FOREWORD

Statement from the Chair of the Independent Investigation

The Godstone Farm *Escherichia coli* O157 outbreak in August/September 2009 was a failure of health protection and exposed a complex regulatory structure. Some 93 cases, the vast majority of whom were children, were affected by this devastating disease causing great pain, the requirement for intensive invasive medical support and immense family disruption. Of the 93 cases, 17 (all of whom were children) suffered the most severe complication of this infection, namely haemolytic uraemic syndrome (HUS), requiring intensive hospital renal and haematological support. Fortunately none of these children died, but they all suffered very severe disease.

The purpose of this Report is to analyse the handling of the outbreak and the regulatory framework surrounding prevention and response. The Investigation Committee is committed to the belief that the Report should be analysed carefully by the relevant bodies with a view to reducing risk to a minimal acceptable level and providing a structure which will reduce the risk of future outbreaks. The Open Farm industry needs help to restructure its operations and eventually assume more of a self-regulatory role alongside a strengthened regulatory scheme which will provide a basis for public confidence. The Committee is pleased that as a result of this investigation, the National Farm Attractions Network has already made progress towards developing an accreditation scheme for Open Farms. We urge all interested parties to give this initiative their full support in tandem with the strengthening of the regulatory system we have also recommended.

The Committee is fully aware that implementation of the recommendations in this Report will call for leadership, co-operation and clear thought between relevant agencies. We strongly advocate such an approach to safeguard public health.

Professor George Griffin

Chair of the *E. coli* O157 Independent Investigation

June 2010

The Purpose of the Independent Investigation

In August and September 2009 an outbreak of *E. coli* O157 led to severe illness in a number of visitors to Godstone Farm in Surrey. The Health Protection Agency established an independent investigation of the outbreak, the factors that contributed to it and its subsequent handling. This was announced on 15 September 2009.

The purpose of the investigation was to make recommendations to reduce the risk of those who visit Open Farms contracting *E. coli* O157 and to improve the health protection response to future outbreaks of *E. coli* O157 infection. In the context of the investigation, an 'Open' Farm is defined as one that invites members of the public to visit and facilitates direct contact with the animals.

Terms of Reference for the Investigation

The Terms of Reference for the Independent Investigation agreed by the Board of the Health Protection Agency were to look at the factors which contributed to the cause of the Godstone Farm outbreak and to review its subsequent handling by the Health Protection Agency and others. This included but was not limited to:

a) The characteristics of *E. coli* O157 and factors affecting its transmission from animals to humans in the context of Open Farms

b) The standards which apply to the operation of Open Farms (including relevant guidance and how this was made operational)

c) The operation of Godstone Farm with reference to these standards

d) The regulatory oversight of Open Farms in general and Godstone Farm in particular

e) The responses to the outbreak from all those involved following the identification of illness in people who had visited Godstone Farm (including the advice given by the Health Protection Agency)

f) The responses to other outbreaks of *E. coli* O157 which have been linked to similar Open Farm facilities

The Investigation would consider any lessons to be learned from the experiences and best practice of the devolved administrations, and relevant evidence from public authorities in other countries.

The Investigation would also ensure that the families of those affected by the outbreak were invited to have an input.

The Report of the Investigation would be presented to the Board of the Health Protection Agency and, once accepted, would be made public.

Pending the final report, any interim recommendations requiring urgent action to protect public health would be published as soon as possible.

The Investigation Team

Professor George Griffin was appointed Chair of the Independent Investigation by Mr Justin McCracken (the Health Protection Agency Chief Executive) following discussion with the Chief Medical Officer for England, Professor Sir Liam Donaldson. Professor Griffin is Professor of Infectious Diseases and Medicine at St George's, University of London, a practising infectious diseases Clinician and Chair of the Advisory Committee on Dangerous Pathogens.

Professor Griffin appointed five other members of the Investigation Committee on the basis of their area of expertise. See **Appendix 1** for Committee membership. The Committee was supported by a full time scientific secretariat, a committee administrator and a legal advisor.

The Conduct of the Investigation

The Terms of Reference for the Investigation were established and a protocol for the Investigation Committee to gather evidence was agreed at the initial meetings of the Committee. Organisations or key individuals provided evidence or expert information. The Investigation also considered lessons to be learned from the practice of the devolved administrations, and relevant evidence from public authorities in other countries.

