The Seveso Directive – learning from experience

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Issue

1. To clear a paper for the HSE Board that is intended to aid discussion about the evolution of the Seveso Directive and issues that will shape its future development.

Timing

2. For clearance on 2 June to enable discussion at the Board meeting on 30 June.

Recommendation

3. To approve the attached paper for submission to the HSE Board.

Background

4. In considering the synopsis of a paper that would update the Board on progress towards a proposal to amend the Seveso Directive, Judith Hackitt advised that she would like to engage the Board in a wider discussion about how Seveso has developed in the past as well as looking at what the future holds.

5. The attached paper responds to her request. It is longer than is usual for Board papers as it describes how Seveso has developed, reflecting on the lessons learned from major accidents, showing how it sits alongside other work, and looking at the need for change.

Consultation

6. Consultation has taken place widely within the UK COMAH Competent Authority (HSE, the Environment Agency and the Scottish Environment Protection Agency in Great Britain, the Northern Ireland Competent Authority, and Gibraltar, via the FCO), with other HSE colleagues (other parts of HID, International Unit, International Chemicals Unit, CSAG, Emerging Energy Technologies Programme, and PEFD), and with officials responsible for planning policy in the devolved administrations. We also routinely consult other government departments with an interest, such as DECC, BIS and Defra.
The Seveso Directive – learning from experience

Purpose of the paper
To consider the evolving role of the Seveso Directive in the regulation of on-shore major accident hazards and advise on the key issues affecting its future scope.

Background

Origins of the Seveso Directive
The earliest chapter of the Seveso story was written, in part, in the UK and it began in 1974 when the peace of a June Saturday in the village of Flixborough was shattered. A sudden release of cyclohexane was followed by a huge explosion which ripped through the nearby Nypro chemical plant, leaving 28 dead on-site and much damage to homes nearby.

The regulatory response in this country was swift. The Health and Safety Commission set up the Advisory Committee on Major Hazards (ACMH) which identified a three-part strategy comprising:

(i) *identification of hazardous installations* which had the potential for major accidents which could harm the public or employees;

(ii) *prevention of accidents through controls* over the design, operation and maintenance of the installation; and

(iii) recognising that zero risk is unattainable, *mitigation of the consequences* of any accidents that occurred through emergency planning, information to the public and the control of off-site populations at risk through land-use planning.

Flixborough resonated beyond Britain and set the European Commission thinking about the need for action at the European level. Then, in 1976, a release of dioxins from a chemical manufacturing plant in Seveso in Northern Italy resulted in severe environmental contamination. This galvanised the European Commission to develop the Seveso Directive which became law in 1982.

The Directive, which was implemented in Great Britain by the Control of Industrial Major Accident Hazards Regulations (CIMAH) in 1984, drew heavily on the ACMH approach. Identification was achieved by specifying certain types of installations with inventories of named, or classes of, substances. There were general duties to prevent and control major hazards backed up by a requirement for safety reports from operators with the greatest inventories – the top tier sites. Mitigation was achieved by requiring operators to prepare and test on-site emergency plans and local authorities had a similar duty off-site. The final
element was the provision of information to people living around such installations on the nature of the hazards and the action they should take in an emergency. Land use planning was not included in the Directive though the UK had already established controls over the siting of installations and developments in their vicinity.

In subsequent years, elements of the Seveso regime were replicated in other sectors. For example, permissioning through safety cases was introduced offshore after Piper Alpha in 1988, for the railways after privatisation in 1994 and for the gas distribution system in 1996.

**Responding to new information and lessons learned – Seveso II**

The basic principles of Seveso have stood the test of time but experience, including from further major accidents, has led to some important developments.

There were 130 incidents that met the Seveso reporting criteria in the EU in the first decade after the Directive was first adopted: ninety percent were caused by management failings. These and other incidents, notably a warehouse fire in Basel that caused major pollution in the Rhine, and a release of methyl isocyanate gas in Bhopal which led to many thousands of deaths, indicated the need for a broader scope and better risk management.

Annex 1 lists some of the notable major accidents that have occurred since Flixborough.

