

L.N.37of 2003

**OCCUPATIONAL HEALTH & SAFETY AUTHORITY ACT
(CAP.424)
Control of Major Accident Hazard Regulations, 2003**

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- L.N. of 2003**

OCCUPATIONAL HEALTH AND SAFETY AUTHORITY ACT

(CAP.424)

Control of Major Accident Hazards Regulations, 2003

IN exercise of the powers conferred by article 12 of the Act providing for the establishment of an Occupational Health and Safety Authority, the Deputy Prime Minister and Minister for Social Policy, after consultation with Minister for Home Affairs and the Environment and the Occupational Health and Safety Authority, has made the following regulations:

1. The title of these regulations is the Control of Major Accident Hazards Regulations, 2003 and they shall come into force on such a date as the Minister responsible for Social Policy may appoint by notice in the Gazette, and different dates may be so appointed for different provisions of these regulations. Citation and commencement

2. These regulations are aimed at the prevention of major accidents that involve dangerous substances, and the limitation of their consequences for humans and the environment, with a view to ensuring high levels of protection. Aim

3. (1) In these regulations, unless the context otherwise requires - Interpretation

"Act" means Act XXVII of 2000 providing for the establishment of the Occupational Health and Safety Authority;

"Authority" means the Occupational Health and Safety Authority;

"competent authority" means -

- (i) the Occupational Health and Safety Authority as set up by the Act, Cap.435, the Environment Protection Directorate within the Malta Environment and Planning Authority in terms of the Environment Protection Act, and the Civil Protection Department established by article 3 of the Civil Protection Act, Cap.411, acting jointly or separately as necessary, or
- (ii) any other agency or authority to which the Minister responsible for occupational health and safety, civil protection or the environment may from time to time, assign any of the responsibilities of the competent authority under these regulations:
Provided that the Minister shall issue a notice of any such assignment of responsibilities in the Gazette;

"control" in relation to a person means control in the course of a trade, business or other undertaking or work activity carried on by him;

"dangerous substance" means a substance, mixture or preparation listed in Schedule 1, Part 2, or fulfilling the criteria laid down in Schedule 1 Part 3 and present as a raw material, product, by-product, residue or intermediate;

"the Directive" means Council Directive 96/82/EC on the control of major accident hazards involving dangerous substances;

"establishment" means the whole area under the control of the same person where dangerous substances are present in one or more

installations, including common or related infrastructures or activities, and for this purpose two or more areas under the control of the same person and separated only by a road, shall be treated as one whole area;

"existing establishment" means an establishment whose operation commenced before the date of implementation of these regulations;

"hazard" means the intrinsic property of a dangerous substance or physical situation which has a potential to cause damage to human health and, or of the environment;

"installation" means a technical unit within an establishment in which dangerous substances are, or are intended to be, produced, used, handled or stored, and it includes –

- (a) any equipment, structures, pipework, machinery and tools,
- (b) private railway sidings, docks and unloading quays serving the installation, and
- (c) jetties, warehouses or similar structures, whether floating or not,

which are necessary for the operation of the installation;

"international body" means any appropriate international body that the Minister by order shall designate in the Gazette;

"major accident" means an occurrence (including in particular, but not limited to, a major emission, fire or explosion) resulting from uncontrolled developments in the course of the operation of any establishment and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving dangerous substances;

"new establishment" means an establishment which commenced operation on or after the date of implementation of these regulations;

"notify" means notify in writing and "notification" shall be construed accordingly;

"operator" means an "employer", as defined in the Act, who is in control of the operation of an establishment or installation (or in relation to an establishment or installation which is to be constructed or operated, the person who proposes to control its operation or, if that person is not known, the person who in the course of a trade, business or other undertaking carried on by him has commissioned its design and construction); and any duty imposed by these regulations on him shall extend only in relation to that establishment or installation;

"presence of dangerous substances" includes the actual and anticipated presence of such substances and the presence of those which it is reasonable to believe may be generated during the loss of control of an industrial chemical process;

"risk" means the likelihood of a specific effect occurring within a specific period or in specified circumstances;

"safety report" means a report sent to the competent authority pursuant to regulation 8;

“state” means any country, or group of countries which the Minister may designate in the Gazette;

“storage” of dangerous substances includes the presence of dangerous substances for the purposes of warehousing, depositing in safe custody or keeping in stock.

(2) Where after the coming into force of these regulations an establishment becomes subject to any of these regulations by reason of any increase in the quantity of dangerous substances present there, any reference in that regulation to the start of operation of the establishment, is a reference to the time when the establishment first becomes so subject.

(3) The columns in Parts 2 and 3 of Schedule 1 shall be applied in accordance with the provisions of Part 1 of that Schedule and notes set out in each of those Parts.

(4) Any reference in these regulations to -

(a) a numbered regulation or Schedule is a reference to the regulation in or Schedule to these regulations so numbered, and

(b) a numbered sub-regulation is a reference to the sub-regulation so numbered in the regulation or Schedule in which the reference appears.

4. (1) These regulations shall apply to an establishment where a dangerous substance listed in Parts 2 and 3 of Schedule 1, is present in a quantity equal to or exceeding the quantity listed in the entry for that substance in column 2 of those Parts:

Application

Provided that regulations 8 to 12 shall apply only to an establishment where such a dangerous substance is present in a quantity equal to or exceeding the quantity listed in the entry for that substance in column 3 of Parts 2 and 3 of Schedule 1.

(2) The reference in sub-regulation (1) to the presence of dangerous substances shall not include the presence of dangerous substances in the following activities –

(a) military establishments, installations or storage facilities;

(b) hazards created by ionizing radiation;

(c) the transport of those substances and their intermediate temporary storage by road, rail, inland waterways, sea or air, outside the establishments covered by this regulation, including their loading and unloading and transport to and from another means of transport at docks, wharves and marshalling yards;

(d) the transport of those substances in a pipeline or pumping station outside establishments covered by these regulations;

(e) the activities of the extractive industries concerned with exploration for, and the exploitation of, minerals in mines and quarries or by means of boreholes;

(f) waste land-fill sites.

