A consultation document on a proposed Legislative Reform Order that will allow HSE to make regulations for the protection of animal health under the Health and Safety at Work etc Act 1974

This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under section 50(3) of the Health and Safety at Work etc Act 1974.

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to reach there no later than 28 March 2010

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultative document will be lodged with the Health and Safety Executive’s Knowledge Centre after the close of the consultation period where they can be inspected by members of the public or be copied to them on payment of the appropriate fee to cover costs.

Responses to this consultative document are invited on the basis that anyone submitting them agrees to their response being dealt with in this way. Responses, or part of them, will be withheld from the Knowledge Centre only at the express request of the person making them. In such cases, a note will be put in the index to the responses identifying those who have commented and have asked that their views, or part of them, be treated as confidential.

Many business e-mail systems now automatically append a paragraph stating the message is confidential. If you are responding to this CD by e-mail and you are content for your responses to be made publicly available, please make clear in the body of your response that you do not wish any standard confidentiality statement to apply.
A consultation document on a proposed Legislative Reform Order that will allow HSE to make regulations for the protection of animal health under the Health and Safety at Work etc Act 1974

To extend the legal powers conferred by Section 1(1) of the Health and Safety at Work etc Act (1974) to confer on the Health and Safety Executive vires to regulate biological agents that pose a risk to animal health when they are handled in a contained use environment.

A Consultation Paper Issued by

The Health and Safety Executive on behalf of the Ministers in the Department for Work and Pensions with responsibility for Health and Safety at Work
Summary of Proposals

The objective of this proposed Legislative Reform Order (LRO) is to amend Section 1(1) of the Health and Safety at Work etc Act 1974 (HSWA) to remove the restriction that limits the Health and Safety Executive’s (HSE) legal powers to protecting human health. It is proposed that this be achieved by extending the general purposes in HSWA to protecting against risks to animal health arising from work with animal pathogens and those pathogens not being adequately contained. As well as the amendment to Section 1(1), there are consequential amendments affecting Sections 7, 8, 9, 20, 22, 25, 33 and 53 that clarify the extent to which other existing provisions in HSWA will apply to contained use work with animal pathogens. HSE proposes to make these changes using a LRO under the Legislative and Regulatory Reform Act 2006 (LRRA).

This consultation is being made in accordance with the requirements of the LRRA and terms of the Government’s Code of Practice on Written Consultations (Annex D).
GLOSSARY OF KEY TERMS


Contained use of animal pathogens – any activity in which animal pathogens are cultured, stored, transported, destroyed, disposed of or used in any other way and for which physical, chemical or biological barriers or any combination of such barriers are used to limit their contact with, and to provide a high level of protection for, animals.

Biological agents – for the purpose of this paper we are using this term to mean-

a) in relation to humans a micro-organism, cell culture, or human endoparasite, whether or not genetically modified, which may cause infection, allergy, and toxicity or otherwise create a hazard to human health;

b) In relation to relevant animals, a micro-organism or cell culture which has not been genetically modified and which poses a risk to the health of any relevant animal and which has an approved categorisation

COSHH – Control of Substances Hazardous to Health Regulations 2002 (as amended)

LRO – Legislative Reform Order

LRRA – Legislative and Regulatory Reform Act 2006

GMM – Genetically Modified Organism

GMO – Genetically Modified Organism - For the purposes of this document, this term is used to include genetically modified micro-organisms (GMMs) as well as genetically modified animals and plants

GMO(CU) – Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended)

Laboratories – When we refer to laboratories in this document, we are using it as shorthand for laboratories and other similar contained use environments such as animal rooms and industrial vaccine manufacturing plants where people work with dangerous micro-organisms,
Micro-organisms – for the purpose of this document, except where the term is qualified we are using it to refer to genetically modified micro-organisms and wild-type animal and human pathogens/biological agents.

Pathogen – Disease causing agent, for example a virus or bacterium


Wild type – a microorganism or pathogen that has not been genetically modified
# TABLE OF CONTENTS

1. Introduction ............................................. 6

2. Background to the Policy and Legislation at Issue .......... 12

3. The Proposals ............................................. 22

4. Legal Analysis Against Requirements of the Legislative and Regulatory Reform Act 2006 ........... 33

## ANNEXES

- **Annex A** List of consultees ............................................. 42
- **Annex B** Response Form .................................................. 43
- **Annex C** Legislative Reform Orders – Parliamentary Consideration ............................................. 52
- **Annex D** Consultation Criteria - Code of Practice on Written Consultation ............................................. 58
- **Annex E** Partial Impact Assessment ............................................. 59
- **Annex F** Draft Legislative Reform Order ............................................. 63
- **Annex G** Offences ............................................. 68
CHAPTER 1 – INTRODUCTION

1.1 BACKGROUND

1.1.1 This consultation paper sets out in detail the Government’s proposals for reforming the legislation governing those working with animal pathogens in laboratories and other similar environments where it is necessary to ensure the effective containment of those pathogens to protect animal health.

1.1.2 The aim of the proposal is to extend the scope of the Health and Safety at Work etc. 1974 (HSWA) to enable the Health and Safety Executive to regulate this work as part of its existing work regulating human pathogens and genetically modified organisms.

1.1.3 We propose to introduce the reform by means of an LRO under section 1 of the Legislative and Regulatory Reform Act 2006 (LRRA). This consultation is being conducted in accordance with the provision of section 13 of the LRRA. Views are invited on all aspects of the consultation paper, and a number of specific questions are set out at the end of the document.

1.2 LEGISLATIVE REFORM ORDER-MAKING POWERS

Section 1

1.2.1 Under section 1 of the LRRA, a Minister can make an LRO for the purpose of ‘removing or reducing any burden, or overall burdens, resulting directly or indirectly for any person from any legislation’.

Section 1(3) of the LRRA defines a ‘burden’ as:

- a financial cost;
- an administrative inconvenience;
- an obstacle to efficiency, productivity or profitability; or
- a sanction, criminal or otherwise, which affects the carrying on of any lawful activity
Section 2

1.2.2 Under section 2 of the LRRA, a Minister can make an LRO for the purpose of securing that regulatory activities are exercised in a way that is transparent accountable, proportionate, consistent, and targeted only at cases in which action is needed.

'Regulatory functions' is defined in section 32 as:

- a function under any enactment of imposing requirements, restrictions or conditions, or setting standards or giving guidance, in relation to any activity; or
- a function which relates to the securing of compliance with, or the enforcement of, requirements, restrictions, conditions, standards or guidance which under or by virtue of any enactment relates to any activity

Section 20 Orders

1.2.3 Section 20 of the LRRA enables a Minister to exercise the order-making powers under sections 1 and 2 together with the power to make an order under section 2(2) of the European Communities Act 1972 in a single instrument. This enables a single order to implement Community law under section 2(2) of the 1972 Act, and, for example, to remove or reduce burdens resulting from pre-existing statutory provisions.

Preconditions

1.2.4 Each proposal for a LRO must satisfy the preconditions set out in section 3 of the LRRA. The questions in the rest of the document are designed to elicit the information that the Minister will need in order to satisfy the Parliamentary Scrutiny Committees that, among other things, the proposal satisfies these preconditions.

1.2.5 For this reason, HSE would particularly welcome your views on whether and how each aspect of the proposed changes in this consultation document meets the following preconditions:

- Non-Legislative Solutions – An LRO may not be made if there are non-legislative solutions that will satisfactorily remedy the difficulty which the LRO is intended to address. An example of a non-legislative solution might be issuing guidance about a particular legislative regime.

- Proportionality – The effect of a provision made by an LRO must be proportionate to its policy objective. A policy objective might be achieved in a number of different ways, one of which may be more onerous than others may and could be considered a disproportionate means of securing the desired outcome. Before making an LRO, the Minister must consider that this is not the
case and that there is an appropriate relationship between the policy aim and the means chosen to achieve it.

- **Fair Balance** – Before making an LRO, the Minister must be of the opinion that a fair balance is being struck between the public interest and the interests of any person adversely affected by the LRO. It is possible to make an LRO that will have an adverse effect on the interests of one or more persons only if the Minister is satisfied that there will be beneficial effects that are in the public interest.

- **Necessary Protection** – A Minister may not make an LRO if he considers that the proposals would remove any necessary protection. The notion of necessary protection can extend to economic protection, health and safety protection, and the protection of civil liberties, the environment and national heritage.

- **Rights and freedoms** – An LRO cannot be made unless the Minister is satisfied that it will not prevent any person from continuing to exercise any right or freedom to which they might reasonably expect to continue to exercise. This condition recognises that there are certain rights that it would not be fair to take away from people using an LRO.

- **Constituted Significance** – A Minister may not make an LRO if he considers that the provision made by the LRO is of constitutional significance.

1.2.6 It should be noted that even where the preconditions of section 3 of the LRRA are met, an LRO cannot:

- Deliver 'highly controversial' proposals;

- Remove burdens which fall solely on Ministers or Government departments, except where the burden affects the Minister or Government department in the exercise of regulatory functions;

- Confer or transfer any function of legislating on anyone other than a Minister, persons or bodies that have statutory functions conferred on or transferred to them by enactment; a body or office which has been created by the LRO itself;

- Impose, abolish or vary taxation;

- Create a new criminal offence or increase the penalty for an existing offence so that it is punishable above certain limits;

- Provide authorisation for forcible entry, search or seizure, or compel the giving of evidence;
• Amend or repeal any provision of Part 1 of the LRRA;
• Amend or repeal any provision of the Human Rights Act 1998;
• Remove burdens arising solely from common law.

Devolution

1.2.7 The LRRA imposes certain restriction regarding LROs and the devolution agreements:

• Scotland – A Minister cannot make an LRO under Part 1 of the LRRA that would be within the legislative competence of the Scottish Parliament. This does not affect the powers to make consequential, supplementary, incidental or transitional provisions.

• Northern Ireland – A Minister cannot make an LRO under Part 1 of the LRRA that amends or repeals any Northern Ireland legislation, unless it is to make consequential, supplementary, incidentally or transitional provisions.

• Wales – The agreement of the Welsh Ministers is required for any provision in an LRO that confers a function upon the Welsh Ministers, modifies or removes a function of the Welsh Ministers, or restates a provision conferring a function upon the Welsh Ministers. The agreement of the National Assembly for Wales is required for any provision in an LRO that is within the legislative competence of the Assembly.

1.3 CONSULTATION

1.3.1 The LRRA requires Departments to consult widely on all LRO proposals. The list of consultees, including the devolved administrations, to which this document has been sent, is at Annex A. It is also available on the internet at:

• http://www.hse.gov.uk/consult/live.htm
• http://bre.berr.gov.uk/regulation/reform/bill/

1.3.2 Comments are invited from all interested parties, and not just from those to whom the document has been sent. A response form is at Annex B.

1.3.3 A note explaining the Parliamentary process for LROs to be made under the LRRA can be found at Annex C. This will help consultees understand when and to whom they are able to put their views, should they wish to do so.
1.3.4 The consultation document follows the format recommended by the BRE for such proposals. The criteria applicable to all UK public consultations under the BRE Code of Practice on Consultation are set out in Annex D.

1.4 DISCLOSURE

1.4.1 Normal practice will be for details of representations received in response to this consultation document to be disclosed, and for respondents to be identified. While the LRRA provides for non-disclosure of representations, the Minister will include the names of all respondents in the list submitted to Parliament alongside the draft LRO. The Minister is also obliged to disclose any representations that are requested by, or made to, the relevant Parliamentary Scrutiny Committees. This is a safeguard against attempts to bring improper influence to bear on the Minister. HSE envisages that, in the normal course of events, this provision will be used rarely and only in exceptional circumstances.

1.4.2 You should note that:

- If you request that your representation is not disclosed, the Minister will not be able to disclose the contents of your representation without your express consent and, if the representation concerns a third party, their consent too. Alternatively, the Minister may disclose the content of your representation but only in such a way as to anonymise it.

- In all cases where your representation concerns information on a third party, the Minister is not obliged to pass it on to Parliament if he considers that disclosure could adversely affect the interests of that third party and he is unable to obtain the consent of the third party.

1.4.3 Please identify any information that you or any other person involved does not wish to be disclosed. You should note that many facsimile and e-mail messages carry, as a matter of course, a statement that the contents are for the eyes of the intended recipient. In the context of this consultation such appended statements will not be construed as being requests for non-inclusion in the post-consultation review unless accompanied by an additional specific request for confidentiality, such as an indication in the tick-box provided for that purpose in the response form of Annex B.
1.5 CONFIDENTIALITY AND FREEDOM OF INFORMATION

1.5.1 It is possible that requests for information contained in consultation responses could be made in accordance with access to information regimes (these are primarily the Freedom of Information Act 2000, the Data Protection Act 1998 and the Environmental Information Regulations 2004). If you do not want your response to be disclosed in response to such requests for information, you should identify the information you wish to be withheld and explain why confidentiality is necessary. Your request will only be acceded to if it is appropriate in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not of itself be regarded as binding in the Department.