In 1996 a new Directive, Seveso II, was introduced with a broader and simplified application. It introduced several important changes which were implemented in Great Britain principally through the Control of Major Accident Hazards Regulations (COMAH) in 1999:

- a move away from an application limited to industrial activities to one aimed at any establishment with threshold quantities of dangerous substances;
- a greater emphasis on effective safety management systems and risk assessment through requirements on lower tier operators to have major accident prevention policies and more explicit management systems requirements for top tier operators;
- land use planning controls for new major hazard sites and on developments in their vicinity aimed at first stabilising, and in the longer term reducing, populations at risk;
- an increased emphasis on environmental protection leading, in GB implementation, to the creation of a single Seveso Competent Authority (CA) comprising HSE, the Environment Agency and the Scottish Environment Protection Agency; and
- specific duties on the CA to undertake activities such as inspections and investigations with the aim of more consistent implementation across EU Member States.

Further accidents (river pollution in Baia Mare, Romania (2000), a fire and explosion at a fireworks factory in Enschede in the Netherlands which led to 22 off-site deaths (also 2000), and an explosion at an ammonium nitrate store in Toulouse, France (2001) which resulted in 30 deaths) showed that further adjustments were needed to Seveso if it was to achieve its goals. Annex 2 shows the current framework of controls following amendments introduced in 2003.
UK approach to Seveso

Whilst the Seveso Directive has been central to much of HID’s work for over 25 years, the environment within which it operates is very different now from when it was first introduced. The structure of the chemical industry and its operating context has changed hugely: the few giant monolithic companies such as ICI have been replaced by many smaller organisations; bulk commodity chemical production has declined in favour of more niche and speciality products; public attitudes to major hazard sites have become less accepting; pressure on land use has grown leading to problems in stabilising populations around sites; and concern for environmental protection has grown. And more changes are on the horizon with the move to a low carbon economy presenting new major hazard potential through technologies such as carbon capture and storage.

The response of the regulators has changed over time too. Under COMAH the environment agencies and HSE came together as a joint CA. The concept of a truly unified CA is now being taken to a new level through the COMAH Remodelling programme which was introduced on 1 April 2010. A single framework of CA governance, joint strategic priorities and unified intervention plans are all part of this change. So too is ensuring that there is a firmer base of evidence to drive CA resource deployment and a shift of emphasis away from office-based safety case assessment and into on-site verification to test more rigorously whether safety is being delivered on the ground.

Implementing Seveso has always required close inter-government co-operation and this will continue. DWP, advised by HSE, has lead responsibility in Great Britain for the worker health and safety aspects, including EU negotiations and policy implementation. Defra, who represent the UK at the Environment Council under which amendments to the Directive are adopted, lead on environmental issues and are advised by HSE on human health and safety aspects. Administrations in Scotland, Wales, Northern Ireland and Gibraltar, and departments such as BIS and DECC also have an interest. We will be working closely with the devolved planning administrations to develop a plan for changing our approach to land use planning in the light of recent Board decisions.

We are preparing for the low carbon economy through the Emerging Energy Technologies programme (EET). This will scope the hazards and risks of emerging technologies and propose regulatory strategies to position us as an enabling regulator capable of facilitating the safe introduction of new processes critical to the country’s future. Finally, we are responding to the new Strategy for health and safety and, in particular, contributing to the work on the goal of avoiding catastrophe. You received detailed reports on EET and avoiding catastrophe in April (HSE/10/41 and HSE/10/42 respectively).

Although the chemicals industry has changed significantly since Seveso was first introduced, it remains a key economic sector. There are currently 1160 COMAH sites in the UK (752 lower tier and 408 top tier) and the sector generates some £50 billion a year as well as making a vital contribution to quality of life and the economy as a whole.

This then is the context within which Seveso is going through its latest iteration to keep pace with a changing world.
Argument

The need for further change

Seveso must continue to respond to external influences and take a more pro-active approach to emerging risks if it is to remain fit for purpose. The outcome of three main areas of work will influence its future scope.

