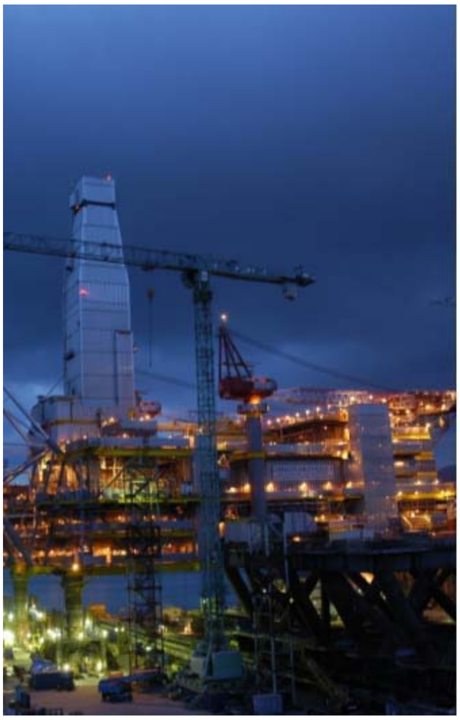
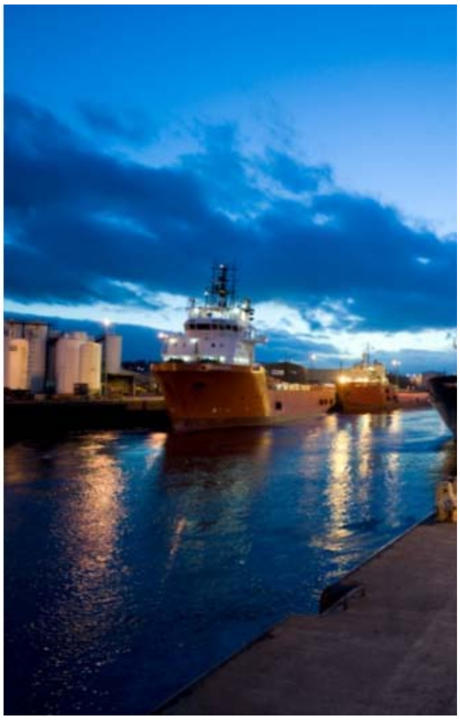
Final report Annex 7: Interpreting results of consequence assessment modelling (Task 7)

Development of an assessment methodology under Article 4 of Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances (070307/2013/655473/ENV.C3)





Report for the European Commission (DG Environment)

AMEC Environment & Infrastructure UK Limited

In association with INERIS and EU-VRi

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European Commission (DG Environment)

Development of an assessment methodology under Article 4 of Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances

Final report – Annex 7

AMEC Environment & Infrastructure UK Limited

December 2014

Report for

European Commission, DG Environment
Directorate C – Sustainable Resources Management, Industry and Air
Unit ENV C.3 – Industrial emissions, air quality and noise
Brussels B-1049
Belgium

Main Contributors

Marion Demeestere (INERIS)
Christophe Bolvin (INERIS)
Anabel Lahoz (INERIS)
Caspar Corden (AMEC)
Victoria Cherrier (AMEC)

Issued by

....
Victoria Cherrier

Approved by

....
Caspar Corden

AMEC Environment & Infrastructure UK Limited

17 Angel Gate, City Road, London EC1V 2SH,
United Kingdom
Tel +44 (0) 207 843 1400
Fax +44 (0) 207 843 1410

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List of abbreviations

ADAM	Accident Damage Assessment Module
ADR	European Agreement Concerning The International Carriage Of Dangerous Goods By Road
ALARP	As Low As Reasonably Practicable
ARIA	Analysis, Research and Information about Accidents
BLEVE	Boiling Liquid Expanding Vapour Explosion
BOD – COD	Biochemical Oxygen Demand – Chemical Oxygen Demand
CE	Critical Event
CFD	Computational Fluid Dynamics
CLP	Classification Labelling Packaging
COMAH	Control Of Major Accident Hazards
DA	Deterministic Approach
ECHA	European Chemicals Agency
e-MARS	Major Accident Reporting System
EU	European Union
EWGLUP	European Working Group on Land Use Planning
F&EI	Fire & Explosion Index
GHS	Globally Harmonised System
JRC	Joint Research Centre
LPG	Liquefied Petroleum Gas
LUP	Land-Use Planning
MAHB	Major Accident Hazard Bureau
MATTE	Major Accident To The Environment
M_F	Material Factor of the Dow's Fire & Explosion Index
MIMAH	Methodology for Identification of Major Accident Hazards
NFPA	National Fire Protection Agency
NOEC	No Observable Adverse Effects Concentration
PA	Probabilistic Approach
PLG	Pressurised Liquefied Gas

RID	European Agreement Concerning the International Carriage of Dangerous Goods by Rail
RMP	Risk Management Plan
STOT-SE	Specific Target Organ Toxicity (Single Exposure)
USEPA	United States Environmental Protection Agency
UVCE	Unconfined Vapour Cloud Explosion

Physicochemical parameters

BCF	Bioconcentration Factor
EC_{50}	Median Effective Concentration
ΔH_r	Standard enthalpy of reaction
K_{st} / K_g	Maximum rate of explosion pressure rise for dust clouds/gas
LD_{50} / LC_{50}	Median Lethal Dose / Median Lethal Concentration
LFL / LEL	Lower Flammability Limit / Lower Explosion Limit
LOC	Limiting Oxygen Concentration
MIE	Minimum Ignition Energy
MTSR	Maximum Temperature of the Reaction Synthesis
NOEC	No Observed Effect Concentration
P_{max}	Maximum explosion pressure
P_{vap}	Vapour pressure
ΔT_{ad}	Adiabatic temperature rise
T_{eb}	Boiling point
TMR_{ad}	Time to maximum rate in adiabatic condition
UFL / UEL	Upper Flammability Limit / Upper Explosion Limit

Contents

1. Introduction

1.1 Purpose of this report

This report forms part of the outputs of a contract for the European Commission on ‘development of an assessment methodology under Article 4 of Directive 2012/18/EU on the control of major-accident hazards involving dangerous substances’. The work has been undertaken by AMEC, INERIS and EU-VRi.

The present report concerns one of a number of specific tasks under the project. It should not be read in isolation, but in conjunction with the main report and in conjunction with the reports concerning the other project tasks.

As indicated in the overall report, the information presented here is intended to provide a ‘framework’ for an assessment methodology for use in the context of Article 4. It presents various elements to take into account as part of an assessment in the context of Article 4. However, it is not intended to be a complete ‘manual’ presenting the steps which must be followed nor does it provide a ‘one-size-fits-all’ approach to assessments under Article 4.Specifically assessments under Article 4 may adopt different approaches to those presented in this report, but it is hoped that the material presented provides a useful conceptual framework, as well as details of practical approaches that could be used in determining whether a major accident is “impossible in practice”. In reality, every candidate substance under Article 4 will involve different issues, and therefore the approaches to assessments in this context will necessarily vary.

The approaches are not prescriptive and member states and other assessors are free to use all, some or none of the information in their analysis of whether a major accident is possible in the context of Article 4.