1.6 RESPONDING TO THE CONSULTATION DOCUMENT

1.6.1 Any comments on the proposals in this consultation document should be sent by 23 April 2010 at the latest to John Newbold, Health and Safety Executive, 1.2 Redgrave Court, Merton Road, Bootle, Liverpool L20 7HS from whom further copies of this document can be obtained.
CHAPTER 2: BACKGROUND TO THE POLICY AND LEGISLATION AT ISSUE

2.1 INTRODUCTION

2.1.1 Dangerous micro-organisms affecting humans, animals represent a major threat to public health and the economy. The research carried out in UK laboratories plays an important role in the international fight against existing and emerging diseases. Such work is essential to fully understanding infectious diseases and in developing effective vaccines and treatments. This requires laboratories that have the ability to handle potentially dangerous micro-organisms in a way that reduces the risk of release into the environment to the lowest level reasonably practicable. The accidental or deliberate release of dangerous micro-organisms from a laboratory could give rise to serious animal or human disease outbreaks and could also have a serious economic impact and cause severe disruption to the food industry. The devastating impact of infectious disease in animals was demonstrated by the outbreaks of Foot and Mouth Disease Virus (FMDV) in 2001 and 2007. An unexpected outbreak of human disease could have similarly devastating consequences.

2.1.2 The outbreak of FMD in Surrey in 2007 brought the issue of effective containment and prevention of release to the top of the political agenda. Subsequently, a number of reports were commissioned including the investigation led by the Health and Safety Executive (HSE) into any potential breach of containment at the site, and the ‘Independent Review of the safety of UK facilities handling foot and mouth disease virus’, chaired by Professor Brian Spratt that published more detailed findings.

2.1.3 Further to these reports on the cause of the outbreak, the Government commissioned two additional reviews. First, Sir Bill Callaghan led a review of the UK regulatory framework for handling animal pathogens, and secondly the Prime Minister and Secretary of State for Environment, Food and Rural Affairs commissioned Dr Iain Anderson to lead an independent review of the lessons learned from the response to the 2007 FMDV outbreak.

2.1.4 The Callaghan Review, published on the 13 December 2007, concluded that the current regulatory systems in place for the regulation of micro-organisms (including those that are genetically modified) in contained use were complicated, with three separate but overlapping sets of regulations. The Review identified the existing regulations as “complex and disjointed” and described the existing regulations relating to human and animal pathogens as having “differing regulatory philosophies and practices
requiring different levels and types of notification, inspection, enforcement and sanctions”.

2.1.5 Sir Bill Callaghan recommended that there should be a new, unified regulatory framework for those micro-organisms that are human and animal pathogens based on risk-assessment with a common set of containment measures. He concluded that, as Defra are the regulatory body, licensor and inspector for those handling animal pathogens and a major customer of animal pathogens research and diagnostics, there was a conflict of interest. He therefore recommended that the responsibility for inspection and enforcement in respect of animal pathogens move to a regulatory body that was not subject to the same conflict of interest and that had access to the range of technical expertise needed to carry out the function fully. He recommended that the Health and Safety Executive (HSE) should extend their regulatory function and become the single regulatory body to encompass both human and animal pathogens. The Government, and the Devolved Administrations, accepted all the recommendations made in the review.

2.1.6 Furthermore, the Innovation, Universities, Science and Skills (IUSS) Select Committee announced an inquiry in December 2007 into ‘Biosecurity in UK Research Laboratories’ and published a report on 25 June 2008. The report upheld the recommendations of the Callaghan Review and concluded that there needed to be a single organisation with the remit to maintain a strategic regulatory overview of these laboratories. The Committee agreed that a new unified, regulatory framework should be introduced in the wake of the Pirbright outbreak and was a positive step for those working in such containment facilities, enabling them to continue their work to protect the UK from the threat of infectious disease.

2.1.7 This consultation document further explains the reasons for amending HSWA and how this is to be achieved legally.

2.2 MAKING A LEGISLATIVE REFORM ORDER TO AMEND HSWA

2.2.1 In order to extend HSE’s existing regulatory role to encompass work with animal pathogens, the Health and Safety at Work etc Act 1974 (HSWA) needs to be amended to extend the general purposes in HSWA to allow it to cover the protection of animal health where the risk is posed by the failure to contain animal pathogens. We are proposing to do this by means of a Legislative Reform Order (LRO). This will enable HSE to become the single regulatory body responsible for regulating contained use activities with human and animal pathogens. It will enable the making of Health and Safety regulations that extend to the protection of animal health, arising from the risk of failure to contain animal pathogens. The amendment would also allow the Government
to align the regulation of animal pathogens with existing health and safety regulations relating to protection of human health from human pathogens and the protection of human health and the environment from genetically modified micro-organisms. This will; result in a system that reduces cost, duplication of effort on the part of the regulator and those being regulated and is consistent and easier to follow. The LRO is made under section 1 of the Legislative and Regulatory Reform Act 2006 (LRRA).

2.2.2 Animal health is a devolved matter and the Specified Animal Pathogens Order (SAPO), with equivalent legislation for Devolved Administrations, is made under the Animal Health Act 1981. The main purpose of the legislation is to prevent the release of dangerous animal pathogens into the environment where they may cause a serious animal disease. Responsibility for enforcement currently lies with the Secretary of State.

2.2.3 The extension of HSWA therefore is for the narrowly defined purpose of protecting against risks to animals arising from the release of animal pathogens from contained use. The powers that will be introduced into HSWA by the LRO are similar to those currently within the Animal Health Act 1981 (AHA). The aim of this LRO is to rationalise those powers by making them available in one Act of Parliament and aligning the circumstances in which they can be used by one regulator.

2.3 THE CURRENT REGULATORY REGIME

2.3.1 There are three separate, but overlapping, sets of regulations that apply to those carrying out activities involving contained use of micro-organisms and GMOs; and prescribe containment requirements for laboratories that handle human and animal pathogens. The following regulations specify the containment requirements proportionate to the risk.

- The Control of Substances Hazardous to Health Regulations 2002 (SI 2002/2677) – general and biological agents provisions - COSHH;

- The Genetically Modified Organisms (Contained Use) Regulations 2000 (SI 1996/1106), as amended by the Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 (SI 2005/2466) – GMO(CU); and

Alongside these specific pieces of legislation, the general provisions of health and safety legislation govern all workplaces.\(^1\)

### 2.4 WORKING WITH BIOLOGICAL AGENTS AND GMOS

2.4.1 The principle objective when handling biological agents or GMOs is managing the work environment to prevent exposure of workers and other people and animals by using appropriate containment. The appropriate level of containment depends on, and is proportionate to, the risk. Each regulatory system has its own relevant hazard groupings with corresponding containment levels.

2.4.2 Each set of regulations has associated guidance material including:

- An Approved Code of Practice (ACoP), which gives practical guidance on compliance and has special legal status, supports the COSHH Regulations
- The Advisory Committee on Dangerous Pathogens (ACDP) provides scientific advice and guidance on the risks from biological agents that are hazardous to humans.
- The Scientific Advisory Committee on Genetic Modification (SACGM) advises the Competent Authority on technical issues arising from activities notified under the GMO (CU) and risk assessments accompanying notifications (including all Class 4 work).
- Two sets of comprehensive guidance accompany the GMO (CU) Regulations: The Guide to the GMO (CU) Regulations and the SACGM Compendium of Guidance. These documents provide an interpretive guide to the legislation and give practical guidance to help duty holders comply with the provisions of these regulations.
- In relation to SAPO, Defra provides general guidance on their website.

2.4.3 Duty holders are expected to notice and understand these disparate pieces of guidance that are neither cross-referenced nor fully compatible making them difficult and onerous to implement and comply with.

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\(^1\) Any reference in this consultation document to the legislative position is in relation to England, Scotland and Wales. However, separate and equivalent legislation exists for Northern Ireland and it is their intention to introduce a single regulatory framework in Northern Ireland albeit to a different timetable.
The Control of Substances Hazardous to Health Regulations 2002 (COSHH)

2.4.4 COSHH regulates substances hazardous to health. This includes micro-organisms that pose a risk to human health referred to in the Regulations as biological agents. COSHH Regulations are made under the European Communities Act 1972 and HSWA. Amongst other things, it implements EC Directive 2000/54/EC on the protection of workers from the risks related to exposure to biological agents and is primarily aimed at preventing exposure of workers to them. HSE regulates COSHH and provides guidance on its requirements by means of an ACoP; and is the enforcing authority across Great Britain.

2.4.5 COSHH uses risk assessment to determine whether and how to protect employees and others from exposure to biological agents. Based on the threat to human health, COSHH categorises biological agents into hazard groups 1 to 4. These hazard groups are detailed in the ‘Approved List of Biological Agents’ drawn up in consultation with ACDP. The hazard group determines the minimum standards of containment required to protect human health. Anyone wishing to work with biological agents must notify, and must receive an acknowledgement from HSE. For hazard group 3 and 4 agents i.e. those that pose the greatest risk to human health, the employer must wait 20 working days before commencing work to enable HSE to consider and assess the risks. HSE can request additional information following notification.

The Genetically Modified Organisms (Contained Use) Regulations 2000 (GMO(CU))

2.4.6 The GMO(CU) Regulations are made under both the European Communities Act and HSWA. These regulations implement EC Directives 2009/41/EC on contained use of genetically modified micro-organisms (GMMs) with the purpose of the protection of human health and the environment from activities involving GMMs. Requirements differ from COSHH since the regulations are designed to protect the environment as well as human health. This legislation also regulates genetically modified organisms other than micro-organisms e.g. genetically modified animals and plants, under HSE’s general purposes to protect against risks to human health.

2.4.7 The regulations apply to the whole of Great Britain. However, as responsibility for the environment is a devolved matter in Scotland, there is a joint competent authority under GMO(CU) namely HSE and Defra for England and Wales; and HSE and Scottish Ministers for Scotland.

2.4.8 GMO(CU) uses a flexible, risk-based process to determine appropriate containment measures to protect human health and the environment from GMOs in contained use. The duty is placed on the person carrying out an activity involving
genetic modification or working with GMOs to carry out a suitable and sufficient risk assessment to human health and the environment. The risk assessment procedure requires all contained use activities involving GMMs to be classified into one of four risk classes i.e. Class 1 (CL1) to Class 4 (CL4) and requires the selection of appropriate containment measures.

2.4.9 Duty holders may only work with GMOs for the first time following notification to the Competent Authority and on receipt of an acknowledgement from HSE. For activities that are classified as high risk (i.e. Class 3 and 4), permission by written consent is required from the Competent Authority prior to work commencing. For administrative purposes, HSE acts as the focal point within the Competent Authority for notifications made under GMO(CU).

The Specified Animal Pathogens Order 2008 (SAPO)

2.4.10 SAPO is made under the Animal Health Act 1981. The main purpose of SAPO is to regulate animal pathogens specified in the Order to prevent a release into the environment where they may cause a serious animal disease. As animal health is a devolved matter, the equivalent SAPO legislates for its respective geographical area.

2.4.11 SAPO prohibits the possession of any specified animal pathogen without a licence from the appropriate Minister (Defra in England, Welsh Assembly Government in Wales and Scottish Government in Scotland). The licence specifies the conditions under which the animal pathogen must be handled following an inspection of the laboratory and close examination of supporting documentation. Licence conditions vary and are usually valid for 5 years.

2.4.12 The containment requirements for those handling animal pathogens are not enshrined in legislation but are published on the Defra website. Defra defines its own hazard groups i.e. SAPO 1 to SAPO 4 and its own corresponding containment measures, categorised by the risk they pose to animal health. These describe the physical features and operating conditions that may be required by Defra of any laboratory to be licensed to hold or work with animal pathogens. These containment requirements are intended only as a guide, as decision on the facilities and procedures required to contain animal pathogens safely at individual establishments are made on a case-by-case basis and specified in the licence. Containment measures are based on the recommendations published by the Office Internationale des Epizooties (OIE – the World Animal Health Organisation).

2.4.13 The SAPO licensing regime, including inspection and enforcement, falls within the competence of the Secretary of State. In England, since April 2008 HSE has been performing the inspection and enforcement functions on behalf of the Secretary of State under an Agency Agreement. Similar Agency Agreements are in place with the
2.5 WHY CHANGE THE REGULATORY SYSTEM FOR WORKING WITH ANIMAL PATHOGENS NOW?

2.5.1 The Callaghan Review concluded that there was compelling argument that the current different regulatory approaches needed to be replaced by a unified, risk-based, permissioning framework for regulating human and animal pathogens. The Government was urged to ensure that regulation of work on dangerous pathogens is simplified as far as is practicable with the minimum number of regulatory bodies involved. Although, it is appropriate for some specialist areas such as counter-terrorist inspection to be administered separately in accordance with the common framework. Co-operation with the Devolved Administrations would also ensure a unified regulatory picture across Great Britain.

2.5.2 The independent inquiry and subsequent report published by the Government's IUSS Select Committee, fully accepted and agreed with both the conclusions of the Callaghan Review and its recommendations. The Select Committee agreed that the introduction of a new unified regulatory framework would move the Government’s policy on the issue in the right direction. It also concluded that “the outbreak of FMDV at Pirbright highlighted that in the long run, proper regulation, running and maintenance of high containment facilities is considerably cheaper than remedying a breach of biocontainment”.

