December 2019

Proposed risk-based approach for the biotoxin monitoring programme in Northern Ireland

SUMMARY REPORT OF STAKEHOLDERS RESPONSES

The consultation on proposed risk-based approach for the biotoxin monitoring programme in Northern Ireland was issued on 4th July 2019 and closed on 29th August 2019.

The purpose of this consultation was to provide stakeholders with the opportunity to share views on our proposals to implement a new risk-based approach to Northern Ireland's biotoxin monitoring programme.

The FSA is grateful to those stakeholders who responded and sets out in the table below responses in order of the questions set out in the formal consultation package.

The key proposals on which the consultation sought views were:

- To implement the new risk-based approach to biotoxin monitoring from 1st October 2019, including a review phase after six months of implementation
- 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

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- Further underpin confidence and assurance in Northern Ireland's live bivalve mollusc industry.

The Food Standards Agency's considered responses to stakeholders' comments are given in the last column of the table. A summary of changes to the original proposal(s) resulting from stakeholder comments is set out in the final table.

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

Question 1: Do you agree with a risk-based approach to reduce risk of a toxin event going undetected?

Respondent	**Comment**	**Response**
Private sampling contractor	General support	Noted.
Newry, Mourne and Down District Council	Newry, Mourne and Down District Council agrees with a risk-based approach regarding the monitoring of biotoxins. It is understood that it is proposed that each bed be sample on at least a monthly frequency. Consideration must be given to beds that are currently not being harvested or operated "dormant". Reduced monitoring of such sites would preserve council resources while still protecting the public as the onus is placed on the FBO to notify.	Noted. FSA has carried out a review of harvesting activity across all NI shellfish production areas. For those sites where we have evidence of sustained inactivity, toxin and phytoplankton monitoring will cease and those sites will be awarded either a 'dormant' or 'de-classified' status, with reduced microbiological monitoring – refer to FSANI's shellfish classification protocol (https://www.food.gov.uk/sites/default/files/media/document/fsani-shellfishclassificationprotocol-v1-jul17_1.pdf. Communications on this has been issued to relevant stakeholders.

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Loughs Agency	Loughs Agency agrees that all reasonable effort should be made to reduce the risk of a toxin event going undetected. However, Loughs Agency is of the opinion that the proposed plan is excessive and 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. The Agency is of the opinion that an alternative to the currently proposed approach will need to be found in order to marry up reduced risk with feasibility.	Noted. The purpose of the toxin monitoring review and risk assessment was in response to a recommendation from a previous FVO audit in relation to the frequency of toxin monitoring across the UK. Regulation EC No. 854/2004 states that toxin monitoring should be weekly, unless a risk assessment suggests very low risk. In order to deviate from the prescribed EU sampling frequency, FSA is required to provide assurances that toxic episodes are not being missed during weeks of no sampling. Therefore, the level of toxin sampling must be increased. This increased data will continue to be reviewed and will feed into future risk assessments. FSA will continue to liaise with Loughs Agency colleagues on options for future delivery.
Aquaculture Initiative	Level of Risk is different depending on site, bay and time of year. The current situation at Carlingford Lough is that biotoxin monitoring takes place from each shellfish bed in contrast to other areas which are monitored on an RMP basis. This is a good system and provides each production area with its own biotoxin data. Each bay / shellfish area is different with different environmental inputs e.g. farming activity, proximity of towns, water treatment, hydrography. Having the same rules for all the different locations doesn't make sense. The	Noted. The risk assessment carried out very much focussed on the data per production area, which is why there is no longer a 'one size fits all' approach.

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	answer is for a targeted sampling schedule that reflects the period of the year for different sites / bays, when more frequent weekly sampling would be needed. It should be noted that when looking at a risk-based approach that Northern Ireland's shellfish production area / East coast of the island of Ireland has a history of less biotoxin events than other areas such as the West coast of the island. When looking at a risk-based model the Aquaculture sector also want to avoid a system that leaves itself open to retrospective recalls of product from the market, which are expensive in terms of money, and reputational damage. It can be seen by the Aquaculture sector that the FSA programme for biotoxin scheduling needs to be able to take into account the sample type (phytoplankton and flesh) toxin type, month, shellfish bed and when the probability is greatest of a biotoxin event to occur. With biotoxins, some periods of the year deserve sampling at a higher rate than other less probable times of year.	
Agri-Food & Biosciences Institute – Marine biotoxin unit	Yes, a risk-based approach would 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.
Agri-Food & Biosciences Institute – Phytoplankton unit	FAEB agree that a risk-based approach has merit in delivering a more robust programme, however, as the statistical analysis and data used has not been presented FAEB cannot fully support the conclusions reached. There	Noted.

