

Guidance for Local Action Groups (LAGs) on handling high *E.coli* results, biotoxin results and pollution events - classification and monitoring of live bivalve molluscs

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2. Introduction

This protocol reflects policy decided by the Food Standards Agency (FSA) as Central Competent Authority in England and Wales for this area of work. It is intended to meet the official control requirements of retained Regulation (EU) 2019/627¹, which lays down the official control (OC) requirements concerning Live Bivalve Molluscs (LBMs), which are filter feeding shellfish such as oysters, mussels and clams. These controls include the classification and monitoring of shellfish production and relaying areas, from which the FSA authorises the harvesting of LBMs. The classification of a production area determines the treatment required before the molluscs may be marketed. In all cases the general food safety requirements of Regulation (EC) 178/2002, Article 14 and more specific standards in Annex III of Regulation (EC) 853/2004 and the microbiological criteria adopted under Commission Regulation (EC) 2073/2005 must be met.

This document outlines the procedures for when 'high' *E.coli* sampling results are received for a harvesting area. The document also references the action to be taken in the event of a biotoxin or pollution event which could impact on the safety of LBMs (Sections 7 & 8).

In this document results above the classification and biotoxin thresholds are referred to as 'high' results. All classification results are based on *E. coli* per 100g of flesh and intravalvular liquid.

This replaces previous guidance on Local Action Groups (LAGs) and Local Action Plans (LAPs) issued in 2019 and supplements the existing guidance in the [Protocol for Classification of Shellfish Harvesting Areas – England and Wales](#).

¹ References to EU Regulations in this Protocol are references to the retained EU law as found at the legislation.gov.uk website and should be read alongside any domestic legislation which amends it.

Table 1: Shellfish classification categories and permitted levels¹

Class A
• 80% of sample results less than or equal to 230 <i>E.coli</i>/100g with none exceeding 700 <i>E.coli</i>/100g • Live Bivalve Molluscs can be harvested for direct human consumption.
Class B
• 90% of sample results must be less than or equal to 4,600 <i>E.coli</i>/100g with none exceeding 46,000 <i>E.coli</i>/100g • Live Bivalve Molluscs can go for human consumption only after a. purification in an approved establishment OR b. relaying in a Class A relaying area OR c. after an approved heat treatment process
Class C
• Less than or equal to 46,000 <i>E.coli</i>/100g • Live Bivalve Molluscs can only go for human consumption after a. relaying in a Class B relaying area followed by purification in an approved establishment OR b. relaying in a Class A relaying area OR c. an approved heat treatment process
Prohibited
• Sample results over 46,000 <i>E.coli</i>/100g – unfit for commercial harvesting for health reasons.

¹ Commission Implementing Regulation (EU) 2019/627

3. Roles and responsibilities

3.1. Local Authority (LA)

As the Competent Authority (CA), local authorities are responsible for shellfish classification sampling for *E.coli*, biotoxin monitoring and dealing with pollution incidents.

During Investigation and Action states they are responsible for informing industry and LAG members of the results and enforcement of control measures such as issuing Temporary Closure Notices (TCN) and temporary downgrades and regulation of Food Business Operators in their local area.

They coordinate the Local Action Group (LAG) and Local Action Plan (LAP) for their area.

3.2. Centre for Environment, Fisheries and Aquaculture Science (Cefas)

On behalf of the FSA, Cefas co-ordinates the classification and biotoxin monitoring programme and provides technical advice. Cefas notifies local authorities of Investigation States and Action States, check the LAP has been initiated, collate information from LAG investigations to produce outcome reports following Action States and inform LAs of high biotoxin results.

3.3. Food Standards Agency (FSA)

As the Central Competent Authority (CCA), the FSA has responsibility for ensuring that monitoring and classification programmes are in place to meet legislative requirements.

As a member of the LAG, it acts in an advisory role for all Investigation and Action states, and pollution events.

Following a high result, FSA reviews the Cefas action state outcome report/ recommendations and determines whether the result should be waived or, if not, whether any change in classification is necessary, such as downgrade or adding a note to the classification list to indicate marginal compliance.

3.4. Other stakeholders

LAGs include a range of other Government agencies and stakeholders. They are vital for the implementation of Local Action Plan procedures, including investigation of the causes associated with high results and dissemination of the high result to interested groups.

Examples include:

- Environment Agency/ Natural Resources Wales local teams can assist in identifying pollution sources attributed to a high result.
- Health Protection Units based in Public Health England/ Public Health Wales can advise on infection control measures.

- Trade bodies can contribute by notifying harvesters and food business operators about the results and voluntary control measures that are advised to be put in place.

