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HEALTH AND SAFETY EXECUTIVE

Senior Management Team

Strategy for negotiating changes to the Seveso II Directive

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Cleared by Giles Denham on 19 December 2008

Issue

1. Work is underway at EU level that will result in an EC proposal in 2010 to amend the Seveso II Directive (96/82/EC) implemented through the Control of Major Accident Hazards Regulations and land-use planning legislation. We need to inform the Board and seek a strategic steer on developing an approach to negotiations.

Timing

2. For clearance on 7 January 2009 to enable an approved paper to go to the HSE Board on 28 January.

Recommendation

3. The SMT is invited to:

- note the work and progress so far,
- consider the suggested approach to negotiations, and
- approve the attached paper for submission to the HSE Board.

Background

4. See attached draft paper.

Consultation

5. HID, International Unit, International Chemicals Unit, Corporate Specialist Division, FOD, PEFD, Communications Directorate, Better Regulation Unit, Legal Advisers Office and the Economic Analysis Unit have been consulted on this paper.

Health and Safety Executive Board			Paper No: HSE/09/
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Strategy for negotiating changes to the Seveso II Directive			

Purpose of the paper

1. Work underway at European Commission (EC) level is expected to lead to a proposal in 2010 to amend EC Directive 96/82/EC on the control of major-accident hazards involving dangerous substances (the Seveso II Directive). The Directive is implemented in Great Britain through the Control of Major Accident Hazards Regulations 1999 and planning legislation. This paper updates the Board and seeks a steer on a UK negotiating strategy.

Background

2. Seveso applies at sites where dangerous substances (including preparations) are present, or may be generated, at or above specified qualifying quantities. For a substance to be dangerous under Seveso it must either:

- fall into one or more of 10 specified categories of danger when classified under EC Directives on the classification and labelling of dangerous substances and preparations (DSD/DPD[1]), regardless of whether or not the substance is required to be classified under those Directives, or
- be included in a list of 'named' substances that have higher or lower qualifying quantities than would otherwise apply.

Further background to Seveso and UK implementation arrangements is in Annex 1.

3. A new EU Regulation on the classification, labelling and packaging of substances and mixtures (CLP), through which the EU will adopt the UN Globally Harmonised System of Classification and Labelling (GHS), is expected to enter into force in late January 2009.

4. CLP will introduce new requirements for classification that will differ slightly from those in DSD/DPD. It will be phased in over a transitional period: substances must be classified under CLP from 1 December 2010 (and classified under DSD/DPD as well between this date and 1 June 2015 i.e. dual classification), and from 1 June 2015 CLP must be used to classify mixtures (currently called preparations)[2]. CLP will replace DSD/DPD in 2015 and break the legislative link between Seveso and DSD/DPD. A new method of determining the scope of Seveso will need to be found which will necessitate an amendment to the Directive. This work must be concluded and transposed into national legislation by 1 June 2015.

5. The EC has set up a Technical Working Group (TWG) to collect information and advise on the impact of CLP on Seveso with a view to maintaining, as far as

[1] DSD – Council Directive 67/548/EEC on the classification, packaging and labelling of dangerous substances. DPD – Council Directive 1999/45/EC on the classification, packaging and labelling of dangerous preparations.
[2] Suppliers may, however, choose to classify according to CLP before the mandatory deadlines apply

possible, the scope of the Directive (see paragraphs 1 to 2 of Annex 2). The UK is taking an active role. The EC is expected to publish a proposal to amend the Seveso II Directive during 2010.

6. Two reviews being carried out by the EC on the effectiveness of the Seveso Directive and administrative costs on businesses may also influence the proposal. Additionally, Member States may take the opportunity to seek changes to Seveso.

Argument

Seveso and the CLP Regulation

7. The aim of the EC has not been clearly set out but appears to be (i) not to extend the current scope of Seveso and (ii) ensure the same level of protection for man and the environment. Formal negotiations will start when the EC publishes its proposal but the UK needs to develop a strategy that will inform our contribution to the TWG and be further developed at the proposal stage. The TWG has considered two approaches.

