

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 (Text with EEA relevance)

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

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee⁽¹⁾,

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure⁽²⁾,

Whereas:

- (1) Council Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances⁽³⁾ lays down rules for the prevention of major accidents which might result from certain industrial activities and the limitation of their consequences for human health and the environment.
- (2) Major accidents often have serious consequences, as evidenced by accidents like Seveso, Bhopal, Schweizerhalle, Enschede, Toulouse and Buncefield. Moreover the impact can extend beyond national borders. This underlines the need to ensure that appropriate precautionary action is taken to ensure a high level of protection throughout the Union for citizens, communities and the environment. There is therefore a need to ensure that the existing high level of protection remains at least the same or increases.
- (3) Directive 96/82/EC has been instrumental in reducing the likelihood and consequences of such accidents thereby leading to a better level of protection throughout the Union. A review of that Directive has confirmed that the rate of major accidents has remained stable. While overall the existing provisions are fit for purpose, some changes are required in order to further strengthen the level of protection, in particular with regard to the prevention of major accidents. At the same time the system established by Directive 96/82/EC should be adapted to changes to the Union system of classification

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of substances and mixtures to which that Directive refers. In addition, a number of other provisions should be clarified and updated.

- (4) It is therefore appropriate to replace Directive 96/82/EC in order to ensure that the existing level of protection is maintained and further improved, by making the provisions more effective and efficient, and where possible by reducing unnecessary administrative burdens by streamlining or simplification, provided that safety and environmental and human health protection are not compromised. At the same time, the new provisions should be clear, coherent and easy to understand to help improve implementation and enforceability, while the level of protection of human health and the environment remains at least the same or increases. The Commission should cooperate with the Member States on the practical implementation of this Directive. That cooperation should, *inter alia*, address the issue of self-classification of substances and mixtures. As appropriate, stakeholders such as representatives of industry, workers and non-governmental organisations promoting the protection of human health or the environment should be involved in the implementation of this Directive.
- (5) The Convention of the United Nations Economic Commission for Europe on the Transboundary Effects of Industrial Accidents, which was approved on behalf of the Union by Council Decision 98/685/EC of 23 March 1998 concerning the conclusion of the Convention on the Transboundary Effects of Industrial Accidents⁽⁴⁾, provides for measures regarding the prevention of, preparedness for, and response to industrial accidents capable of causing transboundary effects as well as for international cooperation in this field. Directive 96/82/EC implements the Convention within Union law.
- (6) Major accidents can have consequences beyond frontiers, and the ecological and economic costs of an accident are borne not only by the establishment affected, but also by the Member States concerned. It is therefore necessary to establish and apply safety and risk-reduction measures to prevent possible accidents, to reduce the risk of accidents occurring and to minimise the effects if they do occur, thereby making it possible to ensure a high level of protection throughout the Union.
- (7) The provisions of this Directive should apply without prejudice to the provisions of Union law relating to health and safety at work and the working environment, and, in particular, without prejudice to Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work⁽⁵⁾.
- (8) Certain industrial activities should be excluded from the scope of this Directive provided they are subject to other legislation at Union or national level providing for an equivalent level of safety. The Commission should continue to examine whether there are significant gaps in the existing regulatory framework, in particular as regards new and emerging risks from other activities as well as from specific dangerous substances and, if appropriate, present a legislative proposal to address those gaps.
- (9) Annex I to Directive 96/82/EC lists the dangerous substances falling within its scope, *inter alia*, by reference to certain provisions of Council Directive 67/548/EEC of 27 June 1967 on the approximation of the laws, regulations and administrative provisions

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relating to the classification, packaging and labelling of dangerous substances⁽⁶⁾ as well as Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations⁽⁷⁾. Directives 67/548/EEC and 1999/45/EC have been replaced by Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures⁽⁸⁾, which implements within the Union the Globally Harmonised System of Classification and Labelling of Chemicals that has been adopted at international level, within the structure of the United Nations (UN). That Regulation introduces new hazard classes and categories only partially corresponding to those used under those repealed Directives. Certain substances or mixtures would, however, not be classified under that system due to an absence of criteria within that framework. Annex I to Directive 96/82/EC therefore needs to be amended to align it to that Regulation while maintaining the existing level, or further increasing the level, of protection provided for in that Directive.

