Contained use work with biological agents

Summary

The OG provides clarity to operational inspectors in HID and FOD on when HSE will charge a fee for intervention (FFI) during the inspection of premises undertaking contained use activities involving biological agents.

Introduction

HSE regulates a variety of contained use work with biological agents, only part of which are functions under Health and Safety at Work etc Act 1974 (HSWA). The other parts are regulated under agency agreements with other government departments and using non-HSWA legislation. Depending on whether the contained use activities involve human, animal or plant pathogens (and whether they are genetically modified or not), the work is often covered by multiple primary and secondary legislation.

When the single regulatory framework (or equivalent) for biological agents contained use is implemented, activities involving biological agents will be subject to a full cost recovery charging regime. In the interim, HSE will **not** apply FFI to biological agents' contained use activities. However, there will be circumstances during such inspections, where FFI may apply. Consequently, this operational guidance sets out circumstances where material breaches identified during interventions at contained use facilities would incur FFI and illustrates this through the use of examples.

Action

In respect of material breaches of health and safety legislation, HSE will continue to take appropriate enforcement action in line with its enforcement policy statement and the enforcement management model. There are limited situations where FFI will be applied to material breaches during interventions at contained use facilities. The cost of the intervention will only be charged for those parts of the intervention where the Fees Regulations can be applied.

Application of the Fees Regulations and associated FFI to biological agents' related legislation is summarised in the following table.

Biological agents related Legislation	Are these relevant statutory provisions (RSPs)?	Does FFI apply?
Control of Substances Hazardous to Health Regulations 2002 (as amended) (COSHH)	**Yes** – regulations such as COSHH made under HSWA s15, are RSPs, to which the Fees Regulations apply	**No** – whilst the Fees Regulations apply, reg 24 (13) of Fees Regulations, disapplies fees for breaches of COSHH and (any other RSPs) that relate to contained use activities defined in COSHH (COSHH para 3(3) Part 1 Schedule 3)

Biological agents related Legislation	Are these relevant statutory provisions (RSPs)?	Does FFI apply?
Genetically Modified Organisms (Contained Use) Regulations 2000 (as amended) (GMO(CU))	**Partly** – the GMO(CU) Regulations were made partly under HSWA s15 (i.e. risks to human health) and partly under European Communities Act 1972 s2(2) (i.e. risks to the environment). Only those made under HSWA s15 are RSPs, to which the Fees Regulations apply. GMO(CU) related to environmental risks is not considered to be an RSP hence Fees Regulations do not apply.	**No** – whilst Fees Regulations apply, reg 24 (11) of Fees Regulations disapplies FFI for breaches of GMO(CU) (and any other relevant RSPs) in relation to human health aspects of the GM work. **No** - Fees Regulations do not apply to GMO(CU) work related to environmental risks hence such breaches do not attract FFI.
Specified Animal Pathogens Order (SAPO) 2008 (any equivalent in Scotland and Wales)	**No** – SAPO is made under the Animal Health Act, and is not an RSP. Fees Regulations do not apply to SAPO work	**No** – Fees Regulations do not apply to SAPO hence such breaches do not attract FFI.
Environmental Protection Act 1990 (EPA), (s.108(1)(a) relates to protection of the environment from harm from larger GMOs)	**No** – EPA is a separate Act of Parliament. This is not an RSP hence Fees Regulations do not apply	**No** – Fees Regulations do not apply to EPA hence breaches of EPA do not attract FFI
Genetically Modified Organisms (Risk Assessment) (Records & Exemptions) Regulations 1996 (RARER)	**No** – RARER is made under EPA and is not an RSP hence the Fees Regulations do not apply	**No** – Fees Regulations do not apply to RARER hence breaches of RARER do not attract FFI
Health and Safety at Work etc Act 1974 (HSWA) and regulations made under s15 of HSWA (e.g. Management Regulations MHSWR)	**Yes** - HSWA and regulations made under s15 of HSWA (e.g. MHSWR) are RSPs, to which the Fees Regulations apply	**Yes** – Fees Regulations apply to breaches of these RSPs, but only where this is **not** related to contained use activities involving biological agents **No** – Fees Regulations apply to breaches of these RSPs, However, *reg 24(11) & 24(13) of Fees Regulations disapply breaches of *any relevant statutory provisions* related to contained use activities involving biological agents

