E Coli O157 - developments arising from the Griffin Committee Enquiry

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Issue

1. This paper outlines the evidence provided by the Health and Safety Executive (HSE) and the Local Authorities Coordinators of Regulatory Services (LACORS) to the independent expert Griffin Investigation Committee set up by the Board of the Health Protection Agency to investigate the outbreak of E. coli O157 at Godstone Farm and Playbarn in the summer of 2009.

Timing

2. Routine. It is not expected that the report of the Griffin Investigation Committee will be published before May 2010.

Recommendation

3. To note the evidence given to the committee and proposals for reviewing existing published guidance to duty-holders and support for local authority staff.

Background

4. An outbreak of vero cytotoxin-producing Escherichia coli O157 (VTEC O157) occurred at Godstone Farm and Playbarn, Tilburstow Hill Road, Godstone Farm, Surrey in the summer of 2009. A total of 93 cases of infection with E. coli O157 linked to the farm were subsequently confirmed by the Health Protection Agency (HPA).

5. On 30 September 2009, the HPA Board agreed the terms of reference for an independent investigation into the outbreak, led by George Griffin, Professor of Infectious Diseases and Medicine at St. George’s, University of London and Chair of the Advisory Committee on Dangerous Pathogens.

6. HSE and LACORS were invited to give evidence and subsequently made a joint written submission to the committee. The submission covered the approach to hazard and risk
in decision making; assessment of the risk from \textit{E.coli O157} at open farms; development of the current strategy for controlling the risk of \textit{E.coli O157} at open farms; and the remits of HSE and the Local Authorities in regulating the activity. A copy of the submission is attached at Appendix 1.

**Argument**

7. We await with interest the outcome of the Griffin review. In particular whether it is successful in identifying any evidence that might explain this particular outbreak.

8. HSE is committed to reviewing AIS23 in the light of the findings of the committee. It is understood that some members of the committee have expressed concerns about the consistency of enforcement at open farms. HSE and LACORS propose considering how best to provide additional support to EHOs and how to strengthen the existing links between EHOs and HSE.

9. Meanwhile as the main petting farm visiting season commences HSE, LACORS and the HPA have issued a joint letter which is attached at Appendix 2. The letter recognises the recreational and educational benefits of visiting open farms but stresses the importance of farm operators, regulators, and the visiting public alike understanding the risks of infection from \textit{E coli O157}, and how to prevent it. The letter was accompanied by public health messages about \textit{E. coli O157} produced in conjunction with the Department of Health.

**Consultation**

10. LACORS

**Costs and Benefits**

11. Any revision of AIS23, of the arrangements for continuous professional development of EHOs on \textit{E. coli O157} and of links between HSE and EHOs are intended to enhance the ability of EHOs to tackle the politically sensitive and challenging issue of \textit{E. coli O157} at open farms.

**Financial/Resource Implications for HSE**

12. The review and support to local authorities will be provided from existing resources.

**Other Implications**

13. None

**Action**

14. HSE will review AIS23 in the light of the findings of the committee.

15. HSE and LACORS, will consider developing an improved centre of reference and expertise on the topic; possibly by developing a package of learning materials for inclusion in the Regulatory Developments Needs Analysis tool and how best to
strengthen the links between EHOs and HSE; both centrally and at local level in support of work on this activity.

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Appendix 1

Griffin Investigation Committee: Independent Investigation into the
*E. coli* O157 Outbreak at Godstone Farm in 2009

Submission on HSE’s approach to hazard and risk in decision making; with particular reference to *E. coli* O157 and open farms

EXECUTIVE SUMMARY

1. This submission is on behalf of the Health and Safety Executive and the Local Authorities Coordinators of Regulatory Services and constitutes a joint position.

2. An outbreak of *E. coli* O157 at Godstone Farm, Surrey involving 93 members of the public (including children) occurred in August/September 2009. On 30 September, the Board of the Health Protection Agency (HPA) established an independent investigation of the outbreak, the factors that contributed to it and its handling, with the aim of making recommendations to reduce the risk to those who visit ‘open farms’ of contracting *E. coli* O157 and improving the response to any outbreaks which do occur.

3. Along with other bodies and independent witnesses, HSE and LACORS were invited to give evidence to the Griffin Investigation Committee. HSE and the local authorities in England, Scotland and Wales are responsible for enforcing occupational health and safety legislation respectively in agriculture and at open farms (as defined) throughout Great Britain (GB).

4. HSE and LACORS gave oral evidence to the committee on 5 November 2009 on a range of issues including:
   - The application of health and safety at work legislation to open farms
   - The allocation of responsibility for enforcement of the legislation at open farms
   - HSE’s strategy for addressing the risk of *E. coli* O157 in relation to the protection of workers and visitors to farms and open farms
   - The development and publication of guidance on *E. coli* O157 for duty-holders under the legislation
   - The provision of guidance (including guidance on enforcement) and technical support for HSE and LA inspectors; and
   - Partnership and other working relationships between HSE and the Las as co-regulators under the Health and Safety at Work etc. Act 1974

5. Subsequently, HSE gave further evidence to the committee on 22 December 2009, specifically on how HSE, as a regulator, views and defines the concepts of hazard and risk, uses them in practice as a basis for decision-making, prioritising activity and allocating finite resources and applies them in the context of the risk of *E. coli* O157 at open farms.

6. This paper summarises the evidence given to the committee but focuses in particular on:
   - HSE’s approach to hazard and risk in decision making
   - The approach to sensible risk management
   - Assessment of the risk from *E. coli* O157 in agriculture on farms and at open farms
• How in practice this has been applied in developing the current strategy for controlling the risk of *E. coli* O157 at open farms; and
• The remit of HSE and the LAs in regulating the activity.

7 The regulatory regime applying to *E. coli* O157 places duties on the duty-holders (operators and teachers) under the control of Substances Hazardous to Health Regulations 2002 (as amended), guidance to duty-holders and guidance to inspectors; including guidance on inspection and investigation, the provision of advice, powers to compel improvement, prohibit activity and prosecute and to engage at strategic and national level with trade associations and other stakeholders.

8 In summary, HSE and LACORS believe that:

(i) Since concerns over the risk of *E. coli* O157 to members of the public were first raised in the late 1990s, there has been no evidence to suggest that the regulatory framework is not fit-for-purpose.

