

## **Guide to Recent Developments in European Food Law for the Seafood Industry**

There has been a major overhaul of food law by the European Commission in the last few years; this has led to some confusion and misunderstandings about the burdens this will place on food businesses. The aim of this guidance is to clarify any new requirements for the seafood industry.

The Commission have introduced regulations to replace existing national food law in all Member States. Previous food law originated from the Commission, but as Member States were permitted to make national laws to enact European law there were differences between the Member States' national laws.

Prior to 1 January 2006, UK food law for the seafood industry also included:

- The Food Safety Act 1990. This act makes it an offence to sell unsafe food. It also covers descriptions, quality and gives powers for enforcing and making food law.
- The Food Safety (General Food Hygiene) Regulations 1995 contained rules for the production of safe food. They applied to all food businesses (except primary production) and those covered by product specific hygiene rules. Fish and shellfish were covered by product specific legislation.
- The Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998. These contained specific rules for fish and shellfish which placed stricter controls on businesses than the general food hygiene rules, although some businesses (such as retail) were exempt and so needed to comply with the general rules.
- The General Food Hygiene and Fishery Product regulations were repealed at the end of December 2005 when the new European rules for food came into force. These can be categorised as: rules on the production of safe food, rules on the enforcement to ensure safe food, and rules to define what safe food is.

## **New rules on the production of safe food**

**Regulation 178/2002/EC laying down the general principles of food law, establishing the European food safety authority and laying down procedures in matters of food safety.** This is the overarching regulation which contains provisions to ensure safe food and feed including traceability and product recall. It contains general definitions applicable to other legislation.

**Regulation 852/2004/EC on the hygiene of foodstuffs.** This contains the basic requirements applicable to all food businesses. It requires food business operators to consider the risks in their business and set acceptable limits for any risks.

**Regulation 853/2004/EC laying down specific hygiene rules for food of animal origin.** This contains additional more prescriptive provisions for food considered to be higher risk. Unless specified, it does not apply to retail premises or where processing takes place for sale direct to the final consumer.

## **New rules on the enforcement to ensure safe food**

**Regulation 854/2004/EC laying down specific rules on the organisation of official controls on products of animal origin intended for human consumption.** These contain the provisions for official controls of products of animal origin and prescribe enforcement procedures to be carried out by competent authorities in respect of Regulation 853/2004/EC.

**Regulation 882/2004/EC on official controls to ensure the verification of compliance with feed and food law, animal health and welfare rules.** These contain the provisions for official controls of products of animal origin and prescribes enforcement procedures to be carried out by competent authorities in respect of Regulation 852/2004/EC and Regulation 853/2004/EC.

## **Rules to define what is safe food**

**Regulation 2073/2005 on Microbiological Criteria for Foodstuffs.** This sets acceptable microbiological limits for some foods. Food safety management plans such as HACCP (see Q 25) must ensure these criteria are met. The criteria will also be used for official controls and ensuring food is 'safe'. For seafood most of these are not new criteria and were previously contained in the product specific directives. There are new criteria for Listeria in ready to eat foods, which will include smoked fish and fish that is consumed raw.

As a result of the new European laws the meaning of 'food' for legal purposes was changed to include food sold live (shellfish). The meaning of 'food business' now includes all food production including primary production (catching, aquaculture and transport). This change will affect those involved in the initial stages of the food

chain such as the catching sector; all stages of the food chain are now responsible for maintaining food safety within their operations.

Regulation 178/2002/EC also introduced a new requirement of traceability (where you obtain your raw material from and where your product goes) and product recall if an unsafe product is placed on the market.

HACCP may be a new requirement for some businesses. It can also be known as Good Management Practice (GMP). Previously a less detailed version of HACCP/GMP was found in the general food hygiene rules and for establishments handling fishery products, but not in the rules for live bivalve molluscs or primary production. For some businesses in the seafood industry this will be a new requirement. HACCP/GMP appears to be very prescriptive, but the requirement is that procedures should be flexible and based on risk and size of business. Therefore it should not place a disproportionate burden on business. A minimum requirement would be that food businesses have in place systems to identify and control significant hazards on a permanent basis, and adapt that system whenever necessary.

