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SETTING NOROVIRUS LIMITS FOR BIVALVE MOLLUSCS AND OTHER EU PROPOSALS

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Summary

- Outline the process for amending EU legislation
- Discuss proposals for amending EU legislation
  - E.coli criteria for class A harvesting areas and end product
  - Salmonella criteria for end Product
- Proposals to introduce norovirus limits shellfish and additional labelling requirements

- [Information on FSA research project on depuration]

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- Food safety, a top priority.
- Since 2000, the Commission has been working towards ensuring a high level of human health and consumer protection, by:
  - modernising legislation into a coherent and transparent set of rules,
  - reinforcing controls from the farm to the table, and
  - increasing the capability of the scientific advice system.
- White Paper on Food Safety (http://ec.europa.eu/dgs/health_consumer/library/pub/pub06_en.pdf)

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FH related legislation

- Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
- Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
- Directive 2002/99/EC laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption, 16 December 2002

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Food Hygiene legislation

- Regulation (EC) 852/2004 on the hygiene of foodstuffs, 29 April 2004
- Regulation (EC) 853/2004 laying down specific hygiene rules for food of animal origin, 29 April 2004
- Regulation (EC) 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption, 29 April 2004
- Regulation (EC) 2073/2005 on the microbiological criteria for foods 15 November 2005

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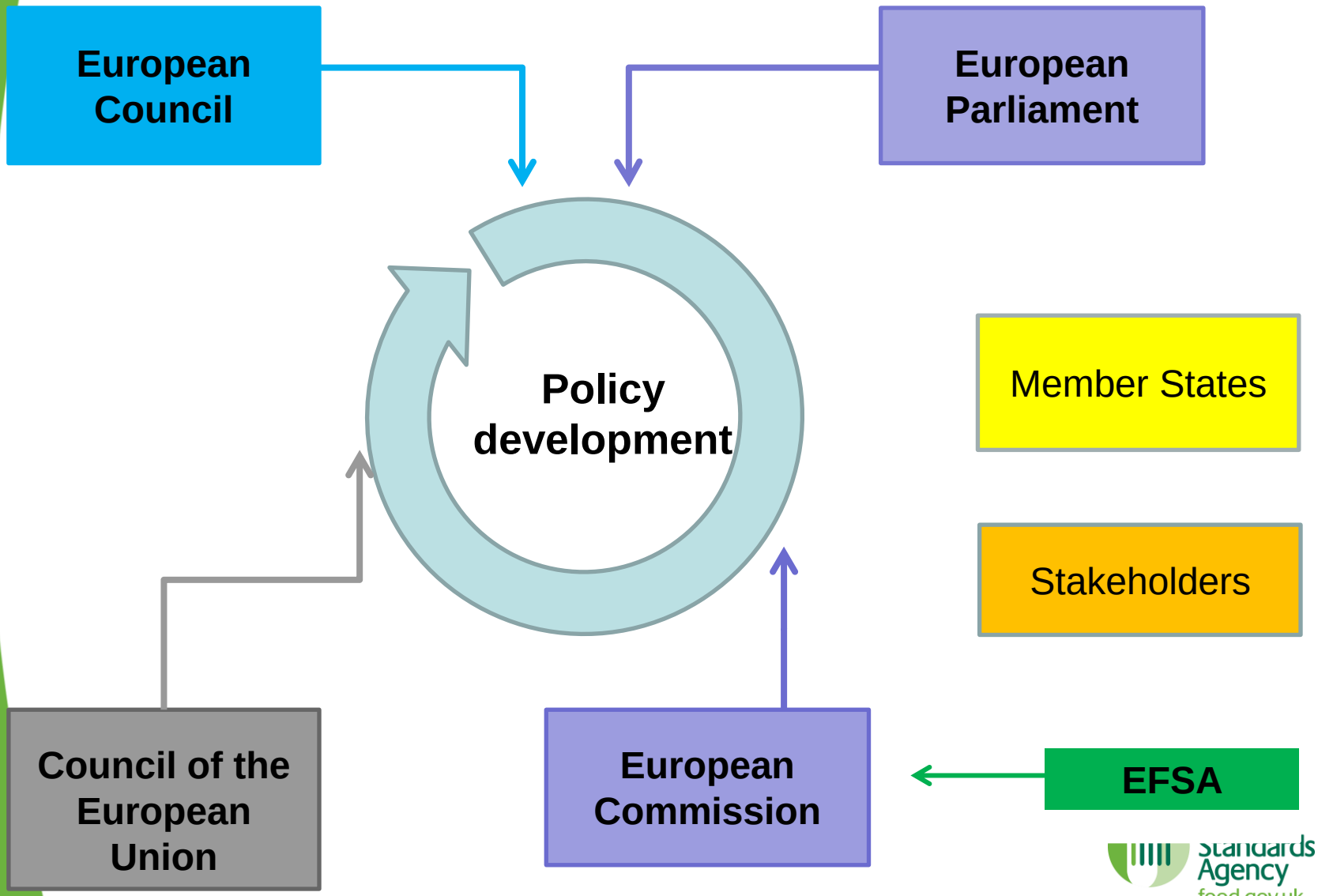
Main players



