EXPLANATORY MEMORANDUM TO THE

CONTROL OF MAJOR ACCIDENT HAZARDS (AMENDMENT) REGULATIONS 2005

2005 No.1088

1. This explanatory memorandum has been prepared by the Health and Safety Executive (HSE) on behalf of the Department for Work and Pensions and is laid before Parliament by Command of Her Majesty.

2. **Description**

2.1 The Regulations amend the Control of Major Accident Hazards Regulations 1999 (COMAH) to implement Directive 2003/105/EC on the control of major-accident hazards involving dangerous substances. They set out timescales for compliance as a result of the changes and introduce a small number of other provisions to clarify or make explicit certain existing administrative requirements.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

4. Legislative background

- 4.1 The Regulations are made under the Health and Safety at Work etc Act 1974 (1974 c37). They give effect as respects Great Britain to Directive 2003/105/EC of the European Parliament and of the Council (OJ No L345, 31.12.2003, p97), amending Council Directive 96/82/EC (OJ No L10, 14.1.97, p13) concerning the control of major-accident hazards involving dangerous substances (the 'Seveso II' Directive, which was implemented through COMAH in 1999). A copy of Directive 2003/105/EC is at Appendix 1. Article 2 requires implementation in Member States before 1 July 2005.
- 4.2 All stages of Directive 2003/105/EC cleared Scrutiny. The Scrutiny history is summarised in Appendix 2.
- 4.3 The Regulations also clarify or make explicit a small number of administrative requirements that have come to light since COMAH was introduced. In addition they implement a provision in the Seveso II Directive that was omitted from COMAH concerning the provision of amended safety reports where information is to be excluded from public registers. Transposition Notes for Directives 2003/105/EC and 96/82/EC are at Appendix 3.

5. Extent

5.1 The instrument applies to Great Britain. Northern Ireland and Gibraltar will introduce separate legislation to implement the Directive.

5.2 Directive 2003/105/EC also necessitates changes to planning law. This is a devolved matter that is being taken forward through changes to existing planning law.

6. European Convention on Human Rights

6.1 Not applicable.

7. Policy background

- 7.1 In giving effect to Directive 2003/105/EC the Regulations are a broadening of the scope of COMAH to better achieve its aims rather than a major revision. In accordance with the Directive, the Regulations:
 - take account of recommendations of two EC working groups on the scientific and practical basis for the inclusion of named carcinogens and the qualifying quantities for substances dangerous for the environment; and
 - implement the lessons learned from major accidents in Europe since Seveso II was introduced, notably a spill of cyanide into a river in Baie Mare which killed thousands of tones of fish, a major explosion at a fireworks factory in Enschede in the Netherlands that killed 20 people, and an explosion involving ammonium nitrate at a fertiliser plant in Toulouse France, in which 30 people died.
- 7.2 The practical effect of these is to extend the application of COMAH to certain activities involving dangerous substances at mines, quarries, boreholes and at waste land-fill sites, and introduce changes to the lists of named dangerous substances and generic categories of dangerous substances and their qualifying quantities that are used to determine whether an establishment comes within scope of COMAH. These are contained in Schedule 1 to the Regulations. There are also a number of administrative changes, including specified timescales for sites affected by the changes.
- 7.3 Although the Regulations do not represent a major change to the COMAH regime, the broader scope created by the scientific and technical changes to Schedule 1 will affect the number of sites subject to COMAH. It is estimated that 158 sites will be brought into scope, increasing the overall number of COMAH sites by around 14%. Additionally, between 83 and 91 sites currently subject to COMAH's lower level of controls requirements will become subject to the more stringent top tier requirements¹.
- 7.4 The Health and Safety Commission (HSC) consulted on the new Regulations between 12 July and 1 October 2004. Seventy three responses were received including 23 from industry, 11 from trade associations, 16 from local authorities (whose emergency planning departments prepare off-site emergency plans for the 'top tier' COMAH sites), 16 from the emergency services, and one from a trade union.

¹ Lower tier requirements are: notification to the competent authority; preparation of a major accident prevention policy; the application of a land-use planning policy; and inspection. In addition, top tier requirements are: the preparation of a safety report; internal and external emergency plans; and the provision of information to the public.

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7.5 There was widespread support for the way the Regulations would implement the Directive and the other proposed changes.

8. Impact

8.1 A regulatory impact assessment is attached to this Memorandum at Appendix 4.

9. Contact for enquiries

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DIRECTIVE 2003/105/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2003

amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION.

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission (1),

Having regard to the opinion of the European Economic and Social Committee (2),

After consulting the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty in the light of the joint text approved by the Conciliation Committee on 22 October 2003 (3),

Whereas:

- Directive 96/82/EC (4) aims at the prevention of major accidents which involve dangerous substances and the limitation of their consequences for man and the environment, with a view to ensuring high levels of protection throughout the Community in a consistent and effective manner.
- In the light of recent industrial accidents and studies on carcinogens and substances dangerous for the environment carried out by the Commission at the Council's request, the scope of Directive 96/82/EC should be extended.
- The cyanide spill that polluted the Danube following the accident at Baia Mare in Romania in January 2000 has demonstrated that certain storage and processing activities in mining, especially tailings disposal facilities, including tailing ponds or dams, have potential to produce very serious consequences. The Commission communications on the safe operation of mining activities and on the sixth environment action programme of the European Community have therefore highlighted the need for an extension of the scope of Directive 96/82/ EC. In its resolution of 5 July 2001 (5) on the Commission Communication on the safe operation of mining activities, the European Parliament also welcomed the extension of the scope of that Directive to cover risks arising from storage and processing activities in mining.

- The proposal for a directive on the management of waste from the extractive industries may be a relevant framework for measures relating to those waste management facilities which present an accident risk but which are not covered by the present Directive.
- The 'fireworks accident' at Enschede in the Netherlands in May 2000 has demonstrated the major accident potential arising from storage and manufacture of pyrotechnic and explosive substances. The definition of such substances in Directive 96/82/EC should therefore be clarified and simplified.
- The explosion at a fertiliser plant in Toulouse in September 2001 has raised awareness of the accident potential arising from the storage of ammonium nitrate and ammonium nitrate-based fertilisers, in particular of material rejected during the manufacturing process or returned to the manufacturer (off-specs). The existing categories of ammonium nitrate and ammonium nitratebased fertilisers in Directive 96/82/EC should therefore be reviewed with a view to include 'off-specs' material.
- Directive 96/82/EC should not be applied to sites of end-users where ammonium nitrate and ammonium nitrate-based fertilisers, which on delivery conformed to the specification in that Directive but subsequently have become degraded or contaminated, are temporarily present prior to removal for reprocessing or destruction.
- Studies carried out by the Commission in close cooperation with the Member States support extending the list of carcinogens with appropriate qualifying quantities and significantly lowering the qualifying quantities assigned to substances dangerous for the environment in Directive 96/82/EC.
- For establishments which subsequently fall within the scope of Directive 96/82/EC, it has been shown necessary to introduce minimum periods for notifications and the establishment of major accident prevention policies, safety reports and emergency plans.
- The experience and knowledge of relevant staff in the establishment can greatly assist in the drawing up of emergency plans, and all staff in an establishment and persons likely to be affected should be appropriately informed on safety measures and actions.

^(*) OJ C 75 E, 26.3.2002, p. 357 and OJ C 20 E, 28.1.2003, p. 255. (*) OJ C 149, 21.6.2002, p. 13. (*) Opinion of the European Parliament of 3 July 2002 (OJ C 271 E, 12.11.2003, p. 315), Council common position of 20 February 2003 (OJ C 102 E, 29.4.2003, p. 1) and position of the European Parliament of 19 June 2003 (not yet published in the Official Journal). Legislative resolution of the European Parliament of 19 June 2003 (not yet published in the Official Journal). November 2003 (not yet published in the Official Journal) and decision of the Council of 1 December 2003.

(*) OJ L 10, 14.1.1997, p. 13.

(*) OJ C 65 E, 14.3.2002, p. 382.

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- (11) The adoption of Council Decision 2001/792/EC, Euratom of 23 October 2001 establishing a Community mechanism to facilitate reinforced cooperation in civil protection assistance interventions () highlights the need to facilitate reinforced cooperation in civil protection assistance interventions.
- (12) It is useful, in order to facilitate land-use planning, to draw up guidelines defining a database to be used for assessing the compatibility between the establishments covered by Directive 96/82/EC and the areas described in Article 12(1) of that Directive.
- (13) There should be an obligation on Member States to supply the Commission with minimum information concerning the establishments covered by Directive 96/ 82/EC.
- (14) It is appropriate at the same time to clarify certain passages in Directive 96/82/EC.
- (15) The measures provided for in this Directive have been the subject of a public consultation process involving interested parties.
- (16) Directive 96/82/EC should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/82/EC is hereby amended as follows:

- 1. Article 4 is amended as follows:
 - (a) Points (e) and (f) are replaced by the following:
 - '(e) the exploitation (exploration, extraction and processing) of minerals in mines, quarries, or by means of boreholes, with the exception of chemical and thermal processing operations and storage related to those operations which involve dangerous substances, as defined in Annex I;
 - (f) the offshore exploration and exploitation of minerals, including hydrocarbons;
 - (b) The following point shall be added:
 - '(g) waste land-fill sites, with the exception of operational tailings disposal facilities, including tailing ponds or dams, containing dangerous substances as defined in Annex I, in particular when used in connection with the chemical and thermal processing of minerals.'
- 2. Article 6 is amended as follows:
 - (a) The following indent is added in paragraph 1:
 - '— for establishments which subsequently fall within the scope of this Directive, within three months after the date on which this Directive applies to the establishment concerned, as laid down in the first subparagraph of Article 2(1).'

