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# The Seveso II directive: guidance and fine-tuning

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#### Abstract

This paper discusses two activities connected with the Seveso II Directive: 'fine-tuning', or the further consideration of topics which could not be not definitively resolved in the course of agreeing to the Directive; and 'guidance', or the preparation of non-binding suggestions and interpretations in technical domains where the Directive's provisions require further development. Both activities are carried out primarily in EU Technical Working Groups ('TWGs'). The paper finishes with some personal conclusions about the nature of the process and its results. © 1999 Elsevier Science B.V. All rights reserved.

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# 1. Introduction

Legislative acts in general, and especially Community Directives, aim at setting down the overall legislative requirements to be met. When the area covered has a substantial technical and scientific component, this often means that there are technical areas which are not fully defined in the legislation, either because the state of scientific knowledge or of industrial practice is evolving, or because setting down the legislative requirements only gives limited guidance as to how to fulfil them.

Both these possibilities occur in the case of the Seveso II Directive. <sup>1</sup> and they have led to action by the European Commission and the Member States, even before the Directive comes into application, to help to complement, and in some cases to fine-tune, the legislative requirements.

In most cases where further technical work is needed, this is being carried out by a Technical Working Group (TWG) set up under the Directive, with the Commission

<sup>&</sup>lt;sup>1</sup> Directive 96/82/EC of 9/12/1996, published O.J. of the E.C., No L 10 of 14 January 1997.

No.	Торіс	Finished?	
TWG2	Inspection systems	No	
TWG3	Content of the safety report	Yes	
TWG4	Safety management systems	Nearly	
TWG5	Major hazard in land-use planning	No	
TWG6	Harmonized criteria under Art. 9(6)	Yes	
TWG7	Substances dangerous for the environment	No	
TWG8	Carcinogens	No	

Table 1 List of TWGs referred to in the text

TWG1, which drew up a gravity scale for accidents reported under the Seveso I Directive, is not discussed here.

supplying both the Chair and the Scientific Secretary for the TWG, and with experts from Member State Authorities, and usually representatives of other interested groups, taking part in the TWG's discussions.

In all cases, the TWG ultimately reports to the Committee of Competent Authorities ('CCA'), which is the official committee established under the Seveso Directives, with representatives of the Commission and the Member State Authorities.

In this paper the various technical areas covered by the TWGs are discussed, and the state of the TWG's deliberations at the time of writing is set down (Table 1). The areas are divided first into two groups: those where fine-tuning (including modifications and possible extensions) of the Seveso II Directive is being considered, and those where there is felt to be a need for guidance on the implementation of the Directive. In each case there are some subjects which have been or are being dealt with by means other than TWGs, and these are also briefly discussed here.

It will be understood that many of the topics here refer to work in progress, and that therefore this paper can only give a snapshot of the situation at the time of writing (May 1998). All the guidance documents referred to here are obtainable on request from the Community Documentation Centre on Industrial Risk ('CDCIR').<sup>2</sup>

#### 2. Fine-tuning

In the course of the discussions on the Directive, various areas came under consideration, either because of uncertainties in scientific knowledge or because of differences of opinion between Member States, or between the Council and the Parliament. In most cases the differences were resolved by discussion, but four particular areas remained to be further investigated after the passing of the Directive.

#### 2.1. Carcinogens

The Seveso II Directive included within its category of named substances (Annex 1, Part 1), a list of ten carcinogenic substances, for which a very low quantitative threshold

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was set, so that an establishment with 1 kg of any of these substances would be classed as a top-tier Seveso site. This list of substances with its associated threshold was essentially carried over directly from the Seveso I Directive.

There is no doubt that the substances listed have extremely unpleasant properties; indeed, in an effort to restrict their use, some of them have been banned. However, doubts remain as to whether the list of substances, and the associated threshold, are appropriate. These doubts arise from two principal sources.

