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# FOOD STANDARDS AGENCY CONSULTATION

## Title: Proposal to amend Regulation (EC) No. 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs (England)

### CONSULTATION SUMMARY PAGE

| Date consultation launched: | Closing date for responses: |
|---|---|
| 2 September 2010 | 24 November 2010 |

**Who will this consultation be of most interest to?**

Shellfish harvesters, industry representatives, consumer groups, testing laboratories and those with an interest in animal welfare issues.

**What is the subject of this consultation?**

A change to the current regulatory testing method for lipophilic toxins, one of the major marine biotoxin groups in shellfish, has been proposed by the European Commission in consultation with Member States. Following the Commission's proposal, the UK is proposing to replace the mouse bioassay (MBA) with liquid chromatography-mass spectrometry (LC-MS) as soon as a validated method is available.

**What is the purpose of this consultation?**

The Agency is seeking views on the Commission's proposal and the Agency's preferred response. Stakeholders are also asked to provide information to allow the impact assessment for this proposal to be finalised.

The overall objective of this proposal is to introduce a more robust testing method in the statutory monitoring programme for marine biotoxins in shellfish. The introduction of the new testing method will ensure increased confidence in monitoring results for both consumers and businesses and address the scientific and ethical concerns identified with the mouse bioassay currently used in the monitoring programme.

**Responses to this consultation should be sent to:**


Name Karin Lemler
Division/Branch Hygiene and Microbiology Division/ Food Hygiene Policy Branch
FOOD STANDARDS AGENCY
Tel: 020 7276 8955
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Postal address:
3rd floor
Aviation House
125 Kingsway
London WC2B 6NH
Email: karin.lemler@foodstandards.gsi.gov.uk


| Is an Impact Assessment included with this consultation? | Yes ☒ | No ☐ See Annex A for reason. |
|---|---|---|

INVESTOR IN PEOPLE

**If you would prefer to receive future FSA consultations by e-mail, or if** you no longer wish to receive information on this subject please notify the named person in this consultation.

POSITIVE ABOUT DISABLED PEOPLE

# Proposal to amend Regulation (EC) No. 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs

## DETAIL OF CONSULTATION

### Introduction

1. In the UK, the Food Standards Agency is the designated Competent Authority responsible for ensuring that the statutory monitoring programme for biotoxins in live bivalve molluscs (LBM) and other shellfish is in place using the methods of detection set out in Regulation (EC) No. 2074/2005[1]. Regulation (EC) 854/2004[2] stipulates that shellfish flesh is to be routinely monitored for three groups of marine biotoxins: paralytic shellfish poisoning, amnesic shellfish poisoning and lipophilic toxins. Mouse Bioassay (MBA) is currently used in the UK as the reference method for detecting lipophilic toxins, including those belonging to the diarrhetic shellfish poisoning (DSP) group. However, while the MBA is currently prescribed in the EU Regulation as the reference method for detecting lipophilic toxins, it is recognised that it has scientific shortcomings and an alternative method for detecting these toxins is required. Furthermore, the use of animals in testing for scientific purposes is regulated under EU[3] and national law[4]. These rules prohibit unnecessary animal testing, and in particular require replacement of animal tests where a scientific alternative is available.

2. For the past few years, the Agency has commissioned research to develop an alternative more effective method for the quantification of lipophilic toxins. Results from the Agency's funded research and similar initiatives at national and international level have shown that liquid chromatography-mass spectrometry (LC-MS), a chemical-based method, has an improved detection capability and is a highly specific method for the quantification of lipophilic toxins. As the LC-MS addresses the ethical and scientific concerns identified with the MBA, the method is now being proposed to replace the bioassay.

3. Following EFSA's review[5] of the available data and recent advances in LC-MS methodology, the Commission has proposed an amendment to the legislation to adopt LC-MS as the reference method for detecting lipophilic toxins. In order to allow Member States time to adapt their monitoring programme and apply the validated LC-MS method, the proposed amendment to the legislation includes a transitional period of three years after which the MBA can only be used to detect new or unknown marine biotoxins. The Commission's proposal was accepted by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in November 2009 and is expected to be adopted before the end of 2010. The Agency's research on the LC-MS will soon provide a validated LC-MS method which would allow early implementation of the requirements of the Commission's proposal and the method could be applied in the UK statutory monitoring programme early in 2011.

[1] Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under the EU Food Hygiene Regulations and the Official Control Regulation (EC) No. 882/2004.
[2] Regulation (EC) No. 854/2004 laying down rules for the organisation of official controls on products of animal origin intended for human consumption
[3] EU Council Directive 86/609/EEC
[4] Animals (Scientific Procedures) Act 1986
[5] Scientific Opinions of the Panel on Contaminants in the food chain - Marine biotoxins in shellfish: Okadaic acid and analogues (adopted on 27 November 2007); Azaspiracid group (adopted on 9 June 2008); Yessotoxin Group (adopted 2 December 2008); Pectenotoxin group (adopted 27 May 2009); Summary on regulated marine biotoxins (adopted on 13 August 2009) http://www.efsa.europa.eu/

4. The replacement of the MBA with the more robust LC-MS method as the recognised testing method for lipophilic toxins will increase confidence in the results of the statutory monitoring programme. In addition, the implementation of the LC-MS will reduce the reliance on animal testing in the statutory biotoxin monitoring programme.

## Proposals for the testing of lipophilic marine biotoxins

5. Options being considered are:

   (1) Do nothing and continue to use the MBA for the testing of lipophilic toxins in the UK's statutory monitoring programme;

   (2) Replace the MBA with LC-MS for the testing of lipophilic toxins in the statutory monitoring programme at the end of the Commission's transitional period; and

   (3) Replace the MBA with LC-MS for the testing of lipophilic toxins in the statutory monitoring programme as soon as the chemical method has been validated i.e. before the end of the transitional period.

## Preferred option

6. Option 3 is the preferred option. Doing nothing (option 1) or delaying the introduction of the LC-MS to the end of the transitional period (option 2) will mean that the best available method is not being used. As the MBA is known to provide variable results and does not quantify levels of lipophilic toxins, its continued use when a better alternative is available will have negative implications for food businesses due to unnecessary closures from compounds that may interfere with the MBA such as free fatty acids in the shellfish samples. The continued use of the MBA will also negatively affect public health due to the potential inability to detect lipophilic toxins at the required levels. In addition, continuing to use an animal assay when a scientific alternative is available is in contravention of EU and National legislation, as well as contrary to the Agency's commitment to minimise use of tests involving animals.

7. The introduction of the LC-MS in the monitoring programme will, however, increase the unit cost of tests for lipophilic toxins in the Agency's funded monitoring programme, as the LC-MS is a more resource intensive method and involves more specialist analysis than the MBA. This may be a short term effect if, overtime, more testing laboratories enter the market, as LC-MS does not require a special operating licence and more laboratories may be able to offer tests at competitive prices. The format in which results are reported within the monitoring programme will also change as the MBA and LC-MS are quite different methods and determine toxicity on a different basis. The costs and benefits are described further in the Impact Assessment in Annexe B.

8. In addition, the changes in the testing regime may also have implications in terms of the reporting of test results to the Agency as it is expected that the new procedures may in some cases add up to a further 24 hours before results of the monitoring programme are available. The LC-MS turn-around of results is similar to that of the MBA carried out with a 24h observation period.

**Key proposals:**

- **To replace the mouse bioassay with LC-MS for the detection and quantification of lipophilic toxins, including DSP toxins, in live bivalve molluscs.**

- **To introduce the LC-MS in the Agency's statutory monitoring programme for marine biotoxins in shellfish as soon as a validated method is available (likely to be early 2011).**

## Consultation Process

9. The current consultation is part of the Agency's commitment to replace animal testing in the statutory monitoring programme for marine biotoxins in shellfish and ensure fit-for-purpose methodology is used in all statutory testing. Informal consultation in meetings and correspondence with the shellfish industry and their representatives and with animal protection organisations has taken place regarding the limitations of the MBA and the intention to introduce the LC-MS in the UK statutory monitoring programme. The introduction of LC-MS is welcomed by industry and animal protection organisations.

10. The Agency now welcomes comments from all interested parties on the proposals set out above. Interested parties are particularly invited to respond to the following questions:

**Q1: Do you agree with the replacement of the MBA by LC-MS for the testing of lipophilic marine biotoxins?**

**Q2: Do you agree that use of the LC-MS method should be introduced as soon as a validated method is available to the UK rather than wait until the end of the transition period (likely to be early 2011)?**

**Q3: Do you agree with the approximate cost per sample used for MBA and LC-MS tests across all countries?**

**Q4: Can you provide any further evidence on the costs and benefits to the industry that would arise from the implementation of the LC-MS to input at the Impact Assessment in Annexe B? Specific information on the likely impact on smaller businesses would be very helpful.**

11. We welcome comments from all interested parties. Please send your response by email or post using the contact details given on page 1. All responses received will be given careful consideration. We would particularly encourage responses from consumers and encourage shellfish harvesters and their representatives to send comments regarding the impact of using the new methodology on their business. A summary of all comments received and the Agency's response to each will be published on the Agency's website within 3 months.