4. Local Action Groups (LAGs) and Local Action Plans (LAPs)

Local Action Groups (LAGs)

LAs responsible for classified shellfish production areas must ensure an effective LAG and LAP are established.

The purpose of a LAG is to protect public health by:

- developing and implementing an effective LAP
- assisting LAs in investigating high results including Action/Investigation States and pollution events
- facilitating electronic data exchange
- providing data and/or other information to identify possible causes of high results.

LAGs consist of representatives from the LAG co-ordinator (LA), FSA, Cefas, local Environment Agency/Natural Resources Wales, Inshore Fisheries and Conservation Authority/Welsh Government, water companies, members of local industry and anyone else interested in local shellfish issues.

Local Action Plans (LAPs)

Each LAG must develop an effective LAP to implement 'Investigation' and 'Action' states when high *E.coli* results or biotoxin or pollution events occur.

LAPs must cover all classified beds and Representative Monitoring Points (RMPs). Plans must

- include a list of members with their contact details
- have templates to be used by the LAG co-ordinator to notify members of high results and short-term control measures
- detail the investigation process during the Investigation and Action states
- allocate roles to members to assist in investigating high results
- outline the data collection process and how information will be shared to members
- determine when and how information should be given to Cefas for analysis and advice
- include criteria and agreed templates for lifting control measures, time scale for reporting results and ending of Investigation and Action states
- cover actions to be taken following a biotoxin or pollution event.

If more than one authority is part of a LAG/LAP, the boundaries of each authority should be identified. It should be clearly indicated which is the lead authority.

The effectiveness of a LAP relies on it being tailored to specific local needs. All members of the LAG should be involved in the development of the LAP. A template 'Action Plan' is provided in Annex A.

LAPs should be sufficiently detailed to ensure that inexperienced local authority officers on duty at weekends are still able to take appropriate action should high results be reported then.

Investigation state procedures

An Investigation State can be viewed predominantly as a warning/need to inform and gather feedback stage, where investigations are carried out to look into the cause of the high result, gather information and to evaluate whether the classification of a production area should be reviewed.

Following a high result falling within Investigation State trigger levels, Cefas will issue an appropriate notification to the LA. The notification type sent will depend on the compliance of the site. Investigation State trigger levels and notification criteria are outlined in Table 2 below.

Table 2: Investigation state trigger levels and notification criteria

Class A
Trigger: Any result above 230 but not greater than 700 in the rolling 12-month period (greater than 700 would trigger an Action State see Section 5) Two notification types: 1. Cause for concern (investigation only) – issued following a result over 230 (but less than 700) in rolling review year. Site still complies with Class A criteria so notification for investigative purposes only. 1-year compliance is 80% or above so no change in classification needed. 2. Possible downgrade - issued following a result over 230 (but less than 700) in rolling review year that takes compliance below 80% limit.
Class B and B Long-Term areas
Trigger: a result above 4,600 but not greater than 18,000 in the rolling 12-month period. (greater than 18,000 would trigger an Action State see Section 5) Three notification types: 1. Cause for concern (investigation only) - site still complies with Class B/B-LT criteria so notification for investigative purposes only. 1-year compliance is above 89.5% so no change in classification needed. 2. Cause for concern (Class B/B-LT: marginal compliance) - site no longer complies with class B/B-LT criteria but does not meet criteria for immediate downgrade. • 1-year compliance is below 89.5% • rolling 3-year (B) or 5-year (B-LT) compliance is 84.5-89.5% so site falls within 5% buffer. 3. Possible downgrade - Triggered by a further result above 4,600 such that 1-year compliance is below 89.5% and rolling 3-year (for Class B) or 5-year (for Class B-LT) compliance is also below 84.5%.
Class C
Not applicable. Any result above 46,000 is a prohibited result and considered an action state.

Upon receipt of the notification, the LA, as the LAG coordinator, will initiate investigation state procedures as set out in the LAP.

LA will notify all LAG members and outline the investigation procedures to be followed.