- (b) The following indent is inserted after the first indent of Article 6(4):
 - '— modification of an establishment or an installation which could have significant repercussions on major accident hazards, or'.
- 3. The following paragraph is inserted in Article 7:
 - '1a. For establishments which subsequently fall within the scope of this Directive, the document referred to in paragraph 1 shall be drawn up without delay, but at all events within three months after the date on which this Directive applies to the establishment concerned, as laid down in the first subparagraph of Article 2(1).'
- 4. Article 8(2)(b) is replaced by the following:
 - '(b) provision is made for cooperation in informing the public and in supplying information to the authority responsible for the preparation of external emergency plans.'
- 5. Article 9 is amended as follows:
 - (a) The first subparagraph of paragraph 2 is replaced by the following:
 - 2. The safety report shall contain at least the data and information listed in Annex II. It shall name the relevant organisations involved in the drawing up of the report. It shall also contain an updated inventory of the dangerous substances present in the establishment.'
 - (b) The following indent is inserted between the third and fourth indents of paragraph 3:
 - for establishments which subsequently fall within the scope of this Directive, without delay, but at all events within one year after the date on which this Directive applies to the establishment concerned, as laid down in the first subparagraph of Article 2(1).
 - (c) In paragraph 4, the reference to 'the second, third, and fourth indents' becomes 'the second, third, fourth and fifth indents' respectively.
 - (d) The following point is added to Article 9(6):
 - '(d) The Commission is invited to review by 31 December 2006 in close cooperation with the Member States, the existing "Guidance on the Preparation of a Safety Report".'
- 6. Article 11 is amended as follows:
 - (a) The following indent is added to points (a) and (b) of paragraph 1:
 - '— for establishments which subsequently fall within the scope of this Directive, without delay, but at all events within one year after the date on which this Directive applies to the establishment concerned, as laid down in the first subparagraph of Article 2(1).'

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- (b) Paragraph 3 is replaced by the following:
 - '3. Without prejudice to the obligations of the competent authorities, Member States shall ensure that the internal emergency plans provided for in this Directive are drawn up in consultation with the personnel working inside the establishment, including long-term relevant subcontracted personnel, and that the public is consulted on external emergency plans when they are established or updated.'
- (c) The following paragraph is inserted:
 - '4a. With regard to external emergency plans, Member States should take into account the need to facilitate enhanced cooperation in civil protection assistance in major emergencies.'

7. Article 12 is amended as follows:

(a) The second subparagraph of paragraph 1 is replaced by the following:

'Member States shall ensure that their land-use and/or other relevant policies and the procedures for implementing those policies take account of the need, in the long term, to maintain appropriate distances between establishments covered by this Directive and residential areas, buildings and areas of public use, major transport routes as far as possible, recreational areas and areas of particular natural sensitivity or interest and, in the case of existing establishments, of the need for additional technical measures in accordance with Article 5 so as not to increase the risks to people.'

- (b) The following paragraph is inserted:
 - The Commission is invited by 31 December 2006, in close cooperation with the Member States, to draw up guidelines defining a technical database including risk data and risk scenarios, to be used for assessing the compatibility between the establishments covered by this Directive and the areas described in paragraph 1. The definition of this database shall as far as possible take account of the evaluations made by the competent authorities, the information obtained from operators and all other relevant information such as the socioeconomic benefits of development and the mitigating effects of emergency plans.'

8. Article 13 is amended as follows:

- (a) The first subparagraph of paragraph 1 is replaced by the following:
 - '1. Member States shall ensure that information on safety measures and on the requisite behaviour in the event of an accident is supplied regularly and in the most appropriate form, without their having to request it, to all persons and all establishments serving the

public (such as schools and hospitals) liable to be affected by a major accident originating in an establishment covered by Article 9.'

- (b) Paragraph 6 is replaced by the following:
 - In the case of establishments subject to the provisions of Article 9, Member States shall ensure that the inventory of dangerous substances provided for in Article 9(2) is made available to the public subject to the provisions of paragraph 4 of this Article and Article 20.'
- 9. The following paragraph is inserted in Article 19:
 - For establishments covered by this Directive, Member States shall supply the Commission with at least the following information:
 - (a) the name or trade name of the operator and the full address of the establishment concerned; and
 - (b) the activity or activities of the establishment.

The Commission shall set up and keep up to date a database containing the information supplied by the Member States. Access to the database shall be reserved to persons authorised by the Commission or the competent authorities of the Member States.'

- Annex I is amended as set out in the Annex.
- 11. In Annex II, point IV part B is replaced by the following:
 - B. Assessment of the extent and severity of the consequences of identified major accidents including maps, images or, as appropriate, equivalent descriptions, showing areas which are liable to be affected by such accidents arising from the establishment, subject to the provisions of Articles 13(4) and 20.'
- 12. In Annex III, point (c) is amended as follows:
 - (a) point (i) is replaced by the following:
 - (i) organisation and personnel the roles and responsibilities of personnel involved in the management of major hazards at all levels in the organisation. The identification of training needs of such personnel and the provision of the training so identified. The involvement of employees and of subcontracted personnel working in the establish-
 - (b) point (v) is replaced by the following:
 - '(v) Planning for emergencies adoption and implementation of procedures to identify foreseeable emergencies by systematic analysis, to prepare, test and review emergency plans to respond to such emergencies and to provide specific training for the staff concerned. Such training shall be given to all personnel working in the establishment, including relevant subcontracted personnel.'

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 1 July 2005. They shall forthwith inform the Commission thereof.

When Member States adopt these measures, they shall contain a reference to this Directive or shall be accompanied by such a reference on the occasion of their official publication. The methods of making such reference shall be laid down by Member States.

2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 3

This Directive shall enter into force on the day of its publication in the Official Journal of the European Union.

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 16 December 2003.

For the European Parliament For the Council
The President The President
P. COX G. ALEMANNO

Annex I to Directive 96/82/EC is hereby amended as follows:

- 1. The following points are added to the introduction:
 - '6. For the purposes of this Directive, a gas is any substance that has an absolute vapour pressure equal to or greater than 101,3 kPa at a temperature of $20\,^\circ$ C.
 - 7. For the purposes of this Directive, a liquid is any substance that is not defined as a gas and that is not in the solid state at a temperature of 20 $^{\circ}$ C and at a standard pressure of 101,3 kPa.'
- 2. In the table in Part 1:

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(a) the entries relating to 'Ammonium nitrate' are replaced by the following:

'Ammonium nitrate (see note 1)	5 000	10 000
Ammonium nitrate (see note 2)	1 250	5 000
Ammonium nitrate (see note 3)	350	2 500
Ammonium nitrate (see note 4)	10	50'

(b) the following entries are inserted after the entries relating to 'Ammonium nitrate':

'Potassium nitrate (see note 5)	5 000	10 000
Potassium nitrate (see note 6)	1 250	5 000'

(c) the entry relating to 'The following CARCINOGENS' is replaced by the following:

The following CARCINOGENS at concentrations above 5 % by weight: 4-Aminobiphenyl and/or its salts, Benzotrichloride, Benzidine and/or salts, Bis (chloromethyl) ether, Chloromethyl methyl ether, 1,2-Dibromoethane, Diethyl sulphate, Dimethyl sulphate, Dimethyl sulphate, Dimethylarbamoyl chloride, 1,2-Dibromo-3-chloropropane, 1,2-Dimethyl-hydrazine, Dimethylaringsmine, Heyamethylpho-	2'
hydrazine, Dimethylnirosamine, Hexamethylpho- sphoric triamide, Hydrazine, 2- Naphthylamine and/or salts, 4-Nitrodiphenyl, and 1,3 Propanesultone	

(d) the entry relating to 'Automotive petrol and other petroleum spirits' is replaced by the following:

'Petroleum products:	2 500	25 000'
(a) gasolines and naphthas,		
(b) kerosenes (including jet fuels),		
(c) gas oils (including diesel fuels, home heating oils and gas oil blending streams)		

- (e) (i) Notes 1 and 2 are replaced by the following:
 - 1. Ammonium nitrate (5 000/10 000): fertilisers capable of self-sustaining decomposition

This applies to ammonium nitrate-based compound/composite fertilisers (compound/composite fertilisers containing ammonium nitrate with phosphate and/or potash) in which the nitrogen content as a result of ammonium nitrate is

- between 15,75 % (') and 24,5 % (') by weight, and either with not more than 0,4 % total combustible/organic materials or which fulfil the requirements of Annex II of Directive 80/876/EEC,
- 15,75 % (3) by weight or less and unrestricted combustible materials,

and which are capable of self-sustaining decomposition according to the UN Trough Test (see United Nations Recommendations on the Transport of Dangerous Goods: Manual of Tests and Criteria, Part III, subsection 38.2).