## Responses

12. Responses are required by close **24 November 2010**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any interested parties your organisation represents).

Thank you on behalf of the Food Standards Agency for participating in this public consultation.

Yours,

**Sylvia Ankrah**
Food Hygiene Policy Branch
Hygiene and Microbiology Division

**Enclosed**

**Annex A: Standard Consultation Information**

**Annex B: Consultation Impact Assessment**

**Annex C: List of interested parties**

**Other relevant documents**

**SANCO /6831/2009 rev5 Draft Commission Regulation amending Regulation (EC) No. 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs**

## Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

## Publication of personal data and confidentiality of responses

2. In accordance with the Agency's principle of openness our Information Centre at Aviation House will hold a copy of the completed consultation. Responses will be open to public access upon request. The Agency will also publish a summary of responses, which may include personal data, such as your full name and contact address details. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at **http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc** Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of the Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the Agency. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

## Further information

5. A list of interested parties to whom this letter is being sent appears in Annexe B. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Separate but similar consultations on the introduction of the same method are taking place in Scotland, Wales and Northern Ireland.

7. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

8. Please let us know if you need paper copies of the consultation documents or of anything specified under '**Other relevant documents**'.

9. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: **http://www.berr.gov.uk/files/file47158.pdf** The Consultation Criteria from that Code should be included in each consultation and they are listed below:

## The Seven Consultation Criteria

**Criterion 1 — When to consult**
*Formal consultation should take place at a stage when there is scope to influence the policy outcome.*

**Criterion 2 — Duration of consultation exercises**
*Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.*

**Criterion 3 — Clarity of scope and impact**
*Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.*

**Criterion 4 — Accessibility of consultation exercises**
*Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.*

**Criterion 5 — The burden of consultation**
*Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees' buy-in to the process is to be obtained.*

**Criterion 6 Responsiveness of consultation exercises**
*Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.*

**Criterion 7 Capacity to consult**
*Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.*

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Impact Assessment at Annex B.

11. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, Room 1B, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

**Comments on the consultation process itself**

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc**

13. If you would like to be included in future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at **http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc** The questionnaire can also be used to update us about your existing contact details.

| Title: | Impact Assessment (IA) |
|---|---|
| **Proposal to amend Regulation (EC) No.2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs** | **IA No:** FoodSA0006 |
| **Lead department or agency:** Food Standards Agency | **Date:** 16/08/2010 |
| **Other departments or agencies:** | **Stage:** Consultation |
| | **Source of intervention:** EU |
| | **Type of measure:** Other |
| | **Contact for enquiries:** Sylvia Ankrah Tel: 0207276 8353 Email:Sylvia.ankrah@foodstandards.gsi.gov.uk |

# Summary: Intervention and Options

**What is the problem under consideration? Why is government intervention necessary?**

Competent Authorities are required to monitor shellfish harvesting areas for marine biotoxins which can accumulate in the flesh of filter-feeding live bivalve molluscs (LBMs) and other shellfish. Recent EFSA work has highlighted shortcomings in the biological method, the mouse bioassay (MBA), currently specified for testing lipophilic toxins. To address these limitations, the EU has proposed an amendment to Regulation (EC) No. 2074/2005 which would replace the MBA with a chemical method, liquid chromatography-mass spectrometry (LC-MS). Government intervention is necessary to ensure that a robust testing method is utilised to monitor levels of biotoxins in LBMs to ensure they are safe to eat, and to meet its obligations under animal welfare legislation.

**What are the policy objectives and the intended effects?**

The policy objective is to use the best available method for detecting lipophilic toxins, one of three major marine biotoxin groups which are subject to regulatory testing to protect human health, and meet obligations under animal welfare legislation, by replacing the MBA with the alternative LC-MS method. This more robust method will address the scientific and ethical concerns identified with the MBA. Increased confidence in the monitoring results will benefit consumers and businesses.

**What policy options have been considered? Please justify preferred option (further details in Evidence Base)**

1. Do nothing and use the MBA in the UK's statutory biotoxin monitoring programme as the method of detection for lipophilic toxins
2. Support the EU proposal and replace the MBA with LC-MS at the end of the transitional period
3. Support the EU proposal and replace the MBA with LC-MS as soon as the method has been validated before the end of the transitional period.

Option 3 is the preferred option as this would bring forward the benefits of increased confidence in monitoring results and meet obligations under animal welfare legislation.

| | |
|---|---|
| **When will the policy be reviewed to establish its impact and the extent to which the policy objectives have been achieved?** | It will/will not be reviewed 2012 |
| **Are there arrangements in place that will allow a systematic collection of monitoring information for future policy review?** | Yes |

**Chief Executive's Sign-off** For consultation stage Impact Assessments:

***I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.***

Signed by the responsible Chief Executive: ..... Date: 18/8/10

pp TIM SMITH

# Summary: Analysis and Evidence

Policy Option 2

**Description:**

Support the EU proposal to replace the MBA with the LC-MS and introduce the method at the end of the transitional period.

| Price Base Year 2009 | PV Base Year 2012 | Time Period Years 5 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** -0.37 | **High:** -0.82 | **Best Estimate: -0.60** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | N/A | | 0.14 | **0.37** |
| **High** | N/A | | 0.32 | **0.82** |
| **Best Estimate** | N/A | | 0.23 | **0.60** |

**Description and scale of key monetised costs by 'main affected groups'**

An additional annual sampling cost of £229,000 for the Agency, which funds the programme, from adopting LC-MS testing.

**Other key non-monetised costs by 'main affected groups'**

Potential cost to industry from the impact on the number of bed closures due to increased sensitivity of LC-MS testing.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | N/A | | N/A | **N/A** |
| **High** | N/A | | N/A | **N/A** |
| **Best Estimate** | N/A | | N/A | **N/A** |

**Description and scale of key monetised benefits by 'main affected groups'**

No benefits monetised, see non-monetised benefits below

**Other key non-monetised benefits by 'main affected groups'**

Lower risk of contaminated shellfish entering the market as LC-MS testing is more robust. This may reduce the number of foodborne diseases resulting from contaminated shellfish.
Increased consumer confidence in shellfish products which could potentially stimulate domestic demand and export demand. Industry will benefit from increased assurance that beds are being closed due to presence of specific toxins rather than a qualitative result from the MBA.

**Key assumptions/sensitivities/risks** **Discount rate (%)** 3.5%

Transition period of 3 years meaning there will be no annual costs to the Agency for the first 3 years of the policy.
Therefore annual testing costs have been up-rated to 2012/13 prices using GDP deflator forecasts. Annual approximated monitoring costs under the new LC-MS testing based on figures from an industry average for marine scientific research. Sensitivity analysis applied to use of LC-MS in biotoxin monitoring estimates using a 10% upper- and lower-bound range based on the number of tests carried out.

| Impact on admin burden (AB) (£m): | | | Impact on policy cost savings (£m): | In scope |
|---|---|---|---|---|
| **New AB:** | **AB savings:** | **Net:** | **Policy cost savings:** | Yes/No |

# Enforcement, Implementation and Wider Impacts

| | | | | | |
|---|---|---|---|---|---|
| What is the geographic coverage of the policy/option? | | | United Kingdom | | |
| From what date will the policy be implemented? | | | TBC | | |
| Which organisation(s) will enforce the policy? | | | FSA | | |
| What is the annual change in enforcement cost (£m)? | | | 0 | | |
| Does enforcement comply with Hampton principles? | | | No | | |
| Does implementation go beyond minimum EU requirements? | | | No | | |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:** | **Non-traded:** | |
| Does the proposal have an impact on competition? | | | No | | |
| What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable? | | | **Costs:** | **Benefits:** | |
| Annual cost (£m) per organisation (excl. Transition) (Constant Price) | **Micro** | **< 20** | **Small** | **Medium** | **Large** |
| Are any of these organisations exempt? | No | No | No | No | No |

# Specific Impact Tests: Checklist

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

| Does your policy option/proposal have an impact on…? | **Impact** | **Page ref within IA** |
|---|---|---|
| **Statutory equality duties**[1] Statutory Equality Duties Impact Test guidance | No | 19 |
| **Economic impacts** | | |
| Competition Competition Assessment Impact Test guidance | No | 18 |
| Small firms Small Firms Impact Test guidance | No | 18 |
| **Environmental impacts** | | |
| Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance | No | |
| Wider environmental issues Wider Environmental Issues Impact Test guidance | No | |
| **Social impacts** | | |
| Health and well-being Health and Well-being Impact Test guidance | Yes | 11 |
| Human rights Human Rights Impact Test guidance | No | |
| Justice system Justice Impact Test guidance | No | |
| Rural proofing Rural Proofing Impact Test guidance | No | |
| **Sustainable development** Sustainable Development Impact Test guidance | Yes | 19 |

[1] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

## Summary: Analysis and Evidence

Policy Option 3

**Description:**

Support the EU proposal and replace the MBA with the LC-MS as soon as the method has been validated before the end of the transitional period

| Price Base Year 2009 | PV Base Year 2009 | Time Period Years 5 | Net Benefit (Present Value (PV)) (£m) | | |
|---|---|---|---|---|---|
| | | | **Low:** 0.50 | **High:** 1.38 | **Best Estimate: -0.94** |

| COSTS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Cost (Present Value) |
|---|---|---|---|---|
| **Low** | N/A | | 0.09 | **0.50** |
| **High** | N/A | | 0.25 | **1.38** |
| **Best Estimate** | N/A | | 0.17 | **0.94** |

**Description and scale of key monetised costs by 'main affected groups'**

An additional annual monitoring cost of £171,000 for the Agency, which funds the programme, from adopting LC-MS testing.