(ii) Although individual cases of infection, particularly those involving young children or the elderly, can be very serious for those affected, the incidence of infection at open farms has been and continues to be low.

(iii) Whilst there is fluctuation in the number of cases of *E. coli* O157 confirmed year-on-year, there is no evidence to suggest a substantive increase in the prevalence or incidence of infection in Great Britain. In the context of between 5 and 10 million visitors to open farms each year the risk of infection is low.

(iv) With the exception of the number of confirmed cases of illness, the outbreak at Godstone Farm in August 2009 was not atypical.

(v) In the context of competing priorities for regulatory attention, the risk from *E. coli* O157 infection at open farms can be adequately controlled to levels and in ways which are acceptable to society by applying the existing regulatory regime, and by duty-holders taking the measures set out in AIS23, including effective communication to visitors about the need for good hygiene procedures to be followed.

9 Whilst we believe the regulatory framework and the guidance to be robust and fit-for-purpose – a view confirmed both by the Joint Scottish Executive / Food Standards Agency Task Force (2001) and the Advisory Committee on Dangerous Pathogens (2009) – that is not to say that it cannot be further improved, clarified and supported within that framework. HSE and LACORS have already committed to reviewing the guidance in AIS23 in the light of the findings of the committee.
GLOSSARY OF TERMS

10 Throughout this submission, the term ‘hazard’ is used to describe anything with the potential to cause harm and ‘risk’ to describe the chance or probability of harm occurring (i.e. of an adverse consequence) coupled with its severity; both at an individual level and in terms of numbers of individuals affected by an occurrence. The translation of a hazard into a risk is clearly closely linked to exposure to the potentially harmful agent or activity.

11 To designate a risk as ‘tolerable’ or ‘acceptable’ does not mean that it is regarded as negligible or something to be ignored but, rather, as something that should be kept under review and possibly be reduced still further, depending on circumstances.

12 But in general, set against the benefits accruing from an activity, the harm and the likelihood of it occurring are seen as being acceptable in our society given that it is neither possible nor desirable to eliminate all risk. It follows that there is also a clear implication that some risks cannot be tolerated. Factors to be taken into account when considering tolerability include: the nature of the hazardous agent and the harm it may cause, the particular vulnerability of certain groups e.g. children and the elderly, and the benefits to individuals and society at large from the particular experience or activity which ‘carries’ the hazard.

13 The term ‘duty-holder’ is used generically to refer to any person or corporate body e.g. employer, self-employed person, body corporate or employee upon whom duties are laid under health and safety legislation.

14 The term ‘open farm’ (sometimes referred to as visitor farm attractions or petting farms) is used to describe farm-type premises, the primary purpose of which is leisure/entertainment where visitors are encouraged to have hands-on contact with typical farm animals. Responsibility for enforcing health and safety legislation at open farms falls to the Local Authorities (LAs) in Great Britain (GB) by virtue of the Health & Safety (Enforcing Authority) Regulations 1998. In contrast, the responsibility for enforcing health and safety legislation at working farms (commercial agricultural undertakings) whose primary purpose is agricultural activity but who may allow visitor access occasionally or as an incidental or educational activity falls to the Health and Safety Executive (HSE). There are however, a small number of permanent ‘visitor farm attractions’ on premises, for which HSE is the enforcing authority. In these cases, the attraction will not be a separate business nor will it have been dissociated from the management of the main farm.

15 Open farms can be distinguished from working farms (commercial agricultural undertakings) by a number of features including:

- That the farm attraction is open to the public by direct access
- That the farm attraction is visited on a daily/throughout the year basis
- The provision of fixed facilities for visitors including hand washing
- The provision of animal petting or feeding areas; and
- The provision of rides and play amusements/facilities.

16 It is important to note that the strategy for controlling the risk of infection from zoonoses including Escherichia coli O157 and the regulatory framework under which control is exercised is the same for all visitor farm attractions irrespective of whether they fall to the LAs or HSE for enforcement.

REGULATION

Escherichia coli O157 – Hazard and risk
Escherichia coli strains are ubiquitously found in nature, in the gut of humans and animals and in most cases these organisms rarely cause human disease. Some members of the *E. coli* species, like the O157 strain are pathogenic to humans due to the fact that they can express virulence factors such as toxins. Human infection with *E. coli* O157 can result in severe disease and serious complications can occur especially in young children and the elderly.

Transmission of *E. coli* O157 occurs in the majority of cases by ingestion from sources including animal to human transmission and a number of outbreaks (as defined) involving members of the public have been confirmed over the past 25-30 years by the Health Protection Agency (HPA) and predecessor organisations such as the Public Health Laboratory Service (PHLS). Experience to date suggests that open farms rather than commercial farming present the most significant risk of exposure to and the greatest potential for infection from *E. coli* O157.

Different types of open farms present different levels of risk of exposure to or infection with *E. coli* O157. The degree of microbiological risk is difficult to quantify but is influenced by factors such as:

- The number and types of animals
- The cleanliness and health of the animals
- The degree of contact between people and animals
- The number of visitors
- Personal behaviour and hygiene
- The presence or absence of eating facilities; and
- The adequacy of control measures, particularly hand washing.

**LA Responsibility for regulation open farms**

The responsibility for enforcing health and safety legislation at open farms falls to the LAs in GB by virtue of the Health & Safety (Enforcing Authority) Regulations 1998. Responsibility for enforcing health and safety legislation in activities allocated to the LAs under the regulations generally falls to councils’ environmental health and/or services departments.

Information on the professional qualifications, competences and continuous professional development of Environmental Health Officers (EHOs) is set out at Annex 1. This includes understanding the routes of infection and the risks associated with pathogens including *E. coli* O157.

**The wider public health role of councils**

Councils have a wider role in protecting the public from communicable diseases. This includes investigation of food and waterborne Category A communicable disease in the community and implementation of control measures after discussion with the HPA’s local Health Protection Units and encompasses the recognition of outbreaks and immediate response. The local nature of council EHOs in relation to the premises, as well as their range of regulatory enforcement activities and training, ensures local councils’ environmental health departments are well placed to regulate open farms.

