



Department  
for Environment  
Food & Rural Affairs

## **Environmental Permitting**

### **Consultation on draft Environmental Permitting (England and Wales) (Amendment) Regulations 2013**

**To transpose Directive 2011/97/EU which specifies  
criteria for the storage of metallic mercury waste  
when stored for greater than 12 months.**

**December 2012**



Llywodraeth Cymru  
Welsh Government



© Crown copyright 2012

You may re-use this information (not including logos) free of charge in any format or medium, under the terms of the Open Government Licence. To view this licence, visit [www.nationalarchives.gov.uk/doc/open-government-licence/](http://www.nationalarchives.gov.uk/doc/open-government-licence/) or write to the Information Policy Team, The National Archives, Kew, London TW9 4DU, or e-mail: [psi@nationalarchives.gsi.gov.uk](mailto:psi@nationalarchives.gsi.gov.uk)

This document/publication is also available on our website at:

[www.defra.gov.uk/consult/open/](http://www.defra.gov.uk/consult/open/)

Any enquiries regarding this document/publication should be sent to us at:

Patrick McKell, Waste Regulation and Crime Team, Waste Programme  
Department for Environment, Food and Rural Affairs, Area 6D, 6th Floor, Ergon House,  
Horseferry Road, London, SW1P 2AL

## Contents

Introduction .....	4
What this consultation paper covers .....	4
Who should read this paper? .....	5
Geographical coverage .....	5
Who will be affected by these proposals? .....	6
Next steps .....	6
Timing and duration of this consultation and how to respond.....	6
Storage of metallic mercury waste.....	9
The proposal .....	9
Discussion.....	9
Questions.....	12
Annex I – List of consultation questions.....	13
Annex II – Draft Environmental Permitting (England and Wales) Amendment Regulations .....	14

# Introduction

## What this consultation paper covers

1.1 The Environmental Permitting (England and Wales) Regulations 2010<sup>1</sup> (EP Regulations 2010) provide a common environmental permitting framework for various industrial, intensive farming, waste, water and groundwater discharge activities and radioactive substances regulation. The aim is to reduce the administrative burden of compliance without compromising environmental standards.

1.2 This consultation paper seeks views on amendments to the EP Regulations 2010, to take effect from 15 March 2013. These arise from the need to transpose criteria for the safe storage of metallic mercury wastes as detailed in Directive 2011/97/EU<sup>2</sup>. The provisions of this Directive are linked to the derogation from the prohibition on liquid landfill allowed for by Regulation (EC) No 1102/2008. The proposed amendments to the EP Regulations 2010 relating to that Directive and that Regulation will affect England and Wales only.

1.3 As part of implementing the derogation in Regulation 1102/2008, an amendment to the Control of Major Accident Hazards Regulations 1999 is also proposed to ensure its scope includes facilities that have been permitted to store metallic mercury waste. This proposed amendment will affect England, Wales and Scotland

1.4 The Government's Regulatory Policy Committee has reviewed these proposals and considers them to be a low-cost regulatory measure. A full impact assessment is consequently not included in this consultation.

1.5 Comments on the practical impacts or consequences of the proposed amendments are sought from stakeholders. Having considered your submissions and published a response, we will draft amending regulations accordingly and lay them before Parliament and the Welsh Assembly.

---

<sup>1</sup> S.I. 2010/675 as amended.

<sup>2</sup> Council Directive 2011/97/EU of 5 December 2011 amending Directive 1999/31/EC as regards specific criteria for the storage of metallic mercury considered as waste.

## Who should read this paper?

1.6 This consultation may be of interest to:

**Operators** who may be considering the development of storage facilities for metallic mercury waste;

**Operators** of waste management facilities that currently handle metallic mercury waste;

**Producers** of metallic mercury waste;

**Regulators** with an interest in the facilities (the Environment Agency in England and Natural Resources Wales, in Wales have the primary interests, but Local Authorities may want to comment); and

**Others** with interest in environmental permitting and compliance systems (e.g. Local Authorities, environmental and consumer groups, the environmental technology and related sectors, the legal profession, academics etc).

## Geographical coverage

1.7 The consultation on the amendments to the EP Regulations covers England and Wales only. The consultation on the amendment to the COMAH Regulations covers England, Wales and Scotland. The Scottish Government will be consulting on separate Scottish legislation to transpose the metallic mercury waste storage requirements required under Directive 2011/97/EU.

