



# Good manufacturing practice guidelines

## Live bivalves workbook



*A step-by-step guide to  
good live bivalve  
preparation for the market*



PROJECT PART-FINANCED  
BY THE EUROPEAN UNION  
THROUGH THE FINANCIAL  
INSTRUMENT FOR  
FISHERIES GUIDANCE



## **Seafish Depuration Guides are being revised and updated**

The six Seafish Depuration Guides and the Seafish Good Manufacturing Practices are currently being updated and will be republished later in 2018. The older guides, first published in the 1990s still contain much technical content that is useful and informative; however the guides are out of date with regard to the following content:

- Seafish contact details are out of date. Seafish's main offices are:
  - Seafish Grimsby, Humber Seafood Institute, Europarc, Grimsby, DN37 9TZ
  - Seafish Edinburgh, 18 Logie Mill, Logie Green Road, Edinburgh EH7 4HS;
- The Legislation has evolved to take account of changes in end product standards;
- Much of the advice available from Seafish is now available online. If you are unable to find the appropriate content then please contact Seafish for further guidance;
- The process of approval has changed and authorising officers will follow current FSA advice for England, Wales and Northern Ireland (see Food Standards Scotland for businesses in Scotland);
- Technical standards covering salinity, turbidity, use of ozone etc. will be updated to reflect changes in best practice;

## **List of Corrections and Amendments to thus edition of the Live Bivalves Workbook**

### **Step 20**

4: All packages of live bivalves leaving the dispatch centre must be closed. This includes transfers between dispatch centres.

Also packages intended for direct sale, must remain closed until they are presented for sale to the final consumer ie the consumer takes off the packaging.

853 / 2004, Annex III, Section VII, Chap VI 2 has been amended by 558/2010

### **Step 24**

3: Don't mix live bivalves from different dispatch centres when re-packed. Repacking can only be carried out at an approved dispatch centre.



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# Introduction

- This workbook is intended to assist live bivalve shellfish operators produce a high quality, safer live bivalve in compliance with legal obligations. It is designed to be used in the production environment, onboard the harvesting vessel or foreshore.
- It is intended that operators will use the workbook as an every dayguide for:
  - Good manufacturing practice and legal compliance.
  - On the job and induction training.
  - Reference information on good work practices.
- The workbook contains the essential work practices and procedures that operators must adhere to in order to be compliant with the European Hygiene Regulations. These Regulations came into force in January 2006 and apply to the placing of live bivalve shellfish on the market for human consumption. A fuller explanation of these Regulations is given in Appendix 6.
- The workbook also contains Seafish advice in the form of Good Manufacturing Practice Guidance (GMPG) at each step in the production process to help operators place high quality live bivalve molluscs on the market.
- The workbook is structured into a series of steps from 1 to 24, each covering the different processes in the production chain, from harvesting to delivery of live bivalves to market. The Navigator Tool running down the right hand side will allow the reader to locate each step in respect to the overall chain.
- The workbook is accompanied by a set of six laminated Work Notices which can be posted on notice boards. Their clear and simple design will allow for good quality photocopy reproduction.
- This workbook is part of a suite of Seafish publications on Good Manufacturing Practice Guidance for live bivalve molluscs.
- For further information, readers should contact:

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### How to use this workbook

Legal Requirements	1	This text box tells you what you <b>must</b> do in order to meet the legal requirements of the European Hygiene Regulations.
	2	The words <b>must</b> or <b>must not</b> and <b>do</b> and <b>do not</b> are used in <b>bold red text</b> to re-enforce the legal requirement.
	3	At the bottom of each page there is a red Legal Reference Box containing the exact section of the European Regulations which details the legal requirement.
The word <b>‘Remember’</b> is used to distinguish Legal Requirements from Seafish Good Manufacturing Practice Guidance (GMPG).		
Good Practice	4	This text box contains Seafish advice on GMPG.
	5	Seafish advice is intended to maintain the quality and extend the shelf-life of the product.
	6	A tick in the Legal Reference Box means that it is intended as Seafish advice for GMPG. Often, GMPG and Legal Requirements overlap.