**Note: this disapplication of HSWA requirements does not apply to contained use activities involving biological agents that affect the environment*

It should be noted that at premises working with biological agents subject to environment related legislation (SAPO, RARER, EPA and environmental aspects of GMO(CU)), there may be circumstances where the work activities present a risk to human health and safety. In such circumstances, whilst the material breaches of the environmental legislation will not incur FFI, the Fees Regulations will still apply to material breaches (to which HSWA and other RSPs apply) of human health and safety and will be subject to FFI.

There may be circumstances where there are breaches of both health and safety legislation and environment related legislation, in which case the most appropriate legislation to the whole of the circumstances of the breach should be applied. Given the range of different biological agents and contained use activities, a series of examples is provided to assist inspectors on the application of FFI to this type of work, which is provided in Annex 1.

Background

What is fee for intervention (FFI)?

In line with Government policy, it is intended to shift the cost of health and safety regulation from the taxpayer to organisations or businesses that break health and safety laws. The Health and Safety (Fees) Regulations 2012 (the Fees Regulations) put a duty on HSE to recover its costs for carrying out regulatory functions from those found to be in material breach of health and safety law.

A material breach is when, in the opinion of the HSE inspector, there is or has been a contravention of health and safety law that requires them to notify the dutyholder, in writing, of that opinion. Written notification from an HSE inspector may be by way of a notification of contravention, an improvement or prohibition notice or prosecution and must include the following information:

- the specific provisions of the law that the inspector's opinion relates to;
- the reasons for their opinion; and
- notification that a fee is payable to HSE in accordance with regulations 23 and 24 of the Fees Regulations.

The written notification should also make it clear, which contraventions are material breaches. The template Notification of Contravention letter should be used to write to the dutyholder about material breaches as this contains all the required information. When a material breach has been identified, HSE will recover costs from the start of the inspection/investigation up to and including the point where HSE intervention is completed. HSE will recover costs by sending the business an invoice for the work carried out. If there is a breach that does not require the inspector to intervene (i.e. a non-material breach), no cost will be recovered. Similarly, businesses that follow (comply with) the law will not pay. Where FFI applies, inspectors are referred to HSE guidance (HSE47) www.hse.gov.uk/pubns/hse47.htm on the application of FFI and the Supplementary guidance for inspectors on FFI www.hse.gov.uk/fee-for-intervention/supplementary-inspector-guidance.pdf, which must be followed.

Organisation

Timing

The Fees Regulations will come into effect on 1 October 2012

Targeting

The OG applies to any places of work (e.g. laboratories, pharmaceutical manufacturing plant) that undertake contained use activities involving biological agents. Regulatory oversight for these facilities is set out in operational circulars (OC349/10 www.hse.gov.uk/foi/internalops/ocs/300-399/349_10.htm and OC349/6 http://www.hse.gov.uk/foi/internalops/ocs/300-399/oc349_6.htm) and agency agreements with other government departments in England www.hse.gov.uk/biosafety/england.htm, Wales www.hse.gov.uk/biosafety/wales.htm and Scotland www.hse.gov.uk/biosafety/scotland.htm.

Recording and reporting

Inspectors need to record the time spent dealing with material breaches subject to FFI on COIN. Specific guidance is available to assist inspectors with this process (see Supplementary guidance for inspectors on FFI www.hse.gov.uk/fee-for-intervention/supplementary-inspector-guidance.pdf).