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2. Ammonium nitrate (1 250/5 000): fertiliser grade

This applies to straight ammonium nitrate-based fertilisers and to ammonium nitrate-based compound/ composite fertilisers in which the nitrogen content as a result of ammonium nitrate is

- more than 24,5 % by weight, except for mixtures of ammonium nitrate with dolomite, limestone and/or calcium carbonate with a purity of at least 90 %,
- more than 15,75 % by weight for mixtures of ammonium nitrate and ammonium sulphate,
- more than 28 % (4) by weight for mixtures of ammonium nitrate with dolomite, limestone and/or calcium carbonate with a purity of at least 90 %,

and which fulfil the requirements of Annex II of Directive 80/876/EEC.

3. Ammonium nitrate (350/2500): technical grade

This applies to:

- ammonium nitrate and preparations of ammonium nitrate in which the nitrogen content as a result of the ammonium nitrate is
 - between 24,5 % and 28 % by weight, and which contain not more than 0,4 % combustible
 - more than 28 % by weight, and which contain not more than 0,2 % combustible substances,
- aqueous ammonium nitrate solutions in which the concentration of ammonium nitrate is more than 80 % by weight.
- 4. Ammonium nitrate (10/50): "off-specs" material and fertilisers not fulfilling the detonation test

This applies to:

- material rejected during the manufacturing process and to ammonium nitrate and preparations of ammonium nitrate, straight ammonium nitrate-based fertilisers and ammonium nitrate-based compound/composite fertilisers referred to in notes 2 and 3, that are being or have been returned from the final user to a manufacturer, temporary storage or reprocessing plant for reworking, recycling or treatment for safe use, because they no longer comply with the specifications of Notes 2
- fertilisers referred to in note 1, first indent, and Note 2 which do not fulfil the requirements of Annex II of Directive 80/87 6/EEC.
- 5. Potassium nitrate (5 000/10 000): composite potassium-nitrate based fertilisers composed of potassium
- 6. Potassium nitrate (1 250/5 000): composite potassium-nitrate based fertilisers composed of potassium nitrate in crystalline form.
- (ii) the note relating to polychlorodibenzofurans and polychlorodibenzodioxins becomes note 7.
- (iii) the following footnotes appear below the table entitled 'International Toxic Equivalent Factors (ITEF) for the congeners of concern (NATO/CCMS)':
 - (1) 15,75% nitrogen content by weight as a result of ammonium nitrate corresponds to 45% ammonium
 - (2) 24,5 % nitrogen content by weight as a result of ammonium nitrate corresponds to 70 % ammonium
 - (3) 15,75% nitrogen content by weight as a result of ammonium nitrate corresponds to 45% ammonium
 - (4) 28 % nitrogen content by weight as a result of ammonium nitrate corresponds to 80 % ammonium

3. In Part 2:

(a) entries 4 and 5 are replaced by the following:

'4. EXPLOSIVE (see note 2) where the substance, preparation or article falls under UN/ADR Division 1.4	50	200
5. EXPLOSIVE (see note 2) where the substance, preparation or article falls under any of: UN/ADR Divisions 1.1, 1.2, 1.3, 1.5 or 1.6 or risk phrase R2 or R3		50'

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(b) entry 9 is replaced by the following:

'9. DANGEROUS FOR THE ENVIRONMENT risk phrases:		
i) R50: "Very toxic to aquatic organisms" (including R50/53)	100	200
ii) R51/53: "Toxic to aquatic organisms: may cause long term adverse effects in the aquatic environment"	200	500'

(c) In the notes:

- (i) Note 1 is replaced by the following:
 - 1. Substances and preparations are classified according to the following Directives and their current adaptation to technical progress:

Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances(1).

Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations (2).

In the case of substances and preparations which are not classified as dangerous according to either of the above directives, for example waste, but which nevertheless are present, or are likely to be present, in an establishment and which possess or are likely to possess, under the conditions found at the establishment, equivalent properties in terms of major-accident potential, the procedures for provisional classification shall be followed in accordance with the relevant article of the appropriate Directive.

In the case of substances and preparations with properties giving rise to more than one classification, for the purposes of this Directive the lowest qualifying quantities shall apply. However, for the application of the rule in Note 4, the qualifying quantity used shall always be the one corresponding to the classifica-

For the purposes of this Directive, the Commission shall establish and keep up to date a list of substances which have been classified into the above categories by a harmonised Decision in accordance with Directive 67/548/EEC.'

- (ii) Note 2 is replaced by the following:
 - '2. An "explosive" means:
 - a substance or preparation which creates the risk of an explosion by shock, friction, fire or other sources of ignition (risk phrase R2),
 - a substance or preparation which creates extreme risks of explosion by shock, friction, fire or other sources of ignition (risk phrase R3), or
 - a substance, preparation or article covered by Class 1 of the European Agreement concerning the International Carriage of Dangerous Goods by Road (UN/ADR), concluded on 30 September 1957, as amended, as transposed by Council Directive 94/55/EC of 21 November 1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road (3).

Included in this definition are pyrotechnics, which for the purposes of this Directive are defined as substances (or mixtures of substances) designated to produce heat, light, sound, gas or smoke or a combination of such effects through self-sustained exothermic chemical reactions. Where a substance or preparation is classified by both UN/ADR and risk phase R2 or R3, the UN/ADR classification shall take precedence over assignment of risk phrases.

Substances and articles of Class 1 are classified in any of the divisions 1.1 to 1.6 in accordance with the UN/ADR classification scheme. The divisions concerned are:

Division 1.1: "Substances and articles which have a mass explosion hazard (a mass explosion is an explosion which affects almost the entire load virtually instantaneously).

Division 1.2: "Substances and articles which have a projection hazard but not a mass explosion hazard."

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Division 1.3: "Substances and articles which have a fire hazard and either a minor blast hazard or a minor projection hazard or both, but not a mass explosion hazard:

- (a) combustion of which gives rise to considerable radiant heat; or
- (b) which burn one after another, producing minor blast or projection effects or both."

Division 1.4: "Substances and articles which present only a slight risk in the event of ignition or initiation during carriage. The effects are largely confined to the package and no projection of fragments of appreciable size or range is to be expected. An external fire shall not cause virtually instantaneous explosion of virtually the entire contents of the package."

Division 1.5: "Very insensitive substances having a mass explosion hazard which are so insensitive that there is very little probability of initiation or of transition from burning to detonation under normal conditions of carriage. As a minimum requirement they shall not explode in the external fire test."

Division 1.6: "Extremely insensitive articles which do not have a mass explosion hazard. The articles contain only extremely insensitive detonating substances and demonstrate a negligible probability of accidental initiation or propagation. The risk is limited to the explosion of a single article."

Included in this definition are also explosive or pyrotechnic substances or preparations contained in articles. In the case of articles containing explosive or pyrotechnic substances or preparations, if the quantity of the substance or preparation contained is known, that quantity shall be considered for the purposes of this Directive. If the quantity is not known, then, for the purposes of this Directive, the whole article shall be treated as explosive.

- (iii) in note 3(b)(1), the second indent shall be replaced by the following:
 - '— substances and preparations which have a flash point lower than 55° C and which remain liquid under pressure, where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards;'
- (iv) note 3(c)(2) is replaced by the following:
 - '2. gases which are flammable in contact with air at ambient temperature and pressure (risk phrase R12, second indent), which are in a gaseous or supercritical state, and'
- (v) note 3(c)3 is replaced by the following:
 - '3. flammable and highly flammable liquid substances and preparations maintained at a temperature above their boiling point.'
- (vi) note 4 is replaced by the following:
 - '4. In the case of an establishment where no individual substance or preparation is present in a quantity above or equal to the relevant qualifying quantities, the following rule shall be applied to determine whether the establishment is covered by the relevant requirements of this Directive.

This Directive shall apply if the sum

$$q_1/Q_{U1}+q_2/Q_{U2}+q_3/Q_{U3}+q_4/Q_{U4}+q_5/Q_{U5}+...$$
 is greater than or equal to 1,

where q_x = the quantity of dangerous substance x (or category of dangerous substances) falling within Parts 1 or 2 of this Annex,

and Q_{tx} = the relevant qualifying quantity for substance or category x from column 3 of Parts 1 or 2.

This Directive shall apply, with the exception of Articles 9, 11 and 13, if the sum

$$q_{_1}/Q_{_{11}}+q_{_2}/Q_{_{12}}+q_{_3}/Q_{_{13}}+q_{_4}/Q_{_{14}}+q_{_5}/Q_{_{15}}+...$$
 is greater than or equal to 1,

where q_x = the quantity of dangerous substance x (or category of dangerous substances) falling within Parts 1 or 2 of this Annex,

and Q_{1X} = the relevant qualifying quantity for substance or category x from column 2 of Parts 1 or 2.

This rule shall be used to assess the overall hazards associated with toxicity, flammability, and eco-toxicity. It must therefore be applied three times:

 (a) for the addition of substances and preparations named in Part 1 and classified as toxic or very toxic, together with substances and preparations falling into categories 1 or 2;

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- (b) for the addition of substances and preparations named in Part 1 and classified as oxidising, explosive, flammable, highly flammable, or extremely flammable, together with substances and preparations falling into categories 3, 4, 5, 6, 7a, 7b or 8;
- (c) for the addition of substances and preparations named in Part 1 and classified as dangerous for the environment (R50 (including R50/53) or R51/53), together with substances and preparations falling into categories 9(i) or 9(ii);

The relevant provisions of this Directive apply if any of the sums obtained by (a), (b) or (c) is greater than or equal to 1.