Bullet point	Legal obligation reference	Seafish GMPG
1-3	Reference to European Legislation here	✓
4-6	No legal requirement but Seafish advise	✓





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## Step 1

### The growing/ harvest area

#### Legal Requirements

- 1 You **must** only harvest from classified waters; A, B or C – refer to Appendix 1.
- 2 Live bivalves **must** meet the legal End Product Standard described in Appendix 3 of the workbook.
- 3 Harvested bivalves **must** meet the legal limit for naturally occurring marine biotoxins described in Appendix 2 – comply with any Closure Orders.

#### Remember:

#### Good Practice

- 4 Don't harvest from areas heavily contaminated with:
  - (i) Sewage waste.
  - (ii) Industrial waste.
  - (iii) High presence of heavy metals.

Bullet point	Legal obligation reference	Seafish GMPG
1	853/2004, Annex III, Section VII, Chap II, A (1)	✓
1	854/2004, Annex II, Chapter II, A (1-5)	✓
2 2	853/2004, Annex III, Section VII, Chap V Reg 2073/2005 Annex I Chap I.17 ans I.24	✓
3	853/2004, Annex III, Section VII, Chap V, 2 (a-e)	✓
4	-----	✓



SEAFISH

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### Step 2 *Harvesting vessel, raft or foreshore equipment*

Legal Requirements

- 1** Harvesting operations **must not** contaminate or damage the animals.
- 2** You **must** keep handling, sorting, grading equipment clean and in good repair.
- 3** You **must** store bivalves in clean, drainable containers.

#### Remember:

Good Practice

- 4** Avoid contamination from:
  - (i) Boat sewage waste.
  - (ii) Smoke or fuel oil.
  - (iii) Lubricants and disinfectants.
  - (iv) Pest and bird droppings.
- 5** Use re-usable plastic boxes – not wooden boxes. Some types of bags will be suitable for use with scallops.

Bullet point	Legal obligation reference	Seafish GMPG
1	853/2004, Annex III, Section VII, Chap II, B I	✓
2	852/2004, Annex I, Part A, II 4 (a-b)	✓
3	852/2004, Annex I, Part A, II 4(b)	✓
4-5	-----	✓



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### Step 3

#### On board handling

Legal Requirements	<b>1</b>	You <b>must</b> be able to identify each batch of bivalves by production, relaying or designated harvesting area.
	<b>2</b>	Fill in a registration document for each batch harvested from a different area (previously called a Movement Document).
	<b>3</b>	You <b>must</b> make sure that they are kept alive and in good condition.
	<b>4</b>	You <b>must not</b> re-immersion them in water that could cause additional contamination.
<b>Remember:</b>		
Good Practice	<b>5</b>	Don't mix batches from different harvest areas.
	<b>6</b>	Keep them cool.
	<b>7</b>	Keep them moist but allow them to drain.
	<b>8</b>	Clean, wash and grade them gently.
	<b>9</b>	Never tread, stamp or drop them to de-clump.
	<b>10</b>	Wash shells free of mud and dirt before it dries hard.

Bullet point	Legal obligation reference	Seafish GMPG
<b>1</b>	853/2004, Annex III, Section VII, Chap I, 4(a)iii, 4(b)i and 178/2002 Article 18 I-5	✓
<b>2</b>	853/2004 Annex III, Section VII, Chap I ,3 & 4(a)i-vi, 4(b)i-ii	✓
<b>3</b>	853/2004, Annex III, Section VII, Chap II B, I	✓
<b>4</b>	853/2004, Annex III, Section VII, Chap II, B, I (c)	✓
<b>5-10</b>	-----	✓





## Step 4

### On Shore reception

#### Legal Requirements

- 1** You **must not** allow contamination from:
  - (i) Dirt and dirty water
  - (ii) Pests such as mice, rats and birds
  - (iii) Chemicals, oils, fuels or detergents.

