Proposed rationalisation of official control shellfish biotoxin and phytoplankton monitoring points in Carlingford Lough

Summary of stakeholder responses

19 November 2021

Introduction

This consultation was issued on 21 April 2021 and closed on 2 June 2021.

The purpose of this consultation was to provide stakeholders with the opportunity to share views on our proposals to rationalise the number of official control monitoring points for biotoxin and phytoplankton monitoring in Carlingford Lough and introduce Representative Monitoring Points (RMPs) and Associated Harvesting Areas (AHAs).

The FSA is grateful to those stakeholders who responded and sets out in the tables below responses in order of the issues considered.

The key proposal on which the consultation sought views were:

- To rationalise the number of official control monitoring points for biotoxin and phytoplankton monitoring in Carlingford Lough and introduce Representative Monitoring Points (RMPs) and Associated Harvesting Areas (AHAs).

We completed a six-week consultation exercise in two phases. This included:

- Issuing the consulation package to stakeholders with an interest in the proposals and publishing it on our website from 21 April 2021 with a request for comments by 2 June 2021.
- Stakeholder engagement event held in May 2021.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table.

A list of stakeholders who responded can be found at the end of the document.

Summary of substantive comments and FSA response

Question 1: Do you agree with a risk-based approach to biotoxin and phytoplankton monitoring within Carlingford Lough?

Respondent	Comment	Response
Loughs Agency	Loughs Agency agrees that all reasonable effort should be made to reduce the risk of a toxin event going undetected. In theory Loughs Agency agrees with a risk based approach to biotoxin and phytoplankton monitoring within Carlingford Lough. However, Loughs Agency is of the opinion that the proposed plan is potentially not feasible. The Agency has experience of biotoxin sampling in another jurisdiction which is compliant with Regulation EC No. 854/2004 without the need for weekly sampling (or less than monthly sampling) for **all** species. There is a need to balance reduced risk with feasibility. Loughs Agency believes that consideration should be given to different sampling frequencies for different species taking contamination risk based on species behaviours and life history traits into account.	Noted. The purpose of the toxin monitoring review and risk assessment was to implement the action proposed by FSA in their response to a recommendation from a previous Food and Veterinary Office audit 2012-6469 - In Order To Evaluate The Control Systems In Place Governing The Production And Placing On The Market Of Bivalve Molluscs, carried out in the United Kingdom from 16 to 27 April 2012. Commission Implementing Regulation (EU) 2019/627 states that the sampling frequency for toxin analysis shall be weekly, except if a risk assessment of toxins or phytoplankton occurrence suggests a very low risk of toxic events. Whilst FSA's current OC biotoxin and phytoplankton monitoring programmes had determined the risk of toxic events as low in Carlingford Lough, the assessment was

Respondent	Comment	Response
		not based on weekly data. In order to meet the legislative requirements & our response to the FVO audit, the level of biotoxin sampling must be increased to weekly until such times as there is sufficient weekly data for a robust risk assessment to be completed. A review of the data will be undertaken following two years of weekly biotoxin monitoring. Phytoplankton monitoring will remain fortnightly.

Respondent	Comment	Response
Agri-Food & Biosciences Institute (AFBI)– Marine biotoxin unit	Yes, a risk-based approach should reduce the probability of not detecting a toxin event. In Northern Ireland there are relatively few marine toxin events and so the data available to perform statistical analysis is limited. With this in mind it may be necessary to review the risk regularly to include data from any subsequent events that may occur.	Noted. FSA will continue to monitor and review the data to ensure official control shellfish monitoring programmes are risk based and remain protective of public health.

Question 2: What potential challenges may this approach present for you, your organisation or your business?

Respondent	Comment	Response
Loughs Agency	The previous approach schedule had Loughs Agency visit 7 sites to collect biotoxin sample monthly. All 7 sites were never visited on one sampling trip – rather the sites were split x4 in one week (Narrow water/C1/C7/C11) and x3 in another week (C9, C15,C17). The split in sites was set up to account for the fact that in order to access sites C9,C15 and C17 a low tide less than 0.5m is required to allow safe access. The new approach requires that x4 RMPs are visited weekly (Narrow water, C1, C15, C11). This means increasing the number of site visits to collect flesh samples from approximately 90 visits per year under the old schedule to 208 visits per year if all 4 sites are to be visited weekly. In addition, the sampling of phytoplankton sites required fortnightly would involve an additional sampling run every other week. As a result Loughs Agency would change from 1 sampling day per week equating to 4 sampling days per month to 6 sampling days per month in a 4 week month. Microbiological samples also have to be factored into this schedule. Only 3 of the proposed RMPs for biotoxin samples are the same sites as the RMPs for Micro samples. This means that on one week out of every 4 Loughs Agency would have to visit 5 sites for flesh samples rather than 4 and 4 of these sites would require x2 samples which further increases the amount of time on site and reduces likelihood of visiting all sites on one tide. The proposed approach is a considerable undertaking for Agency staff for whom this is not core responsibility work. Please refer to	Noted. FSA acknowledges the impacts that increasing biotoxin sampling will bring and is currently engaging with Loughs Agency colleagues to explore options for future delivery. Implementation of weekly monitoring is required to meet EU legislative requirements - Commission Implementing Regulation (EU) 2019/627. A further review of the data will be undertaken following two years of weekly biotoxin monitoring and if the risk of toxic events is deemed to be low we will review the biotoxin and phytoplankton programmes to reflect the risk. FSA continue to engage with ROI colleagues regarding the delivery of shellfish official controls in cross border loughs to ensure a joined up approach were possible. The approach proposed in this consultation is consistent with