Relevant organisations involved in the outbreak were invited to specific meetings of the Investigation Committee and their representatives were briefed by the scientific secretariat. In some cases, the presenters provided supplementary documentation for the Committee. Notes from the meetings were agreed with the presenters for factual accuracy. The notes included a summary, the key messages and the points discussed with the Committee. The Committee also visited Godstone Farm Park and two other Open Farms. In addition, Professor Griffin, one member of the Committee and the scientific secretariat heard the views and concerns of some of the families affected by the outbreak. Each meeting was noted and these notes anonymised and then checked with the individual family for factual accuracy. Interim recommendations were provided to the Health Protection Agency in March 2010 and the draft Report of the Investigation together with recommendations was presented to the HPA Board on 26 May 2010.

Contributors to the Investigation

A list of organisations and individual experts who contributed to the Investigation is included in **Appendix 2**.

The Independent Investigation Website

The body of evidence relevant to the investigation, including source documents, can be accessed through the Investigation website www.griffininvestigation.org.uk

Copies of the Report can be downloaded from the website.

EXECUTIVE SUMMARY

Introduction

In August and September 2009 an outbreak of *Escherichia coli* O157 led to severe illness in a number of visitors to Godstone Farm in Surrey. The Health Protection Agency (HPA) established an independent investigation of the outbreak, the factors that contributed to it and its subsequent handling. The purpose of the investigation was to analyse the events of the outbreak, make recommendations to reduce the risk of those who visit Open Farms contracting *E. coli* O157 and to improve the health protection response to future outbreaks of this infection.

Escherichia coli O157

E. coli O157 infection is relatively uncommon but, because the illness it causes (bloody diarrhoea which can be complicated by haemolytic uraemic syndrome [HUS]) can be severe or fatal, it remains a serious public health issue.

E. coli O157 is a highly virulent organism; it can survive for long periods of time in the environment; ingesting just a few organisms, possibly between 10 and 100, can cause illness in humans; young children (particularly under five years of age) and older people (particularly over 75 years of age) are very vulnerable; the illness can be very serious and is sometimes fatal; after recovery from illness some people are left with permanent kidney or brain damage. There is currently no recognised, specific treatment other than good supportive care, but there are opportunities for new treatments.

E. coli O157 is commonly carried by animals and ruminants are considered the major reservoir of infection, although the organism has been found in a wide variety of animals. *E. coli* O157 causes no clinical signs of infection in animals, but may colonise the rectum of cattle and these colonised animals greatly increase the potential for spread of *E. coli* O157 in their faeces. There are no established on-farm control options, so all ruminants need to be considered as infected by *E. coli* O157.

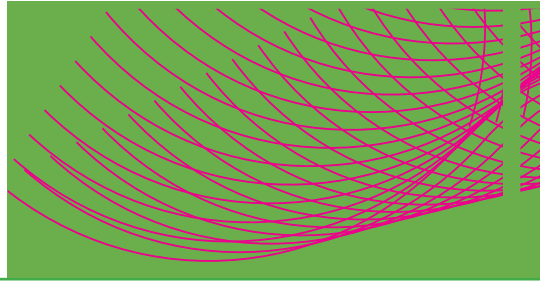
A variety of sources have been identified for *E. coli* O157 outbreaks in humans, including foodborne, waterborne, person-to-person spread and animal contact. The common link is that the organism is excreted in animal or human faeces and gains access to susceptible humans through ingestion. Agricultural and environmental exposures, particularly contact with ruminants, are well recognised causes of *E. coli* O157 human infections, both as outbreaks and sporadic cases.

Standard Public Health Procedures for *E. coli* O157

Each report of a presumptive *E. coli* O157 infection should be actively investigated and the risk of onward spread assessed. Enquiries relating to contact with animals or animal faeces should always be made. A general outbreak of *E. coli* O157 may be defined as two or more cases from separate households linked to a common source.

Early recognition of an outbreak requires careful investigation and documentation of individual cases, co-ordination and exchange of information between Health Protection Units (HPUs) and Local Authorities (LAs), and an efficient and sensitive national surveillance system. In outbreaks of a zoonotic infection such as *E. coli* O157, the HPA has overall responsibility for managing the outbreak. However, LAs are responsible for enforcement actions at Open Farms.