**Guidance**

Concerns about the occupational health risks from *E. coli* O157 first emerged in early 1997 in connection with the occupational risks to farmers and workers. In response, HSE’s Agriculture Industry Advisory Committee (AIAC) published initial advice in its newsletter “Safety Matters”. The advice, directed at all farmers, also targeted those farmers preparing for another season of visits to their farms by the public including school parties. In particular, it referred to concerns about the alleged risks to visitors from *E. coli* O157 and other zoonotic diseases. It focussed on issues such as the importance of risk assessment, the provision and location of washing facilities, the
24 At about the same time, having considered outbreaks on farms in a wider review of the risks from *E. coli* O157 commissioned by the then Ministry of Agriculture, Fisheries and Food (MAFF), the ‘Pennington Group’ report recommended an education/awareness programme for farm workers to raise awareness of the risk and the need for scrupulous personal hygiene. It also recommended that in any further revision of HSE’s guidance targeted at the agriculture industry, reference should be made to *E. coli* O157 as a possible hazard.

25 On further analysis of the available data, HSE concluded the risk was greater to children visiting farms than to workers and that it should therefore direct effort primarily at ‘farms which open to the public’. As a result, Agriculture Information Sheet 23 (rev): ‘Avoiding ill health at open farms – Advice to farmers (with teachers’ supplement’ (AIS23) was published in the spring of 1998.

26 AIS23 was the subject of wide consultation including the Dept for Education and Schools, MAFF Animal Health, the Dept of Health, Professor Hugh Pennington (then Prof of Medical M/biology at Aberdeen), British Veterinary Association, Federation of City Farms and Community Gardens, Farms for Schools and Leisure, Institute of Rural Health, ADAS, National Farm Attraction Network, Pre School Learning Alliance, the Scottish Agricultural College’s Veterinary Centre, PHLS (as was) nationally and locally where they had been involved in the investigation of outbreaks. Drafts were also sent to pressure/lobby groups set up in response to outbreaks in which children had been affected.

27 AIS23 has been reviewed and/or revised on a number of occasions since 1998; most recently in June 2009. The guidance is predicated on the assumption that microbiological hazards, including that of *E. coli* O157, are always liable to be present on farms i.e. that it is not possible to eliminate the potential for exposure. Thus the guidance focuses on adequately controlling the risk.

28 It is aimed at farmers and the operators of open farms and, through the supplement, at teachers or others in charge of visits as a work activity, not at members of the public (visitors). It is important to note, however, that members of the public are generally regarded as having a certain degree of personal responsibility for themselves and their children. In this context it is reasonable for both duty-holders and regulators to rely on the public following basic hygiene advice provided to them when visiting visitor farm attractions, as well as working farms, and maintaining a reasonable level of personal cleanliness, especially if intending to eat.

29 Council environmental health departments have generally been positive about the adequacy of AIS 23 in providing guidance to minimise the risk of infection of *E. coli* O157. More recent feedback has suggested a need for AIS 23 to be broadened in its scope to include further guidance on other premises where there is significant human to animal contact.

30 Questions have similarly been raised about premises which involve animal handling/contact that are outwith the definition of an open farm, or activities that are not traditionally seen as typical for an open farm e.g. Llama trekking and horse riding, as well as secondary areas of contamination such as sand pits/ball parks provided in leisure facilities that may include a petting farm.

**Relevant health and safety legislation**

31 The principal legislation in GB, the Health and Safety at Work etc. Act 1974 (the Act), came into force on 1 April 1975. The Act aims to secure the health, safety and welfare of persons at work and protect the health and safety of others (including members of the public) against risks to their health and safety arising out of or in connection with work activities. It applies to all industrial sectors and work activities throughout GB but with the exception of certain minor provisions, does not apply to Northern Ireland, the Isle of Man or the Channel Isles.
Section 2 of the Act imposes a general duty on employers to their employees and states that “it shall be the duty of every employer to ensure so far as is reasonably practicable, the health safety and welfare at work of all his employees.”

Section 3 of the Act places a general duty on employers and the self-employed to persons other than their employees and states that “It shall be the duty of every employer to conduct his undertaking in such a way as to ensure, so far as is reasonably practicable, that persons not in his employment who may be affected thereby are not thereby exposed to risks to their health and safety.”

The duties under sections 2 and 3 are not absolute, being constrained by the phrase ‘so far as is reasonably practicable’ (see below).

The Act is an enabling Act i.e. it provides for powers to introduce new regulations and to modify, replace and repeal earlier legislation with the aim of bringing all health and safety requirements into a single system of Regulations and Approved Codes of Practice (ACOP).

Regulations supplement the general duties imposed under the Act by laying down more specific requirements and/or implementing the requirements of European Directives. ACOPs give practical guidance about how compliance with the general duties under the Act or the requirements of Regulations might be achieved and have a special legal status. In the event of prosecution for a breach of any requirement of the Act or related Regulations where an ACOP is relevant to the alleged breach, the Code is admissible in evidence. If the guidance in the ACOP has not been followed, it is for the defendant to show that they have satisfactorily complied with the requirement by other means. HSE’s policy on the use of ACOPs has changed over time with increasing reliance being placed on the legislation supported by guidance on good practice.

The Control of Substances Hazardous to Health Regulations 2002 (as amended) [COSHH] both replaces earlier regulations but also implements EC Directive (98/24/EC) Protection of the health and safety of workers from the risks related to chemical agents at work in GB.

COSHH applies to a wide range of substances and preparations with the potential to cause harm including biological agents. The term ‘biological agent’ includes micro-organisms such as bacteria where they have one or more of the harmful properties specified in the definition in regulation 2 i.e. can cause infection allergy, toxicity or otherwise create a hazard to human health. The regulations therefore apply to E. coli O157. Whilst the regulations place duties on employers and the self-employed to their employees and to themselves, it is important to note that where a duty is placed on an employer with respect to his employees, “he shall, so far as is reasonably practicable be under the like duty in respect of any other person, whether at work or not, who may be affected by the work being carried out by the employer.”

In the context of E. coli O157, the regulations place a range of duties on employers and the self-employed including:

- The need to assess risks to health created by work involving substances hazardous to health. (Regulation 6)
- The need to ensure that the “exposure of employees and other persons to substances hazardous to health is either prevented, or where this is not reasonably practicable, adequately controlled.” (Regulation 6); and
- The need to provide information, instruction and training to persons who may be exposed to substances hazardous to their health – including in particular in relation to any hygiene facilities provided and the importance of doing so in accordance with agreed procedures (Regulation 12).

