This paper gives an overview of the requirements of the CIMAH Regulations 1984, in the context of the overall UK strategy of control over major industrial hazards. The potential effect of pending legislative changes are discussed. CIMAH safety case content is reviewed, with special reference to batch processing and environmental risks.

Key Words: Major Hazards: risk; environment; Safety Cases; Seveso Directive; transportation.

1. INTRODUCTION
The UK has been a leading architect in the framing of legislative control for major industrial hazards. We have a system, based mainly on the advice of the Advisory Committee on Major Hazards (1) and confirming the European requirements, (2) which is centred in the following concepts (3):

- identification - via the NIHHS regulations (4)
- assessment and control - via the CIMAH regulations (5), and, of course, HASAWA (6)
- mitigation - via the CIMAH regulations (involving emergency planning and information to the public), and land-use planning control (7) (8) (9)

This approach is very much an interdependent package of controls and responses, appropriately tailored to the relevant risks. In this paper, I am concerned particularly with the assessment and control aspect of the overall strategy. Initially, however, I propose to deal with the 'mitigation' element - mitigation of residual risk, that is to say, the element of risk remaining when the manufacturer has done all that it is reasonably practicable for him to do to reduce the risk. As the concept of reasonable practicability involves a computation of risk set against the cost and effort of reduction of that risk, it is clear that major hazards warrant substantial controls.

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2. MITIGATION

The main elements of mitigation are location, emergency planning and information to the public:

a) LOCATION

Adequate mitigation of major hazard risks is best achieved by planning control of incompatible land uses. Such controls have been applied in the UK, on a formal basis, since 1972. We are, however, the inhabitants of a small island (where intensive land-use is at a premium) and the hazard range of some of our industrial processes may be very great. Additionally, there is an existing legacy of previously permitted and continuing incompatible development. Many of our hazardous installations are less than ideally located in respect of adjacent developments. This most powerful tool of control, is, therefore, only partially applicable to the existing situation, despite continuing developments in planning law, which will shortly introduce a 'consent' procedure for hazardous installations, (and legislation requiring environmental impact assessments is also pending).

b) EMERGENCY PLANNING

CIMAH requires effective arrangements for on and off-site emergency plans, involving close co-operation between site operator, the local authority, the county authority and the emergency services. General advice on emergency planning has been published to both the HSE (10) and industry (11) (12). The recent SI100 booklet is an important addition to this corpus of advice (13).

c) INFORMATION TO THE PUBLIC

Any emergency planning depends for its success on an appropriate response from those covered by the plan, and this necessitates adequate briefing of those liable to be affected. On site personnel will receive this briefing (and training, as appropriate) as part of the preparation and realisation of an emergency plan. Off site, however, such detailed briefing and preparation will rarely be possible. For this reason the CIMAH Regulations impose an additional duty to inform persons who are within the area which it is for the HSE defined. (This area will normally be based on the land-use planning consultation distance). The minimum information to be given is:

- that the hazardous installation is notifiable, and has been notified to HSE

- a description of the operation on site, and the hazards and risks which might affect the recipient of the information
of any emergency measures (including appropriate personal behaviour) to be taken in the event of an incident.

At the time of writing there are EC proposals for extending this along the lines of current UK advice (14). Methods of information given will, of course, vary, as will frequency. Advance and regular information can be given to those resident or working in the area; those in control of public amenities can be similarly informed. Transients may well, however, only receive the information in an emergency situation.

3. ASSESSMENT AND CONTROL

Emergency planning and information to the public are measures primarily designed to mitigate the consequences of any major incident, should it occur (the probability of that accident should, however, be remote) or, in the case of some aspects of emergency planning, to intervene in the escalation process. These aspects apart, however, such issues are concerned with the residual risk after all appropriate, reasonably practicable precautions have been taken. This is, as stated above, a general requirement of the law. In the case of major chemical hazards, there are more detailed requirements - at both a general and a specific level - for assessment of the hazards and risks, and of the safeguards which are in place to control those hazards and risks.