- (10) For the purpose of classifying upgraded biogas, any developments on standards under the European Committee for Standardisation (CEN) should be taken into account.
- (11) Unwanted effects from the alignment to Regulation (EC) No 1272/2008 and subsequent adaptations to that Regulation having an impact on the classification of substances and mixtures may occur. On the basis of criteria included in this Directive, the Commission should assess whether, notwithstanding their hazard classification, there are dangerous substances which do not present a major-accident hazard and, where appropriate, submit a legislative proposal to exclude the dangerous substance concerned from the scope of this Directive. The assessment should start swiftly, in particular after the change of classification of a substance or mixture, in order to avoid unnecessary burdens for operators and competent authorities in the Member States. Exclusions from the scope of this Directive should not prevent any Member State from maintaining or introducing more stringent protective measures.
- (12) Operators should have a general obligation to take all necessary measures to prevent major accidents, to mitigate their consequences and to take recovery measures. Where dangerous substances are present in establishments above certain quantities the operator should provide the competent authority with sufficient information to enable it to identify the establishment, the dangerous substances present and the potential dangers. The operator should also draw up and, where required by national law, send to the competent authority a major-accident prevention policy (MAPP) setting out the operator's overall approach and measures, including appropriate safety management systems, for controlling major-accident hazards. When the operators identify and evaluate the major-accident hazards, consideration should also be given to the dangerous substances which may be generated during a severe accident within the establishment.
- (13) Directive 2004/35/EC of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of

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environmental damage⁽⁹⁾ is normally relevant for environmental damage caused by a major accident.

- (14) In order to reduce the risk of domino effects, where establishments are sited in such a way or so close together as to increase the likelihood of major accidents, or aggravate their consequences, operators should cooperate in the exchange of appropriate information and in informing the public, including neighbouring establishments that could be affected.
- (15) In order to demonstrate that all that is necessary has been done to prevent major accidents, and to prepare emergency plans and response measures, the operator should, in the case of establishments where dangerous substances are present in significant quantities, provide the competent authority with information in the form of a safety report. That safety report should contain details of the establishment, the dangerous substances present, the installation or storage facilities, possible major-accident scenarios and risk analysis, prevention and intervention measures and the management systems available, in order to prevent and reduce the risk of major accidents and to enable the necessary steps to be taken to limit the consequences thereof. The risk of a major accident could be increased by the probability of natural disasters associated with the location of the establishment. This should be considered during the preparation of major-accident scenarios.
- (16) To prepare for emergencies, in the case of establishments where dangerous substances are present in significant quantities, it is necessary to establish internal and external emergency plans and to establish procedures to ensure that those plans are tested and revised as necessary and implemented in the event of a major accident or the likelihood thereof. The staff of an establishment should be consulted on the internal emergency plan and the public concerned should have the opportunity to give its opinion on the external emergency plan. Sub-contracting may have an impact on the safety of an establishment. Member States should require operators to take this into account when drafting a MAPP, a safety report or an internal emergency plan.
- (17) When considering the choice of appropriate operating methods, including those for monitoring and control, operators should take into account available information on best practices.
- (18) In order to provide greater protection for residential areas, areas of substantial public use and the environment, including areas of particular natural interest or sensitivity, it is necessary for land-use or other relevant policies applied in the Member States to ensure appropriate distances between such areas and establishments presenting such hazards and, where existing establishments are concerned, to implement, if necessary, additional technical measures so that the risk to persons or the environment is maintained at an acceptable level. Sufficient information about the risks and technical advice on these risks should be taken into account when decisions are taken. Where possible, to reduce administrative burdens, especially for small and medium-sized enterprises, procedures and measures should be integrated with those under other relevant Union legislation.
- (19) In order to promote access to environmental information under the Convention of the United Nations Economic Commission for Europe on access to information,

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public participation in decision-making and access to justice in environmental matters (the Aarhus Convention), which was approved on behalf of the Union by Council Decision 2005/370/EC of 17 February 2005 on the conclusion, on behalf of the European Community, of the Convention on access to information, public participation in decision-making and access to justice in environmental matters⁽¹⁰⁾, the level and quality of information to the public should be improved. In particular, persons likely to be affected by a major accident should be given sufficient information on the correct action to be taken in that event. Member States should make information available on where to find information on the rights of persons affected by a major accident. Information disseminated to the public should be worded clearly and intelligibly. In addition to providing information in an active way, without the public having to submit a request, and without precluding other forms of dissemination, it should also be made available permanently and kept up to date electronically. At the same time there should be appropriate confidentiality safeguards, to address security-related concerns, among others.