- (vii) the following footnotes appear at the end of the notes:
 - $^{(l)}$ OJ 196, 16.8.1967, p. l. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
 - (²) OJ L 200, 30.7.1999, p. 1. Directive as amended by Commission Directive 2001/60/EC (OJ L 226, 22.8.2001, p. 5).
 - (3) OJ L 319, 12.12.1994, p. 7. Directive as last amended by Commission Directive 2003/28/EC (OJ L 90, 8.4.2003, p. 45).

SCRUTINY HISTORY OF AMENDMENTS TO DIRECTIVE 96/82/EC

1. EM 15275/01, on a proposal to amend Directive 96/82/EC on the control of major accident hazards involving dangerous substances, was submitted by the Department for Transport, Local Government and the Regions on 24 January 2002.

The House of Lords Select Committee on the European Communities cleared the EM on 29 January 2002 (1090th sift).

The House of Commons European Scrutiny Committee considered the EM politically important on 13 February 2002 (Report 19 Session 01/02), requested more information, but didn't clear it. A Ministerial letter replying to their questions, dated 23 May 2002, was considered by the Committee on 26 June 2002 (Report 34 Session 01/02). They considered the letter, didn't clear it and deemed the document politically important and for debate in European Standing Committee (ESC).

- 2. A Ministerial letter on the European Parliament's amendments to the proposal was submitted by the Department for Work and Pensions on 3 September 2002. The House of Lords Select Committee on the European Communities noted the update. The House of Commons European Scrutiny Committee considered the letter on 20 November 2002 (Report 1 Session 02/03) and deemed that it should be considered with EM 15275/01 in ESC.
- 3. A Ministerial letter on the Commission's amended proposal (12530/02) was submitted by Department for Work and Pensions on 9 October 2002. The House of Lords Select Committee on the European Communities noted the update. The House of Commons European Scrutiny Committee considered the letter on 20 November 2002 (Report 1 Session 02/03) and deemed that it should be considered with EM 15275/01 in ESC.
- 4. ESC(B), referring to EM 15275/01 and Ministerial letters of 3 September and 9 October, heard evidence from Nick Brown MP on 4 December 2002. The Motion made, and Question proposed, was put and agreed to by the Committee.
- 5. An OTNYR EM was submitted by the Department for Work and Pensions on 2 July 2003. The House of Lords Select Committee on the European Communities sifted the EM to Sub-Committee D (1149^{th} sift -8 July). We understand the Sub-Committee cleared it on 17 September 2003.

The House of Commons European Scrutiny Committee considered the EM politically important on 16 July (Report 30 Session 02/03), and cleared it.

6. EM 11903/03 was submitted by the Department for Work and Pensions on 13 August 2003. The House of Lords Select Committee on the European Communities sifted the EM to Sub-Committee D (1152^{nd} sift -9 Sept). We understand the Sub-Committee cleared it on 17 September 2003.

The House of Commons European Scrutiny Committee considered it on not legally or politically important on 10 September (Report 31 Session 02/03), and cleared it.

7. EM Pre-cons 3655/03 was submitted by the Department for Work and Pensions on 7 October 2003. The House of Lords Select Committee on the European Communities cleared the EM to Sub-Committee D (1155th sift). The House of Commons European Scrutiny Committee

considered the EM not legally or politically important on 15 October 2003 (Report 33 Session 02/03), and cleared it.

Transposition Note

Directive 2003/105/EC of the European Parliament and of the Council (OJ No L345, 31.12.03, p.97) amending Council Directive 96/82/EC (OJ No L10, 14.1.97, p13) on the control of major-accident hazards involving dangerous substances ("the principal Directive")

Article	Objectives	Implementation	Responsibility
1	Amends the principal Directive, which is aimed at the prevention of major accidents which involve dangerous substances, and the limitation of their consequences to people and to the environment. Reference in this column to an Article or Annex is to an Article or Annex to the principal Directive	Save where indicated below, by the Control of Major Accident Hazards (Amendment) Regulations 2005. They amend the Control of Major Accident Hazards Regulations 1999/743 ("the principal Regulations"), which gave effect to provisions of the principal Directive.	The Secretary of State, by the amending Regulations, save where stated below
1.1	Modifies the list of exclusions in Article 4	Regulation 4 modifies the exclusions in regulation 3(3) of the principal Regulations, save in relation to (Article 1.1(f)) the offshore exploration etc. of minerals: no modification is necessary because the principal Regulations do not apply offshore	
1.2 (a)	Introduces into Article 6 a time limit for notification where an establishment comes within scope; and a notification requirement where an establishment or installation is modified	Regulation 6(1) and (3) amends regulation 6 of the principal Regulations	
1.3	Introduces a time limit for drawing up the major accident prevention policy, where an	Regulation 5 amends regulation 5(1) of the principal Regulations	

Article	Objectives	Implementation	Responsibility
	establishment comes within scope		
1.4	Makes a drafting change to Article 8.2	Already catered for by regulation 16 of the principal Regulations	
1.5	Amends Article 9 (safety report) by requiring the safety report to name	Regulation 17(3) amends Part 2 of	
(a)	organisations drawing it up; modifying the time limit for an establishment which	Schedule 4 to the principal Regulations	
(b),(c)	comes within scope, and a consequential drafting change; inviting the European Commission to review certain guidance	Regulation 7 amends regulation 7 of the principal Regulations	
(d)		No action required	
1.6	Amends Article 11 (emergency plans) by introducing a time	Regulation 9 amends regulation 9(2), which is applied by regulation 10(4), of the principal Regulations	
(a)	limit for drawing up an emergency plan, and for supplying information to the competent authorities, where an establishment comes within scope; by modifying the		
(b)	requirement for consultation over the internal and external emergency plan; and by adding a	Regulation 10 amends regulation 9(3)(a), and regulation 12 amends regulation 11(1), of the principal Regulations Given effect by procedures under	
(c)	requirement relating to enhanced co-operation	regulation 10 of the principal Regulations	
1.7. (a)	Modifies the requirement in Article 12.1 relating to land use and/or other	To be given effect in planning law	The Secretary of State, the Scottish Executive and the National

Article	Objectives	Implementation	Responsibility
	relevant policies; inserts Article 12.1a, inviting the European Commission to draw up guidelines	No action as guined	Assembly for Wales
(b)	1 0	No action required	
1.8	Amends Article 13, by modifying the requirements for the	Regulation 13 substitutes a new regulation 14(1) of the principal Regulations	
(a)	supply of safety information; and by		
(b)	qualifying the duty to make available the inventory of dangerous substances	Already given effect by paragraphs 6 to 18 of Schedule 8 to the principal Regulations	
1.9	Amends Article 19 by requiring Member States to supply information to the European Commission; and the Commission to keep a database	No legislation required No action required	The Health and Safety Executive on behalf of the Competent Authority
1.10	Amends Annex 1 (dangerous substances to which the Directive applies) by adding or revising controls on a	Regulation 14 and the Schedule substitutes a new Schedule 1 to the principal Regulations	
	range of dangerous substances or generic categories of substances	A corresponding change will be made to planning law	The Secretary of State, the Scottish Executive and the National Assembly for Wales
1.11	Amends Annex II (minimum information to be included in a safety report)	Regulation 17 amends Part 2 of Schedule 4 to the principal Regulations	
1.12	Amends Annex III (principles to be taken into account when preparing major accident prevention policy)	Regulation 15 amends Schedule 2 to the principal Regulations	
2.1	Member States to bring into force the	As above, by regulation 1	

Article	Objectives	Implementation	Responsibility
	laws, regulations and administrative provisions necessary to comply with the amending Directive before 1 July 2005		
	Member States to inform the European Commission thereof Measures to contain or be accompanied by a reference to the	In the Explanatory Note to the Regulations and in this Table	The Health and Safety Executive via UKREP
2.2	amending Directive Member States to communicate to the European Commission the text of the main provisions of national law which they adopt		As above
3	Date of entry into force of the amending Directive	No action required	
4	The amending Directive is addressed to Member States	Action required as specified in this Table	

Transposition Note

Council Directive 96/82/EC (OJ No L10, 14.1.97, p13) on the control of major-accident hazards involving dangerous substances

Article	Objectives	Implementation	Responsibility
Part of 13.4	Requiring the operator of an establishment, where certain parts of its safety report are not to be disclosed on specified grounds, to supply an amended report excluding them	Regulation 19 of the Control of Major Accident Hazards (Amendment) Regulations 2005 amends the Control of Major Accident Hazards Regulations 1999/743, which gave effect in other respects to the principal Directive.	The Secretary of State, by the amending Regulations
2.1	Member States to bring into force the laws, regulations and administrative provisions necessary to comply with the Directive not later than 24 months after its entry into force (i.e. by 3 January 2004)	Late implementation, by regulation 1	
	Member States to inform the European Commission thereof Measures to contain or be accompanied by a reference to the amending Directive	In the Explanatory Note to the Regulations and in this Table	The Health and Safety Executive via UKREP
2.2	Member States to communicate to the European Commission the text of the main provisions of national law which they adopt		As above

THE CONTROL OF MAJOR ACCIDENT HAZARDS (AMENDMENT) REGULATIONS 2005

PROPOSED REGULATIONS TO IMPLEMENT DIRECTIVE 2003/105/EC
AMENDING COUNCIL DIRECTIVE 96/82/EC ON THE CONTROL OF
MAJOR ACCIDENT HAZARDS INVOLVING DANGEROUS SUBSTANCES
(SEVESO II)

REGULATORY IMPACT ASSESSMENT (FINAL)

PURPOSE AND INTENDED EFFECT

Issue

This Regulatory Impact Assessment examines the costs and benefits of regulations to implement Directive 2003/105/EC that amends Council Directive 96/82/EC (known as the Seveso II Directive) on the control of major-accident hazards involving dangerous substances.