(3) Where, by reason of any change in –

(a) the classification of a substance (as referred to in note 1 of Part 3 of Schedule 1), or

(b) knowledge of what dangerous substances may be generated during the loss of control of an industrial chemical process;

the area of land on which the substance is present becomes an establishment after the coming into force of these regulations, any requirement imposed by these regulations on an operator which is to be performed by him before an establishment starts to operate shall apply to the operator of the new establishment as if that requirement had to be performed within 12 months after the change in classification takes effect or the change in knowledge occurs.

(4) The provisions of these regulations shall apply without prejudice to the fulfilment of any other measures, which may be required to encourage improvements in safety and health of workers at risk.

5. (1) Every operator shall take all measures necessary to prevent major accidents and limit their consequences to persons and the environment.

General Duty

(2) Every operator shall also, at any time, be in a position to prove to the satisfaction of the competent authority that the measures referred to in regulation (5) (1) are sufficient to fulfill the requirements of these regulations and, in particular for the purposes of inspection and controls referred to in regulation 18.

(3) Every operator shall cooperate fully with the competent authorities in the exercise of any of their functions under these regulations.

6. (1) (a) Within six months, or other period as may be agreed in writing by the Authority, prior to the start of construction of an establishment the operator of the establishment shall send to the competent authority a notification containing the information specified in sub-regulation (2).

Notifications

(b) Within six months, or other period as may be agreed in writing by the Authority, prior to the start of the operation of an establishment, or in the case of an existing establishment within three months of the date of implementation of these regulations, the operator of the establishment shall send to the competent authority a notification containing the information specified in sub-regulation (2).

(2) The notification required by sub-regulation (1) shall contain 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 paragraph (a);

(d) information sufficient to identify the dangerous substances or category of substances involved;

- (e) the quantity and physical form of the dangerous substance or substances involved;
 - (f) the activity or proposed activity of the installation or storage facility;
 - (g) the immediate environment of the establishment (elements liable to cause a major accident or to aggravate the consequences thereof).
- (3) Every operator shall notify the competent authority forthwith if there is -
- (a) any significant increase in the quantity of dangerous substances notified under this regulation, or
 - (b) any significant change in –
 - (i) the nature or physical form of the dangerous substances so notified,
 - (ii) the processes employing them, or
 - (iii) any other information notified to the competent authority in respect of the establishment;
 - (c) permanent closure of an installation in the establishment.
- (4) This regulation shall not require the notification of any information, which has been included in a safety report, which has been submitted to the competent authority.

7. (1) Every operator shall prepare and keep a document setting out his policy with respect to the prevention of major accidents (in these regulations referred to as a "major accident prevention policy document") within the following time limits:

Major Accident
Prevention Policy

- (a) for new establishments, within four months prior to the start of construction or of operation, or other period as may be agreed in writing by the Authority,
 - (b) for existing establishments within nine months of the date of implementation of these regulations,
- (2) The policy referred to in sub-regulation (1) shall be designed to guarantee a high level of protection for persons and the environment by appropriate means, structures and management systems.
- (3) The major accident prevention policy document shall -
- (a) take account of the principles specified in Schedule 2; and
 - (b) include sufficient particulars and be made available to the competent authority for the purposes of amongst others, demonstrating implementation of regulations 5 (2) and 18.
- (4) In the event of the modification of the establishment or installation, the

process carried on there, or the nature or quantity of dangerous substances present there which could (in each case) have significant repercussions with respect to the prevention of major accidents, the operator shall review and where necessary revise the major accident prevention policy document.

(5) Every operator shall implement the policy set out in his major accident prevention policy document.

(6) Subject to paragraph 1 of Schedule 3, this regulation shall not apply to an establishment to which regulation 8 applies.

8 (1) Every operator shall produce a safety report for the purposes of:

Safety Report

- (a) demonstrating that a major-accident prevention policy and a safety management system for implementing it have been put into effect in accordance with the information set out in Schedule 2;
- (b) demonstrating that major-accident hazards have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for man and the environment;
- (c) demonstrating that adequate safety and reliability have been incorporated into the design, construction, operation and maintenance, of any installation, storage facility, equipment and infrastructure connected with its operation which are linked to major-accident hazards inside the establishment;
- (d) demonstrating that internal emergency plans referred to in regulation 10 have been drawn up and that the necessary information to enable the external emergency plan referred to in regulation 10 (4) to be drawn up in order to take the necessary measures in the event of a major accident have been supplied;
- (e) providing sufficient information to the competent authority to enable decisions to be made in terms of the siting of new activities or developments around existing establishments.

(2) The safety report shall contain at least the data and information listed in Schedule 3. It shall also contain an updated inventory of the dangerous substances present in the establishment.

(3) Every operator shall send the safety report provided for in sub-regulation (1) to the competent authority within the following time limits:

- (a) for new establishments, within four months prior to the start of construction or of operation, or other period as may be agreed in writing by the Authority,
 - (b) for existing establishments within twelve months of the date of implementation of these regulations,
 - (c) in the case of the periodic reviews provided for in sub-regulation (5), without delay.
- (4) Before the operator commences construction or operation, or in the cases referred to in sub-regulation (3) (b) and (c), the competent

authority shall within a reasonable period of receipt of the report:

- (a) communicate the conclusions of its examination of the safety report to the operator, if necessary after requesting further information, or
- (b) prohibit the bringing into use, or the continued use, of the establishment concerned, in accordance with the powers and procedures laid down in regulation 17.

(5) The competent authority may limit the information required in the 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, if it is demonstrated to its satisfaction that particular substances present at the establishment, or any part thereof, are in a state incapable of creating a major accident hazard:

Provided that such a dispensation shall be made in writing in accordance with the criteria listed in sub-regulation (6).

(6) The competent authority may grant a dispensation, in terms of the preceding paragraph, if at least one of the following criteria is fulfilled:

- (a) Physical form of substance:
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, is not possible.
- (b) Containment and quantities:
Substances packaged or contained in such a fashion and in such quantities that the maximum release possible under any circumstance cannot create a major accident.
- (c) Location and quantities:
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.
- (d) Classification:
Substances which are defined as dangerous substances by virtue of their generic classification in Schedule 1, but which cannot create a major accident hazard, and for which therefore, the generic classification is inappropriate for this purpose.

