

EXPLANATORY MEMORANDUM AND REGULATORY IMPACT ASSESSMENT

ANIMAL HEALTH, WALES

THE ZONOSSES (MONITORING) (WALES) REGULATIONS 2007

PART 1 – EXPLANATORY MEMORANDUM

1. This Explanatory Memorandum (EM) has been prepared by the Office of the Chief Veterinary Officer and is laid before the National Assembly for Wales.
2. A copy of the Instrument is submitted with this EM.

Description

3. The Zoonoses (Monitoring) (Wales) Regulations 2007 (The Monitoring SI) provide powers to enter premises to monitor for zoonoses and antimicrobial resistance to zoonotic agents and other agents that pose a threat to human health.

Matters of special interest to the Subordinate Legislation Committee

4. There are no matters of special interests to the Committee.

Legislative background

5. The powers enabling these Regulations to be made are contained in Section 2(2) of the European Communities Act 1972. The National Assembly for Wales was designated for the purposes of this Section by virtue of the European Communities (Designation) (No 2) Order 2003 (SI 2003/1246) in relation to measures in the veterinary field for the protection of public health. Functions conferred under the (No.2) Order to the National Assembly for Wales are exercisable by Welsh Ministers by virtue of paragraph 30 of Schedule 11 to the Government of Wales Act 2006.
6. Following negotiations with stakeholders, the Zoonoses Directive 2003/99 and the Zoonoses Regulation 2160/2003 came into force on 12 December 2003. The purpose of the Directive is to ensure that zoonoses (those diseases and infections which are transmitted naturally between animals and man), zoonotic agents and related anti-microbial resistance are properly monitored and that food-borne disease outbreaks receive proper epidemiological investigation. Regulation 2160/2003 requires that Member States put into place control plans for the monitoring and reduction of zoonoses at farm level once the target to reduce the pathogen or infectious agent has been agreed. This is in effect an update of the Zoonoses Directive 92/117, (under which only breeding flocks of domestic flocks of domestic fowl are currently required to be tested and monitored),

that will eventually extend similar testing, monitoring and control requirements to other sectors of the poultry industry, such as laying hens and chickens reared for meat.

7. The Directive requires that Member States collect data on the occurrence of zoonoses and zoonotic agents and anti-microbial resistance, and provide an analysis of the trends and sources of zoonoses to the Commission each year. Member States, including the UK, have been providing this information since the mid-1990's under the previous Directive. The Commission may then use this information to agree Community targets for the reduction of the prevalence of zoonoses and various zoonotic agents, in particular *Salmonella*.
8. Under section 80 of the Government of Wales Act 2006, a Community obligation of the United Kingdom (as the Member State) is also an obligation of the Welsh Ministers. Failure to make this legislation could lead to Wales facing infraction proceedings.
9. The immediate risk is that failure to bring the Monitoring SI into force would result in the absence of powers of entry and sampling for the forthcoming surveys in the pig and turkey sector required by the Zoonoses Regulation. Without these powers the required range of holdings may not be included in the survey with the resultant risk that the results are not representative of the UK situation and the UK would fail to meet its requirements under the European Commissions decisions regarding the design of the surveys.
10. There would also be the long term risk that Wales will not have in place comprehensive enforcement powers for the enhanced monitoring systems described by the Zoonoses Directive to facilitate the collection of data on the trends and sources of zoonotic diseases and new strains of zoonotic organisms.
11. In addition, there would be the significant risk of failing to build on the success of many food producers (in particular poultry operators) in controlling Zoonoses. This could lead to failure to improve the overall public health position in the UK with regard to food-borne pathogens which, as stated in paragraph 13, were deemed to be insufficient, and which have total direct costs of £143 million per year. For *Salmonella* about 3,000 incidents affecting farm animals are reported each year in Great Britain, and about 500 cases of animal feed materials contamination.

Purpose and intended effect of the legislation

12. The main purpose of legislation on zoonoses and zoonotic agents is to protect human health, and, in line with EU Directive 2003/99, to monitor zoonotic agents and trends. It will continue the implementation of Wales's obligations under the Zoonoses Regulation and Directive; obligations that were introduced in response to the opinion on zoonoses adopted on 12 April 2000 by the Scientific Committee on Veterinary Measures relating to public health. That opinion found that the measures in place at the time to

control food-borne zoonotic infections were insufficient and that the epidemiological data that Member States were collecting was incomplete and not fully comparable.

13. The intended effect of Regulations is to: -

- give powers to inspectors appointed by Welsh Ministers or the local authority to enter premises, take samples and gather information to establish the presence or absence of zoonotic agents (viruses, bacteria, fungi, parasites or other biological entities) likely to cause a zoonoses in line with monitoring required by Zoonoses Directive 2003/99 and investigation of food-borne outbreaks;
- to examine zoonotic bacteria for anti-microbial resistance and other bacteria in so far as they might present a threat to public health;
- to enforce surveys of baseline prevalence levels of Zoonoses, as required by EU Decisions made under The Zoonoses Regulation, and to enforce other surveys to establish disease freedom;
- facilitate the monitoring of National Control Plans (NCPs) established to reduce the prevalence of certain zoonoses (any disease and/or infection which is naturally transmissible directly or indirectly between animals and humans) and zoonotic agents in animal populations at primary production level to targets set by EU legislation.

