EXECUTIVE NOTE

THE AQUATIC ANIMAL HEALTH (SCOTLAND) AMENDMENT REGULATIONS 2011

SSI 2011/259

The Aquatic Animal Health (Scotland) Amendment Regulations 2011 ("the 2011 Regulations") are made in exercise of the powers conferred by section 2(2) of, and paragraph 1A of Schedule 2 to, the European Communities Act 1972. Paragraph 1A is relied upon so that any reference in the 2011 Regulations to Regulation (EC) No. 1251/2008 is construed as a reference to that Regulation as amended from time to time. The 2011 Regulations are subject to negative resolution procedure.

Purpose of the instrument

1. The Aquatic Animal Health (Scotland) Regulations 2009 ("the 2009 Regulations") give effect to EU legislation on animal health requirements for aquaculture animals and animal products and for the prevention and control of aquatic animal disease. The 2011 Regulations amend the 2009 Regulations to give effect to new EU legislation which allows the UK to take national measures to make Ostreid herpesvirus (OsHV-1 µvar) ("Oyster Herpes Virus") a notifiable disease. This will allow the implementation of additional UK-wide national measures to provide enhanced security around imports of susceptible species.

Legislative Context

2. The 2009 Regulations transpose Council Directive 2006/88/EC on animal health requirements for aquaculture animals and products thereof and on the prevention and control of certain diseases in aquatic animals. The 2011 Regulations amend the 2009 Regulations to give effect to Commission Decision 2011/187/EU (which amends Commission Decision 2010/221/EU) and which allows the UK to take national measures to make Oyster Herpes Virus a notifiable disease. Decision 2011/187/EU applies throughout the UK from 1 May 2011. The 2011 Regulations also repeal references in the 2009 Regulations to EU legislation superseded in consequence of Decision 2010/221/EU, as amended.

3. Commisison Decision 2011/187/EU has been implemented in England, Wales and N. Ireland through the Aquatic Animal Health (England and Wales) (Amendment) Regulations 2011 (SI 2011/981) and the Aquatic Animal Health (Amendment) Regulations (Northern Ireland) 2011 (SI 2011/118), respectively. However, the Parliament was dissolved when Decision 2011/187/EU was published in the Official Journal on 26 March 2011 and the Decision is therefore yet to be implemented as regards Scotland. Until EU legislation is published, there remains uncertainty as to the legal position at European Union level.

4. The 2011 Regulations make Oyster Herpes Virus a disease which, when suspected, must be reported to the competent authority, i.e. a "notifiable disease". This in turn will allow the implementation of additional UK-wide national measures to provide enhanced security around imports of susceptible species.

5. To allow us to restrict imports from potentially diseased areas in other countries not in a surveillance programme (or not known to be free from the disease), the disease must be listed in Schedule 1 to the 2009 Regulations as notifiable. Regulation 2(4) of the 2011 Regulations provides for this. It is desirable that the 2011 Regulations come into force as soon as possible to protect the Scottish shellfish industry from disease and to ensure consistency of regulation across the UK as a whole.

Territorial Extent and Application

6. The 2011 Regulations apply as regards Scotland. Similar and parallel controls have been introduced in England, Wales and Northern Ireland, where the new controls applied from 1 May.

7. The European Commission has agreed that the UK can use national measures, under Article 43 of Council Directive 2006/88/EC, to make provision for Oyster Herpes Virus, given the significant disease risk it poses to our shellfish industry. The Commission amended relevant EU legislation to reflect this and these changes came into force on 1 May 2011.

8. The UK, as member State, will be in breach of its agreement with the European Commission until Scotland also makes Oyster Herpes Virus notifiable. Any further delay in the coming into force of the 2011 Regulations as regards Scotland could therefore lead to an instruction from the Commission to the UK to remove the additional national controls on Oyster Herpes Virus.

Policy background

- ***What is being done and why***

9. There are 325 authorised shellfish farms in Scotland generating some £8m of product per year. Oysters represent the second largest output by the shellfish industry, with production valued at £1.33 million (2009).

