

# CONSULTATION DOCUMENT

**Title: Risk Based Approach for the Biotoxin Monitoring programme in Northern Ireland**

## CONSULTATION SUMMARY PAGE

<b>Date launched:</b>	4 July 2019	<b>Closing date:</b>	15 August 2019
<b>Who will this consultation be of most interest to?</b>			
<ul style="list-style-type: none"> <li>• District Councils</li> <li>• Loughs Agency</li> <li>• DAERA Marine and Fisheries</li> <li>• Private sampling contractor for Belfast and Larne Lough</li> <li>• Shellfish industry representative – Aquaculture Initiative and Seafish</li> <li>• Shellfish harvesters</li> <li>• Agri-Food Biosciences Institute (AFBI)</li> </ul>			
<b>What is the subject of this consultation?</b>			
<p>This consultation concerns a proposed new risk-based approach to monitoring marine biotoxins in live bivalve molluscs. Sampling frequencies will no longer be set at regular intervals but will be influenced by variables such as location, past exceedance and toxin type.</p> <p>This proposed risk-based approach will aid compliance with requirements laid out in Regulation (EC) No 854/2004, to reduce risk of a toxin event going undetected, ensure biotoxin monitoring programmes are risk based and subsequently increase confidence and assurance in Northern Ireland’s live bivalve mollusc industry.</p>			
<b>What is the purpose of this consultation?</b>			
<p>The FSA seeks views on proposals to implement a risk-based approach to Northern Ireland’s biotoxin monitoring programme.</p>			
<b>Responses to this consultation should be sent to:</b>			
<p>FAO: Michaela Mervyn Executive Support Unit Food Standards Agency in Northern Ireland Email: <a href="mailto:executive.support@food.gov.uk">executive.support@food.gov.uk</a></p>		<p><b>Postal Address:</b> 10A-10C Clarendon Road Belfast BT1 3BG</p> <p><b>For further information contact:</b> Richard Annett (Senior Advisor) 028 9041 7771 Email: <a href="mailto:richard.annett@food.gov.uk">richard.annett@food.gov.uk</a></p>	

## **Background to the Consultation**

Consuming shellfish contaminated with biotoxins can lead to illness, therefore there are legislative requirements laid down in EU Food Hygiene legislation that stipulates shellfish can only be commercially harvested from production areas that are classified and monitored for a range of parameters, including toxin producing phytoplankton and marine biotoxins to ensure the shellfish comply with the regulatory limits.

Section B, paragraphs 4 and 5 of Annex II of the Regulation (EC) No. 854/2004 states:

“The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.”

FSA in Northern Ireland currently implements monthly biotoxin monitoring, however we have now undertaken a risk-based assessment on biotoxins to determine appropriate sampling frequencies.

The risk assessment was completed in August 2018. This assessment used all available data between January 2011 and June 2018 for both biotoxin and phytoplankton across all 7 Loughs, including weekly data relating to Belfast Lough from June 2014 to June 2018.

## **Proposal**

To implement the new risk-based approach to biotoxin monitoring from 1<sup>st</sup> October 2019, including a review phase after 6 months of implementation.

This will:

- aid compliance with Regulatory requirements
- reduce risk of a toxin event going undetected from 17.6% to 2%.
- ensure biotoxin monitoring programmes are risk based
- further underpin confidence and assurance in Northern Ireland’s live bivalve mollusc industry

Sampling schedules can still be forecast six months in advance and will be provided by the FSA as normal, however the sampling frequency for a particular production area (Lough) will vary depending on the month and toxin type.

Phytoplankton monitoring frequencies in NI will remain unchanged. The risk assessment highlighted that current data cannot reliably support that phytoplankton monitoring can be used to predict flesh toxin exceedance. Continual review of monitoring data will strengthen the current data set and allow for future review.

## **Consultation**

The FSA in NI recognises that the implementation of current and future official control monitoring programmes is facilitated by our Delivery Partners. Therefore, we would like your views on the new risk-based approach to biotoxin monitoring, including potential impacts on your business or organisation.