The specific objectives in the preliminary phase of an outbreak investigation are: to confirm the outbreak or incident is real; to quickly describe the nature and extent of the outbreak; to ensure



immediate steps are taken to identify those who are ill or at risk; to ensure those ill or known to be exposed receive appropriate treatment and care; to control the source and contain the infection; to decide whether the incident requires special arrangements for investigation and management; and to alert those who need to know at local, regional or national levels.

All outbreaks warrant a thorough epidemiological description and analysis.

Open Farms

The types of venue where the public may have animal contact are many and varied. Open Farm enterprises may be large scale and include attractions where animal contact is only one part of the visit. The age profile of visitors with an interest in animal contact is predominantly the under-10s and their parents or carers. There is no national list of Open Farms, but evidence gathered during our investigations suggests that there are several hundred Open Farm enterprises in the UK and that some have visitor numbers in excess of 200,000 per annum.

A variety of non-regulatory organisations are involved with the Open Farm sector. No 'badge' for Open Farms exists to provide the public with reassurance of their adherence to safety standards. Farming and Countryside Education (FACE) is a registered charity that has developed curriculum resources and encourages school visits to farms and other rural locations. The Countryside Educational Visits Accreditation Scheme (CEVAS) is run by FACE and exists for the accreditation of educational visits to farms.

Working agricultural enterprises participate in occasional public events, such as Open Farm Sunday, organised by Linking Environment and Farming (LEAF). LEAF and the National Farmers' Union (NFU) Business Guide Reference 058 offer health and safety advice for farms on open days.

The Regulatory Framework for Open Farms

The legal and institutional framework for protection of human health and the prevention of disease outbreaks in Great Britain is complex. The prevention of an outbreak involves different laws and regulatory authorities from those that are involved in the control of an outbreak of disease.

Separate regulatory frameworks have been set up by Parliament for animal health (including zoonoses), public health, food safety and occupational health and safety. Each regime is the responsibility of a different Government Department, with separate agencies and different mechanisms for delivery of the intended outcomes.

Four separate streams of legislation apply to health hazards that may be present at Open Farms, covering public health, food safety, animal health, and health and safety at work. Prevention of risks to human health arising at Open Farms is governed principally by food safety, and by health and safety law which covers risks to visitors and depends primarily on compliance by farm operators with statutory duties.

There is a wide range of regulatory options for the control of risks to health and safety. Options include prohibition, licensing, regulations, approved codes of practice and non-statutory guidance. Enforcement of health and safety law at Open Farms is the responsibility of LAs, who may seek advice from the Health and Safety Executive (HSE). Inspectors have powers to serve improvement or prohibition notices and to prosecute.

International comparisons show that there is no European Directive for Open Farms but we found some regulations and guidance in North American and Australian States. In addition, the Netherlands is currently strongly considering changing a guidance scheme into a structured enforceable scheme.

Description of the Outbreak

An outbreak of *E. coli* O157 occurred at Godstone Farm in August and September 2009. This is the largest outbreak of *E. coli* O157 linked to an Open Farm to have occurred in the UK. There were 93 people affected, of whom 76 (82%) were under 10 years of age. Of the 78 people with symptoms, 27 (35%) were admitted to hospital and 17 (22%), all of them children, were diagnosed with HUS. Eight of the children with HUS required dialysis, some of whom have been left with permanent kidney damage.

It is possible that some children with HUS will experience long term damage including hypertension and kidney failure. Children with reduced kidney function may need a kidney transplant at some stage in the future.

Laboratory investigations confirmed that there were clear microbiological links between nearly all the cases, since all the cases from whom isolates were available were infected with the same strain of *E. coli* O157. The similarity of human, animal and environmental strains of *E. coli* O157 indicates an outbreak with a common source.

Epidemiological investigations point to the main animal petting barn at Godstone Farm as the source of the outbreak. This is corroborated by the high proportion of faecal samples from animals from the main barn that tested positive. There was also evidence of environmental contamination at the Farm, suggesting that even without direct animal contact there was a risk of infection from contact with railings or soiled footwear.

The outbreak ceased after the animal petting barns at Godstone Farm were voluntarily closed on Friday 4 September 2009.

The Views of Parents

The majority of the 20 families who wished to be interviewed were regular visitors to Godstone and said that their children enjoyed visits to the Farm. When asked if there had been anything different about their visit, some noted that the Farm was exceptionally busy. There had been a queue to get in and/or they had to wait to use the handwashing facilities.

