Directive 96/82/EC

"SEVESO II"
Article 9(6)

EXPLANATIONS AND GUIDELINES

Report EUR 18124

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Foreword

From 3 February 1999, the obligations of the "Seveso II" Directive (96/82/EC) will become mandatory for industry as well as the public authorities of the Member States responsible for the implementation and enforcement of the Directive.

The adoption of the Commission Decision of 26 June 1998 on *harmonised criteria* for dispensations according to Article 9 of the "Seveso II" Directive represents the last step necessary to make all provisions of the Directive, in particular the 'dispensation rule' of Article 9, paragraph 6 fully operational.

In order to contribute to a better understanding of the 'dispensation rule' as well as the Commission Decision on *harmonised criteria*, this document called "Explanations and Guidelines" has been elaborated by the same Technical Working Group (TWG 6) that prepared the *harmonised criteria*. The text of Article 9, paragraph 6 of the Directive and the Commission Decision can also be found in this document.

In particular, the guidance clarifies that

• an establishment benefiting from a dispensation remains subject to the provisions of the Seveso II Directive - see §1,

• an establishment benefiting from a dispensation will in general still be obliged to submit a Safety Report (containing limited information) - see §4.3,

• a dispensation cannot be granted on the basis of "active" safety measures, such as sprinklers - see §4.2.

This guidance is not legislation. It should not be considered mandatory and does not preclude other reasonable interpretations of the requirements in the Directive.

I would like to thank all members of TWG 6 (see list next page) for their commitment and valuable contributions to this document.

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EXPLANATIONS AND GUIDELINES
FOR THE APPLICATION OF THE DISPENSATION RULE OF ARTICLE 9, PARAGRAPH 6 OF
COUNCIL DIRECTIVE 96/82/EC
ON THE CONTROL OF MAJOR-ACCIDENT HAZARDS INVOLVING DANGEROUS SUBSTANCES

1. Introduction

Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances1 (the "SEVESO II" Directive) aims at the prevention of major accidents and the limitation of their consequences for man and the environment, with a view to ensuring high levels of protection throughout the Community in a consistent and effective manner.

Article 9 of the SEVESO II Directive requires that the operators of certain establishments that come under the scope of the Directive (so-called *upper tier* establishments; see chapter 3 "Scope" for a more detailed explanation) produce and periodically review a safety report and send it for examination to the national competent authority responsible for carrying out the duties laid down in the Directive.

Article 9, paragraph 6 of the SEVESO II Directive provides for possible dispensations, i.e. limitations of the information contained in safety reports to be granted by the competent authorities of the Member States, upon request from operators of *upper tier* establishments. It contains the following provisions:

> ***a) Where it is demonstrated to the satisfaction of the competent authority that particular substances present at the establishment, or any part thereof, are in a state incapable of creating a major-accident hazard, then the Member State may, in accordance with the criteria referred to in subparagraph (b), limit the information required in safety reports to those matters which are relevant to the prevention of residual major-accident hazards and the limitation of their consequences for man and the environment.***
>
> ***b) Before this Directive is brought into application, the Commission, acting in accordance with the procedure laid down in Article 16 of Directive 82/501/EEC, shall establish harmonized criteria for the decision by the competent authority that an establishment is in a state incapable of creating a major accident hazard within the meaning of subparagraph (a). Subparagraph (a) shall not be applicable until those criteria have been established.***
>
> ***c) Member States shall ensure that the competent authority communicates a list of the establishments concerned to the Commission, giving reasons. The Commission shall forward the lists annually to the Committee referred to in Article 22.***

The provision of Article 9 paragraph 6 is intended to avoid unnecessary administrative requirements if *particular substances* at a specific establishment are in a state incapable of creating a major-accident hazard. The decision concerning each establishment will be made by the competent Authority on a case-by-case basis. However, it is clear that any dispensation granted under this paragraph only relates to a limitation of information required in the Safety Report, and does not release the operator from other obligations under the Directive. The establishment will remain an upper-tier Seveso establishment.

This document is intended to provide further explanations and guidance to assist with the interpretation of the dispensation rule contained in the Directive. The guidance is not legislation Whilst it is not mandatory and does not preclude other reasonable interpretations, it reflects the interpretation of the Directive as agreed by the European Commission and the Member State Authorities.