The regulations recognise and allow for guides to good practice as a simple but effective way to overcome the difficulties in establishing a detailed HACCP/GMP procedure, particularly for small businesses. The use of these guides may help businesses to control hazards and demonstrate compliance without the need for a formal HACCP/GMP procedure. For Seafish guides see [www.seafish.co.uk](http://www.seafish.co.uk)

The microbiological criteria which determine the acceptability of a product or process based on the microbiological levels should be applied within a food safety management system such as HACCP/GMP. This is intended to be proportional to risk and not place unnecessary burdens on business, so it does not necessarily mean actual testing. The criteria can be met by process monitoring to ensure the criteria are met.

If food is found to be unsafe, food business operators have an obligation to withdraw or recall the product. Procedures for traceability and recall must be maintained to facilitate this process.

The criteria will also be used for official controls which require competent authorities to verify business compliance with microbiological criteria.

Regulation 853/2004 does not generally apply to retail, although this is limited to 'activities involving direct sale or supply of food of animal origin to the final consumer'. Any other businesses supplying fish and shellfish products to another business will have to comply with 853/2004, unless the business supply is a 'marginal, localised and restricted activity'.

## **For All Businesses**

### **1. What is a 'food business operator'?**

A 'food business' is any business dealing with food. It does not have to be for profit and can be a public or private business. A 'food business operator' is therefore the actual person or the company responsible for ensuring that the requirements of food law are met within that business. Fishermen are included as 'food businesses'.

### **2. What is primary production?**

Primary production is defined for the purposes of food law as the production, rearing or growing of primary products. It includes fishing, gathering of shellfish and aquaculture. It also includes transport of primary products and live animals, from the place of production to an establishment, as long as this does not substantially alter their nature.

For the seafood industry 'primary production' will be:

- Any handling of fishery products which does not substantially change their nature. It applies to operations on board vessels (except factory and freezer vessels) and transport to the first establishment on land. It also includes the fishing, handling and transport of fish caught in fresh waters. The handling, storage and transport of fishery products on board freezer and factory vessels are not covered by the term 'primary production'.
- The production, rearing, growing and harvesting of fish in aquaculture farms and transport of fish to the first establishment.
- The production, growing and harvesting of live bivalve molluscs. It also includes transport to the first establishment which may be a dispatch centre, purification centre or processing establishment.
- Fishery products remain 'primary products' even after slaughter, bleeding, handling, gutting, removing fins, refrigeration and wrapping at the level of primary production.

### **3. What legislation applies to primary production?**

Most food business operators carrying out primary production must only comply with the general hygiene provisions in part A of Annex I of Regulation 853/2004 and also the general principles of food law in Regulation 178/2002 (enforced by the Food Safety Act 1990). This contains basic requirements that are intended to protect food from contamination, but the end use and any processing that may remove contamination can be taken into account when considering the risks. There are

additional requirements within Regulation 853/2004 for higher risk products such as live bivalve molluscs.

**4. Do all fish and shellfish businesses have to comply with Regulation 852/2004?**

No, there is an exemption for small quantities of primary products sold from the producer directly to the final consumer. However there is still a general requirement that these products are 'safe'. For small quantities see Q 6.

**5. Do all fish and shellfish businesses have to comply with Regulation 853/2004?**

No, there is an exemption for businesses selling directly to the final consumer i.e. retail (although some rules for live bivalves molluscs will apply to retail). Businesses who supply some product to other business may be exempt if this supply is considered to be a 'marginal, localised and restricted activity'.

**6. What about direct sales of small quantities of fish and shellfish?**

The regulations do not apply to small quantities of primary products supplied directly by the producer to the final consumer, or to local retail establishments directly supplying the final consumer e.g. local fishmongers or restaurants.

'Local' is defined as sales within the supplying establishments own food authority plus either the neighbouring county or 30 miles from the boundary of the supplying establishments' county – whichever is greater.

A small quantity continues to be defined as 25 tonnes of live bivalve molluscs or fishery products per calendar year. This can be made up of mixed species subject to individual species limits (for details please see the Food Standards Agency's Food Law – Practice Guidance). While the regulations do not apply to exempt products, The Food Safety Act 1990 still applies, which makes it the responsibility of the harvester to ensure that food is safe i.e. that the end product standard is met. In the case of live bivalve molluscs they must have been harvested from 'Class A Water'. 'Class A Waters' are areas that have been designated by the local food authority as suitable for harvesting live bivalve molluscs for direct human consumption i.e. without purification.

