

# Links between the Marine Strategy Framework Directive, the Shellfish Waters Directive and the EU Food Hygiene Regulations

Factsheet 6

August 2012

## Background

The Marine Strategy Framework Directive (MSFD) commits us to taking the necessary measures to achieve or maintain Good Environmental Status (GES) in the marine environment by 2020 at the latest. One of the descriptors (elements) of environmental status is 'Contaminants in Biota' (for example, mercury in shellfish), which raises the question of the linkages between MSFD and the legislation covering the quality and safety of shellfish and shellfish waters.

This factsheet has been written for the shellfish industry to explain the way in which the implementation of the MSFD will relate to existing regulations for shellfish.

The requirements for shellfish hygiene and shellfish water quality are outlined in two pieces of European legislation:

- Shellfish Waters Directive and
- EU Food Hygiene Regulations.

## How are shellfish waters protected under existing legislation?

The purpose of the Shellfish Waters

Directive (2006/113/EEC) is to ensure that Member States designate waters in need of protection or improvement to support shellfish growth. This Directive simplifies the original Shellfish Waters Directive of 1979 (79/923/EEC). It covers bivalves and gastropods (winkles, whelks etc). This Directive is specifically to *contribute* to the quality of flesh directly edible by man. However, this Directive recognises an important principle when considering shellfish, which is that you cannot directly protect the consumer by protecting water quality alone. For this reason, the Directive sets a guideline standard for faecal coliforms<sup>1</sup> in shellfish flesh but no corresponding standard for waters. No clear relationship has been established between faecal coliform levels in shellfish tissue and the microbiological quality of the surrounding waters, excepting those waters which are polluted<sup>2</sup>.

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<sup>1</sup> An indicator of faecal pollution from either animal or human origin

<sup>2</sup> Investigation of the relationship between indicator bacteria in mussel flesh and intervalvular fluid and surrounding waters. Phase 3 SR97(07) F., Milne, D.P., Higgins, J.E. and Brodie, I.J. (1998). Scotland and Northern Ireland Forum for Environmental Research.



The Shellfish Waters Directive also requires Member States to set mandatory water quality standards for pollutants like metals and organohalogens (for example, DDT), in addition to the shellfish flesh standards that 'contribute' to ensuring that the product is edible. Where waters do not meet the standards, Member States have to develop pollution reduction programmes. These are an integral part of the river basin management plans developed under the Water Framework Directive (WFD).

The vast majority of UK commercial shellfish operations lie within the WFD area. The Shellfish Waters Directive is to be repealed by the WFD in 2013, but these waters will keep the same level of protection<sup>3</sup>. Existing Shellfish Waters will become WFD Protected Areas that are designated to protect economically significant aquatic species. New areas will be considered for designation as long as they are 'economically significant'.<sup>4</sup> This is likely to cover all commercially operated shellfisheries within UK waters. It will give protection to all shellfish waters within the WFD managed area (one nautical mile out to sea for England, Wales and Northern Ireland, and three nautical miles for Scotland). The Scottish Government is currently considering a more pro-active approach to designation in response<sup>5</sup> to its recent consultation.

## How are consumers of shellfish protected under existing legislation?

Consumers of shellfish are protected by three pieces of EU Food Hygiene Regulations:

- Regulation (EC) 852/2004 on the hygiene of foodstuffs
- Regulation (EC) 853/2004 laying down specific rules for food of animal origin and

- Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

These EU Food Hygiene Regulations repealed and replaced the Shellfish Hygiene Directive (91/492/EEC) on 1 January 2006.

The general hygiene requirements for all food business operators are in Regulation (EC) No. 852/2004. Regulation (EC) No. 853/2004 supplements Regulation (EC) No. 852/2004 with specific requirements for food businesses dealing with foods of animal origin. Regulation (EC) No. 854/2004 sets out how controls will operate for products of animal origin that are intended for human consumption.

Regulation (EC) No. 853/2004 lays down the hygiene requirements for the production and harvesting of shellfish and sets specific end product and health standards which the product must meet before being sold for human consumption. These hygiene requirements include the purification of shellfish to reduce the level of faecal contamination, using *E.coli* as an indicator, detected in the flesh. Regulation (EC) No. 854/2004 outlines the controls which the Member State must carry out in relation to shellfish production areas, including the classification and monitoring of such areas.

Classified shellfish production areas are routinely monitored for the Food Standards Agency for microbiological contamination, algal biotoxins (such as amnesic, diarrhoeic and paralytic shellfish poisoning), toxin producing algae and chemical contamination. If levels of contamination are detected in official control samples above the regulatory limits, production areas are closed until satisfactory levels return. Algal biotoxins cannot be directly correlated with other contaminants, and biotoxin events can occur in pristine environmental conditions.