Linking Seveso to new EU legislation on classifying chemicals

EU classification Directives (which determine the scope of Seveso) are being replaced with the new EU Regulation on the classification, labelling and packaging of dangerous substances and mixtures (CLP)1. Seveso must be amended so that it refers to the new classification criteria in CLP. This has the potential to change the scope of Seveso (sites coming into or moving out of scope) and its regulatory effect (movement of sites between the tiers) depending on how the two pieces of legislation are linked. This could have a substantial impact on the sites regulated under the legislation in the UK. Annex 3 explains the implications in more detail.

An EC review of Seveso

The Commission sought the views of industry, public authorities and others on the effectiveness of the Directive. A number of recommendations emerged but overall the review concluded that the fundamental approach of Seveso is correct and there is no need for significant changes to the legislation. However it did recognise that there needs to be greater consistency of implementation of the Directive across the EU. Table 1 of Annex 4 summarises the UK CA response to the report of the second study2. Three issues emerged from the review that we would like to bring to the Board’s attention.

(i) Whether carbon dioxide (CO$_2$) should be within scope

With the emergence of carbon capture and storage (CCS) as a key carbon abatement technology the UK suggested that the Commission should consider whether CO$_2$ involved in CCS processes has major accident potential when taking into account the large quantities likely to be present, and should therefore be introduced into Seveso.

HSE is reviewing the scientific evidence to support its inclusion and the implications for other industries where similar quantities may be present (e.g. food and drink sector). We have met DECC to seek their views and identify the wider implications of including CO$_2$ in Seveso; they are keen that we move forward on the basis of evidence.

The Commission recognises that Seveso could be a suitable way to regulate this aspect of safety at CCS site; familiarity with the Seveso regime could be beneficial (for major hazards regulators and upstream oil companies) and its application could provide public reassurance that the major hazard risks of CCS will be well controlled. The UK has welcomed the Commission approach and offered assistance. Several Member States support its inclusion but in others (where CO$_2$ will be stored onshore rather than offshore) there may be more public sensitisation to CCS risks.

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1 CLP adopts the UN Globally Harmonised System of Classification and Labelling in the EU. It entered into force on 20 January 2009 and will be phased in over a period of years until June 2015.

2 The UK CA response to the first study in the review in Annex 2 of HSE/09/03 Board1 (II/II)
Alongside this work HSE has been considering whether CO₂ should be classified as a dangerous fluid under the Pipelines Safety Regulations. Work is also underway to apply the Health and Safety at Work etc Act to offshore activities involving CCS and, depending on the outcome of the Seveso negotiations, HSE may need to consider whether it is necessary to apply an equivalent permissioning regime offshore. The EET Programme, Policy, Operational Policy and technical staff are working very closely on these issues.

(iii) Whether Seveso should be extended to cover security matters

A recommendation from the Seveso review suggests that a medium-term objective should be to integrate security issues into Seveso, but it is not clear exactly what the EU means by “security”. Some Member States support the idea but two major industry associations who attended the Commission stakeholder consultation meeting said that security should be managed by existing or separate policy measures.

Responding to the Seveso review, the UK CA advised that we did not support the inclusion of security, noting that security matters are the responsibility of specialists outside the CA, and CA inspectors have no expertise in such matters. More importantly, the EU would need the correct legal basis if it wishes to legislate in matters concerning security. Article 4 on the Treaty of the European Union states that national security is a matter for Member States; therefore, matters of security should be dealt with under domestic legislation and inclusion within Seveso should not be encouraged. We are working with the Home Office and others so that we can agree an HSE/CA line, and prepare a UK view to assist negotiations. We will approach the Board for advice in due course.

A review of administrative burdens

The Action programme for reducing administrative burdens in the EU contains two recommendations relating to Seveso. These are to:

- introduce a system to send notifications electronically via a website, and
- improve the coordination of inspections under Seveso and IPPC (Integrated Pollution Prevention and Control).

The CA supports these in principle and we await the final report of the review which will make recommendations to the Commission.

