Agriculture and Rural Development Committee ARD 04-03(p3)

Response to the European Parliament report on foot and mouth disease

1. Purpose

1.1 The paper is to inform the Committee and seek its views on the response of the Welsh Assembly Government to the European Parliament report on foot and mouth disease and the associated draft EU Directive.

2. Summary/ Recommendations

2.1 To inform the Welsh Assembly Government policy, by consulting on the content of the draft European Directive.

3. Timing

3.1 This paper is being presented at the request of the committee, with the Minister's approval.

4. Background

4.1 The request for this paper specifically refers to the report produced by the EP Temporary Committee. However, the report was considered by a Plenary Session of the EP and has resulted in a detailed draft EC Directive on "Community measures for the control of foot-and-mouth disease and amending Directive 92/46/EEC. This paper will cover the report and the subsequent draft Directive.

EP Temporary Committee Report

4.2 In 16 January 2002 the European Parliament announced that it would set up a temporary committee to examine the handling by the UK Government and Scottish Executive of the foot and mouth outbreak in 2001. In Wales, the Assembly were delegated the operational management of the outbreak by DEFRA under the terms of an agreement. The Committee only made one visit to Wales, where they held public meetings and heard evidence from farmers, members of the community, local businesses, Powys CC and others. They also visited Epynt and heard the views of members of the Epynt Action Group.

4.3 Lord Whitty met with Committee and DEFRA's Secretary of State addressed them on 12 September. However, Ministers in Wales had to specifically request a meeting with them, which took place when Carwyn Jones gave evidence to the Temporary Committee in Strasbourg in July 2002.

4.4 The Report was put to a plenary session of the European Parliament on 17 December and was

adopted. It contained a number of debatable points, but did recognise that the scale of the 2001 outbreak was unprecedented; that it would have been disproportionate to gear the FMD Contingency plan to such a large-scale outbreak; and that the Commission's Food and Veterinary Office had found the UK's response to the outbreak to be effective. The report also noted that the UK succeeded in keeping large parts of the country disease free.

4.5 Criticism centred upon the adequacy of the information policy; the effectiveness of the contiguous cull in curbing the epidemic; the late deployment of the army; the methods of carcass disposal; violations of animal welfare legislation and called into question the legality of the 3km cull.

4.6 The report makes clear that vaccination should be considered from the outset of an outbreak, mirroring the finding of the Anderson and Follett inquiries.

EC Draft Directive

General

4.7 The Commission's proposal for a Council Directive on measures to control foot-and-mouth disease (2002/736) updates the previous EU FMD Directive (85/511), taking into account scientific developments and the experience gained in eradicating the disease in 2001.

4.8 The proposal is intended to allow the EU to maintain its internationally recognised status of "free from foot-and-mouth disease without vaccination". The current approach of eradicating FMD by "stamping out" would be retained but the proposal gives greater prominence to the role of emergency vaccination as a control option for use alongside stamping out in some circumstances.

4.9 Section 1. The proposed new EU Directive sets out the minimum control measures Member States must take against foot-and-mouth disease, and Article 1 makes clear that they can take more stringent measures. The proposal provides that as soon as foot-and-mouth disease is suspected, rapid action must be taken so that immediate and effective control measures can be implemented if it is confirmed. FMD must be confirmed by laboratory tests, procedures, which are detailed in an Annex.

4.10 Section 2 of the proposal deals with measures to be taken in case of suspicion of an outbreak of FMD, including movement controls. Article 8 of the proposal provides that animals suspected of being infected may be subject to preventive culling.

4.11 Section 3 of the proposal deals with measures to be taken if an outbreak of foot-and-mouth disease is confirmed, including the culling of infected animals, the disposal of carcasses and subsequent need for cleansing and disinfection. Article 13 deals with the requirements for epidemiological inquiries to determine the extent of the disease and its likely spread. Article 14 provides for the culling of "dangerous contacts" and also requires that, immediately on confirmation of the first case of FMD, all necessary arrangements are made for emergency vaccination in an area at least the size of the

Surveillance Zone (10km radius), should it be deemed necessary. The factors to be considered in introducing an emergency vaccination programme are dealt with in Section 8 of the proposal.