Firstly, the categorising of carcinogens reflects the difficulty, for many substances, of making a definitive decision as to whether a substance is carcinogenic to humans. For this reason, carcinogens are categorised not according to the potency of their carcinogenic effect but according to the strength of the evidence of their carcinogenicity; and while there may be some correlation between the strength of evidence and potency of effect for substances with a long history of industrial use, this is not necessarily the case for new or rarely-used substances. Animal experiments have shown that substances within the same carcinogenic category can vary in potency by a factor of more than  $10^9$  [1].

Secondly, little is known about the effect of short-term exposure to carcinogens. In general, studies have concentrated on long-term exposure. This means that it is not clear in principle how to go about establishing the effects of exposure as the result of an accident, which is the usual starting point for any analysis of the consequences of a particular accident scenario, and hence for the consequences of the presence of a given quantity of a substance.

For these reasons, when the proposed Directive came before the Council of Ministers, the Council, while approving the list of carcinogens proposed by the Commission, expressed the following reservation:

The Council and the Commission acknowledge the need to evaluate the list of carcinogens in Part 1. The Council accordingly invites the Commission in conjunction with the Member States to examine in depth the substances to be retained and their appropriate qualifying quantities in the light of criteria such as their environmental persistence and the risks arising from exposure thereto, within the framework of the objectives of this Directive. Not later than two years after the entry into force of the Directive, the Commission will submit a report on the subject together, if appropriate, with a proposal for amending the list of carcinogens in Part 1.

An expert meeting was therefore called in June 1997, with the help of experts from the European Chemicals Bureau<sup>3</sup> to discuss the scientific underpinning for the substances and thresholds chosen. At this first meeting it was agreed that the group of

<sup>&</sup>lt;sup>3</sup> The European Chemicals Bureau ('ECB'), like the Major Accident Hazards Bureau, is based at the European Commission's Joint Research Centre site at Ispra. The ECB carries out various tasks connected with the regulation of industrial chemicals, including classification and labelling according to Council Directive 67/548/EEC of 27 June 1967, published O.J. of the E.C., No. 196 of 16 August 1967 and its amendments.

experts nominated by the Commission and the Member States had sufficient expertise in the technical domains concerned at least to enable significant progress to be made, and so, with the agreement of the CCA, the group was constituted as a Technical Working Group (no. 8).

The group is currently investigating, on the one hand the chemical properties and industrial use of the 10 carcinogens named in the Directive, and on the other hand the criteria to be used for evaluating these and other substances candidates for inclusion in a list of carcinogens.

#### 2.2. Substances dangerous to the environment

The Seveso I Directive—at least as reflected in the initial implementing member state legislation—is essentially concerned with accidents affecting man; to the extent that the environmental consequences of accidents are considered, they are primarily seen as an indirect means of harming people. Various accidents over the intervening years (most famously the Schweizerhalle accident of 1986, in which the Rhine was polluted by fire-fighting water after a fire in a chemical warehouse) drew the attention of the public to the direct environmental dangers of accidents, and accordingly the possibility of major accidents involving substances dangerous to the environment is addressed in the Seveso II Directive. Thus, within the list of generic categories of substances covered (Annex 1, Part 2) there are included substances which are dangerous to the aquatic environment. <sup>4</sup>

However, it became clear in discussions that there was no clear consensus on the qualifying quantities to be assigned to such substances, partly because of a lack of information about the environmental effects of accidents in the past. The Council of Ministers noted this:

The Council and the Commission acknowledge the need to evaluate the qualifying quantities assigned to substances dangerous for the environment in Part 2. To this end, the Council requests the Commission to carry out a detailed examination, in co-operation with the Member States, of the appropriate qualifying quantities for this category of substance, in the context of the objectives pursued by this Directive. The Commission will submit a report on this matter as soon as feasible, accompanied if appropriate by proposals for amending the qualifying quantities assigned to the substances in question.