**7. Do the regulations apply to internet sales?**

Yes, such business will fall within the definition of a 'food business' and any relevant food law will be applicable.

**8. When does an animal become 'food'?**

'Food' for the purposes of food law includes live animals when they are 'prepared for placing on the market for human consumption'. This has been interpreted to mean that an animal becomes 'food' when it is intended for human consumption, for example bivalve molluscs on harvesting or fish at the point of capture.

## **9. What is the difference between registration and approval?**

Registration with the Local Authority should be done by a business within 28 days of opening or changes to operations. Local Authorities cannot refuse to register a business. The register then allows authorities to plan inspections effectively.

Approval must be sought by some businesses before they can legally trade. The Local Authority can refuse or revoke an approval if the food safety standards are not sufficient.

## **10. Do I need to register with my Local Authority?**

The general hygiene rules require all food business operators to register with their Local Authority. Businesses should provide information on their business operations within 28 days of beginning operations and within 28 days of any changes. This is to allow Local Authorities to plan their inspections and is not a pre-approval for trading. This will apply to all 'food businesses' including primary production and those businesses which only trade in food i.e. businesses who arrange the movement of food between businesses, but do not actually handle or store the food.

## **11. Do I need to be pre approved by my Local Authority?**

Businesses subject to Regulation 853/2004 need to be approved by the Local Authority before trading. However those only subject to Regulation 852/2004 do not have to gain approval before trading, but they do however have to register with their local food authority (see Q 10).

## **12. What is traceability?**

This means the ability to trace the food, feed, food-producing animal or substance to be included in food back through all stages of production, processing and distribution. Traceability systems will also assist in product recalls if a problem is identified after the product is placed on the market.

## **13. Does traceability apply to primary production?**

Yes, it applies to all stages of the food chain from primary production to retail. Those at the beginning of the chain (e.g. fishing vessels) will not have a supplier and so for the purposes of food law, will only need to keep records of who they supply to. Records of catch may still be required by fisheries management and control legislation.

#### **14. Does traceability apply to third country imports?**

The requirement is for traceability within the EU. So in such cases the traceability requirement covers all stages from importer to retail. However the importer must maintain records to identify from whom the product was exported. Seafish has produced separate guidance on imports. Copies of this guide are available at [www.seafish.co.uk](http://www.seafish.co.uk).

#### **15. Do I need to maintain internal traceability within my premises?**

There is no legal requirement for maintaining internal traceability. Nor is there any requirement for records to be kept that identify how batches are split and combined in products. But an internal traceability system will contribute to a more targeted and accurate withdrawal in the event of a food safety issue, which could reduce product losses.

#### **16. How do I implement traceability?**

Operators should have in place systems and procedures to make traceability information available on demand to the competent authority. Food or feed which is placed on the market must be adequately identifiable to enable it to be traced throughout the food chain by documentation. You should be able to identify products and maintain records of supplies from other businesses and supplies to other businesses. There is no requirement (for this purpose) to maintain records of source if it is wild caught or harvested (except for live bivalves molluscs which must be accompanied by registration documents) or of destination if supplied to the final consumer.

The requirement of each operator in the chain is to be able to identify any person from whom they have been supplied with a food, feed, food-producing animal or substance to be included in food, and also be able to identify the other businesses to which they have supplied products.

## **17. What information should be kept?**

There may be specific requirements for the information that must be recorded, such as is already the case with live bivalve molluscs, but the basic requirement for information which must be kept and be made available to competent authorities on demand is:

- Name, address of supplier, nature of products which were supplied.
- Name, address of customer, nature of products received.
- Date of transaction or delivery.
- Volume or quantity (for live bivalve molluscs).

In addition it is recommended information is kept on;

- Volume or quantity.
- Batch number.
- A detailed description of the product.

