

REGULATORY APPRAISAL

THE TSE (WALES) (AMENDMENT) REGULATIONS 2004

Purpose and intended effect of the measure

(i) The Objective

The purpose of the Regulations is to implement Commission Regulation 1915/2003 which introduces measures to eradicate scrapie from farms that have a confirmed case. The measures will apply to any sheep or goat farm with a confirmed case of scrapie.

The Regulations will apply to Wales. Parallel regulations will apply in Scotland, England and Northern Ireland.

(ii) The Background

Scrapie is a fatal brain disease – encephalopathy - of sheep and goats. Other transmissible spongiform encephalopathies include bovine BSE and human CJD. It has been a notifiable disease in the EU since 1993. Scrapie can be transmitted within and between flocks and it is currently believed that transmission is most likely to occur during lambing and other periods of intensified husbandry.

Prior to the Commission regulation, the only requirement where a case of scrapie was suspected was for the suspect animal to be slaughtered, for diagnosis, with compensation payable to the owner. However it is recognised that this approach alone will not eliminate the risk of transmission of disease in and between affected flocks.

In April 2002, the European Union's Scientific Steering Committee issued an Opinion, which recommended that where a case of scrapie occurred on a sheep/goat and cattle holding the entire flock/herd should be culled. However it recognised that culling sheep of the most resistant (ARR/ARR)¹ genotype would provide very little risk reducing benefit. As a result, the European Commission proposed compulsory EU wide measures, which were adopted in December 2002 as Regulation 260/2003. Some detailed amendments to the measures, which introduced more flexibility, were agreed in September 2003 in Regulation 1915/2003. Further amendments, introducing further flexibility at the UK's request, were proposed by the Commission in early 2004 (SANCO 4908/2003).

(iii) Risk assessment

The EU Regulation was introduced in order to eradicate scrapie from affected farms. In the early 1980s it is possible that sheep were exposed to the same contaminated feed which gave rise to BSE in cattle, albeit at lower levels.

¹ A sheep's resistance or susceptibility to scrapie is determined by the PrP gene. Each sheep has two copies (also known as alleles) of this gene, one derived from each parent. The ARR allele denotes the highest level of scrapie resistance and the VRQ level the highest level of scrapie susceptibility.

There is therefore an acknowledged theoretical risk that BSE might have been transmitted to sheep and if so it might be masked by scrapie (as the clinical signs are similar to experimental BSE in sheep). Flocks with scrapie therefore represent a theoretical public health risk, and they also pose a risk in terms of transmitting disease. Goats are also susceptible to scrapie and scientific advice is that goat herds would also pose a public health risk if BSE were to be found in sheep. According to the current scientific advice goats are not known to possess specific genes which confer resistance or susceptibility to TSEs so a genotyping approach is not yet appropriate for them.

The Regulation will apply to holdings with cases of scrapie confirmed from 1 October 2003. There are estimated to be approximately 16,100 holdings that keep sheep and 1,200 holdings that keep goats in Wales (figures for UK are 86,000 and 10,000 respectively). It is difficult to estimate how many of these holdings will have scrapie in the future. In 2002, the number of confirmed scrapie cases and affected farms involving small ruminants in Wales was 90 and 26 respectively. For 2003 the figures are 111 cases in 24 flocks. These cases were reported initially as suspect cases by farmers and then confirmed as clinical cases of scrapie. There have been no reported cases involving goats in Wales in the last ten years. However, most scrapie cases are believed to go unreported. Scrapie can often re-occur, with some flocks having persistent problems. In addition, about 66 cases have been found in the UK through the active surveillance at abattoirs and of fallen stock required by EU law since spring 2002. This surveillance was designed to provide information about scrapie prevalence and is carried out through surveys of sheep aged over 18 months.

(iv) Business sectors affected

Sheep and goat farms which have a confirmed case of scrapie. As indicated above, it is difficult to estimate how many farms will report suspect scrapie.

Flocks/herds in TSE research projects would be exempted from the on-farm measures required by the EU Regulation.

It is not envisaged that there will be an effect on other sectors, apart from possible knock-on effects on processing and other outlets where large dairy flocks /herds have a confirmed case of scrapie.

(v) Issues of equity and fairness

The measures will impact on sheep and goat farmers who report a case of scrapie in their flocks/herds, which is then confirmed. They will also impact on cases confirmed following surveillance at abattoirs where it is possible to trace back to the farm of origin. However there will be cases where tracing back is not possible or, where farmers do not report cases to avoid being caught by the measures. Scrapie cases occur throughout the country where sheep and goats are farmed and in different breeds. There may be some local effects- as affected holdings can occur in clusters – but these are not expected to be significant.

Options – identification

Option 1- do nothing

Option 2- implement the EU Regulation, using the option of (i) whole flock/herd slaughter or (ii) genotyping all sheep and culling the more susceptible ones and culling all goats, according to the circumstances.

