Addendum to the Report on the Equivalence of EU and US Legislation for the Sanitary Production of Live Bivalve Molluscs for Human Consumption

Original report: 1996 **Addendum: 2010**

Introduction

Classification of bivalve mollusc harvesting areas provides an assessment of risk of faecal contamination of an area and dictates whether bivalves can be harvested and, if so, the level of treatment that needs to be applied (if any) prior to sale for consumption. The monitoring on which classification is based is undertaken as follows:

EU: *E. coli* in bivalve mollusc flesh
US: total/faecal coliforms in seawater

An EU working group considered the matter of equivalence of the two systems and, in a report published in 1996, specifically looked at the relationship between faecal coliforms/*E. coli* in bivalve molluscs and faecal coliforms/*E. coli* in bivalve mollusc flesh, using an international data set of paired samples (European Commission, 1996). For the purposes of the report, levels of faecal coliforms and *E. coli* were considered to be equivalent and the data was analysed in terms of the standards set out in the relevant EU and US legislation. The classification requirements under the two systems are shown in Table 1. This is an update of the table in the 1996 report taking account of changes in EU legislation.

Table 1. Synopsis of standards

Shellfish treatment required	US Classification	Microbiological standard per 100 ml seawater	EU Classification	Microbiological standard per 100 g shellfish
None required	Approved	GM[1] < 14 FCs[2] and 90%-ile ≤ 43[3] FCs	Category A	all samples ≤230 *E. coli*
Purification or relaying	Restricted	GM < 88 FCs and 90%-ile ≤ 260[3] FCs	Category B	90% ≤ 4600 *E. coli* and all ≤46,000 *E. coli*
Protected relaying (≥2 months)	-	-	Category C	all samples ≤46,000 *E. coli*

Notes: [1]GM = geometric mean
[2] FCs = faecal coliforms
[3]Values for 5-tube decimal dilution test – different 90%-ile values are given for other test methods

In performing statistical analysis of the comparison of these standards, the 1996 EU report considered the geometric mean element of each US classification category and compared this with the corresponding EU standard. The US FDA subsequently emphasized that the standards in the US legislation contain two separate limits for each classification category,

one of which is a geometric mean and one of which is a 90-percentile (90%-ile) (US FDA 2002). They identified that it was their experience that the 90%-ile compliance tended to drive classification of areas more often than the geometric mean compliance and that it was important to consider the latter when considering equivalence.

The work contained in this addendum is therefore a re-analysis of the data set used for the 1996 report, using the same basic approach (logistic regression) but comparing the EU classification criteria with the US 90%-ile criteria instead of the geometric mean criteria. The 1996 report identified that it was critical to undertake the analyses with respect to site (rather than just sample pairs) and so the same approach has been followed in the present extension.

Methods

The original data set was available as a series of .csv files. These contained a total of 4274 paired faecal indicator results for flesh and seawater for three "species" (European flat oyster (*O. edulis*), Pacific oyster (*C. gigas*) and mussels (various species, mainly *M. edulis* and *M. galloprovincialis*) from six countries (France, Ireland, Italy, Netherlands, New Zealand, UK).

The data set was screened to remove paired results that were not identified to sampling site. Essentially, this meant that that the Irish data set was removed and only four sites remained for Italy (the same screening process was used in the 1996 report).

Weighted logistic regression was undertaken of compliance at each site with class A (using an assumption of 95% compliance with 230 *E. coli* /100 g) and class B (90% compliance with 4600 *E. coli*/100 g) in bivalves against the 90%-ile *E. coli* value in seawater at that site. Separate models were determined for each of the three "species" and for all species combined.

Results

Repeating the weighted logistic regression of compliance with 4,600 *E. coli*/100 g flesh (i.e. category B) against geometric mean *E. coli* in seawater by site, for all species, gave a predicted geometric mean in seawater of 117 *E. coli*/100 ml at 90% compliance with 4,600 *E. coli*/100 g of flesh. This is slightly different from the value in the 1996 report of 112 *E. coli*/100 ml. The difference was thought to be due to slight discrepancies in the way the data sets were screened and the extended time that had elapsed since the original work did not allow this to be reconciled. The difference between the two predicted geometric mean values was deemed to be of no practical significance. An analogous weighted logistic regression of compliance with 4,600 *E. coli*/100 g flesh (category B) against 90%-ile *E. coli* in seawater by site gave a predicted 90%-ile of 436 *E. coli*/100 ml seawater (95% CI = 239, 750). The 95% confidence interval includes the US restricted 90%-ile limit for Restricted areas of 260/100 ml. It was, however, deemed inappropriate to take the same approach for category A compliance as it would have required extrapolation outside the range of the available data.