14. The Monitoring SI is concerned with monitoring and sampling to determine if the zoonoses or zoonotic agent is present or absent. It does not establish controls to reduce the zoonoses and zoonotic agents. These will be part of separate legislation to implement the control plans required by the Zoonoses Regulation, which will be covered by a separate Regulatory Impact Assessments. Any control plans for zoonotic agents not covered in the Zoonoses Regulation would be the subject of further full consultation.

Implementation

15. The instrument was made on 20 August 2007 and is intended to come into force on 1 October 2007. There are no serious legal or other implications for Welsh Ministers should the intended target dates for making not be achieved. However, similar legislation (The Zoonoses (Monitoring) (England) Regulations 2007) is due to come into force in England on 1 October 2007. It would be incongruous not to have similar regulations coming into effect on the same day.

Consultation

16. A 12-week consultation was issued between 14 August and 6 November 2006. Full details are included in Part 2, the Regulatory Impact Assessment (RIA).

Regulatory Impact Assessment (RIA)

17. A RIA has been carried out in relation to this Instrument and is set out in Part 2.

Compliance

18. The information in this Memorandum has been cleared with the Directorate of Legal Services (LS), Constitutional Affairs and Legislative Management Division (CALM) and the Assembly Compliance Officer (ACO).

THE ZONOSSES (MONITORING) (WALES) REGULATIONS 2007

PART 2 – REGULATORY IMPACT ASSESSMENT

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Introduction

1. This Regulatory Impact Assessment (RIA) considers various options for achieving the policy objectives set out in paragraphs 13–15 in Part 1.

Consultation

2. A 12-week consultation on the Monitoring SI was issued between 14 August and 6 November 2006. A list of those consulted is attached at **Annex 1**. Views were sought from the 124 organisations listed. Responses were received from nine organisations. The responses are summarised at **Annex 2**.
3. These Regulations were notified to the Environment, Planning and Countryside Committee, via the list of forthcoming legislation on 5 October 2006 (EPC (2) 11-05 (p7) Annex 1). They were not identified for detailed scrutiny.

Options

4. There are 5 options:

Option 1

5. **Do nothing:** Failure to comply with the monitoring and sampling required by the Zoonoses Directive and Regulation would be a threat to public health and a breach of Community obligations. Without consistent survey procedure and methods in all Member States, data on the EU level of zoonotic diseases would remain incomplete and the setting of EU targets

for reduction would not be on a sound basis. This is not considered to be a feasible option.

Option 2

6. **Introduce specific legislation for each time powers of entry and sampling are required for zoonoses and zoonotic agent and related anti-microbial resistance:** If this option were adopted, Welsh Ministers would bring in separate legislation for each survey carried out under the Zoonoses Regulation. Further legislation would be produced to comply with the Zoonoses Directive each time there was a change in the epidemiological situation and powers of entry were required to carry out sampling in order to monitor a sector or activity.
7. In the short term this approach would meet our European Community obligations. It would, however, increase legislation and administrative costs beyond those of the other options (apart from Option 1) as implementing legislation would have to be laid before the Assembly each time a Decision was published by the Commission requiring specific monitoring action. This approach could also make the monitoring and sampling required at each stage of the implementation of the Zoonoses Directive and Regulation more difficult to manage as Welsh Ministers would not have powers to conduct survey work until legislation implementing the respective Decisions had come into force. The publication dates of EU Decisions cannot always be easily harmonised with Assembly schedules. Specific legislation would also be required for the monitoring of the organisms mentioned in Annex I of the Directive if warranted by a change in the epidemiological situation. As well as creating high administrative costs for the Welsh Assembly Government, this option would go against its policy of reducing the number of regulations and simplifying regulatory burdens on industry.

Option 3

8. **Conduct the sampling and monitoring required by the Zoonoses Directive and Regulation on a voluntary basis:** A means of implementing the monitoring and sampling required by the Zoonoses Directive has been extensively discussed with representatives from the pig and poultry industries. They recognise that to meet the new monitoring requirements Welsh Ministers need to be able to collect accurate data on zoonoses and zoonotic agents, which is comparable with that from other Member States. Industry representatives have encouraged their members to co-operate with survey work required by the Zoonoses Regulation in the poultry and pig sectors and have provided practical assistance at farm level. If such support could guarantee the co-operation of industry in fully meeting the wider monitoring requirements of the Zoonoses Directive, then Welsh Ministers would fulfil their European Community obligations without the costs of drafting and implementing legislation. However, while voluntary support can be relied upon from the majority of operators, there remain a number of operators who will not participate in monitoring

programmes on a voluntary basis. In such cases monitoring programmes may need to be backed by enforcing legislation.

