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UK Shellfish Biotoxin Database Development

Summary Report 1 – Potential user group survey and definition of requirements

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Executive Summary

Potential user group survey and definition of requirements

This report sets out the results of a consultation to scope the requirement for an on-line marine biotoxins database and website designed to be operated by the shellfish industry. From a consultee list of 560, 289 contacts were made using a combination of email and telephone calls, resulting in 41 responses – a 14% response rate.

Based on the analysis of the consultee survey:

- the main potential user groups identified were scallop processors, Local Authorities and the Food Standards Agency Scotland (FSAS);
- the initial industry user group would probably be less than 10 with the potential for up to 20 users if Local Authority representatives are included on a collective basis;
- there appears to be considerable lack of understanding or abdication of responsibility within some sectors of the shellfish supply chain with respect to food hygiene regulations and contingent obligations pertaining to biotoxin testing;
- it seems likely that many shellfish processors dealing with wild caught product have no objective risk assessment in place for informing their biotoxin testing regime;
- the spatial data provided by fishermen in regard to the source/location of their catch is unlikely to be adequate to provide meaningful map based outputs;
- in the absence of adequate spatial data, common batch data is the only possible source comparison;
- no database capable of fulfilling the functionality and interface requirements specified by consultees is currently available in the UK;
- in the first instance, access to the database would need to be restricted to net contributors of data and registered shellfish businesses who are net contributors of data only;
- the cost of operating and administering the website and database would need to be met through direct cost recovery – an annual subscription is recommended.
- a formal study to assess actual levels of compliance with respect to biotoxin testing across the scallop catching sector should be undertaken and, at the same time, objectively define the risk of contaminated product being consumed.

The report sets out a mechanism for using available resources to establish a not-for-profit database company and either:

- purchase and further develop an existing but unused online shellfish traceability system;

or

- develop a new online database and web interface according to the specifications set out in this report.

Database requirements are specified in the report which may be used as the basis for taking forward the development of the website and database.

It is important to note that whilst this report sets out a structure for the development of a marine biotoxins database, caution is also expressed with respect to its utility if steps to encourage and enforce compliance with existing Regulations are not undertaken in parallel.

A further option to use NCOF[1] ecosystem models in combination with biotoxin test results coupled to a formal risk assessment to inform biotoxin testing regimes is also discussed.

For the database to deliver meaningful outputs:

- Fishermen need to provide relevant spatial data with respect to the origin of their catch – preferably a minimum of a single fishing box location
- The majority of processors should be undertaking biotoxin testing according to a formal risk assessment protocol and submit their biotoxin test results to the database

[1] UK National Centre for Ocean Forecasting

Developing a biotoxin test database which is not populated with sufficient spatially relevant data would be a waste of limited resources. In the absence of these data, the only option for reducing the risk of contaminated product being caught is for fishermen to have access to NCOF or similar modelled data showing where harmful algal blooms are likely to occur. To further reduce the risk of contaminated product reaching the consumer, processors could also use such data to inform their purchasing decisions and, through formal risk assessment, determine the need to undertake additional biotoxin testing.

CONTENTS

Introduction

The purpose of this report is to present the outcome of a project to scope the database and interface requirements for an industry UK bioxtins database. The project was divided into two phases: 1. Potential user group survey and definition of requirements; 2. Pilot scale demonstration[2].

Scoping database and interface requirements

The first objective was to develop a formal definition of the scale and scope of interest in an industry led initiative to develop a UK biotoxins database, together with explicit definition of the utility of both the database and the user interface. Only by gaining a first hand understanding of potential user group requirements and willingness to subscribe to an online database has it been possible to specify the level of functionality that is both required and affordable. In addition, this phase of the project has revealed deficiencies in data, risk management, understanding and compliance with regulation. This information has been used to develop a tender document to commission appropriate database and web development experts. However, the option of using modelled data to inform fishing activity and individual processors risk assessments is also presented.

Define the scope and scale of potential user group

A comprehensive list of 559 consultees was compiled from data provided by Seafish, Seafood Scotland and FSAS, together with FRM contacts compiled from extensive internet searches for all relevant businesses and organisations with a potential interest in a biotoxins database. Considerable time has been expended on error checking and correcting the compiled contact data and a final distribution of 202 email and 364 telephone contacts which equated to a total distribution of at least 289 consultees receiving either an email or telephone call or a combination of the two (see Table 1). A full distribution listing (organisation/company names only) is included in Annex 1. This list does not include the names of the 58 local authority sampling officers contacted by email. Consultees were drawn from the full spectrum of individuals and businesses together with public and private organisations and trade bodies who may deal with shellfish. These include; the aquaculture, catching, diving and hand harvesting sectors, buyers/merchants, processors, retailers, restaurateurs, retailers and local authorities.

Table1.

Consultee Category	**Total Number of Listed Consultees***	**Contact By Email****	**Contact By Phone*****	**Primary Responses offered** *(but may not have resulted in full survey response)*
Dive schools and organisations	27	27	3	2
Trade Bodies and Fishermen's Organisations	73	46	57	17
FSAS Fishery Product Supplier	179		106	42
Merchants and Processors	185	36	161	15

[2] James, M.A. (2008) UK Shellfish Biotoxin Database Development – Summary Report 2. Pilot scale demonstration. Commissioned by The Scottish Government, Food Standards Agency Scotland, Seafish, The Scallop Association and Scottish Fishermen's Federation 19pp.

Producers	7	7	5	3
Retailers	17	16	15	3
Local Authority - Principal Food Safety Officers	13	12	13	11
Local Authority - Sampling Officers	58	58		
Totals	559	202	360	93

** Contains duplicates where more than one set of contact details provided.*
*** Contact = email not rejected*
**** Contact = telephone call answered*

Table 2.

Total Distribution/Calls^	289
Total Survey Responses - email	36
Total Survey Responses - telephone	5
Percentage response as a function of Distribution/Calls	14.19

^ *Total distribution/calls = sum of consultees contacted at least one by telephone, email or a combination of the two.*

Develop questionnaires and conduct survey

Introductory correspondence, press release and an online survey form and database was developed and approved by the project steering group (Annex 1 and 2).

Using bulk emailing software to minimise the potential for spam rejection by recipients, a total of 202 consultees were emailed the introductory correspondence which contained an embedded link to the online survey. A number of trade bodies were also targeted and requested to circulate the introductory correspondence to their members. Three trade bodies indicated that they would undertake to circulate the correspondence to their members. This being the case, it is likely that more than 400 invitations to complete the survey were made by a combination of email and telephone.

Bulk emails were followed up by telephone calls to non-responders. During the telephone narrative, consultees were asked if they had received the original email containing the introductory correspondence – if confirmed, the consultee was encouraged to complete the online survey. Further information on the proposed database was provided to the consultee at this stage, if required. If no email had been received the email address was checked with the consultee and the introductory correspondence email resent. If the consultee considered that they were not an appropriate contact and alternative contact within their respective organisations was requested and emailed accordingly. Some consultees responded to the survey questionnaire narrative over the telephone.

Although successful contact was defined as either an email being received or a telephone call being answered, the fact that recipients received email is not a guarantee that they have read it. Where possible email addresses for rejected or non-responding email contacts was confirmed by telephone.