9. (1) Where a safety report has been sent to the competent authority the operator shall, subject to sub-regulation (3), review it -

Review and
revision of safety
report

- (a) at least every 5 years;
- (b) whenever such a review is necessary because of new facts or to take account of new technical knowledge about safety matters and of developments in knowledge concerning the assessment of hazards;

- (c) whenever the operator makes a change to the safety management system (referred to in paragraph 1 of Schedule 3) which could have significant repercussions with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment; and
- (d) whenever so requested by the competent authority;

and where in consequence of that review it is necessary to revise the report, the operator shall do so forthwith and inform the competent authority of the details of such revision.

(2) Where a safety report has been reviewed pursuant to sub-regulation (1)(a) but not revised, the operator shall inform the competent authority of that fact.

(3) Where an operator proposes to modify the establishment or installation in it, the process carried on there, or the nature or quantity of dangerous substances present there, and that modification could have significant repercussions with respect to the prevention of major accidents or the limitation of consequences of major accidents to persons and the environment, he shall in advance of such modification –

- (a) review, and where necessary revise, the major accident prevention policy or safety report prepared in respect of the establishment, installation, process or dangerous substances as the case may be; and
- (b) inform the competent authority of the details of such revision.

10. (1) Every operator shall ensure that, for all establishments to which regulation 8 applies:

Emergency plans

- (a) an emergency plan for the measures to be taken inside the establishment, henceforth referred to as internal emergency plan, is prepared to meet the objectives set out in sub-regulation (2) and shall contain the information set out in Schedule 4;
- (b) the necessary information is supplied to the competent authority to enable them to draw up external emergency plans:

Provided that this obligation is fulfilled within the following periods of time:

- (i) for new establishments, four months prior to the start of operation,
- (ii) for existing establishments within fifteen months of the date of implementation of these regulations.

(2) Emergency plans shall have the following objectives :

- (a) containing and controlling incidents so as to minimise the effects, and to limit damage to man, the environment and property,
- (b) implementing the measures necessary to protect man and the environment from the effects of major accidents,
- (c) communicating the necessary information to the public and to the services or authority concerned in the area,

(d) providing for the restoration and clean-up of the environment following a major accident.

(3) The operator shall ensure that the internal emergency plans provided for in these regulations are drawn up in consultation with personnel employed inside the establishment.

(4) The competent authority shall, within three months of receipt of information required under sub-regulation (1), and its acceptance thereof, consult the public and other interested parties as it considers appropriate. The Civil Protection Department, in terms of article 4 of the Civil Protection Act, relating to the preparation of contingency plans, shall draw up an emergency plan as specified in Schedule 4 Part 2, for the measures to be taken outside the establishment, henceforth referred to as the external emergency plan.

(5) The operator and, if necessary the competent authority shall ensure that emergency plans are put into effect without delay:

(a) when a major accident occurs, or

(b) when an uncontrolled event occurs which by its nature could reasonably be expected to lead to a major accident.

(6) The competent authority may, in view of the information contained in the safety report, decide that the requirement to produce an external emergency plan under sub-regulation (2) shall not apply. Any such exemption, which shall be in writing, shall include the reasons for such decision.

(7) Where an exemption has been given under sub-regulation (6), the competent authority shall, for the purposes of these regulations and while the exemption is in force, have no function in relation to the preparation, review, testing and putting into effect of an off-site emergency plan for the establishment concerned.

11. (1) A person who has prepared an emergency plan pursuant to a duty imposed on him by these regulations shall at suitable intervals not exceeding three years –

Review and testing of emergency plans

(a) review and where necessary revise the plan; and

(b) test the plan and take reasonable steps to arrange for the emergency services to participate in the test to such extent as is necessary,

and any such review shall take into account changes occurring in the establishment to which the plan relates and within the emergency services concerned, new technical knowledge, and knowledge concerning the response to major accidents.

(2) The operator shall co-operate fully with the competent authority in the implementation of the testing of external emergency plans.

12. (1) The operator of an establishment shall -

Provision of information to the public

(a) ensure that persons who are likely to be affected by a major accident originating in an establishment covered by regulation 8

are supplied with information on safety measures at the establishment and on the requisite behaviour in the event of a major accident at the establishment, without their having to request it;

- (b) make that information permanently available to the public, after approval has been obtained from the Civil Protection Department.

(2) The information referred to in sub-regulation (1) shall contain at least the information specified in Schedule 5.

(3) In preparing the information required to be supplied in accordance with sub-regulation (1), the operator may consult any other persons who appear to him to be appropriate, but the operator shall remain responsible for the accuracy, completeness and form of the information so supplied.

(4) The operator shall review and where necessary revise the information referred to in sub-regulation (1) -

- (a) at intervals not exceeding three years; or

- (b) in the event of a modification referred to in regulations 6(3) or 9(3).

(5) The operator shall ensure that the information referred to in sub-regulation (1) is supplied in accordance with that sub-regulation within 2 months after the off-site emergency plan has been prepared for the establishment and that the information is so supplied again -

- (a) at intervals not exceeding 5 years; or

- (b) if it is revised pursuant to paragraph (4).

(6) Every operator shall take the necessary measures to ensure that the safety report is available to the public:

Provided that the operator may ask the competent authority for authorisation not to disclose to the public certain parts of the report, for reasons of industrial, commercial or personal confidentiality, public security or national defence. In such cases, on the approval of the competent authority, the operator shall supply to the competent authority, and make available to the public, an amended report excluding those matters:

Provided further that where information is provided to the competent authority pursuant to a requirement imposed by or under these Regulations then, if the person providing it applies to the competent authority to have the information excluded from the register on the ground that it is commercially or personally confidential (as regards himself or another person), the competent authority shall determine whether the information is or is not commercially or personally confidential.

(7) In the case of establishments subject to the provisions of regulation 8, the operator shall ensure that the inventory of dangerous substances provided for in Regulation 8 (2) is made available to the public.