Option 3- implement the EU Regulation, using the option of whole flock/herd slaughter

Option 4- implement the EU Regulation, using the option of genotyping all sheep and culling the more susceptible ones and culling all goats in all cases.

Benefits of the Options

Option 1-Do nothing

This is not a feasible option because the EU regulation is directly applicable and non-compliance would be a breach of community obligations.

Option 2 -Implement using whole flock/herd slaughter or genotyping all sheep and culling the more susceptible ones, and culling all goats according to the circumstances.

The Regulation allows the following options when a case of scrapie is confirmed and the inquiry to identify all the small ruminants on the farm has been carried out:

(a) killing all the animals (sheep and goats), embryos and ova identified by the inquiry.

or

(b) genotyping all sheep and culling the more susceptible ones. Culling all goats identified by the inquiry.

This option would meet the EU Regulation by applying whichever option would best suit the circumstances of the flock. The competent authority (the State Veterinary Service) would take a decision based on veterinary advice, the farmer's wishes and other factors. Criteria are being drawn up to be followed when taking such decisions. In most cases it is envisaged that the genotyping approach would be used with whole flock slaughter applied only rarely when the farmer was content. This approach will provide for flexibility.

Once an option has been activated, there are then genotype-based restrictions on which animals can be introduced to, and moved off, holdings. A farmer can restock immediately but will be subject to the restrictions for 3 years from the date when all of the sheep are of prescribed genotypes. If goats are to be reintroduced on to the farm there must be increased brain testing of culls and fallen stock and thorough cleaning and disinfecting of all sheep and goat housing on the premises following de-stocking. Derogations from certain provisions are available from certain provisions for breeds with low levels of resistance or at risk of inbreeding.

Alternatively, a farmer who has had his whole flock/herd slaughtered can leave his holding without sheep or goats for a 3 year period if he cannot, or does not wish to, restock immediately. Thereafter, no genotype-based restrictions would apply.

This option will benefit the public sector by reducing sources of TSE infection from known scrapie affected flocks/herds and transmission to other flocks/herds thus helping to reduce the level of risk these flocks/herds pose. It will reduce the risk of theoretical BSE in sheep which would have significant effects for the exchequer and more widely. (BSE in cattle has cost the exchequer £4.5 billion and has led, through vCJD, to the loss of over 100 lives). It has been estimated that the minimum cost should BSE be found in the national flock is £968.5 million.

It will benefit consumers by dealing with flocks/herds with confirmed cases of scrapie so reducing the theoretical public health risk that might arise from eating meat or dairy products from infected flocks/herds. (Whilst dairy products from BSE infected cattle are not considered to represent a risk, due to the different distribution of scrapie agent in scrapie affected sheep, the risk of contamination of sheep dairy products with BSE agent is unknown). Only animals with a certain level of resistance would be allowed to go into the food chain from affected flocks. Consumers would therefore have greater assurance about the meat and dairy products that they eat.

It will benefit farming businesses by eliminating scrapie on farm, and reducing the risk that scrapie might reoccur. Farmers for whom the genotyping approach would apply will be able to retain some of their sheep so making this a sustainable solution, consistent with the Welsh Assembly Government's commitment to sustainable farming and biodiversity. These farmers would also establish a resistant flock, so helping them in the longer term. Farmers who restock will be able to maintain their livestock businesses. Those involved in the export of breeding sheep will be able to export to other Member States any fully resistant (ARR/ARR genotype) breeding sheep regardless of any recent occurrence of scrapie on their farm, as allowed under the Regulation. A total of 63,467 sheep were exported from the UK to other member states in the period April 2003 – March 2004. Of this, approximately 13,000 sheep were exported from Wales in this period.

Option 3 - Implement by whole flock/herd slaughter

This would involve using only the option of slaughtering the whole flock or herd. The restrictions described for option 2 would apply.

This option will benefit the public sector in the same way as option 2 although the benefits might be realised more quickly by whole flock/herd slaughter as the only approach being taken.

The benefit to the consumer will be as for option 2.

The benefit to farming business (with a confirmed case) will be as for option 2 although scrapie might be eliminated more quickly, by a whole flock/herd slaughter policy.

Option 4- Implement using the option of genotyping all sheep and culling the more susceptible ones and culling all goats.

The benefits will be as for option 2 but more sheep farmers than under 2 will be able to retain some of their sheep so making better use of existing resources. This is therefore a more sustainable solution. This option will also help more sheep farmers to secure a more resistant flock than option 2. This should assist them in the longer term and enable those involved in the export of breeding sheep to export on the basis of having fully resistant animals.

Costs of the options for business, charities and voluntary organisations

The costs below have been based on the following assumptions : an historical average of 40 farms with new cases of scrapie per year in Wales; a nominal flock size of 500 animals made up of 5 rams, 200 ewes, 50 cull ewes and 245 lambs; 50% of the animals having to be replaced when the flock is genotyped and 2 genotype tests being necessary to find suitable replacement animals in addition to the 2 tests for replacement animals provided by the National Scrapie Plan budget held by Defra.