- 2** You **must** use clean water only.

#### Remember:

#### Good Practice

- 3** Land bivalves in protective containers or suitable bags (do not use plastic bags).
- 4** Do not immerse in fresh water.
- 5** Land them to clean, hard drainable surfaces.
- 6** If reception area is outdoors, load transportation without delay.

Bullet point	Legal obligation reference	Seafish GMPG
I (i-iii)	853/2004 Annex III Section VII Chap II BI (c)	✓
I (ii)	852/2004 Annex I Part A II 4(f)	✓
I (iii)	852/2004 Annex I Part A II 3(a) & 4(g)	✓
2	852/2004 Annex I Part A II 4(d) & Chap I Article 2. I(h) & (i)	✓
3-6	-----	✓



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### Step 5

#### Raw material transport

Legal Requirements	1	You <b>must</b> keep transport trucks clean.
	2	Transport <b>must</b> allow adequate drainage.
	3	Bivalves <b>must</b> be protected from contamination.
Remember:		
Good Practice	4	Protect from dirt, rain and excessive wind and sun.
	5	Use open transport for short journeys only.
	6	Keep bivalves covered – eg clean tarpaulins.
	7	Avoid bulk uncontainerised transport.
	8	Use durable plastic boxes or bulk bags where appropriate (eg mussels).

Bullet point	Legal obligation reference	Seafish GMPG
1	852/2004 Annex I Part A II 4(b) & Annex II Chapter IV I	✓
2-3	853/2004 Annex III Section VII Chap II, B (2)	✓
4-8	-----	✓



## Step 6

### Transport conditions

Legal Requirements	<b>1</b> You <b>must</b> keep batches of bivalves from different areas (i) Separate. (ii) Identifiable. (iii) and prevent cross-contaminations.
	<b>2</b> You <b>must</b> ensure you receive a copy of the registration document from the harvester with each batch.
	<b>3</b> You <b>must</b> transport live bivalves at the appropriate temperature.
<b>Remember:</b>	
Good Practice	<b>4</b> Load transport trucks as soon as practical.
	<b>5</b> Don't load batches from different classifications unless you can guarantee Point 1.
	<b>6</b> Temperature guide: (i) Most bivalves transport at 2-5°C. (ii) Mussels can be iced or chilled. (iii) Native oysters and scallops at 4-8°C.

Bullet point	Legal obligation reference	Seafish GMPG
<b>1iii</b>	853 / 2004, Annex III, Section VII, Chap II B1 & B2	✓
<b>1i,b ii</b>	853/2004 Annex III Section VII, Chapter I, 3 & 4(a) (i-vi) and 178/2004 Article 18	✓
<b>3</b>	852 / 2004 Annex II Chapter 4 (7) & 853 / 2004, Annex III, Section VII Chapter II B I (b)	✓
<b>4-6</b>	-----	✓

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### Step 7

### Handling

Legal Requirements

- 1** You **must** keep bivalves alive and handle them gently.
- 2** You **must not** re-immerses them in water that could cause additional contamination.
- 3** You **must not** subject them to extreme temperatures.

#### Remember:

Good Practice

- 4** Avoid rough handling.
- 5** Check temperature conditions – neither too hot or too cold.

Bullet point	Legal obligation reference	Seafish GMPG
<b>1-2</b>	853 / 2004, Annex III, Section VII, Chap IV B I (a)	✓
<b>2</b>	853 / 2004, Annex III, Section VII, Chap IV B. I (c)	✓
<b>3</b>	853 / 2004, Annex III, Section VII, Chap IV B. I (b)	✓
<b>4-5</b>	-----	✓



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### Step 8

#### Conditions for re-laying areas

Legal Requirements

- 1 Bivalves **must** only be relayed in approved areas – Classification A only.
- 2 Relaying area **must** be clearly defined.
- 3 Relaying areas **must** be separate from each other and from any production areas, to minimize potential contamination.