13. (1) Every operator of an establishment shall, when requested to do so by the competent authority provide sufficient information to the competent authority to demonstrate that he has taken all measures necessary to comply with these Regulations, and the information shall be so provided within such

Provision of
information to the
competent
authority

period as the competent authority specifies in the request.

(2) Without prejudice to the generality of sub-regulation (1), the operator shall when requested to do so by the competent authority, provide the competent authority with any information necessary to enable the competent authority to –

- (a) fully assess the possibility of a major accident and to determine the scope of possible increased probability or aggravation of a major accident;
- (b) take substances into account which, due to their physical form, particular conditions or location, may require additional consideration;
- (c) perform its functions of obtaining or collecting information;
- (d) enable the preparation of external emergency plans;

and the information shall be so provided within such period as the competent authority specifies in the request.

(3) Where a major accident has occurred at an establishment the operator shall forthwith, by the quickest and most appropriate means, inform the Civil Protection Department of that accident.

(4) Without prejudice to paragraph 3, every operator shall, as soon as practicable following a major accident, and using the most appropriate means supply the competent authority with suitable details of the incident and in particular:

- (a) provide the following information as soon as it becomes available:
 - (i) the circumstances of the accident,
 - (ii) the dangerous substances involved,
 - (iii) the data available for assessing the effects of the accident on man and the environment, and
 - (iv) the emergency measures taken;
- (b) the steps envisaged:
 - (i) to alleviate the medium- and long-term effects of the accident,
 - (ii) to prevent any recurrence of such an accident;
- (c) update the information provided if further investigation reveals additional facts which alter that information or the conclusions drawn.

14. (1) The competent authority shall, using the information received from operators in notifications sent pursuant to regulation 6 and in safety reports, designate groups of establishments where the likelihood or consequences of a major accident may be increased because of the location and proximity of establishments in the group and the dangerous substances present there.

Provision of
information to
other
establishments

(2) The competent authority shall notify each operator of an establishment in a group designated pursuant to sub-regulation (1) of the names and addresses of other establishments within the same group.

(3) The operator of any establishment in a group designated pursuant to paragraph (1) shall -

(a) pass appropriate information about the establishment to other establishments in the group to enable them to take account of the nature and extent of the overall hazard of a major accident in their major accident prevention policy documents, safety reports and on-site emergency plans; and

(b) co-operate with those other establishments to enable them to carry out any obligations they have under regulations 10(2), 12(1) and 13(2).

15. (1) The competent authority shall inform any appropriate international body as soon as practicable of major accidents meeting the criteria of Schedule 6 which have occurred on Maltese territory for the purpose of prevention and mitigation of major accidents. The information provided shall include the following details:

Provision of
information to the
competent
authority

(a) the name and address of the competent authority responsible for the report;

(b) the date, time and place of the major accident, including the full name of the operator and the address of the establishment involved;

(c) a brief description of the circumstances of the accident, including the dangerous substances involved, and the immediate effects on man and the environment;

(d) a brief description of the emergency measures taken and of the immediate precautions necessary to prevent recurrence.

(2). The competent authority shall provide the international body with all relevant information including;

(a) the results of their analysis and recommendations:

Provided that the reporting of this information may be delayed to allow for the completion of legal proceedings where such reporting is liable to affect those proceedings;

(b) of the name and address of any body which might have relevant information on major accidents and which is able to advise the competent authority of another State which have to intervene in the event of such an accident.

(3) The competent authority shall keep records of relevant information as prescribed in Schedule 6.

(4) The competent authority shall provide any appropriate international body with regular reports for establishments covered by regulations 6 and 8, and shall exchange information as necessary with the international body on the experience acquired with regard to the prevention of major accidents and the limitation of their consequences, and in particular on the functioning of the measures taken pursuant to these regulations.

(5) The competent authority shall provide sufficient information to potentially affected States in cases where the possibility exists of a major accident with transboundary effects occurring in establishments falling under regulation 8. Such information shall include information on

emergency plans, land-use planning, and safety measures:

Provided that if the competent authority decides that an establishment is incapable of creating a major accident hazard beyond its boundary for the purposes of regulation 10(6), and is therefore not required to produce an external emergency plan under regulation 10(1), it shall so inform the relevant state.

(6) The competent authority shall communicate a list of establishments falling under regulation 8(5) to the International body, giving reasons for its decisions.

16. (1) It shall be the joint duty of the agencies of which the competent authority is composed to ensure that the overall functions of the competent authority as set out in these regulations are carried out in close collaboration and as efficiently as possible:

Competent
authority

Provided that the Occupational Health & Safety Authority shall take the lead in co-ordinating the administrative actions of the competent authority:

Provided further that anything required to be sent by an operator of an establishment to the competent authority pursuant to these Regulations shall be sent to the competent authority at an office of the Occupational Health and Safety Authority, and any information thus supplied and acknowledged, shall be considered to have been sent to all the agencies comprising the competent authority.

(2) The competent authority shall within a reasonable period of receiving a safety report -

- (a) communicate the conclusions of its examination of the report to the operator of the establishment concerned; or
- (b) prohibit the operation or bringing into operation of the establishment or installation concerned or any part thereof in accordance with regulation 18.

(3) Without prejudice to sub-regulation (1), any additional information requested by a competent authority and supplied separately and in writing to any of the agencies comprising the competent authority shall, for the purpose of these regulations, be considered to have been supplied to all the other agencies.

(4) Without prejudice to the operator's responsibilities, the competent authority shall, if necessary, appoint individuals or set-up bodies to assist the competent authority at technical level.

(5) In the case of the occurrence of a major accident-

(i) the Civil Protection Department shall take the lead, as provided in the Civil Protection Act, to ensure that any immediate, urgent, medium and long-term measures which may prove necessary are taken by whosoever has such an obligation;

- (ii) the competent authority shall jointly:
 - (a) make a full analysis of the technical, organisational and managerial aspects of the major accident and collect, by inspection, investigation or other appropriate means, the

information necessary for that purpose;

(b) take appropriate action to ensure that the operator takes any necessary remedial measures; and

(c) make recommendations on future preventive measures.