9. Zoonoses Directive and Regulation provide for programmes that set specific criteria for selection of holdings. Experience indicates that participation in surveys – even those currently required by the Zoonoses Regulation, which have the support of industry representatives - tends to be more dependable when backed by legislation. In order to demonstrate that the results of a monitoring programme are based on a representative selection of farms, it is important that the selection is not confined only to holdings where operators are willing to volunteer. There is also the danger that conducting survey work on a voluntary basis could unfairly burden those who are prepared to co-operate.

Option 4

10. **Put in place a Statutory Instrument that will provide powers to enter premises and take samples to establish the prevalence of zoonoses and zoonotic agents and anti-microbial resistance in animals kept for food production and their environment:** This option will provide powers of entry and sampling to monitor animals kept for food production for all zoonoses and zoonotic agents and related anti-microbial resistance transmitted through animals kept for food production. This could be used to enforce the forthcoming surveys of turkeys, fattening and breeding pigs required by the Zoonoses Regulation. It would also allow appropriate monitoring of the other zoonoses and zoonotic agents and improve the information on trends and sources of zoonotic agents.
11. Option 4 will not give Welsh Ministers powers of entry and sampling that cover the wild animal population. This would not put Welsh Ministers in breach of their community obligations as the Zoonoses Directive is not intended currently to begin a continuous programme directed at all species. If it were necessary to test these animals to investigate the spread of disease, additional legislation could be brought into force.

Option 5

12. **Put in place a SI that will provide powers to enter premises and take samples to establish the prevalence of zoonoses and zoonotic agents and anti-microbial resistance in all animals and their environment.** The Monitoring SI as drafted provides the powers described in this option.
13. Option 5 provides powers of entry and sampling for all the activities described in Option 4 but these powers are extended to all animals (including wild and companion animals). This makes the powers in the Monitoring SI as wide-ranging and anticipatory as the provisions of the Zoonoses Directive. Although priority will be given to those zoonoses and species which are currently most likely to contribute to the prevalence of zoonoses in humans, it will also facilitate monitoring in response to

emerging or newly emerging zoonotic diseases and strains of zoonotic organisms. If, for instance, there were a requirement to monitor for specific zoonoses in the wild animal population, Welsh Ministers would have the powers in place without the need for additional legislation. An informed risk assessment, based on the results of monitoring, could then be made to determine whether the zoonoses posed a significant hazard to human health and if whether risk management measures should therefore be considered.

14. In developing this Regulatory Appraisal we have sought to identify as much flexibility in legislation as possible to lighten any regulatory burden on affected businesses and government bodies. Widening the scope of the Monitoring SI to all animals as opposed to bringing in specific legislation in each case could be perceived as an unnecessary regulatory burden. However the SI, as drafted, aims to provide Welsh Ministers with wide ranging powers in order to monitor zoonoses and zoonotic agents effectively while at the same time ensuring that such powers are used only where necessary.
15. The Monitoring SI is not intended to initiate comprehensive monitoring programmes to assess the levels of zoonotic organisms in all animals. Its purpose is to facilitate the collection of data on their occurrence to determine trends and sources as required by the epidemiological situation. For this purpose, this is the preferred option.

Pets and Wild Animals

16. With new strains of disease we cannot predict which animal species will be infected. Decisions over whether a monitoring programme is necessary in order to make a risk assessment on emerging organisms that might transmit disease are usually taken according to recommendations from the bodies established to protect human health. There may be circumstances in which it would be necessary to collect samples from pets and their environment. A situation may arise where government could identify the presence of zoonotic agents, or likely zoonotic agents, but needed to assess whether a group of animals was a significant potential source of infection for humans. To assess the significance of a newly introduced strain organism, or newly identified strain of a known organism, it is important to be able to establish its prevalence. Examples of zoonoses which may be identified in pets and wild animals include:
 - *Corynebacterium* bacteria, which causes diphtheria, and which has been identified in domestic dogs.
 - Bovine Tuberculosis in areas where there is suspicion that the disease might be present in wild animals and might be transmitting disease to neighbouring cattle.
17. Without the co-operation of landowners veterinary inspectors may be unable to collect samples to make an assessment of the situation.

Private premises

18. With commercially farmed animals, zoonotic disease is a business risk and has implications for the food chain. Private dwellings and land, as well as pets and other animals, which are not involved in food production, are lower risks with regard to the transmission of zoonoses to the wider public. There are also human rights considerations involved in establishing powers of entry into private dwellings and land not used for food production. Therefore the Monitoring SI applies stricter standards for enforcing the powers of entry on to private premises. It is proposed that a notice should be given or that a warrant should be obtained from a Justice of the Peace.
19. Legislation such as the Animal Health Act 1981, the Zoonoses Order 1989 and the Animal By-Products Order 1995 (updated 2005) has demonstrated that legislation that gives wide ranging powers to government can be used proportionately and without over-committing resources to enforcement.