So far as is reasonably practicable
40 The term ‘so far as is reasonably practicable’ appears in both the Act and COSHH and has been the subject of extensive case law and interpretation by the Courts. In effect it requires a balance to be struck between the costs, for example expenditure in time and trouble, to be set against the risk. Accordingly, it is deemed to be reasonably practicable to take measures up to the point where the taking of further measures becomes grossly disproportionate to any residual risk. The greater the risk, the more likely it is that it is reasonable to go to substantial expense, trouble and invention to reduce it. However, if the risk is small, it would not be considered reasonable to go to great expense. The judgement is an objective one based on the risk not on the size or financial position of the duty-holder.

Legal sanctions

41 The Act provides for a number of legal sanctions including prosecution for defined offences and the use of enforcement notices to require people to take action to improve standards or prevent incidents. There are two types of notice for use in different circumstances: prohibition and improvement. Both are intended to achieve effective control of risk, so far as is reasonably practicable. The former is used when the risk is one of serious personal injury.

42 Provisions exist under the Act for appeals against the issue of a notice, for withdrawal and for extension of the time limit specified. Enforcement notices have the force of law and people can be prosecuted for failure to comply with them.

43 Authorised HSE and Local Authority inspectors also have wide ranging powers under s20 of the Act including the right of access to premises, powers of investigation, powers to require the provision of information, to inspect and take copies of documents etc. and are used in line with operational procedures to ensure proper and legal exercise.

DECISION MAKING IN HSE

Enforcement decisions

At an operational level HSE and LA inspectors will sometimes wish to take enforcement action where duty-holders have not met their legal obligations. Inspectors make decisions on enforcement in accordance with the principles set out in the Crown {Prosecution Services’ Code for Crown Prosecutors which can be found at: http://www.cps.gov.uk/publications/code_for_crown_prosecutors/index.html and is endorsed and supported by the HSE Board’s Enforcement Policy. As a means of meeting that Policy, HSE has also developed an Enforcement Management Model (EMM) which helps inspectors decide on what would be appropriate enforcement action in the particular circumstances. The EMM is not intended to fetter inspectors’ discretion when making enforcement decisions or direct enforcement in any particular case. Rather, it seeks to promote consistency and proportionality in enforcement by confirming the parameters that need to be considered and the risk-based criteria against which decisions are made.

45 HSE’s approach to securing the health, safety and welfare of persons at work and for protecting others (including members of the public) against risks to health and safety arising form work activities and of the procedures, protocols and criteria is set out in its publication ‘Reducing


‘Reducing risks, protecting people etc.’ (R2P2) sets out the basis and criteria by which HSE, in complying with its functions, decides upon the degree and form of regulatory control that it believes should be put in place for addressing work-related hazards. It considers the way scientific evidence (or the lack of it) and uncertainties are taken into account and how the balance is struck between the benefits of adopting a measure to avoid or control the risk(s) and its disadvantages i.e. how decisions are taken to protect people’s health and safety by ensuring risks from the workplace are sensibly and proportionately managed. It also allows, in setting the regulatory regime, for the consideration of the wider benefits to individuals and society of the activities that ‘carry’ the hazard; in this case children’s experience of rural life and domestic animals.

The context for decision making

46 Decisions are made in three broad areas:

(i) determining the regulatory regime – where the HSE Board has to advise Ministers on the degree and form of regulation to control the risks from specific types of hazardous activity;

(ii) assuring compliance with the regulatory regime – where HSE must assess whether the duty-holders in control of a hazardous activity are managing the associated risks effectively and, in particular, have done enough to comply with the law; and

(iii) determining the balance of regulatory activity between the many and varied types of hazardous activity in workplaces.

Guiding principles

47 Decision-making is guided by a set of well established ‘guiding principles’ to maintain a focus on sensible risk management i.e.:

- Good regulation
- Responsibility; ensuring that the ‘risk creators' bear responsibility for controlling those risks, as appropriate.
- Sound evidence; whereby decisions are founded on scientific, social scientific, statistical, economic, risk and evaluation evidence capable of withstanding critical examination;
- The precautionary principle; whereby decision-making is biased on the side of ensuring health and safety. However the achievement of zero risk is not a practical reality nor is it often desirable, given the benefits at stake; and
- Consultation with stakeholders

but ultimately, it is for the HSE Board to take, or propose to Ministers, final decisions irrespective of whether consensus can be reached.

Assessing the risk

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2 Principles of good regulation, available from the Better Regulation Task Force, Room 72q/2, Horse Guards Road, London SW1P 3AL
48 Given that the pursuit of zero risk or absolute safety is not realistic, risk assessment is central to defining and characterising the issue. Consideration needs to be given to a range of factors including the likelihood/level of harm to individuals, the population at risk and, where appropriate to groups of people, to societal concerns associated with the activity, and uncertainty. Thus, when HSE considers introducing/amending a regulatory regime, or judges whether a duty-holder has done enough in a particular case, it has to decide when ‘safe’ is safe enough and to do this in the context of ‘reasonable practicability’. However, there is a good deal of precedent and good practice that can be drawn on.

49 The majority of decisions can be made straightforwardly by reference to existing sources of relevant good practice and good engineering/safety principles. These are authoritative, representing as they do a consensus between stakeholders as to what is required to reduce risk as low as is reasonably practicable. The terms ‘so far as is reasonably practicable’ and ‘as low as is reasonably practicable’ are synonymous and often used interchangeably.

50 In the absence of sources of relevant good practice or where they only provide part of the answer, it is necessary to return to ‘first principles’ of risk reduction which involve making trade-offs between:

(i) costs and benefits - comparing the nature and degree of the benefits from the proposed risk reduction measures with their cost; and

(ii) the ‘tolerability’ of the risk – i.e. what level of risk would society consider ought to be achieved bearing in mind the benefits from the activity in question which, necessarily, involves taking some risk.

The tolerability and acceptability of risk

51 Deciding what the level of acceptable risk ought to be (as opposed to what the level of risk is), implies a value judgement; comparing a given risk against some risk criterion. HSE looks to society’s values to determine whether a given risk is tolerable. At one extreme, some risks are so high they would ordinarily be viewed as unacceptable whatever the benefits; at other, some risks are too small to be of further concern. In between are risks at a level where they are of concern but can be tolerated provided that they are kept as low as is reasonably practicable by sensible and effective risk management.