The communication should outline:

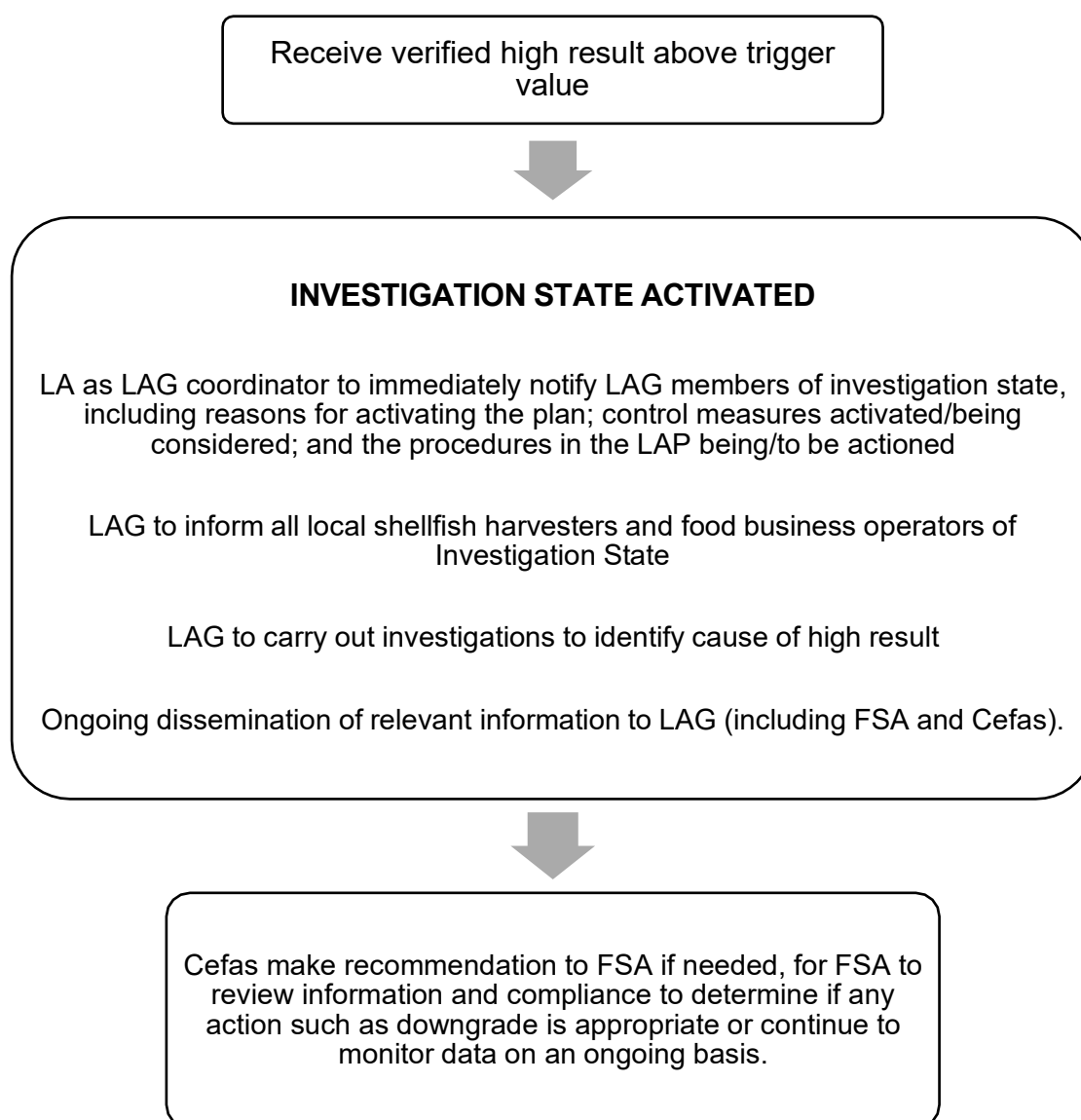
- Reasons for activating the plan
- Control measures activated/being considered
- The procedures in the LAP being/to be actioned.

A template standard notification is provided in Annex 2.

LAG members should circulate information relating to possible causes of high results to all other members and to the LA.

(Please see investigation State flow diagram below)

Figure 1: Investigation state flow diagram – A and B classifications only



5. Action state procedures

An Action State is where immediate action is required to deliver a responsive public health control system. If a sample result is above the Action State trigger levels, as shown in Table 3, the LA will be notified by Cefas or an Official Laboratory.

Table 3: Action state trigger levels

Class A – above 700 <i>E.coli</i> /100g
Class B – above 18,000 <i>E.coli</i> /100g
Class C – above 46,000 <i>E.coli</i> /100g

The first phase is implementation of prompt and appropriate short-term health control measures by the local authority (see Table 4 below for examples). The second phase is for the LAG group to gather information from its members as an investigation into possible causes/issues locally.

Upon receipt of the results, the LA, as the LAG co-ordinator, will initiate Action state procedures as set out in their LAP.

The LA will notify all LAG members and outline the Action State procedures to be followed. A standard notification template is provided in Annex 2.

The LA should implement short term control measures to protect public health, examples of high result scenarios and short-term control measures are shown in Table 4. The FSA Incidents team will confirm that, the LA has received the result and that short-term measures have been implemented.