A Technical Working Group (no. 7) was therefore set up with the help of experts from the ECB in 1997 to study the quantities. When the group met, it was agreed that the objective to be aimed at in setting the threshold quantities for different types of substance was that of 'equivalence of harm'—in other words that the threshold

<sup>&</sup>lt;sup>4</sup> Presumably, the reason for considering only the aquatic environment is connected with questions of dispersion, persistence and mitigation measures: a single release of a substance into the air is likely to have serious consequences only if the substance is harmful to man (and therefore will be covered by other categories), while a release to the soil can be more easily mitigated than one to water.

quantities for substances toxic to the marine environment should be such that an establishment holding these quantities would have approximately the same capacity to cause harm in the event of an accident as an establishment holding the corresponding threshold quantities of, say, a substance toxic to man. However, to attain this objective requires a methodology for comparing harm to the aquatic environment with harm to man, and no such generally agreed methodology exists.

In the course of discussions, however, it became clear that none of the Member States were in favour of raising the threshold quantities; the question was whether or not they should be lowered, and if so by how much. However, before this could be decided, information was needed both about past accidents which had had environmental effects, and about the industrial use of substances of the categories concerned. This would enable an evaluation of the industrial impact of various possible thresholds; it might also enable group members to obtain more concrete information about the hazards involved with particular substances. The group is currently gathering further information on these topics, and is expected to meet again during 1998.

# 2.3. Limitation of information required in the Safety Report

What if certain establishments are able to demonstrate that, despite their holding more than the threshold quantities of hazardous substances, there are good objective reasons why these substances, at the particular establishment concerned, cannot actually cause a major accident? Would it not be appropriate to reduce the administrative burdens on the operators of such an establishment by waiving the requirement to submit a Safety Report? And what if this were true of some but not all substances present at an establishment—could the Safety Report required be in some way limited?

These questions were raised by some Member States in the course of discussions of the new Directive. While other Member States were not in principle opposed to the idea, there was fairly wide agreement that the criteria to be used for granting such 'waivers' or 'dispensations' should be agreed at Community level, even if their actual application would remain the responsibility of the Member State concerned.

The provisions of Article 9(6) were therefore inserted into the Directive, as enumerated below.

(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<sup>5</sup> of Directive 82/501/EEC, shall establish harmonized criteria for the decision by the competent authority that an

<sup>&</sup>lt;sup>5</sup> Article 16 of Directive 82/501/EC makes provision for the CCA to act in certain matters as a Regulatory Committee (of type 3(a), for those familiar with EU 'Comitology').

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.

It will be seen that a tight timetable was thus laid down for the development of the harmonized criteria required, in that they have to be formally adopted by the Commission before the Seveso II Directive is brought into application; indeed the urgency increased further when it became clear that some Member States wished to have a definitive decision on the harmonised criteria to incorporate in legislation to be put before their legislatures in the course of 1998. The TWG (no. 6) which was established to draw up these criteria was therefore required to work particularly rapidly. Between November 1996 and March 1998 five meetings of this TWG were held, and harmonised criteria were indeed agreed, along with an accompanying guidance document.

Under these criteria, a substance can be regarded as incapable of creating a major-accident hazard if it fulfils any one of four broad generic criteria: physical form, location, containment or classification. It is important to note that these criteria do not affect the scope of the Directive. This has two consequences, as discussed below.

Firstly, that the calculation initially made to decide whether an establishment comes under the provisions of the Directive must consider all substances present at the site, irrespective of whether they may turn out to be covered by a dispensation.

Secondly, that a Seveso II site remains a Seveso II site, and hence comes under the other provisions of the Directive (e.g. Articles 5, 6 and 10) even if the Competent Authority concerned should agree that the criteria are satisfied with respect to all the substances present.

At the April 1998 meeting of the CCA, the Member States' representatives unanimously consented to the Commission's proposal for the harmonised criteria. At the time of writing, these criteria are in the course of formal approval by the Commission, and they will probably be formally agreed and published before this paper. The guidance document is also in the course of publication.