All the parents said they were aware of the need to wash their children's hands. A number said they were very careful and had used hand gels. Several commented that the taps were difficult to use, particularly for the younger children, and at most of the sinks there was only cold water. Many of the families commented that there was little supervision by farm staff and considered that there should have been more staff supervision at handwashing and animal contact areas. Most families had noticed signs about handwashing at the Farm but some felt there should have been more.

The majority of parents had heard about *E. coli* but only three were aware of the association with animals and thought this was specifically a problem during pregnancy. None was aware of the association of *E. coli* O157 infection with animal faeces or animal contact in children, or the serious nature of this infection. Communication and advice received by the parents did not appear to be consistent.

Several of the parents made repeated visits to their General Practitioner's surgery or out-of-hours service before the potentially serious nature of bloody diarrhoea was recognised and stool samples were taken. Some decided to present to their local Accident & Emergency Departments and their children were then admitted as their clinical condition deteriorated rapidly.

Many of the families said their experiences had been so traumatic they would not visit an Open Farm with their children again. However, many recognised the value of an animal contact experience for children in general and thought that much more information should be made available so that parents could make an informed decision on animal contact.

Many of the families could not understand why the Farm had not closed earlier and did not realise that the HPA did not have the regulatory authority to implement closure. They felt this situation required changing.

The Management and Control of the Outbreak

There was delay in recognising the outbreak due to the fact that no one person in the HPU appears to have had a clear picture of how many cases of *E. coli* O157 with links to Godstone Farm had been reported. The Outbreak Control Team (OCT) was convened exceptionally late in the course of the outbreak. Had the OCT been convened earlier, there would have been a more timely assessment of the public health risks and almost certainly more effective control of the outbreak.

There was unacceptable delay in initiating strict control measures at Godstone Farm. Had a decision been made on the August Bank Holiday weekend (or even after it, on Tuesday 1 September) to stop all contact with ruminant animals, a substantial number of cases of *E. coli* O157 could have been prevented. There was also unacceptable delay in carrying out the systematic epidemiological investigation of the outbreak, particularly in commencing the case-control study.

General Practitioners and hospital clinicians serving the catchment area of Godstone Farm, including paediatric renal unit staff, should have been alerted much earlier to the occurrence of the outbreak. There was unnecessary delay in reaching a decision about reopening Godstone Farm and in publishing the OCT final report.

Even with prompt action this would have been a big outbreak. Nevertheless, there was a lack of public health leadership and a missed opportunity to exercise decisive public health action and thereby restrict the size of the outbreak.

Assessing and Managing the Risks

The assessment of risk carried out by Godstone Farm was inadequate as it principally relied on the actions of the public, primarily through handwashing, to control the risks. The risk assessment process used by the LA did not facilitate the identification of hazards on the Farm and, despite a regular programme of inspections, the regulatory visits carried out by the LA were ineffective in preventing an outbreak occurring.

The HSE, in a joint statement of position with the Local Authorities Co-ordinators of Regulatory Services (LACORS), have confirmed that they continue to regard the risk of infection to visitors at Open Farms as 'low', and as such, not significant enough to warrant additional action. Due to the potential severity of *E. coli* O157 infection, we conclude that the level of risk on Open Farms is not acceptable and good practices in the industry should have been more actively pursued by the regulators.

It is currently very difficult for families to make their own informed decisions about the risk of visiting an Open Farm. In addition to public education on the risks of infection from *E. coli* O157, an accreditation scheme, led by the farming industry, would assist the public in understanding which farm premises were operated to a known and acceptable standard.

Farm operators must base their risk assessments and any preventative or remedial actions on the assumption that *E. coli* O157 is present on the farm. A risk management approach which relies primarily on handwashing to prevent risk of infection is, in our view, misdirected. Control measures should primarily focus on preventing visitor contact with animal faeces or faecal matter. Handwashing however remains the principal control measure available to the public and must be actively encouraged by the farm operator.

To minimise visitor contact with animal faeces or faecal matter, we have identified specific issues that should be addressed as a matter of urgency. These could form the basis of an agreed code of good practice within the industry. Farm layout and design are critical to reducing the risk of infection. The practice of 'deep bedding' should not be permitted in children-animal contact areas.