52 Adopting a framework around the tolerability of risk provides HSE with a basis for making judgements and for wider dialogue, discussion and negotiation with stakeholders and duty-holders on control strategies and standards of protection to be applied. It also provides a guide as to what more, if anything, ought to be done as regards further risk control at a strategic or operational level.

53 For reasons set out in following sections, HSE believes that on the basis of current information, experience and assessment, the risk from *E. coli* O157 at open farms is generally acceptable and tolerable. Exposure to the hazardous agent can be kept to a low level by taking the measures set out in AIS23; the cultural and educational benefits from visitor attractions and the opportunities for contact with animals are valued by society; and the control measures themselves are seen as reasonable and acceptable by the visiting public.

Alternatives to a risk assessment model

54 The foregoing discussion assumes the framing of occupational health and safety issues in terms of ‘risk’. This is a productive model to use because there exist well-established methods for estimating risk, and a risk-based approach to decision-making can be systematic and analytical,
enabling a proportionate and targeted response regulatory response based on the degree of risk determined.

55 Approaches based solely on hazard assessment e.g. on worst case (rather than credible) scenarios or solely on the propensity to do harm are inadequate as they take little or no account of the likelihood of the harm occurring in practical situations.

ASSESSING THE RISK from E. coli O157

56 Extensive guidance on risk assessment and management has been published by HSE and by a number of its independent expert Advisory Committees; including the Advisory Committee on Dangerous Pathogens (ACDP). By way of example the process of assessing and managing the risks from biological agents is described in Part 2 of the ACDP publication ‘Biological Agents: managing the risks in laboratories and healthcare premises at: http://www.hse.gov.uk/biosafety/biolagents.pdf and can be summarised in a number of stages:

• Stage 1: Consideration of the infection hazards associated with the organism. This will include a range of factors, such as pathogenicity, epidemiological data and medical data. These are discussed in more detail in Appendix One;
• Stage 2: Consideration of the nature of the work (and exposure to the organism); and
• Stage 3: Evaluation of the risks and selection of control measure (including provision of information and training)

subject at each stage to ongoing review and revision.

CONTROLLING THE RISK FROM E. coli O157 Laboratories

57 Based upon the above, it is clear that laboratory work with pathogens like E. coli O157 requires a combination of stringent control measures to protect staff as well as members of the public. This is because the procedures carried out in the laboratory put staff at a much higher risk of infection compared to the risk of acquiring infection in the community. For example laboratory procedures often result in the propagation and concentration of organisms and can include the handling of large volume of solutions containing extremely high numbers of organisms compared to the numbers likely to be present in a natural environment (e.g. in a farm).

58 Common laboratory procedures like centrifugation and pipetting of concentrated bacterial suspensions can also result in the formation of splashes, droplets and aerosols, containing high numbers of bacteria which exceed the classical infectious dose of a particular organism. Laboratory work also generates liquid or solid waste that also contains very high numbers of live bacteria which again require appropriate handling to prevent their release to the environment. These common work practices put laboratory staff at a high risk if routes of exposure are not properly controlled. The risk is also increased by the fact that laboratory staff are handling these agents on a regular basis as part of their everyday work, with repeated potential for exposure and consequent infection.

59 The necessity of tight control measures is reflected in the legislation, with the COSHH Regulations, laying out specific requirements for the deliberate handling of biological agents such as E. coli O157. According to COSHH pathogenic organisms are classified to a Hazard Group (HG) 1 to 4 based on their ability to cause disease, the availability of treatment and the possibility of human to human transmission. As a result of this classification system, ACDP classified E. coli O157 as a HG3 micro-organism. Therefore, COSHH specifically recognises the high risk posed to
laboratory staff by the inclusion of Schedule 3. This provides for stringent and proportionate control measures which have been found to be necessary in order to mitigate an increased risk to laboratory workers. Measures include a combination of engineering controls, laboratory space requirements and tightly controlled laboratory management measures.

Visitor farm attractions

60 In comparison, outside the laboratory environment, protection against *E. coli* O157 can be relatively simple and is still covered by COSHH. In this case, the more relevant guidance is the ACDP’s guidance document “Infection at work: Controlling the risks - A guide for employers and the self employed on identifying, assessing and controlling the risks of infection in the workplace” [http://www.hse.gov.uk/pubns/infection.pdf](http://www.hse.gov.uk/pubns/infection.pdf). This provides practical information on controlling micro biological risk from incidental exposure and emphasises the need for adequate risk assessment, breaking the chain of infection and the use of good hygiene practices.

61 Transmission of *E coli* O157 occurs in the majority of cases by ingestion - hand/mouth contact after handling/touching contaminated animal material and consumption of contaminated meat or other food products. Provision of good hygiene measures such as soap, warm running water and adequate means of hand drying significantly reduce the likelihood of infection with this organism and other micro-organisms that can be transmitted by the oral route. In the open farm environment, additional control measures also include segregation of food areas from animal handling areas, the exclusion of visitors from non-contact areas and ensuring that contact areas are kept free from build up of faeces etc. The application of these relatively simple but effective control measures have been found to be largely successful in limiting the incidental exposure of visitors to *E. coli* O157.

62 HSE is aware of a small number of sporadic cases of infection and in some cases of confirmed outbreaks (two or more cases) associated with open farms reported in most years. Although we are not automatically informed of every case or outbreak, such are the working relationships between the HPA, LAs and HSE that we believe we would be reliably informed about significant cases.

63 There is, therefore, no clear indication as to the number of cases connected with farms or contact with farm animals. Thus there is no evidence to date of which HSE is aware which would suggest a widespread problem that would necessitate a significant change in our advice or enforcement strategy.

64 We also believe it is important that members of the public be reminded that they have personal responsibility for following the good hygiene advice provided to them when visiting visitor farm attractions, as well as working farms. Though it is not directly the responsibility of HSE, there does not appear to be any authoritative, published public health guidance on the hazards of *E. coli* O157 which operators could handout/make available during visits e.g. highlighting some of the practical issues such as nail biting, use of dummies, sucking thumbs etc.

65 More detailed consideration of the factors to be considered in assessing the risk of *E. coli* O157 at open farms is set out at Annex 2.