Approach 1 – Do nothing

8. The EC would retain the classification system in DSD/DPD beyond 2015 as stand-alone legislation or integrate it into Seveso. Existing site operators are familiar with the current classifications, and the scope of Seveso would be unchanged. However, the EC would have to retain the current criteria solely for Seveso purposes, and potentially manage two classification systems. Seveso operators would continue to use DSD/DPD to determine the scope of Seveso but would use CLP for chemical marketing and supply purposes. Such 'dual classification' could cause confusion for industry and regulators and may lead to increased costs. The EC is no longer actively considering this approach.

Approach 2 – Align Seveso with CLP

9. This would link Seveso with CLP across all relevant hazard categories. Although CLP classification is broadly similar to the existing system, a straight forward substitution of the most hazardous classes of DSD/DPD with those in CLP would mean that some substances may be classified more or less severely creating potential for changes to:

- the scope of the Directive i.e. where sites move into or out of Seveso, and
- the regulatory attention sites receive i.e. movement of sites between the lower and top tier requirements.

10. Much of the TWG work so far has focused on the classification criteria for acute toxicity, which has the greatest lack of alignment between DSD/DPD and CLP. Options are being developed (including one by the UK) and these are now converging.

11. A feature common to each option is that not all substances currently classified as 'very toxic' would equate to the most severe category under CLP. This brings a concern that there may be a reduction in the scope/regulatory effect of Seveso, and the EC has asked Member States to identify the impact of this potential shift. From work done so far we are not aware of any UK sites where there would be a change of status. This is because those concerned would still be within scope either because they have properties that are relevant to more than one category of dangerous substance, or because of the way quantities of substances are 'aggregated' to determine application. Paragraphs 3 to 24 of Annex 2 provide further

information about the work of the TWG and illustrate the particular alignment difficulties for the health hazards classes.

12. The EC appears to be taking a precautionary approach in the TWG and has asked Member States to identify other possible options. They have identified a consultant who will undertake an impact assessment study into the options in 2009.

EC Reviews

13. Separately, the EC is reviewing the effectiveness of Seveso to identify possible improvements. A first study sought information from competent authorities (CA)[3], industry and other organisations on the main requirements on operators. Senior CA staff agreed the UK response, which HSE collated on behalf of the UK CA. The findings showed no real need for legislative change, including provisions relating to land-use planning (Article 12), but identified inconsistent implementation. A summary of the overall findings and the UK response are at Annex 3. A second study will look at the effectiveness of requirements on public authorities.

14. Additionally, Seveso is one of over 40 pieces of legislation included in an EC review of administrative costs incurred by businesses in meeting legal obligations to provide information. Existing UK data is being used in a large-scale measurement exercise. The results are expected in early 2009 along with proposals to meet an overall reduction target of 25% by 2012.

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Presentation

17. Linking Seveso with the CLP Regulation is likely to lead to some changes in the scope and/or regulatory effect of Seveso. It is too early to estimate the extent of these but the EC aim is intended to keep them to a minimum. We have developed a plan to engage stakeholders (including industry, trade unions, local authorities, emergency services) and are already working with them to assess the implications of the different approaches. Internally, a group of senior managers is providing advice and a strategic steer. We plan to brief the Minister on this work in March 2009, and will share the submission with the Board.

Consultation

18. The work is being taken forward with our CA partners in collaboration with Northern Ireland and Gibraltar. It has also been presented to HSE's Chemical and Downstream Oil Industries Forum and the Chemical and Pipelines Emergency Planning Liaison Group. A Trade Union representative has indicated preference for a precautionary approach to the Seveso-CLP issue.

Resource implications

19. HSE costs, including HSL costs, are affordable within current budgets for 2008/9 and indicative allocations for 2009/10 (estimates are available from the author on

[3] The UK CA comprises: HSE and the Environment Agency in England and Wales; HSE and the Scottish Environment Protection Agency in Scotland; the Department of the Environment Northern Ireland and the Health and Safety Executive Northern Ireland; and Gibraltar. In GB, HSE leads on occupational health and safety issues and the EA and SEPA lead on environmental aspects.

request). Costs for 2010/11 and beyond, together with an impact assessment, will be developed when more is known about the likely content of the EC proposal.

Action

20. The Board is asked to:

(i) note the implications of the CLP Regulation and options being considered,

(ii) note that outcomes from EC reviews may influence the EC proposal to amend Seveso, and

(iii) advise on whether the strategy proposed in paragraphs 15-16 is appropriate.