(6) The competent authority may charge the operator a fee for performing any of its functions under these regulations and in particular regulations 11 and 12.

(7) (i) The fee shall not exceed the sum of the costs reasonably incurred by the competent authority in performing the functions referred to in sub-regulation (1) in relation to the establishment concerned.

(ii) Without prejudice to the preceding paragraph, this may include, but shall not be limited to, any costs reasonably incurred by the competent authority in arranging for any emergency services to participate in the testing of the off-site emergency plan.

(8) When requiring payment the competent authority shall send or give to the operator a detailed statement of the work done and costs incurred including the dates of any visits to the establishment and the period to which the statement relates; and the fee, which shall be recoverable only as a civil debt, shall become payable one month after the statement has been sent or given.

17. (1) The competent authority shall prohibit the use or bringing into use of any establishment, installation or storage facility, or any part thereof where the measures taken by the operator for the prevention and mitigation of major accidents are seriously deficient.

Prohibition of use

(2) The competent authority may prohibit the use or bringing into use of any establishment, installation or storage facility, or any part thereof if the operator has not submitted the notification, reports or other information required by these regulations within the specified period.

(3) Where the competent authority proposes to prohibit an operation or the bringing into operation of an establishment or installation or any part thereof pursuant to this regulation, it may serve on the operator a notice giving reasons for the prohibition and specifying the date when it is to take effect, and any such notice may be withdrawn in writing by the competent authority.

(4) A notice served pursuant to sub-regulation (3) may specify measures which, if taken, would cause the competent authority to withdraw the notice.

(5) Where a notice has been served on an operator in accordance with sub-regulation (3) the operator shall comply with it (including any such notice as modified on appeal).

(6) The operators may appeal against a prohibition order issued by the competent authority made under sub-regulations (1) and (2) of this regulation in accordance with the provisions in the Occupational Health & Safety Authority Act or the Environment Protection Act as relevant.

Inspections

18. (1) The competent authority shall organise an adequate system of

inspections, or other actions or procedures appropriate to the type of establishment concerned, to ascertain the levels of compliance with these regulations:

Provided that these shall not be dependent solely upon receipt of the safety report or any other report submitted to the competent authority but shall be sufficient for a planned and systematic examination of the systems being employed at the establishment, whether of a technical, organisational or managerial nature, so as to ensure in particular:

- (a) that the operator can demonstrate that he has taken appropriate measures, in connection with the various activities involved in the establishment, to prevent major accidents,
- (b) that the operator can demonstrate that he has provided appropriate means for limiting the consequences of major accidents, on site and off site,
- (c) that the data and information contained in the safety report, or any other report submitted, adequately reflects the conditions in the establishment,
- (d) that information has been supplied to the public pursuant to regulation 12.

(2) The system of inspection specified in sub-regulation (1) shall comply with the following conditions:

(a) there shall be a programme of inspections for all establishments. Unless the competent authority has established a programme of inspections based upon a systematic appraisal of major-accident hazards of the particular establishment concerned, the programme shall entail at least one on-site inspection made by the competent authority every twelve months of each establishment covered by regulation 8;

(b) following each inspection, a report shall be prepared by the competent authority;

(c) where necessary, every inspection carried out by the competent authority shall be followed up with the management of the establishment, within a reasonable period following the inspection.

Confidentiality

- 19.** (1) The competent authority shall make any information received pursuant to these regulations available to any natural or legal person who so requests:

Provided that information obtained by the competent authority may be kept confidential if it calls into question:

- (i) the confidentiality of the deliberations of the competent authority,
- (ii) the confidentiality of international relations and national defence, or public security,
- (iii) the confidentiality of preliminary investigation proceedings or of current legal proceedings,

(iv) commercial and industrial secrets, including intellectual property, personal data and/or files,

(v) data supplied by a third party if that party asks for them to be kept confidential.

(2) Nothing in these regulations shall preclude the conclusion by Government of agreements with third countries on the exchange of information to which it is privy at internal level.

20. (1) Any breach of any of these regulations shall be deemed an offence.

Enforcement

(2) In any proceedings for an offence under these regulations consisting of a failure to comply with a duty or requirement to do something, it shall be for the accused to prove (as the case may be) that it was not practicable to do more than was in fact done to satisfy the requirement or duty, or that there was no better practicable means than was in fact used to satisfy the duty or requirement.

(3) (i) The Occupational Health and Safety Authority shall be the enforcing authority for provisions relating to health and safety at an establishment to which any of these regulations apply.

(ii) The Malta Environment and Planning Authority shall be the enforcing authority for the provisions relating to the environment at an establishment to which any of these regulations apply.

(iii) Without prejudice to the preceding sub-regulations, no proceedings shall be taken against any person who after receiving intimation from the competent authority for the payment of an administrative fine for having contravened the provisions of these Regulations, pays such a penalty within fifteen days of the date of such intimation.

SCHEDULE 1

Regulations 2 and 3(1)

DANGEROUS SUBSTANCES TO WHICH THE REGULATIONS APPLY

Part 1

Introduction

1. This Schedule applies to the presence of dangerous substances at any establishment and determines the application of the relevant regulations in accordance with regulation 3(1).
2. Mixtures and preparations shall be treated in the same way as pure substances provided they remain within the concentration limits set according to their properties under the relevant provisions specified in Part 3, Note 1, unless a percentage composition or other description is specifically given.
3. The qualifying quantities set out in Parts 2 and 3 relate to each establishment.
4. The quantities to be considered for the application of the relevant regulations are the maximum quantities which are present at any one time. Dangerous substances present at an establishment only in quantities equal to or less than 2 per cent of the relevant qualifying quantity shall be ignored for the purposes of calculating the total quantity present if their location within an establishment is such that it cannot act as an initiator of a major accident elsewhere on site.
5. The rules given in Part 3, Note 4 governing the addition of dangerous substances, or categories of dangerous substances, shall apply where appropriate.

Part 2

Named Substances

Where a substance or group of substances listed in this Part also falls within a category of Part 3, the qualifying quantities set out in this Part must be used.