2.5.3 The regulatory landscape that currently applies to laboratories is complex and disjointed with differing philosophies, practices, levels and types of inspection and enforcement. This is a clear example where the complexity of the regulatory system leads to:

- Laboratories being subject to inspections under divergent regulatory regimes with the same overall aim of ensuring effective containment
- Overlapping areas of responsibility by regulators
- Regulators devoting limited resources to activities being replicated by other regulatory bodies, especially in the collation of information
- The provision of similar or duplicate information by the duty holder to different regulators for the same fundamental purpose
Overlapping areas for duty holders to ensure compliance with the separate regulators

- Resource for preparation of visits by the regulator for different purposes
- Provision of similar or duplicate information
- Potential inconsistencies and approaches to inspections as a result of divergent regimes
- Potential conflicting regulatory requirements

**Containment Requirements**

2.5.4 The fundamental aim and common goal of the three separate sets of legislation is to prevent the release of harmful micro-organisms. Whilst there is a need to recognise the different threats posed to animal or human health by different pathogens, it does not make regulatory sense to have in place differing regimes dealing with the same aim i.e. to contain the pathogen and prevent its release such that it can cause harm.

2.5.5 As the majority of laboratories are working with a combination of micro-organisms and/or GMOs that may affect human and animal health, it is important that the regulatory inconsistencies be addressed to enable both duty holder and regulator to ‘do their job’. It is a concern that the various containment requirements are not set out in a way that encourages clear understanding of what measures are necessary to achieve a given level of containment.

2.5.6 As part of the Callaghan Review, duty holders were interviewed covering a range of pathogen risk categories and visits made to laboratories and premises from the Government, commercial and academic sectors where animal and human pathogens are handled. Most practitioners had a high awareness of COSHH, and ACDP guidance, and clearly understood their responsibilities. Those working with GMOs were also well versed in the regulatory requirements and understood their duties under the regulations.

2.5.7 However, SAPO licence holders did not always understand SAPO or its requirements and the predominant view expressed was that, unlike GMO(CU) and COSHH, SAPO does not follow a risk-based approach, as it does not use risk assessment as a formal requirement.

2.5.8 HSE’s general principles and approach to enforcement are clearly set out in its ‘Enforcement Policy Statement’; the fundamental principle is that enforcement action taken is proportionate to the health and safety risks, commensurate to the seriousness of the breach. For example, minor breaches allows compliance to be achieved by the
use of improvement notices allowing duty holders to continue their operations and normal business outputs while taking remedial action simultaneously to improve standards. By contrast, the SAPO regime is seen as a blunt instrument as it provides for only revocation of licence or criminal prosecution.

2.5.9 The Callaghan Review stated that “we consider that this represents a considerable regulatory burden on the activities of laboratories” and that “this is a fertile area to apply the Hampton principles of inspection and enforcement”.

2.6 REDUCING AND REMOVING THE BURDEN OF WORKING UNDER THREE SEPARATE SETS OF REGULATIONS

2.6.1 The restriction in Section 1(1) of HSWA limits HSE’s vires to protecting human health, and means that regulations made under HSWA are currently constrained to those micro-organisms that pose a risk to humans\(^2\).

2.6.2 This position results in a burden within the meaning of Section 1(3) of the LRRA\(^3\) because being governed by three overlapping regimes imposes administrative inconvenience and additional financial costs to facilities working with biological agents and GMOs subject to the regimes. Examples of the burdens created by multiple regulators and regimes include:

- The duty holder is different under each set of regulations, the *employer* in COSHH, the *person undertaking an activity* under GMO(CU), or the *licence holder* in SAPO (this may be an individual or other legal person), who may not be the same in each instance. This is inconsistent and a disproportionate burden on the duty holder;

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\(^2\) This is the case unless the Regulations are implementing European obligations, in which case there are vires under Section 2(2) of the European Communities Act 1972, as is the case for the GMO(CU). SAPO does not implement European obligations.

\(^3\) Section 1(3) In this section ‘burden’ means any of the following –

- a financial cost;
- an administrative inconvenience;
- an obstacle to efficiency, productivity or profitability; or
- a sanction, criminal or otherwise, which affects the carrying on of any lawful activity.
The SAPO licensing regime presents the potential for confusion over where responsibility for compliance lies particularly where multiple licencees are present on sites where a number of operators share facilities;

Different obligations are imposed under the separate regulations. For example, where genetically modified organisms affecting animals and humans are concerned a laboratory will, depending on the microorganism, need to carry out risk assessments under COSHH, apply for a licence under SAPO and comply with a notification regime under GMO(CU), creating an unnecessary administrative and financial burden.

Different containment measures are set out in the regulations or in the case of SAPO in the licence conditions, all of which require consideration. Similarly, each set of regulations has attached guidance that is not cross-referenced. For example, a scientist working with the rabies virus would need to comply with the containment requirements set out in their licence and those in Schedule 3 of COSHH, which may not be consistent.

These burdens result in a financial cost, an administrative inconvenience and an obstacle to efficiency and safety.

2.6.3 A range of duty holders working with micro-organisms in laboratories from Government, Academia, Industry and diagnostic laboratories are affected by these burdens.

2.6.4 HSE wants to amend Section 1(1) of HSWA to increase the general purposes to protect against risks to animal health arising from animal pathogens not being subject to effective contained use. This in turn would enable the creation of a new, single regulatory framework with a consistent philosophy based on risk and notification (not licensing) with a common set of containment measures governing laboratory work with micro-organisms and GMOs in contained use.

2.7 RELEVANT INFORMATION FROM THE PARTIAL IMPACT ASSESSMENT (ANNEX E)

2.7.1 If you are able to supplement or add to any of the information in this partial impact assessment, please provide it with your response to the consultation exercise.
CHAPTER 3: THE PROPOSALS

3.1 PROPOSED AMENDMENT TO SECTION 1 OF HSWA (ARTICLE 43 OF THE LRO)

Section 1 of HSWA – the general purposes

3.1.1 Section 1 of HSWA defines the objectives of Part I of HSWA and acts as a point of reference that defines the purposes of other provisions in Part 1. The LRO increases the general purposes set out in Section 1(1), Part I of HSWA by adding a purpose in paragraph (e) as follows:

“(e) providing for the contained use of animal pathogens in order to protect against risks to animal heath arising from animal pathogens not being subject to contained use or being subject to ineffective contained use.”

We also propose to insert a new section 1A as follows:

:“(1A) The references in sections 7, 8 and 9 to “the relevant statutory provisions” do not include a reference to paragraph (e) of subsection (1) of this section, or to any provision of health and safety regulations made by virtue of that paragraph.”;

and to amend subsection (3) so that it reads

3.1.2 We also propose an amendment to section 1(3) HSWA. This currently states

“For the purposes of this Part risks arising out of or in connection with the activities of persons at work shall be treated as including risks attributable to the manner of conducting an undertaking, the plant or substances used for the purposes of an undertaking and the condition of premises so used or any part of them”

and will be substituted with:

“(3) For the purposes of this Part—
(a) risks arising out of or in connection with the activities of persons at work, and
(b) risks arising from animal pathogens not being subject to contained use, or being subject to ineffective contained use, are to be treated as including risks attributable to the manner of conducting an undertaking, the plant or substances used for the purposes of an undertaking and the condition of premises so used or any part of them”.

22
3.1.3 These changes to HSWA will give HSE the vires to protect animal health but only from risks arising from the failure to adequately contain animal pathogens. The extension would not allow HSE to regulate other areas of animal health. Thus, for example, any outbreak of disease would remain the responsibility of Defra, the Scottish Executive and Welsh Assembly Government as appropriate. Contained use is defined in Article 8(2) of the LRO as “any activity in which animal pathogens are cultured, stored, transported, destroyed, disposed of or used in any other way and in respect of which physical, chemical or biological barriers (or any combination of such barriers), are used to limit the contact of such pathogens with, and to provide a high level of protection for, animals”.

3.1.4 This definition is taken from the Genetically Modified Organisms (Contained Use) Regulations 2000 and covers those deliberately working with such organisms in laboratories as part of research, teaching, development or diagnostic work or as part of industrial processes such as vaccine manufacture. It could also cover those whose job is to dispose of waste from such institutions where that waste contains animal pathogens.

3.1.5 The amendment of Section 1 HSWA affects the working of other sections in HSWA. In particular, it enables the making of regulations under Section 15 and the approval of codes of practice under section 16. Regulations made under Section 15 are health and safety regulations pursuant to section 15(1) HSWA and are part of a number of legislative provisions known collectively as the “relevant statutory provisions” as defined by section 53 HSWA.

3.1.6 The scope of powers in HSWA is frequently defined by reference to “health and safety regulations”, “the general purposes” or the “relevant statutory provisions”.

3.1.7 Section 1(3) HSWA makes clear that “risks arising out of or in connection with the activities of persons at work” includes risks attributable to the manner of conducting an undertaking, to the plant or substances used and to the condition of premises used. Article 3 of the Order extends section 1(3) to refer specifically to risks arising from the contained use of animal pathogens.

3.1.8 The amendment to section 1(1) also has a number of indirect effects. The functions of the Executive are set out in section 11 of HSWA to carry out the general purposes that would include the new purpose in section 1(1)(e). The powers of the Executive set out in section 13 of HSWA to do anything that is calculated to facilitate or is conducive, or incidental to the performance of its functions would include the new

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4 S.I. 2000/2831
purpose. Similarly, the power in section 14 that enables the Executive to direct investigations and inquiries for the general purposes would now encompass the new general purpose.

3.1.9 The duty on the Executive in section 18(1) HSWA to make adequate arrangements for enforcing the statutory provisions will extend to any regulations made in reliance on the new general purpose. It will also mean that the existing power conferred on the Secretary of State when making regulations to make local authorities responsible for their enforcement would be available in relation to any regulations made with respect to protecting animal health arising from work with animal pathogens (although HSE does not intend to recommend that local authorities enforce any such regulations).

3.1.10 Section 19 of HSWA empowers an enforcing authority to appoint inspectors to effect the relevant statutory provisions within its field of responsibility. Any regulations made for the new general purpose under Section 15 will be relevant statutory provisions and accordingly this section will therefore allow the appointment of inspectors to carry into effect those new regulations.

3.1.11 Other general powers in HSWA (listed below) will also be extended to the extent that any regulations made under section 15 are made for the protection of animals from the release of animal pathogens from contained use:

- The power in section 25A to enable customs officers to detain articles and substances;
- the power conferred by section 26 on an enforcing authority to indemnify inspectors where actions are brought against them in respect of an act done while executing or purporting to execute any of the relevant statutory provisions;
- The power in section 27 conferred on the Executive and enforcing authorities to obtain information that it needs for its general functions by serving a notice on that person to furnish such information;
- The power in section 27A to enable the Commissioners of Revenue and Customs to authorise the disclosure of information to an inspector of enforcing authority where to do so would facilitate that person in exercising their powers or duties under the relevant statutory provisions;
- The power in section 43 to make provision for the recovery of Fees in relation to the performance by any enforcing authority for the performance of a function.
• The power conferred on the Executive by section 44 to make a report to the Secretary of State if it considers that an investigation should be made as to whether a local authority who are an enforcing authority have failed to perform any of their enforcement functions. There is no intention to confer such functions on local authorities at present so this is unlikely to be used;

• Section 47 provides that breach of a duty imposed by health and safety regulations so far as it causes damage is actionable except insofar as the regulations provide otherwise. This would also apply to regulations made in respect of animal health.

3.2 OFFENCES IN SECTIONS 2 TO 9 OF HSWA WILL NOT BE EXTENDED TO THE PROTECTION OF ANIMAL HEALTH (ARTICLE 3 OF THE LRO)

3.2.1 A policy decision was taken not to extend the substantive duties in sections 2-9 of HSWA to the protection of animal health. It was felt that specific tailor-made duties that can be imposed by means of health and safety regulations are sufficient and proportionate to the objective of effective regulation.

3.2.2 The duties in sections 2-4 HSWA are clearly expressed to apply in relation to persons. Article 3 of the LRO accordingly provides that for the avoidance of doubt obligations in sections 6-9 are not extended to the contained use of animal pathogens. These are: section 6 (General duties of manufacturers etc as regards articles and substances for use at work) section 7 (general duties of employees); section 8 (duties not to interfere or misuse things pursuant to certain provisions) and section 9 (duties not to charge employees for things done or provided pursuant to certain specific requirements).

3.3 PROPOSED AMENDMENTS TO SECTIONS 20, 22, 25 (ARTICLES 4-6)

3.3.1 Falling out from the proposed amendment to Section 1 of HSWA, the following amendments are also proposed in relation to Sections 20, 22, 25 and 53 to ensure HSE has the appropriate powers to enforce any regulations made in reliance on the new purpose in Section 1(1)(e).

Section 20 – HSWA powers of inspectors

3.3.2 Section 20 empowers inspectors to exercise powers for the purposes of carrying into effect any of the relevant statutory provisions that will include any new regulations
made for the new general purpose under Section 15 HSWA. Most of these powers are identical to those currently in SAPO 2008 that were based on HSWA powers.

3.3.3 Inspectors powers include a power of entry set out in section 20(2)(a). The power of entry under HSWA enables an inspector to enter premises at any reasonable time if he believes it is necessary for the purpose of carrying into effect any of the relevant statutory provisions and to enter at any time in a situation that in his opinion is or may be dangerous. This is slightly different to the power of entry under the Animal Health Act as is set out in more detail in Chapter 4.

3.3.4 The concept of danger and dangerous is used several times in section 20(2) and will be extended by Article 5 of the LRO to clarify that it includes dangers to animal health but only where that danger arises from pathogens not being adequately contained and where protection against that danger is provided for in health and safety regulations.