Initial results suggested that the focus of interest in this initiative was most likely to be positive amongst shellfish processors and scallop processors in particular. The FSAS provided an additional list of shellfish processor contacts which was cross checked against the original consultee listing to eliminate duplicates and used as the basis for a further round of telephone calls to encourage response to the online survey.

A small number of respondents emailed comments to FRM rather than completing the survey. Where appropriate, these respondents were contacted by telephone to clarify their views.

The nature of response to the survey suggested that face-to-face interviews would be of limited value in the initial phase, as the level and scope of interest in the database was limited.

Subject to the survey responses meetings with FSAS, industry and developers of a prototypic web-based shellfish traceability system were conducted.

The purpose of these meetings was to discuss the provisional survey results and to explore some of the practical aspects of implementing the proposed database.

Analysis of survey results

The survey was designed to address a defined list of consultees and was email and telephone based. The majority of respondents were made by email and are therefore self-selecting and cannot be considered random. Later stages of the consultation process focused on shellfish and, in particular, scallop processors. Coupled to the low response rate, these factors preclude detailed statistical analysis. The data is summarised on the basis of percentages and should be treated as indicative only. Where appropriate, free responses have been categorised and interpreted accordingly. All responses have been treated as anonymous.

Responses to initial telephone contact may be regarded as reasonably representative of the sectors involved in the shellfish industry which forms the focus of the survey.

Table 3.

Comment/Other	5
Local Authority	8
Full Industry Responses	28
Total Responses	41

The overall response rate was approximately 14% (41 from a distribution list of 289[3]). Only 36 full online survey responses were returned (8 from Local Authorities and 28 from industry). An additional 5 general responses were made by telephone.

A breakdown of contacts by category is provided in Table 1.

Results Summary

The following are highlights extracted from survey responses. Unless specified otherwise, the percentages or proportions quoted are a function of total responses (36 online survey), and not all consultees. More general comments are derived from online survey comments taken together with telephone responses and feedback from meetings.

Table 4 illustrates the range of activities and the species of interest to the respondents to the survey. The value (n) denotes the total number of positive responses under each activity/species. The highest percentage value under each activity/species has been highlighted in red. None of the activities is exclusive and therefore respondents may undertake a number of activities with respect to any given species. Although in small numbers only, responses have been received for all activities in most species. The majority of respondents were involved in buying and selling shellfish. With, on average, around 20% involved in processing (approximately 25% of industry respondents were involved in processing scallops). Other species mentioned included *Mercinaria*, sand gapers, winkles, otter shells and velvet crabs.

Table 4.

Activity	Scallops	Queen Scallops	Mussels	Oysters	Cockles	Razorshells
Catch/Harvest (n)	4	2	2	5	1	1
Catch/Harvest (%)	11.11	5.56	5.56	13.89	2.78	2.78
Grow (n)	0	0	7	5	0	0
Grow (%)	0.00	0.00	19.44	13.89	0.00	0.00
Sell (n)	12	8	11	10	6	8
Sell (%)	33.33	22.22	30.56	27.78	16.67	22.22

[3] For telephone contacts list – only when telephone call was answered was the data included as a "consultee".

Buy (n)	11	8	5	7	5	7
Buy (%)	30.56	22.22	13.89	19.44	13.89	19.44
Depurate (n)	0	0	3	5	0	0
Depurate (%)	0.00	0.00	8.33	13.89	0.00	0.00
Process (n)	7	5	2	2	0	2
Process (%)	19.44	13.89	5.56	5.56	0.00	5.56
Direct Supply (n)	7	6	8	8	5	7
Direct Supply (%)	19.44	16.67	22.22	22.22	13.89	19.44
Gov. Body (n)	8	6	7	8	5	8
Gov. Body (%)	22.22	16.67	19.44	22.22	13.89	22.22

Of the 28 industry responses, approximately half (54%) were from consultees who indicated that they are aware that they are required to undertake biotoxin testing.

Table 5 shows that approximately 70% of respondents indicated that they would find the database useful as part of their risk assessment process for avoiding shellfish biotoxins and 64% thought that customers might view use of the database as a business's positive commitment to producing safe seafood. Few considered a website of this type would be useful for advertising their businesses.

Table 5

Database use:	Positive Responses	Percentage
- might help you to avoid catching, harvesting or purchasing contaminated product?	22	61%
- your customers might see this a part of your commitment to producing safe seafood?	23	64%
- could be included as part of your risk assessment process for avoiding shellfish biotoxins?	25	70%
- the database website might be a good place to advertise your business?	6	17%
- if you were an Environmental Health Officer, you would find this sort of biotoxin testing information useful?	19	53%

On average for ASP, DSP and PSP more than 82% of respondents who undertake testing for shellfish biotoxins use the services of a commercial laboratory. Only 7% undertake any form of in-house testing.

More than 97% indicated that they would find it useful to be able to access the latest shellfish biotoxin test results on the internet and the results displayed in Table 6 suggest that a map displaying results as a traffic light system would be their preferred option, with only a slightly lower percentage selecting some form of interactive map. Respondents were made aware that the more complex the display/output option, the more it would be likely to cost.

Table 6

Preferred output from database	Positive Responses	Percentage
A table of results	7	19%
A table of results highlighting positive results above the legal threshold	7	19%
A map showing results as a traffic light system - red meaning above the legal threshold, amber approaching legal threshold, green below legal threshold	17	47%
An interactive map that shows the most recent results in traffic light form, but allows you to look at previous results also	11	31%

Half of all respondents including industry and local authority consultees were willing to submit data to the proposed database and the same proportion would also wish to access the database.

Almost 90% of respondents would be content to make their data publicly available immediately after submission to the database. A small number of would wish to place a restriction on access for up to a

week – presumably to ensure that their commercial advantage (real or perceived) might be secured. One respondent was strongly of the opinion that no-one, other than those submitting data to the database, should have access and that submission of data should only give the submitter "free" access for a further week only. As this comment was ventured by one of the few major shellfish processors who responded to the survey, the opinion is noteworthy.

Only about 11% of respondents indicated that they would be willing to pay to access the database. However, a number of respondents who indicated they were unwilling to pay to access the database answered subsequent questions related to mode and scale of payment.

Almost 20% of respondents indicated that they would be prepared to pay to access data on a pay per view basis or through annual subscription. About 11% would be prepared to pay a monthly subscription.

The following proposition was outlined in the survey to provide some basic contingent values for the type and level of financial contribution users of the database might be willing to make to secure access.

Proposition:

"For those submitting test results to the database, access to the database would be free for a period of one month after their data is submitted. Thereafter, access to the database would revert to the same cost as for those who are not contributing data. Those submitting sample data more frequently during each month will reduce the cost of access to the database on a pro rata basis for subsequent months also.

If you would be interested in accessing the database but WOULD NOT be submitting test results each month:

How much would you be prepared to pay for Pay per view access? – (access limited to current results only)
How much would you be prepared to pay for a monthly subscription? – (access limited to current results available, but unlimited access for each month subscribed)
How much would you be prepared to pay for an annual subscription? – (unlimited access to all results for the period of the subscription)"

Whilst more than 47% (17) of respondents would be interested in finding out where shellfish biotoxin outbreaks might be occurring by seeing the results of tests conducted by others, only 19% (7) indicated any willingness to pay to see these data.