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	are considerable risks in agglomerating data from a wide range of locations and environmental drivers without first normalising the datasets. For phytoplankton we do not believe this to be a valid approach in the absence of environmental data.	
Strangford Lough Mussels Ltd	Yes.	Noted.
Rooney Fish	We do agree with the risk-based approach to reduce the risk of a toxin event going undetected, but we do however, disagree with the suggested phytoplankton monitoring frequencies suggested. This is a particular risk during the summer months when phytoplankton blooms are most prevalent. Each year is different in 2018, the summer months were much warmer and the likelihood for higher levels of toxic episodes may have the potential to increase during warmer weather, in light of this based on the suggested collections we feel that toxins should be collected more frequently during the weeks 25-33, in fact following an email alert of DSP in water samples collected from Neighbouring areas showing increased trigger levels in Carlingford lough as per email sent on the 24th July 2019.	Noted. Official control toxin and phytoplankton data was assessed as part of the statistical analysis that was carried out. It was determined that the phytoplankton data did not support a change to sampling frequency at this time. However, this will be monitored and reviewed on an ongoing basis.

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

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Respondent	Comment	Response
Private sampling contractor	Concern that the proposed new approach will mean a change to sampling requirements as laid out in FSA contract.	Noted. FSA will liaise with contractor to discuss revised sampling requirements and agree new contractual arrangements.
Newry, Mourne and Down District Council	Concerns raised in relation to officer time, lab requirements and daylight/tide times.	Noted. FSA will work with sampling officers to consider combining sampling activities and to review sampling from inactive sites.
Loughs Agency	The challenges for the Agency are mostly in relation to significant increases in sampling on Carlingford Lough. Site visit numbers increase from 251 to 455 per year which is an 81.2% increase in site visits per annum. The new approach also poses some significant feasibility issues which would need to be explored in more detail before it could be implemented. 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.	Noted. FSA will engage with Lough Agency colleagues to explore options for future delivery, including the rationalisation of Carlingford Lough for toxin and phytoplankton, in line with other production areas in NI, ROI and GB. FSA is aware that Carlingford Lough is a cross border lough and one water body and will continue to approach the delivery of official controls in a joined-up manner where possible, however FSA is required to address UK wide recommendations from previous FVO

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	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 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.	audits, as a member state, in relation to toxin monitoring.
Aquaculture Initiative	Periods when sites are expected to be harvested. A way to comply with Regulation (EC) No 854/2004, protect the customer and also target sampling / testing to when there is a risk, would be to take into account when beds are not being harvested i.e. when the producer is not intending the shellfish there to be put on the market at that time.	Noted. FSA will not sample inactive sites for toxins or phytoplankton during periods of inactivity. However, it is important that harvesters inform FSA of planned harvesting activity.

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	At times of year, some shellfish beds (mainly mussels) are not scheduled / planned to supply the market. This maybe because the mussels are spawning (e.g. summer), or they are not of the correct size / meat yield or that a better time to sell is later in the year / season. This is an example where the risk to the customer is low (i.e. will not be going to sale) and that logically, less frequent sampling (i.e. monthly) would be required. However, flexibility with this would be needed as a producer may decide to meet a customer at any period of the year. Supplying the market itself is a notifiable operation with a fish movement order filed with DAERA in advance. For some species (mainly some mussel sites), there may be an opportunity to join-up this process and reduce the need for FSA to be carrying out weekly samples on sites, on those sites which are not intended to be harvested. Self-Sampling. A further complication is in the difficulty of phytoplankton and flesh sampling at shellfish sites both oysters (intertidal) and mussels (sub-tidal) at different stages of the tidal cycle. FSA could see if a working solution could be discussed on self-sampling by the aquaculture operator in some cases. This is not self-testing, as the sample would still be supplied to the FSA for analysis by an approved laboratory, but there may be efficiencies to be made in the supplying of the sample by the producers who are after all most	FSA will continue to engage with sampling officers to explore options for future delivery, which may include availing of the FBO to collect samples, under certain conditions.