1.8 The Scottish Government and the Welsh Assembly Government are partners in this process:

Welsh Assembly Government has devolved responsibility for most of the matters covered by this consultation; and

It is desirable for the business community, others who will be affected by the Permitting and Compliance system, and the Environment Agency as the regulatory authority in England and Natural Resources Wales as the regulatory authority in Wales, that there is a common regulatory system in Wales and England. (From 1 April 2013, there will be a new regulatory authority in Wales, Natural Resources Wales. It is proposed that Environment Agency functions under the Environmental Permitting Regulations in Wales will be transferring to this new body from 1 April 2013).

It is in addition desirable for those affected by the COMAH regulations, and for the HSE as the regulatory authority, that there is a common approach in England, Wales and Scotland.

1.9 This is, therefore, a joint consultation paper. For convenience, where the paper refers to “the Government” it should be read as meaning, unless the context indicates otherwise, both the UK Government, the Welsh Assembly Government and, where it relates to the amendments to the COMAH Regulations, the Scottish Government.

## **Who will be affected by these proposals?**

1.10 This consultation paper is directed, in particular, at (i) those who may in future operate facilities for the storage of metallic mercury waste, and (ii) producers of metallic mercury waste.

1.11 The Government recognises that a wide range of other people and groups have an interest in ensuring that metallic mercury wastes continue to be managed in ways which protect the environment and human health. In particular, local communities in which these activities take place, and their elected representatives, need to be confident that this remains the case.

## **Next steps**

1.12 When this consultation ends, we intend to put a copy of the responses, subject to any for which confidentiality is justified, in the Defra library at Ergon House, London. The responses to this consultation will be published by Defra at <http://www.defra.gov.uk/consult/> and by Welsh Assembly Government at <http://wales.gov.uk/consultations>. Each response will be considered.

1.13 The responses will help us draft the amending Regulations for which we shall seek Parliamentary approval early in 2013, the aim being to bring them into force by 15 March 2013. The responses will also help us finalise any draft guidance.

## **Timing and duration of this consultation and how to respond**

1.14 The consultation will last 6 weeks. The timeframe for this consultation has been determined with reference to the Cabinet Office Consultation Principles. The period of the consultation reflects the limited scope of the Directive and the limited number of stakeholders identified during Defra’s engagement with the waste management industry in preparation for the launch of this consultation.

1.15 Please return comments to:

By email: [patrick.mckell@defra.gsi.gov.uk](mailto:patrick.mckell@defra.gsi.gov.uk)

By post: Defra  
Waste Regulation and Crime Team  
Area 6D  
Ergon House  
Horseferry Road  
London SW1P 2AL

*Or in Wales:*

By email: [DESHwaste&LEQCorrespondence@Wales.gsi.gov.uk](mailto:DESHwaste&LEQCorrespondence@Wales.gsi.gov.uk)

By post: Waste Regulation Policy Branch  
Waste and Resource Efficiency Division  
Welsh Assembly Government,  
Cathays Park  
Cardiff CF10 3NQ

*Or in Scotland:*

By email: [gary.gray@scotland.gsi.gov.uk](mailto:gary.gray@scotland.gsi.gov.uk)

By post: Zero Waste Delivery Team  
Area 1-H  
Victoria Quay  
Edinburgh EH6 6QQ

If you have an enquiry relating to this consultation please call:

**0207 238 4407**

*Or in Wales:*

**02920821590**

*Or in Scotland*

0131 244 0363

**Comments must be returned to Defra by 25 January 2013**

**Responses from Wales should be sent to WAG, copied to Defra by 25 January 2013**

Consultees should note that it may not be possible to consider responses which arrive after the deadline.

1.16 This document is available for download from the Defra website, [www.defra.gov.uk/consult/open/](http://www.defra.gov.uk/consult/open/) and from the WAG website <http://wales.gov.uk/consultations>. For your convenience, Annex 1 contains a list of specific questions we have asked. The Government welcomes your response to this consultation in any form. However, your response can be processed more efficiently if, when answering specific consultation questions, your response is clearly marked with question numbers. To help put your response into context, you are also encouraged to indicate a) who you are; b) how many operators or others you represent and who they are; and c) which kinds of activities you are primarily concerned with.