Section 22 – prohibition notices

3.3.5 The existing power to serve improvement and prohibition notices in section 21 and 22 HSWA respectively will apply in respect of any regulations made in reliance on the new purposes introduced by the LRO. The power to serve prohibition and improvement notices was already a feature of SAPO so this will not be a significant change for those being regulated.

3.3.6 Under section 22 HSWA an inspector may only serve a prohibition notice where he is of the opinion that the activities involve or will involve a risk of serious personal injury. Article 6 of the LRO extends the pre-condition to include a risk of serious harm to animal health arising from animal pathogens where that risk is provided for in health and safety regulations.

Section 25 – Power to deal with cause of imminent danger

3.3.7 This section empowers an inspector to seize any article or substance which he finds in premises and in respect of which he has power to enter. The inspector has power to cause that substance to be rendered harmless by destruction, if necessary, if there is reasonable cause to believe it presents an imminent danger of serious personal injury in the circumstances in which it is found. This section has been extended to cover risk to animal health caused by animal pathogens not being subject to contained use or being subject to ineffective contained use where that risk is provided for in health and safety regulations.
3.4 AMENDMENTS TO PENALTY LIMITS IN SECTION 33 (Article 7)

3.4.1 As stated above, the effect of the amendment to section 1(1) HSWA means that health and safety regulations can be made in reliance on the new general purpose to be introduced by paragraph (e). Breach of health and safety offences is a criminal offence pursuant to section 33 HSWA. Offences can be heard in either the magistrates court or the crown court depending on the seriousness of the offence.

3.4.2 In respect of offences tried as summary offences, the existing penalties in HSWA are higher than the penalties allowed by section 6 of the LRRA. Accordingly article 7 of the LRO limits penalties for new offences created in reliance on the new power in section 1(1)(e) to the maximum allowed in the LRRA.

3.4.3 The penalties limits in HSWA for offences heard in the Crown Court are within the limits allowed under the LRRA and accordingly no limit on penalties is proposed in this respect.

3.5 HOW THE LRO SEEKS TO ADDRESS THE CURRENT PROBLEMS IN REGULATING BIOLOGICAL AGENTS THAT CAUSE HARM TO ANIMAL HEALTH

3.5.1 By extending the general purposes as set out above and the consequential amendment of other relevant provisions we have ensured that those working with animals can be regulated by a single and consistent set of regulations that will apply and be enforceable in the same way as regulations governing those working with human pathogens and genetically modified organisms. Furthermore, for those working with zoonoses that affect human and animal health, they will only have to comply with one set of regulations rather than two.

3.6 HOW THE LRO WILL MAKE REGULATORY FUNCTIONS MORE CONSISTENT WITH PRINCIPLES OF GOOD REGULATION

3.6.1 The proposed LRO will amend HSWA enabling HSE to make health and safety regulations that comply with the principles of good regulation. The following demonstrates how the proposed amendment, and subsequent regulations, will ensure that activities are carried out in a way that is:

- **Transparent** – The single set of regulations that will replace the three current sets of legislation will be subject to a formal 12-week consultation allowing consultees to be fully informed and able to respond. A detailed ‘Guide to the Regulations’ will form part of the consultation package that will provide
clarification in plain language of duty holders’ obligations under the new regulatory framework.

- **Accountable** – This document provides the rationale and justification for making the LRO to amend HSWA and sets out the decisions made to ensure the new regulatory regime removes the complexities and incongruities of the current legislation, providing a unified, streamlined and flexible approach to regulation under a robust permissioning regime.

- **Proportionate** – The proposed LRO provides for regulations that are risk-based and provide a proportionate response from both duty holders and regulators in terms of what is required to ‘comply with the law’ i.e. measures that duty holders need to take are proportionate to the risk posed and commensurate with cost compliance imposed.

- **Consistent** – The amendment to HSWA will enable HSE to become the single regulatory body enforcing a single regulatory framework thereby providing a consistent approach to interpretation and enforcement of regulatory activities across GB.

- **Targeted** – The LRO provides for regulations that are primarily risk-based, goal setting, and provide for a proportionate and flexible approach. This allows duty holders to implement controls according to risk thereby achieving regulatory compliance by targeted means. The regulations will also provide for a targeted programme of inspection and enforcement commensurate with those activities that provide the most serious risks.

### 3.7 FORMAL RESPONSE PROCESS

3.7.1 Comments are invited on the proposals that will require changes to primary legislation i.e. HSWA. Views are invited on all aspects of this consultation paper. There are a number of questions for which we are looking for specific feedback in relation to discrete issues of relevance to the proposals. These are outlined in the following section and in the Response Form at Annex B.

**Question 1**

*Do you agree that it is desirable to have a single regulator and a single regulatory framework governing micro-organisms that are human and animal pathogens?*
Question 2

Do you agree that HSE cannot regulate work with animal pathogens in contained use without amending the Health and Safety at Work etc. Act 1974?

Question 3

Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 are proportionate to the final outcome i.e. a single regulatory framework?

Question 4

Do you think the overall effect of the proposals will be to remove or reduce burdens as explained in section 2.6?

Question 5

Do you agree that the proposed extension of inspectors powers of entry in section 20(1)(b) of HSWA to cover risks to animal health arising from contained use activities with animal pathogens are proportionate and for a similar purpose to the existing powers that covers risks arising to human health from human pathogens and zoonoses?

Question 6

Do you agree that the proposed extension to inspectors powers in section 20 of HSWA

a) of search and seizure; and

b) to compel evidence

to cover risks to animal health arising from contained use activities with animal pathogens are proportionate and for a similar purpose to those existing power that currently cover risks arising to human health from contained use of human pathogens and zoonoses arising from the contained use of genetically modified micro-organisms?

Question 7

Do you have views regarding the expected benefits of the proposals as identified in Chapter 2 of this consultation document and addressed in the Partial Impact Assessment?
Question 8

If there is any empirical evidence that you are aware of that supports the need for these reforms, please provide details below.

Question 9

Are there any non-legislative means that would satisfactorily remedy the difficulty that the proposals intend to address?

Question 10

Are the proposals put forward in this consultation document proportionate to the policy objective?

Question 11

Do the proposals put forward in this consultation document, taken as a whole, strike a fair balance between the public interest and any person adversely affected by it?

Question 12

Do you agree that the proposed changes do not have a significant financial impact as set out in the summary impact assessment?

Question 13

Do you agree that the proposed changes to Sections 20, 22, 25 and 53 of the Health and Safety at Work etc Act 1974 are proportionate to the policy objectives in this proposal?

Question 14

Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 do not remove any necessary protection?

Question 15

Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 do not prevent anyone from exercising an existing right or freedom?

Question 16

Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 are not constitutionally significant?
**Question 17**

*Do you agree that the proposed Parliamentary resolution procedure should apply to the scrutiny of this proposal?*

**Question 18**

*Do you agree that the burden on Crown premises is proportionate to the overall objective of ensuring that contained use activities with animal and human pathogens are applied consistently and effectively in respect of those carrying out contained use activities?*

### 3.8 GEOGRAPHICAL EXTENT OF THE CHANGES

3.8.1 The changes would apply to England, Wales and Scotland\(^5\). HSWA does not generally extend to Northern Ireland.

### 3.9 BINDING THE CROWN

3.9.1 HSWA, section 48 states that Part I and regulations made under it bind the Crown, but that sections 20 - 24 (powers for inspectors to require remedial action by notice procedure and to deal with the cause of imminent danger) and sections 32 - 42 (provisions as to offences) are not to bind the Crown. However, other powers of inspectors in, for example, section 19 (for entry, investigation and examination) do apply to the Crown and its premises. There is, however, a power in sub-section (4) to exempt by order particular premises or classes of premises from inspectors if necessary.

\(^5\) There are two exceptions to territorial extent in HSWA. The first, which would be unaffected by the Legislative Reform Order is in section 84(1) HSWA. This provides that health and safety regulations can be made for the whole of the UK for the purposes in paragraph 2 of Schedule 3 HSWA (provisions relating to the prohibition of the importation into the United Kingdom of specified articles or substances or the landing or unloading of those articles or substances). The new general purposes in section 1(1)(e) would not extend to allowing the regulation of importation of animal pathogens so these provisions would be unaffected.

The Health and Safety at Work etc Act 1974 (Application outside Great Britain) Order 2001 (S.I. 2001/2127) applies Part 1 and sections 80 -82 of HSWA to offshore installations and pipelines within territorial waters and areas designated under the continental shelf Act 1964, and to certain work in connection with those installations and pipelines and in certain other activities within territorial waters. In the extremely unlikely event that contained use of animal pathogens was to be carried out on offshore installations within territorial waters the regulations would apply to them.
3.9.2 Although HSE cannot use enforcement sanctions and powers in HSWA against the Crown, HSE does have an effective and established procedure whereby it can serve Crown Notices and a quasi-court procedure of Crown Censure that HSE has used against crown premises in the past.

3.9.3 Further sections 32 to 42 do apply to persons in the public service of the Crown, as to other persons.

3.10 PARLIAMENTARY PROCEDURES

3.10.1 There are three procedures available for Parliamentary scrutiny of LROs. These are negative resolution, affirmative resolution and super-affirmative resolution.

Negative resolution – allows Parliament 40 days to scrutinise the draft LRO after which the Minister can make the LRO if neither House of Parliament has resolved during this time that it should not be made.

Affirmative resolution – allows Parliament 40 days to scrutinise the draft LRO after which the Minister can make the LRO if it is approved by a resolution of each House of Parliament.

Super-affirmative resolution – is a two-stage procedure during which time there is opportunity for the draft LRO to be revised by the Minister. The procedure allows 60 days of initial scrutiny, when the Parliamentary Counsel may report on the draft LRO or either House may make a resolution with regard to the draft LRO. If after this 60-day period the Minister may make the LRO in terms of the draft but only if it is approved by resolution of each House of Parliament. If the Minister wishes to make material changes to the draft LRO he must lay the revised draft LRO and a statement giving details of any representations made during the scrutiny period and of the revised proposal before Parliament. After 25 days, the Minister may only make the LRO if it is approved by a resolution of each House of Parliament.

3.10.2 It is proposed that the LRO will be made under the affirmative resolution procedure. The rational for using this procedure is that while the amendments are not purely administrative they are unlikely to be controversial as their effect is largely to move the regulation of animal pathogens from one legislative regime to another. Overall, the effect will be to remove burdens by removing the duplication of requirements and consultation so far has indicated the changes are welcomed and not controversial. There are some areas in relation to penalties and powers of entry that warrant some closer parliamentary scrutiny.
CHAPTER 4: LEGAL ANALYSIS AGAINST REQUIREMENTS OF THE LEGISLATIVE AND REGULATORY REFORM ACT 2006

4.1 PRECONDITIONS AND RESTRICTIONS FOR AN ORDER UNDER SECTION 1 OF THE LRRA

Preconditions

a) Policy objectives could not be satisfied by non-legislative means

4.1.1 HSE has considered the following alternatives to amending section 1(1) of HSWA in the way proposed.

4.1.2 The first was to continue with current agency arrangements put in place as a temporary measure from April 2008. Under these arrangements the Minister, the Scottish Executive and Welsh Assembly Government have agreed that HSE should exercise their powers to enforce SAPO on their behalf. This option was always intended as a temporary measure and is unsatisfactory in the long run even if further amendments were made to SAPO to make it more like COSHH or GMO (CU) for the following reasons:

- There would remain separate pieces of legislation (SAPO and COSHH/GMO (CU)) that would seek to regulate similar and, in the case of zoonoses and genetically modified animal pathogens, the same organisms for the same purpose of containment.

- Differences resulting from the different legal basis for COSHH and SAPO (made under HSWA and the Animal Health Act respectively) could not be addressed. The powers of entry for example under the Animal Health Act and HSWA are slightly different potentially causing confusion and uncertainty for duty holders and inspectors visiting premises working with animal and human pathogens or zoonoses.

- An agency agreement does not address a significant shortcoming of the Animal Health Act namely that it does not apply to Crown Premises. The only sanction currently available against Crown Premises under SAPO is the revocation of a licence although there is nothing to stop Crown premises from operating without a licence should they choose to do so. A number of the laboratories working with animal pathogens and zoonoses are Crown Premises. HSWA does apply to the Crown and although criminal proceedings and enforcement mechanisms cannot be brought against the Crown under HSWA. HSE has administrative sanctions...
available to it such as the service of Crown notices or Crown Censure proceedings that can be administered very effectively.

- Ultimate responsibility for the two regimes would lie with different public bodies thereby duplicating measures needed to oversee and keep the legislation up to date and effective.

- Currently there is a combined ACoP and Guidance document for CoSHH and Guidance for GMO (CU). HSE clearly would not currently have vires to issue an ACoP and Guidance covering SAPO.

4.1.3 The other alternative that was considered was to make a single statutory instrument relying on the existing vires in the Animal Health Act and HSWA. However the following impediments were identified:

- The Animal Health Act provides for the making of orders and HSWA for the making of regulations. Drafting guidance indicates that the two powers cannot be relied on in one instrument.

- Legislation made under HSWA is G.B. wide whereas because Animal Health is a devolved matter and orders under the Animal Health Act have to be made separately in England Wales and Scotland.