## 2.4. Pipelines [2]

Pipelines are generally recognised as the safest way to transport hazardous substances. Nevertheless pipelines transporting hazardous substances have the potential for creating major-accident hazards. Although the view has been expressed that pipelines should be brought into the scope of EU legislation on major-accident hazards, this view is not universal, and is certainly not accompanied by a consensus as to how to do so. Therefore the following recital (or 'whereas' clause) was added to the Seveso II Directive in the course of its passage through Parliament and Council:

Whereas the transmission of dangerous substances through pipelines also has a potential to produce major accidents; whereas the Commission should, after collecting and evaluating information about existing mechanisms within the Community for regulating such activities and the occurrence of relevant incidents, prepare a communication setting out the case, and most appropriate instruments for action in this area if necessary

In accordance with this request, the Commission has:

• sent a questionnaire to Member States on their existing legislation, co-sponsored <sup>6</sup> two workshops and a consultants' study, invited views from European industry federations, and carried out a cost-benefit analysis.

As a result of this work, it became clear that there was wide variety among Member States, some having extensive 'major-accident hazard' legislation covering pipelines while others do not. It would appear that an EU initiative could therefore improve the situation, but it would be preferable for such an initiative to aim to 'fill gaps' and not require the modification of existing national legislation where that provides adequate control of the hazards concerned.

While the fundamental question of whether EU legislation in this area is needed is still under debate, the second workshop (held in Berlin in October, 1997)<sup>7</sup> came to the conclusions that, if EU legislation is needed:

- it should be of a 'goal-setting' nature, and should allow the continuation of existing good national practice (as noted above);
- it should be based on a requirement for a Safety Management System, combined with specified performance measures to be agreed between the operator and the Authorities.

After reviewing the results of this workshop, the Commission proposes to develop a Regulatory 'benchmark' for reviewing the legislative situation in the Member States.

# 2.5. Ports and marshalling yards (see Porter and Törkel in [3])

Should intermediate temporary storage in transport-related establishments be covered by the Seveso II Directive? After considerable discussion in the course of agreeing to the Directive, the final result was:

- a statement in Article 4 excluding transport and intermediate temporary storage from the scope of the Directive;
- a recital in the preamble noting that Member States may take further measures to control hazards connected with ports and marshalling yards;
- a request from the Council to the Commission to study the matter further:

The Council requests the Commission to submit to it, as necessary, within 3 years, proposals designed to ensure a high level of protection of human beings and/or the environment in respect of the prevention of risks of major accidents connected

<sup>&</sup>lt;sup>6</sup> This work has also been pursued through the OECD's Expert Group on Chemical Accidents; indeed the OECD was one of the co-sponsors of the first workshop on the subject.

<sup>&</sup>lt;sup>7</sup> Final Report for Workshop on 'Major Pipeline Hazards—Safety and Environmental Protection', 22–24 October, 1997, Berlin—available from the CDCIR (see footnote).

with ports and marshalling yards...following examination of the Community and international legislation in force relating to the transport of dangerous substances and the national measures in force in the Member States for the prevention of risks of major accidents connected with such activities.

It should be noted, by the way, that the exclusion only applies to transport-related activities; the Directive may apply to other activities within the establishments, for example to specialised storage establishments within ports.

In response to this request, the Commission, in cooperation with the Italian authorities, organised a workshop in Leghorn/Livorno in May 1996 [3]. The objective of the workshop was to consider the control measures provided by transport legislation and practice, relate them to those defined in the Seveso II Directive, and discuss where it could be said that there was 'broad equivalence' between the two, allowing for the divergences necessarily arising from the different situations involved.

The overall conclusion was that for most of the *preventative* measures, those aimed at preventing major accidents, this 'broad equivalence' could be found—with certain grey areas—but that it was more difficult to find echoes of the *mitigative* measures, those aimed at limiting the consequences of a major accident, such as land-use planning and information for the public.