## **18. How long should I keep traceability records?**

There may be specific requirements for the length of time records should be kept, such as with live bivalve molluscs. Generally it is recommended that documents are held for 5 years for products without a specified shelf life. For products with a shelf life of above 5 years, records should be kept for the 6 months past the shelf life. For highly perishable products with a 'use-by' date of less than 3 months or without a date, destined directly to the final consumer, records should be kept for 6 months after the date of manufacture or delivery.

## **19. I use 'traditional' methods to produce my product that do not comply with the new requirements - will I need to change these practices?**

No, food may be manufactured using traditional methods that have proven their safety, even if not fully compliant with the regulations. However you must be able to demonstrate that the process maintains equivalent standards to those of the relevant hygiene regulations. The safety of such methods must be discussed with your Local Authority.

**20. What is a ‘marginal, localised and restricted activity’?**

This allows a retailer to do two things - produce small quantities of food, most of which is supplied to other businesses; or to produce larger amounts of food, with the prerequisite that the amount of produce supplied to other business represents a small part of their operations (up to a quarter of the business in terms of food). This food would still need to be traded locally (sales within the supplying establishments own food authority plus the greater of either the neighbouring food authority, or 30 miles from the boundary of the supplying establishments’ food authority).

For seafood retailers, the ‘small quantities’ exemption used for Regulation 852/2004 has been extended to cover this exemption. See Q 6.

**21. What is meant by ‘where necessary’, ‘where appropriate’, ‘adequate’ and ‘sufficient’ when used in the regulations?**

Where these terms are used it is up to the food business operator to decide whether a requirement is necessary, appropriate, adequate or sufficient to achieve the objectives of Regulation 852/2004/EC. The operator should take into account the nature of the food and its intended use in determining measures needed to control risk. Risk assessments may be contained in HACCP documents, operational procedures or guides to good practice.

## 22. What are the micro-biological criteria?

As part of the hygiene package,, all food business operators (including primary producers) are required to comply with the Microbiological Criteria for Foodstuffs 2005 which came into force on 1 January 2006. It contains food safety criteria for certain foods (either during production or during the products shelf life) and micro-organisms. For seafood these are:

Food Category	Micro-organism	Limit	Stage of production
Ready to eat foods able to support the growth of <i>L. Monocytogenes</i> .	<i>Listera monocytogenes</i> .	5 samples with less than 100 cfu/g.	Products placed on the market during their shelf life.
		5 samples with no presence in 25g.	Before the food has left the control of the producer.
Ready to eat foods unable to support the growth of <i>L. Monocytogene</i> .	<i>Listera monocytogenes</i> .	5 samples with less than 100 cfu/g.	Products placed on the market during their shelf life.
Cooked crustaceans and molluscan shellfish.	<i>Salmonella</i> .	5 samples with no presence in 25g.	Products placed on the market during their shelf life.
Live bivalve molluscs and live echinoderms, tunicates and gastropods.	<i>Salmonella</i> .	5 samples with no presence in 25g.	Products placed on the market during their shelf life.
Live bivalve molluscs and live echinoderms, tunicates and gastropods.	<i>E. coli</i> .	1 sample (10 animals ) with <230 MPN/100g flesh and intra-valvular liquid.	Products placed on the market during their shelf life.
Fishery products from fish species associated with a high amount of histamine.	Histamine.	9 samples to be taken, of which at least 7 must have levels below 100mg/kg and the remainder below 200mg/kg.	Products placed on the market during their shelf life.
Fishery products which have undergone enzyme maturation treatment in brine, manufactured from fish species associated with a high amount of	Histamine.	9 samples to be taken, of which at least 7 must have levels below 200mg/kg and the remainder below 400mg/kg.	Products placed on the market during their shelf life.

histamine.			
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**23. How are the micro-biological criteria applied?**

The criteria should be applied within the risk based food safety management system, as a validation and verification of HACCP procedures (steps f and g - see Q 25).

The microbiological criteria set limits to determine the acceptability of a product or process based on the microbiological levels. These limits should be used in the food safety management system such as HACCP, which will ensure that any monitoring is proportional to risk. Ensuring your products meet any criteria can be done by microbiological testing, but also by monitoring process controls that will ensure the criteria are met.

The criteria also extend to official controls which require competent authorities to verify business compliance with microbiological criteria.

