ANNEX

FSA protocols for the classification of Live Bivalve Mollusc (LBM) Harvesting Areas: handling of anomalous results above the Class A threshold

Introduction

1. The FSA has been considering changes to the classification process for LBM harvesting areas. Our focus in the short term has been on proposals that are workable within the existing legal framework, evidence-based and that could impact on A/B classified harvesting areas within a reasonably short time-frame. As a first step, our protocols will be updated to include two additional criteria for consideration of anomalous results from Class A harvesting areas.

The Changes

2. The two additional criteria for anomalous results will allow FSA to exclude uncharacteristically high results and take a proportionate response to occasional results slightly above the threshold for Class A harvesting areas. The new criteria are:

    i.   results above the Class A threshold falling more than 3 standard deviations above the mean contamination levels; and

    ii. a proportionate response to occasional results slightly above the threshold for Class A harvesting areas where monitoring data otherwise shows that the area is on-track to remain within the Class A criteria.

Impact

3. These changes ensure the classification process provides appropriate levels of public health protection whilst remaining compliant with the Retained EU Law and EU requirements for third country imports and have the potential to impact on a small number of individual harvesting areas and exports to the EU.

Evidence

4. Class A harvesting areas can be downgraded to Class B or a seasonal A/B on the basis of any results above the 700 *E. coli* per 100g, unless the result is anomalous. Retained EU law Regulation 2019/627[1] allows, on the basis of a risk assessment[2] based on an investigation, an anomalous *E. coli* monitoring result exceeding 700 *E. coli* per 100g to be disregarded in Class A areas. EU Reference Laboratory (EURL) Guides to Good Practice[3] provide guidance to support practical application of the legislation.

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[1] https://www.legislation.gov.uk/eur/2019/627/article/53

[2] In this context, "risk assessment" is considered to mean an assessment of the risk of the cause for an anomalous result recurring within a certain period of time, rather than meaning an assessment of risk to the consumer.

[3] Community Guide for the Microbiological Classification and Monitoring of Bivalve Mollusc Production Areas - published January 2017: https://ec.europa.eu/food/sites/food/files/safety/docs/biosafety_fh_guidance_community_guide_bivalve_mollusc_monitoring_en.pdf
Microbiological Monitoring of Bivalve Mollusc Harvesting Areas Guide to Good Practice: Technical Application - published January 2017: https://www.cefas.co.uk/media/jyzhl1si/good-practice-guide-issue-6.pdf

5. The EURL guidance suggests that *E. coli* results more than 3 standard deviations as a basis may be considered anomalous and excluded from the classification dataset. Investigations would still be required to see if an explanation for the high result could be identified.

6. *E. coli* results using the MPN test method produces a range of results that can straddle the upper Class A compliance limit depending on the number of positive tubes and combination of dilutions. For example, some combinations will provide results just below 700 MPN *E. coli* per 100g and then the next step up is 780 *E. coli* per 100g. Adopting a proportionate evidence-based approach to consideration of individual results marginally above the threshold (i.e. the next 'step up') helps avoid a disproportionate impact on the classification status when other data provides evidence that the result can be considered anomalous.

Risk considerations
7. FSA believe that there is no additional public health risk from the revisions since anomalous results can already be disregarded, and mitigations are in place to reduce any risk. Potential public health risks associated with excluding anomalous results are mitigated by closure or temporary downgrade of the harvesting area pending investigation. Harvesting is only permitted to resume when further monitoring indicates that the contamination event has passed and *E. coli* levels have returned to acceptable levels.

8. A critical requirement for improvements in classification status is improvements in water quality. Until this improves, changes in protocols are not expected to lead to major changes in classifications awarded for shellfish harvesting areas.

Timing
9. Changes to the protocols will apply in respect of England, Wales and Northern Ireland. We are working at pace to consider how these will impact individual harvesting areas and ensure that the protocols are updated to provide the appropriate framework to apply the changes as part of this year's annual review of classifications which take effect from September 2021 in England and Wales . In Northern Ireland, the changes will be implemented at the time of the annual review of shellfish classifications in January 2022.

Next Steps
10. The FSA will be considering the other proposals put forward by stakeholders as a next stage, again prioritising those considered workable within the existing legal framework including sampling protocols, adapting sampling plans to harvesting periods and introducing an appeals mechanism. This will include consideration of recommendations arising from a report looking at the classification process in a number of countries prepared by Seafish[4] for the Shellfish Stakeholder Working Group which was published on 9 June.

Food Standards Agency
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[4] https://www.seafish.org/document/?id=621FFA11-4943-4698-BDD4-BCF3784BDDA8