Paper clearance

21. This paper was produced by Elizabeth Schofield and Sandra Ashcroft and cleared by the SMT.

Seveso II and UK arrangements for implementation and enforcement

The Seveso Directive

1. EC Directive 92/82/EC[4], commonly known as the 'Seveso' Directive (following a dioxin disaster in Italy in 1976), aims to prevent major accidents involving dangerous substances and limit the consequences to people and the environment of any that do occur. It was amended in 2003 to reflect lessons learned from more recent accidents, notably a cyanide spill that polluted the Danube in Baia Mare, Romania, a fireworks accident in Enschede, Netherlands that killed 22 people and an explosion at a fertiliser plant in Toulouse, France in which 30 people died, and also to reflect EC studies on carcinogens and substances dangerous for the environment.

Application through the classification system

2. Seveso applies where dangerous substances, including dangerous preparations, are present at or above specified quantities or may be generated during loss of control of an industrial chemical process.

3. For a substance to be 'dangerous' it must:

- fall into one or more of ten specified categories of danger when classified under EC Directives on the classification, packaging and labelling of dangerous substances and dangerous preparations (DSD/DPD), regardless of whether or not the substance is required to be classified under those Directives. These categories relate to human toxicity, physico-chemical hazards, and the danger for the environment; or
- be included in a list of 'named' substances that have higher or lower qualifying quantities than would otherwise apply. For example, the toxic substances phosgene, phosphine and arsine all have lower qualifying quantities as named substances because of their potential to cause a major accident. The named list takes precedence over the generic categories.

4. A site with no single substance present at its threshold quantity could still come within scope under a rule which requires smaller quantities of substances with similar hazards to be aggregated. Many UK sites come into scope in this way. Also many sites come into scope because they meet the threshold quantities for more than one dangerous category of substance.

5. The Directive doesn't just apply to chemical companies. With a limited number of exceptions, any site having relevant quantities of dangerous substances is within scope e.g. surface engineers using chromium or brick manufacturers storing LPG.

Key requirements

6. There are two tiers of regulatory control depending on the quantity of dangerous substances present. 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 site etc information to the competent authority

[4] Directive 96/82/EC http://mahbsrv.jrc.it/downloads-pdf/Seveso2-LEG-EN.pdf amended by Directive 2003/105/EC http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:345:0097:0105:EN:PDF

- prepare and implement a major accident prevention policy
- plan for emergencies
- notify major accidents to the competent authority,

- the operation of a land-use planning policy, and
- a programme of inspection by the competent authority.

7. In addition, under the top tier controls:

- site operators must:
  - produce a safety report and review it to reflect changes that could have repercussions for major accident safety, or at least every five years
  - provide information to people liable to be affected by a major accident, and review it at least every three years
- local authorities must prepare off-site emergency plans and review, test and where necessary revise them at least every three years
- the competent authority must:
  - 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.

UK implementation and enforcement arrangements

8. In Great Britain, most provisions have been implemented through the Control of Major Accident Hazards Regulations 1999 (COMAH)[5]. COMAH is enforced by a competent authority comprising the HSE and the Environment Agency in England and Wales, and HSE and the Scottish Environment Protection Agency in Scotland (with the Agencies leading on environmental aspects of the legislation). Information recently supplied to the EC showed there are 1147 COMAH sites in Great Britain – 736 lower tier and 411 top tier.

9. Seveso also contains land-use planning controls. These are implemented through separate legislation which is the responsibility of Communities and Local Government and the devolved administrations.

10. N. Ireland and Gibraltar have corresponding legislation.

[5] SI 1999/743 amended by SI 2005/1088

Annex 2

Linking Seveso with the CLP Regulation

Technical working group

1. The UK is taking an active role in discussions between the EC and Member States (MS) on the implications for Seveso of the CLP Regulation. Following two informal meetings in 2007, one of which the UK hosted, the EC formed a Technical Working Group (TWG). Membership is primarily from the Seveso Competent Authorities but is also open to industry representatives and other bodies. Industry representatives have attended including the UK Chemical Business Association. Terms of reference are to:

- collect information and provide guidance on the impact of CLP on Seveso,
- identify CLP categories corresponding to the current ten Seveso categories,
- establish temporary sub-groups to assess specific categories as necessary,
- develop options taking into account the hazard potential of substances and the need for a clear, simple system that keeps the CLP categories intact, and
- estimate the likely impact of options (substances and number of sites affected).