**24. What if my product is outside of the acceptable microbiological criteria?**

When food exceeds the criteria, or the process controls are outside of the acceptable range, the food is considered unsafe. Food business operators have an obligation to correct the failure within the safety management system or withdraw or recall unsafe food if it cannot be made safe.

## 25. What is HACCP?

HACCP (Hazard Analysis and Critical Control Points) identifies specific hazards and measures for their control to ensure the safety of food. It focuses on prevention of unsafe food during production rather than relying on end product testing to remove any unsafe food. HACCP can be applied throughout the food chain from primary production to final consumption. HACCP can improve food safety and also aid inspection by regulatory authorities, and promote international trade as it is an internationally recognised system.

HACCP consists of 7 principles:

- (a) identify any hazards that must be prevented, eliminated or reduced to acceptable levels;
- (b) identify the critical control points at the step or steps at which control is essential to prevent or eliminate a hazard or reduce it to acceptable levels;
- (c) establishing critical limits at critical control points which separate acceptability from unacceptability for the prevention, elimination or reduction of identified hazards;
- (d) establishing and implementing effective monitoring procedures at critical control points;
- (e) establishing corrective actions when monitoring indicates that a critical control point is not under control;
- (f) establishing procedures, which shall be carried out regularly, to verify that the measures outlined in subparagraphs (a) to (e) are working effectively; and
- (g) establish documents and records commensurate with the nature and size of the food business to demonstrate the effective application of the measures outlined in subparagraphs (a) to (f).

This is not a new requirement. Most food businesses were required to carry out steps (a) to (e) previously. The inclusion of steps (f) and (g) means that it must now be demonstrated that steps (a) to (f) are effective and documents must be kept to show that the plan is being implemented effectively.

Prior to considering HACCP, the food business operator should have implemented the basic hygiene requirements. Any hazards to food safety can then be identified and controlled. Factors to be considered include, raw materials, food manufacturing processes to control hazards, likely end use of the product, and categories of consumers who require special care who may consume the product.

HACCP focuses control at critical control points (CCPs) which are the stages of production which are considered critical to the production of safe food e.g. cooking time/temperature to kill bacteria. Each process step should be assessed as to its importance in maintaining food safety. The HACCP should be reviewed when any changes are made in the process.

## **26. Do I need a HACCP?**

With the exception of primary production, all food businesses should have a documented HACCP. This HACCP is not necessarily full HACCP but should be appropriate to size and degree of risk of your business. The requirements for a HACCP could be fulfilled by Good Management Practice (GMP).

## **27. How should I apply HACCP?**

The regulations allow HACCP principles to be implemented with sufficient flexibility in all circumstances.

In certain food businesses, it is not possible to identify critical control points and in such cases, good hygienic practices can replace the monitoring of critical points.

## **28. Can I use guides to good practices to develop a HACCP?**

Guides to good practice are a simple way to implement a HACCP. They can be applied to any food sector but are best suited where the handling of the food is in accordance with well known procedures or part of vocational training. Guides may describe simple ways to control hazards without a formal HACCP.

## **29. Can I use a generic guide?**

Generic guides may suggest hazards and controls common to certain food businesses, and so assist the manager throughout the HACCP process.

In using guides or generic HACCP, you should be aware that other hazards may be present which are unique to your business (such as layout) and therefore not included. There will still be a need for identification and control of these risks.

## **30. When would a food be considered unsafe?**

When a food does not comply with specific rules governing its safety (such as contaminants legislation, hygiene regulations or microbiological criteria), it can be presumed that the food is unsafe. The criteria for unfit food are contained in Regulation 178/2002 which also allows regard to be had for the normal conditions of use of the food by the consumer.

If an operator believes that a food is unsafe, despite conforming to legislation governing its safety it should also be withdrawn. For example the unforeseen presence of glass.

### **31. What do I do if I find an unsafe product?**

Food businesses are required to notify the competent authorities of food that is not in compliance with food safety requirements, which means both the Food Standards Agency and the Local Authority. This can be done using the form found at [www.food.gov.uk/foodindustry/foodfeedform](http://www.food.gov.uk/foodindustry/foodfeedform)

### **32. When should I withdraw unsafe food?**

Operators have an obligation to withdraw and notify competent authorities of an unsafe food which has left their immediate control (where the food has not left the control of the business, and so full withdrawal can be assured there is no need to notify the competent authority). Where the product may have reached the consumer, the operator must inform the consumer and recall any products supplied.