**Other key non-monetised costs by 'main affected groups'**

Potential cost to industry from the impact on the number of bed closures due to increased sensitivity of LC-MS testing.

| BENEFITS (£m) | Total Transition (Constant Price) | Years | Average Annual (excl. Transition) (Constant Price) | Total Benefit (Present Value) |
|---|---|---|---|---|
| **Low** | N/A | | N/A | **N/A** |
| **High** | N/A | | N/A | **N/A** |
| **Best Estimate** | N/A | | N/A | **N/A** |

**Description and scale of key monetised benefits by 'main affected groups'**

No benefits monetised, see non-monetised benefits below

**Other key non-monetised benefits by 'main affected groups'**

Lower risk of contaminated shellfish entering the market as LC-MS testing is more robust. This may reduce the number of foodborne diseases resulting from contaminated shellfish.
Increased consumer confidence in shellfish products potentially stimulating domestic demand and export demand thus helping to facilitate trade. Industry will benefit from greater assurance that beds are being closed due to presence of specific toxins rather than a qualitative result from MBA.

**Key assumptions/sensitivities/risks** **Discount rate (%)** 3.5%

Annual monitoring costs under the new LC-MS system based on figures from an industry average for marine scientific research. Sensitivity analysis applied to use of LC-MS in biotoxin monitoring estimates using a 10% upper- and lower-bound range based on the number of tests carried out.

| Impact on admin burden (AB) (£m): | | | Impact on policy cost savings (£m): | In scope |
|---|---|---|---|---|
| **New AB:** | **AB savings:** | **Net:** | **Policy cost savings:** | Yes/No |

# Enforcement, Implementation and Wider Impacts

| | | | | | |
|---|---|---|---|---|---|
| What is the geographic coverage of the policy/option? | | | United Kingdom | | |
| From what date will the policy be implemented? | | | TBC | | |
| Which organisation(s) will enforce the policy? | | | FSA | | |
| What is the annual change in enforcement cost (£m)? | | | 0 | | |
| Does enforcement comply with Hampton principles? | | | No | | |
| Does implementation go beyond minimum EU requirements? | | | Yes/No | | |
| What is the $CO_2$ equivalent change in greenhouse gas emissions? (Million tonnes $CO_2$ equivalent) | | | **Traded:** | **Non-traded:** | |
| Does the proposal have an impact on competition? | | | No | | |
| What proportion (%) of Total PV costs/benefits is directly attributable to primary legislation, if applicable? | | | **Costs:** | **Benefits:** | |
| Annual cost (£m) per organisation (excl. Transition) (Constant Price) | **Micro** | **< 20** | **Small** | **Medium** | **Large** |
| Are any of these organisations exempt? | No | No | No | No | No |

# Specific Impact Tests: Checklist

Please note this checklist is not intended to list each and every statutory consideration that departments should take into account when deciding which policy option to follow. It is the responsibility of departments to make sure that their duties are complied with.

| Does your policy option/proposal have an impact on…? | **Impact** | **Page ref within IA** |
|---|---|---|
| **Statutory equality duties**[2] Statutory Equality Duties Impact Test guidance | No | 19 |
| **Economic impacts** | | |
| Competition Competition Assessment Impact Test guidance | No | 18 |
| Small firms Small Firms Impact Test guidance | No | 18 |
| **Environmental impacts** | | |
| Greenhouse gas assessment Greenhouse Gas Assessment Impact Test guidance | No | |
| Wider environmental issues Wider Environmental Issues Impact Test guidance | No | |
| **Social impacts** | | |
| Health and well-being Health and Well-being Impact Test guidance | Yes | 11 |
| Human rights Human Rights Impact Test guidance | No | |
| Justice system Justice Impact Test guidance | No | |
| Rural proofing Rural Proofing Impact Test guidance | No | |
| **Sustainable development** Sustainable Development Impact Test guidance | No | 19 |

[2] Race, disability and gender Impact assessments are statutory requirements for relevant policies. Equality statutory requirements will be expanded 2011, once the Equality Bill comes into force. Statutory equality duties part of the Equality Bill apply to GB only. The Toolkit provides advice on statutory equality duties for public authorities with a remit in Northern Ireland.

# Evidence Base (for summary sheets) – Notes

Use this space to set out the relevant references, evidence, analysis and detailed narrative from which you have generated your policy options or proposal. Please fill in **References** section.

## References

Include the links to relevant legislation and publications, such as public impact assessment of earlier stages (e.g. Consultation, Final, Enactment).

| No. | Legislation or publication |
|---|---|
| 1 | |
| 2 | |
| 3 | |
| 4 | |

**+ Add another row**

## Evidence Base

Ensure that the information in this section provides clear evidence of the information provided in the summary pages of this form (recommended maximum of 30 pages). Complete the **Annual profile of monetised costs and benefits** (transition and recurring) below over the life of the preferred policy (use the spreadsheet attached if the period is longer than 10 years).

The spreadsheet also contains an emission changes table that you will need to fill in if your measure has an impact on greenhouse gas emissions.

### Annual profile of monetised costs and benefits* - (£m) constant prices

| | $Y_0$ | $Y_1$ | $Y_2$ | $Y_3$ | $Y_4$ | $Y_5$ | $Y_6$ | $Y_7$ | $Y_8$ | $Y_9$ |
|---|---|---|---|---|---|---|---|---|---|---|
| **Transition costs** | N/A | | | | | | | | | |
| **Annual recurring cost** | 0.17 | 0.17 | 0.17 | 0.17 | 0.17 | 0.17 | | | | |
| **Total annual costs** | 0.17 | 0.17 | 0.17 | 0.17 | 0.17 | 0.17 | | | | |
| **Transition benefits** | N/A | | | | | | | | | |
| **Annual recurring benefits** | N/A | N/A | N/A | N/A | N/A | N/A | | | | |
| **Total annual benefits** | N/A | N/A | N/A | N/A | N/A | N/A | | | | |

* For non-monetised benefits please see summary pages and main evidence base section

Microsoft Office
Excel Worksheet

# Evidence Base (for summary sheets)

## Rationale for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. In the case of filter-feeding LBMs and other shellfish, naturally occurring marine biotoxins can accumulate in the flesh. Consumption of LBMs contaminated with marine biotoxins can therefore pose a risk to public health. As a result, EU Member States are required to routinely monitor classified LBM production areas for marine biotoxins. Government intervention is necessary to ensure that it utilises a more robust testing method to monitor levels of biotoxins in LBMs to ensure they are safe, and to meet its obligations under animal welfare legislation.

2. In the UK, the Food Standards Agency is the designated Competent Authority responsible for ensuring that the statutory monitoring programme for biotoxins in LBMs is in place using the methods of detection set out in Regulation (EC) No. 2074/2005[3]. Regulation (EC) 854/2004[4] stipulates that shellfish flesh is to be routinely monitored for three groups of marine biotoxins: paralytic shellfish poisoning (PSP) toxins, amnesic shellfish poisoning and lipophilic toxins. The mouse bioassay (MBA) is currently prescribed in the EU Regulations as the reference method for detecting lipophilic toxins. However, while this has been the method required by the Regulations and the best method available, recently published EFSA opinions have highlighted shortcomings and an alternative method for detecting and quantifying these toxins is proposed.

3. The use of animals in testing for scientific purposes is regulated under EU[5] and national law[6]. These rules prohibit unnecessary animal testing, and in particular, require replacement of animal tests where a scientific alternative is available. The UK also has an obligation to reduce the ethical burden from the use of animals in testing. While the number of animals used in the monitoring programme is strictly controlled and kept to a minimum, replacing the MBA with a chemical alternative will have a significant impact on reducing the number of animals used in testing.

4. LC-MS is now being proposed by the Commission as a replacement for the MBA. The LC-MS technique is able to quantify toxins in the lipophilic group, unlike the MBA which only provided for a positive or negative result. The replacement of the MBA with LC-MS as the testing method for lipophilic toxins will provide increased specificity in the results of the statutory monitoring programme. The monitoring programme uses the MBA which is the best method available to protect public health until a validated LC-MS method becomes available. However, as the MBA is known to give variable results, use of the LC-MS method will give added reassurance that the testing method is able to detect the presence of lipophilic toxins.