<i>Column 1</i>	<i>Column 2</i>	<i>Column 3</i>
<i>Dangerous substances</i>	<i>Quantity in tonnes</i>	
Ammonium nitrate (as described in Note 1 of this Part)	350	2,500
Ammonium nitrate (as described in Note 2 of this Part)	1,250	5,000
Arsenic pentoxide, arsenic (V) acid and/or salts	1	2
Arsenic trioxide, arsenious (III) acid and/or salts		0.1
Bromine	20	100
Chlorine	10	25
Nickel compounds in inhalable powder form (nickel monoxide, nickel dioxide, nickel sulphide, trinickel disulphide, dinickel trioxide)		1
Ethyleneimine	10	20
Fluorine	10	20
Formaldehyde (concentration =>90%)	5	50
Hydrogen	5	50
Hydrogen chloride (liquefied gas)	25	250
Lead alkyls	5	50
Liquefied extremely flammable gases (including LPG) and natural gas (whether liquefied or not)	50	200
Acetylene	5	50

Ethylene oxide	5	50
Propylene oxide	5	50
Methanol	500	5,000
4, 4-Methylenebis (2-chloraniline) and/or salts, in powder form		0.01
Methylisocyanate		0.15
Oxygen	200	2,000
Toluene diisocyanate	10	100
Carbonyl dichloride (phosgene)	0.3	0.75
Arsenic trihydride (arsine)	0.2	1
Phosphorus trihydride (phosphine)	0.2	1
Sulphur dichloride	1	1
Sulphur trioxide	15	75
Polychlorodibenzofurans and polychlorodibenzodioxins (including TCDD), calculated in TCDD equivalent		0.001
The following CARCINOGENS: 4-Aminobiphenyl and/or its salts, Benzidine and/or salts, Bis(chloromethyl) ether, Chloromethyl methyl ether, Dimethylcarbamoyl chloride, Dimethylnitrosomine, Hexamethylphosphoric triamide, 2-Naphthylamine and/or salts, 1,3 Propanesultone and 4-nitrodiphenyl		0.001
Automotive petrol and other petroleum spirits	5,000	50,000

Notes

1. Ammonium nitrate (350/2500)

This applies to ammonium nitrate and ammonium nitrate compounds in which the nitrogen content as a result of the ammonium nitrate is more than 28 per cent by weight (compounds other than those referred to in Note 2) and to aqueous ammonium nitrate solutions in which the concentration of ammonium nitrate is more than 90 per cent by weight.

2. Ammonium nitrate (1250/5000)

This applies to simple ammonium-nitrate based fertilisers which conform with the requirements of the Fertilisers Regulations 2002 [29], and to composite fertilisers in which the nitrogen content as a result of the ammonium nitrate is more than 28 per cent in weight (a composite fertiliser contains ammonium nitrate with phosphate or potash, or phosphate and potash).

3. Polychlorodibenzofurans and polychlorodibenzodioxins

The quantities of polychlorodibenzofurans and polychlorodibenzodioxins are calculated using the following factors:

International Toxic Equivalent Factors (ITEF) for the congeners of concern (NATO/CCMS)

2, 3, 7, 8-TCDD	1
1, 2, 3, 7, 8-PeDD	0.5
1,2,3,4,7,8-HxCDD	0.1
1,2,3,6,7,8-HxCDD	
1,2,3,7,8,9-HxCDD	
1, 2, 3, 4, 6, 7, 8-HpCDD	0.01
OCDD	0.001
2, 3, 7, 8-TCDF	0.1
2, 3, 4, 7, 8-PeCDF	0.5
1, 2, 3, 7, 8-PeCDF	0.05
1, 2, 3, 4, 7, 8-HxCDF	0.1
1, 2, 3, 7, 8, 9-HxCDF	

1, 2, 3, 6, 7, 8-HxCDF	
2, 3, 4, 6, 7, 8-HxCDF	
1, 2, 3, 4, 6, 7, 8-HpCDF	0.01
1, 2, 3, 4, 7, 8, 9-HpCDF	
OCDF	0.001

(T=tetra, Pe=penta, Hx=hexa, Hp=hepta, O=octa)

Part 3

Categories of Substances and Preparations not specifically named in Part 2

Column 1	Column 2	Column 3
<i>Categories of dangerous substances</i>	Quantity in tonnes	
1. VERY TOXIC	5	20
2. TOXIC	50	200
3. OXIDISING	50	200
4. EXPLOSIVE (where the substance or preparation falls within the definition given in Note 2(a))	50	200
5. EXPLOSIVE (where the substance or preparation falls within the definition given in Note 2(b))	10	50
6. FLAMMABLE (where the substance or preparation falls within the definition given in Note 3(a))	5,000	50,000
7a. HIGHLY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3(b)(i))	50	200
7b. HIGHLY FLAMMABLE liquids (where the substance or preparation falls within the definition given in Note 3(b)(ii))	5,000	50,000
8. EXTREMELY FLAMMABLE (where the substance or preparation falls within the definition given in Note 3(c))	10	50
9. DANGEROUS FOR THE ENVIRONMENT in combination with risk phrases: (i) R50: "Very toxic to aquatic organisms"	200	500
(ii) R51: "Toxic to aquatic organisms"; and R53: "May cause long-term adverse effects in the aquatic environment"	500	2,000
10. ANY CLASSIFICATION not covered by those given above in combination with risk phrases: (i) R14: "Reacts violently with water" (including R14/15)	100	500
(ii) R29: "in contact with water, liberates toxic gas"	50	200

Notes

- Substances and preparations shall be classified for the purposes of this Schedule according to the following Directives (as amended) and their current adaptation to technical progress:
 - Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ,

- Council Directive 88/379/EEC of 7 June 1988 on the approximation of the laws, regulations and administrative provisions of EU Member States relating to the classification, packaging and labelling of dangerous preparations,

- Council Directive 78/631/EEC of 26 June 1978 on the approximation of the laws of EU Member States relating to the classification, packaging and labelling of dangerous preparations (pesticides).