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	frequently on the shellfish sites.	
Agri-Food & Biosciences Institute – Marine biotoxin unit	require Sample volume - The new proposal could require more staff for some weeks compared to others and AFBI would need more instrument time to process the proposed increase in sample numbers. While this would provide a challenge for the biotoxin laboratory it is not insurmountable. A potential means to mitigate this issue would be to defer ASP and PSP testing from some busier weeks to quieter ones. Health & Safety - With increased sample numbers there will be more shells to open and this poses potential health and safety issues for the associated staff such as repetitive strain injury (RSI) as highlighted by Cefas in 2017/18. To alleviate this problem, Cefas investigated the potential of opening less shells while still maintaining the representative aspect of a sample. It was demonstrated 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. At that time it was agreed with FSANI that, because of the lower sample numbers processed by AFBI, there was no need to implement this change in Northern Ireland. However, with the proposed increase in sample numbers, this amendment could now be implemented to reduce the chance of RSI, with the added benefit of reducing sample preparation time. AFBI test protocols require a little over 10g for the three methods so it is proposed that the number of shells opened for mussel samples would be reduced to 15. This does not mean that the number of shells to be collected by the sampling officers can be reduced; this must	Noted. FSA will discuss contractual matters with AFBI colleagues at the quarterly service review meetings.

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	remain the same to constitute a representative sample in accordance with the legislation. Costs - Based on the current unit costs for the testing scheme this will create an overall increase in the cost of the biotoxin monitoring programme. Increases to the unit costs may also be incurred due to analysing some samples for only one test. However, it is envisaged that this will be minor and somewhat offset by reducing the number of shells to be opened. Also, it may be easier to invoice monthly for the actual number of samples tested and reported rather than 1/12 of the predicted annual cost. These issues can be discussed directly between FSANI and AFBI at a future date.	
Agri-Food & Biosciences Institute – Phytoplankton unit	We would have concerns that there are some long gaps in the water sampling schedules at the time when there is potential for phytoplankton growth. E.g. in Carlingford lough water samples are scheduled for week 43 (~27th July) and aren't scheduled again until week 46 (~17th August). At the same time tissue samples for PSP and ASP are taken on week 42 (~20th July) and not taken again until week 47 (24th August). This seems to contrary to known environmental drivers for algal growth and the high degree of inter annual variability in these drivers. Tissue samples for DSP are taken on weeks 42,43,44 and 45. Whilst lipophilic toxins appear to be the highest risk, at the moment there is a significant gap in the schedule (between week 43 and 46) where phytoplankton for PSP/ASP are not being monitored either in water samples or	Noted. Water sampling frequency will remain unchanged – i.e. fortnightly and the pilot of weekly phytoplankton sampling in Belfast Lough will also revert to fortnightly. FSA will work with sampling officers and lab colleagues to ensure the required sampling frequency is achieved. This can be organised as part of the sampling schedule meetings. FSA welcomes your input into the sampling schedule to enable the revised changes to work for all parties as much as possible.

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	shellfish tissue samples and to me this poses a risk. We cannot assume that there will not be shifts in population regimes of algae. Health & Safety With regard to phytoplankton testing FAEB do not perceive any particular changes to Health and Safety. Costs Cost savings for phytoplankton are unlikely to be significant due to the requirement to maintain laboratory capacity and capability.	
Strangford Lough Mussels Ltd	Not a substantial change to current requirements.	Noted.
Rooney Fish	We understand that sampling schedules are forecasted six months in advance, but due to an increase in temperatures over the last two summers, during these times increased sampling can only help us as a business as we are still exporting oysters 12 months of the year and we rely on the existing testing schedules and results, as well as our own monitoring to ensure that we have no potential for any contamination of our oysters which in turn may interrupt our supply to our customers. We also consider toxin history in the immediate and neighbouring areas of Carlingford lough. The use of all trigger levels and wider monitoring data should mean that as a harvester that our product is safe and within the legislative levels, without a supportive test result this could mean that the business may need to increase the testing before placing any oysters on the market and obviously this is an extra cost to the business.	Noted. The data from FSA's official control monitoring programmes can be considered by FBOs as part of their food safety systems/risk management processes, however they are not confirmation that food placed on the market by businesses is safe, which is the responsibility of the food business.

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Question 3: Do you agree the proposed approach will aid compliance with Regulation EC No. 854/2004 Annex II Section B, paragraphs 4 and 5?