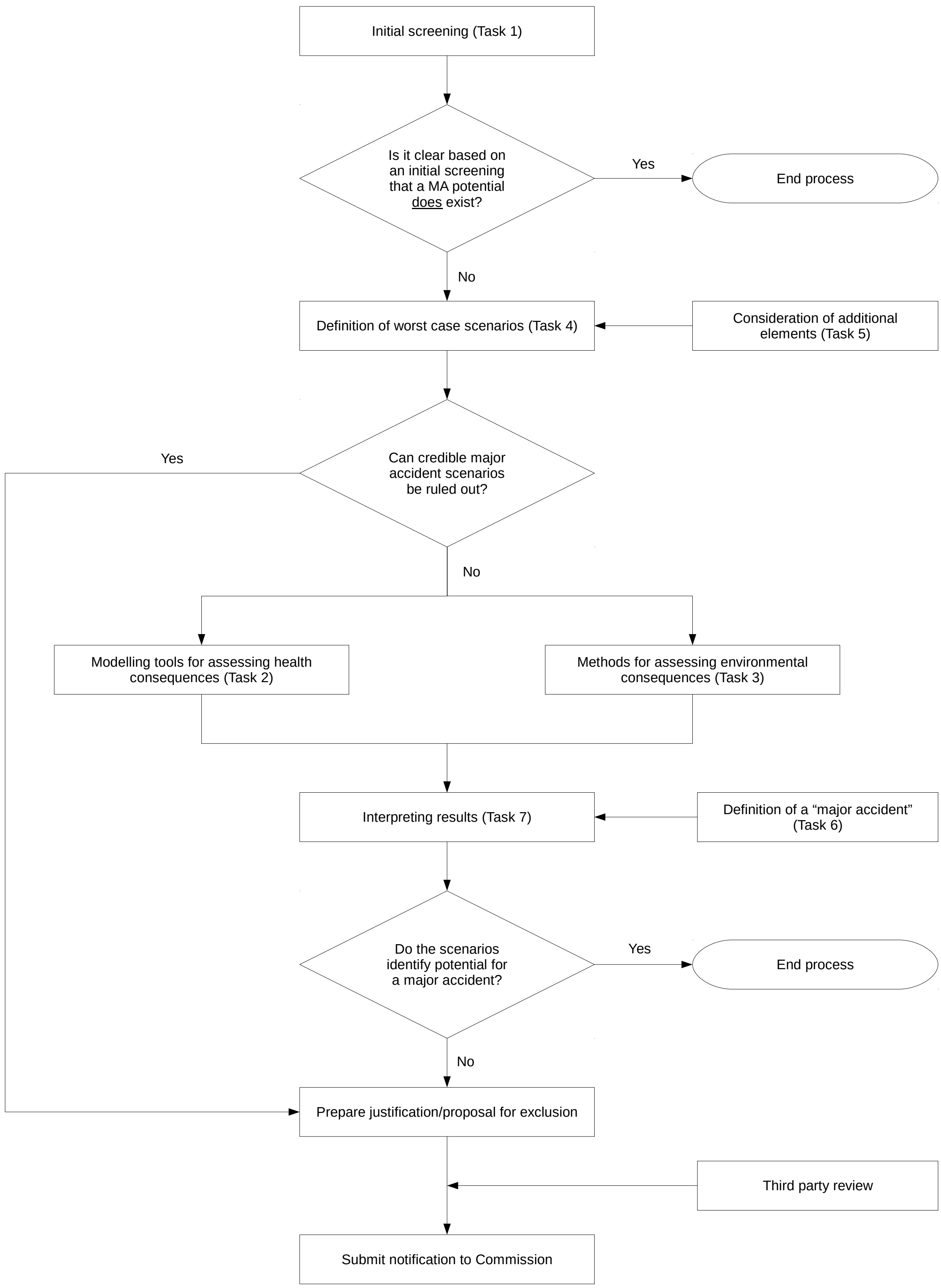
1.2 Scope of Task 7

The focus of the assessment methodology is on assessing the potential consequences of an accident in view of concluding whether the accident could be considered as “major” in the sense of Seveso III Directive. The assessment of the major accident potential of a certain substance should be “substance related” (e.g. physical form under normal processing or handling conditions or in an unplanned loss of containment and inherent properties), and should take into account external factors which could impact on the consequences of an accident. These conditions are referenced in Article 4 as “normal and abnormal conditions which can reasonably be foreseen”.

This part of the report concerns Task 7 on interpretation of assessment results within the decision making process. It involves establishing guidance on how to interpret the results of modelling exercises (Task 4 coupled with Tasks 2 and 3) and possible additional elements (Task 5), taking into account the guidance developed as regards the notion of “major accident” (Task 6).

The flowchart below provides a framework for making the link between the assessment stages considered in Tasks 1 to 5 and the elements provided in Task 6 on the definition of a major accident. This generalised approach constitutes possible steps of the assessment methodology suggested in the context of Article 4 of the Directive.

Figure 1.1 Flowchart of the overall assessment process



1.3 Structure of this report

The present report is divided as follows:

- Sections 2 to 5 provide a quick synthesis of the findings of the previous tasks and the main issues addressed.
- Section 6 provides a suggested approach for how to interpret the modelling results i.e. how to state whether the modelled accident scenario is a major accident or not. It suggests a decision grid that could be used to support the decision making process for human health consequences.
- Section 7 consists of a list of the main steps expected under each of the main parts of the assessment methodology.

2. Initial Screening

The objective of the initial screening is to eliminate those substances for which a potential for major accident hazard clearly exists. It aims at identifying whether a certain substance, based on its key physicochemical properties, could cause a release of matter or energy that could create a major accident. If it is clear from this initial screening that the substance has the potential to create a major accident, the process would be ended at this stage. If it is unclear, the assessment could be taken to the next step i.e. more detailed assessment. It is important to highlight that this initial screening does not aim at definitively identifying substances which could not generate a major accident, and then which could be excluded from the scope of Seveso III.

This stage has been divided into three steps, detailed in Task 1. Member states could follow one, two or the totality of these steps. Applying all steps would allow the member states to cover each of the key physicochemical properties highlighted in the first part of the Task 1 report to draw conclusions on the ability to cause dangerous phenomena in relation to those properties. The three steps are synthesised below:

Step 1: Seveso III scope

It should first be checked that the substance under assessment belongs within the scope of Seveso III. This step seems self-evident but it would help to ensure that time is not wasted in pursuing inappropriate cases.

Step 2: Analysis of past accidents and other assessments

Those substances that have already been involved in a major accident, with no more specific mitigating factors now (e.g. packaging) than there was at the time of the accident, can directly be eliminated from the assessment methodology. Those substances that have been implied in a major accident but which today are regulated at EU scale to be stored / handled in different conditions could warrant further assessment. Furthermore, other safety assessments identifying potential for major accident hazard should be checked. If safety reports or other known assessments have identified credible accident scenarios leading to conclusion of the potential for major accident hazard involving the substance, this is probably a good sign that the assessment should be ended at this initial screening stage.

Step 3: Index approach

This stage consists of ranking the potential for major accident hazard of the substance under assessment in relation to a similar substance (i.e. a substance having similar physicochemical properties and belonging to the same hazard category), or selection of other substances, based on the properties of those substances. If it is evident that the potential for major accident hazard of the substance under assessment is equal to or higher than the "reference" substance (or groups of substances), then it can be eliminated from the assessment methodology unless there are identified reasons why further analysis should be undertaken. If the comparison shows potentially lower accident potential than these reference substances, it is worthwhile proceeding to a more detailed assessment.

Guidance is provided in the Task 1 report as regards the choice of the reference substance.

This approach could be done by using one of more of the following ranking/index methods (although these are not intended to be exhaustive):

- Ranking methods for the acute toxicity aspects of the potential for major accident hazard of chemicals have been reviewed in Wilday (2010)[1]. Health hazard indexes highlighted in this document could be used in order to compare the potential for major accident hazard of the substance under assessment and the reference substance(s) as regard to health hazards. These take into account properties such as vapour pressure, melting point and molecular weight, as well as readily available data on acute LC_{50} values.

- As regards physical hazards, the most widely used hazard index is the Dow Chemical Company's Fire and Explosion Index (the Dow Index)[2]. A factor of this index may be used to rank the physical hazard potential of the substance under assessment and the reference substance(s).

- In terms of environmental aspects, a number of index methods were reviewed in the report on Task 3, such as the Czech H&V index and the Swedish Environment Accident Index (see Section 5). These could potentially be used to compare the relative scale of environmental impacts for the substance under assessment with other Seveso substances with (known) potential for generating a major accident.

Other points to consider

A further option for the initial screening would be to take the available data on the substance and information on its conditions of use, to answer a number of preliminary questions as to why the substance might be relevant for exclusion under Article 4. The idea at this stage would not be to come to a definitive conclusion, but to act as an additional check to see whether there are any overriding factors that mean further assessment is warranted (i.e. which might not have been picked up by the preceding steps). This approach would enable one to draw upon expert judgement to describe whether a substance seems like a credible candidate to take forward to more detailed analysis. If no credible argument can be made based on readily available information (without the need for detailed analysis), it is likely that the substance will have potential for major accident hazard if realistic worst-case (foreseeable) conditions across the EU are taken into account.

It is important to note that the hazard of a substance is intrinsic to the substance, but the risks are always related to the environment or the conditions of use. For instance, a flammable liquid used at a temperature well below its flash point has no risk of ignition: the hazard is still there, but there is no risk of the temperature exceeding the flash point.

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1 Wilday J, Trainor M, Allen J, Hodgson R, 2010, Development of a hazard index method to rank human acute toxicity aspects of major accident potential (not yet submitted).

2 AIChE, 1994, Dow's Fire & Explosion Index Hazard Classification Guide

Lees F.P., Loss Prevention In The Process Industries – Hazard Identification, Assessment and Control, Volume 1, 2nd Edition

Another consideration is in the case of mixtures. There may be some mixtures where substances are present at a sufficiently high concentration for classification of the mixture (according to the CLP regulation) for inclusion under Seveso, but where the concentration of the mixture is too low to produce critical effects that may lead to a major accident (e.g. generation of toxic gases). Such examples will be very case specific.

3. Defining Worst Case Scenarios

If further assessment is needed following the initial screening stage i.e. it is not clear that potential for major accident hazard exists, worst case scenarios in which the substance under assessment may be involved should be defined. Guidelines are provided in the Task 4 report. The development of worst case accident scenarios consists of the following:

Identify one or more “reasonably foreseeable worst case scenarios”.

The critical events in the scenario(s) depend on the type of substance concerned and the type of equipment used. Moreover, additional elements from Task 5 (e.g. packaging) should be taken into account.