4.12 Section 4 of the proposal details measures to be applied in special cases, particularly in the case of zoos, wildlife parks and rare breeds and makes provision for the possible emergency vaccination of such special cases.

4.13 Section 5. Where a holding consists of two or more separate production units, derogation against culling can be granted providing the animals can be proved to be healthy. This Section also defines the requirements for surveillance of contact holdings.

4.14 Section 6 deals with the establishment of a protection zone based on a minimum radius of 3km and a surveillance zone based on a minimum radius of 10km centred on an outbreak of FMD. There are requirements for the treatment of meat and milk produced in the protection and surveillance zones. The treatments include heat treatment, deboning and maturing of meat and meat products and pasteurisation of milk. This Section also covers restrictions concerning gatherings and movements, transport and measures in relation to animal products and foodstuffs.

4.15 Section 7 of the proposal deals with regionalisation, movement control and identification, on the basis that regionalisation would allow the implementation of strict disease control measures in certain parts of the Community without endangering general Community interests. Article 47 allows FMD susceptible animals to be moved from their holding only if they are identified in such a way that their movements can be rapidly traced.

Vaccination

4.16 Section 8 of the proposal deals with the issue of emergency vaccination. The directive requires that susceptible animals on infected farms, and dangerous contacts, should be culled. The option of vaccination relates to what should be done with other livestock on contiguous farms on in the region, which not assessed as dangerous contacts. A decision to introduce emergency vaccination may be made if an outbreak threatens to become widespread, or when other Member States are at risk. Such a decision would normally be made by Standing Committee procedure, either at the request of the Member State directly affected, a Member State at risk, or the Commission itself could also initiate discussion on the use of emergency vaccination. There is also provision for a Member State to introduce emergency vaccination and have its decision reviewed and ratified later by the Standing Committee on the Food Chain and Animal Health.

4.17 The draft directive suggests a range of criteria for a decision to apply protective vaccination and guidelines for emergency vaccination programmes**.** Criteria to be considered include: inability to carry out culling within the 24/48 hour targets; if the density of livestock population is high in the area concerned; if pigs are involved; if airborne spread is predicted; where the origin of the outbreak is unknown; if the incidence is rising steeply; and if "regionalisation" after vaccination is acceptable.

4.18 Detailed conditions applicable in the vaccination zone are set out in Articles 54, 55 and 58 and post vaccination treatments of meat and meat products and milk and milk products are detailed in the Annexes. Some measures will be required until infection free status is recovered and, in some instances, the meat and meat products will have to carry a special mark. The treatments include heat treatment, de-boning and maturing of meat and meat products and pasteurisation of milk from vaccinated animals. A meeting has been arranged for 6 March with Welsh Stakeholders to determine their views on the potential use of vaccination in any future outbreak with particular regard to the possible effect vaccination controls might have.

4.19 Section 9 details provisions on the recovery of foot-and-mouth disease and infection free status are dealt with in of the draft proposal. Requirements depend on whether or not emergency vaccination has been used and, if so, whether "suppressive" vaccination (to kill) or "protective" vaccination (to live). These requirements reflect the code from the Office International des Epizooties (OIE) which was revised in 2002 and so differs from the rules applicable during the 2001 outbreak. Disease-free status can be recovered three months after the last case where vaccination is not used or after the slaughter of all vaccinated animals if stamping out and "suppressive" vaccination to kill is utilised. Where a policy of stamping out and "protective" emergency vaccination to live is used, disease free status can be recovered after six months following completion of serological surveillance which demonstrates the absence of infection in the remaining vaccinated population.However, the detailed procedures for returning to ‘disease free’ status have not yet been specified and the NSP test (required to distinguish between animals where the antibodies present are due to vaccination and not to exposure to field virus) is not yet fully validated.

4.20 Section 10 covers the requirements for laboratories handling FMD virus and those authorised to do so are listed in an Annex, as are the strict biosecurity standards to which they must operate.

4.21 Section 11 refers to Annexes, which detail the standards and tests for the diagnosis of FMD and other vesicular diseases.

4.22 Section 12 and Annex XVII of the draft proposal set out the requirement for detailed contingency plans which have to cover a "worst case scenario" and must give precise indications of how emergency vaccination would be handled, notably in regions containing the most livestock-dense areas. Environmental concerns about carcass disposal are given prominence.