As an alternative, the percentage compliance of bivalve mollusc flesh categories A and B was investigated with regard to the US FDA 90%-ile limits for the corresponding Approved and Restricted standards for seawater. This approach ensured that all predictions were within the range of the overall data set. Figures 1 and 2 show the weighted logistic regression curves for the three separate species, and the combined data, for category A and category B compliance with Approved and Restricted standards respectively. The lines superimposed on the graphs

show the predicted compliance in bivalve molluscs, for the combined data, at the US 90%-ile limits for the equivalent category (i.e. category A versus US Approved and category B against US Restricted). The percentage compliance values are presented in Tables 2 and 3.

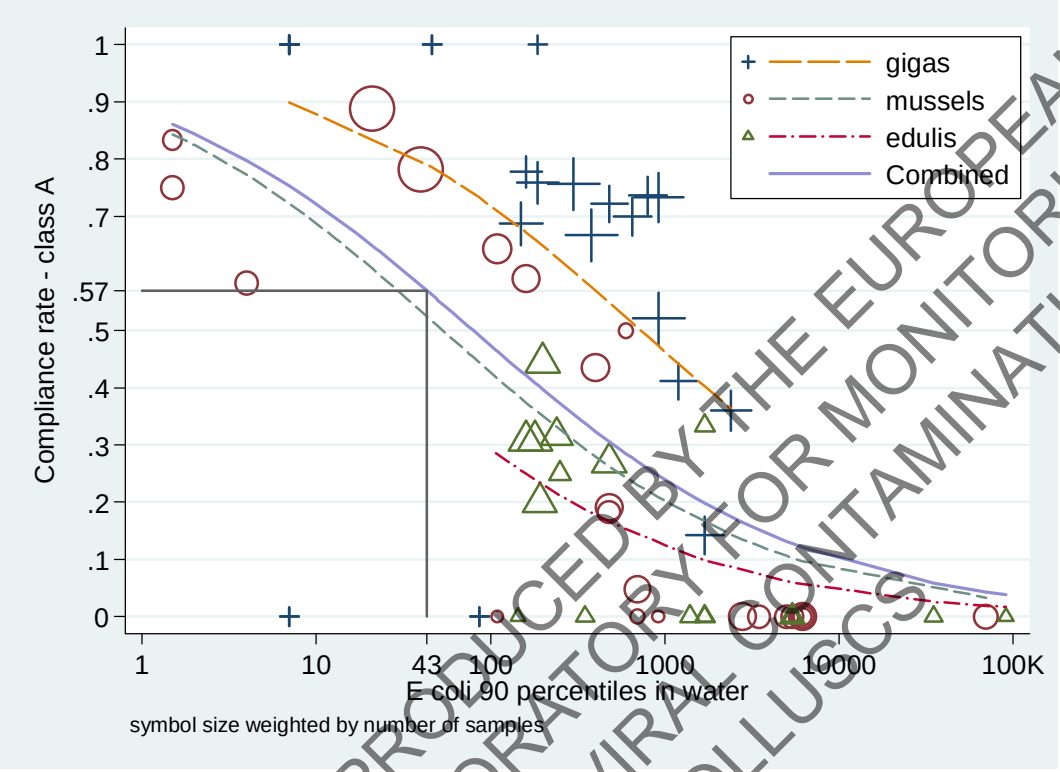

Figure 1. Logistic regression of category A compliance versus 90%-ile *E. coli* in seawater