Further References

HSE 47 - Guidance on the application of FFI www.hse.gov.uk/pubns/hse47.htm.

Supplementary guidance for inspectors on FFI www.hse.gov.uk/fee-for-intervention/supplementary-inspector-guidance.pdf.

OC349/10 - Primary inspection responsibilities and the use of specialist support for work with **biological** agents www.hse.gov.uk/foi/internalops/ocs/300-399/349_10.htm.

OC349/6 - The genetically modified organisms (contained use) regulations 2000 and other regulations relating to the contained use of GMOs www.hse.gov.uk/foi/internalops/ocs/300-399/oc349_6.htm.

Implementing Callaghan recommendations for single regulatory framework for human and animal pathogens and GMOs www.hse.gov.uk/biosafety/callaghan.htm.

Appendices

Appendix 1: *Examples of application of FFI to contained use activities involving biological agents*

Risk to human health: genetically modified biological agent

The parts of GMO(CU) related to risks to human health are made under the powers of HSWA whilst the parts of GMO(CU) related to risks to the environment under the powers of the European Communities Act 1972. The Fees Regulations only apply to parts of GMO(CU) which relate to risks to human health. However, regulation 24(11) of the Fees Regulations disapplies FFI in respect of breaches of any relevant statutory provisions related to genetic modification activities that present a risk to human health.

Where an employer is undertaking activities involving genetic modification, FFI will not apply for any breach of the relevant statutory provision that is linked to those activities. This is not restricted to control of exposure to the biological agent but may extend to other hazards that those undertaking the genetic modification activity may be exposed to (e.g. chemical exposure, manual handling). However, notification under GMO(CU) does incur a fee.

It should also be noted that GMO(CU) also includes the risks to human health from genetically modified organisms that are not microorganisms (e.g. animals, plants, insects, fish). Consequently FFI will not apply to any issues related to human health from these activities.

Example 1
*An employer is undertaking non-notified work involving a **genetically modified** human pathogen, the activity class for which is Class 3. The ventilation system supporting the CL3 laboratory has not been adequately maintained (i.e. within required 14 month period required by COSHH, Reg 9) and the autoclave (whilst calibrated and validated for inactivation of the biological agent) has not been subject to examination according to a written scheme as required for pressure vessels (Pressure Systems Safety Regulations 2000). On the way to the laboratory, the inspector observes maintenance work at height, which is unsafe but outside the laboratory building.*

The inspector having applied the principles of the EMM for each of the identified breaches, concluded formal written notification (e.g. by way of notification of contravention, an improvement or prohibition notice, or a prosecution) was necessary and therefore FFI applies to these material breaches, as follows:

- *i) FFI does apply to the time to resolve the working at height breach as this is not relevant to the genetic modification activity. This would include any other on and off site time taken to resolve this matter and wider non-biological agents related issues that arise (e.g. discussion of control of maintenance contractors on site) and may involve both the contractor and employer.*
- *ii) FFI does NOT apply to either the maintenance of the ventilation system or pressure testing of the autoclave, as both are considered to be relevant to the genetic modification activity*
- iii) *FFI does NOT apply to resolving the non-notification of the work as this is also relevant to the GM activity. However, the work should be notified to HSE and this will incur a notification fee.*

Risk to human health: non-modified biological agent

Fee for intervention will apply following a material breach of COSHH. However, reg 24(13) of the Fees Regulations disapplies FFI in respect of breaches of relevant statutory provisions for any of the activities specified in COSHH paragraph 3(3), Part 1 of Schedule 3. Similarly to reg 24(11) of the Fees Regulations, the relevant statutory provisions encompass any provisions that are linked to the undertaking of the contained use activity and are not restricted to control of exposure to biological agents.

Unlike notification under GMO(CU), notification of biological agents under COSHH does not attract a fee.