- (20) The way information is managed should be in line with the Shared Environmental Information System (SEIS) initiative introduced by the Commission Communication of 1 February 2008 entitled ‘Towards a Shared Environmental Information System (SEIS)’. It should also be in line with Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE)⁽¹¹⁾ and its implementing rules, aimed at enabling the sharing of environmental spatial information among public sector organisations and better facilitating public access to spatial information across the Union. Information should be held on a publicly available database at Union level, which will also facilitate monitoring and reporting on implementation.
- (21) In line with the Aarhus Convention, effective public participation in decision-making is necessary to enable the public concerned to express, and the decision-maker to take account of, opinions and concerns that may be relevant to those decisions, thereby increasing the accountability and transparency of the decision-making process and contributing to public awareness of environmental issues and support for the decisions taken.
- (22) In order to ensure that adequate response measures are taken if a major accident occurs, the operator should immediately inform the competent authority and communicate the information necessary to enable it to assess the effects of that accident on human health and on the environment.
- (23) Local authorities have an interest in the prevention of major accidents and mitigation of their consequences and can have an important role to play. This should be taken into account by the Member States in the implementation of this Directive.
- (24) In order to facilitate the exchange of information and to prevent future accidents of a similar nature, Member States should forward information to the Commission regarding major accidents occurring on their territory, so that the Commission can analyse the hazards involved, and operate a system for the distribution of information concerning, in particular, major accidents and lessons learned from them. That exchange

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of information should also cover ‘near misses’ which Member States regard as being of particular technical interest for preventing major accidents and limiting their consequences. Member States and the Commission should strive to ensure the completeness of the information held on information systems established to facilitate the exchange of information on major accidents.

- (25) Member States should determine the competent authorities responsible for ensuring that operators fulfil their obligations. The competent authorities and the Commission should cooperate in activities in support of implementation such as the development of appropriate guidance and exchanges of best practice. To avoid unnecessary administrative burden, information obligations should be integrated, where appropriate, with those under other relevant Union legislation.
- (26) Member States should ensure that competent authorities take the necessary measures in the event of non-compliance with this Directive. In order to ensure effective implementation and enforcement, there should be a system of inspections, including a programme of routine inspections at regular intervals and non-routine inspections. Where possible, inspections should be coordinated with those under other Union legislation, including Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control)⁽¹²⁾, where appropriate. Member States should ensure that sufficient staff is available with the skills and qualifications needed to carry out inspections effectively. Competent authorities should provide appropriate support using tools and mechanisms for exchanging experience and consolidating knowledge, including at Union level.
- (27) In order to take into account technical developments, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of amending Annexes II to VI to adapt them to technical progress. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.
- (28) In order to ensure uniform conditions for the implementation of this Directive, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission’s exercise of implementing powers⁽¹³⁾.
- (29) Member States should lay down rules on penalties applicable to infringements of the national provisions adopted pursuant to this Directive and ensure that they are implemented. Those penalties should be effective, proportionate and dissuasive.
- (30) Since the objective of this Directive, namely to ensure a high level of protection of human health and the environment, cannot be sufficiently achieved by Member States and can, therefore, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on

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European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve that objective.

- (31) In accordance with the Joint Political Declaration of Member States and the Commission of 28 September 2011 on explanatory documents⁽¹⁴⁾, Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified.
- (32) Directive 96/82/EC should therefore be amended and subsequently repealed,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Subject matter

This Directive lays 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 Union in a consistent and effective manner.

Article 2

Scope

- 1 This Directive shall apply to establishments as defined in Article 3(1).
- 2 This Directive 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 this Directive, 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 this Directive;
 - 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.

Notwithstanding points (e) and (h) of the first subparagraph, onshore underground gas storage in natural strata, aquifers, salt cavities and disused mines and chemical and

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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 this Directive.