Option 1- do nothing

As already explained, this is not a feasible option. We would be in breach of EU obligations and if the Commission took infraction proceedings against the UK for non-compliance there would be costs arising and fines.

Option 2 – implement by whole flock/herd slaughter or genotyping all sheep and culling the more susceptible one and culling all goats according to the circumstances.

Cost to business

Sheep

It is difficult to say how many confirmed cases would be dealt with under whole flock slaughter and how many under the genotyping approach. This will depend on a veterinary assessment against criteria which are being drawn up and to which sector of the sheep industry the flock belongs. For the purposes of this regulatory appraisal it is assumed that there will be a split of approximately 95% involving the genotyping approach and 5% whole flock slaughter. (There may possibly be more cases involving whole flock slaughter in the early years of the scheme but fewer in later years as genetic resistance in the national flock improves).

For sheep farmers, there will be additional costs as follows:

- (a) For gathering together sheep to enable them to be collected for slaughter or for genotyping. This may take time depending on the size of the flock. Sizes of flocks will vary considerably and two or more visits to collect or genotype animals may be needed in larger flocks. For a small flock the farmer may need to set aside 2 hours to assist. For large flocks on a hill farm, this may involve 3 or 4 days at a minimum and involve several people assisting. Assuming that a sheep farmer's time is costed at a rate of about £6 per hour, the cost could range from £12 to £500/600.
- b) For maintaining a farm without income from sheep subsidies (currently Sheep Annual Premia). Payment of 2004 sheep annual premium is dependent on an application having been made during an application window (4 December to 4 February) and sheep being on the farm during a specified retention period (4 February to 15 May). As the Regulations will not take effect until November, there would be no impact on payments made to any flock or animals culled during 2004.

Following the recent CAP reform package, in Wales subsidy will be based on farming activity in the historic reference period 2000-2002.

There may also be an impact on any Tir Mynydd (TM) funding a farmer receives, depending on his individual circumstances. Under Tir Mynydd, farmers currently need to have a minimum stocking density of 0.1 Livestock Unit/ha to qualify for payment. A farmer might not be able to meet this if he has sheep culled under the Compulsory Scrapie Flocks Scheme. It is unlikely that this will have an impact on the Tir Mynydd 2005 scheme as this is based on sheep paid under the Sheep Annual Premium Scheme (SAPS) 2004, the retention period for which ended on 15 May 2004. There is a remote likelihood that there may be an impact on those farmers who previously claimed Hill Livestock Compensatory Allowance (HLCA) and do not claim SAPS this is because checks are carried out on their flocks later in the year. Sheep culls could also impact on the Tir Mynydd enhancements, which are currently available for farmers who can demonstrate that they keep 1 cow to 30 sheep and also where they can demonstrate that their stocking density is less than 1.2 Livestock Unit/ha.

It is expected that the rules for Tir Mynydd 2006 will still expect claimants to satisfy minimum stocking density requirements. In addition, to maximise their payments and be eligible for enhancements, sheep stocking data will be required. As a result, exemptions to allow payment in 2005 and later years where flocks are subject to scrapie would be sought from the European Commission.

In addition, any sheep farmer who has a confirmed case and is in an agri-environment scheme (such as the Tir Gofal scheme or Environmentally Sensitive Areas scheme) may not be able to comply with the required management prescriptions and may have his agreement terminated and

payments withheld under such schemes. The payments will vary according to the prescriptions/option being applied.

Farmers will also lose their sheep and the benefit they could derive from them. However compensation will be payable by Government for animals culled. This will be based on standard rates (which reflect average market rates) with provision for higher compensation for high value e.g pedigree animals based on valuation. The cost of valuation will be payable by the farmer. This will be made up of a nomination fee of £115 plus VAT to the Royal Institution of Chartered Surveyors (RICS) and the valuer's fee for carrying out the valuation. It is difficult to estimate how many cases might involve valuation.

Losses should therefore be relatively small where a farmer restocks quickly.

For flocks where the genotyping approach applies, there would be a shorter period where the farmer has lost sheep and sufficient replacements have not been found. It is expected that the farmer will want to restock quite quickly depending on the availability of suitable genotype animals in the breed. In most cases he will have to replace only a percentage of his flock i.e. only those that are not of the more resistant genotypes, although the percentage will vary from flock to flock and breed to breed. *An explanation of the Genotype classification under the National Scrapie Plan is attached at Annex 1 to this Regulatory Appraisal.*

- (c) For sourcing of suitable replacement sheep over the period during which restrictions apply. Where farmers restock there will be costs in purchasing suitable replacement sheep. The UK sheep breeding industry is very complex with a highly stratified structure and the availability and cost of resistant animals will vary considerably from breed to breed. Prices could be very high for purchase of some pedigree breeding animals but much less for animals in commercial flocks. The number of animals to be replaced will vary considerably from breed to breed and flock to flock and according to whether the option applied is whole flock slaughter or genotyping. The National Scrapie Plan budget held by Defra will pay up to £500 as assistance towards the purchase of a fully resistant ram as a replacement for one that has been culled, based on evidence of purchase and genotype being provided.) Availability of replacement animals will also vary according to the time of year, with autumn being the main period for sales. It may take longer to replace animals outside this period. The period during which farmers will have to comply with the restrictions on what animals can be brought on will also vary depending on how quickly their rams can reach fully resistant ARR/ARR status and their ewes semi-resistant Type II status.