- The differences in terms of applicability to the Crown and differences in powers of entry identified above would also remain.

b) The effects of the provisions are proportionate to the policy objective to be achieved

4.1.4 The policy objective behind our proposal is to align the different regulatory regimes as far as possible within a single regulatory framework with a single set of principles and a single regulator.

4.1.5 The protection of animal health is an extension to HSWA that would appear to be a significant departure from its current legislative purpose of protecting human health. However, in practice the fact that the extension is confined to preventing harm from a failure to contain animal pathogens means the types of activities to be regulated under the extension will be the same as those already regulated by HSE. For instance, scientists working with microorganisms under COSHH such that they need to be effectively contained to prevent them causing harm.

4.1.6 Furthermore, HSE already regulates work with genetically modified versions of those animal pathogens (as well as all other genetically modified micro-organisms) in order to protect human health and the environment (including animals) under
GMO(CU). The power to protect the environment in this case is provided by the European Communities Act as the regulations implement European obligations.

c) The provisions of the proposed order will strike a fair balance between the public interest and the interest of any person adversely affected by them\(^6\)

4.1.7 It is in the public interest to ensure those working with animal pathogens do so to the highest standards to ensure the pathogens are effectively contained. The Callaghan report indicated that the Foot and Mouth outbreak at Pirbright in 2007 cost £100 million and the earlier outbreak in 2001 (not thought to have been caused by a laboratory failure) was estimated to have cost the country £8 billion in total\(^7\).

4.1.8 Having a single regulatory regime and single regulator will help to achieve the most effective and efficient regulatory regime to reduce the risk as far as possible of further outbreaks of the disease caused by a failure to adequately contain animal pathogens.

4.1.9 There will be a significant benefit working with animal pathogens that also pose a risk to human health or are genetically modified because they will avoid the current situation of double regulation under SAPO and health and safety regulations. Even where there is no double regulation for wild-type animal pathogens because they only affect animals we believe that regulating animal pathogens by HSE as part of a consistent risk based regime for human pathogens and GMMs will result in a more proportionate and effective regime.

4.1.10 HSWA does contain significant powers for inspectors enforcing health and safety regulations in section 20 of HSWA. However these powers are currently available to inspectors enforcing SAPO by virtue of Articles 6-8 and Schedule 2 of SAPO.

4.1.11 There are however two potential adverse effects for duty holders working with animal pathogens that only pose a risk to animal health that have to be balanced against the reduction of burdens for duty holders as a whole and the overall benefit to the public of a single more effective regime. Those are the alignment of the slightly different powers of entry in HSWA and the Animal Health Act and the fact that breach of some health and safety offences in section 33 HSWA including breach of health and

\(^6\) As these regulations implement European regulations they rely on section 2(2) of the European Communities Act to enable the regulations to be treated as Health and Safety Regulations for the purposes of enforcement by HSE.

\(^7\) National Audit Office the 2001 the Outbreak of Foot and Mouth Disease (2002)
safety regulations can be tried on indictment if the facts of a particular case are sufficiently serious or the Defendant so elects.

i) Powers of entry

The effect of the LRO is that the powers of entry contained in section 20(2)(a)-(c) of the Health and Safety at Work Act will extend to any regulations made in relation to animal pathogens in reliance on the new purpose in section I(l)(e)HSWA. The powers of entry in HSWA allow an inspector at any reasonable time (or, in a situation which in his opinion is or may be dangerous, at any time) to enter any premises which he has reason to believe it is necessary for him to enter for purpose of carrying into effect any of the relevant statutory provisions. It further allows him to take with him a constable if he has reasonable cause to apprehend any serious obstruction in the execution of his duty or to take any other person authorized by his enforcing authority.

The reality is that to the extent animal pathogens also pose a risk to human health the powers of entry in HSWA already apply under COSHH. Similarly if the animal pathogen is genetically modified the HSWA powers of entry would apply under GMO(CU).

For those duty holders working with wild-type animal pathogens that only pose a risk to animal health they would have been subject to the powers of entry in section 63(2)(c) or (d) the Animal Health Act. These powers allow an inspector to enter at any time a place where he has reasonable grounds to believe:

"(c) that there is to be found any pen, place, vehicle, or thing in respect of which any person has on any occasion failed to comply with the provisions of this Act, or of an order of the Minister, or of a regulation of a local authority; or

(d) that ... an order of the Minister ... has not been or is not being complied with."

The power of entry in the Animal Health Act appears to be broader than that in HSWA in the sense that there is a power to enter at any time whereas the power in HSWA is to enter only at any reasonable time unless there is a situation that in the opinion of the inspector may be dangerous.

However, the power in the Animal Health Act appears more narrowly defined in the sense that it requires the inspector to have reasonable grounds to believe an order of the minister is not being complied with before the power of entry is triggered. HSWA on the other hand allows entry for the purpose of carrying into effect the relevant statutory provisions which would include routine inspections.
However, on closer analysis, as SAPO requires that licence conditions be complied with and, as standard licence conditions granted under SAPO 2008 require the licence holders to adequately control the access of persons to the licensed premises and requires them to allow access to inspectors to the premises, any failure to permit entry to an inspector would trigger a statutory right of entry under section 66(1)(d) in any event because it would amount to breach of an order.

ii) Offences triable on indictment

Offences heard on indictment can attract significantly higher penalties than summary offences. By contrast, offences relating to the breach of SAPO are summary only offences.

Although penalties for summary offences created in relation to animal pathogens have been expressly limited in the LRO to those allowed in section 6 of the LRRA we are not proposing to restrict the power currently available in section 33 of HSWA for offences that are sufficiently serious to be tried as indictable offences with the consequentially higher penalties available.

The reason for this is that it would be inconsistent within a single regulatory framework to restrict the options available to the court for dealing with offences relating to one subset of micro-organisms (animal pathogens) when it is intended that they will be regulated in a single set of regulations with other very similar micro-organisms (e.g. human pathogens and genetically modified micro-organisms at the same establishment by the same duty holder).

For example, it would seem hard to justify restricting an offence involving wild-type foot and mouth virus to summary trial when the same offence with a genetically modified version of the same virus could be heard on indictment under GMO(CU) even though the genetically modified version might have been modified in such a way that it poses less risk or causes less harm. It is also difficult to see how such a restriction could work in relation to zoonoses. For example if there was a release of rabies virus that caused harm to humans and animals the human aspect of the offence would be capable of being heard on indictment but not the animal aspect.

d) The provisions of the proposed order will not remove any necessary protection

4.1.12 Although Section 20 of HSWA contains comprehensive powers for inspectors to take necessary enforcement action these powers are almost identical to those currently in Articles 6 - 9 and Schedule 2 of SAPO which was drafted with a view to aligning the
powers to those in HSWA. Necessary protection for those subject to the exercise of those powers contained in both HSWA and the Animal Health Act has not been removed.

e) The provisions of the proposed order do not prevent a person exercising any right or freedom that they might reasonably expect to continue to exercise

4.1.13 Although the provisions of the order enable the making of regulations under HSWA to control the circumstances in which a person may possess or work with animal pathogens the possession and use of animal pathogens is already regulated in SAPO under the Animal Health Act. Accordingly we do not believe that the provisions of the order prevent anyone exercising an existing right or freedom. We would welcome your views on whether we are correct in thinking that our proposals do not remove any rights or freedoms that anyone could reasonably expect to continue to enjoy.

f) The provisions in the proposed order are not constitutionally significant

4.1.14 Although the extension of HSWA to cover the contained use of animal pathogens allows HSE to regulate for Great Britain in respect of matters touching on animal health for the narrow purposes of ensuring animal pathogens are adequately contained, it does not remove the right of the Scottish Executive or the Welsh Assembly Government to do so should they wish to do so in the future. In reality, those administrations have indicated their support for the Callaghan proposal and have no plans to legislate in this area.

4.1.15 The conferral of functions on HSE to protect animal health does not offend the devolution settlement with Scotland because HSE is a reserved body and the power to confer functions on a reserved body under the Scotland Act 2008 is a function reserved to Westminster and accordingly is not something that Scottish Ministers could do.

4.2 OTHER RESTRICTIONS

CRIMINAL PENALTIES

4.2.1 Section 33 of HSWA creates a number of relevant criminal offences set out in Schedule G including making it an offence for a person to breach health and safety regulations.

4.2.2 Offences under the Animal Health Act for breach of SAPO are summary only offences. The LRO specifically amends section 33 of HSWA with respect to summary offences that have been created in reliance on the new general purpose created by the LRO in section 1(1)(e).
4.2.3 The maximum penalties for such summary offences will be:
   a) imprisonment for a term not exceeding the maximum term; and
   b) a fine exceeding level 5 on the standard scale.

4.2.4 The normal maximum term in paragraph (a) means-
   a) in England and Wales-
      (i) in the case of a summary offence, 51 weeks;
      (ii) in the case of an offence triable either way, 12 months;
   b) in relation to Scotland 6 months.

4.2.5 Where an offence is tried as an indictable offence the current HSWA penalties in the table set out in Schedule G will apply even where the offence relates to animal pathogens and relies on the new general purpose created by the LRO in section 1(1)(e).

4.3 POWERS OF ENTRY, SEARCH, SEIZURE AND THE COMPELLING OF EVIDENCE

4.3.1 Section 7(1) of the LRRA provides that a Legislative Reform Order may not make any provision to authorize forcible entry search or seizure or compel the giving of evidence. However, section 7(2) LRRA provides that this prohibition does not prevent an order from “extending any power for purposes similar to those to which the power applied before the order was made.”

4.3.2 Whilst the LRO does extend the power of entry this is not a power of forcible entry. The inspector has no power to use force to gain entry although it is a criminal offence not to allow the inspector to enter premises.

4.3.3 The powers in section 20 of HSWA do include the power to search, seize and compel the giving of evidence. The powers in section 20 are stated in section 20(1) to be there for the purposes of “carrying into effect any of the relevant statutory provisions” which include health and safety regulations. Once regulations are made under the

_________________________

8 In the case of an offence which if committed by an adult is triable either on indictment or summarily and is not triable on indictment by virtue only of Part 5 of the Criminal Justice Act 1988 (c33) or section 296(2) and (7) of the Criminal Procedure (Scotland) Act 1994 (c46) the fine is the statutory maximum.
increased general purposes in section 1(1)(e) the powers could be used in respect of any animal pathogens covered by those regulations.

4.3.4 Our view is that the extension of the powers to cover animal pathogens once regulated does so for a purpose that is very similar to that for which is already exercised in HSWA for the reasons set out below. However, we would be grateful for your views on whether you agree with this.

Powers of search and seizure for a similar purpose

4.3.5 Section 20(2) (d)-(m) of HSWA allows an inspector to make such examination and investigation as may in any circumstances be necessary for the purposes of carrying into effect any health and safety regulations. It also gives him broad powers to take samples of articles or substances; require any article that appears to have caused or is likely to cause danger to be dismantled or subjected to any test (but not to destroy it unless necessary for the purpose of regulations). A copy of inspector's powers in section 20 is set out in Part 3 of Annex G.

4.3.6 The new general purpose in Section 1(1)(e) of HSWA is defined as “protecting against risks to animal health arising out of or in connection with the release of animal pathogens from contained use”. The purpose of the new vires is to prevent the release of a sub-set of micro-organisms, namely animal pathogens from a contained use environment. The purpose of enforcement powers in Section 20 where they are currently used in COSHH and GMO(CU) is similarly for the purpose of preventing the release of micro-organisms from a contained use environment, in this case micro-organisms that pose a risk to human health or that have been genetically modified and pose a risk.

4.3.7 Thus an inspector exercising Section 20 powers in relation to animal pathogens would only be using those powers in relation to the same type of substances as is currently the case, namely micro-organisms. In many cases this would be the same biological agent, as many animal pathogens currently listed in SAPO are already regulated under HSWA as human pathogens e.g. rabies, avian influenza virus, anthrax, West Nile fever virus, and many more.

4.3.8 The powers would be used in relation to the same duty-holders carrying out the same activities namely those carrying out contained use that is narrowly defined in the LRO i.e. research institutions, universities, virus vaccine manufacturers. Nearly all those duty holders that carry out contained use work in relation to animal pathogens under SAPO are already known to HSE and regulated by HSE for similar if not identical work with human pathogens or genetically modified organisms (with the exception of animal vaccines manufacturers).
4.3.9 Further assuming as is intended a single set of regulations is made following the amendments to HSWA in the LRO the extended enforcement powers would be used for the purpose of enforcing the same regulations which will contain similar if not identical obligations on duty holders with regard to risk assessments, containment measures, notification and cost recovery. For example, under the proposed Contained Use Regulations there would be a requirement to notify the first use of premises for contained use work. That obligation would not differentiate between animal or human pathogens and thus a notification in relation to work with animal pathogens would satisfy the requirement even if work is subsequently carried out with human pathogens or genetically modified organisms.

4.3.10 It is because the requirements necessary to regulate effectively animal and human pathogens are so similar that the Callaghan report advised strongly against separate regulatory regimes.

4.3.11 Inspections of duty holders carrying out contained use would involve the use of the same powers because inspectors would be considering the same key issues irrespective of whether the individual pathogens affect humans, animals or both (in particular whether adequate risk assessments have been carried out; whether appropriate containment measures have been identified and implemented according to the level of risk identified; whether appropriate notifications have been made to the competent authority; whether proper procedures are in place to deal with an incident or accident resulting in the release of biological agents; and in the event of a release of a biological agent ensuring that the release is thoroughly investigated and, if appropriate, enforcement action is taken).