[3] Regulation (EC) No. 2074/2005 laying down implementing measures for certain products under the EU Food Hygiene Regulations and the Official Control Regulation (EC) No. 882/2004.
[4] Regulation (EC) No. 854/2004 laying down rules for the organisation of official controls on products of animal origin intended for human consumption
[5] EU Council Directive 86/609/EEC
[6] Animals (Scientific Procedures) Act 1986

## Background

*Statutory Biotoxin Monitoring programme*

5. Regulation (EC) 853/2004 (as amended) specifies the limits of marine biotoxins that must not be exceeded in shellfish placed on the market. Regulation (EC) 854/2004 also requires Member States to establish a monitoring programme to check for the presence of biotoxins in shellfish production and relaying areas. In the UK the Agency is the central Competent Authority responsible for the statutory monitoring programme. The Agency delegates some official control functions, such as local enforcement, to local Food Authorities, and has contracted the Centre for Environment, Fisheries and Aquaculture Science (Cefas) to co-ordinate the delivery of the biotoxin programme and undertake laboratory analysis in Great Britain; while the Agri-Food Biosciences Institute for Northern Ireland (AFBI) undertakes laboratory analysis in Northern Ireland. The cost of the testing, transport of samples and programme coordination is borne entirely by the Agency in England and Wales, local authorities bear the cost for sample collection, while in NI and Scotland that cost is also borne by the Agency.

6. There are 680[7] classified shellfish beds across the UK (330 in England, 260 in Scotland and 45 each in Wales and in Northern Ireland) within 249 production areas. Under current arrangements, shellfish samples for biotoxin monitoring are collected on a sampling frequency which is risk-based. The collection of samples is carried out by trained sampling officers from Food Authorities (in Northern Ireland, some sampling is carried out by a cross-border Agency and by a contractor) and sent to the testing laboratory for processing. Changes to the testing method would not affect the arrangements for collecting samples or the sampling frequency.

7. When the result of a test shows toxins are present above maximum permitted levels, affected sites are closed for harvesting and only re-opened after two consecutive negative results are received. The closure of harvesting areas due to positive results means the risk to public health from placing contaminated shellfish on the market is reduced. Table 1 give details on the number of samples tested for lipophilic toxins (including diarrhetic shellfish poisoning (DSP) toxins), the number of positive results, and the number of shellfish bed closures and the length of closure from 1 January 2004 to 31 March 2009 in the UK. Graphs 1, 2 and 3 display the length of time that beds were closed for and the frequency of those closures across the different countries.

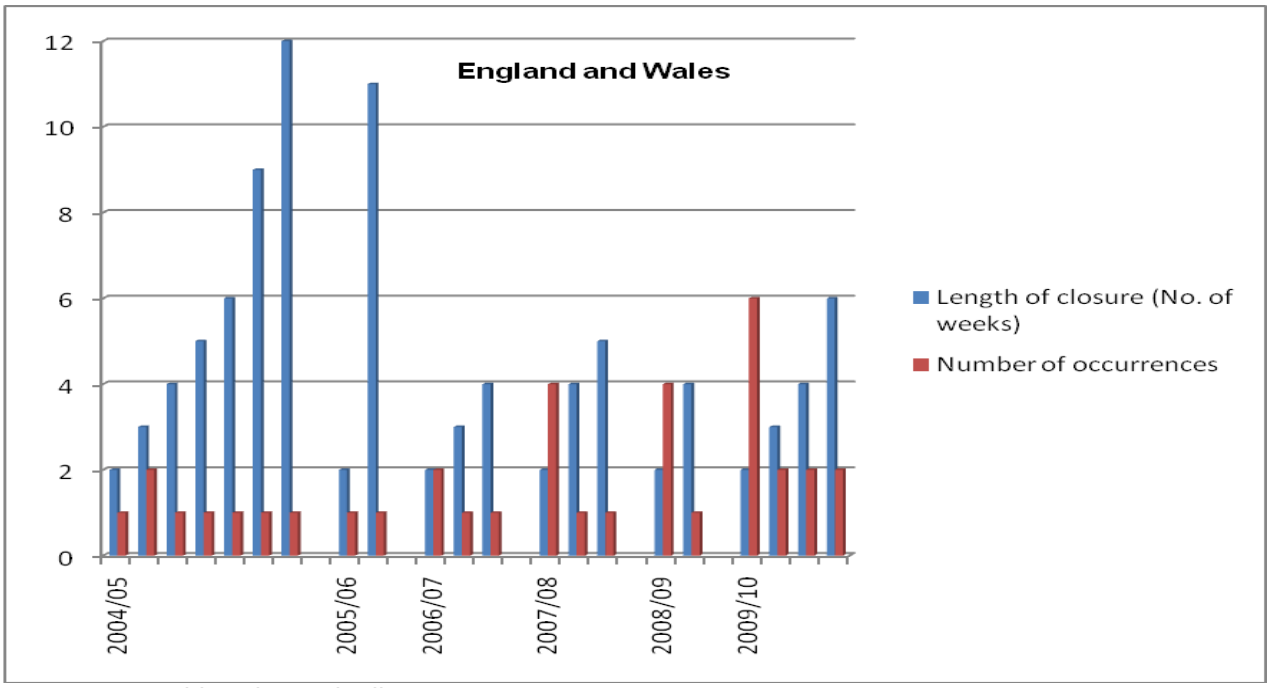
**Table 1: Results of the UK Statutory Monitoring programmes for lipophilic toxins between 2004/05 and 2009/10**

| | England and Wales[(a)] | | | Scotland | | | Northern Ireland | | |
|---|---|---|---|---|---|---|---|---|---|
| **Year[(b)]** | **No of samples tested** | **No. of positive samples** | **No of bed closures** | **No of samples tested** | **No. of positive samples** | **No of bed closures [(c)]** | **No of samples tested** | **No. of positive samples** | **No of bed closures** |
| **2004/05** | 847 | 14 | 8 | 1350 | 44 | 31 | 467 | 2 | 2 |
| **2005/06** | 1023 | 3 | 2 | 733 | 9 | 4 | 469 | 3 | 2 |
| **2006/07** | 821 | 6 | 4 | 1070 | 70 | 30 | 385 | 3 | 3 |
| **2007/08** | 1024 | 9 | 5 | 2266 | 84 | 44 | 426 | 9 | 6 |
| **2008/09** | 926 | 6 | 5 | 2406 | 77 | 54 | 352 | 0 | 0 |
| **2009/10** | 962 | 13 | 11 | 2580 | 106 | 46 | 395 | 5 | 5 |

[7] Data is based on Agency classifications at 1 September 2009

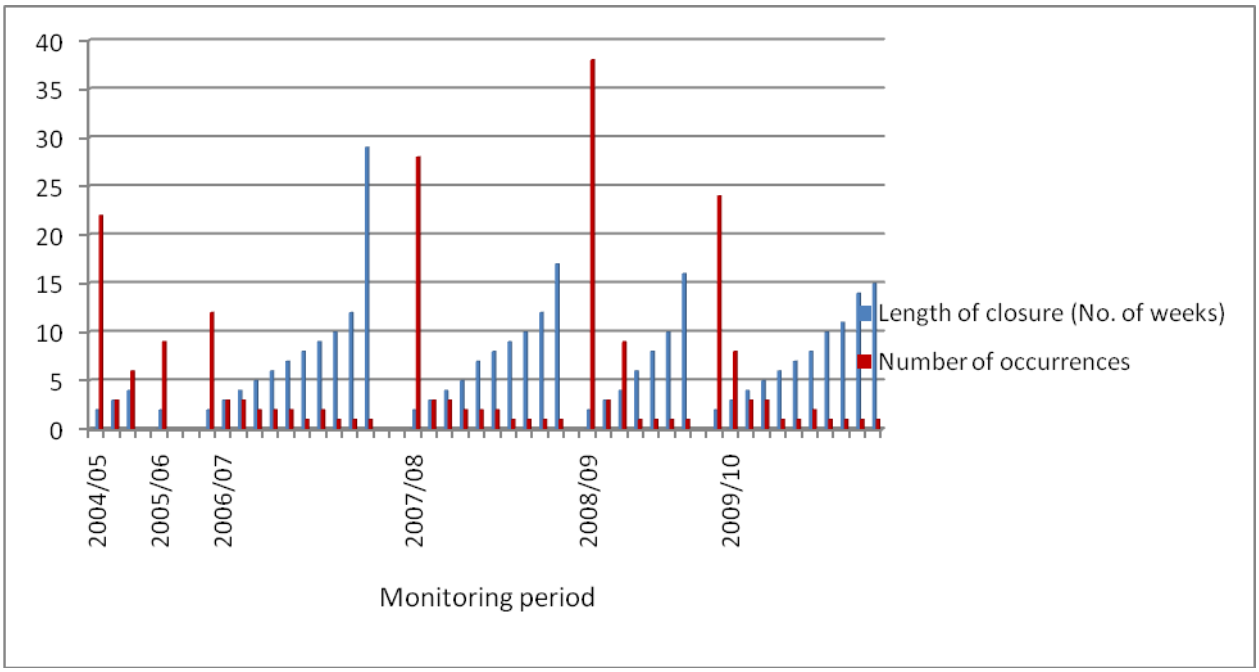
(a) Results of the monitoring programme for England and Wales are reported together as the biotoxin monitoring programme is carried out under the same contract.
(b) The years on which the results are based are from 1 April to 31 March in England, Wales and Scotland. Results for Northern Ireland are reported from 1 January to 31 December.
(c) Number of closures include single beds as well as 'Representative Monitoring points' (RMPs). Single RMP results can cover an area containing numerous individual shellfish beds