Background

The Seveso II Directive aims to prevent major accidents and limit their consequences for people and the environment. It sets out measures which apply to establishments that hold or use specified dangerous substances, or specified generic classes of dangerous substances above qualifying quantities listed in the Directive. There are two levels of regulatory oversight and the level of oversight is determined by the quantities of dangerous substances held. The lower level of control requires notification, development of a major accident prevention policy, the application of a land use planning policy and inspections. In addition the upper level requires a detailed safety report, production of emergency plans and provision of information to the public. The Directive was implemented in Great Britain through the Control of Major Accident Hazards Regulations 1999 (COMAH).

Objectives

The amending Directive is aimed at broadening the scope of Seveso II rather than a major revision of it. It takes account of recent industrial accidents (particularly a mining accident in Baia Mare, Romania in 2000 that resulted in cyanide entering a river and an explosion at a fireworks factory in Enschede in the Netherlands in 2000 in which 20 people were killed), and the results of studies on carcinogens and substances dangerous for the environment carried out by the Commission at the request of the Council when the Directive was adopted in 1996.

The key features of the amending Directive are:

- a broadening of scope with respect to mining/quarrying;
- a redefinition of ammonium-nitrate to cover lower percentage composition, and new classes covering self-sustaining decomposition and reject material;
- new thresholds for potassium nitrate fertilizers;
- seven new carcinogens, and raised threshold limits for all carcinogens;
- a new definition of automotive petrol to include diesel and kerosene, with thresholds that have been halved;
- the redefinition of the classes for explosives;

- lower qualifying thresholds for substances dangerous for the environment;
- a change to the aggregation rule to be applied to all substances classified as toxic, dangerous for the environment, flammable and oxidising; and
- administrative provisions for establishments newly covered by the Directive to have a period of time to comply.

Risk assessment

A large part of risk control at premises involving dangerous goods is aimed at the prevention of serious accidents which occur infrequently. The accident record is unreliable with respect to estimating safety risks, which are typically subject to quantitative risk assessment. Data on the number of reported accidents at sites newly brought under the scope of the regulations, for example, are not collated centrally. Hence, it is not possible to establish an accurate 'baseline' level of risk against which the benefits of the amendment can be assessed. In the benefits section, we use a study of accidents in the UK chemical industry to indicate the potential level of risk and benefit in terms of physical damage to plants from bringing new sites under the scope of the COMAH regulations. However, in advance we recognise that the characteristics and risks associated with the newly introduced sites may differ from those in the study.

Options considered

As the provisions in the amending Directive relate to requirements in Seveso II that were implemented through legislation, the amendments will also require implementation through regulations. We considered implementation through an Approved Code of Practice or guidance but concluded these would be insufficient and could lead to infraction proceedings. It would also be inconsistent with our original transposition of Seveso II, and could cause confusion for stakeholders. There are no provisions in the amending Directive that Great Britain would wish to either over- or under-implement for domestic reasons.

Information sources and background assumptions

A key source for the cost data used in this partial assessment is the Entec report 'Safety report regime – evaluating the impact on new entrants to COMAH, 2003'. The Entec study estimated the costs of compliance with the COMAH regulations following their implementation (COMAH replaced the previous Control of Industrial Major Accident Hazards (CIMAH) regulations). The implementation of Seveso II RIA used cost estimates based on speculative industry information. The cost estimates contained in this RIA are considered to be superior to the previous estimates as they are ex-post estimates rather than ex-ante. Information from the Entec report on possible benefits of COMAH has also been included in the benefits section. In addition Det Norske Veritas (DNV)³ was commissioned by the Department for Environment, Food and Rural Affairs to undertake two studies to assess the number of sites which will be brought into the scope of COMAH based on the storage of 'Substances Dangerous for the Environment', R50, R50/53 and R51/53 substances at current and suggested alternative thresholds. The substances examined by the study were those which will be included solely because of the risk they pose to the environment and will not be included under "toxic (to humans)", "flammable" or any

² "Safety report regime – evaluating the impact on new entrants to COMAH", Entec UK ltd, 2003

^{3.} Latest report: COMAH Site Threshold Levels", Det Norske Veritas, Job number 804003, July 2001

other heading. The Environment Agency have examined the reports and provided estimates for the number of sites affected but the Agency notes that the numbers are subject to some uncertainty because of the age of the reports and assumptions about inventories that have had to be made. These estimates have been used in this RIA.

Costs and benefits have been discounted at a rate of 3.5%. The appraisal period is 10 years. All costs and benefits have been discounted back to the base year 2003. To estimate the cost of the proposed regulations it has been assumed that there will be full compliance.

Equity And Fairness

The only equity and fairness issue identified concerns the fact that EU firms will be affected by the Directive, while non-EU firms will not. To the extent that EU firms directly compete with non-EU firms, the Directive will have an asymmetric impact on the different market players. This issue is further discussed in the competition assessment section.

Atypical Workers

No issues affecting atypical workers have been identified for the proposal.

BENEFITS

Health and Safety Benefits

A Review of UK and Overseas Major Industrial Accidents since Flixborough 1974⁴ details the twenty UK accidents with the highest numbers of casualties. There were 30 fatalities and 877 major injuries in the twenty-four years following the Flixborough accident. Using this data, the cost in an average year is £7.2 million in current prices.

As described in detail in the section 'Business sectors affected', the total number of sites, that either enter COMAH for the first time, or move to a higher classification, is 224 - 249. This represents approximately 19.3%-21.5%⁵ of the existing total of sites. Using this range the amendments to the regulations cover a percentage of the total cost of injuries that equates to a monetary value of £1.5 to £1.7 million per year, a net present value over the appraisal period of £12.9 to £14.4 million.

A recent evaluation study carried out on behalf of the HSE by Risk Solutions has estimated the benefits arising as a result of the reduction in major accidents of the COMAH 1999 regulations. The benefit, which covers all COMAH sites is estimated to be a net present value of £106 million, with £5 million of this being attributed to casualties and the remainder being the societal benefit. The percentage reduction in major accident frequency and impact achieved due to implementation of COMAH is taken from questionnaires. The reduction in costs per major incident was based on the survey results of all respondents. As these estimates are based on dutyholder perceptions, the actual benefits obtained are highly uncertain.

Action to mitigate risks will also benefit members of the public. We do not have information on incidents involving members of the public in sufficient detail to make estimates for the risk from smaller scale events. We also know that no member of the

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⁴ .P Fewtrell (WS Atkins) and I Hirst (HSE, CHID) "A review of high-cost chemical/petrochemical accidents since Flixborough (1974)", IChemE Loss Prevention Bulletin, 140, 1998.

⁵ This range also includes the sites that are changing COMAH status (however, the change from low to high COMAH status is significant and likely to achieve a level of benefits reflecting this).

public has been killed off-site as a result of a serious incident in chemical/petrochemical manufacture. Quantitative risk assessments however, do indicate the presence of significant risks, which would be mitigated to some extent by the proposals (or action prompted by the proposals). The quantitative benefit of reduced risk to the public cannot be estimated but could be substantial.

Benefits to Business.

We cannot estimate the benefits to typical sites brought into the proposal's scope since this information is site specific and varies greatly. We can however, look at the potential benefits of the COMAH regime as a whole and form a judgment as to the scale of potential benefits at the aggregate level.

Research on previously published estimates of the scale of losses incurred following high cost chemical/petrochemical accidents have been undertaken by HSE in conjunction with W S Atkins⁶. The report found a lack of reliable data in the public domain and conflicts between reported values in cases where data was available. These differences are ascribed to the wide scope of costs involved, commercial sensitivity, and changes in monetary values over time and simple clerical error. Therefore the following analysis is based on estimates and subject to estimation error.

The report estimated that the total cost of the 20 major chemical/petrochemical accidents since Flixborough was between £300 to £400 million in 1996 prices. Included in these costs are the costs of reconstruction and lost production (as well as the costs associated with any legal action). Costs excluded from these incidents include indirect production costs (such as loss of business, or forced sale of raw material), off-site damage, personnel costs associated with injury events, civil emergency response, legal costs and public relations costs. Mitigating this to a certain extent is that damaged plant and equipment would have been replaced at some point in the future. Nevertheless, the costs are equivalent to a figure of around £19.5 to 26 million⁷ each year at current values.