Article 3

Definitions

For the purposes of this Directive the following definitions shall apply:

1. ‘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;
2. ‘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 Annex I, but less than the quantities listed in Column 3 of Part 1 or in Column 3 of Part 2 of Annex I, where applicable using the summation rule laid down in note 4 to Annex I;
3. ‘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 Annex I, where applicable using the summation rule laid down in note 4 to Annex I;
4. ‘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;
5. ‘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 this Directive, 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;
6. ‘existing establishment’ means an establishment that on 31 May 2015 falls within the scope of Directive 96/82/EC and from 1 June 2015 falls within the scope of this Directive without changing its classification as a lower-tier establishment or upper-tier establishment;
7. ‘other establishment’ means a site of operation that falls within the scope of this Directive, 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 point 5;
8. ‘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;

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9. 'operator' means any natural or legal person who operates or controls an establishment or installation or, where provided for by national legislation, to whom the decisive economic or decision-making power over the technical functioning of the establishment or installation has been delegated;
10. 'dangerous substance' means a substance or mixture covered by Part 1 or listed in Part 2 of Annex I, including in the form of a raw material, product, by-product, residue or intermediate;
11. 'mixture' means a mixture or solution composed of two or more substances;
12. '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 Annex I;
13. '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 this Directive, 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;
14. 'hazard' means the intrinsic property of a dangerous substance or physical situation, with a potential for creating damage to human health or the environment;
15. 'risk' means the likelihood of a specific effect occurring within a specified period or in specified circumstances;
16. 'storage' means the presence of a quantity of dangerous substances for the purposes of warehousing, depositing in safe custody or keeping in stock;
17. 'the public' means one or more natural or legal persons and, in accordance with national law or practice, their associations, organisations or groups;
18. '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 of the matters covered by Article 15(1); for the purposes of this definition, non-governmental organisations promoting environmental protection and meeting any applicable requirements under national law shall be deemed to have an interest;
19. '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 this Directive.

Article 4

Assessment of major-accident hazards for a particular dangerous substance

1 The Commission shall assess, where appropriate or in any event on the basis of a notification by a Member State in accordance with paragraph 2, whether it is impossible in practice for a particular dangerous substance covered by Part 1 or listed in Part 2 of Annex I, to cause a release of matter or energy that could create a major accident under both normal and abnormal conditions which can reasonably be foreseen. That assessment shall take into account

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the information referred to in paragraph 3, and shall be based on one or more of the following characteristics:

- 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;
- c the maximum concentration of the substances in the case of mixtures.

For the purposes of the first subparagraph, the containment and generic packing of the dangerous substance should, where appropriate, also be taken into account, including in particular where covered under specific Union legislation.

2 Where a Member State considers that a dangerous substance does not present a major-accident hazard in accordance with paragraph 1, it shall notify the Commission together with supporting justification, including the information referred to in paragraph 3.

3 For the purposes of paragraphs 1 and 2, 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 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.

4 Following the assessment referred to in paragraph 1, the Commission shall, if appropriate, present a legislative proposal to the European Parliament and to the Council to exclude the dangerous substance concerned from the scope of this Directive.

Article 5

General obligations of the operator

1 Member States shall ensure that the operator is obliged to take all necessary measures to prevent major accidents and to limit their consequences for human health and the environment.

2 Member States shall ensure that the operator is required to prove to the competent authority referred to in Article 6, at any time, in particular for the purposes of inspections and

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controls referred to in Article 20, that the operator has taken all necessary measures as specified in this Directive.

Article 6

Competent authority

1 Without prejudice to the operator's responsibilities, Member States shall set up or appoint the competent authority or authorities responsible for carrying out the duties laid down in this Directive ('the competent authority') and, if necessary, bodies to assist the competent authority at technical level. Member States which set up or appoint more than one competent authority shall ensure that the procedures for carrying out their duties are fully coordinated.

2 The competent authorities and the Commission shall cooperate in activities in support of implementation of this Directive, involving stakeholders as appropriate.

3 Member States shall ensure that competent authorities accept equivalent information submitted by operators in accordance with other relevant Union legislation, which fulfils any of the requirements of this Directive, for the purposes of this Directive. In such cases the competent authorities shall ensure that the requirements of this Directive are complied with.