10. Oyster Herpes Virus is an emerging disease that has caused large scale mortalities of Pacific oyster stocks in other parts of Europe, notably in France, since 2009. In 2010, Commission Regulation No. 175/2010/EU was introduced in terms of which Scotland (and England, Wales & Northern Ireland) established a UK surveillance programme. This ensured there would be early detection of any occurrence of Oyster Herpes Virus in oyster production areas and allowed for the control of imports from affected areas (and those which did not have similar surveillance programmes). Commission Regulation No. 175/2010/EU lapsed at the end of April 2011.

11. Were the 2011 Regulations not to come into force as soon as possible, Scotland, as a devolved administration of the UK, would have a lower aquatic animal health status than the rest of the UK. In addition, the UK as member State could likely face an instruction from the Commission to remove its additional national controls on Oyster Herpes Virus.

12. Commission Regulation No. 175/2010/EU controlled imports until the end of April 2011. Prior to this lapsing the industry requested a continuation of protection. The 2011 Regulations and national surveillance measures will provide that continuation. The Association of Scottish Shellfish Growers, which is the relevant producer association for this sector has written to the Scottish Government to confirm that the 2011 Regulations would "help Scotland to maintain disease-free status whilst having no negative effect on production or sales".

13. It had been intended to bring forward a statutory instrument to amend the 2009 Regulations in the Autumn in light of certain regulatory changes since the 2009 Regulations came into force and to respond to certain other issues, including a commitment given by the Scottish Government in March 2009 to the Subordinate Legislation Committee (SLC) to correct an error in the 2009 Regulations at "the first convenient opportunity".

14. As Decision 2011/187/EU applies from 1 May, it was considered desirable to bring forward only those provisions necessary to implement that Decision at this time, to ensure consistency of regulation across the UK in relation to the health certification requirements for import of Pacific oysters. It is not considered that the 2011 Regulations comprise a convenient opportunity to bring forward amending legislation to address this issues mentioned at paragraph 13 above. However, the Scottish Government intends to bring forward a further instrument to amend the 2009 Regulations in September which will respond to the SLC`s report and will address the regulatory changes required.

Consultation

15. There has been extensive consultation and discussion with the shellfish industry on the 2011 Regulations, including through the National Shellfish Forum. The industry is keen that action is taken as soon as is possible.

Guidance

16. A letter containing guidance on the 2011 Regulations will be distributed to all oyster producers and processors in Scotland on the day in which the 2011 Regulations are laid (24 May) and before they come into force.

Financial Effects

17. A Regulatory Impact Assessment was produced in relation to the 2009 Regulations. An additional Business and Regulatory Impact Assessment has been prepared for the 2011 Regulations and indicates that compliance and other costs for the oyster industry in Scotland would be very low as a result of the proposed changes, while the benefits of reducing the likelihood of the spread of this diseases to Scotland (and the rest of the UK) could be great.

Monitoring & review

18. The success of the 2011 Regulations lies in the prevention or avoidance of Oyster Herpes Virus occurrence in Scotland, or a reduction in its occurrence compared to an unregulated approach to imports of oysters from areas without commensurate surveillance regimes.

Marine Scotland
Scottish Government
May 2011

FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT (RIA)

1. Title of proposal

Impact assessment of the Aquatic Animal Health (Scotland) Amendment Regulations 2011.

2. Purpose and intended effect

The aim of the regulations is to make Oyster Herpes Virus a disease which when suspected must be reported to the competent authority i.e. "a notifiable disease". This would then allow the implementation of UK-wide measures to provide more security around imports of susceptible species (following parallel changes in England, Wales and Northern Ireland).

3. Consultation

Consultation has taken place with the Scottish shellfish industry through the National Shellfish Forum and through direct communication with the Association of Scottish Shellfish Growers (ASSG), the relevant producer association.

4. Summary of approach

The proposed change would allow the UK to restrict import of live oysters (those destined for on-growing or production in the UK, rather than those destined for consumption) from diseased or potentially diseased areas not in a surveillance programme i.e. not known to be free from the disease.

5. Justification for Government intervention

The Scottish oyster industry produced £1.33 million of product in 2009, the latest year for which figures are available. This measure will provide a degree of protection from a disease which has caused catastrophic mortality of up to 80% in those farms on which it has occurred.