Meeting the Regulatory Challenges

The existing regulatory structure is not securing compliance with standards and is unlikely to reduce the risk of future outbreaks at Open Farms unless reinforced. Non-statutory, unenforceable guidance leaves room for doubt about standards of protection; simply revising guidance will not be sufficient to meet the challenge of improving public health protection.

A voluntary accreditation scheme for Open Farms is strongly recommended as helpful to both operators and regulators but we do not recommend making special regulations or licensing of Open Farms at this time. An Approved Code of Practice (ACoP) would provide clarity and certainty about standards, helping both operators and enforcing authorities.

A definition of an Open Farm is needed and a national register of Open Farms would help to target awareness raising, education and inspection programmes.

The HPA has no enforcement powers and is not an enforcing authority; the powers of the Consultant in Communicable Disease Control (CCDC) and LA inspectors to prohibit activities or close premises need clarification. The confidence and competence of Environmental Health Officers (EHOs) to inspect and enforce standards at Open Farms needs to be strengthened. There is a need for agencies to share information and work much more closely together in regulating Open Farms.

Conclusions and Recommendations

Even with the promptest of control measures, the Surrey 2009 outbreak would have been the largest *E. coli* O157 outbreak associated with animal contact ever reported in the UK. This emphasises the importance, not only of prompt identification and control of outbreaks, but also of measures to reduce the risk of acquiring *E. coli* O157 infection.

Prompt identification and control of outbreaks require implementation of existing HPA procedure and guidelines and clarity regarding the respective roles of the HPU and EHD. The HPU should provide public health leadership and the EHD should have both the competence and confidence to issue prohibition notices if a farm is suspected as the source of an outbreak of zoonotic disease. Animal contact, especially with ruminants, should be prioritised as the activity to be closed at the earliest suspicion of a farm-related *E. coli* O157 outbreak.

The time course of the Godstone Farm outbreak clearly demonstrates that handwashing alone cannot be relied upon to prevent outbreaks of *E. coli* O157 infection acquired by contact with animals or their faeces. Open Farm operators should ensure that visitor contact with animal faeces is minimised or eliminated.

There needs to be greater awareness of the risks of animal contact among farm owners, regulatory authorities and visitors to Open Farms. Public education on the risks of infections acquired by animal contact needs to be reinforced, both before and during the farm visit.

The content of all existing guidance touching on human health and safety at Open Farms needs to be reviewed, improved and clarified, where necessary. Regulatory authorities and industry representatives should pursue the development of an ACoP, and an associated national accreditation scheme for Open Farms.

The evident complexity of the regulatory regime relating to Open Farms requires a strategy of 'joined-up regulation' to provide more effective oversight of safety and opportunities for reducing the inspection burden.

Our enquiry focused on the larger scale Open Farms, as exemplified by Godstone Farm. However, the principles we recommend for reducing the risk of infection may also be applied to a wider range of farm premises and rural activities in which contact with ruminant animals or their faeces may occur.

Summary of Top Six Recommendations:

- Farm operators should ensure that the layout and design of public areas are such that visitor contact with animal faecal matter (particularly ruminant) is minimised or eliminated
- There is a need to raise public awareness of the potential infection risks when arriving at a farm attraction, emphasising the parent/carer's decision to allow children to have animal contact
- There should be a reassessment of the risk of *E. coli* O157 infection as 'low'. Its probability may be low but the impact is high and the consequences very severe
- An Approved Code of Practice (ACoP) should be developed for the Open Farm industry, involving relevant authorities and in close consultation with leading representatives of the industry to underpin the industry's initiative in establishing an accreditation scheme
- The regulatory agencies and others should explore ways of working together in regulating Open Farms clarifying roles, responsibilities and relationships
- Research should be pursued to assist clinicians in the rapid diagnosis of *E. coli* O157 and the identification of and treatment for children likely to develop severe complications of the infection. Research should also be undertaken aimed at preventing or limiting carriage of the organism in animals.

Outline of the Report

The purpose of our Investigation was to make recommendations so as to reduce the risk of contracting *E. coli* O157 in those who visit Open Farms and to improve the health protection response to future outbreaks of *E. coli* O157 infection.