The general requirements of the CIMAH Regulations apply to sites which store or use hazardous substances which satisfy criteria related to toxicity, flammability, reactivity or explosibility, with no qualifying threshold. Several thousand such substances have been identified as being in regular use in industry. In such cases, the operator of the site must:

- notify the HSE of any major accident which has occurred on this site, with details of steps taken to prevent its recurrence; (note - a major accident need only have the potential for harm).

- be prepared to demonstrate to an Inspector, on request, and produce documentary evidence as appropriate) that he has considered the potential for major accidents from his operations, and has taken all appropriate steps both to prevent their occurrence and to mitigate the consequences of any which may occur.

Compliance with RIDDOR (15) and HASAWA will, of course, go some way to meeting these requirements.

Further, more specific duties under the Regulations apply to sites on which are stored or used named substances in excess of specified thresholds. These sites are known as large inventory top tier sites (LITTS) which store large quantities of flammable
toxic or explosive materials, and small inventory top tier sites (SITTS) which store or use materials which are considered particularly toxic, and for which much lower thresholds (1 tonne or less) are prescribed. In the UK there are over 200 LITTS, and over a hundred SITTS notified to HSE. These numbers will, however, increase substantially when amendments in EC Directives are carried through into UK legislation. Regulations are already at the consultation stage (at the time of writing - August 1988) carrying into effect the first amendment (16) of the so-called 'Seveso' Directive. Essentially these Regulations will:-

(i) clarify the application to ammonium nitrate

(ii) reduce threshold quantities for certain substances (eg. chlorine, phosgene and methyl isocyanate)

(iii) increase the thresholds for certain substances (eg. cobalt and nickel metal, oxides, carbonates, sulphides as powders)

(iv) add certain substances (sulphur trioxide in Schedules 2 and 3 and LOX in Schedule 3)

(v) add 'treatment' to the processes in CIMAH Schedule 4; and

(vi) clarify that the definition of industrial undertaking in Schedule 4 is inclusive and not exclusive.

A much more substantial review of Directive 82/501 has, however, recently been completed, and the resultant changes to UK law will have significant implications for the UK chemical industry. This amendment involves:-

(i) the extension of the list of named substances held in 'isolated' storage or process

(ii) the reduction in thresholds of certain named substances in 'isolated storage' or process

(iii) the application of generic categories of substances and preparation, in both isolated storage and process (the categorisation based on the so called 'Sixth Amendment' Directive (17))

(iv) the aggregation of partial fractions of generic categories of dangerous substances

and will bring within the terms of the 'top tier' legislation several hundred more sites, many of them in the batch processing and/or fine chemicals sector. The 'generic' categories and thresholds are as follows:-
Sites currently subject to the CIMAH top tier requirements (there will, of course, be staging arrangements for the sites brought under the regulations by the above changes) are required to submit to HSE, either in advance, for a 'new' installation, or by 8 July 1989 for an 'existing' installation, a written report, the so called 'safety case', which

- describes the installation and places it in its geographical and social context
- identifies any relevant major accident hazards (including type, relative likelihood, and consequences) - and including risks to the environment
- analyses the effectiveness of the safeguards (both hardware and software) which have been applied

The provision of the comprehensive information required by CIMAH Schedule 6, coupled with appropriate on and off site emergency planning and information to the public will, when taken with the general duties of the CIMAH Regulations and Sections 2 and 3 of HASAWA, go a long way towards demonstrating the adequacy of control on the site, and providing reassurance more widely.

This is not a process of approval, nor one of licensing. Nor is it a once and for all exercise, as there are revision and updating requirements, which have to take into account not only changes on site, but advances in risk assessment techniques. The analysis is, however, a written demonstration of the application of good management techniques to major hazard control. It identifies the critical areas, which can then be addressed on a concentrated and continuing basis; and the hazard analysis carried out an early stage of the assessment process highlights, inter alia, the relevant areas for potential mitigation, (including that provided by adequate emergency planning).

The Safety Case consists, therefore, forms part of a package which provides:
1) Facts about the site and
2) Reasoned arguments about the hazards and risks from the site

There is now a substantial literature on the detail of 'safety case' content (eg. 18, 19, 20, 21).