Table 7 indicates that the two most favoured options amongst those willing to pay to see data were Pay per view £10-£15 (17%) and Annual subscription £300-£400 (14%).

Table 7

Contingent value proposition:	Positive Responses	Percentage
Pay per view £10-£15	6	17%
Pay per view £10-£15	0	0%
Pay per view £10-£15	1	3%
Monthly subscription £40-£50	4	11%
Monthly subscription £50-£60	0	0%
Monthly subscription £60-£70	1	3%
Annual subscription £300-£400	5	14%
Annual subscription £400-£500	0	0%
Annual subscription £500-£600	2	6%

General Comments

Some individuals consulted as part of this survey did not appear be aware of their responsibilities with respect to biotoxin testing and took the view that this was a matter for "others", principally the Food Standards Agency or some "official" body to deal with.

Within the catching sector, the general view epitomised below, was that this issue was, or should be, dealt with by downstream elements within the supply chain such as the processors.

Within the aquaculture sector those businesses that operate through some form of co-operative processing and marketing organisation conduct pre-harvest and end product tests as a matter of course. These respondents were unwilling to contribute data to the proposed database as they consider this information both commercially sensitive and valuable to their businesses.

The view was expressed that some shellfish farmers who were not part of a co-operative undertaking testing, might find the proposed database of value, but this respondent also pointed out that free access to the FSAS/FSA test results was sufficient to inform their own testing regime. In any event, each site was considered "unique" and therefore the test results for other locations would be of limited value. This observer considered that the service [database] would probably be of more interest to shellfish gatherers who work from same area but concluded that they were more likely to work together than to pay for a third party to store their results.

The informal view expressed by the main UK shellfish trade body was that they were not in favour of databases of the type proposed because they could serve to unreasonably focus [public] interest on the issue of biotoxins and shellfish hygiene generally.

As a general industry comment, for those who thought the data might be of interest to their business, but was not essential, were reluctant to pay for database access.

Local Authority responses tended to be collective and were supportive of the database concept. However, the view expressed by one official was that the Food Standards Agency should pay for the Local Authority inspectors to have access to the database.

Those supportive of the database concept suggested that *if the majority of processors could be persuaded to commit to data it would be viable.*

However, even for those supportive of the concept, caveats were expressed. The need to link the area that the shellfish were sourced (caught) to the test data was highlighted, as was recognition of the likely resistance from skippers to reveal this information.

The potential to create fishing "honey pots" – areas highlighted by the database as being toxin free was noted by a couple of respondents. Conversely, the potential to exclude fishing competition by submitting false positive data to the database was also highlighted.

Caution (and consternation) was expressed by some at the notion that the database could be open to "public" access. Others were adamant that only those who contributed data should have access to the database.

A strongly held opinion was that in the absence of a rigorously applied Local Authority inspection regime imposed upon shellfish business that may not conduct testing, there would be little incentive for these businesses to test or be equitable contributors to the proposed database. It is important to note that this was an anecdotal expression of opinion and is not based on analysis of data which would substantiate the consistency or rigor with which current inspection regimes are implemented.

Existing databases and models

Existing available databases or relevant models which either deliver or could be adapted to provide the services envisaged for the proposed shellfish biotoxin database were assessed.

A prototypic database coupled to a UK map which displays the designated fishing boxes and the biotoxin results in traffic light colours according to their status was made available for evaluation purposes. The map is web-based, uses functionality provided by free Google mapping software and access to the website is password protected. The underlying database structure, whilst adequate for relatively small amounts of data is unlikely to function effectively with larger volumes of data and the need for more sophisticated interrogation. With some enhancements to the underlying database and a more sophisticated data upload and output display functionality, such a system could potentially provide a low cost solution for industry use.

The FSA are in the process of developing an *E.coli* database in collaboration with CEFAS. During initial discussions with FSAS the potential to either piggy-back or develop the biotoxins database in parallel was superficially explored. In principle, this could be an effective use of the relatively limited resources available to develop the biotoxin database. Significantly greater resources have already been invested in developing the *E.coli* system. However, we have become aware that there is some resistance within the industry to supplying data to what is viewed as a “Government” database – which some believe might be used to further regulate or restrict the industry. This suspicion, however unfounded, is not restricted to the shellfish sector – similar resistance is prevalent within the fish farming community with respect to the provision of fish mortality and other fish health related data to “Government” databases.

On the basis of the above information, it is recommended that the proposed biotoxin database is seen to be clearly rooted in and operated by the industry. Provided the data is collated in a standard database format with appropriate and clearly specified quality controls, there would be no technical barrier to combining these data with other FSA/FSAS data should this be agreed. This concept is in line with the conclusions of FSA’s Incident Prevention Protocol consultation.

Integrin Biosystems Ltd, in collaboration with a software company, developed SAFE-C; a seafood traceability system which, in principle, could offer some functionality relevant to the provision of a biotoxin database. This system was developed in 2005/6 and was never fully implemented and remains unused. Detailed discussions with two of the key individuals responsible for the development of the SAFE-C system revealed that it is fundamentally an online portal based software and database application that could potentially be adapted to serve as the basis for an online marine biotoxins database. Analysis of detailed presentations of SAFE-C functionality show that it is an online application, based on open source scripts, a scalable SQL database (mySQL) and a standard Apache web server. Our assumption is that the Content Management System (CMS) for the website is web browser based, but such a system could easily be manipulated with standard HTML development software.

Provisional assessment of the functionality of the database suggests that unless the biotoxin database requires a comprehensive traceability system, many of the functions the system offers would be redundant. However, the existing structure of the system would lend itself to adaptation to provide the basic requirements defined through this consultation process – with the prospect that in the future the more sophisticated elements of the traceability system could be reinstated. If more widespread and rigorous enforcement of biotoxin testing occurs, there may indeed be potential to utilise these additional traceability functions.