Table 4: Examples of high result scenarios and short-term control measures

Class A
Scenario: a result above 700 but not exceeding 4,600 Action: temporary downgrade to Class B or temporary closure
Scenario: a result above 18,000 but not exceeding 46,000 Action: temporary downgrade to Class C or temporary closure
Scenario: a result above 46,000 Action: temporary closure
Class B and Long-Term B areas
Scenario: a result above 18,000 but not exceeding 46,000 Action: temporary downgrade to Class C or temporary closure
Scenario: a result above 46,000 Action: temporary closure
Class C
Scenario: a result above 46,000 Action: temporary closure

LA will contact local shellfish harvesters and FBOs to inform them of the Action state. Advice should include the following information, where applicable.

- details of the affected area and short-term controls applied (including if a temporary closure notice or temporary downgrade is in place)
- increasing end product testing regimes to ensure remaining stock harvested on or after the day of sampling is safe
- all customers that received the product should be informed
- advice regarding product withdrawals and recalls.

LAG members are asked to supply any information relating to the potential causes of high results. The classification of the site may be affected by the outcome; LAG

members must provide Cefas with this information so it can be collated into an Action state outcome report.

Additional sampling to the monthly monitoring programme may be carried out by the LA. They will identify sampling dates and notify LAG members. **No additional sampling should commence until 7 days after a trigger result sample had been taken.**

Short term control measures should remain in place until two consecutive samples are taken at least one week apart showing results below the classification limit.

An Action state can last for a maximum of 3 months. After this, monthly monitoring should be carried out to assess the status of the bed.

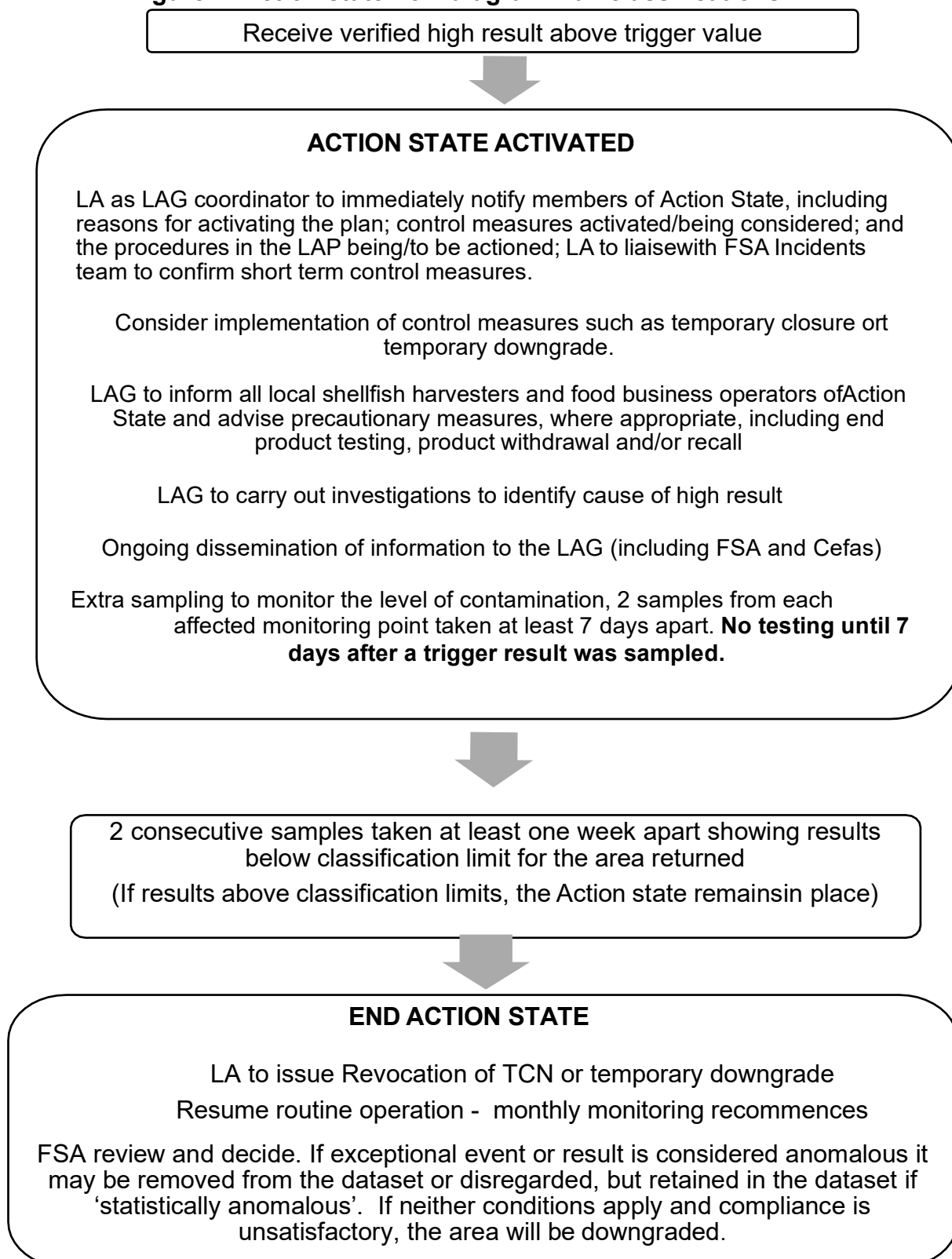
Cefas will coordinate an investigation into the high result. This will include information submitted by the LAG, an assessment of current and 3 year sampling data and a statistical analysis for consideration of the high result and potential impact on classification. Any other available information returned during the investigation will also be included. Investigations and waiving criteria are detailed in Section 6 below and in the [Classification Protocol – section 10](#)).