4. SAFETY CASES - WHAT SHOULD BE CONSIDERED?

The chemical industry and its operations are very diverse in nature and it is not possible to produce a comprehensive manual outlining the totality of issues which should be considered in the safety case. Nor indeed, would this be desirable, as the greater part of the benefit from the preparation of the case lies in the self assessment procedures involved, and the lessons learned. Some attempts have been made by various bodies, with or without HSE assistance, to produce 'model' safety cases, with varying success. (The risk assessment part of the case lends itself particularly to this approach). But in all cases, site specificity remains paramount. There are, however, features common to virtually all plants which need to be addressed. These include:

Hardware failures: -
- vessels
- pipes
- valves
- protection systems
- control systems

Operator error, ie. failure to: -
- close/open valves
- control flow
- respond to an alarm
- carry out a written procedure

Management systems failures: -
- policies
- establishment of standards
- quality assurance
- operating procedures
- training
- supervision
- monitoring
- structure and responsibilities
- communication
- correction of deficiencies

Natural events: -
- earthquake
- lightning
- storm (wind loading, flotation etc)
Man-made events:-

- subsidence
- aircraft impact
- dropped load
- sabotage
- vehicle impact
- fire/explosion

For batch and similar processing operations, the first three categories above are particularly relevant leading as they may to failures in process control.

There is a place for a quantified approach in all of this, but it must not be carried to excess. HS(R)21 suggests that

'Whilst it may be possible for manufacturers to write a safety case in qualitative terms, HSE may well find it easier to accept conclusions which are supported by quantified arguments. A quantitative assessment is also a convenient way of limiting the scope of the safety case, by demonstrating either that an adverse event has a very remote probability of occurring, or that a particular consequence is relatively minor.'

In CIMAH, both for emergency planning purposes, and for safety cases, a quantified hazard assessment is an a priori need. A quantified risk assessment approach, appropriately limited, and selectively applied, is a further tool, sometimes an essential tool, in the application of informed judgement. This is particularly the case for risks associated with process (and batch process) operations, which in many instances depend for their continuing safety on the integrity of protective systems.

5. SAFETY CASES - EXPERIENCE SO FAR

Between five and six hundred safety reports are expected, from the current CIMAH sites. At the date of writing, about 25% of those expected had been received, with discussions in progress in many other areas. It is not the role of HSE to judge any case against any standard, of perfection or otherwise; nor is it our job to rank cases in order of acceptability. HSE, nevertheless, a competent authority within the terms of the Seveso Directive, and carries certain responsibilities on that basis. (The enforcement procedures in CIMAH Reg 9, allowing HSE to seek information additional to that prescribed by CIMAH Schedule 6, emphasise these responsibilities). All cases are seen by relevant parts of HSE, including Technology Division and the operational inspectorates, and each case proceeds through the stages of:

1) assessment of content against Schedule 6 of CIMAH
2) assessment of the adequacy of the investigation of the hazards and risks
3) verification of the content of the case against site conditions

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4) use as one element in choosing future inspection priorities.

Set against the above criteria, a number of the cases so far received have been unsatisfactory. Problems regularly encountered have included:

a) errors of facts. These include significant errors in inventories, locations, procedures, parameters, descriptions of hardware and software which are either at variance with known aspects of the site, or which do not survive even a preliminary validation exercise.

b) inadequate identification of sources and sizes of events. Where limitations in the size or type of incident considered are proposed, these limitations should be justified appropriately.

c) inadequate justification of consequence limitation. Again, the validity of assumptions made should be demonstrated.

d) 'black box' methodologies and assumptions. Unless the methodologies are in the public domain, their basis and sensitivities should be clearly shown.

e) inadequate consideration of escalation risks (particularly, but not solely, in complex plant situations).

f) the validity, availability, and reliability of relevant safeguards, both hardware and software. Performance of these elements is often assessed very conservatively.

g) the significance of protective system failure. What are the implications?

h) common mode failures, at both plant and site level.

i) inadequate quantification of consequences and, where relevant, risks.

j) the implications of human reliability, and the inherent uncertainties.

k) inadequate assessment of management input, and of the implications of failure of management systems.

l) risks to on-site personnel.

m) environmental risks.