If we were to take an example of a small pure bred hill breed flock of 3 stock rams (1 ARR/ARR and 2 ARR/ARQ) 2 shearling (i.e. 18 month old) rams of ARR/ARQ, 113 breeding ewes and 25 shearling ewes, predominantly ARQ and a normal replacement rate of 20%, based on a genotyping approach, it would take a minimum of 2 years for the farmer to

turn his flock around so that all his rams were ARR/ARR and all his ewes ARR/XXX. There would then be a further 3-year period that would apply on top. This assumes that a farmer would not be willing or able to remain viable with a smaller flock.

In the case of commercial flocks, (which are larger - 1000 animals is the typical average in a flock), there is less information about their genetic make up. However it is a reasonable assumption that it should not take too long to get all rams in such flocks most resistant – i.e ARR/ARR- assuming they are sourced from terminal sire breeds, which tend to be larger and have a greater prevalence of resistance and semi- resistant genotypes. There would be a greater problem with getting ewes to semi-resistant status, as in some flocks many are often replaced every year. Therefore, some commercial flocks could be under restriction for a very long time.

It is expected that sourcing of suitable resistant animals should become easier as membership of the National Scrapie Plan increases and more resistant animals become available, so costs should reduce over the years of the scheme.

- d) There will also be additional costs for testing replacement sheep to see if they are of the prescribed genotype, before the flock owner purchases them. In some cases suitable rams will be able to be sourced from the National Scrapie Plan ram register. In other cases sheep will need to be identified and genotyped. The farmer will need to pay for genotype testing of the animals he wishes to purchase, over and above a certain amount per scrapie affected flock that the National Scrapie Plan budget held by Defra will pay for (assumption is 2 tests per animal culled and replaced). The average cost of a sampling/genotype test is estimated at £20. However, the number of tests needed will vary depending on how many animals need to be replaced and on how difficult it is to find suitable replacements of the resistant genotypes. This will differ considerably from breed to breed and flock to flock and also according to the option applied. As indicated above, the period during which the restrictions will apply could be lengthy. In commercial flocks, where a certain proportion of ewes is often replaced on an annual basis costs may be incurred for a very long time/indefinitely. It is not possible therefore to estimate the total number of likely tests but whatever the number, all the costs will be met by the National Scrapie Plan budget held by Defra.

On the basis of a flock size of 500 animals, cost of genotyping in the first year would be £10,200 under the whole flock slaughter approach and £5,080 under the genotyping option (based on 2 genotype tests – in addition to 2 government tests- being required, and 100 ewes and 2 rams to be replaced under the genotyping option). Assuming 40 cases per year in Wales, based on 2 flocks being slaughtered and 38 genotyped total costs would be £213,440. In the following year, costs would reduce. For example, on the assumption of a 20% replacement rate, i.e. 50 of the 250 adult sheep to be replaced, total cost would be around £80,000. (50 x 2 x

£20 = £2,000 x 40 cases). This would be paid for from the NSP budget held by Defra.

For flocks with a low percentage of resistant genotypes or where necessary to prevent inbreeding, the Regulation allows for a derogation from culling either for up to 3 breeding years from the need to have animals culled or to allow animals not of the prescribed genotype onto the holding. In cases where a derogation is granted from the culling requirement, additional costs arising from purchasing and testing of replacement animals will be delayed thus reducing the annual cost slightly. Where it is agreed that less resistant animals can be brought onto the holding there should be no or minimal additional costs as such animals will be more widely available than resistant animals. It is difficult to assess how many farmers will seek derogations and the number that will be granted.

- (e) There will also be loss of earnings. For pedigree flocks selling breeding animals there will be losses in sales of breeding stock as a result of not being able to send semi-resistant or less resistant sheep off the farm for breeding. (Semi-resistant ewes -but with no VRQ genotype- can be sent to other scrapie affected holdings under similar restrictions but this is not expected to be a common occurrence). The price of sheep sold for breeding can vary from hundreds of pounds to many thousands of pounds depending on the quality of the animal. Some sheep breeders may therefore incur considerable losses which could last many years (or may have to close down their businesses) as they would only be able to send semi-resistant animals to the food chain under the Regulation (thus attracting a much lower price eg £50/£90 per animal). Take an example of an 80 ewe pedigree flock producing 100 lambs a year, including 50 ram lambs of which 40 are suitable for breeding. If the genotype situation in the flock is relatively poor only 5 or 10 of these 40 (less than a quarter) might be fully resistant and so able to be sold. The remaining lambs would have to be culled for meat assuming they were semi-resistant, or else destroyed. These animals could be worth anything from £300 to tens of thousands of pounds. It is difficult to estimate how many such cases there would be because it is possible that the stringent requirements of the Compulsory Scrapie Flocks Scheme may result in a fall in scrapie reporting. Where the genotyping approach is used, the costs will last for a longer period than where whole flock slaughter applies.

