

**L.N. 179 of 2015**

**OCCUPATIONAL HEALTH AND SAFETY AUTHORITY ACT  
(CAP. 424)**

**Control of Major Accident Hazards Regulations, 2015**

IN exercise of the powers conferred by article 12 of the Occupational Health and Safety Authority Act, the Minister for Social Dialogue, Consumer Affairs and Civil Liberties, after consultation with the Occupational Health and Safety Authority, has made the following regulations:-

1. (1) The title of these regulations is the Control of Major Accident Hazards Regulations, 2015.

Citation, scope, applicability and coming into force.

(2) The scope of these regulations is to lay down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to ensuring a high level of protection throughout the European Union in a consistent and effective manner. These regulations implement Directive 2012/18/EU of the European Parliament and of the Council of 4 July 2012 on the control of major-accident hazards involving dangerous substances, amending and subsequently repealing Council Directive 96/82/EC.

(3) These regulations shall apply to establishments as defined in regulation 2.

(4) These regulations shall not apply to any of the following:

(a) military establishments, installations or storage facilities;

(b) hazards created by ionising radiation originating from substances;

(c) the transport of dangerous substances and directly related intermediate temporary storage by road, rail, internal waterways, sea or air, outside the establishments covered by these regulations, including loading and unloading and transport to and from another means of transport at docks, wharves or marshalling yards;

(d) the transport of dangerous substances in pipelines, including pumping stations, outside establishments covered by these regulations;

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(e) the exploitation, namely the exploration, extraction and processing, of minerals in mines and quarries, including by means of boreholes;

(f) the offshore exploration and exploitation of minerals, including hydrocarbons;

(g) the storage of gas at underground offshore sites including both dedicated storage sites and sites where exploration and exploitation of minerals, including hydrocarbons are also carried out;

(h) waste land-fill sites, including underground waste storage.

(5) Notwithstanding the provisions of sub-regulation (4)(e) and (h), onshore underground gas storage in natural strata, aquifers, salt cavities and disused mines and chemical and thermal processing operations and storage related to those operations which involve dangerous substances, as well as operational tailings disposal facilities, including tailing ponds or dams, containing dangerous substances shall be included within the scope of these regulations.

(6) These regulations shall come into force on the 1st June 2015.

Interpretation. 2. (1) In these regulations, unless the context otherwise requires -

Cap. 424. "Act" means the Occupational Health and Safety Authority Act;

"Authority" means the Occupational Health and Safety Authority;

"Commission" means the Commission of the European Union;

"competent authority" means -

Cap. 504. (a) the Occupational Health and Safety Authority as set up by the Act, the Malta Environment and Planning Authority, established by the Environment and Planning Authority Act and the Civil Protection Department established by the Civil Protection Act, acting jointly or separately as necessary; or

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(b) 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;

"dangerous substance" means a substance or mixture covered by Part 1 or listed in Part 2 of Schedule I, including in the form of a raw material, product, by-product, residue or intermediate;

"establishment" means the whole location under the control of an operator where dangerous substances are present in one or more installations, including common or related infrastructures or activities; establishments are either lower-tier establishments or upper-tier establishments;

"existing establishment" means an establishment that on 31 May 2015 falls within the scope of the Control of Major Accident Hazards Regulations, 2003\* and from 1 June 2015 falls within the scope of these regulations without changing its classification as a lower-tier establishment or upper-tier establishment; L.N. 37 of 2003.

"hazard" means the intrinsic property of a dangerous substance or physical situation, with a potential for creating damage to human health or the environment;

"inspection" means all actions, including site visits, checks of internal measures, systems and reports and follow-up documents, and any necessary follow-up, undertaken by or on behalf of the competent authority to check and promote compliance of establishments with the requirements of these regulations;

"installation" means a technical unit within an establishment and whether at or below ground level, in which dangerous substances are produced, used, handled or stored; it includes all the equipment, structures, pipework, machinery, tools, private railway sidings, docks, unloading quays serving the installation, jetties, warehouses or similar structures, floating or otherwise, necessary for the operation of that installation;

"lower-tier establishment" means an establishment where dangerous substances are present in quantities equal to or in excess of the quantities listed in Column 2 of Part 1 or in Column 2 of Part 2 of Schedule I, but less than the quantities listed in Column 3 of Part 1 or in Column 3 of Part 2 of Schedule I, where applicable using the summation rule laid down in note 4 to Schedule I;

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\*revoked by these Regulations.

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"major accident" means an occurrence such as a major emission, fire, or explosion resulting from uncontrolled developments in the course of the operation of any establishment covered by these regulations, and leading to serious danger to human health or the environment, immediate or delayed, inside or outside the establishment, and involving one or more dangerous substances;

"mixture" means a mixture or solution composed of two or more substances;

"neighbouring establishment" means an establishment that is located in such proximity to another establishment so as to increase the risk or consequences of a major accident;

"new establishment" means -

(a) an establishment that enters into operation or is constructed, on or after 1 June 2015; or

(b) a site of operation that falls within the scope of these regulations, or a lower-tier establishment that becomes an upper-tier establishment or vice versa, on or after 1 June 2015 due to modifications to its installations or activities resulting in a change in its inventory of dangerous substances;

"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;

"other establishment" means a site of operation that falls within the scope of these regulations, or a lower-tier establishment that becomes an upper-tier establishment or vice versa, on or after 1 June 2015 for reasons other than those referred to in the definition "new establishment";

"presence of dangerous substances" means the actual or anticipated presence of dangerous substances in the establishment, or of dangerous substances which it is reasonable to foresee may be generated during loss of control of the processes, including storage activities, in any installation within the establishment, in quantities equal to or exceeding the qualifying quantities set out in Part 1 or Part

2 of Schedule I;

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

"storage" means the presence of a quantity of dangerous substances for the purposes of warehousing, depositing in safe custody or keeping in stock;

"the public" means one or more natural or legal persons and, in accordance with national law or practice, their associations, organisations or groups;

"the public concerned" means the public affected or likely to be affected by, or having an interest in, the taking of a decision on any matters covered by the provisions of the Environment and Planning Authority Act, the Freedom of Access to Information on the Environment Regulations, and the Plans and Programmes (Public Participation) Regulations; for the purposes of this definition, non-governmental organisations promoting environmental protection and meeting any applicable requirements under national law and, or practice shall be deemed to have an interest;

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"upper-tier establishment" means an establishment where dangerous substances are present in quantities equal to or in excess of the quantities listed in Column 3 of Part 1 or in Column 3 of Part 2 of Schedule I, where applicable using the summation rule laid down in note 4 to Schedule I;

(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 date when the establishment first becomes so subject.

**3.** (1) Where the competent authority considers that a dangerous substance does not present a major-accident hazard, based on one or more of the following characteristics:

Assessment of major-accident hazards for a particular dangerous substance.

(a) the physical form of the dangerous substance under normal processing or handling conditions or in an unplanned loss of containment;

(b) the inherent properties of the dangerous substance, in particular those related to dispersive behaviour in a major-accident scenario, such as molecular mass and saturated vapour pressure;

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(c) the maximum concentration of the substances in the case of mixtures;

it shall notify the Commission together with supporting justification, including the information referred to in sub-regulation (2).