### **33. What documents do I need to keep for Local Authority inspections?**

You need to keep documents relating to your HACCP and its verification and also any other documents to show compliance with any legal requirements. Documentation may be such things as laboratory test results, pest control reports, temperature measurements and documents from the supplier of any construction materials or equipment to show its suitability.

You should keep traceability records as well as any HACCP documentation and records of critical control point checks.

Producers/handlers of live bivalve molluscs will also need to keep registration documents.

### **34. How long should I keep documents for?**

Records should be kept for a period long enough so that in case of a food alert, information is available that can be traced back to the food in question - e.g. two months after the latest date of consumption. The rules for the keeping of traceability records can also be applied here. See Q 18.

### **35. What level of training in food hygiene should my staff receive?**

Training should be proportional to the tasks of the staff in a food business. Training can be by in-house training, organised training courses, information campaigns from professional organisations or competent authorities, guides to good practice etc.

HACCP training may also be required for managers or others responsible for HACCP implementation. The training should be adequate for the complexity of the HACCP.

### **36. Where can I get information on training packages?**

Information on training packages can be obtained from your trade association - who may run courses tailored to meet the needs of your business - or general courses are run by Local Authorities. Seafish also run industry specific courses, see [www.seafish.org](http://www.seafish.org)

### **Additional Requirements For Businesses subject to Regulation 853/2004/EC**

### **37. What types of business does Regulation 853/2004/EC apply to?**

Regulation 853/2004/EC applies to businesses handling unprocessed and processed food of animal origin. It will apply to products using unprocessed fish and/or shellfish and products of plant origin. But it does not apply to foods containing processed seafood, and products of plant origin, as the processed fish and shellfish will have been produced in an approved premise.

In determining if a product of animal origin is processed or unprocessed (and what rules apply) regard should be had for all the definitions contained in the hygiene regulations. These are repeated in annex I of this guidance.

### **38. What is a 'product of animal origin'?**

A product of animal origin is any food product which is derived from any animal source. This includes live bivalve molluscs, live echinoderms, live tunicates, live marine gastropods intended for human consumption and any other animals destined to be prepared for supply to the final consumer.

### **39. Is primary production covered by Regulation 853/2004/EC?**

Yes, certain annexes relating to specific products of animal origin include primary production, where it was felt important to control risks to food safety during primary production.

Primary production of live bivalve molluscs includes any operations before arrival at a dispatch or purification centre. Rules for these operations are contained in Regulation 853/2004.

Primary production of fishery products includes farming/fishing/collection of live fishery products with a view to their being placed on the market. It includes slaughter, bleeding, gutting, removing fins, refrigeration and wrapping carried out on board vessels. Transport which does not substantially alter the nature of the fishery product - within farms or from production to the first establishment - is also considered to be primary production.

#### **40. What is an unprocessed product?**

It is food that has not undergone processing. Processing does not include products that have been; severed, sliced, boned, minced, skinned, cut, cleaned, trimmed, chilled, frozen, deep-frozen or thawed.

#### **41. What is a processed product?**

It is a food resulting from the processing of unprocessed products. These products may contain additional ingredients.

#### **42. What is processing?**

This is any action which substantially alters the initial product. It includes heating, smoking, curing, maturing, drying, marinating, extraction or any combination of these processes. A process is only deemed 'processing' for the purpose of this Regulation if it is applied directly to an unprocessed product, such as smoking of fish. It does not include indirect treatment, such as the assembly of many ingredients to make a composite product.

#### **43. What is retail?**

For general application, 'retail' has been interpreted to mean the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer. It will include distribution terminals, catering and other food service operations, shops and wholesale outlets.

However for the purposes of the hygiene legislation it has been limited to 'activities involving direct sale or supply of food of animal origin to the final consumer'.

Premises supplying the consumer directly are only subject to the general hygiene regulations, but businesses supplying other businesses will be subject to the hygiene rules for products of animal origin. Establishments for which the wholesale activities consist only of storage and transport (and which do not process food) are only subject to the general food hygiene regulation and the temperature requirements of the regulation for products of animal origin.