## Graph 1: Shellfish bed closures due to positive tests for lipophilic toxins between 2004/05 and 2009/10 in England and Wales



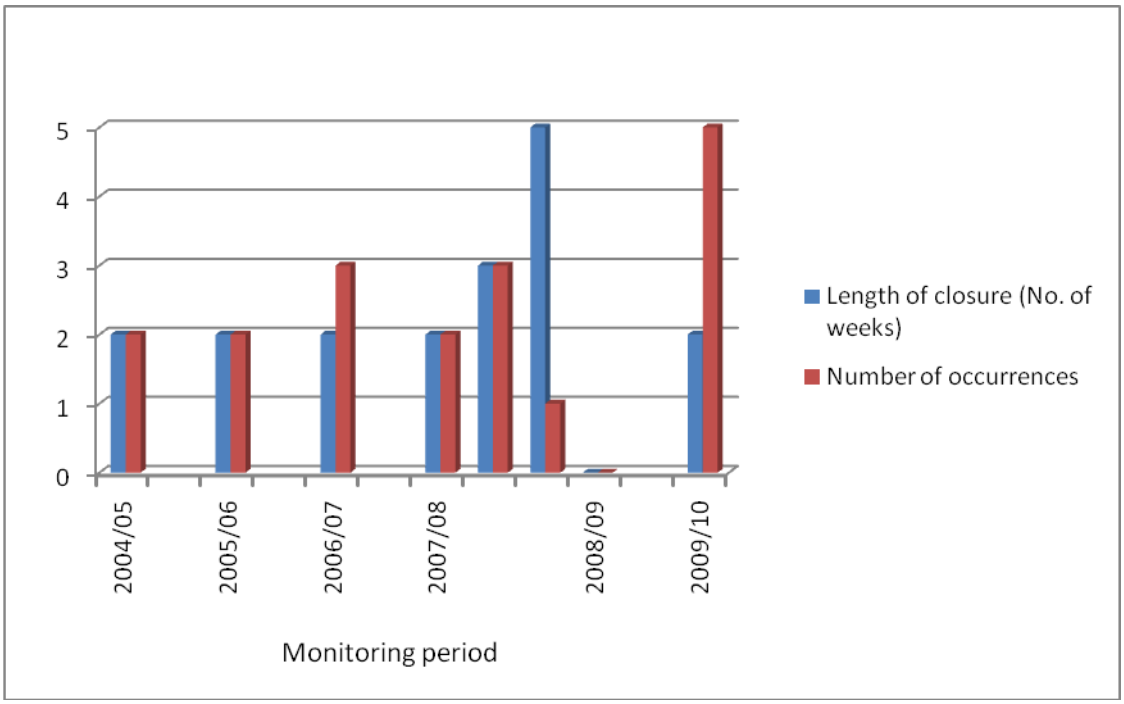

Source: Agency biotoxin monitoriing programme

## Graph 2: Shellfish bed closures due to positive tests for lipophilic toxins between 2004/05 and 2009/10 in Scotland




Source: Agency biotoxin monitoriing programme

**Graph 3: Shellfish bed closures due to positive tests for lipophilic toxins between 2004/05 and 2009/10 in Northern Ireland**




Source: Agency biotoxin monitoring programme

*Testing methodology*

8. Regulation (EC) No. 2074/2005 (as amended) stipulates the methods to be used in the testing of shellfish flesh for the three main marine biotoxin groups which are subject to official control monitoring. Currently the MBA, as described in regulation (EC) No. 2074/2005, is the official method for the detection of lipophilic toxins, including those that can cause DSP, in the edible parts of LBM. The same Regulation also allows the use of alternative methods if they are at least as effective as the biological method, they detect all of the regulated toxin analogues, and if they have been validated following an internationally recognised protocol.

9. In its recent published opinions on Marine biotoxins in shellfish, the European Food Safety Authority (EFSA)[8] concluded that the MBA has shortcomings and is not considered an appropriate tool for control purposes for lipophilic toxins because of the high variability in results, the insufficient detection capability and limited specificity. The EFSA panel further concluded that LC-MS has the greatest potential to replace the animal tests for the specific detection, quantification and confirmation of all listed lipophilic toxins.

10. Following EFSA's assessments and recent developmental work on the LC-MS methodologies, the Commission presented a proposal to Member States which would require them to adopt LC-MS as the reference method for detection of lipophilic toxins. In order to allow Member States time to adapt their monitoring programme and apply validated LC-MS methods, the proposed amendment to the legislation currently includes a transitional period of three years, after which the MBA can only be used to detect new or unknown marine biotoxins. The proposal was accepted by the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in November 2009 and, following the

[8] Scientific Opinions of the Panel on Contaminants in the food chain - Marine biotoxins in shellfish: Okadaic acid and analogues (adopted on 27 November 2007); Azaspiracid group (adopted on 9 June 2008); Yessotoxin Group (adopted 2 December 2008); Pectenotoxin group (adopted 27 May 2009); Summary on regulated marine biotoxins (adopted on 13 August 2009) http://www.efsa.europa.eu/

Commission's usual notification procedure, is expected to be adopted before the end of 2010.

11. The Commission have a preference for harmonised testing across the European Union and currently LC-MS methods are undergoing validation by the Community Reference Laboratory (CRL) for their use in detecting and quantifying marine biotoxins In addition, Cefas has been carrying out a research project for the Agency to validate a similar method that takes account of UK conditions. The research project includes the validation of the sample extraction procedures and analytical method following internationally recognised protocols, establishing method performance characteristics and an evaluation of robustness, practicality and fitness for purpose of the method during routine operation in a high throughput monitoring programme. The project started in January 2008 and is due to be completed in December 2010. A method should therefore be available for use in the UK monitoring programme, for the major species of shellfish tested in UK waters early in 2011.

**Implications for shellfish harvesting areas**

12. The EFSA opinions confirm that LC-MS is a highly specific and more sensitive method for the detection of lipophilic toxins compared to the MBA. The improved performance characteristics of the LC-MS will increase the confidence in results arising from the monitoring programme, as any positive results can only be attributed to the lipophilic toxins selected for monitoring.

**Implications for Public Health**

13. The lipophilic toxin group includes those compounds that cause DSP, which is characterised by symptoms of diarrhoea, nausea, vomiting and abdominal pain. These symptoms occur shortly after consumption of contaminated LBM such as mussels, scallops, oysters, cockles or clams.

14. Data reported on outbreaks of foodborne disease from the Health Protection Agency between 2000 and 2009 indicated that there were 57 outbreaks relating to shellfish in England and Wales. One outbreak in 2004 and two in 2006 were linked to DSP. The outbreak in 2004 was in London and involved 44 people who were reported as being ill from consumption of mussels. Of the outbreaks in 2006, one outbreak in London involved 139 people who were reported being ill after consuming shellfish and the other in Wales affected three people. There have been outbreaks in Scotland and Northern Ireland associated with shellfish, but the cause of the illnesses was not identified.

15. Whilst responsibility for the official monitoring programme falls to the Agency, responsibility for ensuring that only safe product is placed on the market is the responsibility of food business operators (FBOs). The replacement of the MBA will provide further opportunities for FBOs to access commercial reference method tests which will assist them in determining whether or not to place their products on the market. In addition, the change in methodology to a more specific and sensitive method will increase confidence in the results of the monitoring programme for consumers and industry.

**Animal welfare**

16. As stated in paragraph 3, the replacement of animal tests where a scientific alternative is available is a requirement under EU and national Law. The Agency has been committed to reducing animal testing in its biotoxin monitoring programmes and has been working with the UK licensing authorities for the MBA (the Home Office is the licensing authority in GB, and a similar function is carried out by the Department of Health, Social Services

and Public Safety in Northern Ireland) to reduce the ethical burden of the MBA and eventually replace it. The move to LC-MS will have a major impact with a significant reduction in the ethical burden of animal tests. It is estimated that the adoption of LC-MS as an alternative to the MBA should reduce the use of animals in testing for lipophilic shellfish toxins by more than 90%. The MBA will, however, continue to be used for the detection of new or unknown marine biotoxins.

17. Concerns on the use of animals in testing have also been raised by animal protection organisations in correspondence with the Agency. These groups are seeking a reduction or replacement of animals in testing.

**Overview of the Shellfish Industry**

18. There is a wide range of food business operators involved in growing, harvesting, processing and/or placing on the market LBM sourced from UK classified shellfish harvesting beds. Under Regulation (EC) 853/2004, certain establishments are required to be approved for the handling of LBM. There are currently 215[9] approved establishments in the UK (77 in England, 13 in Wales, 118 in Scotland and 7 in Northern Ireland). Approved establishments include: purification or depuration centres where LBM are purified to reduce contamination before being placed on the market; dispatch centres where LBM are received and further handed (e.g. washing, cleaning and grading); wholesale markets; auction halls and processing plants.