#### Remember:

Good Practice

- 4 Use buoys or poles or other fixed means to define relaying areas.

8-9  
Relaying

Bullet point	Legal obligation reference	Seafish GMPG
All	853 / 2004, Annex III Section VII Chap II, C I	✓



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## Step 9

### Handling for re-laying

#### Legal Requirements

Live bivalve molluscs **must**:

- 1** Be handled carefully – to ensure filter feeding activity resumes quickly.
- 2** Be immersed in seawater for at least two months to allow correct reduction in bacterial loading under the supervision of the EHO.
- 3** Be separate and identifiable by batch.
- 4** A batch of re-laid bivalves **must** be removed (harvested) completely – all in all out.
- 5** A permanent record of relayed bivalves **must** be kept.

#### Remember:

#### Good Practice

- 6** The local EHO must approve and supervise any relaying activity.
- 7** Refer to Appendix 4: Record keeping.

Bullet point	Legal obligation reference	Seafish GMPG
<b>1</b>	853 / 2004, Annex III Section VII Chap II, C 2 (a)	✓
<b>2</b>	853 / 2004, Annex III Section VII Chap II, C 2 (c)	✓
<b>3</b>	Regulation 178/2002 Article 18	✓
<b>3-4</b>	853 / 2004, Annex III Section VII Chap II, C 2 (d)	✓
<b>5</b>	853 / 2004, Annex III Section VII Chap II, C 3	✓



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## Step 10 *Preparation for dispatch – handling*

## Legal Requirements

- 1** You **must** avoid contamination or mixing of batches during grading, handling, sorting wrapping and packing.
- 2** You **must** keep bivalves alive and in good condition.
- 3** You **must** wash off dirt and detritus with clean water. Do not immerse.

10-11  
Dispatch**Remember:**

## Good Practice

- 4** Keep clean and hygienic work practices.
- 5** Bivalves must be handled carefully – keep them alive, in good condition, free from dirt and in distinct batches.
- 6** Spray shells with clean water to remove mud and detritus if needed.

Bullet point	Legal obligation reference	Seafish GMPG
1-2	853/2004 Annex III Section VII Chapter IV B and 178/2002 Article 18	✓
3	853 / 2004 Annex III Section VII Chap IV B2	✓
4-6	-----	✓



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## Step 11

### Conditions for dispatch – origin

#### Legal Requirements

1 Bivalves **must** come from either:

- (i) Class A area.
- (ii) Relaying area (Class A).
- (iii) Purification centre.
- (iv) Another dispatch centre.

2 If you dispatch live bivalves from a vessel, they **must** come from Class A or relaying areas and meet the End Product Standard – refer to Appendix 3.

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004 Annex III, Section VII, Chap IV. B3	✓
2	853/2004 Annex III Section VII Chap IV B4	✓

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### Step 12

### Purification – general

#### Legal Requirements

- 1** You **must** purify all live bivalve shellfish unless they are:
  - (i) Harvested from Classification A waters.
  - (ii) Sent for specified heat treatment to an authorised establishment.

- 2** You **must** follow the official conditions of approval.

#### Remember:

#### Good Practice

- 3** Purification removes 'low' level of bacterial contamination and grit from live bivalves.

Bullet point	Legal obligation reference	Seafish GMPG
<b>1 (i)</b>	853 / 2004, Annex III, Section VII, Chap II A2 & Chapter V	✓
<b>1 (ii)</b>	853 / 2004, Annex III, Section VII, Chap II A5	
<b>2</b>	Consult your National Competent Authority	✓
<b>3</b>	-----	✓



## Step 13

### Purification – structural hygiene

Legal Requirements

- 1 Site **must not** be subject to flooding by normal high tides or run off.
- 2 Purification tanks **must** be:
  - (i) Internally smooth and easily cleaned.
  - (ii) Capable of being completely emptied – no residual water left behind.
  - (iii) Positioned so that water intake **does not** contaminate water supply.
  - (iv) Suitable for volume and type of bivalves being purified, to prevent stress and damage.