Further progress was made at a second workshop on the subject, held in Barcelona in April 1997. Since in the meantime an OECD report on the subject had been adopted by the IMO (International Maritime Organisation) Main Safety Committee, the workshop concluded that "the recent joint effort of the OECD and IMO had filled gaps within the interface of transport/Seveso/other legislative approaches for practical and effective implementation within port areas" while requesting further work from railway experts (within their well-established international bodies) to review the measures aimed at limiting the consequences of a major accident, with particular mention of planning for emergencies.

# 3. Guidance

The need for guidance in connection with the Seveso II Directive arises from two closely related sources: on the one hand there are areas where the Directive states requirements but does not state how to meet those requirements; and on the other hand the requirements themselves may be defined in the Directive at a level of detail insufficient for direct operability. This is probably inevitable: the level of detail appropriate for a legal document intended to cover a wide variety of industries and activities is not sufficient to give detailed operational instructions. Hence the guidance documents. These guidance documents are intended to be just that, to provide guidance for operators and authorities, while not excluding other reasonable interpretations; however as they have been agreed over extensive discussions between representatives of the Member States, the European Commission and industry, their interpretations do have a certain authority as presenting 'current European good practice'.

Three of the technical areas concerned—the contents of a Safety Report; the content of information to be supplied to the public; and Safety Management Systems—had already been identified while the new Directive was still only under preliminary discussion, and appropriate action had been started, and in one case finished.

## 3.1. The Safety Report

One of the most significant provisions of the Seveso II Directive is the requirement for top-tier establishments to produce a Safety Report. While article 9 and Annex II of the Directive give a brief outline of the purpose of the Safety Report and of what information should be included, it was clear that more guidance would be needed, and at a very early stage in the discussions on the Directive a TWG (no. 3) was set up to prepare this. This guidance was finalised and published in 1997 [4].

The Safety Report must contain all the information required to convince the National Authorities concerned of the safety of the establishment. It will therefore have to be prepared according to the practices and requirements of the Authority or Authorities concerned; in certain technical areas these practices and requirements vary significantly from one Member State to another. This is particularly the case concerning hazard identification, risk analysis, and consequence assessment. Often the differences reflect fundamental divergences in philosophy, such as for example:

- whether risk assessment should be qualitative, semi-quantitative or fully quantitative;
- whether the assessment of the consequences of a possible accident should be explicitly probabilistic;
- whether the same accident scenarios should be used for Land-Use Planning and for drawing up Emergency Response Plans.

In these areas the TWG3 guidance does not and cannot take a position. It is likely therefore that some Member States will wish to supplement the TWG3 guidance with more specific national guidance.

#### 3.2. Information for the public

People living near a hazardous plant have to know what to do in the event of a major accident. This principle was set out in article 8 of the original Seveso Directive, <sup>8</sup> and was significantly reinforced in 1988 in an amending Directive, <sup>9</sup> which set out a list of items of information to be supplied, and stated explicitly that the information should be supplied without the persons concerned having to request it. However, there was still felt to be a need for further guidance, and a year later the Council called upon the Commission <sup>10</sup> to draft a practical guide to facilitate implementation of the amending Directive.

<sup>&</sup>lt;sup>8</sup> Directive 82/501/EEC of 24/6/1982, published O.J. of the E.C., No. L230 of 5 August, 1982.

<sup>&</sup>lt;sup>9</sup> Directive 88/610/EEC of 24/11/1998, published O.J. of the E.C., No. L 336/14 of 7 December, 1988.

<sup>&</sup>lt;sup>10</sup> Council Resolution of 16/10/1989, published O.J. of the E.C., No. C 273/1 of 16 October, 1989.

At the time of this request, the system of TWGs had not yet been established, so the guidance was prepared by the JRC in consultation with those responsible for the planning and execution of information campaigns. The guidance [5] developed a two-tier information strategy, divided into 'technical' and 'pragmatic' information—the first being of a general character and standardised in all Member States, while the second, what is actively communicated, has to be depend much more on the exact local context. For that reason, the guidance focuses primarily on the technical information.