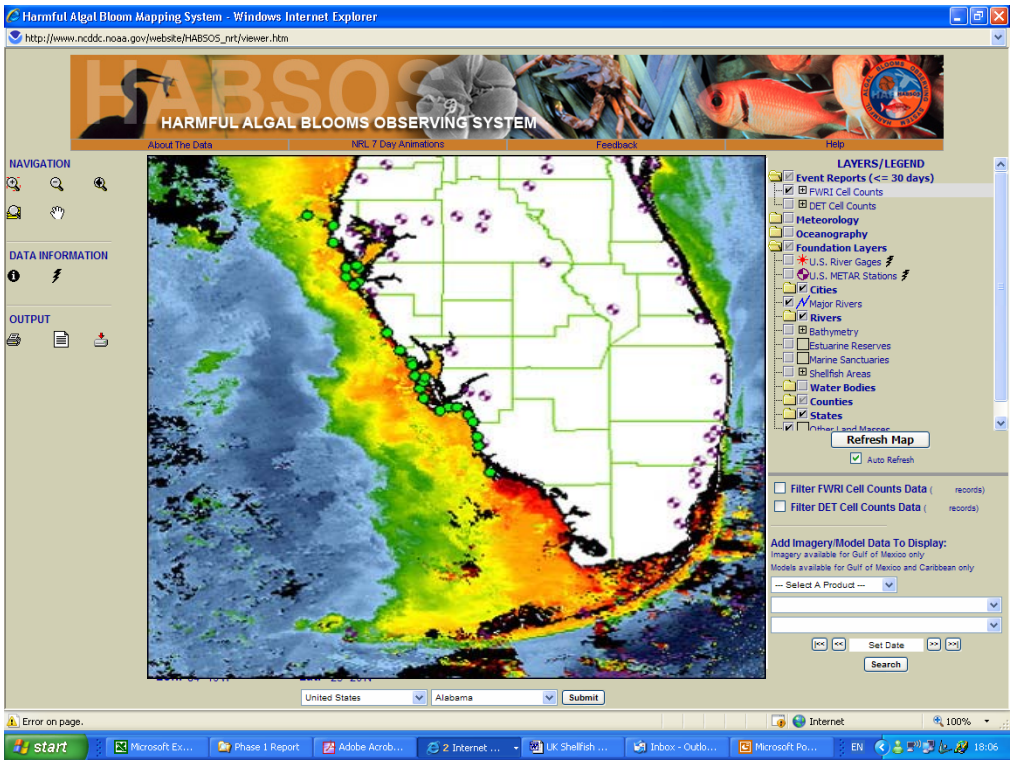
The US National Oceanographic and Atmospheric Administration (NOAA) have developed a sophisticated data collection portal as part of its Harmful Algal Blooms programme (see Figure 1 and http://www.ncddc.noaa.gov/interactivemaps/harmful-algal-blooms-observing-system-habsos). The Harmful Algal Blooms Observing System (HABSOS) website offers a regional, web-based data and information dissemination tool. The website provides a secure data entry tool for collection of cell count observations of the algal species *Karenia brevis*. The HABSOS Internet Mapping Service (IMS) aggregates and displays data entered into the system. This enhances online assessment and analysis of HAB events through the integration of in-situ observations, surface forecasts, and powerful

satellite imagery products into the IMS. This web-based facility has some hind-casting and forecasting capability. The scale and complexity of this system is impressive, but not accessible or usable in a UK context.

Discussions with UK experts regarding the potential to use available data to provide some form of biotoxin forecasting, suggest that our current understanding of the underlying causes and subsequent development of biotoxin events is insufficient. However, the UK National Centre for Ocean Forecasting (NCOF) has recently started to provide near real time maps of Chlorophyll concentrations for UK shelf seas (see Figure 2 and http://www.ncof.gov.uk/forecasts.html).

Since June 2000 the Proudman Oceanographic Laboratory Coastal Ocean Modelling System (POLCOMS) has been run operationally, daily, by the Met Office. The model has been brought to operational status by the Met Office. The model is run to produce real-time predictions, out to two days ahead, of density and current structure over the north-west European shelf sea and at the shelf break.

Figure 1.



NCOF are applying carbon-cycle and biogeochemical models for both the open ocean and UK waters. Through inclusion of the Hadley Centre Ocean Carbon Cycle (HadOCC) model in FOAM, NCOF are able to make predictions of biological parameters for the global oceans. For the shelf-seas around the UK they use the MRCS (Medium-Resolution Continental Shelf) coupled hydrodynamic-ecosystem model, where the hydrodynamics are supplied by POLCOMS and the ecosystem component through the European Regional Seas Ecosystem Model (ERSEM).

For UK and surrounding waters they are working on the coupled POLCOMS-ERSEM system and developing new products in support of the ecosystem-based approach to managing the marine environment which is being advocated by European governments. ERSEM is a generic model which includes all those processes which significantly influence ecosystem dynamics, and provides outputs which are aligned to OSPAR (Oslo-Paris) convention requirements. Such models also have the potential to be used for predicting harmful algal blooms.

The spatial resolution of the model is based on a 7km grid, although the resolution for the Irish Sea is now based on a 1.8 km grid and similar resolution is likely to be delivered as demand for outputs at this level of resolution increases. At present, the outputs shown in Figure 3 are currently freely

available from the Met Office website (http://www.metoffice.gov.uk/research/ncof/mrcs/browser.html). Other more developed services are, however, subject to a charge.

Whilst the model currently predicts chlorophyll concentrations, and these could be used as the basis of a biotoxin risk assessment in the absence of definitive test data, we are aware that an application to support the development of the system to predict harmful algal blooms has been submitted to the Natural Environment Research Council (NERC) for funding which, if supported, could provide within two years, map based outputs that could be used to directly inform the shellfish industry's biotoxin risk assessments.

Figure 2.

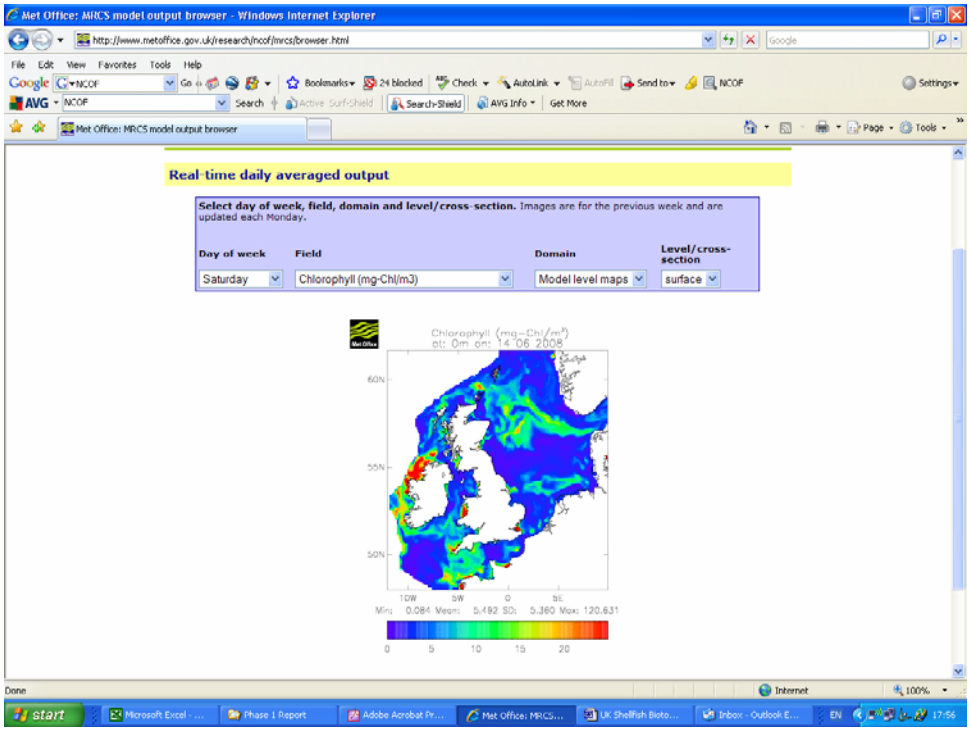
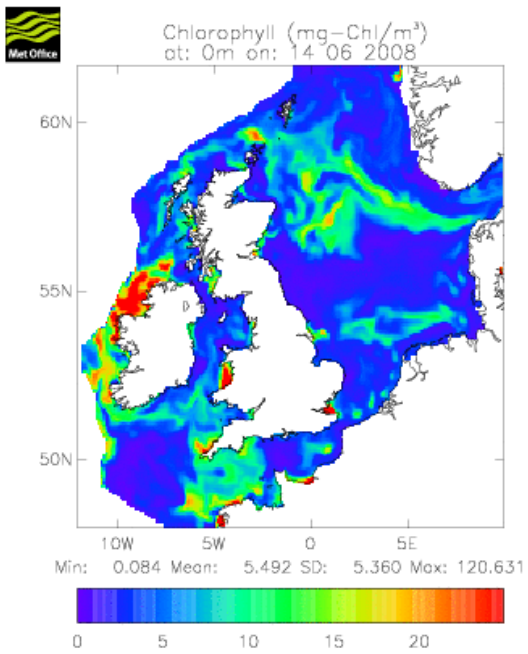


Figure 3



The rationale behind this work is to use the existing models, coupled to specific nutrient data which is known to affect the growth of harmful algal species such as *Dynophysis* and *Pseudonitschia* to predict their growth. The models, together with satellite imagery and fuzzy logic [4]algorithms will provide outputs which would indicated the potential for harmful algal bloom development with specified levels of statistical certainty.