Bullet point	Legal obligation reference	Seafish GMPG
I	853 / 2004, Annex III, Section VII, Chap III.1	✓
2 (i-iii)	853 / 2004, Annex III, Section VII, Chap III.2 (a-c)	✓
2 (iv)	853 / 2004, Annex III, Section VII, Chap III.3	✓





## Step 14

### Purification – loading tanks

#### Legal Requirements

- 1 Before loading – wash bivalves free of dirt, silt, and debris with clean uncontaminated water.
- 2 You **must** load only one type of bivalve shellfish in a tank.
- 3 You **must not** overload tanks.
- 4 For different batches of the same species, purification time **must** be based on the batch requiring the longest period of purification.
- 5 You **must not** place any other fish or animal in the tank with bivalves that are being purified.

#### Remember:

#### Good Practice

- 6 Bivalves have to be alive – check and discard any dead, gaping and damaged shells.
- 7 No dead animals, 'duds' or empty shells should go in the purification tanks. They can hold mud balls and contaminate the batch.
- 8 We advise against placing seaweed in the tanks.
- 9 You must be able to identify the origin of all batches that are mixed.

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004, Annex III, Section VII, Chap IV A.1	✓
2	853 / 2004, Annex III, Section VII, Chap IV A.4	✓
3	853 / 2004, Annex III, Section VII, Chap IV A.3	
4	853 / 2004, Annex III, Section VII, Chap IV A4	✓
5	853 / 2004, Annex III, Section VII, Chap IV A4 & A6	✓
6-8	-----	✓

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## Step 15

### Purification – operation checks

Legal Requirements	1	You <b>must</b> purify for correct time.
	2	Live bivalves <b>must</b> meet the End Product Standard (Appendix 3).
	3	All dispatches of purified bivalves <b>must</b> be labelled to show purification has been carried out.
Remember:		
Good Practice	4	Check water temperature, water flow rate and salinity are suitable for the specific species being purified. This allows normal filter feeding activity to take place.
	5	Keep bivalves submerged at all times.
	6	Check that shells are open and bivalves are filter feeding normally.
	7	Drain tanks completely before removing bivalves to avoid re-contaminating them.

12-15  
Purification

Bullet point	Legal obligation reference	Seafish GMPG
1-2	853 / 2004, Annex III, Section VII, Chap IV A.3	✓
3	853 / 2004, Annex III, Section VII, Chap IV A.7	✓
4-7	-----	✓

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### Step 16 *Purification centre – HACCP systems*

Legal Requirements	1	Operators should establish a HACCP – Hazard Analysis Critical Control Point System at their premises.
	2	You are required to follow your company's HACCP system to protect the food safety of bivalve shellfish for human consumption.
	3	Your employer <b>must</b> provide you with adequate training.
	4	You <b>must</b> abide by staff hygiene and dress procedures.
<b>Remember:</b>		
Good Practice	5	Fill out and maintain records carefully and correctly.

Bullet point	Legal obligation reference	Seafish GMPG
1-2	852/2004, Chap I, Article I (a) & (d) & Article 5 Food Safety Act of Great Britain, 1990	✓
3	852/2004 Annex I Part A II 4 (e)	✓
4	852/2004 Annex II Chapter VIII I & 2	✓
5	-----	✓

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## Step 17

### Purification centre – HACCP systems

Examples of Control Measures when receiving raw material:	
Possible Critical Controls	1 You <b>must</b> know where the bivalve shellfish originated – you must have a Gatherers Registration Document.
	2 You <b>must</b> wash shellfish with clean water before loading into tanks.
	3 Don't allow contamination between batches.
	4 Discard dead, dying or damaged bivalves.
Remember:	
Good Practice	5 There may be other Control Measures not listed here which may be important to your operation.