Respondent	**Comment**	**Response**
Private sampling contractor	General support.	Noted.
Newry, Mourne and Down District Council	Newry, Mourne and Down District Council agrees the proposed approach may aid compliance with Regulation EC No. 854/2004 Annex II section B, Paragraph 4 and 5. The proposed approach may aid with compliance with the legislation however during some of the winter months it will not be possible to gather the required samples. Therefore, if samples cannot be gathered this approach will not aid compliance. Consideration must be given to the answers to Q1 and Q2.	Noted. FSA will continue to work with sampling officers within the council to explore options for sample collection during times when sampling officers cannot access the sites.
Loughs Agency	The Agency agrees that the proposed approach would improve compliance with Regulation EC No. 854/2004 Annex II Section B, paragraphs 4 and 5. However, for the reasons outlined above the Agency does not feel that the	Noted. Further engagement with Loughs Agency colleagues is ongoing.

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	approach is feasible and as such is of the opinion that an alternative approach be explored.	
Aquaculture Initiative	Maintain access to the established EU27 market. The first objective to the Aquaculture sector of a Risk Based monitoring programme is that it complies with Regulation (EC) No 854/2004 and so ensures the continued access of shellfish aquaculture production from N. Ireland to the EU27 market.	Noted.
Agri-Food & Biosciences Institute – Marine biotoxin unit	AFBI agree that any approach must comprise periodic sampling of production, and relaying waters, to check for the presence of toxin-producing phytoplankton and that results indicating breaches of phytoplankton trigger levels are acted upon by increasing the frequency of flesh testing from the affected areas. It is agreed that the sampling frequency for flesh biotoxin analysis in molluscs should be weekly unless an assessment of toxin or phytoplankton occurrence suggests that the risk of a particular toxin event in a particular lough is low, in which case the frequency may be reduced. Therefore, the risk-based approach will allow a specific schedule of sampling to be constructed which complies with the legislation, on the supposition that it will be periodically reviewed.	Noted. As more data becomes available, FSA will review the NI toxin shellfish official control programmes and conduct risk assessments to support any future changes.
Agri-Food & Biosciences Institute – Phytoplankton unit	No, any approach must comprise regular sampling of production and relaying waters to check for the presence of toxin-producing phytoplankton and that results indicating breaches of phytoplankton trigger levels are acted upon by increasing the frequency of testing molluscs from the affected areas. The approach proposed leaves gaps in	Noted. The risk assessment carried out looked at NI official control phytoplankton data and determined that, at this time, could not support reductions in toxin monitoring. Phytoplankton monitoring will remain fortnightly and

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	excess of 3 weeks for sampling some water bodies at peak growing season which is beyond phytoplankton population doubling time. In the absence of other monitoring or modelling of triggers the risk is increased in our view. Scotland and also the Republic of Ireland sample for phytoplankton on a weekly basis at this time of the year. This is also the recommendation in the best practice EURL guideline document which is awaiting publication. The sampling frequency for toxin analysis in molluscs should be weekly unless an assessment of toxin or phytoplankton occurrence suggests that the risk of a particular toxin event in a particular lough is low, in which case the frequency may be reduced. Therefore, the risk-based approach should allow a specific schedule of sampling to be constructed which complies with the legislation on the supposition that it will be periodically reviewed.	FSA will ensure that this frequency is achieved when setting the sampling schedules.
Strangford Lough Mussels Ltd	Yes.	Noted.
Rooney Fish	We do agree but as per points highlighted above in certain times of the year due to increased weather temperatures, we would suggest and increase of sampling, just for that short period of time when a particular risk is increased during the summer months.	Noted. The revised sampling frequencies are based on a risk assessment. Food businesses should consider FSA's official control monitoring data when conducting their own testing, which should also be based on risk.

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Question 4: Do you agree the proposed approach will further underpin confidence and assurance in Northern Ireland's live bivalve mollusc industry?

Respondent	**Comment**	**Response**
Private sampling contractor	General support.	Noted.
Newry, Mourne and Down District Council	This approach has the potential to further underpin confidence however it may not be possible due to limited council resource. To increase confidence individual sampling plans should be created to meet the bespoke geographical needs and restriction such as tides, collection methods of the area.	Noted. FSA will work with sampling officers to ensure the toxin sampling schedule is achievable and fit for purpose.
Loughs Agency	Loughs Agency is unaware of current confidence levels amongst consumers and is unsure if the new approach will improve confidence. The Agency recognises the need to strive for excellence and the need to comply with Regulation EC No. 854/2004 but is of the opinion that this new approach is excessive and not realistic. There is a need for significant consultation with Food Business operators affected by this change in approach before any such change can be implemented. The new approach will have stock implications such as availability	Noted. FSA will engage with Loughs Agency colleagues to consider options for future delivery and sampling schedules. Increased monitoring is required to reduce the current level of risk identified by the risk assessment. This additional data will feed into future risk assessments