Benefits

20. The preferred option, Option 5, will bring immediate benefits in enforcing forthcoming survey work for turkey and pigs, with the associated animal and public health benefits. There would be benefits in the longer term from having a consolidated piece of legislation in place, which is sufficiently flexible to allow monitoring of other zoonoses and zoonotic agents found in animal species (in particular, pets and wild animals) as required by changes in epidemiological situation. This monitoring could be in response to an emergency situation and/or if the EU Commission decided that harmonised monitoring was required for these agents.
21. This will benefit the consumer by:
 - ensuring that measures taken to control zoonoses and zoonotic agents can be informed by accurate data, which in an emergency situation can be quickly acquired by government without the need for additional legislation.
 - ensuring that the government has, in reserve, powers of entry and sampling that can be used to demonstrate the absence of a disease as well as the presence and avoid resources being wasted on control of a zoonoses or zoonotic agent which is not of human health significance.
22. It would also benefit industry and government by:
 - ensuring that monitoring can take place at relevant stages of production without the delays that can be caused by producing additional legislation.

- ensuring rapid response to any emerging epidemiological situation, whether it arises from domestic, companion or wild animal populations
- preventing any lack of clarity or confusion as to entry and sampling powers, which might lead to non-compliance on farms.

Veterinary Surveillance Strategy

23. The wide scope of the Monitoring SI will compliment the investment that government has put into the Veterinary Surveillance Strategy to enhance veterinary surveillance after the outbreak of Foot and Mouth Disease in 2000. This should enable government to integrate monitoring measures that can quickly identify sectors and regions, including those not involved in primary production, where there are heightened risk and enable the development of preventative or remedial action.
24. Data and activity from many sources (such as private veterinary surgeons or animal owners) is being integrated through the RADAR system (Rapid Analysis and Detection of Animal Related Risk) to help analyse and track emerging threats more rapidly.

Health Protection Agency

25. The Monitoring SI as drafted would also support the activities of the Health Protection Agency (HPA), which aims to identify and assess outbreaks of new and emerging infectious diseases. Monitoring programmes may be initiated in response to concerns raised from horizon scanning by the Human Animal Infections and Risk Surveillance (HAIRS) group which was set up by the HPA to carry out risk assessments on zoonoses and zoonotic agents and emerging organisms that might transmit disease. This group has developed a detailed method to indicate where government should take action in the event of a new agent being discovered that might be a significant risk to human health.
26. The monitoring will take place to fulfil the requirements of the Zoonoses Regulation to monitor for specific zoonotic agents. The monitoring could also take place in response to concerns raised from horizon scanning by a committee in the HPA. This would require Welsh Ministers to investigate outbreaks or incidents of new and emerging infectious diseases and syndromes, which might be zoonotic. The relevant committee is the HAIRS group, which was set up to carry out risk assessments on zoonoses and zoonotic agents. The powers in the Monitoring SI would only be used for survey work that is necessary to protect human health, not for reasons of academic research.

27. In summary widening the monitoring to all animals allows the greatest speed of response to a change in the epidemiological situation. It minimises the amount of legislation that needs to be introduced under any situation and provides the maximum protection to both animal and public health from any zoonoses or zoonotic agent.
28. The inclusion of animals that are not directly involved in primary production also makes this the option that offers the most significant compensatory simplification measures to industry, as explained below.

Business Sectors Affected

Food businesses

29. As drafted, the Monitoring SI gives Welsh Ministers the powers of entry and sampling described in Option 5. However, in the immediate future the Monitoring SI will have most impact on primary producers in the pig and turkey sectors where survey work will be conducted to establish current prevalence of *Salmonella* in holdings across the EU. This will involve the collection (or supervision of the collection) of samples either from the animals or from the environment of the animal to determine the presence or absence of a zoonotic agent and its characteristics by an agent of the Competent Authority (CA). Powers may be used, in particular, when checks are made to ensure that operators comply with the requirements of the control plans for their sectors and when official control sampling is carried out.
30. In Wales there are over 8 million fowls and 299,459 turkeys on an unspecified number of holdings¹. There are 897 pig holdings in Wales with 48,414 pigs². Abattoir owners could also be affected, as this is often a convenient place to sample animals of certain ages as they are collected together in the one place. Sampling at the abattoir is also effective in assessing the risks to the food chain. This must be qualified with the understanding that over the next four years surveys to establish baseline prevalence levels of *Salmonella* in pigs and turkeys will only cover holdings that meet the sizes and business profile specified in the technical specifications provided for in the relevant European Commission decisions. For turkeys the survey work applies to holdings with over 500 birds.
31. The scope of the National Control Plan's (NCP's) are also intended to exclude producers who are unlikely to make a significant contribution to the average prevalence of zoonoses in the Community's animal population. In the case of breeding flocks of domestic fowl (*Gallus, gallus*) the NCP applies to holdings with a minimum of 250 birds. The NCP will not apply to producers that directly supply small quantities of products to the final consumer.