The guidance was published in 1994 in English, and has since been published also in French, German and Spanish; an Italian version is in preparation.

#### 3.3. Safety management systems

Most accidents are not simply due to the failure of technical measures, but usually involve an organisational or management failure. This simple fact is now widely recognised [6–8]. For this reason, specific requirements on Safety Management Systems (for top-tier sites) and on a Major Accident Prevention Policy (for lower-tier sites) are included in the new Directive.

But what is a Safety Management System? What should it cover? What is its relationship to other management systems? And what is meant by a Major Accident Prevention Policy, and what sort of document is needed to present it? While many larger companies have their own answers, at least to the first three of these questions, there is widespread confusion and doubt among smaller companies.

A preliminary seminar was held at Ravello in 1994 [9] and a comparative study of a wide variety of SMS recommendations and their implementation in the process industries [10] was carried out under the leadership of TNO. With the results of these two initiatives, a TWG (no. 4) was set up to try to answer these questions. This working group benefited particularly from participation from international industrial groupings such as CEFIC, CONCAWE, and the EPSC<sup>11</sup>, in addition to representatives of Member States and the Commission. In general, the group tried to produce guidance as to the coverage and content of a Safety Management System, noting best practice where there was consensus while remaining very conscious of the danger of imposing a Procrustean solution on widely different industries, activities, and local conditions.

A draft guidance document was produced by this TWG in December 1996. However, there was a feeling among many members of the group (shared by this author, who was secretary to the group) that the resultant document might be too bland and generic to be operationally useful. The document was therefore sent out for testing [11], and the results were evaluated at the end of 1997. While some minor amendments were agreed to in the document, it was broadly confirmed that, although needing adaptation to individual situations, the guidance document was useful and useable. One fairly typical

<sup>&</sup>lt;sup>11</sup> Respectively: the European Chemical Industry Federation; the Oil Companies' European organisation for Environmental, Health, and Safety concerns; and the European Process Safety Centre.

comment was that "all documents of this type are liable to be criticised for being too generic; that is in their nature. It doesn't mean that the document is not useful". The guidance is now in the course of final approval, and is expected to be published in summer 1998.

#### 3.4. Land-use planning

Article 12 of the Seveso II Directive requires Member States to take into account in their land use policies (and/or other relevant policies) of the objectives of preventing major accidents and limiting the consequences of such accidents. The Directive does not specify how this is to be done, nor does it call for the establishment of harmonised criteria in this area. However, preliminary discussions established that this is an area in which practice varies very widely from one Member State to another, and in which some Member States, which are still in the process of establishing methodology and criteria, would welcome guidance. The CCA therefore established a TWG (no. 5) to consider the question of Land Use Planning in the context of major hazards. The activities of this TWG are discussed in detail in another paper in this volume [12].

# 3.5. Inspection systems

Of course, ultimately any law is only as effective as its system of enforcement permits. The inspection of Seveso sites is therefore an essential part of the overall system of major hazard control. One of the very first TWGs (no. 2) was therefore set up in 1992 to discuss Inspection Systems. It is worth noting that this was well before the Commission's proposal for a new Directive was tabled.

This TWG held two meetings, which gave rise to a useful exchange of information (taken into account into the Commission's proposal for a new Directive) but then went into a prolonged period of dormancy. This was due to various reasons, differences of philosophy and approach among the Member States being perhaps one; but in any case, when the topic came under discussion in Council and Parliament in the form of Article 18 of the Seveso II Directive, it was clear that the TWG could make no useful progress until the underlying legislative provisions were agreed.

Once the Directive was agreed, TWG2 was revived, with a remit which had a certain urgency: if it is to produce guidance which will be of use to Member States establishing their inspection systems under the new Directive, the guidance should be available at least in draft form by the end of 1998. The revived TWG has held two meetings, and is currently in the process of discussing a draft guidance document.

