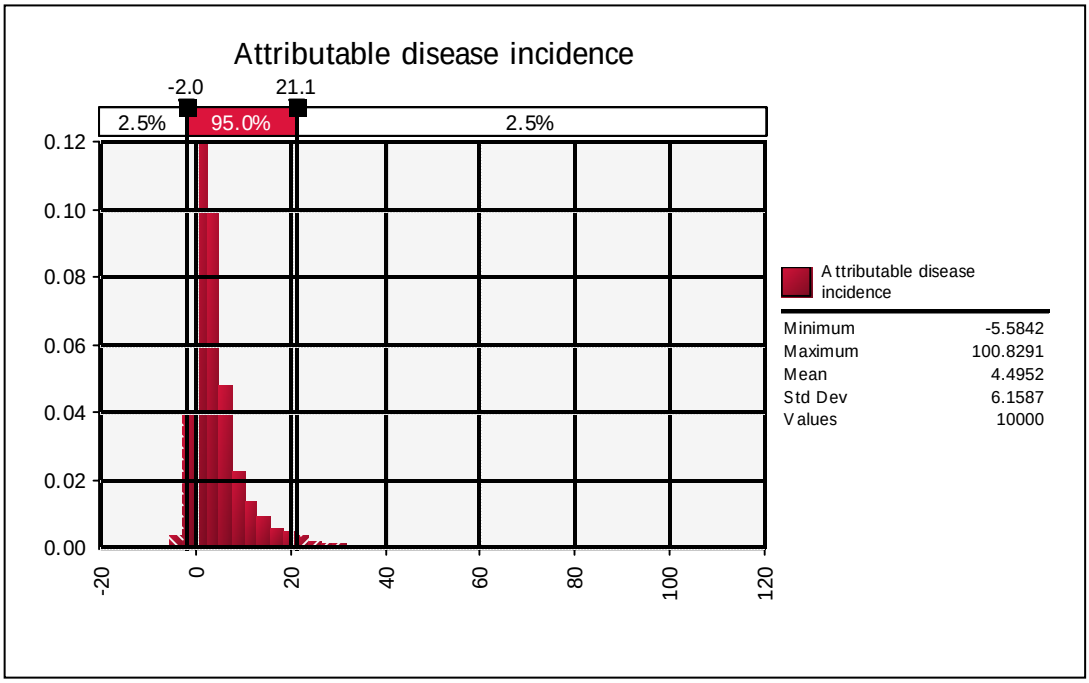

Figure 6 Stochastic model of the attributable risk of gastroenteritis experienced by bathers in marine waters with a 95th percentile value of 200 enterococci per 100ml[9].

[8] For example, the original WHO assessment made the assumption that all beaches world-wide had the same standard deviation for enterococci sampled in the bathing zone, i.e. a log10 value of 0.8103.
[9] This analysis was completed using Monte Carlo simulation within @RISK software of Palisade Corp.

This value is comparable with an attributable illness probability of 5%, calculated using the original WHO analysis which underpins the WHO[10] '*Level B*' and EU[11] '*Good*' criteria for this parameter.

This broad correspondence between the risks derived from the new information for marine waters, generated through the Epibathe project analysed using contemporary approaches, and the risks assumed by the designers of the existing standards, led the WHO expert group to conclude that there was no evidence-base to suggest that the original criteria should be amended in response to any more recent epidemiological information. This recommendation is encapsulated within an addendum to the 2003 WHO Guidelines which will shortly be published by WHO.

For EU freshwaters, the increase in illness rates attributable to incremental elevations of faecal indicator bacterial concentrations was less marked, as seen in Table 4 above. The attributable risks were best characterised by *Escherichia coli*, rather than enterococci, bacteria which is in broad agreement with parallel research in the USA. The Epibathe analysis would suggest that the risks of bathing in freshwaters is lower than attributable to marine water exposures and that the 2:1 risks differential, implied by the stricter standards for marine waters, outlined in Annex 1 of the 2006 Bathing Water Directive, is in broad agreement with the finding of the Epibathe project.

7 Conclusions

1. The Epibathe project has provided new information to supplement the original UK data used to underpin the WHO Guidelines for recreational waters published in 2003.
2. This information, together with new data for the USA, has been evaluated by WHO in January 2009 during an expert consultation to consider revision of the WHO Guidelines in this area from which elements of the EU Bathing Water Directive (2006) criteria derive.
3. A new approach to assessing the risks attributable to bathing in environmental waters was applied to the Epibathe data and reported to the WHO expert meeting in January 2009.
4. This analysis suggested that there was broad correspondence between the attributable risks assumed in deriving the current WHO and EU standards with that calculated using the new information derived from the Epibathe project.
5. The new research has not, therefore, produced a clear evidence-base which would suggest that a revision of the water quality criteria outlined in Annex 1 of the 2006 Bathing Water Directive should be undertaken.
6. The risks attributable to bathing in freshwaters were less marked than in marine water environments. This suggests that a differential in standards applied to both environments, as is evident in the 2006 Bathing Water Directive, is supported by the available and newly derived evidence.

[10] See Tale 4.7: WHO (2003) *Guidelines for safe recreational water environments Volume I*. WHO, Geneva. 219p available from http://www.euro.who.int/watsan/Publications/20031021_1.

[11] See Annex 1: Anon (2006) Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC. *Official Journal of the European Union L 64*, 37-51.

8 Access to the full data analysis

The full data analysis in the form of the five reports noted in Section 6.3 above can be obtained as separate .pdf downloads from the web site below:

http://www.epibathe.eu/