19. There are also a large number of food business operators growing and harvesting LBMs on a commercial scale which, as suppliers of primary products, are only required to be registered with local Food Authorities. The Agency does not hold details on these centrally. However, various published articles and reports on shellfish production in the UK in 2008 include data on farmed shellfish production, some of which is reported below in Table 2. Figures do not include production from wild shellfish beds.

**Table 2: Summary of production of shellfish from farmed shellfish and shellfish beds regulated under Fishery Orders in the UK in 2008 (tonnes) [(a)]**

| | England | Wales | Scotland | Northern Ireland | UK Total |
|---|---|---|---|---|---|
| Pacific Oyster | 841 | 14 | 303 | 180 | 1,338 |
| Native flat oyster | 424 | 0 | 20 | 0 | 444 |
| Scallops | 0 | - | 2 | - | 2 |
| Queens | - | - | 27 | - | 27 |
| Mussels | 7946 | 21,617[(b)] | 5,869 | 16,566 | 51,998 |
| Clams | 65 | - | - | - | 65 |
| Cockles | 13,463 | 960 | - | - | 14,423 |
| Estimated Value (£millions) | 16.5 | 15.9 | 7.6 | 13.2 | 53.2 |

(a) Source: CEFAS Shellfish News 28, Autumn/Winter 2009
(b) Data incomplete as not all returns were available

[9] Source: Agency published data on fish and shellfish approvals http://www.food.gov.uk/foodindustry/farmingfood/fishapprove/ - July 2010

20. In England and Wales, 76 businesses were authorised for shellfish aquaculture production in 2008. The main species cultivated were mussels and Pacific oysters. In Scotland, 168 companies were registered at the end of 2008. Of these, twenty produced 81% of the total mussel production in Scotland and eight accounted for 66% of the Scottish production of Pacific oysters. The industry was dominated by small producers, although there was a continued and marked trend towards large companies contributing to the annual production of all species. A total of 348 workers were employed in the industry in 2008 (149 full-time and 199 part-time and casual workers)[10]. In Northern Ireland the main species of shellfish cultivated is mussels. In Northern Ireland the industry employed 54 full time and 32 part-time staff in 2008.

21. In addition some producers may harvest LBMs, in particular from wild shellfish beds, and directly supply small quantities of these to the final consumer or local retail establishments. It is not possible to provide a figure on the number involved as information on these producers is not collected.

22. In meetings with the Agency to discuss the limitations of the MBA and the Commission's intentions to replace the method with LC-MS, industry and their representatives have indicated that they fully support a move to the LC-MS method particularly as they have been encouraging a replacement for the MBA for some time. Previous experience with adoption of analytical methods for PSP toxins shows that industry viewed the changes positively and have remained supportive throughout implementation.

**Options**

23. Three options have been identified, the details of which are set out below:

**<u>Option 1</u> – Do nothing: continue to use the MBA in the UK's statutory biotoxin monitoring programme as the method of detection for lipophilic toxins**

Doing nothing would mean using the MBA as the detection method for lipophilic toxins after the transitional period set in the EU proposal. This option would result in the UK's non-compliance with that legislation and the requirement to move towards a suitable alternative when that testing method becomes available.

The UK licensing authorities for the MBA are likely to refuse to license its continued use in the biotoxin monitoring programme when the alternatives become available. Breach of EU legislation could give rise to infraction proceedings against the UK by the Commission in the European Court of Justice under Article 258 of the Treaty on the Functioning of the EU for non-application of EU Council Directive 86/609/EEC and EC Regulation 2074/2005.

There is also the risk of damage to the Agency's reputation as an evidence-based organisation if it continues to support animal testing that is not scientifically necessary and hence in contravention of the Animals (Scientific Procedures) Act 1986.

**<u>Option 2:</u> Support the EU proposal and replace the MBA with the LC-MS at the end of the transitional period.**

The EU proposal currently includes a transitional period of three years to allow Member States time to adapt their monitoring programme and apply LC-MS validated methods. The adoption of the LC-MS in the UK's monitoring programme will provide a more robust testing method to detect lipophilic toxins. This will improve confidence in the results of the monitoring programme thereby benefiting consumers and businesses. The UK would be

[10] Source: "Scottish Shellfish Farm Production Survey 2008" (ISN: 1363-5687), available from Marine Scotland

complying with EU legislation on the testing methods for lipophilic toxins. However, not introducing an alternative method once it is validated and available does not fulfil the requirements of the legislation on the use of animals in scientific tests. This could lead to the risk of EU infraction proceedings under Directive EC 86/609. Also licensing authorities are likely to remove licence once alternatives are available effectively halting the UK monitoring programme.

**<u>Option 3</u>: Support the EU proposal and replace the MBA with LC-MS as soon as the method has been validated before the end of the transitional period.**

Option 3 is the Agency's preferred option. This option would bring forward the benefits from improved confidence in the results of the monitoring programme as described above for option 2, and in addition, early introduction of LC-MS would bring forward the benefits of reducing the ethical burden and significantly reduce the need to use animals for testing. The UK would be complying with EU legislation on testing methods for algal toxins and the requirements of the legislation on the use of animals. The risk of EU infraction proceedings in respect of Directive EC 86/609 would be removed, because the earliest possible adoption of LC-MS would mean that animals would not be subjected to unnecessary scientific testing when there was a validated alternative available that did not require their use.

In meetings with the Agency, industry has indicated its full support of the early introduction of LC-MS and has been encouraging its use in the UK's biotoxin monitoring programme for some time.

We would plan to follow the previous approach adopted for introducing High Performance Liquid Chromatography for detection of PSP toxins where there was a phased introduction, with LC-MS being incrementally adopted for the testing of individual shellfish species as the method became available for each species. Mussels, which represent 90% of samples in the monitoring programme, are likely to be the first species tested with LC-MS. The method must be validated for individual shellfish species and will be applied to other species as soon as it is available.

## Costs and benefits

<u>Sectors and groups affected</u>

24. Food business operators involved in harvesting and placing LBMs on the market will be affected as the format in which results are reported in the monitoring programme will change. There may also be a change in the number of bed closures seen year-on-year, but this is likely to be minimal as the increase in specificity will reduce the variability in the results and it will impact equally on both positive and negative results. FBOs may also benefit from increased opportunities to apply the reference method to their own testing regime due to increased availability of testing facilities.

25. Consumers of LBMs will benefit as the change to a more sensitive testing method will provide added reassurance that the monitoring programme is sufficiently robust and LBMs are safe to eat.

26. Testing laboratories could benefit as the change in methodology to a test that can be more easily employed by a wider range of analytical laboratories should provide opportunities for more laboratories to offer biotoxin testing and increase competition in the market place.

27. Local authorities responsible for enforcing the legislation with respect to harvesting and placing LBMs on the market will benefit from increased confidence in the testing results that will lead to enhanced decision making when enforcement action is required.

**<u>Option 1</u> – Do nothing: continue to use the MBA in the UK's statutory biotoxin monitoring programme as the method of detection for lipophilic toxins**

28. There are no incremental costs and benefits resulting form this option. Option 1 is the baseline by which costs and benefits of other options are compared against.

29. The UK Government could potentially incur infraction proceedings from doing nothing due to it not complying with EU legislation.

**<u>Option 2</u> – Support the EU proposal and replace the MBA with the LC-MS method at the end of the transitional period**.

<u>Costs</u>

<u>Biotoxin testing costs</u>

30. The costs to the Agency of testing a sample using LC-MS will be higher as the capital and operational costs of the equipment are more expensive than the MBA, as the method is more resource intensive and involves more specialist analysis than the MBA. Based on an industry average, the cost for testing a sample using the LC-MS is approximately 24% percent higher than the MBA. Based on the number of samples carried out in 2009/10 (as shown in table 1) the approximate[11] cost to the Agency of using the MBA in the UK in 2009/10 was £634,000. This was quantified by multiplying the number of MBA samples, 3,937, by the UK wide approximate cost per sample, £160.

31. This option offers a transition period of three years before LC-MS testing will be adopted. Therefore, the added costs from using LC-MS will not begin until 2012/13. In addition, as the cost of LC-MS testing does not begin until the end of the transition period the cost per LC-MS test has been up-rated to represent 2012/13 prices[12], which results in the UK wide approximate cost of LC-MS testing costing £210 based on an industry average for marine scientific research. The number of samples is based on the 2010/11 contract agreement which states the number of samples which are expected to be tested. Table 3 displays the current costs of using the MBA method broken down by England and Wales, Scotland and Northern Ireland.