Cefas will issue recommendations to the FSA on the outcome of the investigations of the high result and potential changes to classification (if applicable) in an Action state outcome report within 5 weeks. This will also be sent out to LAs.

The FSA will consider the report and recommendation and, if necessary, will downgrade the bed via an interim update to stakeholders.

(Action State flow diagram below)

Figure 2: Action state flow diagram – all classifications



6. Criteria for disregarding results

High results may be removed from the classification dataset by the FSA if there is sufficient information to justify this. Results would have to be attributed quite clearly to very unusual or 'one off' events that have been resolved and are unlikely to recur. For results to be removed due to an event, a period of up to 48 hours prior to sampling is usually considered.

Exceptional events that may allow results to be waived include

- 1 in 5 year storm event - rainfall
- major sewage treatment works failure - since rectified
- other exceptional pollution event e.g. slurry spill or septic tank spill – since rectified
- failure to comply with sampling protocol

Results in Class A or seasonal Class A/B areas where a cause cannot be found but that are markedly higher or lower than those previously seen in an area may potentially be considered 'statistically anomalous' and disregarded for classification purposes. A statistical analysis will be carried out and results more than three standard deviations (SD) above mean contamination levels for a 3 year, log transformed dataset will be disregarded. Whilst these results will not lead to a change in classification, they will remain within the dataset to ensure future calculations are statistically valid.

In addition for Class A or seasonal class A/B areas, occasional results slightly above the threshold for Class A harvesting areas (780 *E. coli*/100g) may also be considered anomalous where monitoring data demonstrates that at least 80% of the samples contain *E. coli* less than or equal to 230 *E. coli* per 100g and a statistical analysis of the 1 and 3 year dataset shows that the area is on-track to remain within the Class A criteria. These results will not lead to a change in classification unless compliance falls below 80%, and will remain within the dataset for future compliance assessments.

Sampling tips

E. coli results can be affected by various environmental conditions; this may affect the compliance and classification of an area if results over the permitted classification limit are recorded frequently. LAs are advised to aim for a degree of flexibility when organising sampling runs.

Sampling may not be necessary if an area is under voluntary closure, for instance, for conservation reasons.

Additional samples taken as part of an investigation or action state may be considered as official control samples. However, other than those additional samples required in this protocol (such as during a pollution event), local authorities should not take classification monitoring samples other than in accordance with the sampling plan unless by agreement with the FSA (such as in marginal sites).

Taking additional samples outside the sampling plan can have the effect of distorting the percentages of compliant results on which the classification is based. The FSA reserves the right to make judgements on classifications based on the sampling plan unless it has requested additional samples.

7. Biotoxin and phytoplankton sampling results

Biotoxin and phytoplankton events

Biotoxin and phytoplankton monitoring results are reported by email to Local Authorities (LA) responsible for sampling. LAs should review the results for samples they have submitted. All [results](#) are published on a weekly basis on the shellfish pages of the FSA's website

Results below trigger level:

Results below trigger and action levels are for information only. No action is required.

Results above trigger level:

Results above trigger levels from phytoplankton or biotoxin monitoring samples would instigate additional flesh and phytoplankton sampling the following week. All additional samples will be requested by Cefas in the covering email when reporting monitoring results.

Action level breaches:

Action levels are equal to or greater than the regulatory limits.