Article 7

Notification

1 Member States shall require the operator to send a notification to the competent authority containing the following information:

- 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 point (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 this Directive, 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 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 this Directive applies to the establishment concerned.

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3 Paragraphs 1 and 2 shall not apply if the operator has already sent a notification to the competent authority under the requirements of national legislation before 1 June 2015, and the information contained therein complies with paragraph 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 paragraph 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 points (a), (b) or (c) of paragraph 1.

Article 8

Major-accident prevention policy

1 Member States shall require the operator to 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, where required by national law, sent to the competent authority within the following time-limits:

- a for new establishments, a reasonable period of time 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 this Directive applies to the establishment concerned.

3 Paragraphs 1 and 2 shall not apply if the operator has already established the MAPP and, where required by national law, sent it to the competent authority before 1 June 2015, and the information contained therein complies with paragraph 1 and has remained unchanged.

4 Without prejudice to Article 11, the operator shall periodically review and where necessary update the MAPP, at least every five years. Where required by national law 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 Annex 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 Annex III.

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Article 9

Domino effects

1 Member States shall ensure that the competent authority, using the information received from the operators in accordance with Articles 7 and 10, or following a request for additional information from the competent authority, or through inspections pursuant to Article 20, identifies 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.

2 Where the competent authority has additional information to that provided by the operator pursuant to point (g) of Article 7(1), it shall make this information available to that operator, if it is necessary for the application of this Article.

3 Member States shall ensure that operators of the establishments identified in accordance with paragraph 1:

- 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 this Directive, and in supplying information to the authority responsible for the preparation of external emergency plans.

Article 10

Safety report

1 Member States shall require the operator of an upper-tier establishment to produce a safety report for the purposes of:

- 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 Annex 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 Annex 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:

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- a for new establishments, a reasonable period of time 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 this Directive applies to the establishment concerned.

4 Paragraphs 1, 2 and 3 shall not apply if the operator has already sent the safety report to the competent authority under the requirements of national law before 1 June 2015, and the information contained therein complies with paragraphs 1 and 2 and has remained unchanged. In order to comply with paragraphs 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 paragraph 3.

5 Without prejudice to Article 11, 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 points (b) and (c) of paragraph 3 and in paragraph 5 of this Article, 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 Article 19, prohibit the bringing into use, or the continued use, of the establishment concerned.

Article 11

Modification of an installation, an establishment or a storage facility

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, Member States shall ensure that the operator reviews, 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.

Article 12

Emergency plans

- 1 Member States shall ensure that, for all upper-tier establishments:
 - a the operator draws up an internal emergency plan for the measures to be taken inside the establishment;

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- b the operator supplies the necessary information to the competent authority, to enable the latter to draw up external emergency plans;
 - c the authorities designated for that purpose by the Member State draw up an external emergency plan for the measures to be taken outside the establishment within two years following receipt of the necessary information from the operator pursuant to point (b).
- 2 Operators shall comply with the obligations set out in points (a) and (b) of paragraph 1 within the following time-limits:
- a for new establishments, a reasonable period of time prior to the start of operation, or prior to the modifications leading to a change in the inventory of dangerous substances;
 - b for existing upper-tier establishments, by 1 June 2016 unless the internal emergency plan drawn up under the requirements of national law before that date, and the information contained therein, and the information referred to in point (b) of paragraph 1, complies with this Article and has remained unchanged;
 - c for other establishments, two years from the date from which this Directive applies 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 Annex IV.

4 Member States shall ensure that the internal emergency plans provided for in this Directive are drawn up in consultation with the personnel working inside the establishment, including long-term relevant subcontracted personnel.

5 Member States 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.

6 Member States shall ensure that internal and external emergency plans are reviewed, tested, and where necessary updated by the operators and designated authorities respectively 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, Member States shall take into account the need to facilitate enhanced cooperation in civil protection assistance in major emergencies.

7 Member States shall ensure that emergency plans are put into effect without delay by the operator and, if necessary, by the competent authority designated for this purpose 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 their decision, in view of the information contained in the safety report, that the requirement to produce an external emergency plan under paragraph 1 shall not apply.