Respondent	Comment	Response
	Annex A- Table shows the change in sampling visits required, original schedule vs proposed. An increased number of sampling days represents an additional cost to Loughs Agency in terms of mileage, staff and resources. This is assuming a single Loughs Agency team can get to all 4 sites in one day to collect samples, which we believe is not possible for the reasons outlined below; • not possible to lift all 4 sites on the one tide, impossible to get to all 4 on one tide safely due to proximity of sites to one another • All sites are not accessible on all low tides – there will be weeks where some sites are not accessible on any day – this is further compounded by samples being limited to the beginning of the week to allow for lab analysis time. • Lifting flesh from all 4 sites in a week (even if tides did allow) would require either more than one day of sampling or a split Loughs Agency Team to cover all 4 sites • Loughs Agency does not have enough staff or vehicle resource to complete every week • Other environmental factors would make access to sites difficult every week – light, weather, tides, accessibility of sites • C1 site requires FBO participation – subtidal site – FBO not available every week • This approach would potentially lead to a significant increase in the number of scheduled samples being missed as a result of day to day feasibility issues The Agency has significant financial concerns with the new approach. Financial considerations;	the approach taken by FSA for all other NI shellfish harvesting areas and in keeping with the action proposed by FSA in our response to the Food and Veterinary Office audit 2012-6469 in 2012.

Respondent	Comment	Response
	• Agency are not currently paid for current work load this has already been queried by senior management within Loughs Agency. The Agency could not possibly sustain this increase without charging for vehicles, vessels, staff (including allowances) and fuel required. • More than one day of sampling will require additional courier deliveries (x2 per week) – the Agency do not pay for this service but FSA do. Other points to consider; There is a need to work towards aligning sampling protocols with ROI otherwise risk is created due to the fact that the cross border loughs are running on two sampling approaches which are not compatible. For example; Oysters are not required for weekly sampling in ROI. ROI protocols also only require one RMP per species per Production Area. The island of Ireland must be considered as a single biogeographic unit. It is important to acknowledge that the environment does not recognise political boundaries and must therefore be considered as such in transboundary management with ensured use of common frameworks where applicable. In marine policy, biogeography acts at a range of different biogeographic scales and is particularly important in the consideration of Marine Spatial Planning and the designation and review of marine protected areas. The Loughs Agency is of the opinion that we should be working to align the northern shore of Carlingford with the Southern shore rather than trying to align the northern shore of Carlingford to the rest of the UK	

Respondent	Comment	Response
	Status reports for Foyle and Carlingford were originally completed as cross-border exercise in order to promote joined up working for the cross border loughs. The current proposal represents a significant change in how biotoxins are assessed in Carlingford and creates a huge difference for producers. The new approach will have stock implications such as availability and cost of stock lost to sampling which will not be consistent with the ROI sites within the cross border loughs.	

Respondent	Comment	Response
Agri-Food & Biosciences Institute (AFBI) – Marine biotoxin unit	**Sample volume** - The new proposal, for Carlingford, will see sampling reduced to four sites with approximately the same frequency for ASP, PSP and LT as proposed in 2019. This would mean a small increase in overall tests as shown in the table in Annex B which would be acceptable for the toxin lab. It is understood that these figures are approximate and may be amended.	Noted.

Respondent	Comment	Response
Agri-Food & Biosciences Institute (AFBI) – Marine biotoxin unit (Continued)	Approximately every 4 weeks samples will be received for analyses of all three tests; while the frequency of ASP and PSP testing may increase for small periods of the year, LT testing will be much more frequent (almost weekly) throughout the year. This is a similar pattern to samples received from the other water bodies. This means that for one out of four weeks the toxin lab receives a large number of samples for all three tests while for other weeks a much smaller number is received with most for LT analysis only. The lab would request that the testing of samples for all three toxin groups is not arranged for one week but instead split over two weeks in any month so the heavy workload is spread somewhat. **Health & Safety** – As described above, the risk based sampling schedule for toxin testing does mean that there are some weeks when multiple samples are received to be analysed for all three toxin groups and there are other weeks when a small number of samples is received for only LT testing. For weeks with larger sample numbers there will be more shells to open and this could pose potential health and safety issues for staff such as repetitive strain injury (RSI) as highlighted by Cefas. Cefas investigated the potential of opening less shells while still maintaining the representative aspect of a sample. It was found that reducing the number of shells to be opened for all species had little impact on the reporting of results and so this was adopted, with the approval of the FSA, FSS and UK NRL for Marine Biotoxins. This does	FSA will engage with sampling officers and laboratory colleagues to ensure that the sampling plan is agreeable to all parties involved. FSA will work with laboratory colleagues to ensure that their protocols are adhered to regarding health and safety should the volume of samples received be particularly high. FSA and AFBI expect the increase in sample numbers to be small.