## **Ensuring your confidentiality**

In line with Defra's policy of openness, at the end of the consultation period, copies of the responses we receive may be made publicly available through the Defra Information Resource Centre, Lower Ground Floor, Ergon House, Horseferry Road, London SW1P 2AL. This information they contain may also be published in a summary of responses.

If you do not consent to this, you must clearly request that your response be treated confidentially. Any confidentiality disclaimer generated by your IT systems in email responses will not be treated as such a request. You should also be aware that there may be circumstances in which Defra will be required to communicate information to third parties on request, in order to comply with its obligations under the Freedom of Information Act 2000 and the Environmental Information Regulations.

The Information Resource Centre will supply copies of consultation responses to personal callers or in response to telephone or email requests (tel: 020 7238 6575 or email [defra.library@defra.gsi.gov.uk](mailto:defra.library@defra.gsi.gov.uk)). Wherever possible, personal callers should give the library at least 24 hours' notice of their requirements. An administrative charge will be made to cover photocopying and postage costs.

Responses provided to WAG will be published. Normally, the name and address (or part of the address) or its author are published along with the response, as this gives credibility to the consultation exercise. If you do not wish to be identified as the author of your response, please state this expressly in writing to us, and your response will be published anonymously.



# Storage of metallic mercury waste

## The proposal

2.1. We have three proposals:

i) To take up the derogation from the prohibition on the landfill of liquid waste in the case of metallic mercury allowed by EC Regulation 1102/2008, by way of amending the Environmental Permitting Regulations (England and Wales) 2010; and

(ii) To include the storage of metallic mercury wastes within the scope of the Control of Major Accident Hazards Regulations 1999, by way of amending the Environmental Permitting Regulations (England and Wales) 2010; and

iii) To implement the requirements of Directive 2011/97 by way of amendment to the Environmental Permitting Regulations (England and Wales) 2010, thereby allowing the storage of liquid metallic mercury waste for more than 12 months if other relevant requirements are complied with.

## Discussion

2.2 Mercury and its compounds are highly toxic to humans, ecosystems and wildlife. High doses can be fatal to humans, but even relatively low doses of mercury containing compounds can have serious adverse neuro-developmental impacts, and have been linked with possible harmful effects on the cardiovascular, immune and reproductive systems. Mercury is persistent and can change in the environment into methyl-mercury, the most toxic form. Methyl-mercury readily passes both the placental and the blood-brain barrier, inhibiting mental development even before birth<sup>3</sup>.

2.3 Regulation (EC) No 1102/2008 placed a ban on the export of metallic mercury in order to reduce the risk of exposure to mercury for humans and the environment. The export ban resulted in surplus amounts of mercury in the Community and safe storage of this mercury needs to be ensured. The aim of Directive 2011/97/EU is to specify safe storage conditions for metallic mercury considered as waste. The UK recognises that the Directive offers the most appropriate interim disposal route for metallic mercury waste pending determination of the best permanent disposal route.

---

<sup>3</sup> Commission Regulation (EU) No 847/2012 of 19 September 2012

2.4 Article 5(3)(a) of Directive 1999/31/EC (the Landfill Directive) prohibits the acceptance of liquid waste in a landfill. Regulation (EC) No 1102/2008 provides that, by way of derogation from Article 5(3)(a) of the Landfill Directive metallic mercury that is considered as waste may, in appropriate containment, be temporarily stored for more than one year in certain types of facility, such as specifically adapted salt mines, deep underground hard-rock formations providing an equivalent level of confinement or temporary storage in above ground facilities that have been specifically equipped<sup>4</sup>.

2.5 In order to ensure implementation of this derogation, we propose to amend the Environmental Permitting (England and Wales) Regulations 2010 to enable regulators to exercise their relevant functions under those Regulations so as to permit the storage of metallic mercury in accordance with the requirements of Regulation 1102/2008. In order to implement the requirement in Article 5(1) of Regulation 1102/2008 that Member States submit copies of permits and safety assessments for metallic mercury storage sites, we also propose to amend the EP Regulations 2010 to impose obligations on regulators to provide copies of those documents to the Secretary of State.