An analysis of 119 events at petrochemical, chemical and refinery sites⁸ concluded that the business interruption losses were on average 2.7 times the property damage losses (with wide variation between the individual cases). This would increase the yearly loss figure to around £50 to 70 million on a conservative basis (allowing for some overlap in the coverage of costs between the reports).

Future catastrophic risks will be lower than these figures indicate because safety has improved over the last two decades. The monetary figures above only relate to the very highest risks (over a quantum of risk) which include many less than catastrophic incidents that could cause significant disruption and damage, require plant evacuation or shutdown, and possibly result in injuries to on-site personnel. It is impossible to estimate the total risk in monetary terms given the uncertainties involved. Using the £50 to 70 million figures above, it is assumed that the current risk at high hazard sites lies in the range of £40 to £80 million per year in monetary terms even if the part of the risk relating to the most serious incidents has been significantly reduced.

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^{6.}P Fewtrell (WS Atkins) and I Hirst (HSE, CHID) "A review of high-cost chemical/petrochemical accidents since Flixborough (1974)", IChemE Loss Prevention Bulletin, 140, 1998.

⁷ Calculated by roughly dividing the total cost by the years covered - £300 to 400m / 24 and uprated to current prices using the nominal GDP series. 8.Loss Control Newsletter, January 1997.

As described earlier and in the section 'Business sectors affected', the total number of sites that either enter COMAH for the first time, or move to a higher classification, represents approximately 19.3%-21.5% of the existing total of sites.

If the risks at both new sites and sites subject to a higher classification are commensurate with those at existing COMAH sites then we would expect the monetary value of the total risk from the sites affected to have a magnitude of between £7.7 million and £17.2 million each year, which is equivalent to £66 million -£148 million over ten years in present terms.

However, it is not possible to quantify the risk reduction that will be achieved by bringing into scope new sites and by changing the status of other sites. In addition, whether the risks at those sites brought under scope by these changes are similar to those of the majority of COMAH sites is a matter of judgment.

As part of the Entec¹⁰ report, participants were asked their views regarding the possible benefits of COMAH to their establishment. They suggested many benefits of COMAH including:

59% more awareness amongst the workforce of major accident hazards

37% more systematic analysis of major accident hazards

36% better understanding of major accident hazards

8% improved dialogue with Competent Authority

5% better knowledge of neighbours' activities

26% of those expressing an opinion stated that COMAH had benefits to their business beyond compliance.

COSTS

Business sectors affected

The amendments will affect all current COMAH sites, bring a number of new sites into its scope and upgrading some sites from lower tier to top tier status. The sites affected will mainly be operated by businesses in the basic chemical, petroleum, electricity and water sectors, and those involved in the manufacturing and storage of explosives. Sites in other sectors will be affected if they store above the threshold quantities of dangerous substances as specified by the Regulations. HSE estimates that there are currently 360 top tier sites and 800 lower tier sites. The following paragraphs set out the expected number of sites coming into scope or upgrading from lower tier to top tier status.

On a preliminary basis using data from several sources we estimate that the amendments will affect a total of between 224 and 249 sites. The numbers of sites in the different risk categories are given in the paragraphs and table below.

Carcinogens

Studies on carcinogens carried out by the European Commission proposed adding seven substances to the list of 'carcinogens' already contained in Annex I, Part 1 of the Directive. Qualifying limits for the whole group of carcinogens have also been increased. The increase will have the effect of excluding some establishments (such

⁹ This range also includes the sites that are changing COMAH status (however, the change from low to high COMAH status is significant and likely to achieve a level of benefits reflecting this).

¹⁰ "Safety report regime – evaluating the impact on new entrants to COMAH", Entec UK ltd, 2003

as hospitals or research institutes) from the scope of the Directive that were not originally targeted by the inclusion of the list of carcinogens, and that are not currently COMAH sites. An initial examination by HSE on the effect of these changes indicates that around 15 sites will be brought into the COMAH regime at the lower tier, 16 will be brought into COMAH at top tier and 34 existing COMAH sites will move from lower tier to top tier.

Explosives

It is proposed to amend the definitions of explosives to reflect the hazard associated with each type. It was considered that although consumer fireworks represent a hazard and therefore should come under the Directive, the hazard is substantially less than for other fireworks and explosives so should be treated differently. The coverage of pyrotechnic establishments in Great Britain already goes beyond that required by the Directive. A preliminary survey by HSE indicates that the changes will bring up to 34 sites into the COMAH regime at the lower tier and up to 10 existing COMAH sites will move from the lower tier to the top tier.

Petroleum products

The named substance "automotive petrol and other petroleum spirits" is replaced with a new category 'petroleum products' which includes medium oil distillates (gasolines, naphtha, kerosene and gasoils) with reduced qualifying thresholds. Data from the DNV report suggests that the changes will bring a minimum of 28 sites into the COMAH regime at lower tier and a minimum of 18 existing COMAH sites will move from lower tier to top tier. Allowing for some uncertainty in these figures, the Environment Agency have advised that a maximum estimate of the numbers affected could be 39 and 22 respectively.

Substances dangerous for the environment

In the light of the incident in Baia Mare, Romania and the outcome of studies by the European Commission the thresholds are to be lowered for substances dangerous for the environment. The DNV report and discussions with the Environmental Agency indicate that this amendment will bring between 26 and 32 sites into the COMAH regime at the lower tier and 21 to 25 existing COMAH sites will move from the lower tier to the top tier.

Ammonium Nitrate

The Commission's amendment on ammonium nitrate is in response to the explosion at a fertiliser factory in Toulouse, France in 2001. The amendment essentially maintains the current classes of ammonium nitrate but makes a detonation test mandatory, adds a class for fertilizers that are capable of self sustaining decomposition (i.e. once alight continue to burn producing toxic gases), and adds an additional class for reject material from the manufacturing process. This is likely to bring more sites within the scope of the Regulations. It is however, very difficult to give a good estimate of the number of sites affected as the quantities of reject material produced are not known. Our best estimate is 2 top tier and 20 lower tier sites.

Table 1: Number of sites affected by changes in scope and COMAH status

Risk category	Effect on site			
	Enters COMAH as lower tier	Enters COMAH as top tier	Moves from lower to top tier	Total

Carcinogens	15	16	34	65
Explosives	34	0	10	44
Petroleum products	28 - 39	0	18 - 22	46 – 61
Substances dangerous for the environment	26 - 32	0	21 – 25	47-57
Ammonium nitrate	20	2	0	22
Total	123-140	18	83 - 91	224 - 249

Compliance costs for individual new and upgraded sites

As a consequence of the proposed changes to the definitions and qualifying quantities of dangerous substances covered by COMAH, compliance with other COMAH provisions automatically becomes necessary. These are:

- a risk assessment
- b notification to the competent authority (by new lower and top tier sites)
- c preparation of a MAPP (lower tier only);
- d preparation of a safety report (top tier only);
- e on and off-site emergency plans (top tier only); and
- f provision of information to the public (top tier only).

Data from the Entec report (see paragraph 7) can assist with the estimation of some of these costs. In particular, it provides information on the cost of assessing the hazards (cost of analysis) and the cost of drafting the MAPP or safety report (cost of writing). The average cost of analysis for new entrant top tier establishments is estimated at £64,000 and the writing cost at £71,000. For lower tier establishments the figures are £9,000 and £8,000 respectively. We assume that corresponding costs for establishments whose status changes from lower to top tier is the difference of the values estimated at top and lower tier, that is £55,000 for analysis costs and £63,000 for writing costs.

As for the remaining costs, estimates from a previous RIA suggest the following figures: £1,600 for notification; £17,300 for provision of information; £10,600 for preparing an emergency plan, £5,300 for the initial testing of the plan and £2,700 each year thereafter for routine testing 11 .

Additional costs stem from the COMAH Competent Authority¹² charges and from cost recovery action undertaken by other authorities. The average charges per low tier site and top tier site levied by the Competent Authority have been estimated at £2,700 and £6,300 per year¹³. This translates into £23,000 and £54,000 over the appraisal period. The corresponding estimates for a low tier site upgrading to a top tier site are £3,600 per year and £31,000 over the appraisal period. Costs recovered by other

¹¹ Original cost figures were in 1998/99 prices and have therefore been uprated using the Consumer Price Index.

¹² COMAH is enforced by a Competent Authority comprising HSE and the Environment Agency in England and Wales and HSE and the Scottish Environment Protection Agency in Scotland.

¹³ Estimates obtained using actual charges to a sample of existing top tier and low tier sites over the past 3 and half years.

authorities have been estimated at £10,500-£24,500 over the appraisal period (£1,200-£2,800 per annum) 14 .

The Entec study also considered 'control' costs and estimated these at £376,000 for the average new top tier establishment and £160,000 for the average lower tier site. On this basis the 'control' cost for an establishment that moves from lower to upper tier would be £216,000.

The Entec report identified 'control' costs as the costs of changes to arrangements for managing major accident hazards identified as a result of writing a MAPP or safety report (one of the benefits identified in the Entec report was that structured consideration of safety driven by MAPPs and safety reports identifies opportunities for improvements).