(2) For the purposes of sub-regulation (1), information necessary for assessing the health, physical and environmental hazard properties of the dangerous substance concerned shall include:

(a) a comprehensive list of properties necessary to assess the dangerous substance's potential for causing physical, health or environmental harm;

(b) physical and chemical properties (for instance molecular mass, saturated vapour pressure, inherent toxicity, boiling point, reactivity, viscosity, solubility and other relevant properties);

(c) health and physical hazard properties (for instance reactivity, flammability, toxicity together with additional factors such as mode of attack on the body, injury to fatality ratio, and long-term effects, and other properties as relevant);

(d) environmental hazard properties (for instance ecotoxicity, persistence, bio-accumulation, potential for long-range environmental transport, and other properties as relevant);

(e) where available, the European Union classification of the substance or mixture;

(f) information about substance-specific operating conditions (for instance temperature, pressure and other conditions as relevant) under which the dangerous substance is stored, used and/or may be present in the event of foreseeable abnormal operations or an accident such as fire.

General obligations of the operator.

**4. (1)** Every operator shall take all necessary measures to prevent major accidents and to limit their consequences for human health and the environment.

(2) Every operator shall also, at any time, be in a position to prove to the satisfaction of the competent authority referred to in regulation 14, that the measures taken are sufficient to fulfil the requirements of these regulations and, in particular for the purposes of inspections and controls referred to in regulation 16.

(3) Every operator shall cooperate fully with the competent

authorities in the exercise of any of their functions under these regulations.

5. (1) Every operator shall send a notification to the competent authority containing the following information: Notification.

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

(d) information sufficient to identify the dangerous substances and category of substances involved or likely to be present;

(e) the quantity and physical form of the dangerous substance or substances concerned;

(f) the activity or proposed activity of the installation or storage facility;

(g) the immediate environment of the establishment, and factors likely to cause a major accident or to aggravate the consequences thereof including, where available, details of neighbouring establishments, of sites that fall outside the scope of these regulations, areas and developments that could be the source of, or increase the risk or consequences of a major accident and of domino effects.

(2) The notification or its update shall be sent to the competent authority within the following time-limits:

(a) for new establishments, a reasonable period of time, or other period as may be agreed in writing by the competent authority, prior to the start of construction or operation, or prior to the modifications leading to a change in the inventory of dangerous substances;

(b) for all other cases, one year from the date from which these regulations apply to the establishment concerned.

(3) Sub-regulations (1) and (2) shall not apply if the operator has already sent a notification to the competent authority under the requirements of the Control of Major Accident Hazards Regulations, L.N. 37 of 2003.

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2003\* before 1 June 2015, and the information contained therein complies with sub-regulation (1) and has remained unchanged.

(4) The operator shall inform the competent authority in advance of the following events:

(a) any significant increase or decrease in the quantity or significant change in the nature or physical form of the dangerous substance present, as indicated in the notification provided by the operator pursuant to sub-regulation (1), or a significant change in the processes employing it;

(b) modification of an establishment or an installation which could have significant consequences in terms of major-accident hazards;

(c) the permanent closure of the establishment or its de-commissioning; or

(d) changes in the information referred to in sub-regulation (1)(a), (b) or (c).

Major-accident  
prevention  
policy.

6. (1) Every operator shall draw up a document in writing setting out the major-accident prevention policy (MAPP) and to ensure that it is properly implemented. The MAPP shall be designed to ensure a high level of protection of human health and the environment. It shall be proportionate to the major-accident hazards. It shall include the operator's overall aims and principles of action, the role and responsibility of management, as well as the commitment towards continuously improving the control of major-accident hazards, and ensuring a high level of protection.

(2) The MAPP shall be drawn up and sent to the competent authority within the following time-limits:

(a) for new establishments, a reasonable period of time or other period as may be agreed in writing by the competent authority, prior to the start of construction or operation, or prior to the modifications leading to a change in the inventory of dangerous substances;

(b) for all other cases, one year from the date from which these regulations apply to the establishment concerned.

(3) Sub-regulations (1) and (2) shall not apply if the operator has already established the MAPP and sent it to the competent

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\*revoked by these Regulations.



authority before 1 June 2015, and the information contained therein complies with sub-regulation (1) and has remained unchanged.

(4) Without prejudice to regulation 9, the operator shall periodically review and where necessary update the MAPP, at least every five years. The updated MAPP shall be sent to the competent authority without delay.

(5) The MAPP shall be implemented by appropriate means, structures and by a safety management system, in accordance with Schedule III, proportionate to the major-accident hazards, and the complexity of the organisation or the activities of the establishment. For lower-tier establishments, the obligation to implement the MAPP may be fulfilled by other appropriate means, structures and management systems, proportionate to major-accident hazards, taking into account the principles set out in Schedule III.

7. (1) The competent authority shall, using the information received from the operators in accordance with regulations 5 and 8, or following a request for additional information from the competent authority, or through inspections pursuant to regulation 16, identify all lower-tier and upper-tier establishments or groups of establishments where the risk or consequences of a major accident may be increased because of the geographical position and the proximity of such establishments, and their inventories of dangerous substances. Domino effects.

(2) Where the competent authority has additional information to that provided by the operator pursuant to regulation 5(1)(g), it shall make this information available to that operator, if it is necessary for the application of this regulation.

(3) The operators of the establishments identified in accordance with sub-regulation (1) shall:

(a) exchange suitable information to enable those establishments to take account of the nature and extent of the overall hazard of a major accident in their MAPP, safety management systems, safety reports and internal emergency plans, as appropriate;

(b) cooperate in informing the public and neighbouring sites that fall outside the scope of these regulations, and in supplying information to the Civil Protection Department.

8. (1) Every operator of an upper-tier establishment shall produce a safety report for the purposes of: Safety report.

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(a) demonstrating that a MAPP and a safety management system for implementing it have been put into effect in accordance with the information set out in Schedule III;

(b) demonstrating that major-accident hazards and possible major-accident scenarios have been identified and that the necessary measures have been taken to prevent such accidents and to limit their consequences for human health and the environment;

(c) demonstrating that adequate safety and reliability have been taken into account in 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 have been drawn up and supplying information to enable the external emergency plan to be drawn up;

(e) providing sufficient information to the competent authority to enable decisions to be made regarding 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 II. It shall name the relevant organisations involved in the drawing up of the report.

(3) The safety report shall be sent to the competent authority within the following time-limits:

(a) for new establishments, a reasonable period of time or other period as may be agreed in writing by the competent authority, prior to the start of construction or operation, or prior to the modifications leading to a change in the inventory of dangerous substances;

(b) for existing upper-tier establishments, 1 June 2016;

(c) for other establishments, two years from the date from which these regulations apply to the establishment concerned.

(4) Sub-regulations (1), (2) and (3) shall not apply if the operator has already sent the safety report to the competent authority under the requirements of the Control of Major Accident Hazards Regulations, 2003\* before the 1 June 2015, and the information

contained therein complies with sub-regulations (1) and (2) and has remained unchanged. In order to comply with sub-regulations (1) and (2), the operator shall submit any changed parts of the safety report in the format agreed by the competent authority, subject to the time-limits referred to in sub-regulation (3).

(5) Without prejudice to regulation 9, the operator shall periodically review and where necessary update the safety report at least every five years.