2. Procedure and Time Frame

2.1. Procedure

The procedure referred to in Article 9, paragraph 6, sub-paragraph (b) of the SEVESO II Directive required the Commission to submit a draft of the *harmonized criteria* to the Committee of Competent Authorities2 (CCA) and the CCA to act as a Regulatory Committee3 (type IIIa) as set out in Article 16 of Directive 82/501/EC on the major-accident hazards of certain industrial activities4 (now known as the "SEVESO I" Directive). This article contains the following provision:

> ***Article 16***
>
> ***1. Where the procedure laid down in this article is to be followed, matters shall be referred to the committee by the chairman, either on his own initiative or at the request of the representative of a Member State.***
>
> ***2. The representative of the Commission shall submit to the committee a draft of the measures to be adopted. The committee shall deliver its opinion on the draft within a time limit which may be determined by the chairman according to the urgency of the matter. It shall decide by a majority of 54 votes, the votes of the Member States being weighted as provided for in article 148(2) of the treaty. The chairman shall not vote.***
>
> ***3. a) The Commission shall adopt the measures envisaged where these are in accordance with the opinion of the committee.***
>
> ***b) Where the measures envisaged are not in accordance with the opinion of the committee, or in the absence of an opinion, the Commission shall forthwith submit a proposal to the Council on the measures to be adopted. The Council shall act by a qualified majority.***
>
> ***c) If the Council does not act within three months of the proposal being submitted to it, the measures proposed shall be adopted by the Commission.***

2.2. Time frame

Article 9, paragraph 6, sub-paragraph (b) contains the obligation to adopt the *harmonized criteria* before the SEVESO II Directive is brought into application.

The SEVESO II Directive entered into force on the 20th day following that of its publication in the Official Journal of the European Communities, i.e. on 3 February 1997. According to Article 24, the Directive has to be implemented by 3 February 1999; hence from that date the obligations of the Directive should have been imposed on the operators and the competent authorities of the Member States responsible for the implementation and enforcement of the Directive. At the same time the SEVESO I Directive will be repealed.

The Commission Decision establishing the *harmonized criteria* was adopted on 26 June 1998, i.e. before 3 February 1999. It was published in the *Official Journal of the European Communities no.L192* on 8 July 1998.

2.3. Amendments to the harmonized criteria

The harmonized criteria may be modified by the CCA, acting as a Regulatory Committee under Article 21 of the Seveso II Directive. This procedure is similar to that described in 2.1 above.

3. Scope

This section explains briefly the scope of the Directive, and the scope of any dispensation, i.e. in respect of what substances a dispensation may be granted. It does not cover the consequences of a dispensation.

3.1. General explanation of the scope of the SEVESO II Directive

The scope of the SEVESO II Directive relates solely to the *presence of dangerous substances* in establishments. The term *'presence of dangerous substances'* is defined as the *actual* or *anticipated* presence of such substances or the presence of substances which may be *generated during loss of control of an industrial chemical process*.

Furthermore, the scope of the SEVESO II Directive follows a *two-tier approach*, which means that for each named substance mentioned in Annex I, Part 1 of the Directive and for each generic category of substances and preparations mentioned in Annex I, Part 2, two different *qualifying quantities* (threshold levels) exist, a lower and an upper tier.

It is assumed that the hazard associated with an establishment increases with the quantities of substances present at the establishment. Consequently, the Directive imposes more obligations on *upper tier* establishments than on *lower tier* establishments.

Article 9 only applies to *upper tier* establishments and these establishments are obliged to produce a safety report. Therefore only operators of such *upper tier* establishments can apply for a dispensation under Article 9, paragraph 6.

Therefore the first decision to be made is whether an establishment qualifies as an *upper tier* establishment. For this decision, all dangerous substances present at the establishment must be taken into account, irrespective of whether a dispensation may be applied for.

3.2. Substances subject to a dispensation according to Article 9, paragraph 6

Once an establishment qualifies as an *upper tier* establishment under the SEVESO II Directive, i.e. has one or more dangerous substances present in quantities equal to or above one or more qualifying quantities for the application of Article 9, the safety report must contain an updated inventory of the dangerous substances present in the establishment.

In other words, all substances present at the establishment that are *'dangerous substances'* as defined in Article 3, point 4 of the Directive must be considered even if their quantities do not meet the threshold levels set out in Annex I.

It follows that a dispensation can relate to any dangerous substances present at an establishment, irrespective of the qualifying quantities of the Directive. It is worth noting that a substance present in one part of an establishment, say one particular installation, may qualify for a dispensation when the same substance elsewhere in the establishment does not.

4. Terms used in Article 9, Paragraph 6

4.1. "... particular substances..."

This term covers only *dangerous substances* as defined in Article 3, point 4 of the Directive.

4.2. "... in a state incapable of creating a major-accident hazard..."

A particular substance is deemed to be "in a state incapable of creating a major-accident hazard" if it fulfils any of the generic criteria set out in the Commission Decision of 26 June 1998.