The duty to identify, assess and manage hazards and risks already exists in other health and safety at work/environmental legislation that applies to most sites. There is therefore an argument for excluding such costs from this RIA on the basis that they relate to measures that should already have been taken and costed for under other legislation. (It is also worth noting that existing safety control measures in certain industries e.g. explosives utilities sectors, may already be higher than those required by general legislation (or COMAH) because of, for instance, regulatory permissioning regimes required by specific legislation or safe ways of working.)

On the other hand, there is a case for their inclusion in this RIA as compliance with COMAH can act as a catalyst for the identification of areas where improvements are necessary, and the taking of additional safety measures. When estimating total costs, we have therefore decided to show two figures, one that includes the cost of additional safety measures and one that excludes them.

All the above estimates are synoptically shown in the following table:

Table 2: Costs to business for individual new and upgraded sites: present value over appraisal period (£ '000).

Risk category	Effect on site (£'000)			
	Enters COMAH as lower tier	Enters COMAH as top tier	Moves from lower to top tier	
Analysis	£9	£64	£55	
Writing	£8	£71	£63	
Notification	£2	£2		
Information		£17	£17	
Emergency Planning and testing		£36	£36	
Competent Authority charges	£23	£54	£31	
Costs recovered by		£11-£24	£11-£24	

¹⁴ For more information on how these latter costs have been calculated see section 'Costs to Competent Authority and others' further below.

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other authorities ¹⁵			
Total excluding control costs	£42	£255-£268	£213-£226
Control costs	£160	£376	£216
Total including control costs	£202	£631-£644	£429-£442

Total compliance costs to business

Using the above information on the number of sites and unit costs per site the aggregate cost over the appraisal period associated with all new and upgraded sites is $\pounds 27.4 - \pounds 31.3$ million (£3.2 - £3.6 million per annum) excluding additional safety measures and £71.7 - £80.1 million (£8.3 - £9.3 million per annum) including additional safety changes. The cost breakdown by risk category is shown in Table 3 below.

Table 3: Costs to business for all new and upgraded sites: present value over appraisal period (£ '000)

Risk category	Effect on site (£'000)			
	Enters COMAH as lower tier	Enters COMAH as top tier	Moves from lower to top tier	Total
Carcinogens	£623	£4,071 - £4,294	£7,238 – £7,712	£11,931 - £12,629
Explosives	£1,412	£0	£2,129 - £2,268	£3,541 - £3,680
Petroleum products	£1,163 - £1,620	£0	£3,832 - £4,990	£4,995 - £6,610
Substances dangerous for the environment	£1,080 - £1,329	£0	£4,470 - £5,671	£5,550 - £7,000
Ammonium nitrate	£831	£509 - £537	0	£1,340 - £1,367
Total excluding control costs	£5,109 - £5,815	£4,579 - £4,830	£17,669 - £20,641	£27,357 - £31,286
Control Costs	£19,680 - £22,400	£6,768	£17,928 - £19,656	£44,376 - £48,824
Total including control costs	£24,789 - £28,215	£11,347 - £11,598	£35,597 - £40,297	£71,733 - £80,110

Costs to all COMAH sites

Amendments to the Seveso II Directive will require top tier operators to provide a map, image or equivalent description as part of their safety report. Latest figures from HSE indicate that there are currently 360 top tier COMAH sites. This figure will rise to 461-469 sites as the Amendment Regulations will lead to a further 18

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¹⁵ Cost initially borne by LAs and Emergency Services For more information on this item see 'Costs to Competent Authority and others' further below.

establishments entering COMAH for the first time at top tier level and another 83 to 91 will move from lower to top tier status. The existing COMAH regime already requires operators to provide information on effect or consequences data in the safety report. As this can often be complicated, some sites already opt to show these effects in map form. Furthermore, HSE estimates that at least 50%, and possibly as many as 66%, of all operators currently choose to provide this information in a map form to the competent authority.

The cost of supplying a map, at between £25 and £100 per map, is estimated at £18,300 - £75,300 over the appraisal period (£2,100 - £8,700 per annum). This cost assumes that 50% (lower end of the range) already have maps and they will be updated every 5 years. We are aware that these maps or images would also need to be updated if there were any modification to these top tier COMAH sites. We estimate that this will not produce additional costs on top of those included because we have taken the lower end of the scale for those who already have a map or image.

A number of other requirements will result in some modest ongoing costs, principally notifications. Operators were previously required to notify the Competent Authority of any change in the quantity or form of substances held. Now they are also required to notify the competent authority of any modifications to their establishment that could have significant repercussions on major accident hazards. HSE estimates that this amendment could result in about 50 notifications a year. Notification costs are estimated at £1,600 per site. Discounted, over 10 years this gives the amendment a net present value of £685,500 (£79,600 per annum).

Finally, Article 13 of the Directive 96/82/EC requires member states to ensure that the safety report is made available to the public (information that is sensitive because of commercial or security reasons can be withheld). The operator will be required to supply an amended safety report, excluding sensitive information, to the competent authority that is suitable for public disclosure. The Competent Authority encourages operators to write their safety report with this in mind (one way is to include such information in an annex). We expect the cost of this to be £2,000 per amended report. It is expected that 5-10% of top tier sites (23-47) per year will prepare an amended report. This yields ca. £397,000 - £807,000 over the appraisal period (£46,100 - £93,800 per annum).

Using the above information on the map/image, notification and modification costs, the cost of Amendment Regulations for all sites is estimated between £1.1 - £1.6 million over the appraisal period (£127,900 - £182,200 per annum).

The total cost to business of the Regulations is £28.5 - £32.9 million (£3.3 - £3.8 million per annum) excluding additional safety measures and £72.8 - £81.7 million (£8.5 - £9.5 million per annum) including additional safety measures.

Costs to Competent Authority and others

Competent Authority

The Competent Authority is required by Government to recover the costs of its regulatory activities under COMAH. This includes work associated with the examination of safety reports, inspection to assess compliance, and the investigation of complaints and incidents. The recovered costs are included in the cost to business section.

The Competent Authority cannot recover certain costs relating to legal proceedings, industrial tribunals, the assessment of off-site emergency plans, or the provision of

advice. HSE's records show that for every hour of COMAH chargeable work, about 4 hours of non-chargeable work is performed. However, recorded non-chargeable work includes also work not related to COMAH. In what follows, it is assumed that for every COMAH chargeable hour, 2 hours of non-chargeable COMAH work is performed. This implies total non-recoverable costs of £12.7 - £14.0 million over the appraisal period (£1.5-£1.6 million per annum)¹⁶.

Costs to Local Authorities (LAs)

LAs are required to prepare off-site plans for top tier establishments. COMAH provides for LAs to charge the operator for any reasonably incurred costs associated with the preparation, review, revision and testing these plans. Information provided by the Emergency Planning Society suggests that the cost to a LA of preparing an off-site emergency plan lies between £6,000 and £10,000. The cost of reviewing and revising a plan as necessary at least every three years is £500-£1,000. This yields a cost per site over the appraisal period of £7,300 to £12,500. LAs are assumed to recover 80% of these costs from site operators.

The LA cost of testing an off-site plan at least once every three years is £1000-£2000 for a 'table-top' exercise, and £6000-£10,000 for a normal 'live-play' exercise. This implies a cost of testing between £2,500 and £25,300 over the entire appraisal period. Information from a survey carried out by the Emergency Planning Society in 2003 suggested that approximately 32% of LAs recover the costs of testing from operators, which recognises that there is mutual benefit to LAs in carrying out the exercise.

Total costs per site to LAs are therefore £9,800-£37,900 over the appraisal period. Of these, between £6,600 and £18,100 are recovered from industry. This leaves LAs with a net cost per site of £3,200-£19,700 over the appraisal period.

Costs to Emergency Services

COMAH provides for the emergency services to recover any reasonably incurred costs associated with their participation in testing off-site plans. They are unable to recover any costs associated with their contribution to the preparation, review and revision of off-site plans. Information from the Fire Service suggests the following cost estimates: £6,000-£10,000 for plan preparation; £500-£2,000 for review/revision; £1,000-£4,000 for testing. Assuming that review/revision takes place every three years yields a present value of £1,300-£5,100 over the appraisal period (£147-£589 per annum). Testing costs are the only costs to be partially recovered. If testing occurs every 3 years, their present value over the appraisal period is £2,500-£10,100. It is estimated that 32% of it is recovered.

Total costs per site to Fire Services are therefore £9,800-£25,200 over the appraisal period. Of these, between £800 and £3,200 are recovered from industry. This leaves Fire Services with a net cost per site of £9,000-£22,000 over the appraisal period.

Information provided by the Association of Chief Police Officers during the consultation period indicates that Police's cost of planning amounts to £11,600, while annual testing and liaison/meetings have a cost of £2,300 and £900, respectively. Most of these costs are borne by the Police themselves with only 15% of testing cost being recovered.

¹⁶ Non-chargeable hours are further discussed in the uncertainty section of the RIA.

Total costs per site to Police are £39,300 over the appraisal period (£4,600 per annum). Of these, only £3,100 are recovered from industry. This leaves Police with a net cost per site of £36,200 over the appraisal period.

Non-recovered costs to LAs and Emergency Services can be obtained by multiplying the cost per site by the number of sites. This yields £4.9 - £8.5 million over the appraisal period (£0.6 - £1.0 million per annum). LAs bear between 6.6% and 25.3% of this cost, while the rest falls on the Emergency Services. A breakdown by risk category is shown in Table 4.