The operator shall also review and where necessary update the safety report following a major accident at its establishment, and at any other time at the initiative of the operator or at the request of the competent authority, where justified by new facts or by new technological knowledge about safety matters, including knowledge arising from analysis of accidents or, as far as possible, 'near misses', and by developments in knowledge concerning the assessment of hazards.

The updated safety report or updated parts thereof shall be sent to the competent authority without delay.

(6) Before the operator commences construction or operation, or in the cases referred to in sub-regulation (3)(b) and (c) and in sub-regulation (5), the competent authority shall within a reasonable period of receipt of the report communicate the conclusions of its examination of the safety report to the operator and, where appropriate, in accordance with regulation 15, prohibit the bringing into use, or the continued use, of the establishment concerned.

**9.** In the event of the modification of an installation, establishment, storage facility, or process or of the nature or physical form or quantity of dangerous substances which could have significant consequences for major-accident hazards, or could result in a lower-tier establishment becoming an upper-tier establishment or vice versa, every operator shall review, and where necessary updates the notification, the MAPP, the safety management system and the safety report and informs the competent authority of the details of those updates in advance of that modification.

Modification of an installation, an establishment or a storage facility.

**10. (1)** Every operator shall ensure that, for all upper-tier establishments:

Emergency plans.

(a) an internal emergency plan for the measures to be taken inside the establishment is drawn up;

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\*revoked by these Regulations.

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(b) the necessary information is supplied to the competent authority, to enable the Civil Protection Department to draw up external emergency plans.

(2) Operators shall comply with the obligations set out in sub-regulation (1)(a) and (b) within the following time- limits:

(a) for new establishments, a reasonable period of time or other period as may be agreed in writing by the competent authority, prior to the start of operation, or prior to the modifications leading to a change in the inventory of dangerous substances;

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(b) for existing upper-tier establishments, by 1 June 2016 unless the internal emergency plan drawn up under the requirements of the Control of Major Accident Hazards Regulations, 2003\* before that date, and the information contained therein, and the information referred to in sub-regulation (1)(b) complies with this regulation and has remained unchanged;

(c) for other establishments, two years from the date from which these regulations apply to the establishment concerned.

(3) The emergency plans shall be established with the following objectives:

(a) containing and controlling incidents so as to minimise the effects, and to limit damage to human health, the environment and property;

(b) implementing the necessary measures to protect human health and the environment from the effects of major accidents;

(c) communicating the necessary information to the public and to the services or authorities concerned in the area;

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

Emergency plans shall contain the information set out in Schedule IV.

(4) The operator shall ensure that the internal emergency plans

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\*revoked by these Regulations.

provided for in these regulations are drawn up in consultation with the personnel working inside the establishment, including long-term relevant subcontracted personnel.

(5) The Civil Protection Department shall ensure that the public concerned is given early opportunity to give its opinion on external emergency plans when they are being established or substantially modified. 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 external emergency plan as specified in Schedule IV for the measures to be taken outside the establishment within two years following receipt of the necessary information from the operator pursuant to sub-regulation (1)(b). Cap. 411.

(6) A person or entity who has prepared an emergency plan pursuant to a duty imposed by these regulations shall ensure that internal and external emergency plans are reviewed, tested, and where necessary updated at suitable intervals of no longer than three years. The review shall take into account changes occurring in the establishments concerned or within the emergency services concerned, new technical knowledge, and knowledge concerning the response to major accidents.

With regard to external emergency plans, the Civil Protection Department shall take into account the need to facilitate enhanced cooperation in civil protection assistance in major emergencies.

(7) The operator and, if necessary, the competent authority shall ensure that emergency plans are put into effect without delay when a major accident occurs, or when an uncontrolled event occurs which by its nature could reasonably be expected to lead to a major accident.

(8) The competent authority may decide, giving reasons for its decision, in view of the information contained in the safety report, that the requirement to produce an external emergency plan under sub-regulation (1) shall not apply.

(9) Where an exemption has been given under sub-regulation (8), 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) Every operator shall ensure that the information referred to in Schedule V is permanently available to the public, including electronically. The information shall be kept updated, Information to the public.

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where necessary, including in the event of modifications covered by regulation 9.

(2) Every operator of an upper-tier establishment shall also ensure that:

(a) all persons likely to be affected by a major accident receive regularly and in the most appropriate form, without having to request it, clear and intelligible information on safety measures and requisite behaviour in the event of a major accident;

(b) the safety report is made available to the public upon request subject to regulation 18(3); where regulation 18(3) applies, an amended report, for instance in the form of a non-technical summary, which shall include at least general information on major-accident hazards and on potential effects on human health and the environment in the event of a major accident, shall be made available;

(c) the inventory of dangerous substances is made available to the public upon request subject to regulation 18(3).

The information to be supplied under sub-regulation (2)(a) shall include at least the information referred to in Schedule V. That information shall likewise be supplied to all buildings and areas of public use, including schools and hospitals, and to all neighbouring establishments in the case of establishments covered by regulation 7. Every operator shall ensure that the information is supplied at least every five years and periodically reviewed and where necessary, updated, including in the event of modifications covered by regulation 9.

(3) The competent authority shall, with respect to the possibility of a major accident with transboundary effects originating in an upper-tier establishment, provide sufficient information to the potentially affected Member States so that all relevant provisions contained in regulation 10, in the Supplementary Planning Policy Guidance on Major Accident Hazards and Hazardous Substances and in this regulation can be applied, where applicable, by the potentially affected Member States.

(4) Where the competent authority has decided that an establishment close to the territory of another Member State is incapable of creating a major-accident hazard beyond its boundary for the purposes of regulation 10(8) and is not therefore required to produce an external emergency plan under regulation 10(1), it shall

inform the other Member State of its reasoned decision.

**12.** Every operator shall, as soon as practicable following a major accident, using the most appropriate means:

Information to be supplied by the operator and actions to be taken following a major accident.

- (a) inform the competent authority;
- (b) provide the competent authority with 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 human health, the environment and property;
  - (iv) the emergency measures taken;
- (c) inform the competent authority of the steps envisaged to:
  - (i) mitigate the medium-term and long-term effects of the accident;
  - (ii) prevent any recurrence of such an accident;
- (d) update the information provided if further investigation reveals additional facts which alter that information or the conclusions drawn.

**13.** (1) The competent authority shall inform the Commission as soon as practicable of major accidents meeting the criteria of Schedule VI 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 following a major accident.

- (a) the name and address of the authority responsible for the report;
- (b) the date, time and place of the 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 human health and the environment;

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

(e) the results of their analysis and recommendations.

(2) The information referred to in sub-regulation (1) shall be provided as soon as practicable and at the latest within one year of the date of the accident, using the database set up by the Commission. Where only preliminary information under sub-regulation (1)(e) can be provided within this time-limit for inclusion in the database, the information shall be updated once the results of further analysis and recommendations are available.

Reporting of the information referred to in sub-regulation (1)(e) by the competent authority may be delayed to allow for the completion of judicial proceedings where such reporting may affect those proceedings.

(3) The competent authority shall inform the Commission of the name and address of any person and, or entity which might have relevant information on major accidents and which is able to advise the competent authorities of other Member States which have to intervene in the event of such an accident.

Competent  
authority.