An example of the proposed sampling schedule beginning Oct 2019 have been provided. We have also included a sample schedule relating to Oct 2018 – April 2019 to aid comparison. Please see Annex C - Comparison of sampling schedules.

This consultation will last for a six-week period, to provide interested parties in Northern Ireland with the opportunity to comment on the proposals.

A stakeholder meeting will also be arranged as an opportunity to discuss the proposed amendments to the FSA in NI's biotoxin monitoring programme. In addition to general views, the FSA in NI would appreciate feedback in relation to the questions below:

**Q1: Do you agree with a risk-based approach to reduce risk of a toxin event going undetected?**

**Q2: What potential challenges may this approach present for you, your organisation or your business?**

**Q3: Do you agree the proposed approach will aid compliance with Regulation EC No. 854/2004 Annex II Section B, paragraphs 4 and 5?**

**Q4: Do you agree the proposed approach will further underpin confidence and assurance in Northern Ireland's live bivalve mollusc industry?**

## Responses

Responses are required by close of business on **15 August 2019**. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

A list of interested parties is attached at Annex B. Should you be aware of anyone else not included on this list who would be interested in or affected by this consultation please do forward it to them or let us know and we can forward it to them.

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

Yours,

Richard Annett  
Food Standards Agency in Northern Ireland  
Senior Advisor (Hygiene)  
[richard.annett@food.gov.uk](mailto:richard.annett@food.gov.uk)

## Enclosed

**Annex A: Standard Consultation Information**

**Annex B: List of Interested Parties**

**Annex C: Comparison of Sampling Schedules - attached separately**

## **Annex A: Standard Consultation Information**

### **Disclosure of the information you provide**

Information provided in response to this consultation may be subject to publication or release to other parties or to disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

If you want information you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence.

In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances.

Any automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding.

The Food Standards Agency will be what is known as the 'Controller' of the personal data provided to us.

### **Why we are collecting your personal data and what we do with it**

Your personal data is being collected as an essential part of the consultation process, so that we can contact you regarding your response and for statistical purposes. We may also use it to contact you about related matters.

The Data Protection Act 2018 states that, as a government department, the Food Standards Agency may process personal data as necessary for the effective performance of a task carried out in the public interest. i.e. a consultation.

We retain personal information only for as long as necessary to carry out these functions, and in line with our retention policy. This means that this information will be retained for a minimum of 7 years from receipt.

All the personal data we process is located on servers within the European Union. Our cloud-based services have been procured through the government framework agreements and these services have been assessed against the national cyber security centre cloud security principles.

No third parties have access to your personal data unless the law allows them to do so. The Food Standards Agency will sometimes share data with other government departments, public bodies, and organisations which perform public functions to assist them in the performance of their statutory duties or when it is in the public interest.

### **What are your rights?**

You have a right to see the information we hold on you by making a request in writing to the email address below. If at any point you believe the information we process on you is incorrect you can request to have it corrected. If you wish to raise a complaint on how we have handled your personal data, you can contact our Data Protection Officer who will investigate the matter.

If you are not satisfied with our response or believe we are processing your personal data not in accordance with the law you can complain to the Information Commissioner's Office (ICO) at <https://ico.org.uk/>, or telephone 0303 123 1113.

Our Data Protection Officer in the FSA is the Information Management and Security Team Leader who can be contacted at the following email address:  
[informationmanagement@food.gov.uk](mailto:informationmanagement@food.gov.uk)

### **Further information**

If you require a more accessible format of this document, please send details to the named contact for responses to this consultation and your request will be considered.

## **Annex B: List of Interested Parties**

District Councils

Loughs Agency

DAERA Marine and Fisheries

Private sampling contractor for Belfast and Larne Lough

Shellfish industry representative – Aquaculture Initiative and Seafish

Shellfish harvesters

Agri-Food Biosciences Institute (AFBI)