It may be demonstrated that particular substances are incapable of creating a major accident provided certain safety measures are in place and in effect. However, a dispensation will not be granted if the "state of incapability" relies on safety measures which are active in nature, such as sprinklers or fire doors.

Whereas the term *"incapable of creating a major accident hazard"* in sub-paragraph (a) relates to *particular substances*, it relates to the *establishment* in sub-paragraph (b). When looking at the text in subparagraph (b) it is important to emphasize the wording *"within the meaning of subparagraph (a)"*. The intent of subparagraph (b) is simply to state that harmonized criteria are required for the application of subparagraph (a).

4.3. "... limit the information required in safety reports to those matters which are relevant to the prevention of residual major-accident hazards and the limitation of their consequences for man and the environment."

A dispensation granted according to Article 9 paragraph 6 permits an operator to limit the information in the safety report to those matters which are relevant to the prevention of residual major-accident hazards. The term "residual major-accident hazards" can only relate to dangerous substances present at the establishment other than those for which the dispensation has been granted (either different substances or the same substance under different circumstances).

Therefore, in general, a dispensation will not release the operator from the obligation to submit a Safety Report.

5. Criteria

The approach chosen is to establish *generic* criteria rather than allowing dispensations for specific industries, sectors or activities. These criteria are flexible enough to encompass a wide range of industries, processes and substances within the scope of the SEVESO II Directive. A dispensation according to Article 9, paragraph 6 may be granted if at least one of the criteria set out below is fulfilled.

5.1. Physical form of substance

5.1.1. Criterion

Substances in solid form, such that, under both normal conditions and any abnormal conditions which can reasonably be foreseen, a release, of matter or of energy, which could create a major-accident hazard, is not possible.

5.1.2. Explanation

The fact that the physical form of certain substances influences their major-accident potential is recognised in the SEVESO II Directive. For example, the entry for nickel compounds only in *inhalable powder form* in the list of named substances in Annex I, Part 1 of the Directive reflects the fact that these compounds when in solid form are incapable of creating a major-accident hazard, yet are classified as being *toxic*.

5.2 Containment and Quantities

5.2.1. Criterion

Substances packaged or contained in such a fashion and in such quantities that the maximum release possible under any circumstances cannot create a major-accident hazard.

5.2.2. Explanation

This criterion can only be applied if the quantities taken out of containment at any one time are insufficient to create a major-accident hazard.

This criterion could be applied to a store of containers of such size, construction, and contents that the release from a small number of containers would not in itself represent a major-accident hazard nor could it have any knock-on effects on other containers, provided that no reasonably foreseeable external aggression could release the contents of a large number of containers.

5.3. Location and Quantities

5.3.1. Criterion

Substances present in such quantities and at such distances from other dangerous substances (at the establishment or elsewhere) that they can neither create a major-accident hazard by themselves nor initiate a major accident involving other dangerous substances.

5.3.2. Explanation

A large establishment consisting of several installations may have dangerous substances in small and isolated quantities at installations distant from those which represent the major-accident hazard potential, and also from any other hazardous establishments.

The inability to cause a major accident, directly or indirectly, must apply to the substances concerned at all moments that they are present at the establishment. It should also be borne in mind that substances will have to be transported within the establishment, and during transport this criterion may not apply.

5.4. Classification

5.4.1. Criterion

Substances which are defined as dangerous substances by virtue of their generic classification in Annex I Part 2, but which cannot create a major-accident hazard, and for which therefore the generic classification is inappropriate for this purpose.

5.4.2. Explanation

Since the generic classifications of Annex I, Part 2 are based on the intrinsic hazard associated with a substance, there may be cases where this is not relevant in the context of a major accident.

This criterion could apply to a substance which is classified as toxic, but for which the only hazard is toxicity by ingestion, provided that route of exposure can reasonably be excluded in the event of a major accident.

This criterion cannot apply to substances which are listed in Annex I, Part 1.

6. Application for a dispensation according to Article 9, Paragraph 6

6.1. Application by the operator of an upper tier *establishment*

6.1.1. Time limits for the submission and review of safety reports

For *new* establishments, the safety report has to be sent to the competent authority within a 'reasonable period of time' prior to the start of construction or operation.

For *existing* establishments and installations previously covered by the SEVESO I Directive, the safety report has to be sent to the Competent Authority by 3 February 2001.

For *existing* establishments not previously covered by the SEVESO I Directive, the safety report has to be sent to the Competent Authority by 3 February 2002.

The safety report must be reviewed and, if necessary, updated
- at least every five years or
- at the initiative of the operator or at the request of the competent authority, where justified by new facts, new technical knowledge about safety or about hazard assessment, or

in case of a *modification* of a site, which means modification of the establishment, the installation, the storage facility, the (chemical) process, the nature of dangerous substance(s) or the quantity of dangerous substance(s).