¹ Welsh Agricultural Statistics 2005

² Hybu Cig Cymru Compendium of Welsh Meat and Livestock Industry Statistics 2005

Other groups and business sectors affected

32. In the longer term this SI may have a wider impact. As stated earlier, the Zoonoses Directive requires member states to have monitoring systems in place which facilitate the detection of emerging or newly emerging zoonotic diseases and new strains of zoonotic organisms as well as those currently posing the greatest risk to human health. The Monitoring SI gives government entry and sampling powers that will anticipate changes to the epidemiological situation to determine the presence or absence of a zoonotic agent. If, for example, a new agent occurred in a sector not associated with primary production (for instance in the wild animal population on land belonging to the National Trust), then in order to assess the risk of the infection to the public it might be necessary to gather epidemiological data in the animal or its environment. In this case, the owners of the land where the animals were present would be affected, as entry onto the land could be necessary in order to collect the appropriate samples of wild animal species being monitored.
33. Consequently this SI gives government powers of entry and sampling on all holdings or areas on which animals or animal feedingstuffs are, or have been kept. This will include animals kept for commercial and leisure purposes (for instance stables and zoological collections) as well as food production and companion animals. It will include sampling at abattoirs, or other convenient locations for sampling to determine the presence or absence of zoonotic agents in the live animal. The powers of the Monitoring SI could also be applied to areas on which wild animals are present including land which belongs to the national parks or country estates or forestry companies and which is designated as a protected area. For the purposes of the Monitoring SI, a wild animal would be defined as a member of any species that is resident in or a visitor to Welsh territory in a wild state.
34. Since these powers would only be applied to other sectors according to epidemiological developments it is not possible to make a realistic forecast of which of these groups and sectors would be most likely to be directly affected.

Costs

Administrative Costs

35. The costs of the survey work, including collection and analysis of samples, enabled by the Monitoring SI in the pig and poultry sectors over the next four years will be met Defra. These estimates were provided by Defra, Animal Health and the Veterinary Laboratories Agency (VLA). They have been calculated to take into account as many factors as possible but will also be influenced by some factors which are difficult to predict such as the distribution of farms and the requirements of survey protocols, which have yet to be determined at an EU level.

Operational Costs

36. We do not anticipate any substantial costs to industry from the SI's provisions, as it does not put in place any cost recovery powers from the sectors and groups selected for the collection and testing of samples. Costs to industry are summarised below, based on previous surveys. If government decided that a cost recovery mechanism should be put in place (for instance for the collection and testing of samples) it would be part of separate legislation.
37. In October 2001 when the Zoonoses Regulation and Directive were at the proposal stage, industry did not identify any costs associated with the sampling and monitoring required by the Zoonoses Regulation to establish the targets for the reduction of *Salmonella*. Subsequently, the concerns of industry representatives have been with the possible costs associated with sampling, including official controls required by Decisions made under the Zoonoses Regulation to demonstrate that the target established by the Commission has been met. Indirectly, the Monitoring SI will have a financial impact as it will inform programmes that public and animal health against zoonoses.
38. The burden this legislation will place on operators or owners selected for survey work enforced by the Zoonoses Directive will be limited to the time it takes to allow an Animal Health or other agency officials onto an operator's land to take samples and provide relevant information and assistance. These obligations will vary according to the data that has to be captured. In previous surveys this has included data on:
- Records of movements and contacts with other animals
 - Identification marks
 - Size of flocks or herds
 - Details of vaccination and medication
39. In previous surveys the assistance that might be required from an operator or owner has included:
- Informing the Animal Health Officer (AHO) of a suitable date for sampling
 - Entry to the premises and location of the animals
 - Selecting and gathering animals or carcasses for sampling (possibly through numbers on ear tags or slap marks)
 - Provisions for health and safety and biosecurity.
40. The Monitoring SI as drafted encompasses a wide range of groups and sectors that could be compelled to allow any agent of the Competent Authority (CA) access to their land, premises or animal(s) for the collection of samples. This, combined with unforeseen epidemiological situations, makes costs difficult to quantify for the purposes of the RIA. It is possible, however, to form an approximate estimate taking into account the experience from other surveys. In the following table, previous surveys

have informed estimated times based on the average number of animals sampled on a typical holding.

41. Some of these samples are collected on a monthly basis (for instance those taken under the Poultry Breeding Flocks and Hatcheries Order 1993). Others are taken when required for disease control (for instance blood sampling horses). Since survey work conducted under the Monitoring SI is also likely to be on an ad-hoc basis it is difficult to describe the costs in terms on an annual cost for industry.

Table 1

Taking environmental samples from laying and broiler flocks and completing questionnaires.....	4 hours
Taking samples from breeding flocks under PBFHO 1993	1 hour
Testing sheep for brucellosis under the Brucellosis Order 2000:	
<i>Brucella Abortus</i> - To take blood samples from a herd of cattle can take a considerable period of time (sometimes a day) and additional help and handling equipment may be required.	
<i>Brucella Melitensis</i> - up to twenty sheep or goats are sampled, which can take up to 2 hours and sometimes extra help is needed.	
Testing horses for notifiable diseases (blood sampling 5-10 horses)	2 hours
Testing of pig carcasses for ZAP Salmonella programme	4 hours

42. If there was a need to capture wild animals for testing, it is likely to require much more of the owner's time per animal than for farm animals, as wild animals are not accustomed to being caught and handled and may be dispersed over a large area. The cost of this time for gathering must be added to the time needed for actually taking samples.