Lessons learned from the Buncefield incident have a place in influencing greater consistency of implementation of the Directive. To this end, CA staff are actively involved in technical working groups and other fora. Examples include: shaping and actively participating in a recent workshop on Safety Leadership, Safety Culture and Safety Performance Indicators; working with the Commission to draft a document to encourage similar standards of overfill protection for bulk gasoline storage tanks across Europe to those described in the Buncefield PSLG report; and subsequent discussion at a working group meeting planned for June.

Commission view on way forward
Impact assessment

HSE has commissioned a research project, to be undertaken by external contractors ORC, which will gather information from businesses on the use and storage of dangerous substances, including some which are currently classified as harmful. This will help HSE to understand the impact of any change to the scope of the Directive and thus inform the UK’s negotiating position and subsequently, the way the UK chooses to implement the revised Directive. The project started in April and is expected to report its findings in October.

Next steps

Engaging stakeholders
Implementation of the communications plan is underway. The two main objectives are to: (i) raise awareness of the changes and (ii) engage directly with stakeholders to obtain information to inform and support the negotiating strategy and impact assessment.

To help raise general awareness HSE launched a new CA-sponsored page on the HSE website\(^3\) in January, supported by an e-bulletin service. These have received positive feedback. We are using more targeted approaches to reach specific stakeholders, taking advantage of existing fora and events such as the BIS Chemicals Regulatory Forum and a joint HSE/SIESO\(^4\) workshop. Over the coming months we plan to meet sector-based associations and other organisations to discuss the changes and the proposed UK approach to negotiations.

We have met a number of OGDs including BIS (Chemicals/the Better Regulation Executive), DECC and Defra to seek officials’ views on the changes. HSE will establish a cross-government group during the summer to guide the policy principles which will underpin the UK negotiating strategy.

Formal proposal
The Commission has announced that it will publish its formal proposal for changes to the Directive in the second half of 2010, possibly as late as December.

Negotiating strategy
Subject to the Commission’s progress, we anticipate seeking the Board’s agreement to a negotiating strategy in the autumn. We will be engaging with UKREP and MEPs during the coming months.

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\(^3\) [http://www.hse.gov.uk/seveso/index.htm](http://www.hse.gov.uk/seveso/index.htm)

\(^4\) Society of Industrial Emergency Services Officers
Action
The Board is invited to:

(i) note the role of Seveso in the regulation of on-shore major hazards;
(ii) consider the key issues affecting its future scope in paragraphs 18-37; and
(iii) note the next steps in paragraphs 39-43.