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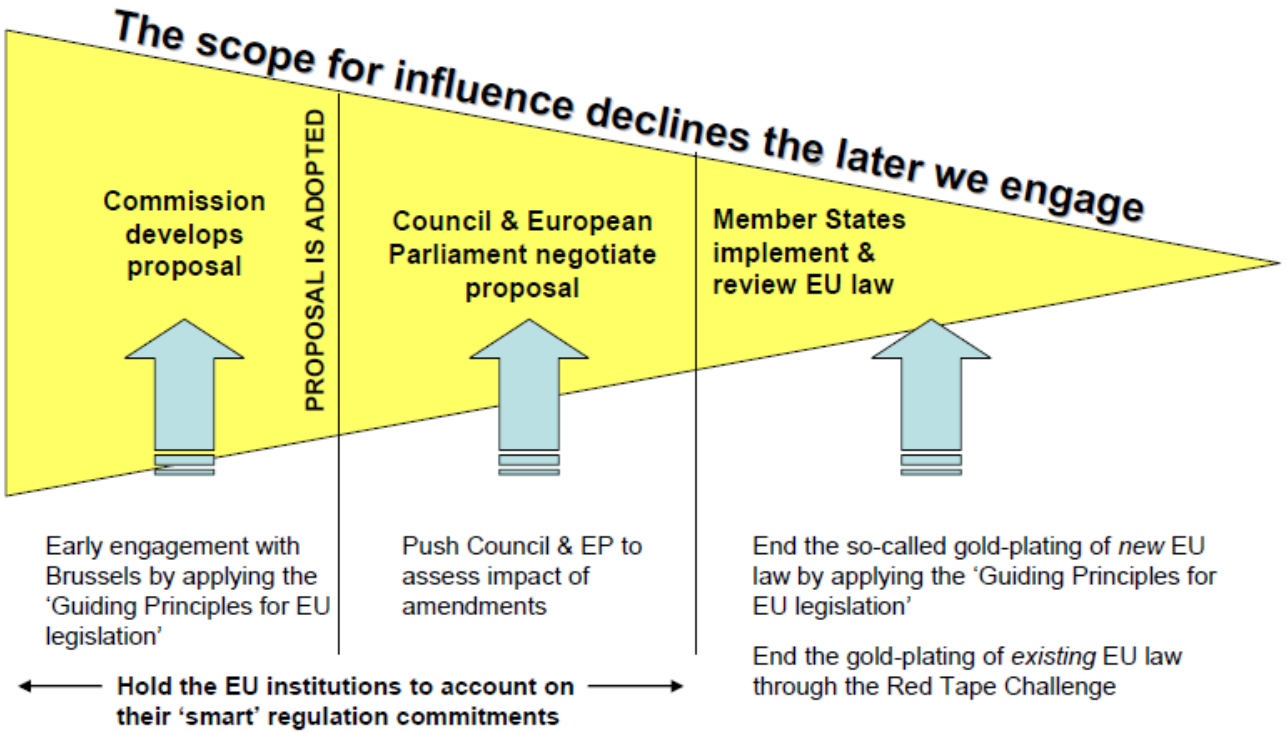