**14.** (1) It shall be the 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:

Provided that the Occupational Health and 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 15.

(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 -

(a) 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; Cap. 411.

(b) the competent authority shall jointly:

(i) ensure that any urgent, medium-term and long-term measures which may prove necessary are taken;

(ii) collect, by inspection, investigation or other appropriate means, the information necessary for a full analysis of the technical, organisational and managerial aspects of the accident;

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

(iv) make recommendations on future preventive measures; and

(v) inform the persons likely to be affected, of the accident which has occurred and, where relevant, of the measures undertaken to mitigate its consequences.

(6) The competent authority shall charge the operator a fee for performing its functions under these regulations according to regulation 8, provided that such 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.

(7) When requiring payment, the competent authority shall

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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.

(8) The competent authority may also charge the operator other fees under such provisions as specified in sub-regulations (6) and (7), for performing any other functions under these regulations. 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.

Prohibition of use.

**15. (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. To this end, the competent authority shall, *inter alia*, take into account serious failures to take the necessary actions identified in the inspection report.

(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).

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

**16. (1)** The competent authority shall organise a system of inspections which shall be appropriate to the type of establishment concerned:

Provided that these inspections shall not be dependent upon receipt of the safety report or any other report submitted 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 that:

(a) the operator can demonstrate that he has taken appropriate measures, in connection with the various activities of the establishment, to prevent major accidents;

(b) the operator can demonstrate that he has provided appropriate means for limiting the consequences of major accidents, on-site and off-site;

(c) the data and information contained in the safety report, or any other report submitted, adequately reflects the conditions in the establishment;

(d) information has been supplied to the public pursuant to regulation 11.

(2) The competent authority shall ensure that all establishments are covered by an inspection plan and shall ensure that this plan is regularly reviewed and, where appropriate, updated.

Each inspection plan shall include the following:

(a) a general assessment of relevant safety issues;

(b) the geographical area covered by the inspection plan;

(c) a list of the establishments covered by the plan;

(d) a list of groups of establishments with possible domino effects pursuant to regulation 7;

(e) a list of establishments where particular external risks or hazard sources could increase the risk or consequences of a major accident;

(f) procedures for routine inspections, including the programmes for such inspections pursuant to sub-regulation (3);

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(g) procedures for non-routine inspections pursuant to sub-regulation (5);

(h) provisions on the co-operation between different inspection authorities.

(3) Based on the inspection plans referred to in sub-regulation (2), the competent authority shall regularly draw up programmes for routine inspections for all establishments including the frequency of site visits for different types of establishments.

The period between two consecutive site visits shall not exceed one year for upper-tier establishments and three years for lower-tier establishments, unless the competent authority has drawn up an inspection programme based on a systematic appraisal of major-accident hazards of the establishments concerned.

(4) The systematic appraisal of the hazards of the establishments concerned shall be based on at least the following criteria:

(a) the potential impacts of the establishments concerned on human health and the environment;

(b) the record of compliance with the requirements of these regulations.

Where appropriate, relevant findings of inspections carried out under other regulations shall also be taken into account.

(5) Non-routine inspections shall be carried out to investigate serious complaints, serious accidents and 'near misses', incidents and occurrences of non-compliance as soon as possible.

(6) Within four months after each inspection, the competent authority shall communicate the conclusions of the inspection and all the necessary actions identified to the operator. The competent authority shall ensure that the operator takes all those necessary actions within a reasonable period after receipt of the communication.

(7) If an inspection has identified an important case of non-compliance with these regulations, an additional inspection shall be carried out within six months.

(8) Inspections shall, where possible, be coordinated with inspections under other regulations and combined, where appropriate.

(9) Every operator shall provide the competent authorities

with all necessary assistance to enable those authorities to carry out any inspection and to gather any information necessary for the performance of their duties for the purposes of these regulations, in particular to allow the authorities to fully assess the possibility of a major accident and to determine the scope of possible increased probability or aggravation of major accidents, to prepare an external emergency plan and to take into account substances which, due to their physical form, particular conditions or location, may require additional consideration.

**17.** (1) The competent authority and the Commission shall exchange information on the experience acquired with regard to the prevention of major accidents and the limitation of their consequences. This information shall concern, in particular, the functioning of the measures provided for in these regulations.

Information system and exchanges.

(2) By 30 September 2019, and every four years thereafter, the competent authority shall provide the Commission with a report on the implementation of these regulations.

(3) For establishments covered by these regulations, the competent authority shall supply the Commission with at least the following information:

- (a) the name or trade name of the operator and the full address of the establishment concerned;
- (b) the activity or activities of the establishment.

**18.** (1) The competent authority shall ensure, in the interests of transparency, that any information held pursuant to these regulations is made available to any natural or legal person who so requests in accordance with Directive 2003/4/EC.

Access to information and confidentiality.

(2) Disclosure of any information required under these regulations, including under regulation 11, may be refused or restricted by the competent authority where the conditions laid down in Article 4 of Directive 2003/4/EC are fulfilled.

(3) Disclosure of the complete information referred to in regulation 11(2)(b) and (c) held by the competent authority may be refused by that competent authority, without prejudice to sub-regulation (2) of this regulation, if the operator has requested not to disclose certain parts of the safety report or the inventory of dangerous substances for the reasons provided for in Article 4 of Directive 2003/4/EC.

The competent authority may also decide for the same

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reasons that certain parts of the report or inventory shall not be disclosed. In such cases, and on approval of the competent authority, the operator shall supply to the competent authority an amended report or inventory excluding those parts.

Enforcement. **19. (1)** Any breach of any of these regulations shall be deemed an offence.

(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) (a) 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.

(b) 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.

(c) Without prejudice to the preceding sub-regulations, no proceedings shall be taken against any person who after receiving an intimation from the competent authority for the payment of an administrative fine for having contravened the provisions of these regulations, pays such a penalty and provides sufficient proof that all remedial action has been taken to the satisfaction of the competent authority, within fifteen days of the date of such intimation.

Revocation of  
the Control of  
Major Accident  
Hazards  
Regulations,  
2003.  
L.N. 37 of 2003.

**20.** The Control of Major Accident Hazards Regulations, 2003 are hereby revoked.

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## SCHEDULE I

### DANGEROUS SUBSTANCES TO WHICH THE REGULATIONS APPLY

Dangerous substances covered by the hazard categories listed in Column 1 of Part 1 of this Schedule are subject to the qualifying quantities set out in Columns 2 and 3 of Part 1.

Where a dangerous substance is covered by Part 1 of this Schedule and is also listed in Part 2, the qualifying quantities set out

in Columns 2 and 3 of Part 2 apply.