These reasonably foreseeable worst case scenarios would be selected from all the physically possible accident scenarios for the substance under assessment, which could lead to the release of the highest energy potential, for example the full release of matter or energy due to catastrophic rupture of a tank.

As indicated in the Task 4 report, it may also become evident that there are no credible accident scenarios that could foreseeably lead to a major accident, for example on the basis of the substance properties or the full range of foreseeable operating conditions (e.g. negligible potential for dispersion). In such cases, there may be no need to undertake more detailed modelling and assessment of the consequences of potential accidents. The assessor would therefore need to compile the evidence and detail the scenarios considered (and discarded) in putting forward their notification for proposed exclusion.

Set the modelling parameters.

Certain parameters need to be fed into the accident scenarios in order to assess the intensities of the scenarios. For example meteorological conditions, quantities of substance involved and operating conditions are susceptible to variations. The parameters should be set at levels allowing the worst case scenario to be identified, both regarding the source term and the environmental conditions, taking into account EU-wide implementation. It is acknowledged that these conditions, especially those related to the environment, can vary hugely from one European country to another and one establishment to another.. Here again, additional elements from Task 5 (e.g. containment) should be taken into account.

The objective of the first step is to build event trees, constituting the reference accident scenarios, based on credible series of events. Guidance on defining worst case accident scenarios is provided in Task 4, based on the Methodology for Identification of Major Accident Hazards (MIMAH) developed in the context of the European ARAMIS project. The objective of the MIMAH approach is to define the maximum hazardous potential of an installation by predicting which major accidents could potentially occur on given equipment, without preconceptions on probability of occurrence. This seems appropriate in the context of Article 4 of Seveso III, but use of the MIMAH approach should not be considered as mandatory, and it is recognised that member states may wish to apply different approaches. Among the dangerous phenomena that may result from a scenario, some are chosen and others excluded, according to the physicochemical properties of the substance under assessment.

Additional elements such as containment and packaging play a role in the identification of accident scenarios. For example, a substance may be regulated at the EU level to be used in specific conditions, eliminating the risk of full release. Central events likely to occur are then dependent on these additional elements, which are covered in the Task 5 report.

The second step consists of modelling the consequences that may arise from the realisation of the identified scenarios, in the worst case conditions (assuming that credible accident scenarios have been identified). To model these situations, a number of tools may be used (Task 2), each of them requiring specific parameters. Factors that influence the extent of the consequences of an accidental release may be categorised as follows:

- Parameters concerning the conditions of the release i.e. the characterisation of the source term, considering feasible equipment types and taking into account the likely worst case situation across the EU.

  The source term conditions include pressure, temperature, quantity (e.g. maximum expected in EU, possibly based on a multiple of upper tier thresholds, largest storage tanks in use, etc.), release type (instantaneous, continuous), height, etc.

- Parameters concerning the conditions at the site at the time of the release i.e. the characterisation of the environment.

  This includes for example the terrain roughness, the meteorological conditions, obstacles and topography.

A similar approach can be taken for environmental consequences, though the available methods in this case are more variable and the assessment results subject to greater uncertainty and variability, given the wide range of environments encountered across the EU (Task 3).

The role of the additional elements previously mentioned is also important at this step, potentially influencing the source term conditions. For instance, a substance regulated at EU scale to be packaged in small quantities located in different areas on the site could be involved in the scenario in only limited quantities. Further considerations are given in the Task 5 report.

Furthermore, the parameters important to characterise the source term and the environmental conditions differ according to the type of dangerous phenomenon under assessment. For example, meteorological conditions greatly impact the modelling of an atmospheric dispersion but have no influence on the behaviour of a boil-over. A section of Task 4 highlights the important parameters for a number of dangerous phenomena.

Guidance provided in the Task 4 report mainly consists of suggestions on how to define and model accident scenarios in the context of Article 4. Those persons undertaking an assessment under Article 4 could decide to adopt alternative approaches where better suited to the particular case or substance under consideration. It is suggested that a third-party review should be undertaken to verify the accident scenarios identified and the modelling parameters chosen.

4. Estimating Human Health Consequences

Once worst case scenarios have been identified and the worst case parameters for source term and environmental conditions set, appropriate modelling tools should be used to assess the consequences of the scenarios identified in terms of human health consequences – unless it is obvious that there are no credible accident scenarios where modelling would shed additional light on the potential for a major accident.

The choice of the best suited tool should be justified related to the dangerous phenomena of relevance, the limitations set out for the tool and its validity domain. The modelling stage requires overpressure, thermal radiation and toxic concentration thresholds to be set in order to estimate different effect distances. These thresholds constitute vulnerability data for human beings. Once the results are obtained, several key issues should be kept in mind, like for example the uncertainties inherent in the modelling and the sensitivity of the parameters.

The specificities of the tools in terms of dangerous phenomena or validity domain should be documented in order to demonstrate the relevance of the tool and the validity of the results obtained in the context of the assessment methodology. It is suggested that the following are documented:

- A general description of the tool;
- The mathematical and physical models which form the basis of the tool;
- The tool's domain of validity;
- The tool outputs and a short evaluation of the tool robustness.

Template summaries have been developed in Task 2 for four of the most established modelling tools in Europe: PHAST (DNV), EFFECTS (TNO), ALOHA (NOAA-EPA) and FLUMILOG (INERIS). These can help to support with documenting the choice of the tool, where one of these models is used. If other tools are to be used, the four points listed above should be considered and reported on, in order to demonstrate why a particular modelling approach was selected.

Once a suited modelling tool has been chosen, worst case accident scenarios previously identified can be modelled using source term and environmental parameters that reflect the worst case conditions. The results of the modelling consist of effect distances i.e. spatial extent (area) of consequences. These effect distances are distances to different overpressure, thermal radiation or toxic concentration thresholds (according to the substance properties), which are to be set in the modelling tool. The thresholds used should take into account the different thresholds from the member states, as different thresholds are used because the approach to what is considered as a major accident is different. The Task 6 report provides further details about the different threshold values used.

The table below (Table 4.1) presents the thresholds used in the context of the European ARAMIS project.

Table 4.1 Effect thresholds to consider in the modelling stage based on the ARAMIS project

	Level 1 Small effect	Level 2 Reversible injuries	Level 3 Irreversible injuries	Level 4 Start of lethality
Thresholds for overpressure effects (in mbar)				
ARAMIS	<30	30 - 50	50 - 140	>140
Thresholds for thermal radiation (in kW/m²)				
ARAMIS - 60 sec	<1.8	1.8 - 3	3 - 5	>5
Thresholds for toxic effects				
ARAMIS	TEEL[1]-1 – TEEL-2	TEEL-2 – TEEL-3	>TEEL-3	

Note 1: Temporary Emergency Exposure Levels (TEEL) developed by the US Department of Energy and used in the ARAMIS project for setting default toxic release thresholds[3].

As explained in the Task 6 report, the use of these thresholds is considered appropriate in the context of Article 4 as they are already widely accepted and they consider the most stringent thresholds used among the member states. As a result, they can be set in the modelling tools to calculate the effects distances of the accident scenarios identified.

The validity of the chosen modelling tool must be assessed, relative to the set of input data fed into the tool and the distance range calculated. Indeed, modelling tools have been calibrated and validated for a certain set of conditions and distance ranges. For instance, regarding toxic or flammable atmospheric dispersion there is a wide set of conditions that have been tested: meteorological conditions, topography, types of substance, etc. Also the validity of the output data is of interest and extensive literature exists regarding the analysis of models/tools that provide reliable results within a certain distance range. In any case it is the user's role to ensure that the modelling results fall into the validity domain of the tool.

The expertise of the assessor plays a key role in both the interpretation of the results of modelling and the combination with human health thresholds. Thus, it is not infrequent that several users may obtain different results in terms of effects distances even if the same modelling tool was used and the same vulnerability data were taken into account. Therefore, it is important to underline the need for a third party review of the calculation of effects distances.

The MAHB modelling tool ADAM mentioned in the Task 2 report could potentially be used a benchmark modelling tool to cross-check the modelling results by the member state.

[3] Advanced Technologies and Laboratories International , Protective action criteria, http://www.atlintl.com/DOE/teels/teel/teel_pdf.html

5. Estimating Environmental Consequences

Once the worst case scenarios have been identified and the worst case parameters for source term and environmental conditions set, appropriate modelling tools or other assessment methods can be used to assess the consequences of the scenarios in terms of environmental impacts. The review conducted in Task 3 showed that (unlike the modelling tools used to assess the human health consequences) models, methods or guidance on the assessment of environmental consequences of accidents are less well documented in the literature.

Task 3 identified a number of different methods available and in use for the assessment of environmental consequences of accidents. Many of these share very similar characteristics and approaches, but there are distinct types of methods available. These range from qualitative approaches based mainly on expert judgement, through various approaches based on:

Indexes of environmental consequences

The examples provided in the Task 3 report are the Czech Hazard and Vulnerability (H&V) Index and the Swedish Environment-Accident Index (EAI). Other approaches are used in other member states.