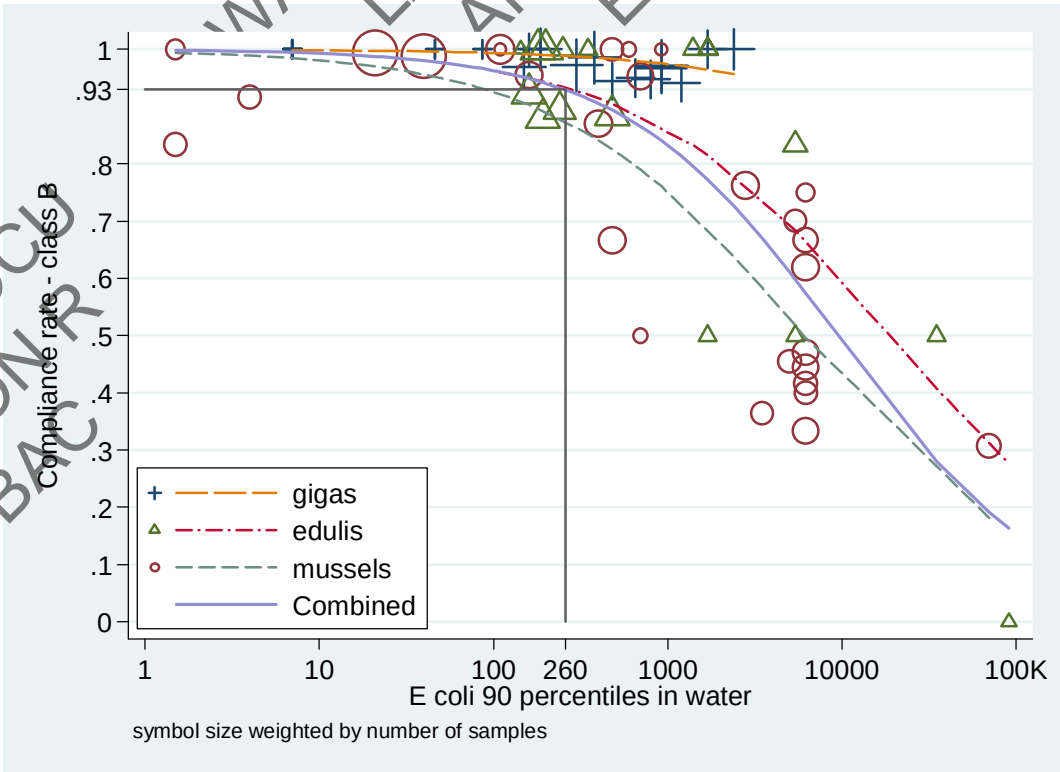

Figure 2. Logistic regression of category B compliance versus 90%-ile *E. coli* in seawater

Table 2. Predicted compliance with 230 E. coli/100 g flesh (category A) at a 90%-ile value of 43 *E. coli*/100 ml seawater (the US Approved area standard)

Species	Percentage compliance with 230 *E. coli*/100 g
Mussels	53
C. gigas	79
O. edulis	38
Combined	57

Table 3. Predicted compliance with 4,600 *E. coli*/100 g flesh (category B) at a 90%-ile value of 260 *E. coli*/100 ml seawater (the US Restricted area standard)

Species	Percentage compliance with 4,600 *E. coli*/100 g
Mussels	87
C. gigas	99
O. edulis	93
Combined	93

Conclusions

1. The predicted 90%-ile value in seawater corresponding to the upper limit of category B compliance for all species was 436 *E. coli*/100 ml. This is higher than the US Restricted area 90%-ile limit of 260/100 ml. **However, the 95% confidence interval for the estimate included the US restricted limit.**
2. The 90%-ile limit for the US Approved category (88/100 ml) gave predicted compliance rates with 230 *E. coli*/100 g in bivalves that were all markedly lower than the nominal 95% compliance for EU category A used in the original 1996 report (100% compliance is implied in the legislation). **Therefore, the EU category A is more stringent than the US Approved category.**
3. The 90%-ile limit for the US Restricted category (260/100 ml) gave predicted compliance rates in bivalves that bracketed the 90% compliance with 4,600 *E. coli*/100 g for category B as given in the EU legislation. Mussels gave slightly lower compliance and *C. gigas* gave markedly higher compliance. The combined data set gave a compliance that was slightly higher than the class B requirement (93% versus 90%). This suggest that, overall, the US Restrictive standard is slightly more stringent than the EU category B, but that this also varies with mollusc species. **However, given the limitations of this type of analysis, the overall conclusion is that the EU and US standards for category B and Restricted are broadly equivalent.**
4. **The outcomes from these additional analyses using the US 90%-ile limits are in general accordance with the conclusions of the 1996 report in which the analyses were based on the US geometric mean limits.**

References

European Commission 1996. Report on the Equivalence of EU and US Legislation for the Sanitary Production of Live Bivalve Molluscs for Human Consumption. EU Scientific Veterinary Committee Working Group on Faecal Coliforms in Shellfish, August 1996. (downloadable from the information centre of www.crlcefas.org)

US FDA 2002. A Microbiological Comparison of the United States and European Union Shellfish Programs. Draft report.