For commercial farmers, losses will be less as their main business is selling lambs for meat. A small amount of wool may also be sold. (Value estimated to be on average £2 per ewe per year in Wales).

For farms selling dairy products, losses could amount to £250-£300 per ewe per year if they were selling milk as a commodity. If they were a producer/retailer selling yoghurt/ice cream/cheese, loss in sales could be 4 or 5 times this. They would also incur further costs, for example buying in their own milk. It may take two or three years for a commercial milk flock to recover production levels. They may lose their market in that

period and be unable to recover it for some time. However the implications for Wales are minimal as there are currently only four Welsh dairy farms applied for sheep annual premium in 2004.

- (f) For farmers with high value animals opting for compensation on the basis of valuation, there would be the cost of having a valuation carried out. This will include a nomination fee of £115, payable to Royal Institute of Chartered Surveyors (RICS) and the cost of the valuer's fee for carrying out the valuation. This could range from £100 to value one high value animal to as much as £1000 a day to value 100 animals. Assuming 5 valuation requests in the 1st year of the scheme with an average valuation fee of £300 plus £115 RICS nomination fee, the cost of valuation to the industry would be £2,075. However, because the farmers who opt for valuation will have high value animals, they will ultimately receive higher compensation than if they received standard rates. The value of the animals will be determined by a valuer from RICS. The higher compensation is expected to be a minimum of £500, this will be paid for out of the National Scrapie Plan budget held by Defra.
- (g) Costs of maintaining animals that cannot be sent off holdings. Animals that would normally be sent off to graze on other farms ("tack") will not be able to be sent there if they are not fully resistant because under the Regulation susceptible genotypes will not be allowed to be moved from the holding unless for slaughter. The cost to the farmer for sending his animals off to "tack" is approx. £5-£8 per animal per winter (October to April). There will be extra costs for the farmer in looking after animals. However, in many cases it will not be physically possible to maintain the animals on the holding as the infrastructure is not present to meet legal restrictions on welfare grounds on methods of feeding and maintaining flocks on hills and uplands. In the remote possibility that the owner may be able to construct extra housing for these animals, there would be a one off cost of £50-£80 per sheep place. The cost of feed and ancillary machinery to feed and maintain the sheep in good health would be £35 per animal per winter. In this case the maximum cost to a farmer in Wales would be £80 + £35 -£8 = £107 per sheep per winter.
- (h) Loss in asset value of farm. Farmers under restriction wishing to sell their farm will find that its value will be less than before any action was taken. However, it is very difficult to quantify the reduction in value. A sheep farm sells for £1,000 to £1,600 an acre at current prices. It will depend on the ease with which the land may be put to alternative use. Where there are substantial buildings in an attractive location they may command a premium that far exceeds the value of the farm land.

Goats

For goat farmers, there will be additional costs as follows:

- (a) for gathering together goats to enable them to be collected for slaughter. As indicated above, this will take time depending on the size of the herd.

Assuming that a goat farmer's time is costed at a rate of £6 per hour, the cost could range from £12 for a small herd to £1,200 for a large herd.

- (b) loss of income when goats are killed which could last for 3 years if they are not able to restock. This may include income from sales of dairy products and other products. Markets once lost may not be recoverable and it is likely that many businesses may not wish to restock.

However goat farmers can restock within this period if they meet specified requirements relating to cleansing and disinfecting the animal housing, allowing only fully resistant sheep to be present on the holding and requiring goats brought on to be subject to intensive monitoring involving scrapie testing of dead on-farm animals and culls. Goat farmers will therefore incur costs of finding and purchasing replacement animals and of cleansing and disinfecting all animal housing on the premises before replacements can be reintroduced. The cost of a replacement goat will vary but an average figure would be £ 200-£300 for a stud male, £100 for goat kids and £250 for milking goats. It will be difficult to find replacement stock as goats kept in large dairy units need to be reared together in large numbers in order to perform to their potential. Many small pedigree breeders with long established herds will find it difficult or will not wish to restock.

Time and cost of cleaning and disinfecting would vary according to the size of herd, ranging from 5 staff days for a small herd to 20 staff days for a large herd. There would also be associated costs, for example for chemicals, disinfectants, protective clothing. The farmer would be liable for the whole cost of cleansing and disinfecting. No CAP subsidies are payable to goat farmers so loss of premia would not be a factor. Based on previous experience, the number of scrapie cases confirmed per year is likely to be negligible if not zero in Wales.

