Summary: Intervention & Options

Department /Agency:	Title:	
Food Standards Agency	Impact Assessment of a Commission Regulation measure amending rules for official controls for screening biotoxins in live bivalve molluscs (Regulation (EC) 1244/2007)	
Stage: Final	**Version:** 1	**Date:** February 2010

Related Publications: http://www.food.gov.uk/consultations/consulteng/2007/hygieneenglandamend08; http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_281/l_28120071025en00120018.pdf

Available to view or download at: http://www.food.gov.uk/foodindustry/regulation/betregs/ria/

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

Food can pose a risk to human health if it is not produced, manufactured and handled hygienically. Consumers are not usually able to observe this, and it is difficult for food business operators to credibly inform consumers how far food safety risks have been minimised. Government intervention is necessary to address this information asymmetry.

The Food Standards Agency is responsible for monitoring Live Bivalve Molluscs from classified shellfish beds for the presence of biotoxins and the measure allows the Agency, as a competent authority, the use of an alternative screening method.

What are the policy objectives and the intended effects?

The measure permits Member State competent authorities the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may bring high capacity at low cost without lowering the standards of public health protection.

What policy options have been considered? Please justify any preferred option.

1. Do nothing

2. Support application of the EU measure and provide for their enforcement by amendment of the Food Hygiene (England) Regulations as described. Option 2 is preferred because it allows the use of an alternative screening method, providing a choice and the potential for lower cost monitoring, while maintaining public health protection.

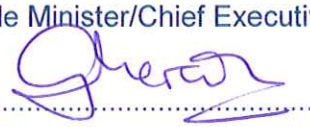
When will the policy be reviewed to establish the actual costs and benefits and the achievement of the desired effects?

November 2012.

Ministerial/CEO Sign-off For final proposal/implementation stage Impact Assessments:

I have read the Impact Assessment and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) the benefits justify the costs.

Signed by the responsible Minister/Chief Executive*:



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..... Date:

* for Impact Assessments undertaken by non-ministerial departments/agencies and NOT being considered by Parliament

Summary: Analysis & Evidence

Policy Option: 2	Description: Option 2; Support application of the measure allowing an alternative method of testing live bivalve molluscs for Amnesic Shellfish Poisoning

COSTS

ANNUAL COSTS		Description and scale of **key monetised costs** by 'main affected groups' None identified.
One-off (Transition)	**Yrs**	
£ 0	5	
Average Annual Cost (excluding one-off)		
£ 0		**Total Cost** (PV) **£ 0**

Other **key non-monetised costs** by 'main affected groups' The costs of any sample testing changes are expected to be negligible.

BENEFITS

ANNUAL BENEFITS		Description and scale of **key monetised benefits** by 'main affected groups' None monetised.
One-off	**Yrs**	
£	5	
Average Annual Benefit (excluding one-off)		
£		**Total Benefit** (PV) **£**

Other **key non-monetised benefits** by 'main affected groups' Potential improvements in the efficiency and choice of methods of sampling for biotoxins.

Key Assumptions/Sensitivities/Risks

Price Base Year 2007	Time Period Years	**Net Benefit Range** (NPV) **£ N/A**	**NET BENEFIT** (NPV Best estimate) **£ N/A**

What is the geographic coverage of the policy/option?				England
On what date will the policy be implemented?				November 2007
Which organisation(s) will enforce the policy?				N/A
What is the total annual cost of enforcement for these organisations?				£ 109.7 million
What is the incremental annual cost of enforcing **this proposal**?				£ negligible
Does enforcement comply with Hampton principles?				Yes
Will implementation go beyond minimum EU requirements?				No
What is the value of the proposed offsetting measure per year?				£ N/A
What is the value of changes in greenhouse gas emissions?				£ N/A
Will the proposal have a significant impact on competition?				No
Annual cost (£-£) per organisation (excluding one-off)	Micro **0**	Small **0**	Medium **0**	Large **0**
Are any of these organisations exempt?	No	No	N/A	N/A