2. The TWG met three times in 2008 and the UK attended each meeting. We also hosted an informal meeting of MSs, the EC's Major Accident Hazards Bureau, the CIA and CEFIC in April 2008 to discuss an alignment option developed by HSE and the Health and Safety Laboratory (HSL). Two further TWG meetings are planned for 2009 after which the EC will develop proposals to amend Seveso.

Options to align Seveso with CLP

3. Alignment issues are being considered separately for the ten categories of dangerous substance. Very few CLP classifications align exactly with DSD/DPD. Acute toxicity to people appears the least straightforward, especially inhalation exposure routes.

Health hazards - acute toxicity classes

4. There are three DSD/DPD categories for acute toxicity: Toxic, Very Toxic and Harmful. However, for the purposes of the generic Seveso categories of danger only the Toxic and Very Toxic categories are relevant (with qualifying quantities of 50/200 tonnes and 5/20 tonnes respectively). A substance falls into one of these categories if its overall DSD/DPD classification (the most severe of the classifications for oral, dermal and inhalation exposure routes) is Toxic (T) or Very Toxic (T+). The CLP health hazards class has four categories for acute toxicity - 1, 2, 3 and 4 – with toxicity criteria for categories 1, 2 and 3 overlapping those for T and T+. The difficulty is how to align the current T and T+ classifications with the three differently defined CLP Categories.

5. Acute toxicity classifications under both DSD/DPD and CLP are defined in terms of cut-off values on LD_{50} for exposures for the oral or dermal routes and on LC_{50} for the inhalation routes[6]. For the latter, the physical state of the substance (gas, vapour and dust or mist) is also taken into account. A comparison of the legislation shows:

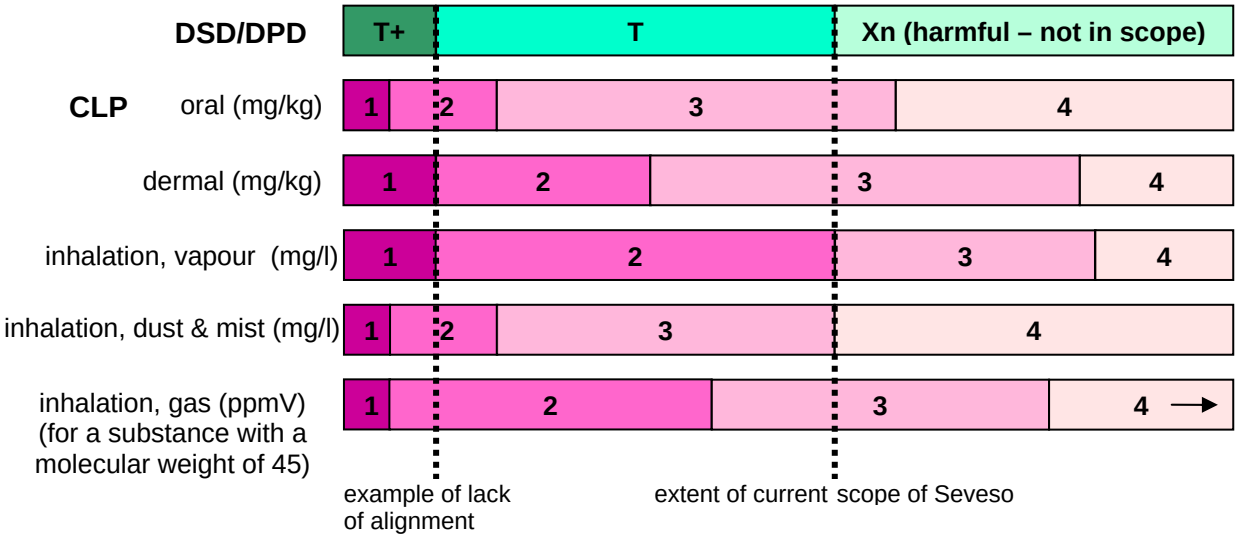
- a straight forward shift in some boundaries of dermal and oral routes, and

[6] For a particular species, LD_{50} is the concentration of a chemical that will kill 50% of the exposed population whilst the LC_{50} is the equivalent airborne concentration for a specified exposure period.