4.4 SECTION 9 – PROVISIONS THAT WOULD BE WITHIN THE COMPETENCE OF THE SCOTTISH PARLIAMENT

4.4.1 Section 9 of the LRRA prohibits an LRO from making any provision that would be within the competence of the Scottish Parliament to do. As HSE is a conferred body and the effect of the proposed amendments are to confer additional functions on that reserved body which is something especially reserved to Westminster the provision would not be within the competence of the Scottish Parliament.
ANNEX A: LIST OF CONSULTEES

Advisory Committee on Dangerous Pathogens
Association of Clinical Microbiologists
Association of Medical Microbiologists Clinical Services Committee
Better Regulation Executive
British Society for Microbial Technology
Cabinet Office
Confederation of British Industry
HM Revenue and Customs
Department for Environment, Food and Rural Affairs
Duty holders, including Academia, Government, Healthcare, Veterinary and Industry
Department for Work and Pensions
Enterprise Directorate
Home Office
Institute of Biomedical Scientists
Institute for Safety in Technology and Research
Local Authorities
National Blood Transfusion Service
Royal College of Pathologists
Scientific Advisory Committee on Genetic Modification
Scottish Government
Scottish Trade Union Council
Society for General Microbiology
Trade Union Council
Welsh Assembly Government
ANNEX B: RESPONSE FORM

RESPONSE FORM FOR THE CONSULTATION PAPER ON CHANGES TO THE REGULATION OF BIOLOGICAL AGENTS AND GMOS IN CONTAINED USE

Respondent Details

Name:

Organisation:

Address:

Town/City:  County/Postcode:

Telephone:  Fax:

E-mail:

☐ Please check this box if you do not wish details of your comments to be available to the public (NB if you do not check the box they will be made public).

General

What is your type of organisation?

☐ Industry ☐ Trade association

☐ Local Government ☐ Charity

☐ National Government ☐ Academic

☐ Non-governmental organisation ☐ Consultancy

☐ Non-departmental ☐ Member of the public

☐ Public body ☐ Pressure group

☐ Trade union ☐ Other (please specify)
In what capacity are you responding?
(Please select one option from the list)

☐ An employer
☐ Safety representative
☐ An employee
☐ Training provider
☐ Trade union official
☐ Other (please specify)

Size of organisation:
(Please choose one option)

☐ Not applicable
☐ 250 to 1000 employees
☐ 1 to 9 employees
☐ 1000+ employees
☐ 10 to 49 employees
☐ Self-employed
☐ 50 to 249 employees

Specific questions

Question 1
Do you agree that it is desirable to have a single regulator and a single regulatory framework governing micro-organisms that are human and animal pathogens?

☐ Yes
☐ No

Please provide some comments to support your answer
Question 2
Do you agree that HSE cannot regulate work with animal pathogens in contained use without amending the Health and Safety at Work etc. Act 1974?

☐ Yes  ☐ No

Please provide some comments to support your answer

Question 3
Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 are proportionate to the final outcome i.e. a single regulatory framework?

☐ Yes  ☐ No

Please provide some comments to support your answer

Question 4
Do you think the overall effect of the proposals will be to remove or reduce burdens as explained in section 2.6?

☐ Yes  ☐ No

Please provide some comments to support your answer
**Question 5**

Do you agree that the proposed extension of inspectors’ powers of entry in section 20(1)(b) of HSWA to cover risks to animal health arising from contained use activities with animal pathogens are proportionate and for a similar purpose to the existing powers that cover risks arising to human health from human pathogens and zoonoses?

☐ Yes ☐ No

Please provide some comments to support your answer

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**Question 6**

Do you agree that the proposed extension to inspectors’ powers in section 20 of HSWA

a) of search and seizure; and

b) to compel evidence

to cover risks to animal health arising from contained use activities with animal pathogens are proportionate and for a similar purpose to those existing powers that currently cover risks arising to human health from contained use of human pathogens and zoonoses arising from the contained use of genetically modified micro-organisms?

☐ Yes ☐ No

Please provide some comments to support your answer
Question 7

Do you have views regarding the expected benefits of the proposals as identified in Chapter 2 of this consultation document and addressed in the Partial Impact Assessment?

☐ Yes  ☐ No

Please provide some comments to support your answer

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Question 8

If there is any empirical evidence that you are aware of that supports the need for these reforms, please provide details below.

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Question 9

Are there any non-legislative means that would satisfactorily remedy the difficulty that the proposals intend to address?

☐ Yes  ☐ No

Please provide some comments to support your answer
Question 10

Are the proposals put forward in this consultation document proportionate to the policy objective?

☐ Yes  ☐ No

Please provide some comments to support your answer

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Question 11

Do the proposals put forward in this consultation document, taken as a whole, strike a fair balance between the public interest and any person adversely affected by it?

☐ Yes  ☐ No

Please provide some comments to support your answer

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Question 12

Do you agree that the proposed changes do not have a significant financial impact as set out in the summary impact assessment?

☐ Yes  ☐ No

Please provide some comments to support your answer

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Question 13
Do you agree that the proposed changes to Sections 20, 22, 25 and 53 of the Health and Safety at Work etc Act 1974 are proportionate to the policy objectives in this proposal?

☐ Yes  ☐ No

Please provide some comments to support your answer

Question 14
Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 do not remove any necessary protection?

☐ Yes  ☐ No

Please provide some comments to support your answer

Question 15
Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 do not prevent anyone from exercising an existing right or freedom?

☐ Yes  ☐ No

Please provide some comments to support your answer
Question 16
Do you agree that the proposed changes to the Health and Safety at Work etc Act 1974 are not constitutionally significant?

☐ Yes ☐ No

Please provide some comments to support your answer

Question 17
Do you agree that the proposed Parliamentary resolution procedure should apply to the scrutiny of this proposal?

☐ Yes ☐ No

Please provide some comments to support your answer

Question 18
Do you agree that the burden on Crown premises is proportionate to the overall objective of ensuring that contained use activities with animal and human pathogens are applied consistently and effectively in respect of those carrying out contained use activities?

☐ Yes ☐ No

Please provide some comments to support your answer
Are there any further comments you would like to make on the issues raised in this consultation document that you have not already responded to in this questionnaire?

Is there anything you particularly liked or disliked about the questionnaire?
Introduction

1. These reform proposals in relation to the regulation of animal pathogens in contained use will require changes to primary legislation in order to give effect to them. The Minister could achieve these changes by making a Legislative Reform Order (LRO) under the Legislative and Regulatory Reform Act 2006 (LRRA). LROs are subject to preliminary consultation and to rigorous Parliamentary scrutiny by Committees in each House of Parliament. On that basis, the Minister invites comments on these reform proposals in relation to the regulation of animal pathogens in contained use as measures that might be carried forward by a LRO.

Legislative Reform Proposals

2. This consultation document on the regulation of animal pathogens in contained use has been produced because the starting point for LRO proposals is thorough and effective consultation with interested parties. In undertaking this preliminary consultation, the Minister is expected to seek out actively the views of those concerned, including those who may be adversely affected, and then to demonstrate to the Scrutiny Committees that he or she has addressed those concerns.

3. Following the consultation exercise, when the Minister lays proposals before Parliament under the section 14 of the Legislative and Regulatory Reform Act 2006, he or she must lay before Parliament the Explanatory Document that must:

   I. Explain under which power or powers in the LRRA the provisions contained in the order are being made;

   II. Introduce and give reasons for the provisions in the Order

   III. Explain why the Minister considers that:

       • There is no non-legislative solution which will satisfactorily remedy the difficulty which the provisions of the LRO are intended to address;

       • The effect of the provisions are proportionate to the policy objective;
• The provisions made in the order strike a fair balance between the public interest and the interests of any person adversely affected by it;

• The provisions do not remove any necessary protection;

• The provisions do not prevent anyone from continuing to exercise any right or freedom which they might reasonably expect to continue to exercise;

• The provisions in the proposal are not constitutionally significant; and

• Where the proposals will restate an enactment, it makes the law more accessible or more easily understood.

IV. Include, as far as appropriate, an assessment of the extent to which the provision made by the order would remove or reduce any burden or burdens;

V. Identify and give reasons for any functions of legislating conferred by the order and the procedural requirements attaching to the exercise of those functions; and

VI. Give details of any consultation undertaken, any representations received as a result of the consultation and the changes (if any) made as a result of those representations.

4. On the day the Minister lays the proposals and explanatory document, the period for Parliamentary consideration begins. This lasts 40 days under negative and affirmative resolution procedure and 60 days under super-affirmative resolution procedure. If you want a copy of the proposals and the Minister’s explanatory document laid before Parliament, you will be able to get either from the Government department concerned or by visiting the BRE website at:

• http://bre.berr.gov.uk/regulation/reform/bill/

Parliamentary Scrutiny

5. Both Houses of Parliament scrutinise legislative reform proposals and draft LROs. This is done by the Regulatory Reform Committee in the House of Commons and the Delegated Powers and Regulatory Reform Committee in the House of Lords.
6. Standing Orders for the Regulatory Reform Committee in the Commons stipulate that the Committee considers whether proposals:

   a) appear to make an inappropriate use of delegated legislation;

   b) serve the purpose of removing or reducing a burden, or the overall burdens, resulting directly or indirectly for any person from any legislation (in respect of a draft Order under section 1 of the Act);

   c) serve the purpose of securing that regulatory functions are exercised so as to comply with the regulatory principles, as set out in section 2(3) of the Act (in respect of a draft Order under section 2 of the Act);

   d) secure a policy objective which could not be satisfactorily secured by non-legislative means;

   e) have an effect which is proportionate to the policy objective;

   f) strike a fair balance between the public interest and the interests of any person adversely affected by it;

   g) do not remove any necessary burden;

   h) do not prevent any person from continuing to exercise any right or freedom which that person might reasonably expect to continue to exercise;

   i) are not of constitutional significance;

   j) make the law more accessible or more easily understood (in the case of provisions restating enactments);

   k) have been the subject of, and take appropriate account of, adequate consultation;

   l) give rise to an issue under such criteria for consideration of statutory instruments laid down in paragraph (1) of Standing Order No 151 (Statutory Instruments (Joint Committee)) as are relevant, such as defective drafting or failure of the department to provide information where it was required for elucidation;

   m) appear to be incompatible with any obligation resulting from membership of the European Union.

7. The Committee in the House of Lords will consider each proposal in terms of similar criteria, although these are not laid down in Standing Orders.
8. Each Committee might take oral or written evidence to help it decide these matters, and each Committee would then be expected to report.

9. Copies of Committee Reports, as Parliamentary papers, can be obtained through HMSO. They are also made available on the Parliament website at

- Regulatory Reform Committee in the Commons; and
- Delegated Powers and Regulatory Reform Committee in the Lords

10. Under negative resolution procedure, each of the Scrutiny Committees is given 40 days to scrutinise an LRO, after which the Minister can make the order if neither House of Parliament has resolved during the period that the order should not be made or to veto the LRO.

11. Under affirmative resolution procedure, each of the Scrutiny Committees is given 40 days to scrutinise an LRO, after which the Minister can make the order if it is not vetoed by either or both of the Committees and it is approved by a resolution of each House of Parliament.

12. Under super-affirmative procedure, each of the Scrutiny Committees is given 60 days to scrutinise the LRO. If, after the 60 day period, the Minister wishes to make the order with no changes, he may only do so after he has laid a statement in Parliament giving details of any representations made and the LRO is approved by a resolution of each House of Parliament. If the Minister wishes to make changes to the draft LRO he must lay the revised LRO and as well as a statement giving details of any representations made during the scrutiny period and of the proposed revisions to the order, before Parliament. The Minister may only make the order if it is approved by a resolution of each House of Parliament and has not been vetoed by either or both relevant Committees.

How to Make Your Views Known

13. Responding to this consultation document is your first and main opportunity to make your views known to the relevant department as part of the consultation process. You should send your views to the person named in the consultation document (in this case Mr John Newbold). When the Minister lays proposals before Parliament you are welcome to put your views before either or both of the Scrutiny Committees.

14. In the first instance, this should be in writing. The Committees will normally decide on the basis of written submissions whether to take oral evidence.
15. Your submission should be as concise as possible, and should focus on one of more of the criteria listed in paragraph 6 above.

16. The Scrutiny Committees appointed to scrutinise Legislative Reform Orders can be contacted at:

<table>
<thead>
<tr>
<th>Delegated Powers and Regulatory Reform Committee</th>
<th>Regulatory Reform Committee</th>
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<tr>
<td>House of Lords</td>
<td>House of Commons</td>
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<tr>
<td>London</td>
<td>7 Millbank</td>
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<tr>
<td>SW1A 0PW</td>
<td>London</td>
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<tr>
<td>Tel: 0207 219 3103</td>
<td>SW1P 3JA</td>
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<td>Fax: 0207 219 2571</td>
<td>Tel: 0207 7219 2830/2833/2837</td>
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<tr>
<td>e-mail: <a href="mailto:DPDC@parliament.uk">DPDC@parliament.uk</a></td>
<td>Fax: 0207 7219 2509</td>
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<td>e-mail: <a href="mailto:regreform@parliament.uk">regreform@parliament.uk</a></td>
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**Non-disclosure of responses**

17. Section 14(3) of the LRRA provides what should happen when someone responding to the consultation exercise on a proposed LRO requests that their response should not be disclosed.