#### **44. Does Regulation 853/2004/EC apply to retail?**

No, most retail premises are subject only to Regulation 852/2004/EC. There is also an exemption for 'marginal, localised and restricted' supply to other businesses for business whose operations would otherwise be subject to regulation 853/2004/EC.

#### **45. What parts of Regulation 853/2002/EC do apply to retail?**

Some of the rules for live bivalve molluscs apply to retail as business supplying other businesses. These are the rules governing health standards, wrapping and packaging, identification marking and labelling and storage conditions. The only new

requirement is that live bivalve molluscs can no longer be sprayed or re-immersed in water once they have left the dispatch centre.

There are also specific requirements for the retail sale of scallops. Scallops may not be placed on the market unless they have been handled and harvested in accordance with the rules that apply to live bivalve molluscs and meet the specified health standards.

If scallops are harvested from classified waters then the requirements for production areas also applies.

#### **46. What is an establishment?**

An establishment is now defined as 'any unit of a food business'. In businesses made up of different 'units' some units may require approval while others do not.

#### **47. What establishments require approval?**

Establishments handling foods are specified in Regulation 853/2004/EC e.g. live bivalve molluscs and fishery products (includes shellfish). This includes establishments handling both non-processed products and processed products of animal origin. It does not include establishments handling processed products of animal origin and non-animal origin, provided that the processed animal products have come from an approved establishment.

Examples of premises which will require approval will be: live bivalve mollusc dispatch centres and purification plants, freezer and factory vessels, establishments on land such as wholesale markets and auction halls where fishery products are displayed for sale, freezing establishments, establishments producing mechanically separated fish flesh and processing establishments.

#### **48. Will approval place extra burdens on the small business?**

No, the approvals for such establishments are largely the requirements that applied already to them under the previous rules. The reduction in the availability of exemptions from approval may mean that some businesses may need approval for the first time. However small business selling directly to the final consumer will be exempt from Regulation 853/2004/EC and will not require approval. See Q 5.

#### **49. Do cold stores need approval?**

Regulation 853/2004/EC includes cold stores within its scope. Therefore cold stores handling products included in this regulation will require approval from the competent authority.

Cold stores operated by retail outlets and those which are limited to transport and storage only are not covered by Regulation 853/2004/EC and do not need to be approved. These will need to comply with the temperature control requirements.

**50. I re-wrap products; do I need to be approved?**

If the re-wrapping includes the un-wrapping and hence exposure of product then it is considered to be handling foods of animal origin and therefore within the scope of Regulation 853/2004/EC and will therefore require approval.

**51. What changes will it make to my business?**

Businesses which had previously to comply with the Food Safety (Fishery Products and Live Shellfish) (Hygiene) Regulations 1998 will now have to comply with Regulation 852/2004 and Regulation 853/2004 which will introduce some new requirements and controls, as well as additional requirements resulting from Regulation 178/2002/EC.

The requirements of Regulation 852/2004/EC will apply to all businesses. This will mean food safety management based on HACCP principles and procedures to ensure compliance with any microbiological criteria. There will also be a requirement for traceability and product recall procedures in the event of unsafe food being placed on the market.

**52. What changes have been made to the Health Mark required on products from approved premises**

The Health Mark information i.e. the two letter code to indicate the country in which the establishment is located, the approval number of the establishment and the include the abbreviation CE,EC,EF,EG,EK or EY. This information must now be in an oval shape.