Although the indexes are highly dependent on parameters related to the receiving environment and the quantities potentially released, they constitute examples where some of the key parameters influencing potential environmental consequences can be taken into account – such as water solubility, physical form, vapour pressure, viscosity – as well as the inherent hazards of a substance (typically based on LC_{50} values or similar). As a result, the use of these indexes is probably most suited to be part of the initial screening stage, where the environmental hazard potential of the substance under assessment can be compared to a reference substance (see Section 2). These methods are unlikely to be sufficient alone to conclude that a potential for major accident hazard does not exist.

Environmental risk assessment approaches

The United Kingdom and Spanish methods are described in Task 3.

Even though environmental risk assessments are usually very site-specific, they provide useful illustrations of some of the important factors that should be taken into account in assessing the potential for a major accident affecting the environment. The consequence assessment parts of both of these methods highlight key considerations such as:

- The importance of defining appropriate source-pathway-receptor relationships to identify how a release could affect different types of environmental receptors.
- The need to go beyond the Seveso Annex VI reporting criteria in deciding what constitutes a major accident (e.g. the UK approach includes a number of other criteria to define what constitutes a Major Accident to the Environment – MATTE).

- The need to undertake some form of modelling of dispersion of pollutants, though no particular models are specifically recommended in either method (nor within the present report) .

Approaches for estimating dispersion of substances in water

The approach in the paper published by Kontic and Gerbec and that in the Netherlands Proteus model are illustrated in Task 3.

Kontic and Gerbec's (2009) approach leads to the estimation of the extent of releases in a form that allows benchmarking against criteria such as those in Annex VI of Seveso, and is therefore of potential use in the context of Article 4. The specific models used in this paper are less important than the description of the overall approach to estimating dispersion of a substance following release (similar approaches are applied in safety reports in a number of different member states).

The Proteus model provides an approach whereby the source-term can be defined and effects of direct release to water bodies can be calculated. The results are not presented in directly comparable terms to e.g. those in Annex VI of Seveso, but it is understood that they could relatively easily be converted to such values.

Any or all of the above types of approaches may be useful in the context of a substance considered under Article 4 of Seveso. It is not considered to be appropriate to recommend any one method for use in this context, given the variety of different substances potentially of relevance in the context of Article 4. Instead, expert judgement will be needed based on the properties of the substance and its expected conditions of use to determine what method best demonstrates the potential (or not) for a major accident to occur. It may be that in some cases a reasoned argument based on the physicochemical properties of a substance could provide the main element of a demonstration of limited/no potential for a major accident (e.g. a substance used only as a liquid which solidifies under ambient conditions, illustrating no credible source-pathway-receptor linkages), rather than undertaking detailed modelling of environmental dispersion.

6. Interpreting Modelling Results

6.1 Environmental consequences

From Section 5, it appears that the nature of the results that may be obtained when assessing environmental consequences is very dependent on the type of approach used e.g. environmental index, extent of damage in the event of an accident, behaviour in case of release into water, etc. Because of this disparity, no particular approach is prescribed for the interpretation of modelling results regarding environmental consequences. It is likely that expert judgment will be needed to decide on whether the accident should be considered major as regards its environmental consequences. However, comparison against the Seveso Annex VI criteria would provide a sensible starting point.

Despite the heterogeneity of the nature of the results obtained following an environmental assessment, it is worth underlying that the Task 3 report provides guidance on the interpretation of major accident to the environment (MATTE). Criteria on the extent of damage in the event of an accident are provided for four types of environmental receptors: terrestrial habitats, freshwater habitats, marine habitats and groundwater bodies. They can be used to draw conclusions on the potential for major accident hazard of the substance under assessment. These are similar to, but go beyond, the criteria in Annex VI of Seveso III on notification of major accidents to the Commission. Regarding environmental consequences, Annex VI criteria are the following:

"*3. Immediate damage to the environment:*

- *Permanent or long-term damage to terrestrial habitats:*
  - *0.5 ha or more of a habitat of environmental or conservation importance protected by legislation;*
  - *10 or more hectares of more widespread habitat, including agricultural land;*
- *Significant or long-term damage to freshwater and marine habitats:*
  - *10 km or more of river or canal;*
  - *1 ha or more of a lake or pond;*
  - *2 ha or more of delta;*
  - *2 ha or more of a coastline or open sea;*
- *Significant damage to an aquifer or underground water: 1 ha or more."*

The United Kingdom's guidelines provide more specific information on the type of environment affected as well as figures for numbers of animals killed or injured, for example. Also the duration of harm is accounted for. This could provide a useful framework for demonstrating whether an accident involving an Article 4 candidate substance could cause an accident constituting a MATTE. Details can be found in the Task 3 report.

The approach also provides a useful framework for ensuring that all sources, pathways and receptors are considered in the context of reasonably foreseeable uses of a substance at Seveso establishments. Nevertheless, the approach is not specific about the use of any particular models for atmospheric dispersion or releases to water. A significant challenge remains in defining the range of environmental characteristics which may influence a substance's fate and behaviour following a release, when these can vary so significantly amongst establishments across the EU.

Overall, the Annex VI reporting criteria (for environmentally-relevant accidents) may provide a useful starting point against which to compare the results of any modelling undertaken, and in helping to conclude whether a major accident is impossible or not. However, these are not necessarily sufficient on their own, and consideration should be given to the approaches adopted in the member states and whether other criteria and effects should be taken into account in drawing conclusions.

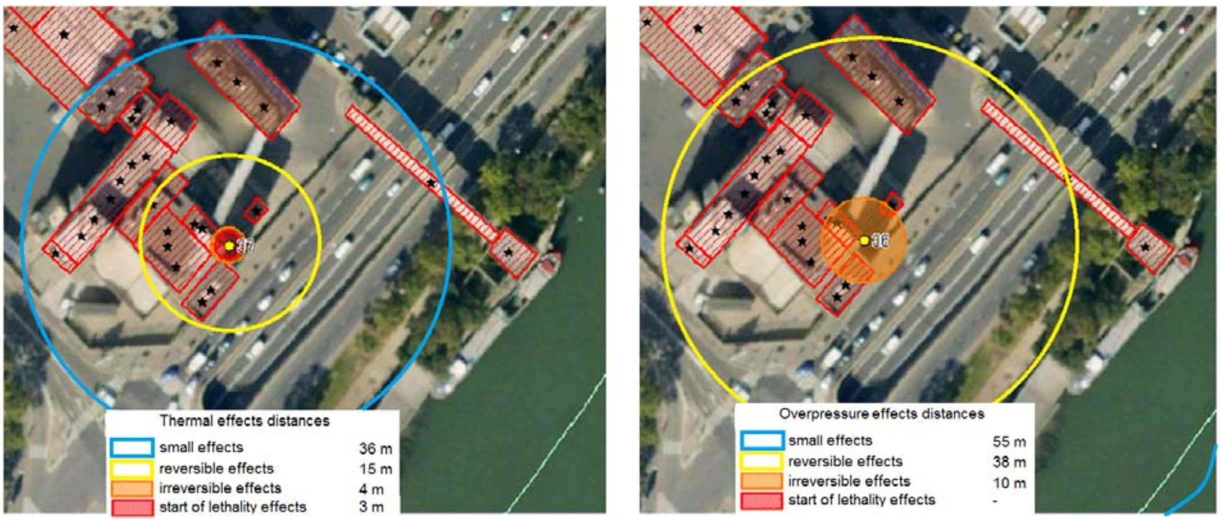
The following sections (Sections 6.2 to 6.7) address the interpretation of modelling results regarding human health effects.

6.2 Nature of the modelling results

Typical modelling results of an unconfined vapour cloud explosion (UVCE) are illustrated in Figure 6.1. Distances to four different thresholds are represented for thermal effects (on the left) and for overpressure effects (on the right). These correspond to the values in the ARAMIS project and are:

- Small effects;
- Reversible effects;
- Irreversible effects;
- Start of lethality effects.

Figure 6.1 Example of modelling results of a UVCE



This example highlights the two types of data that are obtained following the modelling stage:

- Different levels of effects generated: from small to start of lethality effects;
- Distances reached for each type of effect.

The distances will vary according to the substance characteristics, source term and environmental characteristics.

The interpretation of the modelling results will rely on these two types of data. The question to be answered is: "does the modelled accident constitute a major accident based on the distances reached for the different levels of effects?" This is further explored in the next sections.

6.3 General considerations about major accidents

Before undertaking a literature review about the different definitions of major accident used in member states, the Task 6 report recalls the definition used in Seveso III and the interpretation made by the JRC.

As defined in Article 3 of the Seveso III Directive, "major accident" means "an occurrence such as major emission, fire or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by this Directive and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances".

Based on this definition, the Joint Research Centre (2005)[4] highlighted three criteria to be fulfilled to qualify an accident as a "major accident":

- The accident must be initiated by an "uncontrolled development";
- "One or more dangerous substances" listed in Annex I of the Directive must be involved;
- The accident must lead to "serious danger" to human health, the environment or the property.