If NERC funding is not forthcoming, it may be possible to take forward a less ambitious project which would still offer significant benefit to the shellfish sector. Other databases exist, largely as a function of Government or regulatory measures elsewhere, but it is unlikely they would be accessible or of practical use in the context of a UK industry led system.

Interpretation of the results

Fundamental issues

For the proposed database to be useful, it must provide outputs that:

- inform users risk assessments;
- help to minimise testing and thus reduce cost and;
- where possible, prevent the catching or harvesting of contaminated shellfish.

Risk Assessment

Those respondents who expressed an interest in the database highlighted the potential for such a system to inform their risk assessments. General consultation as part of this project suggests that many shellfish businesses in the catching sector probably use no formalised or reasonably objective method for assessing the risk of their product being contaminated by biotoxins. The risk-reward ratio for many within the shellfish sector sourcing and processing caught product in particular, may favour a majority of participants who may not test for biotoxins. Whilst the potential cost of a product recall may be very high, the risk of incurring such a financial and reputational penalty is perhaps insufficient to encourage widespread "risk-based" biotoxin product testing by Food Business Operators.

Fishermen appear to face little or no financial liability if the product they provide to processors subsequently proves to be biotoxin positive. The myriad of smaller businesses that make up the shellfish supply chain seem to assume that the incidence of biotoxin contamination is relatively infrequent and therefore the chance of it affecting their business is also "low". Presumably, few have experienced significant "impact" – financial or otherwise, as a result of adopting this view and therefore there is little incentive for them to change.

There is a general assumption, predominantly amongst those either upstream or downstream of processors, that biotoxin testing is something that is either conducted "officially" by Government or is at least the responsibility of someone else. This survey was not designed to establish what proportion of wild caught shellfish sold to the consumer is tested as a function of biotoxin risk but feedback from this work suggests that a formal assessment would be worth while.

It is important to define "risk" with respect to the both the consumer and the supplier [in this case, by general consensus, the processor]. For the consumer, risk can be defined in terms of frequency of exposure and the impact of exposure to shellfish products contaminated with biotoxins. For the supplier, the risks are not necessarily related to the consumption of product but the frequency and impact of financial and legal penalties to which they may be exposed as a result of not complying with their legal obligations or being identified as the supplier of contaminated product.

If we assume from a suppliers risk perspective, that the risk (perceived or real) of :

- the products they are selling being contaminated with biotoxins is low;
- illness resulting from contaminated product being reported is low;
- incurring any financial or legal penalty for supplying contaminated product is low;
- detection and sanction by EHO's for non compliance with regard to testing is low;
- their customers requiring proof of testing is low;

[4] Fuzzy logic is designed for situations where information is inexact and traditional digital on/off decisions are not possible. It divides data into vague categories such as "hot", "medium" and "cold".

the net result is likely to be that there are few commercial pressures to encourage biotoxin testing – hence a "risk-reward" scenario which clearly favours non-compliance. The effectiveness of regulation and enforcement in minimising the risk to public health in such a scenario requires a dedicated and controlled study.

These observations suggest that, with respect to shellfish biotoxins, there is a need:

- to continue to improve the industry's understanding of their responsibilities and potential liabilities, perhaps through a structured information campaign orchestrated by an appropriate industry body;

- although the responsibility for biotoxin testing is applicable to all Food Business Operators and could therefore apply to many parts of the shellfish supply chain, the default position within this sector appears to be that processor are "best placed" to undertake this responsibility. This being the case, there should be recognition within the supply chain that processors must be adequately compensated by those upstream in the supply chain in the event of biotoxin positive product being supplied;

- undertake a formal study to assess actual levels of compliance with respect to biotoxin testing across the scallop sector and, at the same time, objectively define the risk of contaminated product being consumed.

- for the shellfish supply chain and processors specifically, to have access to a standard and user friendly risk assessment matrix or information source to allow them to make reasoned judgements about the need for biotoxin testing.

It is suggested that the biotoxin database could provide the basis for conducting an on-line risk assessment based on a combination of historic and contemporary data coupled to the NCOF model outputs.

The way that the matrix is structured and the associated hazard scores would need to be carefully considered. The results would need to be tested against real data to ensure that predicted risk equates favourably with actual risk. As detailed below, there are potentially significant data deficiencies with respect to the catching sector that may seriously limited the utility of the database. These deficiencies will also impact on any risk assessment, tending to increase the predicted hazard and hence the amount of testing required.

Minimising testing, reducing cost and preventing the catching or harvesting of contaminated shellfish

Minimising or optimising a business's biotoxin testing regime can be achieved through:

- a robust risk assessment (see above);

- the ability to reduce risk by having access to contemporary sample data from the same or similar location and, to a lesser extent, historic data taken at approximately the same time during the year and same or similar location;

- the capacity to access other's sample test results prior to catching/harvesting or processing;

[NOTE: none of the above obviates the requirement for end product testing]

The requirements for robust *a priori* risk assessment is outlined above, however, there are two fundamental prerequisites which determine the utility of any test data – where (location) and when (date) the sample was caught or harvested.

Feedback during the consultation phase of this project suggests that the majority of fishermen do not provide accurate information on the location/origin of their catch. At best they may provide information which might provide some regional definition. Few would be willing to divulge meaningful co-

ordinates. In the absence of these data, it may not be possible to map test results at a resolution that is useful. This deficiency represents a potentially serious constraint on the utility of the proposed database with respect to the catching sector.

Annex II Section VII Ch.1 of 853/2004, lays down the general requirements for the placing on the market of Live Bivalve Molluscs and includes the requirement to provide a location (in as precise detail as possible) for the origin of their catch/harvest on the Registration document.

It indicates that a business should only accept live bivalve molluscs if they are accompanied by a Registration document, which should accompany every batch of product between establishments up to and including the arrival at dispatch or processor. An explicit requirement of the document is the:

"Location of production area/offshore area described in detail or by a code number" This could mean. in Scotland the box number for offshore areas."

In terms of traceability requirements enshrined in 178/2002, the "one up, one down" principle also applies which means that the next recipient in the supply chain from the fishermen should also be able to trace the geographic origin of the product. The minimum standard for the definition of location could be a designated fishing "box" (see Figure 1.).