Paper clearance
Cleared by Gordon MacDonald on 5 May and the SMT on [date]
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<tr>
<th>Incident</th>
<th>Description</th>
<th>Harm/Damage/Seveso implications</th>
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| 1974 Nypro UK Ltd Flixborough, UK | Release of cyclohexane leading to a vapour cloud explosion after a plant modification was made without a full assessment of the consequences | • 28 employees killed  
• 36 injured on-site  
• 53 injured off-site  
• devastating damage to buildings on-site and large-scale damage to buildings off-site  
• Advisory Committee on Dangerous Substances set up 1974  
• influenced Seveso I content |
| 1976 Hoffmann La-Roche Seveso, Italy | Runaway thermal reaction led to a release of TCDD (tetrachlorodibenzo-dioxin), a highly toxic form of dioxin                                                                                                    | • affected a 18km² area  
• over 700 residents evacuated  
• 220,000 people under medical surveillance  
• 442 cases of skin lesions or chloracne  
• 3000+ animals dead  
• 80,000 animals slaughtered (to prevent TCDD entering food chain)  
• $200m costs  
• led to Seveso I Directive |
| 1984 PEMEX LPG Terminal, San Juan Ixhuatepec, Mexico City | LPG leak from pipework connecting two spheres was ignited by gas burners. Two spheres BLEVE’d simultaneously, with numerous further BLEVE’s in next 75 minutes. Only 4 out of 54 vessels left intact (BLEVE – boiling liquid expanding vapour explosion) | • 500 killed (high death toll due to proximity of plant to residential population  
• 2500 injuries (mostly burns)  
• terminal destroyed  
• one of the world’s largest industrial accidents  
• proximity to residential populations influenced Seveso land use planning provisions |
| 1984 Union Carbide India Ltd, Bhopal, India | Release of 40 tonnes of methyl isocyanate gas (MIC) from a pesticide plant. Water entered a tank of MIC causing an exothermic reaction and emergency venting of MIC and other toxic gases | • fatality numbers uncertain – reports refer to 3000 - 8000 immediate deaths and 18,000 – 20,000 in total  
• significant on-going damage to human health and the environment - 400 tonnes of toxic chemicals abandoned at the site are still leaking and polluting groundwater  
• $470m paid in compensation  
• led to changes to Seveso I thresholds and proximity to residential populations influenced land use planning provisions |
| 1986 Sandoz (now part of Novartis), Basel, Switzerland | Fire at a warehouse. Fire-water run-off containing mercury, organophosphate pesticides and other chemicals entered the Rhine                                                                                   | • largely wiped out flora and fauna in the Rhine for several hundred miles (reached the North Sea)  
• 500,000 fish killed  
• Seveso I extended to include storage activities |
| 2000 SE Fireworks | Fire in a work area where 900kg of fireworks were stored.                                                                                                                                             | • 22 people killed, including four fire fighters  
• 947 injured, plus many hundreds requiring |
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| Enschede, Netherlands | Spread to illegally placed containers and 177 tonnes of fireworks which eventually exploded | counselling after the event  
- Explosions heard 60km away  
- 2000 homes destroyed  
- 1250 people homeless  
- 0.5 billion euros of damage to property  
- changes to definition of explosives in Seveso II |
| 2000 | Extreme weather conditions created a 23 metre breach in a tailings dam releasing 100,000 m$^3$ of cyanide-rich tailings waste (cyanide plus heavy metals including copper) into rivers feeding the Danube and Black Sea | contamination and interruption of drinking water supplies in 24 locations affecting 2.5m people  
- massive fish kill  
- destruction of aquatic species in river systems  
- Severe negative impact on biodiversity  
- application of Seveso II extended |
| 2001 | Explosion in a downgraded ammonium nitrate store containing approximately 300-400 tonnes of off-specification material. Adjacent to a sack-filling building. | 21 people killed on-site  
- 9 people killed off-site  
- 2500 injured (20 seriously)  
- crater 40m diameter and 7m deep where factory had been  
- 25,000 homes damaged – 11180 seriously and 1000 completely destroyed  
- 40,000 people temporarily homeless (10% of local population)  
- steel girders found 3km away and windows blown out 7km away  
- damage estimated at 10-16 billion euros  
- 2 billion euros paid in compensation  
- changes to application of Seveso II to ammonium nitrate |
Annex 2

General approach of the Seveso Directive

Seveso\(^5\) regulates major-accident hazards involving dangerous substances with the aim of preventing major accidents and limiting their consequences to people and the environment. It applies where dangerous substances are present, or may be generated, at or above specified qualifying quantities.

For a substance to be ‘dangerous’ it must either:

- fall into one or more of ten specified categories of danger when classified under EU Directives on the classification and labelling of dangerous substances and preparations. These categories relate to human toxicity, physico-chemical hazards, and the danger for the environment (classification changes can affect the scope and/or regulatory effect of Seveso), or
- be included in a list of around 50 ‘named’ substances that, based on their potential to cause a major accident, have higher or lower qualifying quantities than would otherwise apply.

The Directive doesn’t just apply to businesses in the chemical sector: any businesses with sufficient quantities of dangerous substances are in scope, for example, whisky distilleries, chrome platers, or brick manufacturers storing LPG.

Regulatory framework

Seveso takes a proportionate, hazard-based approach through a two-tier system of controls based on the quantity of dangerous substances present. This reflects the premise that, generally, increased hazards equals increased risk although there are exceptions to this e.g. complex processes using lesser quantities of dangerous substances may present a greater risk than a site storing a single dangerous substance.