Bullet point	Legal obligation reference	Seafish GMPG
All	852/2004, Chap II Article 5	✓

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## Step 18

### Purification centre – HACCP systems

Examples of Control Measures when operating purification systems:	
Possible Critical Controls	1 Follow purification operating and approval conditions issued by the EHO and advise issued by Seafish.
	2 Do not overfill tanks – make sure all shellfish are immersed.
	3 Do not 'bag' the animals prior to purification.
	4 Check temperature, salinity and flow rate are suitable for shellfish.
	5 Check UV system is operational and the quartz sleeve is cleaned on a regular basis.
	6 Purify for correct time and check bivalves regularly.
	7 Drain tanks slowly and completely and then remove bivalves carefully.
Remember:	
Good Practice	8 Animals should not be prevented from opening their shells/siphons fully.
	9 There may be other Control Measures not listed here which may be important to your operation.

Bullet point	Legal obligation reference	Seafish GMPG
All	852/2004, Chap II Article 5	✓



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## Step 19 *Purification centre – HACCP systems*

Examples of Control Measures when packing and distributing:	
Possible Critical Controls	1 Make sure grading, sorting and de-bearding equipment is clean and free from any previous batches.
	2 Use clean, uncontaminated water.
	3 Use clean, approved packaging materials.
	4 Label packs and bags correctly and securely.
	5 Use clean, uncontaminated water for re-watering or immersed storage.
	6 Store off the ground.
	7 Use appropriate transport that is clean, hygienic and maintains the correct transport temperature.
Remember:	
Good Practice	8 There may be other Control Measures not listed here which may be important to your operation.

Bullet point	Legal obligation reference	Seafish GMPG
All	852/2004, Chap II Article 5;	✓

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## Step 20

### Wrapping and packing

Legal Requirements	1	Bivalves <b>must</b> be handled carefully – keep them alive and in good condition.
	2	Oysters and scallops <b>must</b> be wrapped or packaged with concave shell downwards.
	3	Wrapping and packaging <b>must not</b> contaminate bivalves.
	4	..... <b>must</b> .....
	5	After packaging, bivalves <b>must not</b> be re-immersed, sprayed or placed in contact with water including melt water from ice.
Remember:		
Good Practice	6	Don't use damaged, soiled or non-approved packaging.

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004, Annex III, Section VII, Chap IV.B I	✓
2	853 / 2004, Annex III, Section VII, Chap VI. I	✓
3	852/2004 Annex II Chap X I-2	✓
4	..... .....	✓
5	..... .....	✓

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### Step 21

### Labelling for market

Legal Requirements	1	Labels, including the Identification Mark (Health Mark) <b>must</b> be waterproof.
	2	Labels <b>must</b> include species name – common and scientific names.
	3	Label <b>must</b> include date of packing – day and month minimum.
	4	Label <b>must</b> be legible, permanent and clearly displayed.
	5	Label <b>must</b> include the approval number of the processing facility – official oval style.
Take note:		
Good Practice	6	The retailer must keep the label from non-consumer ready packs for 60 days.
	7	Food approved dye/ink should be used on labels.

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004, Annex III, Section VII, Chap VII 1	✓
2	853 / 2004, Annex III, Section VII, Chap VII 2 (a)	✓
3	853 / 2004, Annex III, Section VII, Chap VII 2 (b)	✓
4	853 / 2004, Annex II, Section I B5	✓
5	853 / 2004, Annex II, Section I B 7 & B8	✓
6	853 / 2004, Annex III, Section VII, Chap VII 3	
7	-----	✓



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### Step 22

#### Storage of bivalves

Legal Requirements	1	Store bivalves at the correct temperature to keep them alive and in good condition.
	2	Live bivalve molluscs <b>must</b> have normal amounts of intra-valvular liquid and show an adequate response to a percussive tap.
Remember:		
Good Practice	3	Store bivalves in cool conditions.
	4	Avoid extreme temperature regimes.
	5	Live mussels can be stored on ice.
	6	Store them off the ground to avoid contamination.
	7	Keep storage times as short as practical – bivalves must be delivered to the customer alive.