Although there may be some room for interpretation of the precision associated with defining a location, for practical purposes it should be possible to provide data that would be relevant to informing risk assessment and help protect public health. Given that the provision of location is a prerequisite of Registration it is, by definition, enforceable. If a shellfish supplier (e.g. processor) is not able to define the origin of any given shellfish product, then they may not be compliant with the provisions in 853/2004. Unless the catching sector can be persuaded to provide meaningful spatial data it will not be possible to produce a biotoxin hazard risk map that is likely to be of significant use in reducing the amount/ cost of testing, or more fundamentally, preventing the harvest of contaminated shellfish.

Without a spatial reference, the only option available for sample comparison is source – i.e. shellfish caught by the same vessel at the same time. In this scenario, a user of the database could filter the data by date and source rather than date and location. If test results are available for a sub-sample of the original "batch" this could be used to inform the risk assessment of those who had purchased a proportion of the batch. In addition, if those purchasing product were to register the details of their purchase on a database immediately, it would be possible to screen the database for associated sub-batches to potentially reduce the overall number of biotoxin tests required confirm product safety. However, indications from our consultations suggest that most vessels supply a single processor with any given catch thus obviating the potential to share information and cost.

The FSAS has agreed in principle to provide historic and contemporary biotoxin and toxic phytoplankton monitoring programme data. Whilst initially only data from Scotland would be made available, the intention would be to secure FSA data once the utility of the biotoxin database is demonstrable.

The FSAS biotoxin data would be derived from official control samples. The majority of the FSAS data pertains to near shore (within approximately 200 meters) sites that are primarily harvested through aquaculture. Whilst historic data from the period when offshore sampling was conducted will be included in the database, we are given to understand that these data are reasonably comprehensive for Scotland.

As the consultation revealed very limited interest from the aquaculture sector in the database development, coupled to the fact that the most cogent requirement for data is for offshore wild caught shellfish such as scallops, the value of the historic data may be limited. Historic and contemporary Official Control samples taken from processors, whilst important with respect to the batch tested, will be of limited use to others if source location is not properly specified. However, there is clearly a case for those harvesting shellfish (by diving for example) near to official control monitoring sites to have access to these data in order to inform their own risk assessments. A simple map base system displaying the weekly monitoring results in the form of a traffic light system of sample site markers has been developed (see Pilot Scale Demonstration). Although the official control sample results are

published weekly on the FSA website in tabular form, the map based presentation of these data makes this information easier to interpret.

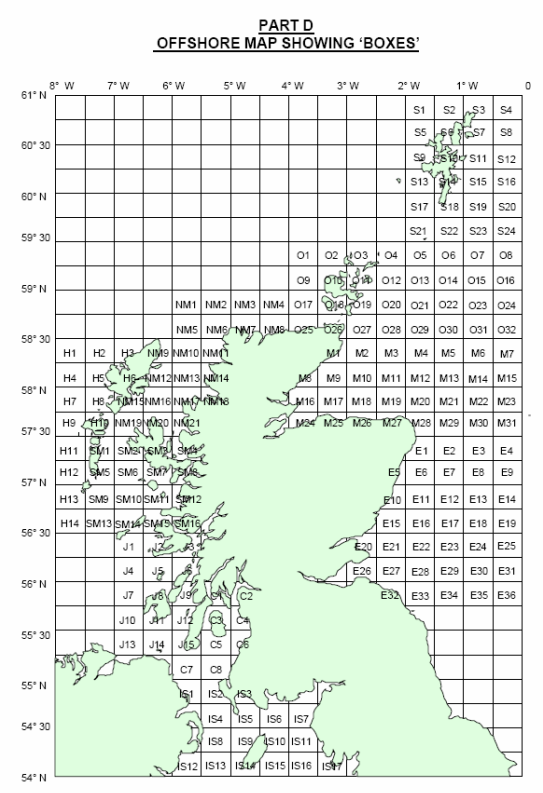
Any proposed investment will need to consider the merits of developing a biotoxin test database which may not contain data with sufficient quantity or quality to be useful, against the potential to access modelled data such as that provided through NCOF. If, as the this consultation suggests, the few organisations who conduct testing of wild caught shellfish are unable to provide useful data on the source location of their product, coupled to reservations related to commercial confidentiality and equitable use of their data, it might well be better for the industry to focus on the use of models, FSA(S) data and their own test results, to undertake formal risk assessments to inform their biotoxin testing regimes.

User group

The results of the survey suggest that the main potential user group for the proposed database is likely to be restricted to shellfish processors who are principally involved in processing wild caught product. The limited response to the survey would further suggest that the potential number of users will be, initially at least, less than ten. Local Authority personnel would also find the data useful could collectively increase the user group to perhaps 20. Users are defined here as those who are net contributors of data.

If the database was populated with spatially and temporally relevant biotoxin data, displayed in an accessible format, with more flexible, low or no-cost access to all stakeholders the size of the user group would probably remain restricted to those with a direct vested interest in knowing where and when biotoxin events were occurring. This would equate to some shell fishermen (principally scallopers), processors, regulators and a few enlightened members of the supply chain.

Figure 4.



Security and access

There are clearly concerns related to the ability of those who do not contribute data, having access to the database, together with possible misuse of the database. Mechanisms to ensure the security of the database and restricted access will be fundamental to securing the support of the prime user group. However, as with all such ventures, there will be a requirement for a degree of trust and goodwill from participants if it is to succeed.

It is recommended that, in the first instance, access to the database would be restricted to registered shellfish businesses, Local Authority representatives and FSAS staff only that agree to be net contributors of data.

Functionality
The degree of functionality required by consultees was essentially limited to secure and prescribed access, upload and download of data together with the provision of results as some form of easily visually interpreted traffic light warning colours in tabular or preferably map based format.

Subscription
Given that the prime user group is likely to be restricted to a few processors from the outset, all of whom are likely to be data contributors and users, we suggest that a standard annual subscription be used to cover the operational costs of the database. To encourage use of the database, we recommend that prospective users are provided with a 30 day free trial subscription, after which they must pay the full annual subscription to use the database. A range of possible pay per view and monthly subscription options could be explored in the future if the size and nature of the user group changes, but the divergent and strongly held views of some consultees – particularly those who are likely to use the database, suggests that a straight forward cost recovery through annual subscription is the most viable business model. There is little prospect that any significant revenues could be generated through advertising, although sponsorship of the database by a major processor/retailer or industry body may be worth exploring further once the database is demonstrable.

If the proposed online risk assessment function of the website and database proves feasible, the number of users could increase if more open access to the website is encouraged. This database function is only likely to develop “popular” use if it is either at minimal or no cost to the user. The idea of “popular” access to the database is, however, likely to discourage the participation of some key industry data providers.

Terms and Conditions of Use
Based on the information and data presented in this report, careful consideration of the Terms and Conditions of use for the database and the website is required. Whilst there are established models with respect to intellectual property rights, copyright etc., careful consideration of liability is required to cover misuse, misinterpretation, loss or disclosure of data. It is suggested that any data submitted to the database, becomes the property of the proposed not-for-profit database company (see below) and that the company undertakes to ensure that the data supplied is handled appropriately and in accordance with the Terms and Conditions under which it is supplied and published. Any value added to the data in the database then, by definition, becomes the property of the database company. Because the FSAS and FSA data provided will also be freely published elsewhere, there should be no conflict of interest with the use of these data. Indeed there are numerous examples of data that have been collected at public expense which are then sold commercially once reinterpreted or presented in a different format. Users of the database must comply with a standard set of agreed Terms and Conditions, bespoke agreements with individuals or companies should be avoided.