SENSIBLE RISK MANAGEMENT

66 Sensible risk management is about ensuring that workers and the public are properly protected but HSE does not seek to eliminate all risk because this is neither achievable, is often not desirable when set against the benefits associated with a given activity, and in any event is not required by current health and safety legislation.
Against this background HSE is actively engaged in debunking the myths that have emerged in recent years, characterised by the so called ‘elf and safety’ culture, by promoting awareness and education about health and safety risks and encouraging duty-holders and members of the public to make sensible and proportionate judgements and to take reasonably practicable precautions.

The approach described above for assessing and controlling the risks for E. coli O157 is in accordance with this approach – and demonstrates the need to consider not only the inherent hazard, but the full range of other factors that contribute to the magnitude of the resulting risk. So the stringent control measures vital within the laboratory setting would be inappropriate and disproportionate for the farm or open farm setting. Moreover it is important that control measures fall within the bounds of what may be deemed to be “culturally acceptable precautions”. By way of example, it would be unacceptable and inappropriate to seek to impose what could easily be considered by members of the public to be oppressive supervision by staff at washing facilities.

CONCLUSION

Understanding and assessment of hazard and risk underpins HSE’s approach to putting in place an appropriate regulatory regime, prioritising activities and allocating its finite resources. It is responsible for wide ranging risks including conventional health and safety risks in traditional industries such as agriculture, construction, commercial and consumer services, manufacturing, transport and the utilities through the major hazards sectors such as chemical manufacturing and the UK Offshore sector to the nuclear power industry.

Biological hazards are present in many of the industries for which we are responsible and the strategies which have emerged for dealing with them have necessarily been evidence based.

Over the past 30 years, knowledge and understanding of the hazards associated with E. coli O157 has improved. The potential for and the incidence of illness is better understood but determining the risk remains difficult. Allowing for possible under reporting, there are approximately 1000 confirmed cases of illness in each year; a small but unspecified proportion of which are diagnosed as haemolytic uraemic syndrome (HUS) or thrombotic thrombocytopenic purpura (TTP). Of the cases reported annually, 5-10 % are thought to be the result of animal to human transmission but the number of these associated with farming activities or more specifically, open farms, is unknown. These figures need to be set against the context of a minimum of 5 million visits by members of the public visit; but this figure is highly conservative and may more realistically be closer to 10 million.

It is also important to bear in mind the many other situations and every-day settings in which members of the public may come into contact with the organism – for instance, butchers shops, livery and other riding establishments, domestic pets, accessing countryside recently occupied by animals etc. – as these are relevant to the assessment and tolerability of the risk and sensible risk management.

With the exception of the number of confirmed cases of illness, neither HSE nor LACORS are aware of any features of the outbreak at Godstone Farm in August 2009 which would suggest it is atypical.

Accordingly HSE concludes that the risk from E. coli O157 at open farms can be can be adequately controlled by taking the measures set out in AIS23. LACORS view as to the evidence of substantive regulatory failure at Godstone Farm in the summer of 2009 can be found at Annex 3.

Pending the outcomes and any recommendations of the Griffin Investigation Committee, we believe the guidance in AIS23 has been shown to be robust and fit-for-purpose since 1998, and that the basic hygiene advice - the key to avoiding infection from animals - is, and is likely to remain, sound.
76 Though it is not the responsibility of HSE, we also believe that simple guidance on hygiene measures should be produced and provided to members of the public visiting farm attractions.
THE COMPETENCE AND CONTINUOUS PROFESSIONAL DEVELOPMENT OF LOCAL AUTHORITY / ENVIRONMENTAL HEALTH OFFICERS

The competence both of HSE inspectors and local authority officers including Environmental Health Officers (EHOs) is determined in Section 18 of the Health and Safety at Work etc. Act 1974 which places a duty on the HSE and LAs to make adequate arrangements for enforcement.

Section 18 toolkits have been developed to help HSE and the LAs comply with their duty and which act as basic checklists. They also provide links to additional supporting information. The toolkits cover various duties set out in section 18 including the duty to operate systems to train, appoint, authorise, monitor, and maintain a competent inspectorate.

The Regulatory Competence Framework is the set of competencies expected of a fully qualified HSE inspector or local authority health and safety inspector, authorised to carry out health and safety duties. A web-based Regulators’ Development Needs Analysis (RDNA) Tool has also been developed reflecting the framework and the additional skills and knowledge requirements of specific groups of regulatory staff in HSE and LAs. The RDNA is used by staff and managers to help identify, prioritise and address development needs which can be aggregated and collated periodically to provide a broad picture of training priorities to help inform learning and development planning.

The normal academic requirement for an environmental health practitioner (EHP) (in England) is a degree accredited by the Chartered Institute of Environmental Health (CIEH), with routes available at both undergraduate and postgraduate levels. Academic study is reinforced by work-based learning and is followed by professional examinations. Qualifying as an EHP provides underpinning knowledge and skills in all aspects of environmental health practice, including Food Safety; Health & Safety at Work; Environmental Protection; Housing; and Public Health.

The CIEH can provide further detailed information regarding EHPs. With regard to health and safety, the main focus is on practitioners securing sensible risk management of health and safety, the improvement of health, safety and welfare standards in businesses and a higher profile for health and safety. Public health will include understanding the risks and pathways of all main pathogens including E. coli O157.
FACTORS TO BE CONSIDERED IN ASSESSING THE RISK OF E. coli O157 AT OPEN FARMS

Pathogenicity

The pathogenicity of E. coli O157 is summarised on the HPA website as follows:

- E. coli are common bacteria which live in the intestines of warm blooded animals. Certain forms (strains) are normally found in the intestine of healthy people and animals without causing any ill effects. Some strains are known to cause illness in people. Among these is a group of bacteria which are known as Vero cytotoxin-producing E. coli or VTEC.[This group includes E. coli O157]
- VTEC can cause illness ranging from mild through severe bloody diarrhoea (mostly without fever) to haemolytic uraemic syndrome (HUS) and thrombotic thrombocytopaenic purpura (TTP) affecting the blood, kidneys and in severe cases the central nervous system.
- The most important property of these strains is the production of one or more potent toxins important in the development of illness
- VTEC are relatively rare as the cause of infectious gastro-enteritis in England and Wales; however the disease can be fatal, particularly in infants, young children and the elderly

Epidemiological data

Epidemiological data comprising the annual total of laboratory confirmed cases of E coli VTEC (predominantly O157 human infection) in England and Wales is published by the HPA on its website at: http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1249113624846 which indicates that from 1999-2008 (provisional) the number of cases fluctuated from a low of 595 to a high of 1048 cases p.a. Data for Scotland suggests there were between ~150 and ~300 faecal positive isolates p.a. over the same ten year period (Source: NHS National Services Scotland). The data for England, Scotland and Wales is not presented consistently but further analysis e.g. by region and on a month-by-month basis is available.