Impact on Admin Burdens Baseline (2005 Prices) (Increase - Decrease)

Increase of £ N/A Decrease of £ N/A **Net Impact** **£** N/A

Key: **Annual costs and benefits: Constant** **(Net) Present**

Evidence Base (for summary sheets)

Reason for Intervention

1. Food can pose a risk to human health if it is not produced, manufactured and handled hygienically.

2. In general, consumers cannot observe the production, manufacturing or handling processes of foodstuffs. Food safety hazards in foodstuffs tend to be microscopic or otherwise not observable, and so not readily identifiable by consumers. In most cases it is not possible for food business operators to credibly inform consumers of the degree to which risk in foodstuffs has been minimised. This information asymmetry implies a benefit from government intervention to require hygiene standards of food business operators.

3. In this specific situation, government intervention takes the form of monitoring Live Bivalve Molluscs from classified shellfish beds for the presence of biotoxins. The Food Standards Agency is responsible for this monitoring. To be efficient, the monitoring methods need to be cost effective and in line with the latest scientific understanding. Therefore there is a need to update the legislation in line with the latest scientific evidence on a potential alternative screening mechanism.

Intended Effect

4. The intended effect is to update the EU food hygiene legislation to allow alternative ways of carrying out controls, which make use of developments in science and technology. In this case, specifically, to permit the use of an alternative screening method for the detection of Amnesic Shellfish Poisoning (ASP) toxins, which may have the benefit of being cheaper.

Background

5. Regulation (EC) 854/2004 requires EU Member State competent authorities to fix the location and boundaries of live bivalve mollusc (LBM) production and relaying areas. It also requires the competent authority to classify authorised LBM production areas as being Class A, B or C, with A being the cleanest. The Food Standards Agency, as the UK competent authority, is directly responsible for ensuring these rules are complied with.

6. One of the requirements set down in Regulation (EC) 854/2004 is for competent authorities to monitor LBMs for the presence of biotoxins (854/2004, Annex II, B). The role of the Agency as competent authority as regards the designation and classification of shellfish harvesting areas is set out in the National Control Plan[1], which the Agency is required to produce in line with EU Regulation (EC) 882/2004[2].

7. This measure concerns the way in which competent authorities carry out official controls, and will not have any impact on industry as testing costs are borne solely by the Agency.

[1] The UK National Control Plan 2007 – 2011. Reference to shellfish harvesting can be found in Appendix C, paragraph 16 of the FSA web site at: http://www.food.gov.uk/multimedia/pdfs/uknationalcontrolplan.pdf

[2] Regulation (EC) 882/2004 sets down the principles and approach to be to be taken by competent authorities in EU Member States that have responsibility for monitoring and enforcing compliance with feed, food, animal health and animal welfare rules.

Detecting Amnesic Shellfish Poisoning

8. The method for detecting the biotoxin Amnesic Shellfish Poisoning (ASP) was laid down in Commission Regulation (EC) 2074/2005, Chapter II and was the high performance liquid chromatography (HPLC) method. However, Commission Regulation 1244/2007 permits the use, for screening purposes, of edible parts of molluscs, of the 2006.02 ASP ELISA method (as published in the AOAC Journal of June 2006). The measure proposes a possible alternative that the Agency could consider for testing official control samples and which may be more cost effective. The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use.

Amendment of the Food Hygiene (England) Regulations 2006 (as amended)

9. The draft Statutory Instrument (SI) was issued with the public consultation on 2 October 2007. The SI will provide for the execution and amendment of the EU
10. measure in English law.

Options

11. Two Options were identified in relation to these Regulations:

- *Do nothing*.
- *Support the regulation's application to allow the method for screening for ASP and provide enforcement through amendment of the Food Hygiene (England) Regulations*

Costs & benefits of Options

Option 1. Do nothing.

12. There are no incremental benefits or costs.

Option 2. Support the measure's application to allow the method for screening for ASP and provide enforcement through amendment of the Food Hygiene (England) Regulations 2006 (as amended).