As highlighted in Task 6, the first two criteria are viewed as relatively unambiguous, unlike the third on "serious danger". Some direction regarding the interpretation of what can be considered "serious danger" can be found in Annex VI of the Directive, which has been drafted in order to identify major accidents that need to be reported by member states to the European Commission.

In the context of Article 4, member states could compare the results of the modelling stage with those criteria for reporting in Annex VI that are relevant to the type of accident scenario being considered. If one criterion is deemed to be met there should not be any exclusion from the scope of Seveso III. However, it should be noted that such a comparison is not readily feasible, especially for health effects, since no generally applicable hypothesis about the occupancy of the impacted area can be formulated. Guidance is given in Section 6.4 below on a possible

[4] Joint Research Centre, 2005, Guidance on the preparation of a safety report to meet the requirements of Directive 96/82/EC as amended by Directive 2003/105/EC (Seveso II), Institute for the Protection and Security of the Citizen. Report EUR 22113 EN

approach to conclude whether at least one criterion of Annex VI is deemed to be met, based on the levels of effects generated.

Moreover, Task 6 highlights that for the assessment methodology, the scale of effects should not be considered in isolation, but rather defined in relation to the distance at which the effects thresholds are exceeded. This idea is developed in Section 6.5.

6.4 Seveso Annex VI criteria and levels of effects

Annex VI of the Seveso III Directive aims at providing criteria for the notification of a major accident to the Commission. In the context of Article 4, some of these criteria can be used to determine whether an accident is deemed to be major regarding its consequences. It is emphasised that the Annex VI criteria do not define what a major accident is, and that a definition for major accident is included in Article 3 of the Seveso III Directive. Annex VI criteria are criteria for reporting accidents to the Commission. As highlighted in Task 6, some accidents may not meet any of the criteria and still be considered a major accident. Section 6.7.2provides further considerations.

However, these criteria provide one of the only sources of information (additional to Article 3) that include quantitative values to allow comparison with the results of consequence assessments. They are therefore considered to be of potential use to some assessors in the context of Article 4, but it should not be assumed that these criteria are sufficient on their own to determine whether a major accident is possible.

Key elements of the criteria are the following:

- Potential life-threatening consequences to one human (on-site or off-site);
- Potential health-threatening consequences and social disturbance involving a number of humans;
- Potential harmful consequences to the environment;
- Potential severe damage to property (on-site or off-site).

In the context of the assessment methodology, the levels of effects generated in case of an accident can be connected to some of the Annex VI criteria. The first two types of criteria, related to human health consequences, are of relevance here. They are recalled below:

"2. Injury to persons […]:

- *A death;*
- *Six persons injured within the establishment and hospitalised for at least 24 hours;*
- *One person outside the establishment hospitalised for at least 24 hours;*
- *[...]"*

The other criteria of this category are not usable in the context of the assessment methodology because they are site-specific and not readily comparable to the results of consequence modelling/assessment.

One approach that could be applied, as a first step, is to try to conclude whether at least one criterion of Annex VI is deemed to be met, based on the levels of effects generated. The table below (Table 6.1) specifies, for each level of effects, if at least one criterion of Annex VI would be deemed to be met.

Table 6.1 Level of harm and achievement of Annex VI criteria

<table>
<tr><th colspan="2">Level of harm</th><th>Annex VI criteria deemed to be met?</th></tr>
<tr><td>Level 1</td><td>Small effects</td><td>No</td></tr>
<tr><td>Level 2</td><td>Reversible effects</td><td rowspan="2">No if effects are located in the immediate surroundings of the loss of containment (see Section 6.5.1).

Otherwise, the following criteria could be met[1]:
- Six persons injured within the establishment and hospitalised for at least 24 hours
- One person injured outside the establishment and hospitalised for at least 24 hours</td></tr>
<tr><td>Level 3</td><td>Irreversible effects</td></tr>
<tr><td>Level 4</td><td>Start of lethality</td><td>Yes: one death</td></tr>
</table>

Note 1: The Annex VI criteria do not distinguish between reversible and irreversible effects.

The interpretations given below should be considered as guidance to decide whether the accident generated is major or not, based on its level of effects. They are only applicable in the context of the assessment methodology. It is recalled that the Annex VI criteria do not provide a definition of a major accident and that their use in the context of Article 4 does not imply a wider applicability.

Small effects lead to slight injuries for which no hospitalisation would be required. Hence, if only small effects are generated, none of the Annex VI criteria would be deemed to be met. If the distance reached by this level of effect is acceptable (see Section 6.5.2) then it can be concluded that the accident should not be considered a major accident.

If reversible or irreversible effects are generated, hospitalisation may be needed for at least 24 hours. However, if the effects are limited to the immediate area where the accident happened (e.g. the workplace), it is unlikely that six people or more would be exposed i.e. none of the Annex VI criteria would be deemed to be met and the accident would not be considered a major accident. Section 6.5.1 provides further considerations about what might be considered the surroundings of the loss of containment.

If “start of lethality” effects occur then at least one person could die, whatever the distance reached by this level of effect. A criterion of Annex VI is deemed to be met and the accident should therefore be considered a major accident. It is important to recognise that all accidents that could lead to one person being killed are necessarily considered major accidents in the context of the wider EU legislation. For example, worker protection legislation is a more appropriate means of addressing certain risks. However, in the context of a Seveso establishment, with large inventories of a dangerous substance, the potential to cause a death (due to that substance) is indicative of a loss of control within the establishment and hence an accident that could have been much worse.

6.5 Considering the distances reached

6.5.1 Area in the surroundings of the loss of containment

As underlined above, if reversible or irreversible effects only occur in the immediate surroundings of the loss of containment causing the accident, it seems unlikely that six people would suffer from these effects. The surroundings of the loss of containment can be the area around e.g. the workplace where the substance is handled, the tank where it is stored or processed, the pipe within which it circulates, etc. The idea is to use a distance within which it is unlikely to have more than 5 people. This is illustrated in Figure 6.2.

Figure 6.2 Illustration of the distance defining the area surrounding the loss of containment

It does not seem appropriate to prescribe a distance that could be representative of the area surrounding the loss of containment. A distance of 5 metres can be suggested as an example but it is acknowledged that as the conditions of use and environments are widely different across the EU, this may vary significantly. Member States assessing a particular substance could consider any other distance subject to solid argumentation of why no more than 5 people can be present in the area defined by the proposed distance. As the assessment methodology is to be followed at EU-scale, the justification should not be based on site-specific arguments.

This approach, which takes into account people within the establishment, should be supplemented by an approach that considers people in the vicinity of the establishment. This is the subject of the section below.

6.5.2 Area outside the Establishment

Underlying idea

The generation of reversible or irreversible effects beyond the surroundings of the loss of containment is considered a major accident if six or more people working on the site could be impacted (and hospitalised). The present section concerns the case where only small effects are generated, potentially impacting people outside the establishment. These people are less aware of the risk than workers and will thus have a lower tendency to accept the risk.

Risks to workers are covered by other legislation such as the Chemical Agents Directive and the ATEX (User) Directive. Workers who are handling substances are trained on their hazards and are aware about the level of risks to which they are exposed. This is not to say that accidents only affecting workers are not relevant (which of course they are), but rather to highlight that a lower level of harm may be considered acceptable for the general population (and hence the threshold for effects constituting a major accident may also be lower).

In this context, it seems appropriate to consider that if only small effects affect workers in the vicinity of the loss of containment of the substance, then exclusion could be possible (e.g. no deaths and no hospitalisations). However, if people outside the establishment are largely impacted by small effects, the (worst case) accident could be considered a major accident.

One approach to the interpretation of the expression "largely impacted" falls within the context of the approaches adopted by member states and their Competent Authorities with regard to land-use planning (LUP). Land-use planning policies are a relevant source of information on the interpretation of the dangerousness of Seveso establishments and their potential to create major accidents. It was within the remit of this project to consider whether cut-off values and distances used in land use planning could inform the decision-making process on whether a major accident is possible in the context of Article 4.

The review of member states' practices on restricting land use in the vicinity of Seveso establishments (Task 6) has found two main trends:

- The restriction of land use based on fixed zoning policies; and
- The restriction of land uses based on vulnerability levels.

The restriction of land use by zoning is based on the principle that uses of land that are not compatible with each other should be separated by specific distances (called safety distances). The idea behind this approach can be used and adapted in the context of the assessment methodology under Article 4, keeping in mind that the methodology is to be applied at a EU-wide level (i.e. site-specific conditions cannot be accounted for). If effects go beyond certain safety separation distances, it could be stated that people outside the establishments will be largely impacted i.e. the accident is a major accident.

In the context of Article 4, it does not seem appropriate to prescribe distances to be used in the assessment based on those applied in one country or another. One approach would be to take the most stringent (i.e. most conservative) approach whereby a relatively short value would be considered in relation to the distance at which relevant dangerous phenomena are predicted to occur. While the member states that use safety distances are set with reference to different variables (and as a result are not directly comparable), taking into account the range of distances applied by member states, and in particular the shortest distances, when interpreting the results of consequence models, provides an indication of whether a modelled accident scenario might be likely to be considered ‘major’.