Database ownership and administration
If, in light of the caveats expressed above, development of the biotoxin test database is taken forward, it is recommend that a simple, not-for-profit limited company is established as a vehicle to take ownership of the database and administer its use and development.

A Board of Directors should be appointed. Appointees should be drawn from the major stakeholders who will benefit from the use of the database and it is suggested that a provisional list of candidates be compiled and agreed by the steering group for this project. It is recommended that FSAS/FSA, Government and Seafish are offered observer status on the Board. The Board may wish to appoint an independent Chairperson. Given the scale of company business activity anticipated is relatively small, and with appropriately rigorous administrative structures in place, the workload of the Board should be minimal.

The specification for the proposed database set out below makes provision for its operation to be as automated as possible with minimal administrative requirements. The database company will need to identify an organisation or individual to administer the database on a "day-to-day" basis. Experience of other web-based applications and databases in particular suggests that whilst the level of administration required can be minimised, a modicum of computing expertise will inevitable be required, particularly at the outset to troubleshoot and provide technical support to users. Provided the web content remains fairly static and the site's functionality is robust and relatively simple, the time required to physically administer the functions of the database could be as little as a few hours each month.

It is recommend that the subscription model is also based on a limited trial followed by a fixed annual subscription payable through a standard online payment service such as PayPal or equivalent. This mechanism should minimise financial administration.

Liability/Indemnity
Although this will need to be considered more fully by the project steering group and subsequently the database company, it is suggest that company takes out appropriate liability and indemnity insurance on behalf of Board members and any associated company office bearers. In reality, the risk of litigation is probably low, but until the full ramifications of using and providing this service and data are understood, insurance would be prudent.

Options for database development

It is clear from the foregoing results and discussion that existing and currently collected data may be of limited value in satisfying some of the primary objectives of developing the biotoxins database.

The need for a biotoxin database is predicated on assumption that it will:

- inform users risk assessments by providing quantitative evidence;
- help to minimise testing and thus reduce cost through data sharing;
- reduce the catching or harvesting of contaminated shellfish;
- help to protect public health
- help to minimise the potential of a damaging "food scare" on the industry as a whole

Although the evidence gathered through this project is limited, together with respected opinions within the scallop processing sector, the suggestion is that many processor and suppliers of scallops are not testing their product for biotoxins. If this is the case and non-compliance with the regulations is occurring, it would seem reasonable to predict that the risk of biotoxin contaminated product being consumed and resulting in ill-health is more likely.

Developing some form of database remains an option, and it would potentially serve a useful purpose if development in parallel with a targeted enforcement regime.

For the database to deliver meaningful outputs:

- Fishermen must provide relevant spatial data with respect to the origin of their catch – preferably a minimum of a single fishing box location
- The majority of processors should be undertaking biotoxin testing according to a formal risk assessment protocol and submit their biotoxin test results to the database
- The above must be sufficiently well policed by a combination of Local Authorities and industry codes of practice to ensure compliance is maintained.

In the absence of useful data, there will be no demand for the database and consequently no funds to support its operation.

Summary of Options

Option 1.
Provide a minimalist database and website at lowest cost, for registered users only. Running costs would be limited to the cost of hosting together with the absolute minimum of administration required to keep the system going. If an organisation such as an industry trade body could be persuaded to hold the data on their server and host the website it might not be necessary to establish a company infrastructure – particularly if all use is clearly at the risk of the user. The functionality of the website would be limited and outputs restricted to simple tables of results and a Google based map system.

Option 2.
Develop a database as per the specification given below on the assumption that users will require and be prepared to pay for the functionality and company infrastructure needed to support the administration and development of the database.

Option 3.
Further develop an existing prototypic shellfish traceability system to provide the outputs specified under Option 2. Reinstate the traceability functions of the system should demand for these options increase alongside the database.

Option 4.
Develop either Option 2 or 3 on the basis that there is open access to any registered user which will provide both simple GIS map based and tabular outputs derived from FSA(S) surveillance and official control sample data together with any unrestricted industry data submissions – quality controlled on the basis of source and type of test.

The site would also provide a link to the most recent NCOF model outputs and a simple risk matrix which could be populated with default or live data from the database or by user inputs.

Those wishing to submit data, but restrict access to others who do not submit data would be required to pay a set annual subscription for this privilege. Subscribers would also have the facility to pre-screen the database and other subscriber data to assess whether tests were in progress or had recently been completed for locations co-incident with their own product or area of interest.

Option 4 would be the most complex and costly system to implement and operate, but is perhaps the best option to satisfy the requirements of the original objectives of this project. A cursory assessment suggests that the financial viability of Option 4 is either equivalent or slightly less than Options 2 or 3. Caveats related to the utility of the database remain, but the simple display of FSA(S), NCOF and freely available industry data would potentially make the site useful for those reliant on FSA(S) surveillance and official control sample data. The NCOF information would be useful to all sectors and may encourage fishermen to use the site to inform their fishing activities. The capacity to use a risk assessment matrix on-line might further encourage use of the site.

Financial viability
Based on between 10 and 20 subscribers paying between £300 and £400 per year, the income generated would be between £3000 and £8000 per year. If we assume a reasonably consistent income of £5,500 it should, in principle, be sufficient to operate a highly automated website and database.

Website hosting can be obtained for approximately £400 per year, but additional security and functionality may incur costs of up to £1000.

If users are prepared to waiver all rights to the use of their data based on the Terms and Conditions specified it might be possible to reduce the need for liability and indemnity insurance. Directors and Officers insurance could, however, cost in the region of £3,000 annually. If the company is prepared to operate without insurance there could be between £3,000 and £4,000 per year available to support

basic administrative and website maintenance. If insurance is a requirement, the cost of the annual subscription would need to increase.

On the basis that the database company is a not-for-profit entity Limited by Guarantee with any administrative functions (including website maintenance) being provided by a self employed person or company on an *ad hoc* basis, there should be no requirement for employees.

If Option 4 (above) is the preferred choice, the open access to a convenient map display of FSA(S) data, the NCOF model output together with a risk matrix might significantly expand the number of site visits which, in turn, might make sponsorship of the site a more attractive proposition.

ANNEX 1.

Dear Stakeholder

UK Shellfish Biotoxin Database

Seafood Scotland is leading a project to establish the first UK Shellfish Biotoxin Database for the industry, operated by the industry. We are seeking your views on how this initiative might benefit your business.

New EU hygiene regulations require that all food businesses undertake risk assessments and end product testing for marine biotoxins to ensure product safety. The responsibility for providing safe shellfish rests with the entire supply chain from fisherman or grower through to those selling the product to the consumer.

End product testing for biotoxins such as Amnesic Shellfish Poisoning (ASP), Diarrhertic Shellfish Poisoning (DSP) and Paralytic Shellfish Poisoning (PSP) can add significantly to operating costs. Failure to test as part of a risk assessment could result in contaminated product being consumed, causing serious illness and undermining the shellfish sector as a whole.

To reduce the overall cost to the industry of end product testing, whilst encouraging responsible product sourcing, we are assessing the potential to set up a common pool of biotoxin testing results for the whole of the UK in the form of an interactive web-based database.