## PART 1

### Categories of dangerous substances

This Part covers all dangerous substances falling under the hazard categories listed in Column 1:

Column 1	Column 2	Column 3
Hazard categories in accordance with Regulation (EC) No 1272/2008	Qualifying quantity (tonnes) of dangerous substances as referred to in regulation 2 for the application of	
	Lower-tier requirements	Upper-tier requirements
Section 'H' - HEALTH HAZARDS		
H1 ACUTE TOXIC Category 1, all exposure routes	5	20
H2 ACUTE TOXIC - Category 2, all exposure routes - Category 3, inhalation exposure route (see note 7)	50	200
H3 STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE STOT SE Category 1	50	200
Section 'P' - PHYSICAL HAZARDS		
P1(a) EXPLOSIVES (see note 8) - Unstable explosives or - Explosives, Division 1.1, 1.2, 1.3, 1.5 or 1.6, or - Substances or mixtures having explosive properties according to method A.14 of Regulation (EC) No 440/2008 (see note 9) and do not belong to the hazard classes Organic peroxides or Self-reactive substances and mixtures	10	50
P1(b) EXPLOSIVES (see note 8) Explosives, Division 1.4 (see note 10)	50	200
P2 FLAMMABLE GASES Flammable gases, Category 1 or 2	10	50
P3(a) FLAMMABLE AEROSOLS (see note 11.1) 'Flammable' aerosols Category 1 or 2, containing flammable gases Category 1 or 2 or flammable liquids Category 1	150 (net)	500 (net)

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Column 1	Column 2	Column 3
Hazard categories in accordance with Regulation (EC) No 1272/2008	Qualifying quantity (tonnes) of dangerous substances as referred to in regulation 2 for the application of	
	Lower-tier requirements	Upper-tier requirements
P3(b) FLAMMABLE AEROSOLS (see note 11.1) 'Flammable' aerosols Category 1 or 2, not containing flammable gases Category 1 or 2 nor flammable liquids category 1 (see note 11.2)	5000 (net)	50000 (net)
P4 OXIDISING GASES Oxidising gases, Category 1	50	200
P5(a) FLAMMABLE LIQUIDS - Flammable liquids, Category 1, or - Flammable liquids Category 2 or 3 maintained at a temperature above their boiling point, or - Other liquids with a flash point $\leq 60^{\circ}\text{C}$ , maintained at a temperature above their boiling point (see note 12)	10	50
P5(b) FLAMMABLE LIQUIDS - Flammable liquids Category 2 or 3 where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards, or - Other liquids with a flash point $\leq 60^{\circ}\text{C}$ where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards (see note 12)	50	200
P5(c) FLAMMABLE LIQUIDS Flammable liquids, Categories 2 or 3 not covered by P5(a) and P5(b)	5000	50000
P6(a) SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES Self-reactive substances and mixtures, Type A or B or organic peroxides, Type A or B	10	50
P6(b) SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES Self-reactive substances and mixtures, Type C, D, E or F or organic peroxides, Type C, D, E, or F	50	200



Column 1	Column 2	Column 3
Hazard categories in accordance with Regulation (EC) No 1272/2008	Qualifying quantity (tonnes) of dangerous substances as referred to in regulation 2 for the application of	
	Lower-tier requirements	Upper-tier requirements
P7 PYROPHORIC LIQUIDS AND SOLIDS Pyrophoric liquids, Category 1 Pyrophoric solids, Category 1	50	200
P8 OXIDISING LIQUIDS AND SOLIDS Oxidising Liquids, Category 1, 2 or 3, or Oxidising Solids, Category 1, 2 or 3	50	200
Section 'E' - ENVIRONMENTAL HAZARDS		
E1 Hazardous to the Aquatic Environment in Category Acute 1 or Chronic 1	100	200
E2 Hazardous to the Aquatic Environment in Category Chronic 2	200	500
Section 'O' - OTHER HAZARDS		
O1 Substances or mixtures with hazard statement EUH014	100	500
O2 Substances and mixtures which in contact with water emit flammable gases, Category 1	100	500
O3 Substances or mixtures with hazard statement EUH029	50	200

## Part 2

## Named Dangerous Substances

Column 1	CAS number ( <sup>1</sup> )	Column 2	Column 3
Dangerous substances		Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
1. Ammonium nitrate (see note 13)	-	5000	10000
2. Ammonium nitrate (see note 14)	-	1250	5000
3. Ammonium nitrate (see note 15)	-	350	2500
4. Ammonium nitrate (see note 16)	-	10	50
5. Potassium nitrate (see note 17)	-	5000	10000

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Column 1	CAS number ( <sup>1</sup> )	Column 2	Column 3
Dangerous substances		Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
6. Potassium nitrate (see note 18)	-	1250	5000
7. Arsenic pentoxide, arsenic (V) acid and/or salts	1303-28-2	1	2
8. Arsenic trioxide, arsenious (III) acid and/or salts	1327-53-3	-	0.1
9. Bromine	7726-95-6	20	100
10. Chlorine	7782-50-5	10	25
11. Nickel compounds in inhalable powder form: nickel monoxide, nickel dioxide, nickel sulphide, trinickel disulphide, dinickel trioxide	-	-	1
12. Ethyleneimine	151-56-4	10	20
13. Fluorine	7782-41-4	10	20
14. Formaldehyde (concentration $\geq$ 90%)	50-00-0	5	50
15. Hydrogen	1333-74-0	5	50
16. Hydrogen chloride (liquefied gas)	7647-01-0	25	250
17. Lead alkyls	-	5	50
18. Liquefied flammable gases, Category 1 or 2 (including LPG) and natural gas (see note 19)	-	50	200
19. Acetylene	74-86-2	5	50
20. Ethylene oxide	75-21-8	5	50
21. Propylene oxide	75-56-9	5	50
22. Methanol	67-56-1	500	5000
23. 4, 4'-Methylene bis (2-chloraniline) and/or salts, in powder form	101-14-4	-	0.01
24. Methylisocyanate	624-83-9	-	0.15
25. Oxygen	7782-44-7	200	2000
26. 2,4 -Toluene diisocyanate 2,6 -Toluene diisocyanate	584-84-9 91-08-7	10	100
27. Carbonyl dichloride (phosgene)	75-44-5	0.3	0.75
28. Arsine (arsenic trihydride)	7784-42-1	0.2	1
29. Phosphine (phosphorus trihydride)	7803-51-2	0.2	1
30. Sulphur dichloride	10545-99-0	-	1
31. Sulphur trioxide	7446-11-9	15	75

Column 1		Column 2	Column 3
Dangerous substances	CAS number ( <sup>1</sup> )	Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
32. Polychlorodibenzofurans and polychlorodibenzodioxins (including TCDD), calculated in TCDD equivalent (see note 20)	-	-	0.001
33. The following CARCINOGENS or the mixtures containing the following carcinogens at concentrations above 5 % by weight: 4-Aminobiphenyl and/or its salts, Benzotrichloride, Benzidine and/or salts, Bis (chloromethyl) ether, Chloromethyl methyl ether, 1,2-Dibromoethane, Diethyl sulphate, Dimethyl sulphate, Dimethylcarbamoyl chloride, 1,2-Dibromo-3-chloropropane, 1,2-Dimethylhydrazine, Dimethylnitrosamine, Hexamethylphosphoric triamide, Hydrazine, 2-Naphthylamine and/or salts, 4-Nitrodiphenyl, and 1,3 Propanesultone	-	0.5	2