An example of use of safety separation distances used in LUP covered in Task 6 is presented below. Member states putting forward a notification under Article 4 could, however, use any other safety separation distances subject to solid argumentation.

Indeed, based on feedback at the project workshop held in October 2014, there is considerable reluctance to use LUP safety separation distances directly in the context of Article 4. This is an important finding of the project, and an indication of an area that may require further research in the future.

Example of safety separation distances

As mentioned above, the safety distances of the LUP policies of various member states are set with reference to different variables. The approaches used are mentioned in the Task 6 report. An example of the use of one such approach in the context of Article 4 is provided below. Other methods may be more appropriate depending on the substance under consideration.

In Germany, the distance varies according to the substances used in the establishment whereas in Spain (Catalonia), it varies according to the type of dangerous phenomena that may be generated. Nevertheless, there is a direct link between hazardous substances and dangerous phenomena, highlighted in Task 1. Hence, even though the LUP distances set by Germany and Spain are not readily comparable, they rely on the same philosophy, that is the hazard potential of the substance in question and the fact that industrial areas cannot border directly on residential or other sensitive areas.

The distances set in the German and Catalonian LUP policies are summarised in the tables below (Table 6.2 and Table 6.3). These examples are presented because they are amongst the shortest distances used by the member states.

Table 6.2 German LUP distance requirements

Class 1 – distance required 200 m	Class 2 – distance required 500m	Class 3 - distance required 900m	Class 4 - distance required 1500m
Ethylene oxide	Oleum 65% (sulphur trioxide)	Sulphur dioxide	Phosgene
Acrylonitrile	Bromine	Hydrogen sulphide	Actolein
Hydrogen chloride	Ammonia	Formaldehyde (>90%)	Chlorine
Methanol	Hydrogen fluoride	Hydrogen cyanide	
Propane	Fluorine	HCN	
Benzene			

Table 6.3 Catalonian LUP distance requirements

Substance type	Dangerous phenomenon	Perimeter of the no self protection zone (in metres)[1]
Toxic gases and liquids with low boiling point	Toxic cloud	350
Extremely flammable liquefied gases	BLEVE	250
Very flammable liquid fuels in large distribution centres	Fires, explosions	250
Very flammable liquids (low boiling point)	Flammable cloud, explosion, jet fire	100
Flammable liquids	Pool fire	50
Other	Spills causing pollution	50

Note 1: With protective measures (e.g. physical barriers against thermal radiation and shock wave)

The general distance requirements set in Germany are based on consequence calculations using standard assumptions. The substances in Class 1 are mainly highly flammable liquids and gases, and those in classes 2 to 4 are, among others, corrosive, toxic, and dangerous for the environment. As a result, a comparison with Spanish LUP distance requirements could be made as presented in Table 6.4.

Table 6.4 Comparison between German and Catalonian LUP distance requirements

Catalonia		Germany	
Substance type	**Distance required (m)**	**Class**	**Distance required (m)**
Toxic gases and liquids with low boiling point	350	Classes 2 to 4	500 - 1500
Extremely flammable liquefied gases	250	Class 1	200
Very flammable liquid fuels in large distribution centres	250		
Very flammable liquids (low boiling point)	100		
Flammable liquids	50		
Other	50	-	-

In the context of the assessment methodology under Article 4, one approach would be to compare the distance to "small" effects from the modelling results to the shortest safety separation distance. As mentioned previously, the choice of the reference distance depends on the type of substance under assessment (i.e. on the type of dangerous phenomena that may be generated). The reference distances that could be used come from the German and Catalonian distance requirements (see Table 6.4) and are summarised in the table below (Table 6.5).

Table 6.5 Possible safety separation distances in the context of Article 4

Dangerous phenomenon	Layer to consider	Distance suggested (m)
Toxic cloud	Toxic effects	350
BLEVE	Thermal and overpressure effects	200
Fires, explosions	Thermal and overpressure effects	200
Flammable cloud, explosion, jet fire	Thermal and overpressure effects	100
Pool fire	Thermal effects	50
Spills causing pollution	-	50

This table constitutes an example of use of LUP distances prescribed in various member states. These distances have been considered as some of the only quantitative indicators available against which to compare the results of consequence modelling. However, a key conclusion from this study is that these are not sufficient on their own to allow a conclusion to be drawn as to whether a major accident is possible or not. For example, a cloud generating toxic effects could certainly still cause a major accident even if the distance to relevant toxic effects were less than 350 metres.

Therefore, these land-use planning distances may be of interest as a source of information on reference distances used amongst the member states, but additional arguments will need to be put forward by member states to demonstrate, for the specific substance under assessment, that the distances to relevant effects are not sufficient to constitute a major accident.

This is an area where further work would be required in order to reach a consensus on how to determine whether a major accident is possible or not in the context of Article 4.

6.6 Decision Grid

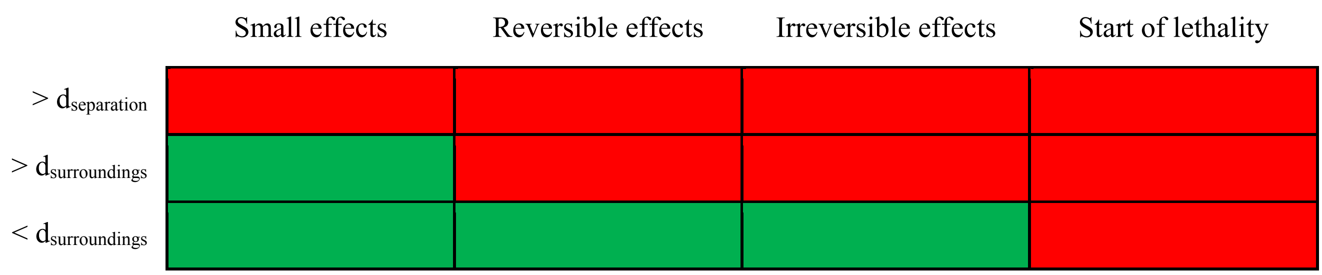
6.6.1 Presentation

A possible decision grid is presented below (Figure 6.3) based on the ideas developed in the previous two sections. As a reminder, these ideas are the following:

- If one criterion of Annex VI is deemed to be met, no exclusion should be possible;
- Impact on people outside the establishment should be limited i.e. if any effect distance exceeds a safety separation distance from the establishment (which may depend on the type of effects generated e.g. thermal, overpressure or toxic effects), no exclusion should be possible.

As with all parts of this assessment methodology, it should be reiterated that use of the approach presented here is not mandatory, and member states and other assessors are free to adopt other approaches, which will of course need to be justified as appropriate to the Commission and to other member states.

Figure 6.3 Decision grid suggested for the assessment methodology



(red)	No exclusion possible
(green)	Exclusion possible subject to demonstration of the robustness of the study
$d_{surroundings}$	Distance defining the area surrounding the loss of containment beyond which ≥ 6 people may be present at any one time (see Figure 6.2)
$d_{separation}$	Safety separation distance from the establishment (see Section 6.5.2)

If only "small" effects are generated, none of the Annex VI criteria would be deemed to be met. Hence, if the distance reached by "small" effects is lower than the relevant "safety separation distance" chosen by the assessor, (see Section 6.5.2) then it might reasonably be concluded that the accident should not be considered a major accident. If this is not the case, people outside the establishment could be largely impacted and the (worst case) accident should be considered a major accident. Further work is needed before any conclusions can be drawn on what an appropriate "safety separation distance" might be, and indeed these might vary from substance to substance.

If reversible or irreversible effects are limited to the immediate area where the accident happened (e.g. the workplace, the tank) none of the Annex VI criteria would be deemed to be met and it seems unlikely that the accident would be considered a major accident. However, if such effects go beyond the immediate surroundings of the loss of containment, six or more people could potentially be hospitalised for at least 24 hours i.e. the accident would be considered a major accident.

If "start of lethality" effects occur then at least one person could die, whatever the distance reached by this level of effect. A criterion of Annex VI is deemed to be met and the accident should therefore be considered a major accident.

6.6.2 Example of positioning in the decision grid

Consider the modelling results of the UVCE presented in Section 6.2 (see Table 6.6).

Table 6.6 Modelling results of a UVCE - Effects distances

	Scenario 1a Thermal effects distances	Scenario 1b Overpressure effects distances
Small effects	36 m	55 m
Reversible effects	15 m	38 m
Irreversible effects	4 m	10 m
Start of lethality effects	3 m	-

The positioning of scenario 1 (divided into its different types of effects: 1a for thermal effects and 1b for overpressure effects) in the decision grid is illustrated in Figure 6.4 below.