Table 4: Non-recovered costs to LAs and Emergency Services for all new and upgraded sites: present value over appraisal period (£ '000)

Risk category	Effect on site (£'000)			
	Enters COMAH as lower tier	Enters COMAH as top tier	Moves from lower to top tier	Total
Carcinogens	0	£774-£1,247	£1,645-£2,650	£2,420-£3,897
Explosives	0	£0	£484-£779	£484-£779
Petroleum products	0	£0	£871-£1,715	£871-£1,715
Substances dangerous for the environment	0	£0	£1,016-£1,948	£1,016-£1,948
Ammonium nitrate	0	£97-£156	£0	£97-£156
Total	0	£871-£1,403	£4,017-£7,092	£4,888-£8,495

On top of the costs shown in the table above, the various authorities will incur familiarisation and training costs following the introduction of the amendment. Information provided by HSE, EA, SEPA and the police indicate that these costs will amount to £9.6 million over the appraisal period (£1.1 million per annum). Nearly all these costs will fall on the police force.

Adding together all costs to competent and other authorities yields a total of £27.2 - £32.0 million over the appraisal period (£3.2- £3.7 million per annum).

Total costs to society

The total costs to society over the appraisal period are £55.6 - £64.9 million (£6.5 - £7.5 million per annum) excluding additional safety measures and £100.0 - £113.7 million (£11.6 - £13.2 million per annum) including additional safety changes. These costs include all costs to industry and to competent authorities.

Costs can be classified either as policy or as implementation costs depending on whether they are directly attributable to the policy goal or not. With regard to business, only the following costs are considered to be implementation costs: writing, notifications, provision of information, production of maps, report amending and competent authority charges. These amount to £16.9 - £18.8 million over the appraisal

period (£2.0 - £2.2 million per annum) with 62% (or £10.6 - £11.8 million) being paperwork costs ¹⁷. All costs that do not fall on business have been classified as policy costs ¹⁸. Hence, total policy costs to society over the appraisal period amount to £38.7 - £46.0 million (£4.5 - £5.3 million per annum) excluding additional safety measures and £83.0 – £94.8 million (£9.6 - £11.0 million per annum) including additional safety changes.

Impact on small and medium sized businesses

Only a very small number of top tier COMAH sites is likely to be operated by small companies. Costs may be disproportionately higher for those sites (if any) that are operated by small/medium sized companies. The costs of a major incident are however, far less likely to be absorbed by a these companies, especially if the company operates only one site.

Competition Assessment

A number of markets will be affected by the Amendment Regulations. Three have been selected to examine the competition effects of the changes. The three markets are refineries, medium-sized fuel storage and distribution, and power generation utilities.

Refineries

The market for refining contains 11 firms. All companies are large (with two particularly large companies) although no single firm supplies more that 20% of the market. The regulatory changes relevant for refineries are an expanded definition for automotive petrol and the qualifying thresholds being halved.

Neither of these changes will have a significant effect on the market because all refineries currently fall into the higher tier of regulation and they will continue to do so after the Regulations come into force. For this reason there are no additional competition concerns raised in this market by the Amendment Regulations.

It is not necessary to produce a detailed competition assessment.

Medium-sized fuel storage and distribution

Medium sized fuel storage and distributors are affected by the expanded definition of petroleum products and the halving of qualifying thresholds. There will be a substantive effect in this market with an increased number of firms subject to either the higher or lower tier of the regulation. Market concentration will not be a concern because no firm supplies more that 10% of the market.

The regulation costs firms will face depend upon the tier into which they fall. This is determined by the quantity of petroleum products held on site. Firms in the higher tier will face higher costs than those in the lower tier but costs are similar for firms within each tier. These differential costs could cause concern if it were likely that they will have an effect on the number or size of firms operating in the market i.e. changes the market structure.

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¹⁷ The only implementation costs that are not considered to be paperwork are the competent authority charges.

¹⁸ The only exception is familiarisation costs which are a negligible fraction of the costs borne by competent and other authorities.

Evidence from the Entec report¹⁹ indicates that although a number of firms close to the lower threshold might slightly reduce the quantities they hold (thus avoiding COMAH classification), this number of firms is likely to be small with the quantities involved minimal. Thus it is unlikely to have a significant effect on the overall market structure.

There are no other competition concerns and the regulation will not impose different costs on entrants compared to incumbents.

It is not necessary to produce a detailed market assessment. Although there is a potential concern about a change in the market structure brought about by firms altering their production to avoid COMAH classification, this is the only possible competition issue and based on the Entec report, it is unlikely to cause a significant problem.

Utilities (Power Stations)

Power stations will be affected by the classification of hydrazine as a named carcinogen (if they are unable to engineer out the use of hydrazine). This change will produce a one-off cost associated with the administrative requirements of COMAH (i.e. the completion of safety reports). Any safety control measures (see para 35) are likely to be insignificant due to existing industry wide safety systems.

The regulation is unlikely to have an effect on the size or number of firms in the market because all firms will fall within the higher tier of the regulation. For this reason the regulation will have a similar effect on all firms in the market and all potential entrants to the market.

The power generation market contains a small number of large businesses operating 30-40 power stations. There is a degree of concentration with three or four large firms but their combined output, measured crudely by generating capacity, does not exceed 50% of the market.

The market has experienced technological change during the last 20 years with the shift from coal to gas fired stations but the potential for further shifts in this respect are nearly exhausted. Further rapid technological change is unlikely.

It is not necessary to produce a detailed competition assessment for this market. The only competition issue raised was market concentration but, as all firms will be equally affected, this should not be of concern.

Conclusions

There are no substantive competition concerns that arise from the Amendment Regulations in the three markets considered.

As mentioned in the equity and fairness section, EU companies will have increased operating costs and may therefore find themselves at a competitive disadvantage visà-vis non-EU firms that are not subject to the same legislation. As a consequence, some loss of GB/EU business may result. This type of effect is common to all regulations impacting on sectors open to international competition and it is difficult to quantify. Moreover, a loss of domestic business does not imply *per se* lower market competition. Only if the amendment led to market concentration, it would have an adverse effect on competition. The preceding analysis, however, suggests that an increase in market concentration is not likely to occur.

¹⁹ "Safety report regime – evaluating the impact on new entrants to COMAH", Entec UK ltd, 2003

ENVIRONMENTAL IMPACTS

The environmental benefits of preventing a serious incident where a substance hazardous to the environment is released could be very significant. We therefore expect the environmental impact of the proposals to be positive, though unquantifiable.

BALANCE OF COSTS AND BENEFITS

The total costs to society over the appraisal period are £55.6 - £64.9 million (£6.5 - £7.5 million per annum) excluding additional safety measures and £100.0 - £113.7 million (£11.6 - £13.2 million per annum) including additional safety changes.

The total risk that the Amendment Regulations are addressing is estimated at £79.4 - £162.2 million over the appraisal period (£9.2 - £18.9 million per annum). However, it has not been possible to quantify the risk reduction that the Regulations will achieve.

It follows that the available evidence does not allow us to unambiguously establish whether the benefits from the new regulations will outweigh the costs. The uncertainty about whether benefits exceed costs extends to the specific categories. The cost/benefit balance for these cannot be estimated without reference to quantitative assessment of the sites.

Nevertheless, the cost and benefit ranges allow us to work out how large the reduction in risk must be for benefits to balance costs. Specifically, in the best-case scenario (i.e., low cost, large total risk addressed) the amendment needs to achieve a reduction in risk of at least 34% for benefits to balance costs. In the worst-case scenario (i.e., high cost, small total risk addressed), cost will certainly exceed benefits; in particular, even if the amendment was to remove risk completely, cost would still be 43% larger than benefits.

Uncertainties

There is uncertainty surrounding the number of sites that will come into the scope of the amendment or will change their COMAH status. The estimates used were based on the Det Norske Veritas report which were the best available.

The level of risk addressed by the amendment is uncertain. A monetary estimation of the potential benefits of COMAH was made based on the HSE/WS Atkins report. Duty holders' assessments of the benefits of COMAH were taken from the Entec report.

There is a degree of uncertainty about the costs of compliance due to changes in scope and COMAH status. Cost estimates from the Entec report were the best information available but they were averages, so that costs for individual sites may be substantially different from the estimates of this RIA.

Finally, non-recoverable cost to competent authorities were estimated to be twice the recoverable costs. However, this estimate is highly uncertain and these costs may turn out to be higher (up to four times the recoverable costs) or lower. For example, if they turned out to be three times as large as the recoverable costs, total costs to the competent authorities (and, hence, to society) would increase by £6.3 and £7.0 million over the appraisal period. They would decrease by the same amount if, instead, non-recoverable costs turned out to be approximately the same as the recoverable ones.

Arrangements for monitoring and evaluation

Monitoring and evaluation of the Amendment Regulations will be incorporated into existing arrangements for the COMAH Regulations. As part of this, Directive 96/82/EC as amended requires Member States to provide the EC with a three-yearly report on a range of information on implementation of the Directive.

Declaration

I have read the Regulatory Impact Assessment and I am satisfied that the benefits justify the costs.

Signed by the responsible Minister

Chris Pond

Date 4 April 2005

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