18. The name of the person who has make representations will always be disclosed to Parliament. If you ask for your representation not to be disclosed, the Minister should not disclose the content of the representation without your express consent and, if the representation relates to a third party, their consent too. Alternatively, the Minister may disclose the content of the representation in such a way as to preserve your anonymity and that of any third party involved.

**Information about Third Parties**

19. If you give information about a third party which the Minister believes may be damaging to the interests of the third party, the Minister does not have to pass on such information to Parliament if he does not believe it is true or he is unable to obtain the consent of the third party to disclosure. This applies whether or not you ask for your representation not to be disclosed.
20. The Scrutiny Committees may, however, be given access on request to all representations as originally submitted, as a safeguard against improper influence being brought to bear on Ministers in their formulation of legislative reform orders.

Better Regulation Executive

Department for Business, Enterprise and Regulatory Reform
ANNEX D: CODE OF PRACTICE ON WRITTEN CONSULTATION

The criteria in the Code of Practice on Written Consultation published by the BRE apply to all UK national public consultations on the basis of a document in electronic or printed form. They will often be relevant to other sorts of consultation.

Though they have no legal force, and cannot prevail over statutory or other mandatory or external requirements (eg under European Community law) they should otherwise generally be regarded as binding on UK Departments and their agencies unless Ministers conclude that exceptional circumstances require a departure.

The criteria should be reproduced in consultation documents with an explanation of any departure, and confirmation that they have otherwise been followed.

1. Timing of consultation should be built into the planning process for a policy (including legislation) or service from the start, so that it has the best prospect of improving the proposals concerned, and so that sufficient time is left for it at each stage.

2. It should be clear who is being consulted, about what questions, in what timescale and for what purpose.

3. A consultation document should be as simple and concise as possible. It should include a summary, in two pages at most, of the main questions it seeks views on. It should make it as easy as possible for readers to respond, make contact or complain.

4. Documents should be made widely available, with the fullest use of electronic means (though not to the exclusion of others), and effectively drawn to the attention of all interested groups and individuals.

5. Sufficient time should be allowed for considered responses from all groups with an interest. Twelve weeks should be the standard minimum period for consultation.

6. Responses should be carefully and open-mindedly analysed, and reasons for decisions finally taken.

Designating a consultation co-ordinator who will ensure the lessons are disseminated.
ANNEX E: PARTIAL IMPACT ASSESSMENT

Description of the intervention

To extend the legal powers conferred by Section 1(1) of the Health and Safety at Work etc Act 1974 (HSWA), using a Legislative Reform Order.

Objectives

The objective of this proposed Legislative Reform Order (LRO) is to amend Section 1(1) of the Health and Safety at Work etc Act 1974 (HSWA) to remove the restriction that limits the Health and Safety Executive’s (HSE) vires to protecting human health and to extend the general purposes in HSWA to protecting against risks to animal health (arising from work with biological agents in contained use). This amendment to Section 1(1) would also require consequential amendments to Sections 7, 8, 9, 20, 22, 25 and 53 to give HSE appropriate enforcement powers. HSE proposes to make these changes using a LRO under the Legislative and Regulatory Reform Act 2006 (LRRA).

Background

The outbreak of FMD V at Pirbright in 2007 brought the issue of effective containment and prevention of release of animal pathogens to the top of the political agenda. The Government commissioned Sir Bill Callaghan to lead a review of the UK regulatory framework for handling animal pathogens. The Callaghan Review concluded that the current regulatory systems in place for the regulation of micro-organisms and larger GMOs in contained use were complicated and disjointed, with three separate but overlapping sets of regulations.

The Review recommended that there should be a new, unified regulatory framework based on risk-assessment with a common set of containment measures and that the responsibility for inspection and enforcement in respect of animal pathogens move to the Health and Safety Executive (HSE). This will extend their regulatory function such that they become the single regulatory body to encompass both human and animal pathogens.

The aim of the proposal is to extend the scope of the Health and Safety at Work etc. 1974 (HSWA) to enable the Health and Safety Executive to regulate this work as part of its existing work regulating human pathogens and genetically modified organisms. The reform will be introduced by means of a LRO under section 1 of the LRRA. This consultation is being conducted in accordance with the provision of section 13 of the
LRRA. Indirectly the amendment would expand the functions of HSE\textsuperscript{9}, enabling the making of Health and Safety regulations to protect animal health, which would become Relevant Statutory Provisions. This amendment would allow the Government to align the existing sets of regulations into a system that is consistent and easier to follow.

**Other options**

The following options were considered and discounted for the reasons set out below:

The first was to continue with current agency arrangements put in place as a temporary measure from April 2008. Under these arrangements the Minister, the Scottish Executive and Welsh Assembly Government have agreed that HSE should exercise their powers to enforce SAPO on their behalf. This option was always intended as a temporary measure and is unsatisfactory in the long run even if further amendments were made to SAPO to make it more like COSHH or GMO(CU)for the following reasons:

- There would remain separate pieces of legislation (SAPO and COSHH/GMO (CU)) that would seek to regulate similar and, in the case of zoonoses and genetically modified animal pathogens, the same organisms for the same purpose of containment.

- Differences resulting from the different legal basis for COSHH and SAPO (made under HSWA and the Animal Health Act respectively) could not be addressed. The powers of entry for example under the Animal Health Act and HSWA are slightly different potentially causing confusion and uncertainty for duty holders and inspectors visiting premises working with animal and human pathogens or zoonoses.

- An agency agreement does not address a significant shortcoming of the Animal Health Act, such that it does not apply to Crown Premises. The only sanction currently available against Crown Premises under SAPO is the revocation of a licence although there is nothing to stop Crown premises from operating without a licence should they choose to do so. A number of the laboratories working with animal pathogens and zoonoses are Crown Premises. HSWA does apply to the Crown and although

\textsuperscript{9} This amendment to Section 1(1) would result in consequential amendments to Sections 11 (on the extent of the functions of the Executive), 13 (on the general powers of the Executive), 14 (on the extent to which the Executive has power to direct investigations and inquiries), 15 (on the power of the Secretary of State to make health and safety regulations), 49 (on the power to amend an enactment to adapt the regulations to appropriate metric units), and Schedule 2 (on the exercise by the Secretary of State of his power to appoint members of the Executive).
criminal proceedings and enforcement mechanisms cannot be brought against the Crown under HSWA. HSE has administrative sanctions available to it such as the serving of Crown notices or Crown Censure proceedings that can be administered very effectively.

- Ultimate responsibility for the two regimes would lie in two different public bodies thereby duplicating measures needed to oversee and keep the legislation up to date and effective.

- Currently there is a combined ACoP and Guidance document for CoSHH and Guidance for GMO (CU). HSE clearly would not currently have vires to issue an ACoP and Guidance covering SAPO.

The other alternative that was considered was to make a single statutory instrument relying on the existing vires in the Animal Health Act and HSWA. However the following impediments were identified:

- The Animal Health Act provides for the making of orders and HSWA for the making of regulations. Drafting guidance indicates that the two powers cannot be relied on in one instrument.

- Legislation made under HSWA is GB wide whereas because Animal Health is a devolved matter and orders under the Animal Health Act have to be made separately in England Wales and Scotland.

- The differences in terms of applicability to the Crown and differences in powers of entry identified above would also remain.

The Callaghan Review therefore recommended that the only way to ensure the safe operation of laboratories working with potentially dangerous micro-organisms was to change the current regulatory framework, and Government and the Devolved Administrations supported this conclusion. HSE can only produce effective secondary legislation to regulate biological agents and GMOs in contained use by amending HSWA. Hence, the policy objective cannot be satisfactorily secured by non-legislative means.

**Calculation of costs**

There will be costs to HSE associated with consulting on the LRO; to Parliament in terms of the Regulatory Reform Committee and the Delegated Powers and Regulatory Reform Committee in reviewing and reporting on the LRO and to duty holders who read the consultation and reply. However, preliminary indicative estimates of these costs are deemed insignificant.
Benefits

The main benefit of the LRO will be the power to change HSWA to create new regulations that, in turn, will deliver a number of benefits. For instance, the current regulatory system results in a burden within the meaning of Section 1(3) of the LRRA as being governed by three overlapping regimes imposes administrative inconvenience and additional financial costs. The new regulatory landscape will remove the current complexities and replace them with a unified philosophy practice and type of inspection and enforcement provided by a single regulator. Duty holders will no longer be subjected to:

- inspections under divergent regulatory regimes with the same overall aim of ensuring effective containment
- overlapping areas of responsibility by regulators
- providing similar or duplicate information to different regulators for the same or similar fundamental purpose
- assessing compliance against differing sets of regulations within which there are overlapping, and sometimes conflicting areas of compliance
- the need for extra resource to prepare for separate regulatory visits for different purposes
- potential inconsistencies and approach to inspections
DRAFT STATUTORY INSTRUMENTS

2010 No.

REGULATORY REFORM

HEALTH AND SAFETY

Legislative Reform (Contained Use of Animal Pathogens) Order 2010

Made - - - - 2010

Coming into force - 2010

The Secretary of State for the Department for Work and Pensions (“the Secretary of State”) makes this Order in exercise of the powers conferred by section 1 of the Legislative and Regulatory Reform Act 2006(10) (“the 2006 Act”).

For the purposes of section 3(1) of the 2006 Act, the Secretary of State considers, where relevant, that the conditions under section 3(2) are satisfied.

The Secretary of State has consulted in accordance with section 13(1) of the 2006 Act.

The Secretary of State laid a draft Order and an explanatory document before Parliament in accordance with section 14(1) of the 2006 Act.

As provided for in section 15 of the 2006 Act, the affirmative resolution procedure (within the meaning of Part 1 of the 2006 Act) applies in relation to the making of this Order.

(10) 2006 c.51; see section 32 for the definition[s] of “Minister of the Crown”.

63
In accordance with section 17(2) of the 2006 Act, the draft has been approved by resolution of each House of Parliament after the expiry of the 40-day period referred to in that provision.

Citation and commencement

1. This Order may be cited as the Legislative Reform (Contained Use of Animal Pathogens) Order 2010 and comes into force [on 2010].

Amendments to the Health and Safety at Work etc. Act 1974

2. The Health and Safety at Work etc. Act 1974(1) is amended as provided for in Articles 3 to 8.

3. In section 1 (Preliminary)—
   (a) at the end of subsection (1) add—
   “(e)(12) (subject to subsection (1A)), providing for the contained use of animal pathogens, in order to protect against risks to animal health arising from animal pathogens not being subject to contained use, or being subject to ineffective contained use.”;
   (b) after subsection (1) insert—
   “(1A) The references in sections 7, 8 and 9 to “the relevant statutory provisions” do not include a reference to paragraph (e) of subsection (1) of this section, or to any provision of health and safety regulations made by virtue of that paragraph.”;
   (c) For subsection (3) substitute—
   “(3) For the purposes of this Part—
   (a) risks arising out of or in connection with the activities of persons at work, and
   (b) risks arising from animal pathogens not being subject to contained use, or being subject to ineffective contained use,

   are to be treated as including risks attributable to the manner of conducting an undertaking, the plant or substances used for the purposes of an undertaking and the condition of premises so used or any part of them.”

4. In section 20 (powers of inspectors), after subsection (8) add—
   “(9) For the purposes of this section “dangerous” includes dangerous to animal health but only where—
   (a) the danger arises from animal pathogens not being subject to contained use, or being subject to ineffective contained use; and
   (b) protection against that danger is provided for in health and safety regulations;

   and “dangers” and “danger to health” are to be construed accordingly.”.

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(11) 1974 c.37.

(12) Paragraph (d) of Section 1(1) repealed by the Environmental Protection Act 1990, section 162, Schedule 16 part 1.
5. In section 22 (prohibition notices) in subsection (2) for the words from “a risk of” to the end of the subsection substitute—

“—

(a) a risk of serious personal injury; or
(b) a risk of serious harm to animal health arising from animal pathogens not being subject to contained use, or being subject to ineffective contained use, being a risk against which protection is provided for in health and safety regulations,

the inspector may serve on that person a notice (in this Part referred to as “a prohibition notice”).”.

6. In section 25 (power to deal with cause of imminent danger), in subsection (1), for the words from “is a cause of” to the end of the subsection substitute—

“—

(a) imminent danger of serious personal injury; or
(b) imminent danger of serious harm to animal health, being danger which arises from animal pathogens not being subject to contained use, or being subject to ineffective contained use, and protection against which is provided for in health and safety regulations,

the inspector may seize it and cause it to be rendered harmless (whether by destruction or otherwise).”.

7. In section 33 (Offences) insert after subsection (6)—

“(7) To the extent that Schedule 3A provides for a penalty on summary conviction to exceed—

(a) imprisonment for a term exceeding the normal maximum term, or
(b) a fine exceeding level 5 on the standard scale,

the provision does not have effect in relation to an offence falling within subsection (8).

(8) An offence falls within this subsection if it is—

(a) an offence by virtue of a provision of health and safety regulations made under section 1(1)(e);
(b) otherwise an offence by virtue of the general purpose provided for in section 1(1)(e).

(9) Where a provision of Schedule 3A does not have effect, a person convicted of an offence falling within subsection (8) is liable on summary conviction—

(a) to imprisonment for a term not exceeding the normal maximum term, or
(b) to a fine not exceeding level 5 on the standard scale,

or to both.