Figure 6.4 Modelling results of a UVCE positioned in the decision grid

	Small effects	Reversible effects	Irreversible effects	Start of lethality
> $d_{separation}$				
> $d_{surroundings}$	1a / 1b	1a / 1b	1b	
< $d_{surroundings}$			1a	1a

Note: if one "scenario" is positioned in a red box, it is sufficient to conclude that the potential for major accident hazard exists i.e. no exclusion should be possible.

In this specific example, the substance at the origin of the accident should not be excluded from the scope of the Seveso III directive. It could have been excluded if none of the red boxes were filled.

6.6.3 Further thoughts

The above decision grid enables one to make a decision that relies on the two types of data provided by the modelling results i.e. the levels of effects generated and the distances reached. Moreover, the effects on people both inside and outside the establishment are accounted for.

It is important to underline that the main idea behind the decision making process is based on the fact that certain levels of effects can reach certain distances. One should keep in mind the uncertainties inherent in the modelling results, highlighted in the Task 2 report. For a given set of inputs, the modelling results may not exactly match the real physical outcomes and they can differ from one user to another. Hence, in order to consider the modelling results reliable, the outcomes should be subjected to third party review.

Moreover, the Task 2 report mentions that the modelling tools are dimensioned for a certain distance range. Hence, there is a minimum distance below which the modelling results cannot be considered valid. Extensive literature exists regarding this topic. For example, the Yellow Book considers that the diffusion coefficients of Gaussian models are valid between 100 m and 10 km. However, integral models like jet models are considered valid in the near-field, provided there is no significant local effect. 3D models are expected to provide reliable results in the near-field and could be used in the context of Article 4 by setting generic worst-case conditions. Also, some other modelling tools have been dimensioned on small equipment and are thus able to provide valid results near the place of the loss of containment. As a result, when positioning the accident scenario in the decision grid, attention must be paid to the distance range validity of the modelling tool. If effects distances are out of the distance range, another tool should be used in order to refine the modelling in the surroundings of the loss of containment.

6.7 Possible Alternative Decision Grids

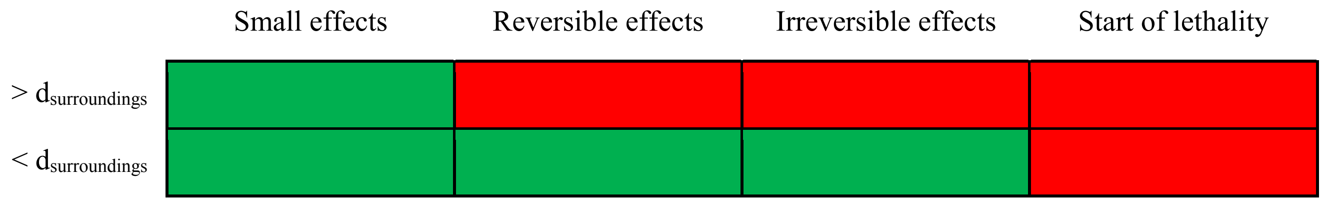
6.7.1 Consider only one Reference Distance

The decision grid suggested in Section 6.6 is based on two reference distances, which are the distance characterising the surroundings of the loss of containment and a safety separation distance (or several) from the establishment. It is not the purpose of the present report to prescribe either of these two distances. Instead, examples are provided and member states are free to use any other distances subject to solid justification.

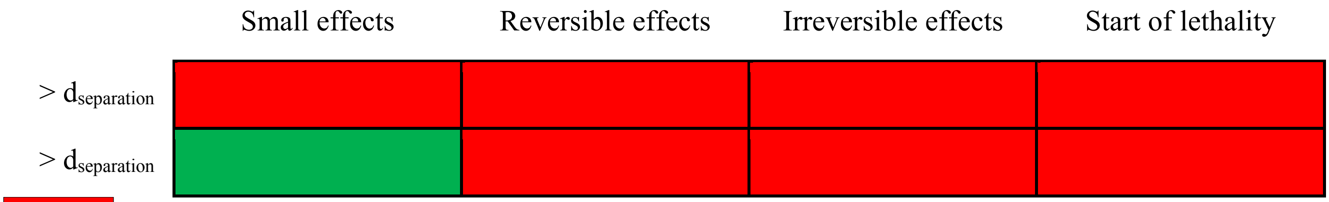
Two possible alternative decision grids are provided, each one based upon only one of the two reference distances. They are presented in Figure 6.5.

Figure 6.5 Alternative decision grids – One reference distance

Only the distance characterising the area in the surroundings of the loss of containment is considered:



Only the safety separation distance from the establishment is considered:



No exclusion possible

Exclusion possible subject to demonstration of the robustness of the study

$d_{surroundings}$ Distance defining the area surrounding the loss of containment beyond which ≥ 6 people may be present at any one time (see Figure 6.2)

$d_{separation}$ Safety separation distance from the establishment (see Section 6.5.2)

These grids may be easier to build because the choice of reference distances is limited to only one distance. However, they have the following shortcomings:

- When considering only the distance characterising the surroundings of the loss of containment, the decision-maker may overlook impacts on people outside the establishment. It may not be acceptable to affect people over large distances, even if effects are "small".
- When considering only safety separation distances from the establishment, the decision-maker may overlook the higher risk-awareness and hence the higher risk acceptance of the workers within the establishment. The resulting decision grid is very stringent, and perhaps does not take into account that some accidents in the workplace/ establishment are best managed through other legislation.

As a result, it appears that the combination of the two kinds of distances seems to cover most of the issues that can arise following a loss of containment (i.e. impact on workers and also people outside the establishment).

6.7.2 Beyond Annex VI criteria

As highlighted in the Task 6 report, the Annex VI criteria are to be used for notifying a major accident to the Commission and are not criteria for defining what is considered to be a major accident. Consequently, it could be possible to have an accident meeting one or several criteria of Annex VI which is not considered a major accident. Similarly, there may be other accidents which do not meet the criteria of Annex VI but which nonetheless are considered to be major.

Task 6 underlines that the extent of consequences of accidents described in the Annex VI criteria differ from the extent of accidents that initiated the negotiation for a Seveso Directive at a European level[5]. The Annex VI criteria may encompass some events which might be better classified as occupational accidents, whereas regulations and tools that aim at preventing and controlling major accidents typically focus the attention on accidental scenarios that cause dangerous effects to people or the environment outside an industrial site.

This idea is reinforced by Marshall (1985)[6] who wrote in a report reviewing annexes I, II and III of the original Seveso Directive:

"No one would contend that an accident which produces fatalities is not a serious accident. Nor would it be contended that an accident which killed, say, thirty people, is not a major accident. [...]

If fatality is to be the principal, though not necessarily the sole, criterion for determining whether or not an accident hazard is to be treated as a major accident hazard, it is necessary to decide on a level of fatality which represents the most probable level of realisation of a major accident hazard.

Many people die in industry from accidents which involve one or two fatalities. No one regards these as major accidents. On the other hand, an accident which killed twenty people would not fail to be regarded by the public as a major accident. The level of fatalities for a major accident could, therefore, be regarded as falling between 2 and 20. The Report suggests that the figure be taken as 10. 10 would be the central tendency, the most probable level of fatality resulting from the realisation of those hazards, which would just qualify as major accident hazards."

It is interesting to note that most of the quantity thresholds defined in Annex I Part 2 of the Seveso III Directive rely upon these reflections.

Based on these elements and on the fact that no exclusion should be possible if people outside the establishment are largely impacted by irreversible effects, an alternative decision grid could be as illustrated in Figure 6.6.

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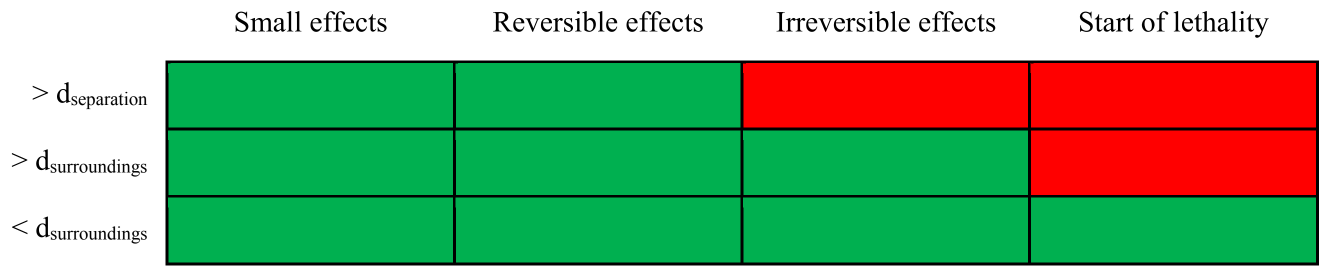
[5] The preamble to the Seveso III Directive highlights that "major accidents often have serious consequences, as evidenced by accidents like Seveso, Bhopal, Schweizerhalle, Enschede, Toulouse and Buncefield".

[6] Marshall VC, 1985, Implementation of the Directive on Major Accident Hazards of Certain Industrial Activities (82/501/EEC) – Article 19. Review of Annexes I, II and III. Final Report.