- (c) For farmers opting for compensation on the basis of valuation, there would be the cost of having a valuation carried out. This could be as much as £1000 a day to value 100 animals. However farming opting for this route should receive higher compensation than the standard rates.

Other Costs

- (a) There will be additional costs associated with carrying out an inquiry to identify the animals affected, and tracing back to the holding or flock of origin if necessary. These additional costs will be met by the National Scrapie Plan budget held by Defra. It is estimated that an inquiry would take 2.5 days of a Veterinary Officer's time, slightly longer for larger flocks. There would also be Veterinary Officer's time in visiting flocks to assess which option should be applied – slaughter or genotyping – and in visiting to explain the implications of genotyping results to the farmer. Estimated costs are £35,420 in 1st year based on an average flock size of 500 sheep and 40 affected flocks.

- (b) Where the genotyping approach is used, there will be cost of genotyping (estimated at £20 for a sampling/genotype test). The number of sheep to be sampled/genotyped will vary from flock to flock/breed to breed. Assuming 500 animals in a flock, the cost would be £10,000 in the first year.
- (c) There will be slaughter and disposal costs for animals that have to be culled- estimated at around £20 per animal. Based on a flock size of 500 sheep, the cost per flock would be around £10,000 for slaughter/disposal. Based on 50% cull rate when genotype option used, the cost per flock would be £5,000. Assuming 40 confirmed cases per year in Wales, (and a 5:95% whole flock slaughter and genotyping split) total cost would be £240,000 as a minimum.
- (d) There will be the cost of compensation, which is proposed should be payable for animals disposed of at the standard rate of £90 per sheep or goat, £50 per lamb or kid and £30 per cull female. (For embryos a rate of £150 is proposed and for ova a maximum rate of £5 although numbers that might be involved cannot be quantified at present.) There will be an option for higher value i.e. pedigree animals to be compensated at a higher rate. This is likely to be based on a valuation for which the farmer would pay. Assuming an average of 500 animals in a flock, comprising 200 sheep, 50 cull ewes and 245 lambs, with compensation payable at standard rates, the annual cost would be £32,200 on the basis of a whole flock slaughter approach and £17,600 on the basis of a genotyping approach. (If the animals were higher value pedigree animals, costs could be much higher). Total annual costs based on 40 cases and a 5:95 split would be £739,200 at a minimum. Where a derogation is granted to delay culling, these costs will be delayed.
- (e) Although not required by the EU Regulation, we envisage that the National Scrapie Plan budget held by Defra will help with the cost of assistance, of up to £500, towards replacement of a ram culled, with a fully resistant ram. As indicated earlier it is difficult to estimate how many rams will need to be replaced. Sampling/genotype tests up to a certain amount per flock will be paid for from the National Scrapie Plan budget held by Defra. It is assumed that this will be on average 2 tests per animal. On the basis of a flock of 500, the cost per flock of assistance for ram replacement and for genotyping on the basis of whole flock slaughter would be £12,700 (£10,200 for genotyping plus 5x£500 for ram replacement assistance) and on the basis of the genotyping approach would be £6,080 (£5,080 for genotyping plus 2 x £500 for ram replacement assistance). Assuming 40 new cases per year with a 5:95% split of whole flock slaughter and genotyping, total annual cost of genotyping and assistance for ram replacement to the National Scrapie Plan budget held by Defra would be £256,440.
- (e) There will be administrative costs and set up costs well as costs in training SVS staff and adjusting the current IT system. Estimated costs are £100,00 per year (costs averaged over three years).

- (f) There will be costs in dealing with appeals from farmers against decisions on the action to be taken on their farm. The costs are expected to be in the region of £6,000. Of this £1,500 is expected to be spent in Wales. All costs will be paid for out of the National Scrapie Plan budget held by Defra.
- (g) There will be enforcement costs in ensuring that the farmers concerned comply with the restrictions. This will involve checks on records, spot checks and genotype testing of animals and intensive monitoring of goats by SVS. Costs at the end of the 1st year, based on 245 lambs to be tested per flock, genotyping costs are estimated at £4,900 per flock plus two SVS staff time at £253 per day totalling £5,406 per affected flock.
- (h) There will be costs of carrying out TSE testing of all culled and dead-on-farm sheep over the age of 18 months of age during the period of restrictions on a holding. Based on an average Welsh flock size of 500 animals and assuming 150 animals destined for human consumption and 7 cases dead-on-farm are put down for health reasons, estimated costs would be £14,900 per flock, 40 flocks in the 1st year = £596,000 annually over the three year test period. Compulsory Scrapie Flocks Scheme State Aid Notification section 14.3 (i) Dead-on-farm £200 per animal, culls £90 per animal). (Detailed arrangements for testing will be considered at meetings over summer 2004 with abattoirs and industry).
- (i) There may be some environmental costs where whole flock slaughter applies in that if holdings are left unstocked for 3 years the land may not be grazed sufficiently and land management would be affected. There may be some effect on the rural economy and knock-on effect on other businesses related to sheep farming if there were to be a number of cases involving destocking in areas where over-grazing occurs. There may be some effect on the rural economy and knock on effect on other businesses related to sheep farming if there were to be a number of cases involving de-stocking in an area. Certain flocks, e.g. hefted flocks may be adversely affected.