**Table 3: Additional testing cost of LC-MS**

| | ***MBA*** | | | ***LC-MS*** | | | |
|---|---|---|---|---|---|---|---|
| | ***Number of samples tested in 2009/10*** | ***Cost per MBA test*** | ***Total cost MBA tests*** | ***Number of samples tested in 2012/13*** | ***Cost per LC-MS test **** | ***Total cost LC-MS tests*** | ***Additional annual cost of LC-MS tests*** |
| **England & Wales** | 962 | £160 | £155,000 | 1,000 | £210 | £214,000 | £59,000 |
| **Scotland** | 2,580 | £160 | £415,000 | 2,683 | £210 | £574,000 | £159,000 |
| **Northern Ireland** | 395 | £160 | £64,000 | 350 | £210 | £75,000 | £11,000 |
| **UK** | 3,937 | £160 | £634,000 | 4,033 | £210 | £863,000 | £229,000 |

Figures may not total due to rounding
*Sampling costs inflated to 2012/13 prices

[11] Approximations are used to keep the specific costs of sampling confidential
[12] Figures up-rated by 7.25% using forecast data up to financial year 2012/13 from Treasury GDP deflator: www.hm-treasury.gov.uk/data_gdp_fig.htm.

**Do interested parties agree with the approximate cost per sample used for MBA and LC-MS tests across all countries?**

32. The additional cost of using LC-MS is displayed in table 3 by calculating the difference between the approximate total cost of LC-MS and approximate total cost of MBA. LC-MS testing approximately adds an additional £229,000 in annual costs from 2012/13.

33. The number of samples anticipated to be carried out in the contract agreement may overestimate or underestimate the number of samples actually tested. Given the sensitivity of these estimates we present the approximate sampling cost of using LC-MS after the three-year transition period within a 10% upper- and lower-bound range for the number of samples carried out. Table 4 displays a range of the additional cost of using LC-MS which ranges from an additional £315,000 to £143,000. The midpoint equates to an additional annual cost of LC-MS of £229,000, as in table 5.

**Table 4: Range of testing cost of LC-MS 2012/13**

| | | | ***Upper bound estimations*** | | | ***Lower bound estimates*** | | |
|---|---|---|---|---|---|---|---|---|
| | Total cost MBA tests | Cost per LC-MS test* | Number of samples tested + 10 % | Upper bound total cost of LC-MS tests | Upper bound additional annual cost of LC-MS tests | Number of samples tested - 10 % | Lower bound total cost of LC-MS tests | Lower bound additional annual cost of LC-MS tests |
| England & Wales | £155,000 | £210 | 1,100 | £235,000 | £80,000 | 900 | £192,000 | £38,000 |
| Scotland | £415,000 | £210 | 2,951 | £631,000 | £216,000 | 2,415 | £516,000 | £101,000 |
| Northern Ireland | £64,000 | £210 | 385 | £82,000 | £19,000 | 315 | £67,000 | £4,000 |
| **UK** | **£634,000** | **£210** | **4,436** | **£949,000** | **£315,000** | **3,630** | **£776,000** | **£143,000** |

Figures may not total due to rounding
Upper bound number of samples is the number of samples carried out, as stipulated in the contract, plus 10%
Lower bound number of samples is the number of samples carried out, as stipulated in the contract, minus 10%
*Sampling costs inflated to 2012/13 prices

34. However, costs for samples tested with LC-MS may reduce over time as the methodology and expertise is developed. The replacement of the MBA with LC-MS could also increase interest for the contract with laboratories bidding for the work and driving down the price.

35. There may be increased costs to the industry as the sensitivity of the LC-MS when compared to the MBA could result in more bed closures. This cost is unquantifiable as it is dependent on the size of business, volume and profit from production, the duration of closure of shellfish beds and the prevalence of toxins in a given year.

36. We do not expect there to be any major familiarisation costs for industry and enforcement authorities.

Benefits

37. As the LC-MS is a more robust testing method for detecting lipophilic toxins its use in the statutory monitoring programme would further reduce the risk of contaminated shellfish being placed on the market. Consumers would benefit from a reduced risk of foodborne illness from consumption of contaminated shellfish, which may lead to fewer days of sick with a reduction in loss of earnings. There could also be a reduction in the burden placed on the NHS from treating illness associated with the consumption of contaminated

shellfish and costs to the economy due to fewer lost work days. However, these benefits are unquantifiable as we are unable to attribute the impact of this option to the reductions highlighted. Less association of shellfish products with foodborne disease can only benefit the image of the industry.

38. It is anticipated that the accuracy of decision making in terms of opening or closing shellfish beds contaminated with lipophilic toxins will increase with the introduction of the more specific quantitative LC-MS method and the replacement of the qualitative MBA, by avoiding closures due to compounds other than lipophilic toxins, such as free fatty acids. The competent authority will be better informed regarding the emergence or decline of a toxic event; this can only benefit the risk management procedures as applied by the Agency and local authorities.

39. A more robust testing methodology should result in increased consumer confidence in shellfish products. This could benefit the industry through additional revenue from domestic and export markets thus helping to facilitate trade. The move away from the MBA may increase the availability of testing for shellfish businesses as LC-MS does not require a special operating licence and more laboratories may be able to offer tests at competitive prices.

40. The LC-MS would also significantly reduce the number of animals used in testing. Since the testing method on animals can cause substantial suffering there is a strong ethical drive to move to alternative methods. The removal of an association between shellfish products and animal testing is likely to benefit the industry in terms of public perception and is something industry has indicated it would strongly support.

**Can shellfish businesses provide any further evidence on the costs and benefits to the industry that would arise from the implementation of the LC-MS to input at the impact assessment? Specific information on the likely impact on smaller businesses would be very helpful.**

**<u>Option 3</u> – support the proposal and replace the MBA with the LC-MS as soon as the method has been validated before the end of the transitional period**

<u>Costs</u>

**41.** There will be an immediate additional annual sampling cost to the Agency of adopting the LC-MS sampling method. Table 5 displays the immediate additional annual sampling cost of adopting LC-MS sampling broken down by England & Wales, Scotland and Northern Ireland.

**Table 5: Additional annual testing cost of adopting LC-MS method**

| | ***MBA*** | | | ***LC-MS*** | | | |
|---|---|---|---|---|---|---|---|
| | ***Number of samples tested in 2009/10*** | ***Cost per MBA test*** | ***Total cost MBA tests*** | ***Number of samples tested in 2010/11*** | ***Cost per LC-MS test*** | ***Total cost LC-MS tests*** | ***Additional annual cost of LC-MS tests rounded*** |
| **England & Wales** | 962 | £160 | £155,000 | 1,000 | £200 | £199,000 | £45,000 |
| **Scotland** | 2,580 | £160 | £415,000 | 2,683 | £200 | £535,000 | £120,000 |
| **Northern Ireland** | 395 | £160 | £64,000 | 350 | £200 | £70,000 | £6,000 |
| **UK** | 3,937 | £160 | £634,000 | 4,033 | £200 | £804,000 | £171,000 |

42. The added cost of LC-MS testing sampling is displayed in table 5 by calculating the difference between the approximate total cost of LC-MS and the approximate total cost of MBA. Use of LC-MS in testing adds approximately an immediate additional £171,000 in annual costs from 2010/11.

43. The number of samples anticipated to be carried out may overestimate or underestimate the number of samples actually tested. Given the sensitivity of these estimates we present the approximate biotoxin testing cost of using LC-MS with a 10% upper- and lower-bound range for the number of samples carried out. Table 6 displays a range of the additional annual cost of using LC-MS of between an extra £90,000 to £251,000. The midpoint equates to an additional annual cost of LC-MS of £171,000, as in table 5.

**Table 6: Range of testing costs using LC-MS 2010/11**

| | | | ***Upper bound estimations*** | | | ***Lower bound estimates*** | | |
|---|---|---|---|---|---|---|---|---|
| | Total cost MBA tests | Cost per LC-MS test* | Number of samples tested + 10 % | Upper bound total cost of LC-MS tests | Upper bound additional annual cost of LC-MS tests | Number of samples tested - 10 % | Lower bound total cost of LC-MS tests | Lower bound additional annual cost of LC-MS tests |
| England & Wales | £155,000 | £200 | 1,100 | £219,000 | £65,000 | 900 | £179,000 | £25,000 |
| Scotland | £415,000 | £200 | 2,951 | £589,000 | £173,000 | 2,415 | £482,000 | £66,000 |
| Northern Ireland | £64,000 | £200 | 385 | £77,000 | £13,000 | 315 | £63,000 | -£1,000 |
| **UK** | **£634,000** | **£200** | **4,436** | **£885,000** | **£251,000** | **3,630** | **£724,000** | **£90,000** |

Figures may not total due to rounding
Upper bound number of samples is the number of samples carried out, as stipulated in the contract, plus 10%
Lower bound number of samples is the number of samples carried out, as stipulated in the contract, minus 10%

Benefits

44. Option 3 would give the same benefits as option 2, but these would be brought forward as soon as the policy is implemented. In addition, the UK would not be at risk of infraction proceedings from the unnecessary scientific testing of animals.

**Small Business Impact test**

45. We do not think the proposed change in the testing method for detecting lipophilic toxins will impact on small shellfish businesses, however we are seeking the views of small firms through the consultation.

**Competition Assessment**

46. The proposed change in the testing method for detecting lipophilic toxins will not impact on how businesses operate. Therefore the Agency does not believe that option 3, the Agency's preferred option, will have any effect on competition between shellfish firms.