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Article 13

Land-use planning

1 Member States shall ensure that the objectives of preventing major accidents and limiting the consequences of such accidents for human health and the environment are taken into account in their land-use policies or other relevant policies. They shall pursue those objectives through controls on:

- a the siting of new establishments;
- b modifications to establishments covered by Article 11;
- c new developments including transport routes, locations of public use and residential areas in the vicinity of establishments, where the siting or developments may be the source of or increase the risk or consequences of a major accident.

2 Member States shall ensure that their land-use or other relevant policies and the procedures for implementing those policies take account of the need, in the long term:

- a to maintain appropriate safety distances between establishments covered by this Directive and residential areas, buildings and areas of public use, recreational areas, and, as far as possible, major transport routes;
- b to protect areas of particular natural sensitivity or interest in the vicinity of establishments, where appropriate through appropriate safety distances or other relevant measures;
- c in the case of existing establishments, to take additional technical measures in accordance with Article 5 so as not to increase the risks to human health and the environment.

3 Member States shall ensure that all competent authorities and planning authorities responsible for decisions in this area set up appropriate consultation procedures to facilitate implementation of the policies established under paragraph 1. The procedures shall be designed to ensure that operators provide sufficient information on the risks arising from the establishment and that technical advice on those risks is available, either on a case-by-case or on a generic basis, when decisions are taken.

Member States shall ensure that operators of lower-tier establishments provide, at the request of the competent authority, sufficient information on the risks arising from the establishment necessary for land-use planning purposes.

4 The requirements of paragraphs 1, 2 and 3 of this Article shall apply without prejudice to the provisions of Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment⁽¹⁵⁾, Directive 2001/42/EC of the European Parliament and of the Council of 27 June 2001 on the assessment of the effects of certain plans and programmes on the environment⁽¹⁶⁾ and other relevant Union legislation. Member States may provide for coordinated or joint procedures in order to fulfil the requirements of this Article and the requirements of that legislation, inter alia, to avoid duplication of assessment or consultations.

Article 14

Information to the public

- 1 Member States shall ensure that the information referred to in Annex V is permanently available to the public, including electronically. The information shall be kept updated, where necessary, including in the event of modifications covered by Article 11.
- 2 For upper-tier establishments, Member States 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 Article 22(3); where Article 22(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 Article 22(3).

The information to be supplied under point (a) of the first subparagraph of this paragraph shall include at least the information referred to in Annex 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 Article 9. Member States 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 Article 11.

- 3 Member States 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 Articles 12 and 13 and in this Article can be applied, where applicable, by the potentially affected Member States.

- 4 Where the Member State concerned 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 Article 12(8) and is not therefore required to produce an external emergency plan under Article 12(1), it shall inform the other Member State of its reasoned decision.

Article 15

Public consultation and participation in decision-making

- 1 Member States shall ensure that the public concerned is given an early opportunity to give its opinion on specific individual projects relating to:
 - a planning for new establishments pursuant to Article 13;
 - b significant modifications to establishments under Article 11, where such modifications are subject to obligations provided for in Article 13;
 - c new developments around establishments where the siting or developments may increase the risk or consequences of a major accident pursuant to Article 13.

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2 With regard to the specific individual projects referred to in paragraph 1, the public shall be informed by public notices or other appropriate means, including electronic media where available, of the following matters early in the procedure for the taking of a decision or, at the latest, as soon as the information can reasonably be provided:

- a the subject of the specific project;
- b where applicable, the fact that a project is subject to a national or transboundary environmental impact assessment or to consultations between Member States in accordance with Article 14(3);
- c details of the competent authority responsible for taking the decision, from which relevant information can be obtained and to which comments or questions can be submitted, and details of the time schedule for transmitting comments or questions;
- d the nature of possible decisions or, where there is one, the draft decision;
- e an indication of the times and places where, or means by which, the relevant information will be made available;
- f details of the arrangements for public participation and consultation made pursuant to paragraph 7 of this Article.

3 With regard to the specific individual projects referred to in paragraph 1, Member States shall ensure that, within appropriate time-frames, the following is made available to the public concerned:

- a in accordance with national legislation, the main reports and advice issued to the competent authority at the time when the public concerned was informed pursuant to paragraph 2;
- b in accordance with the provisions of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information⁽¹⁷⁾, information other than that referred to in paragraph 2 of this Article which is relevant for the decision in question and which only becomes available after the public concerned was informed in accordance with that paragraph.