The database will enable food businesses to inform their risk assessments for end product testing and help to ensure that safe shellfish enter the food chain. It will also enable demonstration of responsible practice, promote increased efficiency, cost reduction, supply chain transparency and offer marketing advantages.

The database will include current and historical data and will encourage those who pay for product testing to share their results whilst providing the possibility of 'buy-in' for companies that do not currently test. We are keen to understand the requirements of those who may wish to use the database in order that it will be fit for purpose and deliver the information you need in the way that you need it and at acceptable cost.

As potential user of the database we would be grateful if you would take a few moments to complete the short web based survey by following the link below (please cut and paste the link into your web browser if it does not link to our site directly):

www.frmltd.com/Shellfish%20Biotoxin%20Questionnaire.html

If you represent an industry trade body or association, we would be grateful if you could forward this email to your members.

Many thanks for your participation.

Dr Mark James
FRM Ltd

The UK Industry Shellfish Biotoxin Database project is sponsored and steered by: Seafish, The Scottish Fishermen's Federation, The Scottish Government and the Food Standards Agency Scotland and the Scallop Association.

ANNEX 2.

UK SHELLFISH BIOTOXIN DATABASE DEVELOPMENT

A web-based resource developed by the industry for the industry!

This survey is designed to be completed in a few minutes by anyone who deals with shellfish destined for human consumption, from fishermen and growers through to processors, retailers, pubs and restaurateurs. All the information you provide will be treated as confidential and will be used for the purpose of this research only.

All you have to do is click on the boxes to answer "Yes" and either select, or type in any comments.

By completing this survey you will help us to determine whether an industry operated web-based database for shellfish biotoxins is required, is likely to be viable and, if so, to ensure that it will meet the needs of the industry and protect everyone in the shellfish supply chain by promoting the supply of safe product to the consumer. The vision is that the database will be web-based and operated on a not-for-profit basis by the industry for the industry. We need to find out if there is sufficient interest and willingness to pay for access to the database to cover the cost of operating it.

New EU hygiene regulations require that all food businesses undertake risk assessments and end product testing for marine biotoxins to ensure product safety. The responsibility for providing safe shellfish rests with the entire supply chain from fisherman or grower through to those selling the product to the consumer. End product testing for biotoxins such as Amnesic Shellfish Poisoning (ASP), Diarrhertic Shellfish Poisoning (DSP) and Paralytic Shellfish Poisoning (PSP) can add significantly to operating costs. Failure to test as part of a risk assessment could result in contaminated product being consumed, causing serious illness and undermining the shellfish sector as a whole.

The database will only be as good as the data provided and will rely on a combination of users who are prepared to submit their toxin test results to gain access to the results of other contributors. And, for those who are not involved in testing but have a vested interest in the results, to be prepared to pay to access the database.

Food Standards Agency Scotland have agreed in principle to contribute their historic records to the database together with current data they collect from shellfish toxin testing and toxic phytoplankton monitoring.

When you have completed the survey below, just click on the "Submit" button.

We thank you in advance for your help and look forward to receiving you responses. The survey will remain open until **Friday 11th April**.

Please check the boxes in the following table that best describe your activities

	Scallops	**Queen Scallops**	**Mussels**	**Oysters** *(Native and Pacific)*	**Cockles**	**Razorshells**	**Crabs**	**Lobsters**	**Nephrops**	**Other species including gastropods***(specify)*
Catch/Harvest (pot/trawl/dredge/dive/etc.)										
Grow (longline/tressel/on-beach/etc.)										
Sell										
Buy										
Depurate										
Process										
Supply to consumers directly										
Government Body e.g. Environmental Health										
Other - *please specify below*										

Are you required to test for shellfish biotoxins? - if the answer is "Yes", which ones and how often?

	Amnesic Shellfish Poison (ASP)	**Diarrhertic Shellfish Poison (DSP)**	**Paralytic Shellfish Poison(PSP)**	**Other - *please specify below***
Do you currently test for any of the following shellfish biotoxins - click on the box to indicate "Yes":	**ASP**	**DSP**	**PSP**	**Other**
How frequently do you test in the **summer**:	**ASP**	**DSP**	**PSP**	**Other**
How frequently do you test in the **winter**:	**ASP**	**DSP**	**PSP**	**Other**
Do you conduct the test yourself?	**ASP**	**DSP**	**PSP**	**Other**

Does a laboratory conduct the tests for you?	**ASP**	**DSP**	**PSP**	**Other**

Would you find it useful to have access to web-based shellfish biotoxins database?

Would you find it useful to be able to see the most up to date shellfish biotoxin test results on the internet? Select option:	If the answer is "Yes" - how would you like to see the test results presented - remember, the more complicated your requirements the more it is likely to cost. *Click on the appropriate check boxes to indicate your preferred option(s)*	A table of results	
		A table of results highlighting positive results above the legal threshold	
		A map showing results as a traffic light system - red meaning above the legal threshold, amber approaching legal threshold, green below legal threshold	
		An interactive map that shows the most recent results in traffic light form, but allows you to look at previous results also	

If you used the database, do you think:	Click on the box to answer "Yes".
- this might help you to avoid catching, harvesting or purchasing contaminated product?	
- your customers might see this a part of your commitment to producing safe seafood?	
- this could be included as part of your risk assessment process for avoiding shellfish biotoxins?	
- the database website might be a good place to advertise your business?	
- if you were an Environmental Health Officer, you would find this sort of biotoxin testing information useful?	

How might the database website work?

Would you be prepared to submit your toxin test results to a UK database if it gave you access to everyone else's test results? *(e.g. by adding your test results, you gain one months unlimited access to the database)* Select option:	If the answer is "Yes" - how soon would you allow others to see your results Select option:	Comment:

If you do not test, would you be interested in finding out where shellfish biotoxin outbreaks might be occurring by seeing the results of tests conducted by others.	If you found the database useful would you consider paying by subscription? Select option:

Select option: If the answer is "Yes" - would you be prepared to pay to see these test results. Select option:	

In answering the questions below remember that to test for ASP, DSP and PSP costs about £200 per sample - by both testing and sharing data you maximise the usefulness and potential overall cost saving that the database could deliver for your business

Read the proposition below and select the payment option(s) and range(s) that best describe your level of interest ***(Please note these questions are to provide us with an indication of whether there is sufficient interest in the database to cover the cost of providing it. You are not committing to paying any money).***

PROPOSITION:

For those submitting test results to the database, access to the database would be free for a period of one month after their data is submitted. Thereafter, access to the database would revert to the same cost as for those who are not contributing data. Those submitting sample data more frequently during each month will reduce the cost of access to the database on a pro rata basis for subsequent months also.

If you would be interested in accessing the database but WOULD NOT be submitting test results each month:

How much would you be prepared to pay for Pay per view access? - *access limited to current results only*	£10-£15	£15-£20	£20-£30
How much would you be prepared to pay for a monthly subscription? - *access limited to current results available, but unlimited access for each month subscribed.*	£40-£50	£50-£60	£60-£70
How much would you be prepared to pay for an annual subscription? - *unlimited access to all results for the period of the subscription.*	£300-£400	£400-£500	£500-£600

Add any additional comments or suggestions in the text box below:

Please enter your email address *(this will be used for reference purposes only)*

Would you be happy for us to contact you if we have any questions related to your responses to this questionnaire?

Select option:

Click on the "SUBMIT" button to send us your completed questionnaire

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