This list is not exhaustive; but it does highlight commonly found errors and omissions.
6. **ENVIRONMENTAL RISKS**

The EC Directive (and the CIMAH Regulations) have always had an environmental dimension; this had, however, generally been interpreted as indirect risk to man via an environmental vector—indeed the triggering episodes at Seveso and Manfredonia involved precisely this aspect of risk. Nevertheless, danger to the environment **per se** is clearly covered by the Directive and the Regulations, and is discussed in HSE guidance, for example paragraph 84 of HSE(R) 21:

> '.... significant, relatively long lasting (but not necessarily inevitable) damage to crops, plants or animals or the contamination of land or water. The extent of the contamination will depend upon the characteristics of the material released, including the toxic properties, the persistence, and the ability to disperse. It should be noted that, in most cases, precautions taken to protect man should also protect the environment. However, the possibility cannot be excluded of a major accident release that affects the environment and not man. For example, serious pollution by a toxic substance of a water course which is not used for drinking water could pose a threat to the aquatic life without affecting the surrounding population'.

This environmental dimension was given new emphasis by the results of the fire in the Sandoz complex in Basle, in late 1986. Essentially, this incident triggered the second amendment to the 'Seveso Directive', outlined earlier in this paper; and accelerated and intensified the OECD programme in this field (22). Environmental risks have, thus far, rarely been addressed in safety cases; and even less frequently with any degree of adequacy. Many of the SITT substances are particularly hazardous to the environment; and most are produced via batch as opposed to continuous processing. They can be stored, in substantial quantities, in a warehousing context where fire protection may be less than ideal, and where the potential for 'chemical cocktails' always exists. A safety case for such substances should consider the different types of consequences of accidental pollution of land and air by toxic gases, aerosols and particulates and the pollution of water courses by escapes of toxic liquids and solids. The issues which should be addressed include:—

1. The identification of the nature of the uses of all land surrounding the site giving details of flora and fauna that might be at risk.

2. The environmental hazards that substances stored or processed on a site can present by reference to ecotoxicity and persistence.
3. A description of the potential environmental impact of a major release in terms of the effect on:

1. Animals, birds, insects and vegetation.
2. Local amenities.
3. Livestock and crop production.
4. Possible effects on the balance of nature.

Where there is potential for an industrial accident to directly or indirectly (ie. via fire fighting water run off) to contaminate a water course, reservoir or aquifier the following additional information is required (23) (24):

1. A map and a description of all local waterways/reservoirs above and below ground.
2. A description of the use of the identified waterways/reservoirs in terms of:
   1. potable water supplies
   2. livestock water
   3. crop irrigation
   4. fishing
   5. amenities such as swimming, boating, etc
   6. the habitat of wild life other than fish, ie. birds and small mammals.

The consequences of a release of a toxic substance into a water course/reservoir should be described in terms of:-

1. The extent of the water polluted.
2. The persistence of the pollutant taking account of flushing time, absorption onto sediments and biological half life.
3. The short and long term effects of the release on all forms of wild life giving estimates of the fraction of the populations effected.
4. Any direct and indirect effect on man.

There are very considerable problems in environmental assessments of this nature. Ecotoxicity data are often scarce or non existent; such data as may exist present substantial extrapolation problems. Modelling variations in flow characteristics and concomitant effects requires detailed specialised knowledge. Hazard ranges can be shown to be significantly greater than those of 'conventional' major hazard substances with all the implications this brings for emergency planning; information to the public and, above all, the cost/effectiveness (ie. reasonable practicability) of relevant controls (including difficult
decisions as to how, or whether to fight a fire). There are even fewer criteria of 'tolerability' in the public domain than for nuclear (25) or more general (eg. 26) risks. The uncertainties involved are such that a more transparent analysis of hazard and risk - in terms of the assumptions involved, as a minimum - is clearly required.

**SUMMARY**

This paper has outlined the legislative control strategy in the UK for major chemical hazards, in the framework of the relevant EC Directives. Pending changes are discussed, with particular reference to their effect on batch processing of chemicals. The problems of assessing environmental risks from such processes have also been outlined, and a general framework of assessment described.
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V/TD1/J01