In the case of substances and preparations which are not classified as dangerous according to any of the above Directives but which nevertheless are present, or are likely to be present, in an establishment and which possess or are likely to possess, under the conditions found at the establishment, equivalent properties in terms of major-accident potential, the procedures for provisional classification shall be followed according to the relevant Article of the appropriate Directive.

In the case of substances and preparations with properties giving rise to more than one classification, for the purposes of these Regulations the lowest thresholds shall apply.

2. An "explosive" means:

(a) (i) a substance or preparation which creates the risk of an explosion by shock, friction, fire or other sources of ignition (risk phrase R 2),

(ii) a pyrotechnic substance is a substance (or mixture of substances) designed to produce heat, light, sound, gas or smoke or a combination of such effects through non-detonating self-sustained exothermic chemical reactions, or

(iii) an explosive or pyrotechnic substance or preparation contained in objects;

(b) a substance or preparation which creates extreme risks of explosion by shock, friction, fire or other sources of ignition (risk phrase R 3).

3. "Flammable", "highly flammable", and "extremely flammable" in categories 6, 7 and 8 mean:

(a) flammable liquids –

substances and preparations having a flash point equal to or greater than 21°C and less than or equal to 55°C (risk phrase R 10), supporting combustion;

(b) highly flammable liquids –

(i) substances and preparations which may become hot and finally catch fire in contact with air at ambient temperature without any input of energy (risk phrase R 17), - substances which have a flash point lower than 55°C and which remain liquid under pressure, where particular processing conditions, such as high pressure or high temperature, may create major accident hazards;

(ii) substances and preparations having a flash point lower than 21°C and which are not extremely flammable (risk phrase R 11, second indent);

(c) extremely flammable gases and liquids –

(i) liquid substances and preparations which have a flash point lower than 0°C and the boiling point (or, in the case of a boiling range, the initial boiling point) of which at normal pressure is less than or equal to 35°C (risk phrase R 12, first indent), and

(ii) gaseous substances and preparations which are flammable in contact with air at ambient temperature and pressure (risk phrase R 12, second indent), whether or not kept in the gaseous or liquid state under pressure, excluding liquefied extremely flammable gases (including liquefied petroleum gas) and natural gas referred to in Part 2, and

(iii) flammable liquid substances and preparations maintained at a temperature above their boiling point.

4. The addition of dangerous substances to determine the quantity present at an establishment shall be carried out according to the following rule: -

if the sum

$$q_1/Q + q_2/Q + q_3/Q + q_4/Q + q_5/Q + \dots > 1$$

where

q_x = the quantity of dangerous substances x (or category of dangerous substances) falling within Parts 2 or 3 of this Schedule,

Q = the relevant threshold quantity from Parts 2 or 3,

then the establishment is covered by the relevant requirements of these Regulations. This rule will apply for the following circumstances –

- (a) for substances and preparations appearing in Part 2 at quantities less than their individual qualifying quantity present with substances having the same classification from Part 3, and the addition of substances and preparations with the same classification from Part 3;
- (b) for the addition of categories 1, 2 and 9 present at an establishment together;
- (c) for the addition of categories 3, 4, 5, 6, 7a, 7b and 8, present at an establishment together.

SCHEDULE 2

Regulation 7(3)

PRINCIPLES TO BE TAKEN INTO ACCOUNT WHEN PREPARING MAJOR ACCIDENT PREVENTION POLICY DOCUMENT

1. For the purpose of implementing the operator's major accident prevention policy and safety management system account shall be taken of the following elements. The requirements laid down in the major accident prevention policy document should be proportionate to the major accident hazards presented by the establishment.
2. The major accident prevention policy should be established in writing and should include the operator's overall aims and principles of action with respect to the control of major accident hazards.
3. The safety management system should include the part of the general management system which includes the organisational structure, responsibilities, practices, procedures, processes and resources for determining and implementing the major accident prevention policy.
4. The following issues shall be addressed by the safety management system -
 - (a) organisation and personnel - the roles and responsibilities of personnel involved in the management of major hazards at all levels in the organisation. The identification of training needs of such personnel and the provision of the training so identified. The involvement of employees and, where appropriate, sub-contractors;
 - (b) identification and evaluation of major hazards - adoption and implementation of procedures for systematically identifying major hazards arising from normal and abnormal operation and the assessment of their likelihood and severity;
 - (c) operational control - adoption and implementation of procedures and instructions for safe operation, including maintenance of plant, processes, equipment and temporary stoppages;
 - (d) management of change - adoption and implementation of procedures for planning modifications to, or the design of new installations, processes or storage facilities;
 - (e) planning for emergencies - adoption and implementation of procedures to identify foreseeable emergencies by systematic analysis and to prepare, test and review emergency plans to respond to such emergencies;
 - (f) monitoring performance - adoption and implementation of procedures for the on-going assessment of compliance with the objectives set by the operator's major accident prevention policy and safety management system, and the mechanisms for investigation and taking corrective action in the case of non-compliance. The procedures should cover the operator's system for reporting major accidents or near misses, particularly those involving failure of protective measures, and their investigation and follow-up on the basis of lessons learnt;
 - (g) audit and review - adoption and implementation of procedures for periodic systematic assessment of the major accident prevention policy and the effectiveness and suitability of the safety management system; the documented review of performance of the policy and safety management system and its updating by senior management.

SCHEDULE 3

CONTENTS OF SAFETY REPORTS

(minimum information to be included in safety report)

The information referred to in regulations 8 and 9 is as follows -

1. Information on the management system and on the organisation of the establishment with a view to major accident prevention.

This information shall contain the elements set out in Schedule 2.

2. Presentation of the environment of the establishment:

- (a) description of the site and its environment including the geographical location, meteorological, geographical, hydrographic conditions and, if necessary, its history;
- (b) identification of installations and other activities of the establishment which could present a major accident hazard;
- (c) description of areas where a major accident may occur.