HSE is not aware of any published data on the number of confirmed cases (sporadic or as part of an outbreak) attributable to animal to human transmission; but is aware of suggestions that possibly 5-10% of the annual number of confirmed cases may be associated with animal to human transmission.

Outbreak data (i.e. where two or more cases of infection are confirmed) published by the HPA indicates that there were 195 outbreaks of E. coli O157 in England and Wales between 1992 and 2008. Of these, 27 (14%) involving 131 people were the result of contact with animals. HPA advises that determining the route of transmission for sporadic cases is much more difficult and that accordingly it relies on outbreak data.

Notwithstanding, it remains unclear what proportion of the cases is associated with infection at open farms. We are also aware of suspicion that there may be some under-reporting of cases; possibly associated with mild forms of illness in members of the public who do not present at GP surgeries and from whom samples are not taken for diagnosis.

The available data suggests there has historically been between ~820 and ~1375 confirmed cases of E. coli O157 (sporadic and outbreaks) from all known sources in GB each year over the past decade. Of these possibly 5-10% of cases are thought to be the result of animal to human transmission but it is not known how many of these are the result of infection at open farms. Whilst
there is noticeable fluctuation in the number of cases year-on-year, HSE is not aware of any
evidence of a substantive increase in the prevalence or incidence of infection in GB.

*E. coli* O157 infections are not notifiable under regulation 5 and Schedule 3 of the Reporting of
Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995. Notwithstanding, 6
or 7 reports of *E. coli* O157 infections at HSE regulated premises have been notified to HSE since
April 2005; out of ~1 million RIDDOR reports. None of these were connected with farms or farming
activity.

**The infectious dose**

The infectious dose of *E. coli* O157 appears to be very low, probably less than 100 organisms and
possibly as low as 10. People can become infected through contact with the faeces of infected
animals, by passing the organism from person to person, or by the consumption of contaminated
foods or water. (Source: Joint SE/FSA Task Force on *E. coli* O157 [June 2001]).

**Routes of transmission and communicability**

The principal routes by which humans can be exposed to the organism are:

- Direct contact with animals or their faeces (or laboratory specimens)
- Occupationally e.g. working with animals or in settings in which animals are regularly present
- The recreational use of land contaminated with *E. coli* O157 by grazing or stockholding
  animals
- Water i.e. drinking water from a contaminated source
- Food i.e. eating contaminated foodstuffs
- Person-to-person i.e. spread from an infected person to another in a family household or
  institution such as a nursery or health care facility.

Given the low infectious dose it would appear that the organism is easily ingested and can be
readily spread between humans in the absence of good standards of personal hygiene.

**Post-exposure prophylaxis**

There is no known post-exposure prophylaxis.

**Environmental stability**

The environmental stability of the organism has been a matter of debate and is important not least
in the context of visiting open farms but also of access to and the recreational use of agricultural
land. Maule (2000) reported survival of up to 130 days in soil, 50 days in cattle faeces, <27 days in
river water and <10 days in cattle slurry. Air dried on stainless steel and plastic surfaces the
organism was reported as surviving more than 60 days.

The outbreak at the New Deer Millenium Camp in Aberdeenshire (2001) provided additional useful
information, facilitated analysis of decay rates in soil and resulted in the revision of guidance and
recommended further research amongst other things into the survival of the organism in the
environment. HSE is not aware of further research having been carried out and continues to
promote the Joint task Force recommendations regarding the recreational use of agricultural land
i.e. that in order to reduce the risk, where fields are to be used for recreational purposes animals
should be removed at least three weeks prior to use and during the event.

**Severity**

As previously indicated VTEC can cause illness in humans ranging from mild through severe
bloody diarrhoea (mostly without fever) to haemolytic uraemic syndrome (HUS) and thrombotic
thrombocytopenic purpura (TTP) affecting the blood, kidneys and in severe cases the central
nervous system. Whilst VTEC are relatively rare as the cause of infectious gastro-enteritis, the disease can be fatal, particularly in infants, young children and the elderly. There have been a number of well publicised outbreaks resulting in serious infection and one or more cases of HUS over the years including Bowmans Farm (1997) and Godstone Farm (2009). HSE is not aware of any cases of TTP or of any separate data on the incidence of HUS or TTP published by the HPA/Department of Health or the equivalent Scottish health agencies or departments. Although the majority of reported cases have been less severe, they have nonetheless been very distressing for the children and the parents involved.

The population at risk – farm attractions

It is difficult to estimate the population at risk because the number of open farms in GB is unknown, neither is there any accurate data as to visitor numbers.

The National Farms Attraction Network (NFAN), a voluntary registration scheme, has approximately 400 members, but not all open farms are registered with it. In addition many working farms are visited by organised school parties but whilst the visits are planned they are occasional activities. Other farms participate in various educational schemes and/or open for specific seasonal events e.g. during lambing or as part of the national Open Farm Sunday scheme; but these are not open farms as the visits by members of the public (including children) are incidental to the main (commercial) farm business.

Approximately 1000 working farms in England and Wales participate in the Learning outside the classroom (Lotc) scheme, administered by Farming and Countryside Education (FACE) through the Countryside Education Visits Accreditation Scheme (CEVAS). CEVAS has identified a further 700 farms that receive children and other visitors as part of the Government programme to ensure learning outside the classroom. Farm visits are a priority under these educational programmes and are not primarily intended to promote contact between the children and animals; though this may take place on some farms and at certain times of the year, e.g. during lambing. The Lotc farms have been through a formalised process to participate in the scheme and should be well aware of the controls required. To indicate the scale of these activities, it is estimated that approximately 1 million children visited a farm under one or other of these schemes during the Year of Food and Farming 2007/08; the last year for which figures are currently available.