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Column 1		Column 2	Column 3
Dangerous substances	CAS number ( <sup>1</sup> )	Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
34. Petroleum products and alternative fuels (a) gasolines and naphthas, (b) kerosenes (including jet fuels), (c) gas oils (including diesel fuels, home heating oils and gas oil blending streams) (d) heavy fuel oils (e) alternative fuels serving the same purposes and with similar properties as regards flammability and environmental hazards as the products referred to in points (a) to (d)	-	2500	25000
35. Anhydrous Ammonia	7664-41-7	50	200
36. Boron trifluoride	7637-07-2	5	20
37. Hydrogen sulphide	7783-06-4	5	20
38. Piperidine	110-89-4	50	200
39. Bis(2-dimethylaminoethyl) (methyl)amin	3030-47-5	50	200
40. 3-(2-Ethylhexyloxy) propylamin	5397-31-9	50	200
41. Mixtures (*) of sodium hypochlorite classified as Aquatic Acute Category 1 [H400] containing less than 5% active chlorine and not classified under any of the other hazard categories in Part 1 of Schedule I.  (*) Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].	-	200	500
42. Propylamine (see note 21)	107-10-8	500	2000
43. Tert-butyl acrylate (see note 21)	1663-39-4	200	500

Column 1	CAS number ( <sup>1</sup> )	Column 2	Column 3
Dangerous substances		Qualifying quantity (tonnes) for the application of	
		Lower-tier requirements	Upper-tier requirements
44. 2-Methyl-3-butenenitrile (see note 21)	16529-56-9	500	2000
45. Tetrahydro-3,5-dimethyl- 1,3,5,-thiadiazine-2- thione (Dazomet) (see note 21)	533-74-4	100	200
46. Methyl acrylate (see note 21)	96-33-3	500	2000
47. 3-Methylpyridine (see note 21)	108-99-6	500	2000
48. 1-Bromo-3-chloropropane (see note 21)	109-70-6	500	2000
<sup>(1)</sup> The CAS number is shown only for indication.			

#### Notes to Schedule I

1. Substances and mixtures are classified in accordance with Regulation (EC) No 1272/2008.

2. Mixtures shall be treated in the same way as pure substances provided they remain within concentration limits set according to their properties under Regulation (EC) No 1272/2008, or its latest adaptation to technical progress, unless a percentage composition or other description is specifically given.

3. The qualifying quantities set out above relate to each establishment.

The quantities to be considered for the application of the relevant regulations are the maximum quantities which are present or are likely to be present at any one time. Dangerous substances present at an establishment only in quantities equal to or less than 2% 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 at that establishment.

4. The following rules governing the addition of dangerous substances, or categories of dangerous substances, shall apply where appropriate:

In the case of an establishment where no individual dangerous substance is present in a quantity above or equal to the relevant

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qualifying quantities, the following rule shall be applied to determine whether the establishment is covered by the relevant requirements of these regulations.

These regulations shall apply to upper-tier establishments if the sum:

$q_1 / Q_{U1} + q_2 / Q_{U2} + q_3 / Q_{U3} + q_4 / Q_{U4} + q_5 / Q_{U5} + \dots$  is greater than or equal to 1,

where  $q_x$  = the quantity of dangerous substance x (or category of dangerous substances) falling within Part 1 or Part 2 of this Schedule,

and  $Q_{UX}$  = the relevant qualifying quantity for dangerous substance or category x from Column 3 of Part 1 or from Column 3 of Part 2 of this Schedule.

These regulations shall apply to lower-tier establishments if the sum:

$q_1 / Q_{L1} + q_2 / Q_{L2} + q_3 / Q_{L3} + q_4 / Q_{L4} + q_5 / Q_{L5} + \dots$  is greater than or equal to 1,

where  $q_x$  = the quantity of dangerous substance x (or category of dangerous substances) falling within Part 1 or Part 2 of this Schedule,

and  $Q_{LX}$  = the relevant qualifying quantity for dangerous substance or category x from Column 2 of Part 1 or from Column 2 of Part 2 of this Schedule.

This rule shall be used to assess the health hazards, physical hazards and environmental hazards. It must therefore be applied three times:

(a) for the addition of dangerous substances listed in Part 2 that fall within acute toxicity category 1, 2 or 3 (inhalation route) or STOT SE category 1, together with dangerous substances falling within section H, entries H1 to H3 of Part 1;

(b) for the addition of dangerous substances listed in Part 2 that are explosives, flammable gases, flammable aerosols, oxidising gases, flammable liquids, self-reactive substances and mixtures, organic peroxides, pyrophoric liquids and solids, oxidising liquids and solids, together with dangerous substances falling within section P, entries P1 to P8 of Part 1;

(c) for the addition of dangerous substances listed in

Part 2 that fall within hazardous to the aquatic environment acute category 1, chronic category 1 or chronic category 2, together with dangerous substances falling within section E, entries E1 and E2 of Part 1.

The relevant provisions of these regulations apply where any of the sums obtained by (a), (b) or (c) is greater than or equal to 1.

5. In the case of dangerous substances which are not covered by Regulation (EC) No 1272/2008, including waste, 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, these shall be provisionally assigned to the most analogous category or named dangerous substance falling within the scope of these regulations.

6. In the case of dangerous substances with properties giving rise to more than one classification, for the purposes of these regulations the lowest qualifying quantities shall apply. However, for the application of the rule in Note 4, the lowest qualifying quantity for each group of categories in Notes 4(a), 4(b) and 4(c) corresponding to the classification concerned shall be used.

7. Dangerous substances that fall within Acute Toxic Category 3 via the oral route (H 301) shall fall under entry H2 ACUTE TOXIC in those cases where neither acute inhalation toxicity classification nor acute dermal toxicity classification can be derived, for example due to lack of conclusive inhalation and dermal toxicity data.

8. The hazard class Explosives includes explosive articles (see Section 2.1 of Annex I to Regulation (EC) No 1272/2008). If the quantity of the explosive substance or mixture contained in the article is known, that quantity shall be considered for the purposes of these regulations. If the quantity of the explosive substance or mixture contained in the article is not known, then, for the purposes of these regulations, the whole article shall be treated as explosive.

9. Testing for explosive properties of substances and mixtures is only necessary if the screening procedure according to Appendix 6, Part 3 of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria (UN Manual of Tests and Criteria)\* identifies the substance or mixture as potentially having explosive properties.

10. If Explosives of Division 1.4 are unpacked or repacked,

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they shall be assigned to the entry P1(a), unless the hazard is shown to still correspond to Division 1.4, in accordance with Regulation (EC) No 1272/2008.

11.1. Flammable aerosols are classified in accordance with the Council Directive 75/324/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to aerosol dispensers (Aerosol Dispensers Directive). 'Extremely flammable' and 'Flammable' aerosols of Directive 75/324/EEC correspond to Flammable Aerosols Category 1 or 2 respectively of Regulation (EC) No 1272/2008.

11.2. In order to use this entry, it must be documented that the aerosol dispenser does not contain Flammable Gas Category 1 or 2 nor Flammable Liquid Category 1.

12. According to paragraph 2.6.4.5 in Annex I to Regulation (EC) No 1272/2008, liquids with a flash point of more than 35°C need not be classified in Category 3 if negative results have been obtained in the sustained combustibility test L.2, Part III, section 32 of the UN Manual of Tests and Criteria. This is however not valid under elevated conditions such as high temperature or pressure, and therefore such liquids are included in this entry.