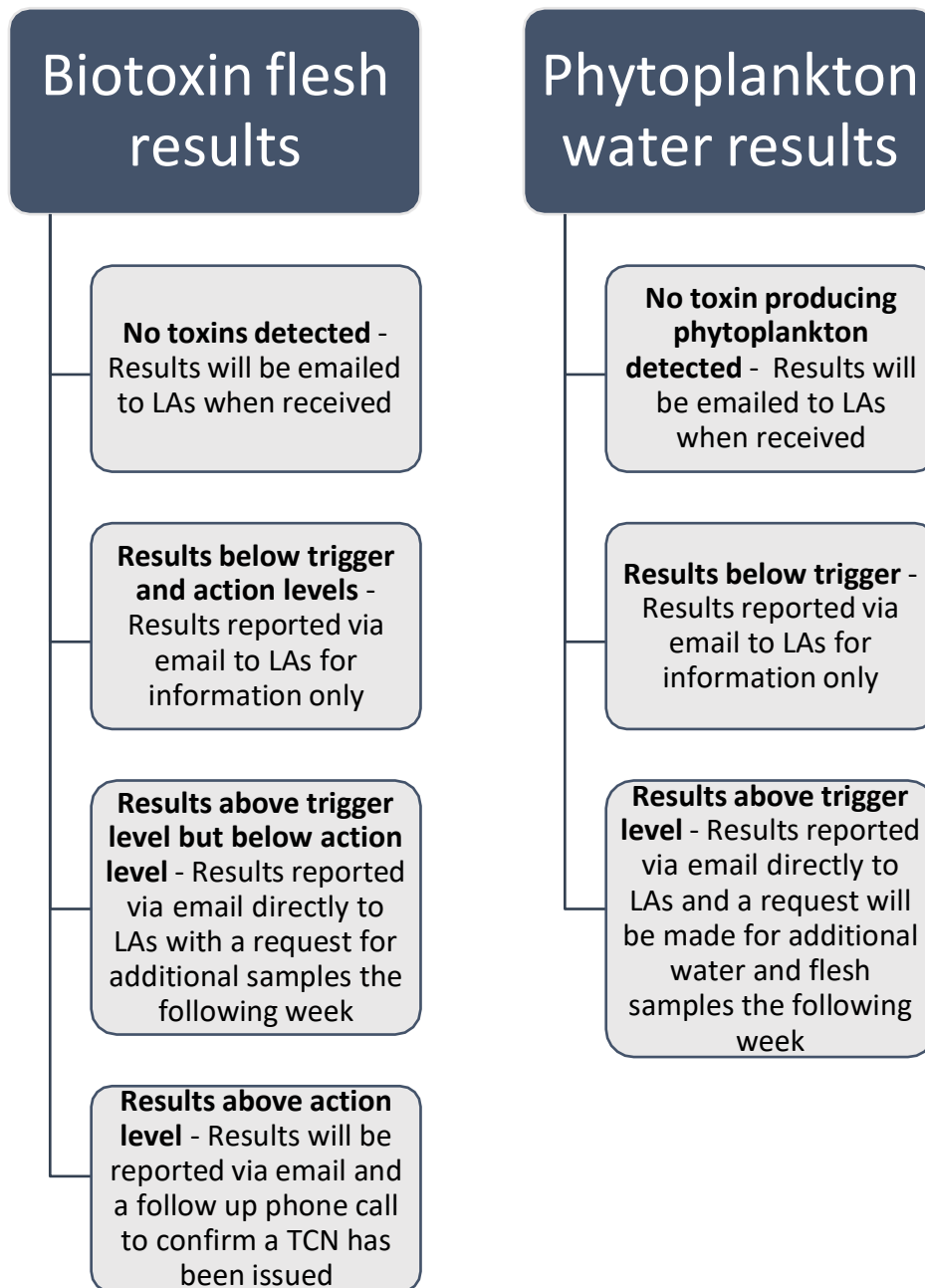
Biotoxin action level breaches would instigate a closure of the area monitored by the RMP sampled. The results will be emailed as usual with the request to close the areas affected in the covering email, a phone call will also be made to the LA responsible to ensure the email has been received and a TCN is being applied.

An additional flesh sample will be requested for the following week, phytoplankton samples will not be required until the first sample below the action level regulatory limit has been reported. The area will only be permitted to re-open once two flesh samples have returned results below the regulatory limit.

The LA should inform the local industry of the result, and they should amend their end product testing and food safety management controls accordingly. If any shellfish has been harvested since the collection date which have been placed on the market, this should be withdrawn/recalled. As a precautionary measure, they should also consider any shellfish harvested shortly before the collection date.

(See flow diagram overleaf)

Figure 3: Biotoxin and phytoplankton results flow chart



The published biotoxin and phytoplankton results are updated on a weekly basis. A link to the results can be found on the [biotoxin and phytoplankton monitoring page](#) of the FSA's website.