## ANNEX I

### Definitions

Contamination	Presence or introduction of a hazard.
Potable water	Water meeting the minimum requirements laid for human consumption.
Clean seawater	Natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food.
Clean water	Clean seawater and fresh water of a similar quality.
Bivalve molluscs	Filter feeding lamellibranch molluscs.
Marine biotoxins	Poisonous substances accumulated by bivalve molluscs, in particular as a result of feeding on plankton containing toxins.
Conditioning	The storage of live bivalve molluscs coming from class A production areas, purification centres or dispatch centres in tanks or any other installation containing clean seawater, or in natural sites, to remove sand, mud or slime, to preserve or to improve organoleptic qualities and to ensure that they are in a good state of vitality before wrapping or packing.
Gatherer	Any natural or legal person who collects live bivalve molluscs by any means from a harvesting area for the purpose of handling and placing on the market.
Designated Production area	Any sea, estuarine or lagoon area, containing either natural beds of bivalve molluscs or sites used for the cultivation of bivalve molluscs, and from which live bivalve molluscs are taken for commercial purposes.
Relaying area	Any sea, estuarine or lagoon area with boundaries clearly marked and indicated by buoys, posts or any other fixed means, and used exclusively for the natural purification of live bivalve molluscs.
Dispatch centre	Any on-shore or off-shore establishment for reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs for human consumption.
Purification centre	An establishment with tanks fed by clean seawater in which live bivalve molluscs are placed in for the time necessary to reduce contamination to make them fit for human consumption.
Relaying	The transfer of live bivalve molluscs to sea, lagoon or estuarine areas for the time necessary to reduce contamination to make them fit for human consumption. This does not include the specific operation of transferring bivalve molluscs to areas more suitable for further growth or fattening.
Fishery products	All seawater or freshwater animals (except live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods, and all mammals, reptiles and frogs) whether wild or farmed and including all edible forms, parts and products of such animals.
Factory vessel	Any vessel on board which fishery products undergo one or

	more or the following operations followed by wrapping or packaging and, if necessary, chilling or freezing: filleting, slicing, skinning, shelling, shucking, mincing or processing.
Freezer vessel	Any vessel on board which freezing of fishery products is carried out, where appropriate after preparatory work such as bleeding, heading, gutting and removal of fins and, where necessary, followed by wrapping or packaging.
Fresh fishery products	Unprocessed fishery products, whether whole or prepared, including products packaged under vacuum or in a modified atmosphere that have not undergone any treatment to ensure preservation other than chilling.
Prepared fishery products	Unprocessed fishery products that have undergone an operation affecting their anatomical wholeness, such as gutting, heading, slicing, filleting and chopping.

## **ANNEX II**

### **Changes in Legal Requirements for,**

**Primary producers of fish** – will now be classed as ‘food business operators’. Such businesses will now be subject to food law. For most businesses classed as primary production, this will mean registration with the local food authority as a ‘food business’ and to consider, remove or control any risks to food safety within their business. Records will also need to be kept to enable traceability throughout the food and animal feed chain.

**Primary producers of live bivalve molluscs – as above.** There are changes to the way harvesting waters are classified. The levels of *E.coli* in molluscan flesh for water classification remains unchanged but 100% of samples must now conform to these standards. The movement document has been renamed as registration document.

**Purification Centres** – will now be subject to the general food hygiene rules which will introduce HACCP as a new requirement. The product specific rules do not make any changes to requirements for purification centres, except that there is no longer a legal requirement to wash molluscs after purification. There is also a new style health mark.

**Dispatch Centres** - will now be subject to the general food hygiene rules, although this should not introduce any new requirements. The product specific rules do not make any major changes to requirements for dispatch centres, except that there is now a legal requirement to wash molluscs in clean water before dispatch. There is also a new style health mark.

**Fish merchants (selling directly to the consumer)** – are considered as retail (see below).

**Fish merchants (selling to other businesses)** – are considered to be establishments, although there are exemptions where they supply to other businesses in small quantities or to a small part of the food business. These businesses will need to comply with the general food hygiene rules (above) and the more specific rules for fishery products and/or live bivalve molluscs. The new product specific rules do not impose any extra requirements than under the previous regulations. There is also a new style health mark.

**Transporters** – where primary products are being transported to the first establishment ashore (and this does not substantially alter their nature) is classed as primary production (above). If frozen products are being transported to be thawed, they can be transported unfrozen for distances up to 50Km or 1 hour.

**Processors** – are subject to the general food hygiene rules and the product specific rules. This will introduce new requirements for traceability, HACCP and microbiological criteria. There is also a new style health mark.

**Cold stores** – Cold stores that hold fishery products will now need to be approved. Display freezers and storage freezers at retail premises are exempt.

**Retail** - There will be new requirements in having to apply full HACCP and maintaining traceability records. Some of the product specific controls found in 853/2004 are applied to retail. As a result of this, immersion or spraying of live bivalve molluscs will only be able to take place at an approved dispatch centre.