2. Description of installation:

- (a) a description of the main activities and products of the parts of the establishment which are important from the point of view of safety, sources of major accident risks and conditions under which such a major accident could happen, together with a description of proposed preventive measures;
- (b) description of processes, in particular the operating methods;
- (c) description of dangerous substances:
 - (i) inventory of dangerous substances including –
 - the identification of dangerous substances: chemical name, the number allocated to the substance by the Chemicals Abstract Service, name according to International Union of Pure and Applied Chemistry nomenclature;
 - the maximum quantity of dangerous substances present;
 - (ii) physical, chemical, toxicological characteristics and indication of the hazards, both immediate and delayed for people and the environment;
 - (iii) physical and chemical behaviour under normal conditions of use or under foreseeable accidental conditions.

4. Identification and accidental risks analysis and prevention methods:

- (a) detailed description of the possible major accident scenarios and their probability or the conditions under which they occur including a summary of the events which may play a role in triggering each of these scenarios, the causes being internal or external to the installation;
- (b) assessment of the extent and severity of the consequences of identified major accidents;
- (c) description of technical parameters and equipment used for the safety of installations.

5. Measures of protection and intervention to limit the consequences of an accident:

(a) description of the equipment installed in the plant to limit the consequences of major accidents;

(b) organisation of alert and intervention;

(c) description of mobilisable resources, internal or external;

(d) summary of elements described in sub-paragraphs (a), (b) and (c) necessary for drawing up the on-site emergency plan.

SCHEDULE 4
EMERGENCY PLANS

Part 1

information to be included in internal emergency plan

The information referred to in regulation 10(1) is as follows –

1. names or positions of persons authorised to set emergency procedures in motion and the person in charge of and co-ordinating the on-site mitigatory action;
2. name or position of the person with responsibility for liaison with the local authority responsible for preparing the off-site emergency plan;
3. for foreseeable conditions or events which could be significant in bringing about a major accident, a description of the action which should be taken to control the conditions or events and to limit their consequences, including a description of the safety equipment and the resources available;
4. arrangements for limiting the risks to persons on site including how warnings are to be given and the actions persons are expected to take on receipt of a warning;
5. arrangements for providing early warning of the incident to the local authority responsible for setting the off-site emergency plan in motion, the type of information which should be contained in an initial warning and the arrangements for the provision of more detailed information as it becomes available;
6. arrangements for training staff in the duties they will be expected to perform, and where necessary co-ordinating this with the emergency services;
7. arrangements for providing assistance with off-site mitigatory action.

Part 2

information to be included in external emergency plan

The information referred to in regulation 10(4) is as follows –

1. names or positions of persons authorised to set emergency procedures in motion and of persons authorised to take charge of and co-ordinate off-site action;
2. arrangements for receiving early warning of incidents, and alert and call-out procedures;
3. arrangements for co-ordinating resources necessary to implement the off-site emergency plan;
4. arrangements for providing assistance with on-site mitigatory action;
5. arrangements for off-site mitigatory action;
6. arrangements for providing the public with specific information relating to the accident and the behaviour which it should adopt;
7. arrangements for the provision of information to the emergency services of other States in the event of a major accident with possible transboundary consequences.

SCHEDULE 5

INFORMATION TO BE SUPPLIED TO THE PUBLIC

The information referred to in regulation 12(1) is as follows –

- 1.** name of operator and address of the establishment;
- 2.** identification, by position held, of the person giving the information;
- 3.** confirmation that the establishment is subject to these regulations and that the notification referred to in regulation 6 or the safety report has been submitted to the competent authority;
- 4.** an explanation in simple terms of the activity or activities undertaken at the establishment;
- 5.** the common names or, in the case of dangerous substances covered by Part 3 of Schedule 1, the generic names or the general danger classification of the substances and preparations involved at the establishment which could give rise to a major accident, with an indication of their principal dangerous characteristics;
- 6.** general information relating to the nature of the major accident hazards, including their potential effects on the population and the environment;
- 7.** adequate information on how the population concerned will be warned and kept informed in the event of a major accident;
- 8.** adequate information on the actions the population concerned should take, and on the behaviour they should adopt, in the event of a major accident;
- 9.** confirmation that the operator is required to make adequate arrangements on site, in particular liaison with the emergency services, to deal with major accidents and to minimise their effects;
- 10.** a reference to the off-site emergency plan for the establishment. This should include advice to co-operate with any instructions or requests from the emergency services at the time of an accident;
- 11.** details of where further relevant information can be obtained, unless making that information available would be contrary to the interests of national security or personal confidentiality or would prejudice to an unreasonable degree the commercial interests of any person.

SCHEDULE 6

CRITERIA FOR NOTIFICATION OF A MAJOR ACCIDENT TO INTERNATIONAL BODIES AND INFORMATION TO BE NOTIFIED

The criteria referred to in regulation 15(1) are as follows:

1. Any accident covered in sub-paragraph (a) or having at least one of the consequences described in paragraphs (b), (c), (d) and (e) shall be notified to the international body –

(a) substances involved:

any fire or explosion or accidental discharge of a dangerous substance involving a quantity of at least 5 per cent of the qualifying quantity laid down in column 3 of Parts 2 or 3 of Schedule 1;

(b) injury to persons and damage to property:

an accident directly involving a dangerous substance and giving rise to one of the following events: -

(i) death,

(ii) six persons injured within the establishment and kept in hospital for at least 24 hours,

(iii) one person outside the establishment kept in hospital for at least 24 hours,

(iv) dwellings outside the establishment damaged and unusable as a result of the accident,

(v) the evacuation or confinement of persons for more than two hours (person x hours): the value is at least 500,

(vi) the interruption of drinking water, electricity, gas or telephone services for more than two hours (person x hours): the value is at least 1,000;

(c) immediate damage to the environment:

(i) 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;

(ii) 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;

(iii) significant damage to an aquifer or underground water:

- 1 ha or more;

(d) damage to property:

(i) damage to property in the establishment of at least euro 2 million,

(ii) damage to property outside the establishment of at least euro 0.5 million;

(e) cross-border damage:

any accident directly involving a dangerous substance giving rise to effects outside the territory of a State concerned;

2. Accidents or 'near misses' which may be regarded by the Competent authority as being of particular technical interest for preventing major accidents and limiting their consequences and which do not meet the quantitative criteria above should be notified to the international body.