- an exact agreement for inhalation exposures to vapours that are not near the gaseous state i.e. T+ = CLP Category 1 and T = CLP Category 2, but
- differences for exposures to gases and vapours near the gaseous state because:
  - o CLP makes a classification distinction between vapours and gases, and
  - o the current system measures acute inhalation toxicity in terms of the *mass* (mg/l) inhaled in a given volume, whereas the CLP measurement for gases is based on the *number of molecules* inhaled in a given volume (ppm/V).

6. These alignment difficulties can be illustrated as follows[7]:

Comparison of DSD/DPD and CLP acute toxicity hazards



7. Alignment options that bring Category 3 substances into the Seveso regime could bring sites with no major accident hazard potential into scope. It is difficult to estimate how many sites would be affected because of the difficulty in identifying how many industrially significant substances this applies to since they are not, by definition, in any existing Seveso databases.

8. Also, CLP Categories 1 and 2 may exclude some substances that are currently T or T+. These are primarily substances that are T with the least severe acute toxicity within the range. Also, because CLP uses a different method of classifying inhalation exposures to gases, some lower molecular weight T and T+ gases with relatively severe acute toxicity within the range would be excluded from CLP Categories 1 and 2. For the UK only two such gases have been identified as has having regulatory significance - ammonia and sulphur dioxide. Both substances bring UK installations with major accident potential into the scope of Seveso on the basis of the inventory of these substances alone.

9. The TWG has discussed a number of alignment possibilities and three options are currently being developed – by the UK, the Netherlands/Czech Republic, and Germany. MSs seem unwilling to voice their preferences so it is difficult to say which approach/es may be favoured.

[7]This is a simplified comparison which omits the associated LD_{50} and LC_{50} scales.

Simple alignment – developed by the UK

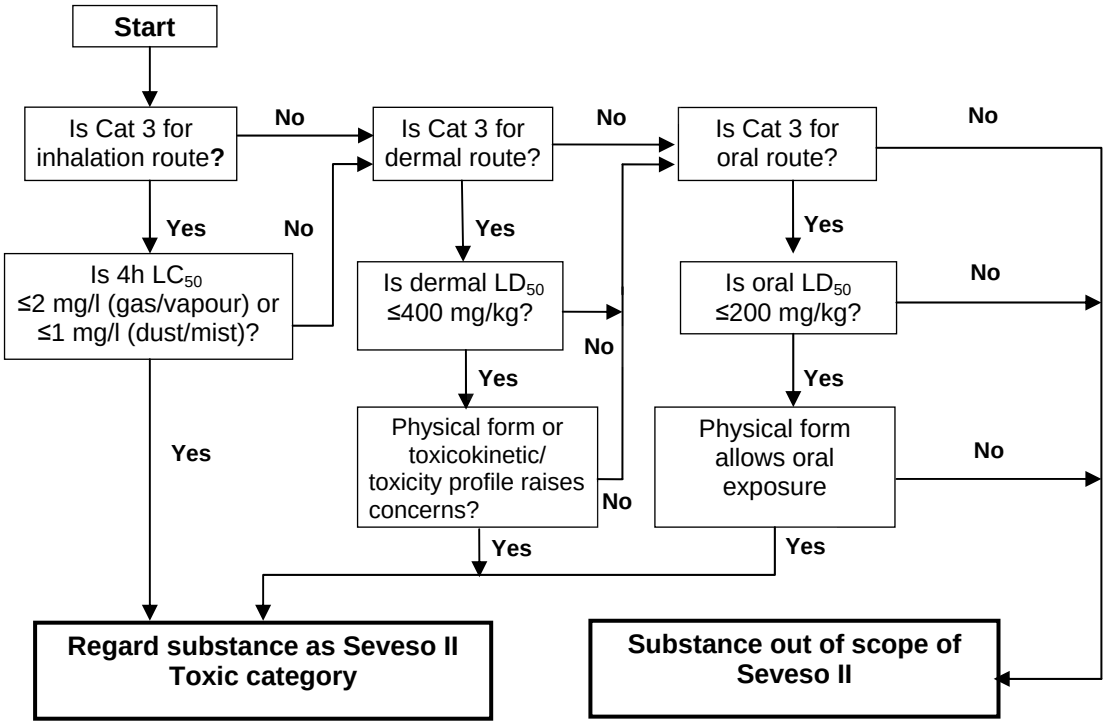
10. This is a two-stage option: the first stage aligns T+ with CLP Category 1 and T with CLP Category 2 for all exposure routes and physical states. However, this on its own would create regulatory gaps. To resolve this, the second stage includes as Named Substances any Category 3 substances that are currently in the scope of Seveso and correspond to installations with major accident hazard potential that would otherwise not be covered. These would have either the current lower qualifying quantities (5/20 tonnes) for Category 1 substances, or the higher (50/200 tonnes) qualifying quantities for Category 2 substances.