Form Filling and other administrative costs to industry

43. The survey work, which will be enforced by the Monitoring SI, does not oblige operators or landowners to complete any paper work. Regulation 7 of the Monitoring SI does, however, oblige them to provide information to enable an officer appointed by Welsh Ministers to take a meaningful sample. For primary producers this includes details on the animals on a holding and the production type. In the survey work for the Zoonoses Regulation this information is included in a compulsory questionnaire. Experience of a survey conducted last year by Defra on behalf of England and Wales on *Salmonella* prevalence in laying flocks indicates that it takes on average an operator 20 minutes to provide this information.

44. For the forthcoming survey work in turkeys and pigs the details of the questionnaires will depend on the requirements of Decisions taken by the European Commission and related technical specifications. It is reasonable to assume that it will take a similar length of time for the operator to provide information for the compulsory questionnaires.

45. The cost of the administration time needed as well as the time required for taking samples is summarised in the **Table 2** below.

Table 2

	No. holdings/ abattoirs sampled	No. visits per year	Time needed per visit (hours - sample & qu'aire)	Value of time (£ / hour)	Industry cost per survey
Breeding Flocks					£135,000
Parent flocks	415	6	4	£8.50	£85,000
Grandparent flocks	123	12	4	£8.50	£50,000
Turkeys (forthcoming)	373	1	4	£8.50	£13,000
Costs at abattoirs					
Pig carcasses (Salmonella)	25	3	4	£7.00	£2,000

Industry Costs Summary

46. The examples listed in the **Table 1** above can be used to estimate the total industry costs of a single survey. However, where surveys take place on an ad-hoc basis, industry costs are far more variable and dependent on a positive or negative sample results, and so have not been estimated here as examples of possible industry costs.

47. The costs are based on the assumption that one worker either on the holding or at abattoir would be able to carry out the sampling and questionnaire work. Therefore, the cost of extra staff where required for sampling has not been estimated.

Small Firms Impact Test

48. It is not anticipated that there will be a disproportionate impact on small firms.

Issues of equity and fairness

49. There is no unequal impact by gender, age, or by race. It is not expected that any impact on particular income groups will be significant.

Enforcement and Sanctions

50. The Monitoring SI will be enforced by Local Authorities. Welsh Ministers may however in relation to a case of a particular description or circumstance direct that they discharge enforcement activities. Since this SI is intended to cover all the monitoring requirements of the Zoonoses Directive that are not already provided for by Welsh legislation, it is very difficult to estimate the precise costs to enforcement agencies. However, Welsh Ministers have not experienced any serious non-compliance problems with the survey work for layers and broilers (domestic fowl) and it is not envisaged that the powers set out in the Monitoring SI should suddenly lead to large scale resistance from farmers.

Post Implementation Review

51. If there were large-scale resistance to survey work enforced by this SI, Welsh Ministers would initially work with industry in order to encourage their members to participate voluntarily. Discussions are on going with local authorities (LACORS) regarding specific responsibilities for enforcing the Monitoring SI.

Annex 1

Zoonoses (Monitoring) (Wales) Regulations 2006: Consultation List

ADAS (Wales)

Agri food Partnership for Wales

All Wales Committee for Health Professionals

Animal Health & Welfare Strategy Steering Group

Association of National Parks

Badger Face Welsh Mountain Sheep Society

Balwen Welsh Mountain Sheep Society

Black Welsh Mountain Sheep Breeders Association

Blaenau Gwent CBC

Bodafon Farm Park

Brecknock Hill Cheviot Sheep Society

Brecon Beacons National Park Authority

Bridgend County Borough Council

British Charollais Sheep Society Lt

British Deer Farmers Association

British Free Range Egg Producers Association

British Veterinary Association North

British Veterinary Association South

Business Eye (previously Business Connect)

Caerphilly County Borough Council

Campaign for the Protection of Rural Wales

Carmarthenshire County Council

Central Association of Agricultural Valuers (Wales)

Ceredigion County Council

Chartered Institute of Environmental Health

City & County of Cardiff

City & County of Swansea County Council

Conwy County Borough Council

Country Land and Business Association

Countryside Council for Wales

Cymdeithas Defaid Mynydd Cymraeg Tregaron a'r Cylch

Denbighshire County Council

Environment Agency Wales

EPC Committee, National Assembly for Wales

Eppynt Hill & Beulah Speckled Face Soc

Farm & Livestock Concern UK

Farm Animal Welfare Council

Farm Assured Welsh Livestock

Farmers Union of Wales

Farming & Livestock Concern UK

Federation of Small Businesses in Wales
Flintshire County Council
Foel Farm Park
Folly Farm Family Adventure Park
Food Standards Agency (Wales)
Friends of the Earth Cymru

Greenacres Farm Park
Guild of Welsh Lamb & Beef Suppliers
Gwent County Council
Gwent Health Authority
Gwynedd County Council

Hill Radnor Flock Book Society
Hybu Cig Cymru

Institute of Grassland and Environmental Research
Institute of Rural Health
Institute of Rural Studies
Isle of Anglesey County Council
Interspecies Infection Group