13. Ammonium nitrate (5000 / 10000): fertilisers capable of self-sustaining decomposition

This applies to ammonium nitrate-based compound/composite fertilisers (compound/composite fertilisers contain ammonium nitrate with phosphate and/or potash) which are capable of self-sustaining decomposition according to the UN Trough Test (see UN Manual of Tests and Criteria, Part III, subsection 38.2), and in which the nitrogen content as a result of ammonium nitrate is

- between 15.75%\* and 24.5%\*\* by weight, and either with not more than 0.4% total combustible/organic materials or which fulfil the requirements of Annex III-2 to Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers

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\*More guidance on waiving of the test can be found in the A.14 method description, see Commission Regulation (EC) No 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (OJ L 142, 31.5.2008, p. 1).

\* 15.75% nitrogen content by weight as a result of ammonium nitrate corresponds to 45% ammonium nitrate.

\*\* 24.5% nitrogen content by weight as a result of ammonium nitrate corresponds to 70% ammonium nitrate.



- 15.75% by weight or less and unrestricted combustible materials.

#### 14. Ammonium nitrate (1250 / 5000): fertiliser grade

This applies to straight ammonium nitrate-based fertilisers and to ammonium nitrate-based compound/composite fertilisers which fulfil the requirements of Annex III-2 to Regulation (EC) No 2003/2003 and in which the nitrogen content as a result of ammonium nitrate is

- more than 24.5% by weight, except for mixtures of straight ammonium nitrate-based fertilisers with dolomite, limestone and/or calcium carbonate with a purity of at least 90%,
- more than 15.75% by weight for mixtures of ammonium nitrate and ammonium sulphate,
- more than 28%\* by weight for mixtures of straight ammonium nitrate-based fertilisers with dolomite, limestone and/or calcium carbonate with a purity of at least 90%.

#### 15. Ammonium nitrate (350 / 2500): technical grade

This applies to ammonium nitrate and mixtures of ammonium nitrate in which the nitrogen content as a result of the ammonium nitrate is

- between 24.5% and 28% by weight, and which contain not more than 0.4% combustible substances,
- more than 28% by weight, and which contain not more than 0.2% combustible substances.

It also applies to aqueous ammonium nitrate solutions in which the concentration of ammonium nitrate is more than 80% by weight.

#### 16. Ammonium nitrate (10 / 50): 'off-specs' material and fertilisers not fulfilling the detonation test

This applies to

- material rejected during the manufacturing process and to ammonium nitrate and mixtures of ammonium nitrate, straight ammonium nitrate-based fertilisers and ammonium

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\* 28% nitrogen content by weight as a result of ammonium nitrate corresponds to 80% ammonium nitrate.

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nitrate-based compound/composite fertilisers referred to in Notes 14 and 15, that are being or have been returned from the final user to a manufacturer, temporary storage or reprocessing plant for reworking, recycling or treatment for safe use, because they no longer comply with the specifications of Notes 14 and 15,

- fertilisers referred to in first indent of Note 13, and Note 14 to this Schedule which do not fulfil the requirements of Annex III-2 to Regulation (EC) No 2003/2003.

#### 17. Potassium nitrate (5000 / 10000)

This applies to those composite potassium-nitrate based fertilisers (in prilled/granular form) which have the same hazardous properties as pure potassium nitrate.

#### 18. Potassium nitrate (1250 / 5000)

This applies to those composite potassium-nitrate based fertilisers (in crystalline form) which have the same hazardous properties as pure potassium nitrate.

#### 19. Upgraded biogas

For the purpose of the implementation of these regulations, upgraded biogas may be classified under entry 18 of Part 2 of Schedule I where it has been processed in accordance with applicable standards for purified and upgraded biogas ensuring a quality equivalent to that of natural gas, including the content of Methane, and which has a maximum of 1% Oxygen.

#### 20. Polychlorodibenzofurans and polychlorodibenzodioxins

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

WHO 2005 TEF			
2, 3, 7, 8-TCDD	1	2, 3, 7, 8-TCDF	0.1
1, 2, 3, 7, 8-PeCDD	1	2, 3, 4, 7, 8-PeCDF	0.3
		1, 2, 3, 7, 8-PeCDF	0.03
1,2,3,4,7,8-HxCDD	0.1		
1,2,3,6,7,8-HxCDD	0.1	1, 2, 3, 4, 7, 8-HxCDF	0.1
1,2,3,7,8,9-HxCDD	0.1	1, 2, 3, 7, 8, 9-HxCDF	0.1
		1, 2, 3, 6, 7, 8-HxCDF	0.1
1, 2, 3, 4, 6, 7, 8-HpCDD	0.01	2, 3, 4, 6, 7, 8-HxCDF	0.1

OCDD	0.0003	1, 2, 3, 4, 6, 7, 8-HpCDF	0.01
		1, 2, 3, 4, 7, 8, 9-HpCDF	0.01
		OCDF	0.0003
(T = tetra, P = penta, Hx = hexa, Hp = hepta, O = octa)			
Reference - Van den Berg et al: The 2005 World Health Organisation Re-evaluation of Human and Mammalian Toxic Equivalency Factors for Dioxins and Dioxin-like Compounds			

21. In cases where this dangerous substance falls within category P5(a) Flammable liquids or P5(b) Flammable liquids, then for the purposes of these regulations the lowest qualifying quantities shall apply.

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## SCHEDULE II

Minimum data and information to be considered in the safety report referred to in regulation 8

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 indicated in Schedule III.

2. Presentation of the environment of the establishment:

(a) description of the establishment and its environment including the geographical location, meteorological, geological, 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) on the basis of available information, identification of neighbouring establishments, as well as sites that fall outside the scope of these regulations, areas and developments that could be the source of, or increase the risk or consequences of a major accident and of domino effects;

(d) description of areas where a major accident may occur.

3. Description of the installation:

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(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; where applicable, taking into account available information on best practices;

(c) description of dangerous substances:

(i) inventory of dangerous substances including:

- the identification of dangerous substances: chemical name, CAS number, name according to IUPAC nomenclature,

- the maximum quantity of dangerous substances present or likely to be present;

(ii) physical, chemical, toxicological characteristics and indication of the hazards, both immediate and delayed for human health 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; including in particular:

(i) operational causes;

(ii) external causes, such as those related to domino effects, sites that fall outside the scope of these regulations, areas and developments that could be the source of, or increase the risk or consequences of a major accident;

(iii) natural causes, for example earthquakes or

floods;

(b) assessment of the extent and severity of the consequences of identified major accidents including maps, images or, as appropriate, equivalent descriptions, showing areas which are likely to be affected by such accidents arising from the establishment;

(c) review of past accidents and incidents with the same substances and processes used, consideration of lessons learned from these, and explicit reference to specific measures taken to prevent such accidents;

(d) description of technical parameters and equipment used for the safety of installations.

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

(a) description of the equipment installed in the plant to limit the consequences of major accidents for human health and environment, including for example detection/protection systems, technical devices for limiting the size of accidental releases, including water spray; vapour screens; emergency catch pots or collection vessels; shut-off-valves; inerting systems; fire water retention;

(b) organisation of alert and intervention;

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

(d) description of any technical and non-technical measures relevant for the reduction of the impact of a major accident.