11. From a UK perspective two substances would need to become Named Substances: the lower molecular weight gases ammonia and sulphur dioxide. Although many other current T, T+ substances are Category 3, from a UK perspective they do not need to be within the Seveso regime as they do not significantly impact on the scope/regulatory attention of Seveso. This is because most UK installations are in scope either through the aggregation rule, or because they have properties that are relevant to more than one category of dangerous substances. Therefore, reductions at the level of individual substances brought within the regime in terms of acute toxicity have little impact at the level of installations.

12. Some other substances may have regulatory significance for other MSs but overall, we would expect the number of extra Named Substances to be limited.

13. To apply the second stage, HSE has developed a technical screening tool (or methodology) that would filter out any proposed candidates that do not have major accident potential based on their inherent properties (e.g. vapour pressure and toxicity for relevant physical form/processing conditions). The tool has been simplified considerably since its inception and would be applied as follows:

Screening tool for substances with CLP acute toxicity Category 3 classification



14. Discussions are continuing on whether the tool would be applied as a one-off at the transition stage or whether it could have a more permanent use, and also on who would apply it e.g. centrally by a technical committee or individually by operators.

Proposal from the Netherlands and the Czech Republic

15. The Netherlands (NL) supported the simple alignment option being developed by the UK. Together with the Czech Republic (CZ), they have developed this into a second alignment option, part of which uses the UK-developed screening tool.

16. Under this option:

- T+ would be aligned with Category 1 and keep the existing qualifying quantities for all exposure routes and physical forms (as with the UK-developed approach)
- T would be aligned with:
  - Category 2 for the oral and dermal routes and inhalation of vapours - in most circumstances, overall exposure is dominated by exposure through inhalation in the first hours after an accident. Where exposure occurs through the oral and dermal routes, mitigation measures (such as sheltering, fencing off contaminated areas, not bathing in contaminated water) are sufficient to limit exposure. For inhalation of vapours, CLP Categories 1 and 2 align exactly with DSD/DPD T+ and T,
  - Categories 2 and 3 for inhalation of dusts and mists - CLP Categories 1, 2 and 3 cover the same concentration range as the current T+ and T. This alignment would keep the scope and level of protection very close to the current situation. A general hurdle facing all alignment proposals for inhalation of dusts and mists is that, because of different cut-off limits, CLP Category 2 covers substances previously covered by the current T+ category. It is possible that there may be some (minor) changes in the regulatory effect of Seveso (i.e. some movement of sites between the tiers), and
  - Category 2 and selected Category 3 substances for inhalation of gases – would make use of the UK-developed screening tool to identify CLP Category 3 gases that have major accident potential and include then as Named Substances

17. No work has yet been done to assess the impact of this proposal.

Proposal from Germany

18. This is a precautionary approach which aims to maintain the scope of Seveso as far as possible and be simple to apply. It includes greater coverage of Category 3 substances which they consider provides a significant overlap with the current T classification. The proposal is that:

- T+ would be aligned with Category 1 and keep the existing qualifying quantities for all exposure routes and physical forms (as with the UK and NL/CZ options)
- T would be aligned with Categories 2 and 3 except:
  - CLP Category 3 would be excluded for the inhalation of vapours
  - CLP Category 3 would be excluded for the dermal route if the substance is also classified as Category 3 for the inhalation of vapours route.

19. Automatically bringing in Category 3 substances could bring sites with no major hazard potential into scope. The process of ‘filtering out’ unwanted Category 3 substances could be resource intensive, site by site work, and could possibly lead to inconsistencies across the EU.