2.6 Where the derogation is used in relation to above-ground storage facilities, Regulation 1102/2008 provides that Directive 96/82/EC (on the control of major accident hazards involving dangerous substances) applies<sup>5</sup>. Directive 96/82/EC has been implemented in Great Britain by the Control of Major Accident Hazards Regulations 1999, and so to ensure implementation of this requirement we propose an amendment to those Regulations (in England, Wales and Scotland) so as to bring such storage sites within their scope.

2.7 While the Landfill Directive aims to prevent or reduce as far as possible the negative effects on the environment from the land filling of waste, it does not fully address the specific characteristics of metallic mercury and consequently additional requirements are therefore needed.

2.8 Council Directive 2011/97/EU, amending the Landfill Directive as regards specific criteria for the storage of metallic mercury considered as waste, sets out the criteria for the safe storage of metallic mercury wastes and envisages the storage of metallic mercury waste for up to five years. This will enable further assessment of the long-term behaviour of metallic mercury in underground storage in order to determine sound, knowledge-based requirements for permanent storage.

---

<sup>4</sup> Article 3(1).

<sup>5</sup> Article 3(2).

2.9 The Landfill Directive, which Directive 2011/97/EU amends, sets out criteria and standards for the disposal of waste by landfill. In England and Wales, the Landfill Directive is implemented via the Environmental Permitting Regulations (England and Wales) 2010, in particular, Schedule 10. The Environmental Permitting (EP) regime aims to protect the environment while simplifying the regulatory system and minimising the administrative burden on the regulators and the operators of the facilities regulated under the regime.

2.10 We therefore propose that the amendments to the Landfill Directive as detailed by Directive 2011/97/EU will be transposed in England and Wales by amendments to the EP Regulations 2010. This will involve updating the definition of the Landfill Directive in regulation 3 of the EP Regulations 2010, following which the requirements on the regulator in Schedule 10 to the EP Regulations to comply with various Articles of the Landfill Directive will be read as references to that Directive as amended by Directive 2011/97/EU.

2.11 Defra has engaged actively with industry stakeholders and the UK regulators on the implementation of the Directive. This engagement has revealed little evidence of any UK business currently storing metallic mercury waste long enough to be subject to the Directive. Nevertheless the UK is required to transpose the requirements of the Directive or face infraction proceedings. Transposition of the Directive and the enactment of the derogation on the landfill of liquid waste will also ensure that any UK business that wishes in the future to provide for the safe storage of metallic mercury waste for periods greater than 12 months can do so.

2.12 Article 2 of Regulation 1102/2008 provides that certain types of metallic mercury are to be considered as waste. As a result, only these types of metallic mercury waste are captured under the provisions of Directive 2011/97/EU. They are:

- (a) metallic mercury that is no longer used in the chlor-alkali industry;
- (b) metallic mercury gained from the cleaning of natural gas;
- (c) metallic mercury gained from non-ferrous mining and smelting operations; and
- (d) metallic mercury extracted from cinnabar ore in the Community as from 15 March 2011.

2.13 Consequently only the above types of metallic mercury waste will be affected by the proposed amendments to the EP Regulations and only when stored for greater than 12 months.

2.14 The majority of metallic mercury waste arising in the UK is relatively small in volume and is derived from the disposal of small amounts of redundant or damaged laboratory and medical equipment, redundant micro batteries or the residues from the treatment of redundant mercury lamps.

2.15 The current cost of treating this waste by extracting and distilling the elemental mercury for sale as a product is approximately £2,000 to £5,000 per tonne dependant on the nature of the waste. In the short term there remains a demand for the small amounts of mercury produced by UK based recycling operations for a range of laboratory and academic research applications in the UK.

2.16 The storage criteria laid down in Directive 2011/97/EU specify that waste with a purity of 99.9% mercury content must be stored in specialised shock and corrosion resistant containers. These containers must be stored in a facility that has engineered or natural barriers to protect the environment against mercury emissions. The waste mercury must also be stored separately from other wastes.

2.17 Certain deep strata former salt mines naturally meet the above storage requirements. The cost of storage of liquid metallic mercury in deep strata former salt mines is estimated to range from approximately £1,000 to £5,000 per tonne, dependant on the nature of the waste. There are currently no deep strata storage facilities in the UK that meet these criteria although suitable deep strata facilities do exist in Europe, most notably Germany.