Respondent	Comment	Response
	not mean that the number of shells to be collected by the sampling officers can be reduced; this must remain the same to constitute a representative sample in accordance with the legislation. This approach could also be applied to Northern Ireland or alternatively the monthly analysis of samples for all three toxin groups could be split so that half the water bodies are sampled one week and half another week in the same month. **Costs** – As for the other water bodies, adoption of the risk based approach for Carlingford would see sample numbers for ASP and PSP analysis reduced by approximately 26%, while lipophilic testing would increase by around 20%. This will have negligible effect on the cost of analysis. The 2019 consultation prompted an amendment to the charging schedule for biotoxin testing to reflect the changes in sample numbers. The previous annual fixed sample volume of 400 for all three tests has been changed to 200 for ASP and PSP and 560 for LT. This ensures the minimum income required by AFBI to perform all scheduled analyses is received and no further change is currently envisaged by AFBI.	

The following table consists of summarised comments made during a virtual stakeholder meeting with shellfish producers.

Respondent	Comment	Response
Food Business Operator	Relocation of Narrow Water Representative Monitoring Point (RMP)- Proposed moving sampling location from current point to better accessible area which was suggested at around 10 metres from current point.	Noted In line with the European Union Reference Laboratory 'Microbiological Monitoring of Bivalve Mollusc Harvesting Areas- Guide to Good Practice', each representative sampling point should be at a fixed geographical location, identified by latitude/longitude or national grid reference to an accuracy of 10 metres. Samples should be taken within an identified distance of this location. FSA is currently liaising with the sampling officer to identify current accessibility issues in this part of Carlingford Lough and to agree and finalise the sampling location.
Respondent	**Comment**	**Response**
Food Business Operator	A suggestion was made that oyster farmers may be able to facilitate leaving additional trestles (with contributions from other sites) at RMP C15 to support accessibility for Loughs Agency and remove the need for additional journeys to other, less easily accessible AHA's. Suggested creating a collection point at an alternative location for samples to be collected. This may assist the	Noted. Sampling officers will engage with harvesters of RMP C15 and AHA's C7, C9 and C11 prior to implementing the revised sampling arrangements, to establish a sampling plan that meets the requirements of all parties, the legislative requirements and ensures that there is minimum impact

Respondent	Comment	Response
	Loughs Agency and FBOs to alternate between sample collection/storage at FBO premises.	caused to stock levels at RMP C15. The sampling plan for RMP C15 will be agreed and formalised by all parties involved prior to implementation.

Summary of changes made

The consultation process has identified some issues which are currently being addressed by FSA and key stakeholders involved; this has subsequently delayed the proposal from August 2021 to January 2022; however no changes have been made to the overarching proposals as a result of the consultation process.

Actions to be implemented

- The proposed OC sampling plan in the consultation is to be implemented with effect from January 2022.
- The biotoxin and phytoplankton sampling plan have to be agreed with the sampling officer prior to implementation of the new proposals.
- The arrangements for maintaining stock levels at RMP C15 & OC sampling of the RMP have to be agreed prior to implementation of the new proposals.
- The arrangements for finalising sampling locations have to be agreed prior to implementation of the new proposals.

List of respondents

1. Loughs Agency
2. Agri-Food & Biosciences Institute – Marine Biotoxin Unit
3. Food Business Operators

Annex A

Loughs Agency's original sampling plan schedule and the proposed sampling plan schedule

Week	Original schedule	Proposed schedule
1	4 sites Biotoxin + Micro	3 sites Biotoxin + Micro 1 site Biotoxin only 1 site Micro only (5 sites total)
2	5 sites Phytoplankton	4 sites Biotoxin 5 sites Phytoplankton
3	3 sites Biotoxin	4 sites Biotoxin
4	5 sites Phytoplankton	4 sites Biotoxin 5 sites Phytoplankton
Total site visits	**17**	**27**
Total Samples	**21**	**31**
Total Sampling Days	**4**	**6**

Annex B

AFBI's original sampling scheme and the proposed sampling scheme

Sampling scheme	No. of weeks	No. of samples	No. of tests	Total tests	Totals for year
Current	12	4	3 (ASP, PSP, LT)	144	261
Current	13	3	3 (ASP, PSP, LT)	117	261
Proposed	16	4	3 (ASP, PSP, LT)	192	312
Proposed	30	4	1 (LT)	120	312