8. Other pollution events

This plan will apply to pollution events which could affect the safety of shellfish in harvesting areas. Examples include:

- a) An abnormal and significant discharge/s of sewage/effluent such as unconsented discharges.
- b) Chemical spillage e.g. oil/fuel affecting the waters around the relevant shellfish harvesting areas

Any member of the LAG who is aware of a pollution incident with the potential to affect the shellfish harvesting areas covered by this plan, should notify details of the incident to the relevant LA.

Specifically, the Water Company/EA will notify details of any exceptional discharges of sewage/effluent and also significant extraordinary discharges from consented overflows.

FSA Food Incidents team will contact you if we have received information directly that may impact on a classified harvesting area for which you are responsible. However, if you obtain intelligence of a pollution event impacting on a shellfish production area before being notified by the FSA, please alert the FSA Food Incidents team, copying-in our shellfish delivery team via the links below.

England foodincidents@food.gov.uk and shellfish@food.gov.uk
Wales wales.foodincidents@food.gov.uk and lasupportwales@food.gov.uk

LAG members should also notify the relevant LA of other exceptional events which have the potential to adversely affect the shellfish beds e.g. unusual dredging, piling or other constructional activity.

The LA will undertake a risk assessment in conjunction with FSA and other members of the LAG, as appropriate, as to the public health significance of the incident. The outcome of the risk assessment may result in one or more of the following:

- Sampling/re-sampling of shellfish from relevant harvesting beds
- Short term control measures - temporary downgrade/closure of relevant harvesting beds
- Tracing & recall of product harvested from relevant harvesting beds
- No further actions

Shellfish harvesting seasons/restrictions and trade patterns will be taken into account in determining the necessity of the above measures.

Annex 1: Local Action Plan Template

Title: Local Action Plan for the Local Action Group covering shellfish production areas [Production areas]

1. Members of the Local Action Group

Recommended organisations:

Co-ordinating local authority

Other local authorities/Shellfish Liaison Group

Environment Agency (England)/Natural Resources Wales (Wales)

Local Industry Representative(s)

Official Laboratory

Water Authority

Inshore Fisheries and Conservation Authority (England)/Welsh Government (Wales)

Cefas

FSA

Harbour Authorities

2. Scope of Local Action Plan

This plan covers the following classified production areas

To include the following:

- Production area name(s)
- Zone name(s)
- Species
- Classification(s)
- RMP location(s)

3. Conditions for operation of the plan

The plan will come into operation when the following high results are received for *E. coli* per 100g:

Action State
Class A – Above 700
Class B – Above 18,000
Class C – Above 46,000
Investigation State
Class A – Any result above 230 but below 700
Class B – Above 4,600 but below 18,000

You may wish to also include biotoxins and pollution events such as crude oil or chemical spills and unconsented sewage discharges/emergency sewage discharges or any other event likely to have an adverse impact on live bivalve molluscs in a classified harvesting area.

4. Communication and notification

Initiating the Local Action Plan

All members of the Local Action Group will be notified by the coordinating LA immediately when the Local Action Plan has been activated following a high result. Details will include:

- Reasons for activating the plan
- Control measures activated/being considered
- The procedures in the LAP being/to be actioned and the individual(s) responsible

See Annex 2 for standard notification messages for an Investigation and Action State.

This communication will be through e-mail or by telephone to the Local Action Group contact details found in Annex 4.

Review of Local Action Group contact details

A test message, as shown in Annex 3, should be sent by the coordinating authorities on a yearly basis, at a minimum, to ensure Local Action Group contact details are up to date.

All members should ensure that the coordinating authority is made aware of changes to contact details. The coordinating authority will update the Local Action Plan with new contact details, as required.

1. Procedures to be followed for Investigation State

[Procedures should be tailored to suit Local Action Group members and the local area.

See Section 4 of the LAG guidance on Investigation States for further information.]

2. Procedures to be followed for Action State

[Procedures should be tailored to suit Local Action Group members and the local area. See Section 5 of the LAG guidance on Action States for further information.]

3. Weekends and out of hours arrangements

There must be arrangements in place to cascade the details of a pollution events, including other relevant information obtained during investigations to all harvesters, traders and food business operators concerned. Local Action Plans should be sufficiently detailed for even inexperienced officers to work through so that appropriate actions can be taken to protect public health.

Annex 2: Template of standard notification message of an Investigation/Action State result

Subject line:

Investigation [notification type]/Action¹ State Activated - Local Action Group for [Production area(s)]²

Email:

To all members of the Local Action Group for **[Production area(s)]²**.