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	and cost of stock lost to sampling which will not be consistent with the ROI sites within the cross-border loughs. Loughs Agency Queries How was this schedule put together? – does not seem to be a discernible pattern: • Why on weeks 6, 8, 10, 12 are we required to lift less than 7 sites worth of flesh samples? • Weeks 7, 9, 11, 32, 33, 46 we are required to lift waters only? • Week 29 and 31 state we are to be at 7 RMPs but only list 4 samples and 3 samples of each test?	that could support changes in monitoring frequencies in the future.
Aquaculture Initiative	The aquaculture shellfish produced here, has established good reputation as a quality product and with a hard won, high value. A central objective for aquaculture is a system that also ensures the protection of the customer. This in effect means compliance to Regulation (EC) No 854/2004. Which itself means that sampling should be moving towards a more weekly schedule. The costs and logistical difficulty of this are a challenge. Water Quality. The way to further underpin the confidence and assurance of NI's aquaculture shellfish product is for water quality is a key issue to be considered when considering biotoxins. The Aquaculture sector is keen to raise the profile of the science of preventing biotoxins.	Noted.

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	Specifically, the cause of biotoxins, from man-made activities and an analysis of how actions at different times of year could be taken to reduce the incidence of biotoxin events arising in the first place. This may be an area that researchers like AFBI could look at. Once again from a risk-based approach, if there are actions identified to reduce the incidence of biotoxins, reducing occurrence is a very effective way to protect the aquaculture producers and their customers.	
Agri-Food & Biosciences Institute – Marine biotoxin unit	Yes, a statistically based risk assessment that predicts a significant reduction in the probability of not discovering a toxin event should promote greater confidence in Northern Ireland's shellfish industry. Observations/Queries of proposed sampling schedule A proposed sampling schedule laid out in the file Annex C comparison of sampling schedules details which samples are to be collected on each week of the year from each water body. The following observations are based on week 1 of the proposed schedule corresponding with the beginning of October 2019. Although there is weekly sampling of shellfish for lipophilic analysis from Belfast Lough between weeks 43-47 there is none for the two weeks prior to (approx. end of July) and three weeks after (early September) this period. These times of the year would be considered relatively higher risk for the	Noted. The revised toxin monitoring regime was based on historic official control toxin and phytoplankton data. The additional data will be monitored and, if required, reviewed should evidence support this.

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	occurrence of lipophilic toxins than January through February which is to be sampled weekly from weeks 17-21. Similarly, Dundrum Bay is to be sampled weekly for weeks 16-29 (end of January to mid-April) for lipophilic toxin analysis while a higher risk period between weeks 35-46 (June-August) is to be sampled for only 7 out of these 12 weeks. Carlingford Lough and Strangford Lough are both sampled quite often for lipophilic toxin analysis throughout the year. However, for both water bodies there is no sampling for this toxin group on week 46 (mid-August) which has previously been shown to be a high-risk period; an oyster sample from Carlingford displayed concentrations of okadaic acid above the action level on 13/8/18.	
Agri-Food & Biosciences Institute – Phytoplankton unit	A statistically based risk assessment that predicts a 15.6% reduction in the probability of not discovering a toxin event may promote confidence in Northern Ireland's shellfish industry. However, again without presenting full details of the statistical analysis it is difficult to see how this will achieve support, particularly given the mismatch that will develop between the approach taken in the Republic of Ireland and Scotland.	Noted.
Strangford Lough Mussels Ltd	Yes	Noted.
Rooney Fish	Any adjustment to the sampling frequency will have consequences for our industry. We would also like to make a suggestion on the actual sample collection points which is	Noted.

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	currently C7 production area. We feel that the current sample point is too close to Warrenpoint docks and that the current samples are being collected at the high tide line. This has the potential to compromise the results from samples collected under the current sampling plan.	FSA is required to carry out official control sampling in line with harvesting practices. Should this not be the case, we would appreciate further information to support any changes to the current regime.

List of Respondents:

1. Private sampling Contractor
2. Newry, Mourne and Down District Council
3. Loughs Agency
4. Aquaculture Initiative
5. Agri-Food & Biosciences Institute – Marine Biotoxin Unit
6. Agri-Food & Biosciences Institute – Phytoplankton Unit
7. Strangford Lough Mussels Ltd
8. Rooney Fish

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