20. The rationale is as follows:

- oral route – differs from the NL/CZ approach as it includes Category 3 substances to reflect differences in concentration limits in the two pieces of legislation
- dermal route - the T category covers Category 2 as well as a large part of Category 3. Including Category 3 completely could lead to a significant expansion of the scope of Seveso. To keep the scope as close as possible, it is proposed that a Category 3 substance should only be included if it is not already in scope through the inhalation of vapours route
- inhalation of vapours and dusts and mists– same as NL/CZ proposal
- inhalation of gases – agrees with UK and NL/CZ options in that it recognises that the legislation expresses toxicity values in different ways and that it is not necessary to include all CLP Category 3 substances. Some Category 3 substances would need to be identified and included in the Named Substance list using a screening tool comparable to the UK-developed method.

21. This option has the potential to expand the scope of Seveso. Germany believes the increase would be small but they have not assessed its impact.

Physico-chemical hazards

22. A range of issues. Topics currently under discussion within the TWG relate to:

(i) Oxidizing solids – substances which in themselves are not necessarily combustible but which, generally by yielding oxygen, may cause or contribute to the combustion of other material. DSD/DPD has one category of danger (oxidising solids) and two risk phrases (R8, R9). CLP also has one class (oxidising solids) but three categories. Alignment with Categories 1 and 2 may mean that some substances fall outside scope. TWG is discussing whether this is an area that may justify an increase in the scope of Seveso or whether, if Category 3 substances are included, tonnage thresholds could be increased to balance out the effect. Impact assessment required.

(ii) Self-reactive substances – thermally unstable substances likely to undergo a strongly exothermic decomposition even without oxygen. Covered by the 'Explosive' category of danger in DSD/DPD (with risk phrases R2, R3). CLP has a new 'Self-reactive substances and mixtures' category covering Type A-F substances. Closest alignment is with Types A and B with a question mark over Type C. Impact assessment required.

(iii) Flammable liquids – liquids with a flashpoint of not more than 60^{o}C. Three categories of danger in DSD/DPD (extremely flammable, highly flammable and flammable liquids) with additional Notes in Seveso relating to e.g. Flammable liquids, Flammable gases. Revised CLP cut-offs e.g. for flashpoints have the potential to increase the number of sites in scope as manufacturers may have formulated mixtures to be just outside the current DSD/DPD limits.

(iv) Pyrophoric solids – substances which, even in small quantities, are liable to ignite within five minutes after coming into contact with air. DSD/DPD subsume pyrophoric liquids as solids under the Highly Flammable category of danger with risk phrase R17 but CLP classifies them separately. Emerging view from TWG is to include the solids category as pyrophoric liquids would already be within scope. There are not many candidate substances for the 'solids' category and industry

advise that many are likely to be covered already by other Seveso categories of danger. Yet to gain industry support.

(v) Flammable aerosols – non-refillable receptacles containing a gas under pressure, with a liquid, paste or powder, to be released as particles in suspension in a gas as foam, paste, powder, liquid or in a gaseous state. Aerosols are currently classified for Seveso purposes by aggregating the contents according to the Seveso aggregation rule. Under this, the propellant (usually LPG) is compared with relevant thresholds (usually the LPG Named Substance category) and the other contents compared with the relevant Named Substance or categories of danger thresholds. CLP creates a new classification category for flammable aerosols which brings the EU classification system into line with the specific testing done for aerosols and improves the consistency of information throughout the supply chain. Options are to retain the current system (but using CLP classifications) or use the new CLP category with appropriate thresholds. TWG seem to be moving towards the latter. The European Aerosol Federation and the British Aerosol Manufacturing Association are involved in discussions and providing information on the contents of aerosols to inform discussions.

Environmental hazards

23. In Seveso terms, substances dangerous for the environment are those whose intrinsic properties present a hazard to the aquatic environment. There are currently two categories of danger relevant to Seveso – "very toxic to aquatic organisms" with risk phrases R50 (including R51/53) and "toxic to aquatic organisms: may cause long-term adverse effects in the aquatic environment" (with risk phrases R51/53). CLP classification reflects the current system and although work is at an early stage there appears to be a reasonable degree of alignment. The UK Environment Agencies are leading work on these categories.

Environmentally classified mixtures

24. A separate issue unrelated to alignment has come to light concerning 'M' (multiplying) factors used for environmentally-classified mixtures[8]. 'M' factors were introduced through the 2nd ATP (Adaptation to Technical Progress) of the Dangerous Preparations Directive which came into force in GB on 1 October 2008 through an amendment to the CHIP Regulations. The way the factors are applied means that there is scope to extend coverage of Seveso, potentially bringing into scope sites that are unlikely to pose a realistic major accident hazard e.g. warehouses with paint cans. Possible solutions include:

- increasing tonnage thresholds for environmental effects
- filtering out 'small packages', or
- ensuring that assessment only refers to the amount of classified substance rather than the total quantity.