Without presuming on the conclusions of the group, it seems safe to state that this is an area in which some Member States have well-established procedures—often coordinated with inspections under other legislative provisions. Provided that those established procedures are conformant with the formal requirements of the Directive, and are felt to function satisfactorily in practice, the Member States concerned are unlikely to wish to change them. Therefore, the overall tenor of the resultant document is likely to be: 'if you are doing it already in a different way, fine; if not, here are some ideas for how you could organise it.' While this holds for all the guidance documents discussed in this paper, it seems particularly valid in this domain.

# 4. Conclusion

It will be seen from this paper that over these years there have been 7 TWGs active. This represents a considerable commitment of resources, both in terms of expert time and money, from the Commission and the Member States. Two obvious questions can be posed: 'Is the whole enterprise worthwhile?' and 'Is this an activity limited in time, or will it continue for the foreseeable future?'.

Different members of the TWGs will doubtless have different opinions, but for what it is worth let me offer a personal opinion—based on my experience as Scientific Secretary of two of the TWGs discussed (TWG4 and TWG6), and member of another (TWG5). In my opinion, a group of typically 20 people represents a poor way to draft text, and if that were the primary objective of the TWGs it would be very difficult to justify the resources involved. But what is valuable is that the representatives at the TWGs, in addition to their own personal experience and expertise, discuss the TWGs' work with their colleagues: thus each TWG becomes a means of defining a consensus view over a very wide area (geographical, academic, and industrial). In the case of the guidance documents, this is particularly important: it is all too easy to produce a guidance document which does not actually serve the purpose of offering useful guidance, because those drawing it up have insufficient knowledge of the situation and constraints of the potential users. Worse, a guidance document drawn up without sufficiently wide knowledge of best industrial practice may be counter-productive.

As for the question of time limits, I think that the activity will quite rapidly decline from its current peak. There will doubtless continue to be evolution in scientific knowledge and industrial practice, and some of the TWGs may continue their activities at a less intense level, or indeed be revived to discuss developments; but the present activity is driven by the need across all the Member States of the European Union—and indeed the applicant countries too—to adapt to a Directive which in turn represents many years of technical progress and of experience with the Seveso I Directive.

Overall, therefore, my judgement is that in a few years, when we look back on the Seveso II Directive, its implementation, and its consequences, we will see that the guidance produced by some of the TWGs, and the fine-tuning of the Directive which other TWGs made possible, were an important and positive contribution to the coherent and effective control of major-accident hazard across Europe.

#### 5. Note added in proof

Today the Seveso II Directive comes into mandatory application in the Member States.

Unsurprisingly there has been considerable progress since May 1998, especially in the areas directly relevant to the implementation of the Directive. The Commission decision on harmonised criteria for dispensations according to Article 9 was taken on 26 June 1998<sup>12</sup>, and the related explanatory document drawn up by TWG6<sup>13</sup> has been published while TWG2, TWG4 and TWG5 have all produced guidance documents <sup>14,15,16</sup>.

The Regulatory 'benchmark' on pipelines referred to above has been prepared and sent to the Member States for comments on the relationship between this benchmark and their legislation, while in the area of chemical risks in ports and marshalling yards the Commission is consulting the Member States to ask whether they envisage developing further national legislative measures.

Work on substances dangerous to the environment (TWG7) and carcinogens (TWG8) continues.

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<sup>&</sup>lt;sup>12</sup> O.J. of the E.C., No. L192 of 8 July 1998.

<sup>&</sup>lt;sup>13</sup> Wettig J. and Mitchison N. (Eds.), *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* EUR 18124 EN, Joint Research Centre, Ispra, Italy 1998.

<sup>&</sup>lt;sup>14</sup> Papadakis G.A. and Porter S. (Eds.) *Guidance on Inspections as required by Article 18 of the Council Directive 96 / 82 / EC (Seveso II)* EUR 18692 EN, Joint Research Centre, Ispra, Italy 1999.

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