Option 3- implement by whole flock/herd slaughter

Costs to business

Sheep

For sheep farmers, additional costs will differ from those in Option 2 as follows:

- (a) For maintaining farms without income/subsidies. In comparison with option 2, more farmers are likely to be subject to loss of income where they have lost sheep and sufficient numbers of replacements have not been found.

- (b) Loss of earnings are likely to be greater as the farmer will find it more difficult to get back into business. The action may mean that he cannot resume his business at all given the loss in trade or markets he has suffered.
- (c) Although difficult to estimate, it is possible that fewer farmers will be able to restock immediately. If so a smaller number of replacement animals of the prescribed genotypes will need to be found. As already indicated, the availability and cost of resistant animals and period over which restrictions will apply will vary considerably. (This may mean fewer genotyping tests to find suitable animals compared with option 2). It is expected that sourcing of suitable resistant rams might be difficult to start with but should become easier as membership of the National Scrapie Plan increases and as more resistant animals become available. So cost should reduce over the years.

Assuming 40 cases per year in Wales, with an average flock size of 500 animals, total costs to the sheep industry under (b) could range from £408,000 (£10,200 per flock x 40) in the 1st year (if industry needs to have 2 genotype tests in addition to the 2 offered by Government) to £80,000 (based on a 20% replacement rate) in the following year.

Goats

There are no differences compared with Option 2.

Other Costs

- (a) Compared to Option 2, costs of genotyping are not likely to occur normally. However, there would be greater slaughter and disposal costs as all animals would need to be destroyed. On the basis of a flock of 500 animals, and a cost of £20 per animal for slaughter/disposal, the cost per flock would be £10,000 in the first year.
- (b) The cost of compensation for animals disposed of would be greater given the larger number of animals to be destroyed. Based on a flock of 500 animals, the annual cost per flock would be £5,200 assuming a split of 205 sheep, 50 cull ewes and 245 lambs and £1,408,000 based on 40 flocks. (If animals were higher value, and compensation was sought on the basis of a valuation, costs would be greater).

On the basis of a flock size of 500, and assuming 40 cases per year, the total cost of genotyping and assistance for ram replacement to the public sector would be £508,000 (£12,700 per flock x 40).

Option 4 - implement using option of genotyping all sheep and killing the more susceptible ones and culling all goats

Cost to business

Sheep

For sheep farmers additional costs will differ from those in option 2 as follows:

- (a) Loss of income/subsidies will be less of a factor with fewer farmers affected and over a shorter period.
- (b) Although difficult to estimate it is possible that more farmers may wish to restock. If so, the cost of replacing animals could be less as will the cost of replacement tests because less animals will be slaughtered than under option 3.

Assuming 40 cases per year in Wales, with a flock size of 500 animals, total costs to the sheep industry under (b) could range from £203,200 (£5,080 per flock x 40) in the 1st year (if industry requires 2 genotype tests in addition to the 2 offered by Government) to £122,000 (based on a 20% replacement rate) in the following year.

Goats

There will be no differences compared with option 2.

Other costs

- (a) Cost of genotyping the sheep on affected farms would be greater as larger number of animals would need to be genotyped. Assuming a flock size of 500, the cost per flock would be £10,000 (500 x £20 per test).
- (b) Slaughter and disposal costs would be less as fewer animals would be destroyed. Assuming an average of 50% susceptibility in the 40 affected flocks with 500 animals per flock on average, then slaughter and disposal would cost £200,000 (based on a cost of £20 per animal).
- (c) Cost of compensation would also be less as a result. Assuming 500 animals per flock made up of 205 sheep, 50 cull ewes, 245 lambs, compensation would cost £17,600 per flock and £704,000 based on 40 flocks in year 1. This is the minimum based on no high value animals in an affected flock.
- (d) Costs of assistance towards replacement of rams that have been culled could be greater, although this will depend on the situation in the flock and breed and genotyping replacement animals. Based on the flock assumption above and two genotype tests per animals to be replaced, the cost would be £243,200 (£6080 per flock x 40 flocks).

Consultation with small business: the Small Firms' Impact Test

The majority of sheep and goat farms could be classified as small businesses. The National Sheep Association has seen a draft of the partial RIA and their comments and suggestions have been included in this draft RA.