[8] There are 5 factors (x1, x10, x100, x1000, x10000) applied to one of five 'toxicity bands' (EC50 0.1-1; 0.01-0.1; 0.001-0.01; 0.0001-0.001; 0.00001-0.0001) and the more toxic the substance, the higher the M-factor applied. So, for example, for a mixture containing an AT1 substance, if the sum of the concentration x M-factor is > 25%, then the mixture is classified as AT1. This has an effect slightly opposite to that of dilution of substances toxic to human health in that it still assumes dilute substances still have potent environmental toxicity and the M-factor cranks the toxicity back up in spite of dilution (perhaps as a reflection of dispersive effects).

Annex 3

EC review of the effectiveness of Seveso

1. The EC is carrying out a review of Seveso to assess its effectiveness and identify possible improvements. The outcome will complement information provided by Member States in their triennial reports on implementation. The first study, carried out by consultants during 2008, focussed on:

- the adequacy of the requirements imposed on operators of Seveso sites and the objectives to prevent major accidents and mitigate their consequences
- the real impact of the requirements and the most effective way to measure it, and
- the effectiveness of implementation, in terms of compliance in the various Member States and industrial sectors, and the assessment of possible market distortions.

2. A second study will look at the effectiveness of requirements on public authorities. The EC will consider the findings and include any proposals for change in the 2010 proposal to amend Seveso.

Summary of EC findings

3. The report[9] on the first study was published in September 2008. It reflected views expressed in 155 completed questionnaires (102 industry, 33 Competent Authorities, 20 other organisations) and 23 interviews.

4. The main findings are that Seveso is appropriate and fit for purpose. There is no real need for legislative change but implementation is inconsistent. Responses showed:

- all targeted groups consider that Seveso is appropriate to prevent major accidents and mitigate their consequences and has led to recognisably higher standards of safety in comparison with non-Seveso sites
- the approach complements other directives, but there are areas of overlap
- there are no unnecessary provisions
- the two-tier approach implementing the precautionary principle is appropriate, but a very small number suggest some provisions could be extended to the lower tier
- implementation is inconsistent within the EU and even within a given country, and the different authorities within some Member States should be better coordinated
- the scope should be extended to include the transport of dangerous substances and pipelines
- there should be greater consistency with IPPC (Integrated Pollution Prevention and Control), and
- a need for new guidance and a review of existing guidance.

UK response

5. The UK Competent Authority responded to the study and a number of our comments are evident in the report. Our main recommendations, agreed with senior CA managers, were for:

(i) an improved method of defining the application of Seveso to avoid substances and preparations (mixtures) with no major hazard potential coming into scope as a result of CLP

[9] Annex 1A and Annex 1B are published separately.

(ii) clarification and removal of overlaps with other legislation, such as IPPC

(iii) removing anomalies for preparations. Illustratively, as a result of changes to 2nd ATP (Adaptation to Technical Progress) of the Dangerous Preparations Directive, 99 tonnes of biocide would not attract Seveso, but 100 tonnes of the same product diluted with only ½ tonne (if present at 0.5%) of biocide would

(iv) proportionality in respect of work needed for a dispensation (derogation) to limit the information in a safety report. The process is burdensome (for industry and regulators) and would benefit from a simplified approach or clarification on what is considered an adequate application

(v) also on the dispensation rule, consideration of an extension to include other areas of the Directive in cases where the substances present are incapable of creating a major-accident hazard

(vi) clarification on the uncertainty over application to gas storage in depleted oilfields

(vii) consideration of the need to extend Seveso to include CO_2 sequestration and storage activities

(viii) consideration of whether Seveso might move towards a more hazard/risk-based approach in future with less reliance on threshold quantities, and

(ix) aditional guidance covering:

- terminology of the Directive
- emergency planning
- information on safety measures
- basic investigation techniques i.e. how to approach inspection (this, in particular, may help new Member States)
- scope and application
- dispensation rule (derogations), and
- possible use of benchmarks to help determine the 'all measures necessary' that could be applied across sites/industries operating similar procedures.