2.18 Suitably designed, equipped and managed above ground storage facilities can also meet the storage criteria laid down in Directive 2011/97/EU. The cost of storage of liquid metallic mercury in above ground storage facilities is estimated to range from approximately £500 to £900 per tonne. These figures are derived from a 2007 study by the United States Environmental Protection Agency. The most cost effective solution would currently appear to be above ground storage.

2.19 In the medium to longer term there may be a surplus of metallic mercury waste with no commercial application. This may mean that waste producers in the UK will require a disposal option.

2.20 The transposition of the Directive through an amendment to the Environmental Permitting regime will enable the Environment Agency to permit and monitor above ground storage facilities in the UK providing a cost effective solution to the future storage of this hazardous waste.

## Questions

**Question 1:** Do you have any comments about the practical impacts or consequences of the proposed amendments which are required under Council Directive 2011/97/EU?

**Question 2:** If you are a producer of metallic mercury waste or a waste management company that handles waste of this type, do you have any comments about the desirability or practical consequences, including costs, of the proposed amendments?

## **Annex I – List of consultation questions**

**Question 1:** Do you have any comments about the practical impacts or consequences of the proposed amendments which are required under Council Directive 2011/97/EU?

**Question 2:** If you are a producer of metallic mercury waste or a waste management company that handles waste of this type, do you have any comments about the desirability or practical consequences, including costs, of the proposed amendments?

# Annex II – Draft Environmental Permitting (England and Wales) Amendment Regulations

---

## STATUTORY INSTRUMENTS

---

2013 No.

### ENVIRONMENTAL PROTECTION, ENGLAND AND WALES

### HEALTH AND SAFETY

The Environmental Permitting (England and Wales) (Amendment) Regulations 2013

*Made* - - - - - \*\*\*

*Laid before Parliament* \*\*\*

*Laid before the National Assembly for Wales* \*\*\*

*Coming into force in accordance with regulation 1*

The Secretary of State in relation to England (and Wales and Scotland, so far as relating to regulation 3 of the following Regulations), and the Welsh Ministers in relation to Wales (except so far as relating to regulation 3), have consulted—

- (a) the Environment Agency,
- (b) such bodies or persons appearing to them to be representative of the interests of local government, industry, agriculture and small business as they consider appropriate, and
- (c) such other bodies or persons as they consider appropriate,

in accordance with section 2(4) of the Pollution Prevention and Control Act 1999<sup>(6)</sup> (“the 1999 Act”).

The Secretary of State has also consulted the Scottish Environment Protection Agency in relation to regulation 3, in accordance with section 2(4)(b) of the 1999 Act.

The Secretary of State makes the following Regulations—

---

<sup>(6)</sup> 1999 c. 24. Functions of the Secretary of State under or in relation to section 2, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales, except in relation to offshore oil and gas exploration and exploitation, by article 3(1) of the National Assembly for Wales (Transfer of Functions) Order 2005 (S.I. 2005/1958). But this was subject to article 3(2), which provided that, so far as any of those functions are exercisable by the Secretary of State in relation to a cross-border body but which, by their nature, are not functions which can be specifically exercised in relation to Wales, such functions are exercisable by the National Assembly for Wales in relation to that body concurrently with the Secretary of State. Functions of the National Assembly for Wales were transferred to the Welsh Ministers by section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006 (c. 32).

- (a) so far as relating to regulation 3, in relation to England, Wales and Scotland in exercise of the powers conferred by section 2 of, and paragraph 20(1) of Schedule 1 to, the 1999 Act;
- (b) otherwise, in relation to England in exercise of the powers conferred by sections 2 and 7(9) of, and Schedule 1 to, the 1999 Act.

The Welsh Ministers make the following Regulations, except so far as relating to regulation 3, in relation to Wales in exercise of the powers conferred by sections 2 and 7(9) of, and Schedule 1 to, the 1999 Act.

### **Citation, commencement and extent**

1.—(1) These Regulations may be cited as the Environmental Permitting (England and Wales) (Amendment) Regulations 2013.

(2) They come into force on 15th March 2013.

(3) Subject to paragraph (4), these Regulations extend to England and Wales.

(4) Regulation 3 extends to England and Wales and Scotland.