Example 2
An employer is undertaking diagnostic testing of human specimens within the Microbiology Department of a Trust, without a suitable and sufficient risk assessment specifically in relation to the transport of microbiological waste from the laboratory to a communal

autoclave facility. Consequently the inspector identified inadequate equipment (i.e. an absence of suitable leak proof and secure containers); and inadequate arrangements to reduce the likelihood of musculoskeletal injury. Employees were not familiar with the emergency arrangements to deal with a spillage outside the containment laboratory. Furthermore, several cases of dermatitis related to chemical disinfectant exposure had been reported within the laboratory. Overall, the health and safety management of the contained use activity was considered poor. The trade union representative also mentioned other cases of dermatitis on site related to latex glove use, not evident in the Microbiology Department (where latex gloves are not used).

The inspector having applied the principles of the EMM for each of the identified breaches, concluded formal written notification (e.g. by way of notification of contravention, an improvement or prohibition notice, or a prosecution) was necessary and therefore FFI applies to these material breaches, as follows:

i) *FFI does apply to the time to resolve the breach of COSHH in relation to dermatitis arising from allergy to latex as this was unrelated to the contained use activity. This would include any other on and off site time taken to resolve this matter*
ii) *FFI does NOT apply to the breach of MHSWR where this related to the management of the contained use facility*
iii) *FFI does NOT apply to the time in addressing the breach of HSWA related to the system of work used for the transport of microbiological waste (including selection/use of appropriate work equipment, training in emergency procedures and implementation of system to reduce musculoskeletal injury) or the breach of COSHH in relation to the chemical exposure to disinfectant as these are part of the contained use activity*

Risk of environmental harm: GM pathogens & animals/plants
The Fees Regulations do not apply to material breaches of EPA, RARER or SAPO, as well as environmental aspects of GMO(CU). Any breach of these duties is not a breach of the relevant statutory provisions. Consequently, FFI will not apply to breaches involving contained use activities that fall under this specific legislation.

Example 3
An employer is undertaking work with genetically modified plant pathogens, which are being used to infect genetically modified plants in containment glasshouses. The HEPA filters on the exhaust ventilation had not been tested, and are required to prevent release of plant pollen and viral plant pathogens from the glasshouse. The contaminated plant material was being composted without prior inactivation. The inspection also revealed that there are several examples of inadequate insulation on the electrical supplies to fans within the glasshouse. The containment area was not subject to routine checks on sealability (and the fabric of the containment area was poor) to permit effective gaseous fumigation/decontamination of the glasshouse. The genetic modification activity being undertaken had not been notified to HSE.

The inspector having applied the principles of the EMM for each of the identified breaches, concluded formal written notification (e.g. by way of notification of contravention, an improvement or prohibition notice, or a prosecution) was necessary and therefore FFI applies to these material breaches, as follows:

i) *FFI may or may NOT apply to the electrical insulation issue depending on whether the inspector considers the overarching issue to be one of loss of power to the fans hence loss of containment (breach of GMO(CU)) or a*

risk of electrocution (breach of Electricity at Work Regulations 1989). The former does NOT attract FFI whilst the latter is subject to FFI

ii) *FFI may or may NOT apply to the lack of sealability of the glasshouse depending on whether the inspector considers the overarching issue to be one of effectiveness of the decontamination process (breach of GMO(CU)) or potential for exposure of employees to a hazardous chemical/fumigant (breach of COSHH). The former does NOT attract FFI whilst the latter is subject to FFI*

iii) *FFI does NOT apply to any breaches of GMO(CU) related to protection of the environment (i.e. the maintenance and testing of the HEPA filter, inactivation of the contaminated waste)*

iv) *FFI does NOT apply to resolving the non-notification of the work. However, the work should be notified to HSE and this will incur a notification fee.*

Example 4

An employer is undertaking work with genetically modified animal viral pathogens, which are being used to infect genetically modified mice in flexible film isolators. The employer is also generating lines of transgenic mice. The inspector identified a number of issues relating to the validation of disinfection for inactivation of the animal virus, testing and maintenance of the flexible film isolators, an absence of environmental risk assessment for the transgenic mice and insufficient controls to minimise exposure to animal bedding and dander whilst cage changing.