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Proposals for amendments to EU controls on bivalve molluscs

- Amendments to criteria for Class A harvesting areas and end product standards
  - E.coli (harvesting area; end product)
  - Salmonella (end product)
- Introduction of controls for norovirus
  - Limits for harvesting areas
  - Labelling requirements

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Amendment of E.coli criteria for Class A harvesting areas (854/2004)

LBMs from Class A areas

- must not exceed 230 E.coli per 100g of flesh and intravalvular fluid in 80% of samples.
- must not exceed 700 E.coli per 100g in the remaining 20% samples
- Review period for sampling data must be defined

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Amendment of E.coli criteria for Class A harvesting areas (854/2004)

- Response to FVO audit findings which showed uneven application of current criterion for Class A areas. Should lead to better harmonisation across MS.
- Statistical evaluation shows public health protection comparable to current criterion.
- Benefits for harvesters – more class A areas?
- Seek clarification on intended sampling period

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Amendments to End Product criteria (2073/2005)

E. coli

- Adoption of Codex standard
- Similar to proposed amendment to harvesting areas

Criterion

5 samples (n)

Range (m-M) 230-700 E.coli /100g

All samples ≤ 700 E.coli/110g

1 sample (c) can be between ≥ 230 and ≤ 700

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Amendments to End Product criteria (2073/2005) - E.coli

- Statistical assessment shows provides at least equivalent public health protection. Increased sampling rates could provide better public health protection
- Potential for increased sampling costs if 5 samples are taken each time but flexibilities in the Regulation allow sampling lots to be reduced.
- Would like clarification on intended sampling requirements e.g. sample size (5 x 10 individual animals?)

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Amendments to End Product criteria (2073/2005)

Salmonella

Remove end product criterion for Salmonella in LBM.

International risk assessment shows this does not provide additional public health protection beyond that provided by the E.coli criterion

Good example of working within better regulations

Proposal removed but we will seek clarification as we understood this was supported by the majority of MS.

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Introduction of Norovirus standards (854/2004)

- LBM destined or intended to be eaten raw must not exceed the viral limit of XXX NoV PCR genome copies per gram (measured in the whole body) detected by using PCR based detection method.
- Harvesting areas must be monitored to ensure levels above the established limit are detected

NO LIMIT HAS YET BEEN PROPOSED

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Proposed Labelling requirements (853/2004)

Bivalve molluscs not destined or not intended to be eaten raw [labels includes] the sentence ‘to be cooked before consumption’.

Understand this is to support norovirus controls which focus on shellfish to be eaten raw.

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Introduction of Norovirus standards (854/2004)

- Response to European Food Safety Authority recommendation that criteria limits for Norovirus in bivalve molluscs could be established. EFSA did not provide a limit and indicated this is a risk management decision.
- Last discussed June 2014. Commission expecting MS to have established their position and come to next WG ready to discuss an appropriate limit.

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Introduction of Norovirus standards (854/2004)

- EFSA opinion and EURL technical document provide evidence underpinning the proposals.
- EFSA indicates limits up to 10,000 copies per g would have a positive public health impact
- Presence/absence limit disproportionate
- Evidence suggests <200 copies/g are unlikely to cause illness, while >1000 copies/g this is more likely to occur.