6.1.2. Appropriate time of application for a dispensation

The operator must submit an application for a dispensation to the competent authority within a reasonable period of time before the expiry of the deadline(s) before which he has to send the safety report to the competent authority. If the operator wishes, he may submit, along with this application, the limited safety report which may be required in the event of his application being successful.

In this context, a *reasonable period of time* means that the competent authority must have sufficient time to examine the application, including, if necessary, further requests for information and/or on-site inspection, and, following the decision by the competent authority, the operator must have sufficient time to take account of this decision, i.e. to complete his safety report in the case of a negative decision or to make reference in the safety report in the case of a positive decision (see point 6.4. below).

In the case of *new* establishments, the operator may prefer to submit the application for a dispensation together with a limited safety report. This is because in these cases - contrary to the cases where establishments are already in use - the bringing into use of the *new* establishment depends on the competent authority's communicating to the operator the conclusions of its examination of the Safety Report.

Submitting the application for a dispensation together with a limited safety report may also be appropriate in the event of *modifications* to existing establishments.

6.2. Contents of an application

An application for a dispensation should include the following details:

a) the name or trade name of the operator and the full address of the establishment concerned;

b) the registered place of business of the operator, with the full address;

c) the name or position of the person in charge of the establishment, if different from (a);

d) a general description of the activities of the establishment, and specific information concerning the installation for which a dispensation is being sought;

e) the immediate environment of the establishment, to the extent relevant to the application;

f) description of the dangerous substance(s) for which a dispensation is requested:

1. inventory of dangerous substances including
   - the identification of dangerous substances: chemical name, CAS number, name according to IUPAC nomenclature, classification;
   - the maximum quantity of dangerous substances present or likely to be present;
2. physical, chemical, toxicological and ecotoxological characteristics;
3. physical and chemical behaviour under normal conditions of use and under foreseeable accident conditions;

g) the criterion or criteria under which a dispensation is being sought;

h) the operator's demonstration that the criterion is applicable (for each criterion concerned);

i) the limitation of information in the safety report which is being requested.

6.3. Reference in the safety report

In any safety report for which the information required has been limited by a dispensation, reference should be made to the dispensation concerned.

6.4. Information for the public

As Member States shall ensure that the safety report is made available to the public, the public should also have access to the information that leads to permitting an operator to limit the information contained in the safety report, subject to restrictions concerning confidentiality.

7. Duties of the Competent Authorities when granting a dispensation

The competent authority should examine the application put forward and should within a reasonable period after receipt of the application communicate the conclusions of its examination to the operator, if necessary after requesting further information and/or after making an on-site inspection.

The administrative act by which a dispensation is granted should specify to which substance(s) the dispensation applies, what part of the establishment is concerned, what are the conditions of the dispensation's continuing validity, and what information is not required in the safety report.

8. Communication by the Member States of a List of Establishments for which dispensations have been granted to the Commission; Information from the Commission to the Committee of Competent Authorities (CCA)

8.1. Notification of establishments for which dispensations have been granted

The Member States will notify dispensations granted to the Commission.

The notification should be made as soon as possible after the dispensation has been granted. It should contain the following details:

a) the name or trade name of the operator and the full address of the establishment concerned;

b) a brief general description of the activities of the establishment, and information concerning the installation for which a dispensation has been granted;

c) the particular dangerous substance(s) for which a dispensation has been granted;

d) the reasons for the dispensation, with reference to the harmonised criteria.

8.2. Information for the Committee of Competent Authorities (CCA)

The Commission will establish a database containing information on dispensations notified by the competent authorities of the Member States.

A consolidated list of establishments for which dispensations have been granted will be forwarded to the Member States on an annual basis. It will contain the information mentioned under point 8.1 above.

8.3. Review of the scope of the SEVESO II Directive in specific cases

Should cases be notified to the Commission where operators of upper tier establishments can demonstrate that all dangerous substances present at their establishment are in a state incapable of creating a major-accident hazard and that therefore no major-accident potential resides, the Commission will review the scope of the SEVESO II Directive in the light of these cases, and submit a report on the subject to the CCA.

European Commission

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This document addresses the harmonized criteria which the European Commission has established for the application of the dispensation rule of Directive 96/82/EC ("Seveso II"). The document has been drawn up by a Technical Working Group (TWG) of representatives from the Commission and from Member States.

After a foreword in English from Jürgen Wettig of DG XI/E/1 Chairman of the TWG, the document presents, in all 11 official languages of the European Union, the text of the Official Journal with the Commission's decision, and a document explaining this decision and giving guidelines as to procedures to be followed.