We have received notification of a high *E. coli* result that falls within **[Investigation [notification type]/Action]¹** State criteria obtained in a classification sample:

Classification zone (including sample co-ordinates)	Sample date	Result <i>E. coli</i> /100g	Species sampled	Existing classification

As the LAG co-ordinating authority this message is notification that the Local Action Plan has been activated. In accordance with the agreed LAP we would refer members to the procedures for **[Investigation/Action]¹ States**.

Actions:

1. Our initial response will be to **temporarily close/ temporarily downgrade/[other control measures]^{1 3}** the production area.
2. Additional sampling to the monthly monitoring programme **[will/will not]** be carried out.
3. Members are requested to investigate and submit any information on incidents or other factors that may have contributed to this high result(s) to assist with the investigations.
4. Nominated members should cascade the information to all harvesters, traders and food business operators concerned.
5. **[Tracing/withdrawal/and recall]¹** of already harvested products **[will/will not]¹** be required on this occasion.
6. The results of other sample sites from [insert sampling area] were satisfactory and well within the classification limits/are being awaited etc.

Many thanks for your assistance.

¹ Delete as appropriate. ² To complete. ³ If other control measures, please specify what the measures are.

Annex 3: Test message

Subject line:

Test message: Local Action Group covering **[Shellfish production area(s)]** ¹

Email:

To all members of the Local Action Group for **[Production area(s)]** ¹.

This is a test message for all members of the above Local Action Group.

Please respond to this email to **[LAG coordinator email address]** ¹ confirming your contact details remain correct. **No other action is required.**

If you have received this email in error and are not a member of the Local Action Group please reply in order that your details can be removed from the circulation list.

¹ To complete.

Annex 4: Contact details for Local Action Group members
(last checked on date/month/year)

Organisation	Routine/Non-emergency	Out of hours/ Emergency*
Coordinating Local authority	[Name], [job title], [organisation], [email address], [telephone number]	[Name], [job title], [organisation], [email address], [telephone number]
Other Local Authorities/ Shellfish Liaison Group		
Environment Agency (England)/ Natural Resources Wales (Wales)		
Local Industry Representative(s)		
Official Laboratory		
PHE Health Protection Team		
Water Company		
Inshore Fisheries and Conservation Authority (England)/ Welsh Government (Wales)		
Marine Management Organisation		
Cefas		
FSA		
Harbour Authorities		

*where applicable

Annex 5 – Model notice of temporary closure of production area(s) (live bivalve molluscs/shellfish)

NOTICE OF TEMPORARY CLOSURE OF PRODUCTION AREA(S) [insert production area]

Retained REGULATION (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Retained Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EU) No 2074/2005 as regards official controls.

Food Safety and Hygiene (England) Regulations 2013 S.I. 2013 No 2996

Pursuant to the power conferred on it by Article 18(6) and Article(8)(b) of Retained Regulation 2017/625, and Article 62 of Retained Regulation 2019/627, being satisfied that [the results of sampling show that the health standards for molluscs are exceeded] [there might be a risk to human health]

As Competent Authority for the purposes of the above EC provision by virtue of regulation 4 of the Food Safety and Hygiene (England) Regulations 2013 S.I. 2013 No 2996:

[Insert authority] has temporarily closed the production area identified in the Schedule to this notice for the production and harvesting of [insert list of all affected species] by Food Business Operators until further notice.

Signed: Dated this [] day of [] 20[[]

[Insert official position of signatory]
On behalf of the [insert authority]

SCHEDULE

Area[s] in which the production of [insert list of all species affected] by food business operators is prohibited by reason of this order:-

- (a) [Insert area]
- (b) [Insert area]

Food business operators must not collect the affected animals from this area by any method; it is unsuitable for their production for health reasons and has been temporarily closed. Collection of affected animals from the area that is temporarily closed amounts to the commission of a criminal offence under regulation 19 of the Food Safety and Hygiene (England) Regulations 2013 S.I. 2013 No 2996. On

conviction, a fine or imprisonment for a term of up to two years or both might be imposed.

[PRIVATE INDIVIDUALS ARE STRONGLY ADVISED NOT TO GATHER [insert description of affected animals] FOR THEIR OWN CONSUMPTION FROM THE AFFECTED PRODUCTION AREA. THERE MIGHT BE A RISK TO HUMAN HEALTH IN DOING SO.]

Recent analysis of samples taken by [insert authority] from the affected area has shown that [insert animals] are affected by [insert problem].

[insert authority] will continue to take samples for analysis and keep its decision to close the area under review. To check the current status of the area you may contact [insert authority] by [insert preferred method of contact, e.g. telephone no.]