

LONG TERM CLASSIFICATION OF SHELLFISH HARVESTING AREAS

Proposal to Improve Classification Arrangements for Designated Shellfish Harvesting Areas in England and Wales.

Full Regulatory Impact Assessment.

1. PURPOSE, OBJECTIVE AND INTENDED EFFECT OF MEASURES

- 1.1 The proposal aims to improve public health protection by facilitating more responsive actions to deal with potential microbiological contamination of designated shellfish harvesting areas. The current arrangements are legally compliant however increased monitoring and the proposed short-term measures to control shellfish harvesting in areas where high level microbiological results occur, will improve public health protection.
- 1.2 Determination of the underlying Long-Term Classification (LTC) status of shellfish harvesting areas will facilitate a more stable planning programme for marketing of live bivalve molluscs (e.g. filter feeding shellfish such as oysters, mussels, cockles and clams) particularly from Class B areas (See 1.4 below).
- 1.3 The LTC system will improve the classification arrangements in a way that is practical, enforceable, legally acceptable, and which delivers improved public health protection. The scheme that has been developed is intended to be the first stage of an on-going process.
- 1.4 LTC is a statistical system for classifying shellfish beds on the basis of trends in data. In the first instance LTC is proposed to apply to B Class shellfish beds (described below) with 5 years accumulated compliance data. Unlike present arrangements, the new system would provide for immediate investigation into all classification sample results above the regulatory *E. coli* levels, which in turn will increase public health assurances. The LTC is proposed to last for 5 years.
- 1.5 The proposed new 'Action State' facility would also contribute to increased public health protection by applying short-term measures in areas where unusually high results of microbiological tests suggest the potential public health risk would be greatest. These measures would include a temporary downgrade/closure for a minimum period of 14 days up to a maximum period of 3 months. Where there is a possible risk to public health Council Regulation 2004/854 states that the "competent authority must close the production area concerned". In the case of designated shellfish harvesting areas the enforcement authority is the Local Authority (LA). The Action State would result in increased sampling in the first two weeks following the high sample

result, along with a full investigation aimed at identifying the cause of it. In such cases Local Action Groups (LAGs), comprising representatives from industry, local authorities (LAs), the Environment Agency (EA) and the Marine Fisheries Agency (MFA) will be responsible for investigating incidents. Investigation will be by way of predefined Local Action Plans (LAPs).

- 1.6 The FSA is developing guidance on LAPs. There will be an electronic exchange of information to assist the LA to make an informed decision when considering whether a shellfish harvesting area should be re-opened. A number of the above actions already take place but this system will, for the first time, set down the procedures to be followed by all parties with an interest in contributing relevant information. FSA aim to issue this draft guidance by the end of March 2006.

2. BACKGROUND

- 2.1 In October 2002 the FSA instigated a public review to consider whether the classification system for shellfish harvesting in England and Wales could be improved. The outcome showed there was a good deal of support for a system of Long Term Classification (LTC) incorporating 'Action States' when test results exceeded specified limits. Such a system should secure improvements in the protection of public health and increase stability to the classification of certain harvesting areas. A set of proposals was therefore devised with the aim of improving classification arrangements by delivering improved public health protection in a way that is manageable, affordable and beneficial to both the general public and the shellfish industry. The proposals have also been developed to comply with EU hygiene legislation which sets down the rules for the production and placing on the market of live bivalve molluscs (Council Regulations 852/2004, 853/2004 and 854/2004).

Current Arrangements

- 2.2 The current classification arrangements for shellfish harvesting areas in England and Wales conform with EU legislation and are essential for protecting public health. The risk to health arises from microbiological pollutants in shellfish waters. The classification status given to a harvesting area is an indication of the likely microbiological safety of shellfish taken from that area. It determines the handling procedures that have to be undertaken before shellfish from the area may be placed on the market for human consumption. Infectious human disease acquired from the consumption of bivalve molluscan shellfish (e.g. oysters, mussels, and cockles) is an internationally recognised problem and occurs because bivalves filter pollutants from the water. Some outbreaks of food poisoning can be directly related to shellfish but these are quite small in number. It is, however, possible that outbreaks are under reported because of their sporadic nature and that the food vehicle can seldom be confirmed.
- 2.3 In accordance with EU legislation, shellfish harvesting areas are classified as A, B, C or prohibited (ie where an area is considered unsuitable for health reasons):

- Class A - shellfish samples must have less than 230 *E. coli* per 100g of mollusc flesh and intravalvular liquid. Shellfish from these areas may be sold direct for human consumption;
- Class B - shellfish samples must have less than 4,600 *E. coli* per 100g of mollusc flesh and intravalvular liquid. Shellfish from these areas must be subject to treatment in an approved purification centre or after relaying a heat treatment (set down in EU legislation) by an approved process in an approved establishment. Purification centres have to be approved and inspected. Processing establishments are also approved and regularly inspected.
- Class C - shellfish samples must have less than 46,000 *E. coli* per 100g of mollusc flesh and intravalvular liquid. Shellfish from these areas must be relayed for at least two months and heat-treated if necessary in the same manner for shellfish from Class B areas.
- Prohibited – shellfish samples show levels of *E. coli* per 100g of mollusc flesh and intravalvular liquid greater than 46,000.
- Relaying Areas – Areas where molluscs from lesser classification areas may be placed for a designated period of not less than two months. Those shellfish will then be designated as from the improved classification (ie. B Class to A class)

2.4 In 2005/6 there are 65 designated harvesting areas in England and Wales covering 371 classified shellfish beds:

- 13 Class A beds
- 321 Class B beds
- 30 Class C beds
- 7 Relaying areas

2.5 Shellfish from Class A areas are considered to be more valuable (quality issue) than those from Class B areas. Some of the major retail outlets will only purchase shellfish from Class A waters. Shellfish from Class B areas must meet the same end product standard shellfish from Class A.

2.6 Some classified beds are very large and are therefore regulated by LAs issuing licences and permits. Under supervision of the LAs the relevant Sea Fisheries Committee or the Port Health Authority normally carries out enforcement in these areas. Other beds may be very small and only fished a few times during the year. Some beds may only be accessible by diving. The LA may also close beds for periods of time for conservation reasons. Unless beds are privately owned they may be fished by more than one person. The boundaries are set where the beds start and finish. The shellfish industry is relatively small, generally very localised, and important to local, mainly coastal, economies. In 2004, the total shellfish catch for human consumption from classified areas throughout the UK was estimated at 43,168 tonnes at an estimated value of £24m.