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Introduction of Norovirus standards (854/2004) – UK position

- Recognise the public health risks associated with norovirus in shellfish and support the principle that limits should be established.
- However, there is currently insufficient evidence to allow proportionate limits to be established.
- Limited information on infectious dose. Knowledge is improving but based on very few studies.
- Limitations in the analytical method – inability to distinguish between infectious and non infectious virus particles.

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Introduction of Norovirus standards (854/2004)

- UK position agreed cross government and presented throughout EU discussions.
- Stakeholder Workshop to discuss initial proposals (2011). Lead Commission official present.
- Discussing directly with Commission and other MS to influence and secure support for UK position.
- Working to clarify position of other MS prior to next Working Group.
- Working with stakeholders to present an alternative non-legislative approach
- Encouraging harvesters to engage with the Commission

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Risk management options for norovirus – harvester toolkit

- Established and facilitating a drafting Group including key stakeholders (e.g ASSG, SAGB, Seafish, LAs)
- Aim is to support harvesters in producing a document that presents all the options available to harvesters to minimise the risks associated with norovirus in oysters.
- Basis of EU guidance document?
- Needs to provide assurance that risks can be managed without a legislative limit

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Controls for norovirus

Recognise it is difficult to control norovirus contamination in shellfish as viruses are often present in growing areas. Also post harvest controls have limited impact on norovirus levels

Ask yourself if you are doing everything you can to reduce the norovirus risk as much as possible.

Current E.coli-based are effective against bacterial pathogens and provide the basis specific controls for norovirus.

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Controls for norovirus

- Be aware of the norovirus risk associated with your harvesting area (using sanitary surveys, FSA survey of UK harvesting areas (Nov 2011), own checks)
- Establish a working limit/trigger levels.
- Voluntary exclusion zones around contamination sources.
- Apply voluntary restrictions on harvesting e.g following heavy rainfall, sewage spill, during outbreak investigation.
- Apply enhanced depuration techniques

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RESEARCH PROJECT ON DEPURATION

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FSA Project: Effectiveness of depuration in removing norovirus from oysters

Background:

- Results from a study to investigate the prevalence, distribution and levels of norovirus titre in UK oyster harvesting areas, published by the Food Standards Agency in November 2011 showed that 76% of oysters tested from UK oyster growing beds contained norovirus (including infectious and non-infectious virus material).

- EFSA has published two Scientific Opinions on foodborne viruses in 2011 and 2012. These contain a number of recommendations on the need to gather data and on potential control options for shellfish.

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Background:

- The FSA is working with the UK shellfish industry to facilitate the development and implementation of practical controls to manage the risk from norovirus contaminated oysters.

- The Agency's Foodborne Viruses Research Programme aims to gather data to provide a robust science and evidence base to inform development of a risk management programme on foodborne viruses (with a particular focus on norovirus), as part of the 2010-15 Foodborne Disease Strategy.

- Among the priorities identified was research to assess the effectiveness of depuration in removing norovirus from oysters and ways this process could be improved.

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Research:

- The Agency has commissioned work to quantify and optimise the effectiveness of standard UK depuration practices in reducing norovirus in oysters and to explore the potential for novel approaches to significantly improve the effectiveness of this process. The two-year project is expected to commence in October 2014 and is being conducted by the company Seafood Safety Assessment Ltd.

- The approach for this work will consist of a Literature Review of the published and non-published literature and a series of pilot experiments to investigate depuration of norovirus in Pacific oysters using a novel approach that aims to release norovirus from its specific receptor/ligand within oyster tissues using specific compounds (treatments) prior to depuration.

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Objectives:

- Consistent with the identified research needs, the Food Standards Agency has planned and procured a research project that aims to provide a thorough evaluation of the usefulness of depuration as a control option for norovirus in oysters.

The aims of the project are to:

I. Undertake a critical review of international literature
II. Complete a series of pilot experiments to investigate depuration of norovirus from Pacific oysters using a novel approaches to release norovirus from its specific receptor;
III. Develop recommendations on future research and/or field trials that could be undertaken to underpin the commercial application of depuration by oyster growers.

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