Jacob Sheep Society

Kerry Hill Flock Book Society

LACORS Wales
Lantra
Llandovery Whiteface Hill Sheep Society
Llanwenog Sheep Society
Lleyn Sheep Society

Manor House Wildlife & Leisure Park
Margam County Park

Merthyr Tydfil County Borough Council
Milk Development Council
Monmouthshire County Council

National Beef Association (Wales)
National Farmers Union Wales
National Sheep Association (Wales and Border Region)
National Trust
National Public Health Service
Neath Port Talbot County Borough Council
Newport County Borough Council
North Country Cheviot Sheep Society
North Wales Goat & Smallholders Society

Organic Farming Centre for Wales

Pembrey Country Park
Pembrokeshire Coast National Park Authority
Pembrokeshire County Council
Powys County Council
Public Health Laboratory Service in Wales

Radnorshire Wildlife Trust
Rare Breed Survival Trust in Wales
Rhondda Cynon Taff County Borough Council
Royal Society for the Prevention of Cruelty to Animals
RSPB

Shared Earth Trust
Snowdonia National Park Authority
South Wales Milk Recording Group
South Wales Mountain Sheep Society
South West Wales Goat Club
Suffolk Sheep Society

Talybont Welsh Sheep Society
Torfaen County Borough Council
The Dyfed Shires & Leisure Farm

Vale of Glamorgan Council
Veterinary Laboratories Agency Wales

Wales Rural Forum
Wales Wildlife & Countryside Link
Wales Young Farmers Club
Warren Mill Farm Park
Welsh and Marches Goat Society
Welsh Bee Keepers Association
Welsh Black Cattle Society
Welsh Consumer Council
Welsh Deer Initiative
Welsh Food Microbiological Forum
Welsh Half-Bred Society
Welsh Highland Shepherds
Welsh Hill Speckled Face Sheep Society
Welsh Institute for Rural Studies
Welsh Lamb and Beef Promotions
Welsh Livestock Auctioneers Association
Welsh Local Government Association
Welsh Mountain Sheep Society - Hill Sec
Welsh Mountain Sheep Society – Pedigree
Welsh Scientific Advisory Committee
Welsh Water
Wildlife Trusts Wales
Wrexham County Borough Council

Annex 2

Responses to the consultation on the draft Statutory Instrument The Zoonoses (Monitoring) (Wales) Regulations 2007

Views were sought from 124 organisations (listed at Annex 1) on a draft Statutory Instrument (SI), the Zoonoses (Monitoring) (Wales) Regulations 2007 ('The Monitoring SI'), which would be the means by which EU Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents ('The Zoonoses Directive') would be implemented in Wales. The Regulations provide inspectors with the powers of entry to monitor for zoonoses and antimicrobial resistance to zoonotic agents and other agents that pose a threat to public health.

The Regulations:

- Set out what inspectors may do on those premises, including take samples, examine records and make inquiries of any person.
- Require food business operators involved in primary production to preserve isolates that have been tested for a zoonosis and to keep the results of those tests and provide them to the National Assembly for Wales on demand.
- Create offences for obstructing an inspector and sets out the applicable penalties.
- Deal with enforcement.

Responses were received from the following 9 organisations. The responses are summarised below.

Name	Organisation	Sector	Do you agree with the analysis accompanying the options set out in the partial RIA?	Do you support the proposed SI as drafted?	Have any practical or affordable implementation options been left out? What are they?
W Haresign	UCW Aberystwyth	Academia	Yes. The arguments for and logic of Option 5 as the preferred option are unquestionable	Fully support.	No
Brenda Howell	Jacob Sheep Soc.	Primary production	Yes. Very clearly stated and presented	Fully support. Very important to include “wild animals & birds” and “water life”. Many of us working in the countryside are <u>very</u> concerned about factors beyond our control, e.g. in waterways, birds and especially <u>fox</u> and <u>badger</u> impact.	For “Guidance” information to be made available before problems arise, e.g. ‘How to avoid problems’ – ‘What to look out for’. Perhaps in easy to understand pictorial or “comic strip” format in order to attract attention.
Emyr Jones	Gwynedd CC	Local unitary authority	Yes. The options are a good account of the type of problems faced when there is a need to research, manage and restrict the spread of zoonotic diseases that arise regularly, or those that occur occasionally where their source is unknown.	Generally support. Whilst general authority already exists under other statutory instruments, e.g. under the requirements of public health laws, introducing this proposed statutory instrument would ensure better clarification regarding the management role of enforcement agencies in relation to specific zoonoses.	In a perfect world, it would be good if agreement could be reached on the best way to act when the spread of zoonoses truly needs to be controlled. It should be in everybody’s interest to avoid threats to public health, impact on the economy and environmental damage, or the impairment of the welfare and interest of animals. While this situation is never likely to be reached in a short time, without reasoning and detailed consultation, there remains little choice apart from the proposed options.