Benefits

13. The availability of an approved alternative to HPLC would mean that if HPLC became unavailable for any reason, the competent authority would still be able to conduct the requirements for testing classified shellfish beds for ASP toxins. If no alternative to HPLC were available the competent authority would be unable to carry out tests, perhaps leading to sanctions by the European Commission.

14. The measure proposes a potential alternative that the Agency could consider for testing official control samples, which is potentially both cheaper and faster, and hence could lead to savings for competent authorities when screening for Amnesic Shellfish Poisoning (ASP). The Agency will assess this alternative test and ensure it is at least as safe as the current testing regime before it is further considered for use and any potential savings made

15. Option 2 was preferred as it enables the benefit of potential improvements in the efficiency and choice of methods of sampling for biotoxins in LBMs, with no lowering of public health protection. Providing for Commission Regulation 1244/2007 in English law also avoids any risk of the UK failing in its Treaty obligations with the consequence of sanctions by the European Commission (although there is no certainty that this would follow in this particular case).

Cost of enforcement, specific impacts, public consultation and date of policy implementation

Cost of enforcement for the 'competent authority'

16. The regulations with which this IA is concerned place requirements on, or give permission to, the Food Standards Agency (FSA) as the Competent Authority. The **total** cost of the Agency in 2007 was £109,651,000[3] which represents the cost of administration, inspections, surveillance, managing research and development, education, publicity and publications.

Sustainability and other Specific Impacts

17. The Agency considers that Option 2 is the most sustainable as it provides an alternative screening method with more flexibility but with no impact on sustainability.

18. No comments were received during the public consultation on any of the impact areas.

Public consultation

19. This IA was subject to public consultation which was issued on 2 October 2007 and closed 4 January 2008. No further evidence was received with regard to costs or benefits resulting from the measure or the affect on sustainability or other identified areas of impact.

20. The Agency is obliged to place a summary of stakeholders' responses to each of its public consultations on its website within three months of the closure of the consultation, and the summary for the Draft Food Hygiene (Amendment) v(England) Regulations (2008) can be seen at: http://www.food.gov.uk/multimedia/pdfs/consultationresponse/hygamendeng08resp.pdf

21. Originally this issue was issued for consultation in an IA along with two measures which impacted on the official controls for red meat. The IA has been routinely updated where relevant between the end of the consultation and clearance as a final document.

Date policy will be implemented

22. Commission Regulation (EC) 1244/2007 applied 20 days after being published in the EU Official Journal (i.e. 20 days after 25 October 2007).

23. The impact of the measure is due to be looked at in November 2012. However, it is not controversial, and the decision to allow use of the screening method described is highly unlikely to be revoked.

[3] This figure is taken from the Food Standards Agency Consolidated Resource Accounts: http://www.food.gov.uk/multimedia/pdfs/publication/470465. It represents the cost of operations at the FSA Westminster office and does not include the costs of the Meat Hygiene Service or the Agency's offices in Scotland, Wales or Northern Ireland. The number can therefore be considered a reasonable approximation of the TOTAL cost of enforcement as it applies to this IA.

Specific Impact Tests: Checklist

Type of testing undertaken	*Results in Evidence Base?*	*Results annexed?*
Competition Assessment	No	Yes
Small Firms Impact Test	No	Yes
Legal Aid	No	No
Sustainable Development	Yes	Yes
Carbon Assessment	No	No
Other Environment	No	No
Health Impact Assessment	Yes	No
Race Equality	No	Yes
Disability Equality	No	Yes
Gender Equality	No	Yes
Human Rights	No	No
Rural Proofing	No	No

Annexes

Competition Assessment

The measure is not considered to have any effect on competition as it impacts solely on control bodies and not upon business.

Small Firms Impact Test

The measure is not considered to be a burden on small firms as it impacts solely on control bodies.

Sustainable development

The measure is considered to be more sustainable in that it provides more flexibility and is potentially cheaper with no lowering of the protection of public health. There do not appear to be any negative impacts on sustainability.

Race equality issues

None.

Gender equality issues

None.

Disability equality issues

None.