Bullet point	Legal obligation reference	Seafish GMPG
1	853/2004 Annex III Section VII Chap VIII I	✓
2	853/2004 Annex III Section VII Chap V I	✓
3-7	-----	✓



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## Step 23

### Product dispatch

Legal Requirements

- 1 You **must** keep transport containers clean and in good repair.
- 2 You **must not** subject live bivalve shellfish to extremes of temperature during transport.

### Remember:

Good Practice

- 3 The transport hold must be:
  - (i) Clean and corrosion free.
  - (ii) Covered to protect from excess wind, rain and sun.
  - (iii) Be loaded such that there is no risk of cross contamination between different products.

Bullet point	Legal obligation reference	Seafish GMPG
1	852/2004 Annex II Chap IV I	✓
2	853 / 2004, Annex III, Section VII, Chap VIII. I	✓
3(i-iii)	-----	✓



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## Step 24

### Handling after dispatch

Legal Requirements	If bivalve consignments are split before reaching the final consumer:	
	1	The original Identification Mark (health mark) <b>must</b> be kept.
	2	Records of the origin and dispatch <b>must</b> be kept.
	3	Don't mix live bivalves from different dispatch centres when re-packed.
	4	A new Identification Mark (Health Mark) <b>must</b> be attached when re-packed.

Repacking can only be carried out at an Approved Dispatch Centre

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004, Annex III, Section VII, Chap VII.3	✓
2-3	853/2004 Annex II Section IA 4 & 178/2002 Article 18	✓
3-4	853/2004 Annex II Section I A2	✓

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## Appendix 1: *Classification of bivalve shellfish waters*

- Bivalves **must** only be obtained from defined classified areas and treated accordingly.
- **Class A** – **must** meet requirements for food quality bivalves for direct sale for human consumption.
- A maximum limit of 230 colony forming units of ***Escherichia coli*** in 100g of flesh and intra-valvular liquid.
- **Class B** – **must** be purified before selling as live bivalve molluscs.
- A maximum limit of 4,600 colony forming units of ***E.coli*** in 100g of flesh and intra-valvular liquid.
- **Class C** – **must** be relayed in designated 'relaying sites' for at least two months, then purified if required or subjected to heat treatment.
- A maximum limit of 46,000 colony forming units of ***E.coli*** in 100g of flesh and intra-valvular liquid.

Bullet point	Legal obligation reference	Seafish GMPG
<b>All</b>	854/2004 Annex II Chap II A1-5 Refer to relevant Competent Authority	

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## Appendix 2: *Bivalve shellfish biotoxin limits*

### Limits for toxins after which bivalves cannot be sold for human consumption

- **PSP (Paralytic Shellfish Poison):**  
800 micrograms per kilogram.
- **ASP (Amnesic Shellfish Poison):**  
20 milligrams of domoic acid per kilogram.

#### For DSP

- **For okadaic acid, dinophysistoxins and pectenotoxins together:**  
160 micrograms okadaic acid equivalents per kilogram.
- **Yessotoxins:**  
1 milligram equivalent per kilogram.
- **Azaspiracids:**  
160 micrograms of azaspiracid equivalents per kilogram.

Bullet point	Legal obligation reference	Seafish GMPG
All	853 / 2004, Annex III, Section VII, Chap V.2 (a-e)	



## Appendix 3: *Product standard for live bivalve shellfish*

- 1 Less than 230 colony forming units of ***Escherichia. coli*** in 100g of flesh and intra-valvular liquid.
- 2 **Must not** contain ***Salmonella bacteria*** in 25g of flesh.
- 3 Be alive, fresh and in good condition.
- 4 Normal amounts of intra-valvular liquid at sale and adequate response to percussive tap.
- 5 **Must** taste fresh, no off-flavours and be free of detritus.
- 6 **Must not** contain marine biotoxins in excess of those stated in **Appendix 2**.