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### SCHEDULE III

Information referred to in regulation 6(5) and regulation 8 on the safety management system and the organisation of the establishment with a view to the prevention of major accidents

For the purpose of implementing the operator's safety management system, account shall be taken of the following elements:

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(a) the safety management system shall be proportionate to the hazards, industrial activities and complexity of the organisation in the establishment and be based on assessment of the risks; it 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 (MAPP);

(b) the following issues shall be addressed by the safety management system:

(i) organisation and personnel - the roles and responsibilities of personnel involved in the management of major hazards at all levels in the organisation, together with the measures taken to raise awareness of the need for continuous improvement. The identification of training needs of such personnel and the provision of the training so identified. The involvement of employees and of subcontracted personnel working in the establishment which are important from the point of view of safety;

(ii) identification and evaluation of major hazards - adoption and implementation of procedures for systematically identifying major hazards arising from normal and abnormal operation including subcontracted activities where applicable and the assessment of their likelihood and severity;

(iii) operational control - adoption and implementation of procedures and instructions for safe operation, including maintenance, of plant, processes and equipment, and for alarm management and temporary stoppages; taking into account available information on best practices for monitoring and control, with a view to reducing the risk of system failure; management and control of the risks associated with ageing equipment installed in the establishment and corrosion; inventory of the establishment's equipment, strategy and methodology for monitoring and control of the condition of the equipment; appropriate follow-up actions and any necessary countermeasures;

(iv) management of change - adoption and implementation of procedures for planning modifications to, or the design of new installations, processes or storage facilities;

(v) planning for emergencies - adoption and implementation of procedures to identify foreseeable emergencies by systematic analysis, to prepare, test and review emergency plans to respond to such emergencies and to provide specific training for the staff concerned. Such training shall be given to all personnel working in the establishment, including relevant subcontracted personnel;

(vi) monitoring performance - adoption and implementation of procedures for the ongoing assessment of compliance with the objectives set by the operator's MAPP and safety management system, and the mechanisms for investigation and taking corrective action in case of non-compliance. The procedures shall 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. The procedures could also include performance indicators such as safety performance indicators (SPIs) and/or other relevant indicators;

(vii) audit and review - adoption and implementation of procedures for periodic systematic assessment of the MAPP 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, including consideration and incorporation of necessary changes indicated by the audit and review.

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#### SCHEDULE IV

Data and information to be included in the emergency plans referred to in regulation 10

1. Internal emergency plans:

(a) Names or positions of persons authorised to set emergency procedures in motion and the person in charge of and coordinating the on-site mitigatory action;

(b) Name or position of the person with responsibility for liaising with the authority responsible for the external emergency plan;

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(c) 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;

(d) 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;

(e) Arrangements for providing early warning of the incident to the authority responsible for setting the external 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;

(f) Where necessary, arrangements for training staff in the duties they will be expected to perform and, as appropriate, coordinating this with off-site emergency services;

(g) Arrangements for providing assistance with off-site mitigatory action.

## 2. External emergency plans:

(a) Names or positions of persons authorised to set emergency procedures in motion and of persons authorised to take charge of and coordinate off-site action;

(b) Arrangements for receiving early warning of incidents, and alert and call-out procedures;

(c) Arrangements for coordinating resources necessary to implement the external emergency plan;

(d) Arrangements for providing assistance with on-site mitigatory action;

(e) Arrangements for off-site mitigatory action, including responses to major-accident scenarios as set out in the safety report and considering possible domino effects, including those having an impact on the environment;

(f) Arrangements for providing the public and any neighbouring establishments or sites that fall outside the scope of these regulations in accordance with regulation 7 with specific information relating to the accident and the behaviour which should be adopted;



(g) Arrangements for the provision of information to the emergency services of other Member States in the event of a major accident with possible transboundary consequences.

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## SCHEDULE V

Items of information to the public as provided for in regulation 11(1) and in regulation 11(2)(a)

### PART 1

For all establishments covered by these regulations:

1. Name or trade name of the operator and the full address of the establishment concerned.
2. Confirmation that the establishment is subject to the regulations and/or administrative provisions implementing these regulations and that the notification referred to in regulation 5(1) or the safety report referred to in regulation 8(1) has been submitted to the competent authority.
3. An explanation in simple terms of the activity or activities undertaken at the establishment.
4. The common names or, in the case of dangerous substances covered by Part 1 of Schedule I, the generic names or the hazard classification of the relevant dangerous substances involved at the establishment which could give rise to a major accident, with an indication of their principal dangerous characteristics in simple terms.
5. General information about how the public concerned will be warned, if necessary; adequate information about the appropriate behaviour in the event of a major accident or indication of where that information can be accessed electronically.
6. The date of the last site visit in accordance with regulation 16(3), or reference to where that information can be accessed electronically; information on where more detailed information about the inspection and the related inspection plan can be obtained upon request, subject to the requirements of regulation 18.
7. Details of where further relevant information can be obtained, subject to the requirements of regulation 18.

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## PART 2

For upper-tier establishments, in addition to the information referred to in Part 1 of this Schedule:

1. General information relating to the nature of the major-accident hazards, including their potential effects on human health and the environment and summary details of the main types of major-accident scenarios and the control measures to address them.

2. 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.

3. Appropriate information from the external emergency plan drawn up to cope with any off-site effects from an accident. This should include advice to cooperate with any instructions or requests from the emergency services at the time of an accident.

4. Where applicable, indication whether the establishment is close to the territory of another Member State with the possibility of a major accident with transboundary effects under the Convention of the United Nations Economic Commission for Europe on the Transboundary Effects of Industrial Accidents.

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SCHEDULE VI

Criteria for the notification of a major accident to the Commission as provided for in regulation 13(1)

I. Any major accident covered by paragraph 1 or having at least one of the consequences described in paragraphs 2, 3, 4 and 5 must be notified to the Commission.

1. Dangerous substances involved

Any fire or explosion or accidental discharge of a dangerous substance involving a quantity of at least 5% of the qualifying quantity laid down in Column 3 of Part 1 or in Column 3 of Part 2 of Schedule I.

2. Injury to persons and damage to real estate:

(a) a death;

(b) six persons injured within the establishment and hospitalised for at least 24 hours;

(c) one person outside the establishment hospitalised for at least 24 hours;

(d) dwelling(s) outside the establishment damaged and unusable as a result of the accident;

(e) the evacuation or confinement of persons for more than 2 hours (persons × hours): the value is at least 500;

(f) the interruption of drinking water, electricity, gas or telephone services for more than 2 hours (persons × hours): the value is at least 1000.

3. Immediate damage to the environment:

(a) permanent or long-term damage to terrestrial habitats:

(i) 0.5 ha or more of a habitat of environmental or conservation importance protected by legislation;

(ii) 10 or more hectares of more widespread habitat, including agricultural land;

(b) significant or long-term damage to freshwater and marine habitats:

(i) 10 km or more of river or canal;

(ii) 1 ha or more of a lake or pond;

(iii) 2 ha or more of delta;

(iv) 2 ha or more of a coastline or open sea;

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

1 ha or more.

4. Damage to property:

(a) damage to property in the establishment: at least EUR 2,000,000;

(b) damage to property outside the establishment:  
at least EUR 500,000.

5. Cross-border damage

Any major accident directly involving a dangerous substance giving rise to effects outside the territory of the Member State concerned.

II. Accidents or 'near misses' which the competent authority regards 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 Commission.

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