The emergence of Oyster Herpes Virus in much of Europe also provides an export opportunity for Scottish juvenile oysters, predicated on Scotland maintaining its disease free status.

6. Background

The Aquatic Animal Health (Scotland) Regulations 2009 ("the 2009 Regulations") give effect to EU legislation on animal health requirements for aquaculture animals and animal products and for the prevention and control of aquatic animal disease. An amendment to the 2009 Regulations is now required in order to give effect to new EU legislation (Commission Decision 2011/187/EU which amends Commission Decision 2010/221) which allows the UK to take national measures to make Ostreid herpesvirus (OsHV-1 µvar), or Oyster Herpes Virus, a notifiable disease. Decision 2011/187 applies throughout the UK from 1st May 2011. The proposed amendments to

the 2009 Regulations also repeal references in the 2009 Regulations to EU legislation superseded in consequence of Decision 2010/221, as amended.

The 2011 Regulations make Oyster Herpes Virus a disease which, when suspected, must be reported to the competent authority, i.e. a "notifiable disease". This will allow the implementation of additional UK-wide national measures to provide more security around imports of susceptible species.

Oyster Herpes Virus is an emerging disease that has caused large scale mortalities of Pacific oyster stocks in other parts of Europe, notably in France, since 2009. In 2010, Commission Regulation No. 175/2010 was introduced in terms of which Scotland (and England, Wales & Northern Ireland) established a UK surveillance programme. This ensured there would be early detection of any occurrence of Oyster Herpes Virus in oyster production areas and allowed for the control of imports from affected areas (and those which did not have similar surveillance programmes). Commission Regulation No. 175/2010 lapsed at the end of April 2011.

7. Explanation of the alternative options

Do nothing
This alternative course of action would result in the European Commission instructing the UK to remove its restrictions on imports of live oysters from diseased or potentially diseased areas not in a surveillance programme. This would create disease risk for Scottish oyster farmers and for those in the rest of the UK.

8. Aim of Government intervention

To limit the spread of a commercially damaging disease to the Scottish oyster industry. This regulation would also allow the rest of the UK to maintain its import controls and would therefore also be to the benefit of oyster farmers outwith Scotland.

9. Cost analysis

Sectors and groups affected
- Shellfish farmers

Compliance costs
The additional requirement for oyster farmers would be the creation of a duty to inform Marine Scotland upon the suspicion of Oyster Herpes Virus.

Estimates of compliance costs
This is likely to be minimal. Previous experience suggests that farmers would in any case contact the Fish Health Inspectorate of Marine Scotland for advice following the suspicion of serious disease without this legal requirement. The importance of the establishment of a *requirement* to notify is therefore largely in the associated import controls that such a requirement would allow.

10. Benefit analysis

Assumed benefits of new regime
It is difficult to quantify the benefits of the new regime. The Scottish oyster industry tends to receive juvenile oysters from hatcheries in England and Guernsey which are currently unaffected by the disease. It is believed that Scottish oyster farmers would not knowingly import oysters from an area where there is a disease risk. This regulation therefore provides some assurance that this is the case and protects the wider industry from any high risk activity by individual operators.

A Scottish oyster hatchery is in development. That project is likely to benefit from the export opportunities presented by Scotland's disease free status. This regulation will help to protect that status and so the viability of this project.

That this regulation allows the rest of the UK to maintain import controls also lessens the risk of an oyster farmer in another part of the UK importing from a high risk source, perhaps leading to spread from that part of the UK to Scotland.

Compliance and other costs for the oyster industry in Scotland would likely be very low as a result of the proposed changes, while the benefits of reducing the likelihood of the spread of this diseases to Scotland (and the rest of the UK) could be great.

Small/Micro Firms Impact Test
The oyster farming sector in Scotland largely consists of small or micro firms. There have been no instances of any oyster farmer objecting to the proposed controls. The Association of Scottish Shellfish Growers has written to the Scottish Government to state that this regulation would "help Scotland to maintain disease-free status whilst having no negative effect on production or sales".

11. Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed ..... Date .....

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