Article 73 of the proposal requires regular review of contingency plans, in the light of "real time alert" exercises in the Member States. The results of these exercises have to be submitted to the Commission. Contingency plans must be updated at least every five years and initially Member States will have to submit their updated contingency plans to the Commission within six months of the Directive coming into force.

4.23 Section 13 refers to the requirement to set up national and local disease control centres, together with their functions, duties and technical requirements. Also covered is the requirement for Member

States to create a permanently operational expert group to ensure preparedness against an outbreak of FMD.

4.24 Section 14 covers antigen and vaccine banks are dealt with in. It authorises Member States to maintain reserves of antigens or ready-to-use vaccines. To guard against emergencies, the Community has established reserves of inactivated FMD virus antigen stored at designated antigen banks and details of access to these are covered in Article 83. Arrangements with regard to the rapid formulation, production, bottling, labelling and distribution of vaccines are set out in Article 82 and requirements for independent potency testing of vaccines are covered in Article 84.

4.25 Section 15 prohibits the feeding of catering waste to FMD susceptible animals across the EU. This provision applies until separate EU legislation comes into force in April 2003. Such a ban is already in place in the UK.

Emergency Vaccination

4.26 Work is currently being carried out to establish how vaccination might work in practice. DEFRA is leading on this. Key issues include:

- Availability of appropriate vaccines
- Availability of sufficient numbers of trained and qualified staff to carry out the vaccination programme
- Criteria for determining the boundaries of the vaccination zone
- Practical issues surrounding the use of meat from vaccinated animals
- Detailed agreed international criteria for the return to ‘disease free’ status following the use of vaccine
- Progress on validating the NSP test to distinguish between animals carrying antibodies to vaccine and those that have been exposed to viral challenge in the field.

For vaccination to live to operate, meat from vaccinated animals would need to be allowed into the human food chain. The Commission’s draft directive provides for this to happen, but only if meat is de-boned and matured or undergoes heat treatment. The concern is that while this may be economic for pork and beef, it is unlikely to be so for lamb, especially light hill lambs, given the high ratio of bone to meat. The Welsh Assembly Government has raised this concern with DEFRA.

Welsh Contingency Plan

4.27 The EU Directive (Section 12) requires that member states should produce contingency plans to enable the effective control of any future outbreak of foot and mouth disease. Under the Animal Health Acts 1981 and 2002 DEFRA have statutory responsibility for dealing with any outbreak of FMD.

However, it has been agreed with DEFRA that the operational control of any future outbreak would be handled the Welsh Assembly Government. Welsh Assembly Government and DEFRA officials are in discussions examining the case for the transfer of further animal health powers to the Assembly, which cover foot and mouth. The Welsh Contingency Plan, which sets out how the Assembly would deal with the operational aspects of any future FMD. The Welsh Plan is additional to the detailed strategic and tactical arrangements contained in the DEFRA Contingency Plan.

4.28 The Welsh Plan has been prepared in consultation with stakeholders, organisations with an interest, and partners, organisations who would be actively involved in a future operation. The interim Welsh Plan was the subject of public consultation between July and October 2003. The Plan has been redrafted taking account of the responses to the consultation exercise and the joint Government Response to the Inquires into the handling of the 2001 outbreak published on 6 November 2002. Stakeholders and Partners will have an opportunity to consider the redrafted document and it will be discussed at a meeting with them on 18 February.

4.29 The UK Contingency Plan will be put to Parliament on 24 March and the Welsh Plan will be put to the Assembly on 25 March.

4.30 The Contingency Plans will be subject to review and amended as appropriate. Exercises will be undertaken to test the various systems and procedures contained in the Plans.

Compliance

5.1 Section 18 of The Animal Health Act 2002 requires the Welsh FMD contingency plan to be produced and put before the Assembly. Assembly functions under the 2002 Act were delegated to the First Minister in Plenary on 21 January 2003. Under section 62 of the Government of Wales Act 1998 the First Minister can then delegate them to the Rural Development portfolio. There are no issues of regularity or propriety. The Assembly Compliance Office is content. ACO Ref: CME/2288/02/03

6. Action for subject committee

6.1 To note the report and comment accordingly.

Contact

Tony Joss, CAPM, FMD Contingency Branch, tel. 2068-1328