i) The inspector having applied the principles of the EMM for each of the identified breaches, concluded formal written notification (e.g. by way of notification of contravention, an improvement or prohibition notice, or a prosecution) was necessary and therefore FFI applies to these material breaches, as follows:

ii) FFI does NOT apply to breaches related to the risk of sensitivity to laboratory animal allergens as this risk arises directly from the contained use activity (risk to human health comes from GM animals - GMO(CU) regulations

iii) FFI does NOT apply to any breaches of GMO(CU), EPA, RARER related to protection of the environment (i.e. the validation of the disinfectant, or testing/maintenance of the isolator or absence of environmental risk assessment)

Risk of environmental/ economic harm: specified animal pathogens

Specified animal pathogens are defined in SAPO. The Fees Regulations do not apply to material breaches of SAPO. Consequently, FFI will not apply to control of exposure of specified animals from contained use activities with specified animal pathogens or genetically modified versions thereof.

If the specified animal pathogen is zoonotic (e.g. rabies), then the contained use activity will be subject to the requirements of COSHH and the Fees Regulations will apply but the activity will be exempt from FFI (under reg 24(13) of the Fees Regulations).

Example 5

An employer is undertaking work with specified animal pathogens (including one virus not included on their licence), which are being used to infect insects. The inspector identified issues including the adequacy of the containment of the infected insects, the biosecurity arrangements (e.g. alarms, access restriction) and the absence of an inventory of specified

animal pathogens within the large liquid nitrogen storage containers. There was also an absence of oxygen level monitors and alarms in the liquid nitrogen storage room.

The inspector having applied the principles of the EMM for each of the identified breaches, concluded formal written notification (e.g. by way of notification of contravention, an improvement or prohibition notice, or a prosecution) was necessary and therefore FFI applies to these material breaches, as follows:

i) *FFI does apply to the breach related to risk of asphyxiation (COSHH)*
ii) *FFI does NOT apply to breaches of the SAPO licence (i.e. inadequate containment of the insects, the biosecurity arrangements, the absence of an inventory);*
iii) *FFI does NOT apply to the breach of SAPO related to using a non-licensed pathogen. This would require submission of a licence amendment to Defra – this does not incur a fee.*

Appendix 2: *(Excerpt from) Part 1 of Schedule 3 to the Control of Substances Hazardous to Health Regulations 2002*

Special control measures for laboratories, animal rooms and industrial processes
3.—

(1) Every employer who is engaged in any of the activities specified in sub-paragraph (3) shall ensure that measures taken to control adequately the exposure of his employees to biological agents include, in particular, the most suitable combination of containment measures from those listed in Parts II and III of this Schedule as appropriate, taking into account:

(a) the nature of the activity specified in sub-paragraph (3);
(b) the minimum containment level specified in sub-paragraph (4);
(c) the risk assessment; and
(d) the nature of the biological agent concerned.

(2) An employer who is engaged in:

(a) any of the activities specified in sub-paragraph (3)(a) or (b) shall select measures from Part II of this Schedule;
(b) the activity specified in sub-paragraph (3)
(c) shall select measures from Part III of this Schedule and, subject to sub paragraph (4), when making that selection he may combine measures from different containment levels on the basis of a risk assessment related to any particular process or part of a process.

(3) The activities referred to in sub-paragraph (1) are:

(a) research, development, teaching or diagnostic work in laboratories which Involves working with a Group 2, Group 3 or Group 4 biological agent or material containing such an agent;
(b) working with animals which have been deliberately infected with a Group 2, Group 3 or Group 4 biological agent or which are, or are suspected of being, naturally infected with such an agent; and

(c) industrial processes which involve working with a Group 2, Group 3 or Group 4 biological agent.