Many other working farms in England and Wales allow access to visitors for various activities; though these do not necessarily involve direct contact with animals. By way of example, 425 farms received 140,000 visitors in a single day as part of the Open Farms Sunday scheme in June 2009.

Similar schemes operate in Scotland and are administered by the Royal Highland Education Trust (RHET).

During the summer school holiday period, it is reported that a single open farm (Godstone Farm) attracted between 1500 and 2000 visitors daily. On that basis, estimates of the number of visits by members of the public to open farms in GB ranging from 5 to 10,000,000 p.a. are credible and the true figure is probably closer to the upper figure.
Tandridge District Council, the responsible enforcing authority, implemented a range of measures following the outbreak of *E. coli* O157 at Godstone Farm to further minimise risk. Whilst the Council served four Improvement Notices on Godstone Farm, to the best of our knowledge there is no evidence to suggest any significant regulatory failure at the premises.

The Council has however suggested a number of factors that may have been relevant to the virulence of the outbreak and should be considered in any future review of AIS 23: including:

- Farm practices – use of deep bedding?
- Warm Weather – ideal for breeding organism-warm nights-virulence?
- Visits duration longer in school holidays – higher exposure risk?
- Number of visitors – pressure on animals (~2000 per day in August)
- Numbers also putting pressure on facilities
- Visitor behaviour – can it be managed? Supervision in leisure settings.
- Visitor awareness – public knowledge?

with the possible exception of the depth and frequency of changing animal bedding, the above are generic factors applicable to all open farms. It is understood there were a number of possible sources of infection at Godstone Farm but no evidence to suggest that conditions were atypical when considered against similar premises. On the basis of the available evidence, there is no clear reason as to why the number of confirmed cases associated with the farm was so high.
Joint letter issued from LACORS, HSE and HPA.

Understanding and managing the risks from *E. coli* O157 in an open farm context

Following the outbreak of *E. coli* O157 infection associated with Godstone animal petting farm last summer, an independent investigation was established by the Health Protection Agency into the causes and implications. Although the investigation committee, led by Professor George Griffin, has not yet finalised its considerations and report, the agencies agree that it is timely to share important points emerging from its work, bearing in mind the upcoming Easter holidays and the start of the main visiting season.

‘Open farms’ (or ‘petting farms’) provide a valuable recreational and educational experience for many people. As with many activities in life, visits to open farms can never be considered free from all risk – such an environment is not attainable – and one of the risks which needs to be understood by farm operators and their staff, regulators and the visiting public alike is that of infection caused by the bacterium, *E. coli* O157.

The assumption must be that all ruminant animals carry *E. coli* O157 and excrete it in their faeces. *E. coli* O157 is a very infectious disease. Swallowing a small number of the bacteria can cause illness. While relatively rare in relation to the millions of visits paid to open farms each year, there must be no complacency as *E. coli* O157 can cause very severe complications in all age groups but especially in children under 5. This advice is intended to help with sensibly managing the risk to visitors, especially children, while retaining the enjoyment.

The standards which the operators of open farms, including ‘petting farms’ are expected to meet are set down in an information sheet published by HSE – this is [http://www.hse.gov.uk/pubns/ais23.pdf](http://www.hse.gov.uk/pubns/ais23.pdf) ‘Avoiding ill health at open farms – advice to farmers’. This guidance, which has a supplement aimed at teachers who may take groups of children on organised outings to such farms, is used by inspectors from the Local Authorities and HSE to judge compliance with the relevant health and safety legislation.

The guidance describes how to minimise the risk to visitors from being contaminated and accidentally ingesting the bacteria. It covers aspects such as livestock management, the importance of farm layout, the need for cleanliness of contact areas, keeping eating and picnic facilities away from animal contact areas, good visitor information and signage, the need for visitor supervision, especially in contact areas, by trained staff and the importance of washing facilities - their location, attractiveness, capacity, cleanliness, maintenance and use.

The need to strengthen the guidance in any areas will be reviewed in the light of Professor Griffin’s report when it is published. Meanwhile, the emerging findings from the investigation committee reinforce the importance of these precautions, and highlight the importance of three areas of risk management. In particular in the light of the Godstone outbreak, they and we wish to emphasise:

1. People should not have contact with animal faeces – this is the committee’s strongest recommendation. There is a need to keep all areas accessible by the public clean
and free of faecal material, including preventing faecal seepage and runoff from pens. The public should not have access to non-visitor areas, such as manure heaps. Other parts of the farm such as play areas, sandpits and picnic areas should especially be kept clean and free from contamination.

2. Visitors may have little appreciation of the hazard posed by E. coli O157 or on how to avoid infection. It is therefore important that everyone on starting a visit to an open farm, particularly those with children, is made aware that:
   - E. coli O157 should be assumed to be present in the faeces of all ruminant animals and on the animals themselves and on many surfaces.
   - A very small dose can cause infection.
   - The serious nature of the illness E. coli can cause, especially in children under five.
   - Handwashing with soap and water is the most effective method of reducing risk of infection - gels and wipes should not be used as an alternative to hand washing.
   - Handwashing should take place after any contact with animals and when moving from any animal areas to other areas including non-animal play areas and places where food is consumed such as picnic areas, cafes and similar.
   - Any personal items of visitors which may have had contact with animals or have fallen on the floor and possibly contaminated should be cleaned thoroughly before being handled, particularly by children.

3. Supervision of children’s handwashing is essential. Young children cannot be expected to understand and follow the guidance, so the responsibilities for adult supervision must be clear.

Working with the Department of Health we are also promoting some straightforward public health message about E. coli O157, and attach these here for your information.

Public Health Messages

- You should assume that all cattle, sheep and goats are infected with E. coli O157 bacteria, even if the animals look clean and healthy.
- You can therefore pick up E. coli O157 by touching animals, fences and other surfaces and accidentally transfer the bacteria to your mouth.
- Children, especially those under 5, are particularly vulnerable to E. coli O157 infection and are more likely to suffer very serious illness as a result.
- Washing your hands thoroughly with soap and water will reduce the chance of infection.
- Remember to wash your hands after touching an animal, before eating or drinking, and after removing clothing and shoes worn on the farm.
- Children should be closely supervised to ensure that they wash their hands properly after contact with animals.

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