Bullet point	Legal obligation reference	Seafish GMPG
1	854/2004 Annex II Chap II A3	✓
1-2	2073/2005 Annex I Chap I.17 & I.24	
3-5	853/2004 Annex III Section VII Chap V I	✓
6	853/2004 Annex III Section VII Chap V 2(a-e)	✓



## Appendix 4: *Record keeping – general*

- 1 All food business establishments **must** keep and retain records relating to the safety and legality of products and make them available on request to the competent authorities.
- 2 Specifically, a Registration Document **must** be completed for every batch of live bivalve shellfish.
- 3 A copy of the document **must** be kept for 12 months.
- 4 Records relating to the hygiene conditions of the operation should be kept to demonstrate compliance with legal obligations.
- 5 Purification centres **must** keep records of the permanent management procedures for the control and elimination of hazards to the safety of live bivalve shellfish.
- 6 Supplier, production and distribution records **must** be kept to ensure the traceability and if required the recall of goods according to the requirements of 178/2002.

Bullet point	Legal obligation reference	Seafish GMPG
1	853 / 2004, Annex III Section VII Chap II, C 3	✓
2-3	853 / 2004, Annex III, Section VII, Chap I.3-7	✓
4	852/2004 Annex I Part B 2(j)	✓
5	852/2004 Article 5 (g)& Annex I AIII 7	✓
6	178/2002 Article 18 1-5	✓



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### Appendix 5: *Record keeping – registration document*

#### 1 The Gatherers Registration Document must include:

- (i) Gatherer's identity and address
- (ii) Date of harvesting
- (iii) Location of production area
- (iv) Health status of production/harvesting area – classification '**A**', '**B**' or '**C**'
- (v) Bivalve species and quantity
- (vi) Batch destination
- (vii) Biotoxin status of the precise area.

#### 2 For relayed bivalves:

- (i) Relaying period (if applicable)
- (ii) Relaying area (if applicable)
- (iii) Destination of the live bivalve molluscs
- (iv) Biotoxin status of the precise area.

#### 3 For purified bivalves:

- (i) The address of the purification centre
- (ii) Duration of purification
- (iii) Dates of entry and leaving purification centre.

#### 4 On receiving a batch of bivalves, the document must be date stamped or the date recorded in another manner.

#### 5 A copy of the document must be kept for at least 12 months.

#### 6 Gatherer's document must be readable and unaltered.

N.B. In certain cases a 'Permanent Transport Authorisation' may be granted if the gatherer and receiver are the same legal entity.

Bullet point	Legal obligation reference	Seafish GMPG
<b>All</b>	853 / 2004, Annex III, Section VII, Chap I.3-7	



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### Appendix 6: *The european hygiene regulations*

The European Commission has introduced Regulations to replace existing national food law in Member States. Previous food law originating from the Commission allowed Member States to make national laws to bring European law into force which led to differences in national laws between member states.

Since 1 January 2006 The European Hygiene Regulations have replaced the following General Food Hygiene and Fishery Product regulations:

The Food Safety (General Food Hygiene) regulations 1995.

The Food Safety (Fishery Products and Live Shellfish) (Hygiene) regulations 1998.

In addition since 1 January 2005 European Regulation 178/2002 laying down the general principles of food law has made some changes to the responsibilities of food businesses. An objective of the new rules contained in the Hygiene Regulations is to simplify the application of hygiene law across the European Union to facilitate the free movement and trade of food products within the Community. A major change to the definition of food is that it will now include 'primary production' and food sold 'live' and therefore includes the placing in the marketplace of live bivalve shellfish.

#### **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 piece of legislation contains provisions to ensure safe food and feed including traceability and product recall.

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 to food safety 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 the additional more prescriptive provisions for different categories of food. Annex III Section VII contains the specific rules on live bivalve molluscs.

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 the enforcement procedures to be carried out by competent authorities in respect to Regulation 853/2004/EC.

Regulation 2073/2005 Microbiological Criteria for Foodstuffs. This sets acceptable microbiological limits for all foods including live bivalve shellfish.



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