### **Amendment of the Environmental Permitting (England and Wales) Regulations 2010**

2.—(1) The Environmental Permitting (England and Wales) Regulations 2010<sup>(7)</sup> are amended as follows.

(2) In regulation 3 (interpretation: Directives), for the definition of “the Landfill Directive” substitute the following definition—

““the Landfill Directive” means Council Directive 1999/31/EC on the landfill of waste<sup>(8)</sup>, as read with Council Decision 2003/33/EC establishing criteria and procedures for the acceptance of waste at landfills pursuant to Article 16 of, and Annex II to, Directive 1999/31/EC<sup>(9)</sup>.”

(3) In paragraph 5 of Schedule 10 (landfill), after sub-paragraph (3) insert—

“(4) The regulator may exercise those relevant functions so as to permit the storage of metallic mercury in accordance with Regulation (EC) No 1102/2008 of the European Parliament and of the Council on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury<sup>(10)</sup>.

(5) For the purposes of Article 5(1) of that Regulation, the regulator must send to the Secretary of State—

- (a) a copy of any permit issued for a facility designated to store metallic mercury temporarily or permanently; and
- (b) the respective safety assessment pursuant to Article 4(1) of that Regulation.”.

---

<sup>(7)</sup> S.I. 2010/675; a relevant amendment was made by S.I. 2011/988. There are other amendments not relevant to this instrument.

<sup>(8)</sup> OJ No L 182, 16.7.99, p 1, as last amended by Council Directive 2011/97/EU amending Directive 1999/31/EC as regards specific criteria for the storage of metallic mercury considered as waste (OJ No L 328, 10.12.11, p 49).

<sup>(9)</sup> OJ No L 11, 16.1.03, p 27.

<sup>(10)</sup> OJ No L 304, 14.11.08, p 75.

## **Amendment of the Control of Major Accident Hazards Regulations 1999**

3. For regulation 3(3)(d) (application) of the Control of Major Accident Hazards Regulations 1999<sup>(1)</sup>, substitute—

“(d)waste land-fill sites, except—

- (i) tailing ponds or dams and other operational tailings disposal facilities containing dangerous substances, in particular when any such facilities are used in connection with the chemical and thermal processing of minerals;
- (ii) sites used for the storage of metallic mercury pursuant to Article 3(1)(b) of Regulation (EC) No 1102/2008 of the European Parliament and of the Council on the banning of exports of metallic mercury and certain mercury compounds and mixtures and the safe storage of metallic mercury.”.

*Name*

Parliamentary Under Secretary of State

Date

Department for Environment, Food and Rural Affairs

Signed on behalf of the Welsh Ministers

*Name*

Minister for Environment and Sustainability Development

Date

One of the Welsh Ministers

### **EXPLANATORY NOTE**

*(This note is not part of the Regulations)*

These Regulations implement Council Directive 2011/97/EU (OJ No L 328, 10.12.11, p 49), which amends Council Directive 1999/31/EC on the landfill of waste (OJ No L 182 16.7.99, p 1) (“the Landfill Directive”) as regards specific criteria for the storage of metallic mercury considered as waste.

Article 5(3)(a) of the Landfill Directive prohibits of the storage of liquid waste in landfill. Regulation (EC) No 1102/2008 (OJ No L 304, 14.11.08, p 75) (“the Mercury Regulation”) contains a derogation from that prohibition. These Regulations make provision relating to the use of that derogation.

Regulation 2(2) amends the Environmental Permitting (England and Wales) Regulations 2010 (S.I. 2010/675) to replace the definition of the Landfill Directive so as to take account of that Directive’s amendment by Council Directive 2011/97/EU. Regulation 2(3) amends those Regulations to enable the regulator to exercise its functions so as to permit the storage of liquid waste in accordance with the Mercury Regulation and to impose obligations to send copies of environmental permits and safety assessments to the Secretary of State.

Regulation 3 amends the Control of Major Accident Hazards Regulations 1999 (S.I. 1999/743) in relation to England, Wales and Scotland to bring sites used for the storage of metallic mercury pursuant to Article 3(1)(b) of the Mercury Regulation within the scope of application of those Regulations.

---

<sup>(1)</sup> S.I. 1999/743. Regulation 3(3)(d) was substituted by regulation 4(1) of S.I. 2005/1088. There are other amendments not relevant to this instrument.