<sup>3</sup> WFD Preamble Paragraph 51 and Article 22

<sup>4</sup> WFD Annex IV 1ii

<sup>5</sup> <http://www.scotland.gov.uk/Publications/2012/05/8479>

## Will the levels of protection change with the introduction of MSFD?

As explained above, the most relevant legislation for the management of shellfish waters will be the pollution reduction programmes put in place as part of the river basin management plans under the WFD. Shellfish water protected areas will be required to meet the environmental quality standards set out in the river basin management plans.

In addition to this, the Commission Decision on Good Environmental Status<sup>6</sup> for MSFD proposes that the concentrations of contaminants do not exceed the relevant maximum levels listed in the European Commission Regulation 1881/2006 on the levels of contaminants in foodstuffs. These standards are to protect human health. *Charting Progress 2*<sup>7</sup> reports that chemical contaminant levels rarely exceed maximum levels in classified production areas used for commercial harvesting. Where levels are exceeded, the MSFD would require the Government and the Devolved Administrations to put in place a programme of measures to reduce contaminant levels by 2016. This is to ensure that the quality standards can be achieved by 2020 as part of GES.

It is accepted that the quality standards in shellfish flesh should be standardised around the Regulation 1881/2006 for both WFD and MSFD. This was the approach generally taken within *Charting Progress 2*, although other quality standards were used where a substance was not covered in Regulation 1881/2006.

<sup>6</sup> Commission Decision (2010/477/EU) on criteria and methodological standards on good environmental status of marine waters.

<sup>7</sup> <http://chartingprogress.defra.gov.uk/>

## Why are biotoxins and microbial contamination not included under Descriptor 9 – Contaminants in Biota?

The International Council for the Exploration of the Sea (ICES) and the Commission's Joint Research Centre (JRC), which produced advice on the scope of this Descriptor, agreed that hazardous substances should be defined in this instance as substances (i.e. chemical elements and compounds) or groups of substances that are toxic, persistent and liable to bio-accumulate, and other substances or groups of substances which give rise to an equivalent level of concern.

This means that microbial contaminants do not fall within the interpretation of this Descriptor (although their status is considered in the UK Initial Assessment). For biotoxins, the ICES and JRC specifically agreed that although regulatory levels have been set, they should not be considered, as their presence in fish and seafood cannot always be clearly linked to human activities. For example, harmful algal bloom events can arise from climatic and hydrographical circumstances as well as from human induced eutrophication and the distinction is not necessarily clear. The UK will continue to maintain the robust systems we have in place to protect public health from contamination of seafood by biotoxins and microbial contamination.

## Will bacteria or viruses be incorporated in GES in the future?

No criteria and indicators have been developed for pathogens like bacteria or viruses since the Commission Decision on GES criteria in 2010. Likewise, bacteria and viruses are not mentioned within Annex I of the MSFD (2008/56/EC). Although these could, in theory be incorporated in the future, it is important to recognise the principles outlined in the existing legislation.

These are that

- consumers of shellfish cannot be protected by water quality protection measures alone;
- environmental protection measures can only *contribute* to the quality of product edible by man; and
- the health protection measures under the EU Food Hygiene Regulations will always be essential in protecting public health.

Microbiological standards in coastal waters will continue to be driven by the Bathing Water Directive and Shellfish Water Protected Areas under WFD.

Research will also continue to be carried out to understand the potential health implications of bacterial (for example, *E.coli*) and viral (for example, norovirus) contamination in shellfish.

Cefas (Centre for Environment, Fisheries and Aquaculture Science) has recently (2011<sup>8</sup>) completed a study into norovirus and *E.coli* in oysters, funded by the Food Standards Agency. Both pathogens can lead to serious illness so understanding their distribution is important. Results show that levels of norovirus varied seasonally, with higher levels and prevalence in samples collected between October and March, compared to those obtained between April and September. Several factors may contribute towards the higher levels of norovirus seen during the winter months. This result is consistent with previous studies carried out at Cefas and at other laboratories.

The study found a statistically significant and predictive correlation between *E.coli* and norovirus levels, and a strong

correlation between norovirus contamination and environmental temperatures.

The Cefas team developed a risk scoring system based on existing and recent harvesting area classifications, *E.coli* contamination profiles, population densities in adjacent areas and reported shellfish-associated outbreaks. The observed correlation between norovirus levels and identified risk factors could improve predictions about norovirus for the future.

**You can find out more about the MSFD at:**

[www.defra.gov.uk/environment/marine/msfd/](http://www.defra.gov.uk/environment/marine/msfd/)

**If you have any questions, please contact:**

[MSFDTeam@defra.gsi.gov.uk](mailto:MSFDTeam@defra.gsi.gov.uk)

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<sup>8</sup> <http://www.cefas.defra.gov.uk/news/web-stories/first-time-systematic-study-into-norovirus-in-oysters-published.aspx>