**Administrative burden and policy costs**

47. The replacement of the MBA with the LC-MS is not expected to add significant administrative burdens for industry or policy makers. The LC-MS method is not new and Standard Operating Procedures already exist.

## Enforcement

48. There should be no significant impact on enforcement authorities as the level of sampling is not expected to change.

## Sustainable development

49. Impacts under the three pillars of sustainable development (environmental, economic and social) have been, and continue to be considered in the preparation of this Impact Assessment. Option 3 is the preferred option because it gives increased confidence in the results of the monitoring programme benefiting consumers and businesses, and significantly reduces animal testing. It is considered that the benefits of this proposal would outweigh any potential negative impacts.

## Statutory Equality Duties Impact

50. Under the statutory equality duties test the FSA does not forsee any additional impact in terms of equality.

# Annex 1: Post Implementation Review (PIR) Plan

A PIR should be undertaken, usually three to five years after implementation of the policy, but exceptionally a longer period may be more appropriate. A PIR should examine the extent to which the implemented regulations have achieved their objectives, assess their costs and benefits and identify whether they are having any unintended consequences. Please set out the PIR Plan as detailed below. If there is no plan to do a PIR please provide reasons below.

| |
|---|
| **Basis of the review:**<br>The statutory monitoring programme is reviewed annually. The effectiveness of the new testing regime will be assessed as part of that review. |
| **Review objective:**<br>To ensure the method is fit for purpose and protects public health. |
| **Review approach and rationale:**<br>A combined approach of reviewing monitoring data and stakeholder informal feedback. |
| **Baseline:**<br>Current testing method |
| **Success criteria:**<br>Public health is protected and the best scientifically available method is used. |
| **Monitoring information arrangements:**<br>On-going collection of data provided as part of the biotoxin monitoring programme. |
| **Reasons for not planning a PIR:**<br>N/A |

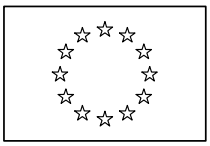
**Annexe C**

**Consultation on a proposal to amend Regulation (EC) No. 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs (England)**

## List of Interested Parties

Aquafish Solutions Ltd.
Association of Sea Fisheries Committees of England and Wales
Billingsgate Market
British Frozen Food Federation
British Retail Consortium
British Trout Association
British Union for the Abolition of Vivisection (BUAV)
Calshot Oyster Fishermen Ltd.
Centre for Environment Fisheries and Aquaculture Science (Cefas)
Chartered Institute of Environmental Health
Chilled Food Association Ltd.
Consumer Focus
Co-operative Group
Cornwall Sea Fisheries Committee
Dart Estuary Environmental Management
Department for Environment, Food and Rural Affairs (Defra)
Environment Agency
EU Commission
Food and Drink Federation
Food and Environment Research Agency
Friends of the Earth
Gala Productions Ltd.
Grimsby Fish Dock Enterprises Ltd.
Health Protection Agency
Home Office
Humane Society International
Indigo Limited
Institute of Consumer Affairs
International Association for the Study of Obesity
LGC
Limosa Farms Ltd.
Local Authorities in England with classified shellfish beds
Local Government Regulation
Marine Management Organisation
Marks and Spencer plc
National Association of British Market Authorities
National Consumer Federation
National Federation of Fishermen's Organisations
Natural England
National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs)
Offshore Farms
PETA
Reading Scientific Services Ltd.
Scallop Association
Sea Fish Industry Authority
Seafood Processors Association
Shellfish Association of Great Britain
Society of Food Hygiene and Technology
Sustain – The alliance for better food and farming
The Company Shed
University of Newcastle upon Tyne, School of Marine Science and Technology
Which?
Worshipful Company of Fishmongers

**SANCO/6831/2009 rev 5**



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels,

Draft

**COMMISSION REGULATION (EC) No …/..**

**of […]**

**amending Regulation (EC) No 2074/2005 as regards recognized testing methods for detecting marine biotoxins in live bivalve molluscs**

**(Text with EEA relevance)**

Draft

**COMMISSION REGULATION (EC) No …/..**

**of […]**

**amending Regulation (EC) No 2074/2005 as regards recognized testing methods for detecting marine biotoxins in live bivalve molluscs**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin[1], and in particular Article 11(4) thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption[2], and in particular Article 18(13)(a) thereof,

Whereas:

(1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin and Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin. Implementing measures for those Regulations as regards recognized testing methods for marine biotoxins are set out in Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004[3]. It is necessary to modify those implementing measures in the light of new scientific evidence.

(2) In July 2006 the Commission requested the European Food Safety Authority (EFSA) to provide a scientific opinion to assess the current limits and methods of analysis with regard to human health for various marine biotoxins as established in the Community

1 OJ L 139, 30.4.2004, p.55.
2 OJ L 139, 30.4.2004, p.206.
3 OJ L 338, 22.12.2005, p. 27.

legislation, including new emerging toxins. The last of a series of opinions was published on 24 July 2009.

(3) The mouse bioassay (MBA) and the rat bioassay (RBA) are is the official methods for the detection of lipophilic biotoxins. The Panel on Contaminants in the Food Chain of EFSA noted that these bioassays have shortcomings and are not considered an appropriate tool for control purposes because of the high variability in results, the insufficient detection capability and the limited specificity.

(4) Recently developed alternatives to the biological methods for the determination of the marine biotoxins with lower limits of detection (LOD) have successfully been tested in prevalidation studies.

(5) The technique of liquid chromatography (LC) mass spectrometry (MS) should be applied as the reference method for the detection of lipophilic toxins and used as matter of routine, both for the purposes of official controls at any stage of the food chain and own-checks by food business operators. The performance criteria of that technique should be stipulated after a successful prevalidation. It is appropriate that the performance criteria be established by the Community Reference Laboratory on marine biotoxins and that an interlaboratory validation is carried out by the Member States.

(6) In the long term, an interlaboratory validation of the method should be made, following an internationally agreed protocol. The Community Reference Laboratory on marine biotoxins should facilitate such a validation process.

(7) Other detection methods, different from the liquid chromatography (LC) mass spectrometry (MS), could be applied for the detection of lipophilic toxins provided that they fulfil the method performance criteria stipulated by the Community Reference Laboratory on marine biotoxins. Such methods should be intralaboratory validated and successfully tested under a recognised proficiency test scheme.

(8) To allow Member States to adapt their methods to the chemical method, the biological methods should continue to be used for a limited period of time. After this period, the biological methods should be used not as a matter of routine and only during the periodic monitoring of production areas for detecting new or unknown marine toxins.

(9) Therefore, Regulation (EC) No 2074/2005 should be amended accordingly.

(10) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

*Article 1*

Annex III to Regulation (EC) No 2074/2005 is amended in accordance with the Annex to this Regulation.

*Article 2*

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [……..].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, […]

*For the Commission*
*[…]*
*Member of the Commission*

**ANNEX**

In Annex III to Regulation (EC) No 2074/2005, Chapter III is replaced by the following:

"CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. Chemical methodology

(1) Liquid chromatography (LC) mass spectrometry (MS) shall be the reference methodology for the detection of marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. The methodology shall determine at least the following compounds:

- okadaic acid group toxins, including their esters

- pectenotoxins group toxins : PTX1 and PTX2,

- yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,

- azaspiracids group toxins: AZA1, AZA2 and AZA3.

(2) Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(3) If new analogues of public health significance are discovered, they should be included in the analysis. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.

(4) The liquid chromatography (LC) mass spectrometry (MS) procedures used as detection method must follow an interlaboratory validation process coordinated by the Community Reference Laboratory (CRL) on marine biotoxins. The CRL on marine biotoxins shall define performance criteria for these procedures on the basis of prevalidation data.

(5) As long term objective, an interlaboratory validation of the method should be made following an internationally agreed protocol. The CRL on marine biotoxins shall support activities toward inter-laboratory validation and standardization of the procedures.

(6) Other detection methods, such as high-performance liquid chromatography (HPLC) with fluorimetric detection, immunoassays and functional assays, such as the phosphatase inhibition assay, can be used as alternatives or supplementary to the liquid chromatography (LC) mass spectrometry (MS) method, provided that:

(a) either alone or combined they can detect at least the analogues as identified in point A (1) and respect the conditions of point A(4) of this Chapter; more appropriate criteria shall be defined when necessary;

(b) as a long term objective, an interlaboratory validation of the method should be made following an internationally agreed protocol; the CRL on marine biotoxins shall support activities toward inter-laboratory validation of the technique to allow for formal standardization;

(c) their implementation provides an equivalent level of public health protection.

B. Biological methods

(1) To allow Member States to adapt their methods to the chemical method as defined in point A(1) of this Chapter, a series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be still used until 31 December 2012 for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004.

(2) Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.

(3) A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, azaspiracids, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences.

(4) Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.

(5) A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

(6) A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

C. After the period established in point B(1) of this Chapter, the mouse bioassay shall be used only during the periodic monitoring of production areas and relaying areas for detecting new or unknown marine toxins on the basis of the national control programmes elaborated by the Member States."