The main lower tier duties require site operators to:

- take all necessary measures to prevent major accidents and limit the consequences for people and the environment of any that do happen
- notify specified information to the competent authority
- prepare and implement a major accident prevention policy
- plan for emergencies, and
- notify major accidents to the competent authority.

The Directive also requires the operation of a land-use planning policy and a programme of inspection by the competent authority.

In addition, for top tier sites:

- operators should produce a safety report and provide information to people liable to be affected by a major accident
- local authorities should prepare off-site emergency plans, and
- the competent authority should examine the safety report and communicate conclusions to the operator, and designate ‘domino groups’ i.e. groups of sites within sufficiently close proximity such that an incident at one may trigger an event at another.

\(^5\) Directive 96/82/EC amended by Directive 2003/105/EC on the control of major accidents involving dangerous substances
Annex 3

Implications for Seveso of the new EU legislation on classifying chemicals

In June 2015, after a transitional period, the EU Regulation on the classification, labelling and packaging of substances and mixtures (CLP) will replace DSD/DPD. This will break the legislative link between DSD/DPD and Seveso necessitating an amendment to Annex 1.

The issue is further complicated because some of the new classification criteria in CLP differs from that in DSD/DPD: this creates the potential for changes to the scope of Seveso (sites moving into or out of scope) and its regulatory effect (movement of sites between the lower and top tiers of duties).

Health hazards

This is where there is the greatest difference between CLP and DSD/DPD.

Participating in a Technical Working Group, the UK, Germany, Netherlands, Czech Republic and the European Environment Bureau have identified various ‘alignment’ options, all of which are likely to impact to some degree or other on the scope of Seveso.

Options taking a precautionary approach might increase the scope/regulatory effect of the Directive. The application of a UK-developed ‘screening’ tool to some precautionary options could mitigate the effect of an increased scope but might be too complex to be practical. More moderate options exclude some substances currently in scope which are ‘industrially significant’ but compensate for this by introducing them into the list of named substances. The Commission has been taking a precautionary approach and has not indicated a preference for any particular option, or allowed the TWG to reach a single recommendation.

Physical hazards

There is much more similarity between CLP and DSD/DPD across the physical hazards categories. The most significant change relates to a new category for ‘flammable aerosols’. The TWG and EU/GB industry aerosol organisations agree that Seveso should include the new category and are now considering possible qualifying quantities and criteria.

Environmental hazards

The CLP and DSD/DPD environmental hazards categories are broadly similar.

There will be some classification changes for individual substances but these are unlikely to affect the overall scope of Seveso.

During the alignment work a separate issue has come to light concerning a change in 2006 to the way mixtures are classified for environmental purposes under the Dangerous Preparations Directive. It could mean that sites that are unlikely to pose a realistic major accident hazard could come into Seveso. The CA is discussing one example with industry (sodium hypochlorite - liquid bleach - and its storage in warehouses) and looking into the wider impact of the change.
Annex 4

Issues featuring in the UK CA responses to the Commission on the review of Seveso

| Table 1 - Second study on the effectiveness of the main requirements on public authorities (ERM study) |
|---------------------------------------------------|--------------------------------------------------|
| **Issue**                                         | **Summary of UK CA view**                        |
| Land use planning - technical advice should be clear and consistent and planning authorities should be able to understand and interpret advice. | Support the principle but may be hard to achieve. UK would be happy to share its approach on current initiatives. |
| Inspections – authorities with resource shortages can use the safety report to plan inspections. | Support the recommendation. UK is taking a similar approach through the COMAH remodelling programme. |
| Safety reports – provide tools to understand the differences between reports for similar sites to achieve greater consistency in assessment. | Support the recommendation for additional guidance/tools. Industry should be encouraged to lead. |
| External emergency plans – Directive should include timescales for preparation. | Support in principle. COMAH already has timescales. |
| Informing the public – improve the monitoring of the provision of information. Distribute information via the internet. | Agree active engagement is important but the internet, by itself, is not an adequate method of distributing information. |
| Accident reporting – provide more guidance on ‘near misses’ or incidents of interest. | Support the recommendation. |