Guided by the Terms of Reference, the Independent Investigation Committee requested evidence from key stakeholder organisations and a number of individual experts. The background evidence is brought together in four Chapters that comprise Part A (The Context) of the Report. This is followed by two Chapters in Part B (The Outbreak) that describe the outbreak of *E. coli* O157 at Godstone Farm with a synopsis of interviews with the parents of affected children. In Part C (Management of the Outbreak) we evaluate and analyse the management and control of the outbreak and in Part D (The Challenge of Reducing the Risks) we provide a critical assessment of the way in which the risks associated with *E. coli* O157 are assessed and managed and propose solutions to meet this challenge. Our recommendations and conclusions are gathered together in Part E.

From the outset of the Investigation we were presented with two fundamental issues. First, an Open Farm was defined for us by the Health Protection Agency as one that invites members of the public to visit and that facilitates direct contact with the animals. However, it became clear that venues which allow the public to have contact with animals are many and varied. To focus on the types of premises and the animal contacts that led to the outbreak of *E. coli* O157 at Godstone Farm requires us to define the type of premises that are the primary attention of our investigation and the target of our recommendations.

We therefore define Open Farms as 'those premises that maintain farm animals, actively attract visitors for leisure purposes, have visitor facilities and encourage, permit and allow animal contact, and such premises need not be open on a daily basis nor solely operating as commercial leisure activities'. Our recommendations for regulation, inspection and operational procedures are predominantly focused on Open Farms like these and are outlined in Parts D and E. However, the risks that may arise from all agricultural animal contact have been considered and appropriate risk management practices that should be made available are also commented on in Chapter 8 of Part D.

The second important issue for us was that public health is a devolved matter and there are significant differences in the structures and responsibilities in each of our devolved countries. The report has primarily described the situation in England but we have sought evidence from across Great Britain and Northern Ireland and have noted that in many aspects therein lies a considerable wealth of experience and knowledge. We have sought to make recommendations in Part E that are pertinent to England but we recommend that in view of the complex regulatory arrangements for Open Farms each devolved territory should initiate an examination of these recommendations to ensure their implementation for the protection of public health.

PART A THE CONTEXT

Chapter 1: *Escherichia coli* O157 sets out the nature of the organism *E. coli* O157, its pathogenicity and the range of clinical symptoms it can produce. A review of the epidemiology of *E. coli* O157 is included, together with the nature of sporadic cases versus outbreaks. Examples of other outbreaks of *E. coli* O157 associated with animal contact are also described.

Chapter 2: Standard Public Health Procedures for *E. coli* O157 discusses the process of controlling an outbreak, beginning with how an outbreak is recognised and the key organisations involved in outbreak control.

Chapter 3: Open Farms describes the wide range of Open Farm premises that offer educational visits and/or entertainment to the public. A summary of the functions of the many non-regulatory organisations related to the Open Farm industry is provided, together with an overview of the existing schemes for accreditation of educational visits to farms.

Chapter 4: The Regulatory Framework for Open Farms presents an overview and lists the main regulatory Bodies responsible for the inspection of Open Farm premises. Reference is made to the Guidance that is used to monitor and inspect standards at Open Farms. This chapter reviews the current UK legislation and compares the framework in the UK with that of Europe, the USA and other countries.

PART B THE OUTBREAK

Chapter 5: The Outbreak at Godstone is described in detail. A timeline setting out the main events during the outbreak is included, as well as details of the clinical impact of the outbreak.

Chapter 6: The Views of Parents is a synopsis of interviews with parents whose children were affected by the outbreak. A compilation of the interviews is included in Appendix 8.

PART C MANAGEMENT OF THE OUTBREAK

Chapter 7: The Management and Control of the Outbreak deals with how and how quickly the outbreak was identified and what was done to control it. This Chapter examines the work of the outbreak control team and reviews what was done to disseminate information about the outbreak.

PART D THE CHALLENGE OF REDUCING THE RISKS

Chapter 8: Assessing and Managing the Risks contains a critical assessment of the current levels of hazard and risk as applied to Open Farms. The perception of risk of *E. coli* O157 infection on Open Farms is also assessed and a view is presented on what additional prevention and control measures are needed in the light of the outbreak at Godstone.

Chapter 9: Meeting the Challenges. In this Chapter, the Committee provides a critical assessment of the existing regulatory framework and presents a series of potential solutions to improve the regulatory structure.

PART E CONCLUSIONS AND RECOMMENDATIONS

Chapter 10: Conclusions and Recommendations brings together and puts into perspective the key points from all the separate strands of the investigation and presents the conclusions of the Investigation Committee. This chapter also combines the full set of recommendations from the preceding chapters.