(10) In subsections (7) and (9), “the normal maximum term” means—

(a) in relation to England and Wales—

(i) in the case of a summary offence, 51 weeks; and
(ii) in the case of an offence triable either way, twelve months; and
(b) in relation to Scotland six months.

(11) In the case of an offence which, if committed by an adult, is triable either on indictment or summarily and is not an offence triable on indictment only by virtue of—

(a) Part 5 of the Criminal Justice Act 1988 (c33), or
(b) section 292(6) and (7) of the Criminal Procedure (Scotland) Act 1995 (c46),

the reference in subsection (7)(b) and (9)(b) to a fine exceeding level 5 on the standard scale is to be construed as a reference to the statutory maximum.
(12) In the case of a summary offence committed before the date on which section 281(5) of the Criminal Justice Act 2003 (c. 44) comes into force any reference to a term of imprisonment of 51 weeks is to be read as a reference to six months.

(13) In the case of an offence triable either way committed before the date on which section 154(1) of the Criminal Justice Act 2003 (c.44) comes into force any reference to a term of imprisonment of 12 months is to be read as a reference to six months.”.

8. In section 53 (General interpretation of Part 1)—
   (a) before the definition of “article for use at work” insert—
       ““animal” means any multi-cellular animal other than a human;
       “animal pathogen” means a micro-organism, cell culture, endoparasite or prion that may cause harm to animals and includes—
       (a) animal pathogens which have been attenuated or genetically modified by any means; and
       (b) any nucleic acid derived from an animal pathogen that could produce an animal pathogen when introduced into a biological system in which the nucleic acid is capable of replication;”;
   (b) after the definition of “conditional sale agreement” insert—
       ““contained use” means any activity in which animal pathogens are cultured, stored, transported, destroyed, disposed of or used in any other way and in respect of which physical, chemical or biological barriers (or any combination of such barriers), are used to limit the contact of such pathogens with, and to provide a high level of protection for, animals;”;
   (c) after the definition of “the general purposes of this Part” insert—
       ““health” means human health;”;
   (d) after the definition of “self-employed person” insert—
       ““serious harm to animal health” means—
       (a) serious harm to an animal; or
       (b) some harm to an animal caused by an animal pathogen where that animal pathogen is likely to spread between animals of different species or groups of animals of the same species in different locations;”.

Signed by authority of the Secretary of State for Work and Pensions

William D McKenzie
Parliamentary Under Secretary of State

Date
Department for Work and Pensions

EXPLANATORY NOTE
(This note is not part of the Order)

This Order amends the Health and Safety at Work etc Act 1974 ("the 1974 Act").

1. The purpose of the Order is to enable the Health and Safety Executive to regulate the contained use of animal pathogens in the same regulatory framework as biological agents that pose a risk to human health and enable the making of health and safety regulations for this purpose.
2. Article 3 extends the general purposes of the 1974 Act to the protection of animals at risk from not being contained or being ineffectively contained. The new general purpose does not apply to the general duties in sections 2-9 of the 1974 Act.

3. Article 4 extends the powers available to inspectors to take action in respect of things that are not only dangerous to human health but those that are dangerous to animal health where the danger arises from animal pathogens not being contained or ineffectively contained and where that is provided for in health and safety regulations made under the 1974 Act.

4. Article 5 extends the power of inspectors to serve prohibition notices requiring someone to stop an activity where there is a risk of serious personal injury to humans to situations to where there is a risk of serious harm to animal health in so far as protection from risks to animal health from that activity is specifically provided for in health and safety regulations under the 1974 Act.

5. Article 6 extends the powers available to inspectors to deal with imminent danger beyond imminent danger to humans to imminent danger to animal health where the danger arises from animal pathogens not being contained or ineffectively contained provided for in health and safety regulations under the 1974 Act.

6. Article 7 makes specific provision limiting the penalties for offences punishable on summary conviction where those offences rely on the new purpose of protecting animal health.

7. Article 8 makes consequential amendments to the definitions contained in the 1974 Act in particular clarifying that “health” in the 1974 Act means human health except where otherwise qualified.
ANNEX G - OFFENCES

Part 1 - Section 33 – Relevant Offences

“...It is an offence for any person...

(c) to contravene any health and safety regulations ... or any requirement or prohibition imposed under any such regulations (including any requirement or prohibition to which he is subject by virtue of the terms of or any condition or restriction attached to any licence approval exemption or other authority issued, given or granted under the regulations;

(d) to contravene any requirement imposed by or under regulations under section 14 [powers of the Executive to direct investigations and enquiries] or intentionally obstruct any person in the exercise of his powers under that section;

(e) to contravene any requirement imposed by an inspector under section 20 [general powers of inspectors including powers of entry] or section 25 [power to deal with a cause of imminent danger];

(f) to prevent or attempt to prevent any other person from appearing before an inspector or from answering any question to which an inspector may by virtue of section 20(2) require an answer;

(g) to contravene any requirement or prohibition imposed by an improvement notice or prohibition notice (including any such notice as modified on appeal);

(h) intentionally to obstruct an inspector in the exercise or performance of his powers or duties or to obstruct a customs officer in the exercise of his powers under section 25A;

(i) to contravene any requirement imposed under section 27(1) [power of the Executive to serve notices requiring information];

(j) to disclose or use any information in contravention of section 27(4) or section 28;

(k) to make a statement which he knows to be false or recklessly to make a statement which is false where the statement is made-

   (i) in purported compliance with a requirement to furnish any information imposed by or under any of the relevant statutory provisions; or

   (ii) for the purpose of obtaining the issue of a document under any of the relevant statutory provisions to himself or another person;
(l) intentionally to make a false entry in any register, book, notice or other document required by or under any of the relevant statutory provisions to himself or another person;

(m) with intent to deceive to use a document issued or authorized to be issued under any of the relevant statutory provisions or required for any purpose there under or to make or have in his possession a document so closely resembling any such document as to be calculated to deceive;

(n) falsely to pretend to be an inspector;

(o) to fail to comply with an order made by the court under section 42.

**Part 2 - Mode of trial and maximum penalty for existing offences in HSWA**

The mode of trial and maximum penalty applicable to each offence listed in the first column of the following table are as set out opposite that offence in the subsequent columns of the table.

<table>
<thead>
<tr>
<th>Offence</th>
<th>Mode of trial</th>
<th>Penalty on summary conviction</th>
<th>Penalty on indictment</th>
</tr>
</thead>
<tbody>
<tr>
<td>An offence under section 33(1)(c).</td>
<td>Summarily or on indictment.</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding £20,000, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
</tr>
<tr>
<td>An offence under section 33(1)(d).</td>
<td>Summarily only.</td>
<td>A fine not exceeding level 5 on the standard scale.</td>
<td></td>
</tr>
<tr>
<td>An offence under section 33(1)(e), (f) or (g).</td>
<td>Summarily or on indictment.</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding £20,000, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
</tr>
<tr>
<td>An offence under section 33(1)(h).</td>
<td>Summarily only.</td>
<td>Imprisonment for a term not exceeding 51 weeks (in England and Wales) or 12 months (in Scotland), or a fine not exceeding level 5 on the standard scale, or both.</td>
<td></td>
</tr>
<tr>
<td>Offence Description</td>
<td>Summary or on indictment</td>
<td>Punishment 1</td>
<td>Punishment 2</td>
</tr>
<tr>
<td>---------------------</td>
<td>--------------------------</td>
<td>--------------</td>
<td>--------------</td>
</tr>
<tr>
<td>An offence under section 33(1)(i).</td>
<td>A fine not exceeding the statutory maximum.</td>
<td>A fine.</td>
<td></td>
</tr>
<tr>
<td>An offence under section 33(1)(j).</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding the statutory maximum, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
<td></td>
</tr>
<tr>
<td>An offence under section 33(1)(k), (l) or (m).</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding £20,000, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
<td></td>
</tr>
<tr>
<td>An offence under section 33(1)(n).</td>
<td>A fine not exceeding level 5 on the standard scale.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>An offence under section 33(1)(o).</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding £20,000, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
<td></td>
</tr>
<tr>
<td>An offence under the existing statutory provisions for which no other penalty is specified.</td>
<td>Imprisonment for a term not exceeding 12 months, or a fine not exceeding £20,000, or both.</td>
<td>Imprisonment for a term not exceeding two years, or a fine, or both.</td>
<td></td>
</tr>
</tbody>
</table>

**Part 3 - Powers of Inspectors set out in section 20 of HSWA**

20 Powers of inspectors

(1) Subject to the provisions of section 19 and this section, an inspector may, for the purpose of carrying into effect any of the relevant statutory provisions within the field of responsibility of the enforcing authority which appointed him, exercise the powers set out in subsection (2) below.

(2) The powers of an inspector referred to in the preceding subsection are the following, namely—
(a) at any reasonable time (or, in a situation which in his opinion is or may be dangerous, at any time) to enter any premises which he has reason to believe it is necessary for him to enter for the purpose mentioned in subsection (1) above;

(b) to take with him a constable if he has reasonable cause to apprehend any serious obstruction in the execution of his duty;

(c) without prejudice to the preceding paragraph, on entering any premises by virtue of paragraph (a) above to take with him—

   (i) any other person duly authorised by his (the inspector's) enforcing authority; and

   (ii) any equipment or materials required for any purpose for which the power of entry is being exercised;

(d) to make such examination and investigation as may in any circumstances be necessary for the purpose mentioned in subsection (1) above;

(e) as regards any premises which he has power to enter, to direct that those premises or any part of them, or anything therein, shall be left undisturbed (whether generally or in particular respects) for so long as is reasonably necessary for the purpose of any examination or investigation under paragraph (d) above;

(f) to take such measurements and photographs and make such recordings as he considers necessary for the purpose of any examination or investigation under paragraph (d) above;

(g) to take samples of any articles or substances found in any premises which he has power to enter, and of the atmosphere in or in the vicinity of any such premises;

(h) in the case of any article or substance found in any premises which he has power to enter, being an article or substance which appears to him to have caused or to be likely to cause danger to health or safety, to cause it to be dismantled or subjected to any process or test (but not so as to damage or destroy it unless this is in the circumstances necessary for the purpose mentioned in subsection (1) above);

(i) in the case of any such article or substance as is mentioned in the preceding paragraph, to take possession of it and detain it for so long as is necessary for all or any of the following purposes, namely—

   (i) to examine it and do to it anything which he has power to do under that paragraph;

   (ii) to ensure that it is not tampered with before his examination of it is completed;
(iii) to ensure that it is available for use as evidence in any proceedings for an
offence under any of the relevant statutory provisions or any proceedings relating
to a notice under section 21 or 22;

(j) to require any person whom he has reasonable cause to believe to be able to give
any information relevant to any examination or investigation under paragraph (d) above
to answer (in the absence of persons other than a person nominated by him to be
present and any persons whom the inspector may allow to be present) such questions
as the inspector thinks fit to ask and to sign a declaration of the truth of his answers;

(k) to require the production of, inspect, and take copies of or of any entry in—

(i) any books or documents which by virtue of any of the relevant statutory
provisions are required to be kept; and

(ii) any other books or documents which it is necessary for him to see for the
purposes of any examination or investigation under paragraph (d) above;

(l) to require any person to afford him such facilities and assistance with respect to any
matters or things within that person’s control or in relation to which that person has
responsibilities as are necessary to enable the inspector to exercise any of the powers
conferred on him by this section;

(m) any other power which is necessary for the purpose mentioned in subsection (1)
above.

(3) The Secretary of State may by regulations make provision as to the procedure to be
followed in connection with the taking of samples under subsection (2)(g) above
(including provision as to the way in which samples that have been so taken are to be
dealt with).

(4) Where an inspector proposes to exercise the power conferred by subsection (2)(h)
above in the case of an article or substance found in any premises, he shall, if so
requested by a person who at the time is present in and has responsibilities in relation
to those premises, cause anything which is to be done by virtue of that power to be
done in the presence of that person unless the inspector considers that its being done in
that person’s presence would be prejudicial to the safety of the State.

(5) Before exercising the power conferred by subsection (2)(h) above in the case of any
article or substance, an inspector shall consult such persons as appear to him
appropriate for the purpose of ascertaining what dangers, if any, there may be in doing
anything which he proposes to do under that power.
(6) Where under the power conferred by subsection (2)(i) above an inspector takes possession of any article or substance found in any premises, he shall leave there, either with a responsible person or, if that is impracticable, fixed in a conspicuous position, a notice giving particulars of that article or substance sufficient to identify it and stating that he has taken possession of it under that power; and before taking possession of any such substance under that power an inspector shall, if it is practicable for him to do so, take a sample thereof and give to a responsible person at the premises a portion of the sample marked in a manner sufficient to identify it.

(7) No answer given by a person in pursuance of a requirement imposed under subsection (2)(j) above shall be admissible in evidence against that person or the spouse or civil partner of that person in any proceedings.

(8) Nothing in this section shall be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for discovery in an action in the High Court or, as the case may be, on an order for the production of documents in an action in the Court of Session.
A consultation document on a proposed Legislative Reform Order that will allow HSE to make regulations for the protection of animal health under the Health and Safety at Work etc Act 1974

The full text of this and other Consultative Documents can be viewed and downloaded from the Health and Safety Executive web site on the internet: www.hse.gov.uk/consult/index.htm