Name	Organisation	Sector	Do you agree with the analysis accompanying the options set out in the partial RIA?	Do you support the proposed SI as drafted?	Have any practical or affordable implementation options been left out? What are they?
Chris Pollock	IGER	Research	Yes. Consider the document to be a thorough assessment of the Assembly's position with regard to the new EU regulation. Agree that the preferred option would be Option 5.	Suggest enlarging the list of zoonoses listed in Schedule 1 to the SI to include protozoan parasites such as those causing Cryptosporidiosis or Giardiasis. These 2 parasites have caused a major problem in North Wales within the last 12 months. There could also be a case for others to be added.	
Gwyn Howells	Hybu Cig Cymru	Meat promotion	No comment to make but would appreciate being kept informed of any further developments in this area.		.
Mrs S D Bartram	North Wales Goat & Small Holders Soc.	Primary production	Mostly. Sampling of wildlife may prove difficult on smallholdings. Attempted local trapping of foxes on smallholding has proved unsuccessful	Generally support. Provided that costs incurred in laboratory testing and veterinary inspecting are not recovered from farmers and smallholders. Testing required should be covered by EC budgets.	Can think of no other option. Straightforward and simplified legislation would be appreciated.
Dr Sarah Evans	Veterinary Laboratories Agency	Veterinary investigation	Yes.	Comments On balance, the VLA is in favour of the SI. The flexibility afforded by option 5 is also favoured.	.

Name	Organisation	Sector	Do you agree with the analysis accompanying the options set out in the partial RIA?	Do you support the proposed SI as drafted?	Have any practical or affordable implementation options been left out? What are they?
Peter Watson	Deer Initiative	Deer management	<p>Concerned about the wide-ranging powers of 'sampling' wild animals, its broad scope and potential impact. Arguments for preferred Option 5 are vague and leave many questions unanswered. The discussion re capturing of wild animals appears naïve in respect of wild deer. The approach applied to farm livestock of capturing and sampling is unlikely to be directly to be directly applied to wild animals, living wild on the land in question. Would it include killing wild animals for the purpose of determining possible disease presence? What, if any, safeguards would there be as to the methods used or the time of year it was undertaken?</p>	<p>Not clear quite what 'samples' are. It refers to carcasses but is this intended to cover animals that are already dead or does it extend to killing them for the purpose of providing the sample? In relation to wild animals in many cases 'sampling' could be a euphemism for killing wild animals. For example, wild deer are very difficult to catch alive and the process can be enormously stressful to the animal. In such a situation sampling may therefore entail killing deer but it is not clear whether this is the intention.</p>	

Name	Organisation	Sector	Do you agree with the analysis accompanying the options set out in the partial RA?	Do you support the proposed SI as drafted?	Have any practical or affordable implementation options been left out? What are they?
Kate Parkes	RSPCA	Animal welfare	<p>Very concerned at the wide-ranging powers of 'sampling' wild animals, its broad scope and potential impact. Prefer Option 4 as it would comply with the requirement of the Directive since it is apparently not intended currently to begin a continuous programme directed at all species. Option 5 thus goes further that the directive and, although the government put forward an argument about flexibility for the future, the proposals regarding 'sampling' wild animals and pet animals are vague and leave many questions unanswered. The discussion re capturing of wild animals appears naïve in respect of wild deer. The approach applied to farm livestock of capturing and sampling is unlikely to be directly to be directly applied to wild animals, living wild on the land in question. Would it include killing wild animals for the purpose of determining possible disease presence? What, if any, safeguards would there be as to the methods used or the time of year it was undertaken? Wild animals have varying degrees of legal protection. Would these safeguards apply or be overridden?</p>	<p>Not clear what training or competence the inspector will have or be required to have, or indeed how such sampling is to be carried out. Urge National Assembly to consider the type of skill and training required to carry out these procedures and ensure that anyone granted the power of inspection is competent to carry out the procedures associated with this position in a humane manner. Not clear from draft SI quite what 'samples' are or how they are to be collected. It refers to carcasses but is this intended to cover animals that are already dead or does it extend to killing them for the purpose of providing the sample?</p>	

Annex 3

Glossary of terms

A **zoonosis** is any disease and/or infection that is naturally transmissible directly or indirectly between animals and humans.

A **zoonotic agent** means any virus, bacterium, fungus, parasite or other biological entity that is likely to cause a zoonoses.

A **National Control Programme** (NCP) is a framework of measures required by Zoonoses Regulation 2160/2003 for the control and monitoring of zoonoses and zoonotic agents that must be implemented by all EU Member States.

A **flock** means all poultry of the same health status kept on the same premises or in the same enclosure and constituting a single epidemiological unit; in the case of housed poultry, this includes all birds sharing the same airspace.

A **breeding flock** for the purposes of this Regulatory Impact Assessment (RIA) comprises at least 250 poultry of the species *Gallus gallus* (domestic fowl) that are reared or kept for the production of hatching eggs. Turkeys, ducks and geese are not required to be tested under The Breeding Flocks Order.

Official control sampling means sampling that takes place under the Competent Authority (CA)

Competent Authority (CA) means a government body, or agency of the government body responsible for the implementation and enforcement of the legislation.