Figure 6.6 Alternative decision grid – Beyond Annex VI criteria



Red	No exclusion possible
Green	Exclusion possible subject to demonstration of the robustness of the study
$d_{surroundings}$	Distance defining the area surrounding the loss of containment beyond which ≥ 6 people may be present at any one time (see Figure 6.2)
$d_{separation}$	Safety separation distance from the establishment (see Section 6.5.1)

7. Synthesis of Possible Steps to be Undertaken in the Assessment Methodology

The table below (Table 7.1) is a suggested list of the main steps to be undertaken in undertaking an assessment in the context of Article 4. . This is a synthesis of the key steps described in earlier parts of the present reports and in the reports on Tasks 1 to 6.

It is recalled that each of these steps are only suggestions on possible approaches that can be applied and that none of the steps are prescriptive. It is hoped that the guidance provided is useful, but member states may choose to adopt all, some or none of the various steps in conducting their assessments under Article 4.

Table 7.1 Main steps to be undertaken in the assessment methodology

Steps		Examples	Issues
Initial screening (see Task 1) Objective: eliminate substances which clearly have the potential to generate a major accident			
1	Collect basic substance properties	Chemical name, CAS number, physical form in the context of use	
2	Check that the substance is not a named substance under Seveso III	See Part 2 of Annex I of Seveso III	
3	List the CLP hazard categories		If the substance has no harmonised (or notified) CLP classification, skip steps 4, 10 and 11.
4	Identify the hazard categories relevant under Seveso III	Hazard categories listed in Part 1 of Annex I of Seveso III	1st step of the initial screening. The substance should fall within the scope of Seveso III.
5	Specify the substance purity	Concentration of each component, solubility of the substance	A substance may be present in mixtures in different concentrations i.e. the risk is different. Every use across EU should be studied.
6	Collect intrinsic substance properties	Molar mass, density, viscosity, vapour pressure	
7	Describe substance-specific containment and operating conditions	Temperature and pressure operating conditions, volume, storage conditions	A number of containment and operating conditions may be identified across the EU. Each of them should be studied.
8	Specify incompatibilities if any	See Section 10 in material safety data sheet	
9	Check past accidents and other safety assessments		2nd step of the initial screening. • The conditions of occurrence of past accidents are site-specific. Substance-specific conditions should be identified. • Potential safety assessments in which the substance is involved should be valid at EU scale.

Steps		Examples	Issues
10	For every hazard category, list the relevant (readily available) parameters	See Table 4.1 in Task 1 (Part 1)	The link between hazardous properties and dangerous phenomena should be clearly identified.
11	Choose appropriate reference substances and calculate physical, health and environmental indexes		3rd step of the initial screening. The reference substances may not be readily identified. If so, this step would be omitted.
12	Consider additional elements that may suggest further analysis is warranted	Expert judgement on physicochemical properties, conditions of use, packaging, etc.	
Defining worst case scenarios (see Tasks 4 and 5) **Objective: identify accident scenarios in which the substance may be involved**			
1	Identify one or more reference accident scenarios i.e. worst case accident scenarios: • Define credible central events • Identify consequences in terms of events and dangerous phenomena that may be generated	In case of the use of MIMAH matrices: • Consider the physicochemical properties of the substance • Consider the type of containment or packaging Full loss of containment	• Different types of containment or packaging may be used across the EU. Each of these should be considered. • The scenarios identified should reflect the release of the highest energy potential. • Scenarios related to incompatible reactions should be studied. • The scenario should cover all process stages: basic operations, chemical reactions, storage, loading-unloading operations, pipework, etc.
2	Document the approach followed to identify the accident scenarios		If the approach used is not the MIMAH, information should be provided to assess the relevance of the approach used.
3	Determine whether there are accident scenarios warranting further analysis	Possible justification for exclusion based on physicochemical and other properties of the substance without undertaking detailed modelling.	• Physicochemical properties or other substance-specific data may preclude the use of modelling approaches (e.g. in case no dispersion is possible).
4	Choose the modelling parameters according to the dangerous phenomena identified: * parameters related to the source term * parameters related to the environment	 Maximum quantity released, burst pressure, worst release rates Worst case meteorological conditions, terrain roughness, obstacles	• Consider the type of containment or packaging • The choice of the source term modelling parameters should reflect practices across the EU in terms of conditions of use. • The modelling parameters should reflect the worst conditions
Modelling step - Human health (see Tasks 2, 5 and 7) **Objective: estimate effects distances generated by the identified dangerous phenomena on the human health**			
1	Choose the most relevant modelling tool: • Consider all dangerous phenomena to be modelled • Check the validity domain of the modelling tool (e.g. input data, distance range) and its limitations	See existing templates for a number of modelling tools. The proforma can be used to support the choice. Unreliable results under specific conditions (e.g. obstructed terrain), conservative assumptions when modelling certain dangerous phenomena	The best suited modelling tool should be selected and the choice justified.
2	Conduct the modelling:		

Steps		Examples	Issues
	• Use the previously defined modelling parameters (source term and environment) • Set vulnerability data for human beings to estimate specific effect distances: overpressure, thermal radiation and/or toxic concentration thresholds	Recommended use of the effects thresholds used in the European ARAMIS project: small effects, reversible effects, irreversible effects, start of lethality	
3	Critically appraise the modelling results: • Document the uncertainties of the modelling results and the parameters' sensitivity • Compare the modelling results with those obtained using e.g. the MAHB tool ADAM or a third party review	Inherent model uncertainties, variability of ambient conditions	The expertise of the user plays a key role. A third party review of the calculation of effects distances should be undertaken.
Modelling step – Environment (see Task 3) **Objective: estimate impacts generated by the identified dangerous phenomena on the environment**			
1	Check if there is a reasoned argument based on the physicochemical properties of the substance that could provide the main element of a demonstration of limited/no potential for a major accident regarding the environment	Substance used only as a liquid which solidifies under ambient conditions, illustrating no credible source-pathway-receptor linkages	
2	Select appropriate modelling/estimation method	Provided in Task 3 report	The choice of the best suited estimation method should be determined by expert judgment.
3	Conduct the modelling/estimation stage: • Identify the worst-case environmental conditions in terms of source term and environmental receptors identified • Set relevant thresholds for effects concentrations	Mass flow, characteristics of water bodies, water flow Aquatic LC_{50}, LC_5, LC_{50} multiplied by an assessment factor	There are many parameters that can influence the dispersion of a substance in the environment, both related to the source term and the conditions of the receiving environment. The worst-case environmental conditions expected across the EU should be identified (this may be a resource-intensive process).
4	Determine spatial extent of receiving environment affected		Consider the duration of harm
5	Undertake sensitivity analysis on source term and environmental receptor		It should be demonstrated that the range of environmental consequences are genuinely the worst-case.
Interpretation step - Human health (see Task 7) **Objective: determine whether the human consequences constitute a major accident**			
	Position the accident scenarios in the decision grid:		
1	• Choose the distance defining the immediate surroundings of the loss of containment	5 metres	The distance should be small enough so it is unlikely that more than 5 people will be present in the area.

Steps		Examples	Issues
	• Document the choice of the distance defining the surroundings of the accident		Justification is required. As the assessment methodology is to be followed at EU-scale, the justification should not be based on site-specific arguments
2	• Choose the safety separation distances delimiting a large impact on people outside the establishment	See Table 6.5 in Task 7	LUP distances can be used. The distances that are the shortest among the member states should be taken into account.
	• Document the choice of the safety separation distances delimiting a large impact on people outside the establishment		Justification is required, especially if distances are greater than those used for LUP purposes somewhere in the EU.
3	Check the distance range of the modelling tool and compare with the effects distances calculated	3D models are expected to provide reliable results in the near-field.	If effects distances are out of the distance range of the modelling tool, another tool should be used in order to refine the modelling in the surroundings of the loss of containment.
4	Position each scenario according to its different types of effects	1a for thermal effects, 1b for overpressure effects, 1c for toxic effects	
5	Draw overall conclusion on whether a major accident hazard can be excluded		As the decision making is based on the fact that certain levels of effects reach certain distances, one should keep in mind that uncertainties are inherent to the modelling results.
Interpretation step – Environment (see Task 3) **Objective: determine whether the environmental consequences constitute a major accident**			
1	Document potential accident in terms of spatial extent, possible effects on environmental receptors		The nature of the results that may be obtained when assessing environmental consequences is very dependent on the type of approach used. A significant challenge remains in defining the range of environmental characteristics which may influence a substance's fate and behaviour following a release, when these can vary so significantly amongst establishments across the EU.
2	If the results consist of extents of damages, use criteria to state on the potential for major accident hazard	Comparison with Annex VI criteria National approaches e.g. UK approach with a number of other criteria to define what constitutes a major accident to the environment	It would be relevant to go beyond the Seveso Annex VI reporting criteria in deciding what constitutes a major accident in terms of environmental consequences.