Competition assessment

The proposals have been checked against the competition filter. The policy options are not expected to have an impact on shares of the market for breeding animals and commercial animals. There would be implications for all sectors of the sheep industry (i.e. breeding sector and commercial sector) and for the goat sector but only for individual farmers with confirmed cases of scrapie. It is possible that some of these farmers may not wish to continue in business but this is not likely to change market structure given the large number of farmers in the markets. It is possible that there may be some impact on the availability of breeding animals from certain small breeds with low levels of resistant animals but this should decrease as levels of resistance in individual breeds increase over time. New farmers entering the markets would not be subject to additional barriers to entry compared with existing businesses.

Enforcement and sanctions

The State Veterinary Service (Veterinary Officers and the National Scrapie Plan Administration Centre) will enforce the Regulations. The regulations will include criminal sanctions for non-compliance with the restrictions in the EU legislation. Penalties will be those in the existing TSE (Wales) Regulations. These are 1. If the offence is one triable in the Magistrates' court only, then the offender will be fined, or imprisoned for a term not exceeding three months or both. 2. If the offence is one triable in the Crown Court, then the offender will be fined or imprisoned to a term not exceeding two years or both.

Monitoring and review

The effectiveness of the legislation in eradicating scrapie in flocks with a confirmed case will be measured by the impact it has on the number of scrapie cases picked up at abattoirs, the recurrence or otherwise of otherwise of scrapie on affected farms and whether the legislation has an adverse effect on reporting of scrapie. These impacts will be monitored by the Welsh Assembly Government on an annual basis starting in November 2005.

Consultation

- (i) This has been drawn up in consultation with relevant divisions within the Welsh Assembly Government, Defra and the other Devolved Administrations.
- (ii) We have consulted all stakeholders on the draft Regulatory Appraisal as part of the consultation on the new Regulations. A total of 7 responses were received and most thought that, of the options, option 2 – genotyping with whole flock slaughter only where the farmer was content – was the best approach. A number of concerns were raised about the EU regulation which we have taken up with the European Commission, so far without success. As a result, officials from the Welsh Assembly Government, Defra, SEERAD and DARDNI will be

keeping a close eye on the impact of the EU regulations and in particular on the level of reporting. If there is a reduction in the numbers of cases being reported, the issue will be taken up with the Commission.

Summary and recommendation

Option public	Total cost in Wales per annum (paid from the National Scrapie annum Plan budget held by Defra)	Total benefit to the sector in Wales per
2	£3,921,407	£968.5m
3	£3,528,755	£968.5m
4	£2,852,599	£968.5m

Having regard to the issues, costs and benefits discussed in this Regulatory Appraisal, it is recommended that option 2 should be pursued. This is marginally more expensive than option 4 but it would enable culling of a whole sheep flock in the rare cases that this was the most effective option in the circumstances and the farmer was content.

Genotype classification under the National Scrapie Plan

Scrapie develops when the normal form of the PrP protein in a sheep's brain converts to an abnormal form. The PrP gene, which produces this PrP protein, also determines a sheep's resistance or susceptibility to scrapie i.e. whether or not it is likely to develop scrapie in its lifetime if exposed to the infectious agent.

The sheep PrP gene has two copies (or alleles), one derived from each parent. Each position or "codon" on the gene gets translated into one of the 256 amino acids that form the PrP protein.

Scientists have identified variations in the amino acids encoded at three specific codons on the alleles. The particular codons are 136, 154 and 171.

Based on variations at these three codons five different scrapie related alleles in sheep have been identified. These are:

136	154	171
A	R	R
A	H	Q
A	R	H
A	R	Q
V	R	Q

(Key: Amino acids: A = alanine; H = histidine; Q = glutamine; R = arginine; and V = valine)

The genotype is determined by referring to the amino acids encoded at the three relevant sites on both alleles.

An animal that has inherited the same information on the alleles from both of its parents is said to be a homozygous genotype (e.g. ARR/ARR, AHQ/AHQ). If it has inherited different information it is said to be a heterozygous genotype (e.g. ARR/ARQ).

Taking the homozygous or heterozygous pairing of alleles inherited from both parents into account allows for the generation of up to 15 different genotypes. Some breeds are known to contain all 15.

NSP Genotypes Table

Genotype result	Type	Degree of resistance/susceptibility.
ARR/ARR	1	Sheep that are genetically most resistant to scrapie.
ARR/AHQ ARR/ARH ARR/ARQ	2	Sheep that are genetically resistant to scrapie, but will need careful selection when used for further breeding.
ARR/AHQ	3	Sheep that genetically have little resistance to scrapie

AHQ/ARH AHQ/ARQ ARH/ARH ARH/ARQ ARQ/ARQ		and will need careful selection when used for further breeding.
ARR/VRQ	4	Sheep that are genetically susceptible to scrapie and should not be used for breeding unless in the context of a controlled breeding programme approved by NSPAC.
AHQ/VRQ ARH/VRQ ARQ/VRQ VRQ/VRQ	5	Sheep that are highly susceptible to scrapie and should not be used for breeding.