4 Member States shall ensure that the public concerned is entitled to express comments and opinions to the competent authority before a decision is taken on a specific individual project as referred to in paragraph 1, and that the results of the consultations held pursuant to paragraph 1 are duly taken into account in the taking of a decision.

5 Member States shall ensure that when the relevant decisions are taken, the competent authority shall make available to the public:

- a the content of the decision and the reasons on which it is based, including any subsequent updates;
- b the results of the consultations held before the decision was taken and an explanation of how they were taken into account in that decision.

6 Where general plans or programmes are being established relating to the matters referred to in points (a) or (c) of paragraph 1, Member States shall ensure that the public is given early and effective opportunities to participate in their preparation and modification or review using the procedures set out in Article 2(2) of Directive 2003/35/EC of the European Parliament and of the Council of 26 May 2003 providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment⁽¹⁸⁾.

Member States shall identify the public entitled to participate for the purposes of this paragraph, including relevant non-governmental organisations meeting any relevant requirements imposed under national law, such as those promoting environmental protection.

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This paragraph shall not apply to plans and programmes for which a public participation procedure is carried out under Directive 2001/42/EC.

7 The detailed arrangements for informing the public and consulting the public concerned shall be determined by the Member States.

Reasonable time-frames for the different phases shall be provided, allowing sufficient time for informing the public and for the public concerned to prepare and participate effectively in environmental decision-making subject to the provisions of this Article.

Article 16

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

Member States shall ensure that, as soon as practicable following a major accident, the operator shall be required, using the most appropriate means to:

- (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.

Article 17

Action to be taken by the competent authority following a major accident

Following a major accident, Member States shall require the competent authority to:

- (a) ensure that any urgent, medium-term and long-term measures which may prove necessary are taken;
- (b) 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;
- (c) take appropriate action to ensure that the operator takes any necessary remedial measures;

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- (d) make recommendations on future preventive measures; and
- (e) inform the persons likely to be affected, of the accident which has occurred and, where relevant, of the measures undertaken to mitigate its consequences.

Article 18

Information to be supplied by the Member States following a major accident

1 For the purpose of prevention and mitigation of major accidents, Member States shall inform the Commission of major accidents meeting the criteria of Annex VI which have occurred within their territory. They shall provide it with the following details:

- a the Member State, 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;
- 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 paragraph 1 of this Article shall be provided as soon as practicable and at the latest within one year of the date of the accident, using the database referred to in Article 21(4). Where only preliminary information under point (e) of paragraph 1 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 point (e) of paragraph 1 by Member States may be delayed to allow for the completion of judicial proceedings where such reporting may affect those proceedings.

3 For the purposes of providing the information referred to in paragraph 1 of this Article by Member States, a report form shall be established in the form of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

4 Member States shall inform the Commission of the name and address of any body 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.

Article 19

Prohibition of use

1 Member States 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, Member States shall, inter alia, take into account serious failures to take the necessary actions identified in the inspection report.

Member States 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

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notification, reports or other information required by this Directive within the specified period.

2 Member States shall ensure that operators may appeal against a prohibition order by a competent authority under paragraph 1 to an appropriate body determined by national law and procedures.

Article 20

Inspections

1 Member States shall ensure that the competent authorities organise a system of inspections.

2 Inspections shall be appropriate to the type of establishment concerned. They shall not be dependent upon receipt of the safety report or any other report submitted. They 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 Article 14.

3 Member States shall ensure that all establishments are covered by an inspection plan at national, regional or local level 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 Article 9;
- 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 paragraph 4;
- g procedures for non-routine inspections pursuant to paragraph 6;
- h provisions on the co-operation between different inspection authorities.

4 Based on the inspection plans referred to in paragraph 3, 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.

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5 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 this Directive.

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

6 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.

7 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.

8 If an inspection has identified an important case of non-compliance with this Directive, an additional inspection shall be carried out within six months.

9 Inspections shall, where possible, be coordinated with inspections under other Union legislation and combined, where appropriate.

10 Member States shall encourage the competent authorities to provide mechanisms and tools for exchanging experience and consolidating knowledge, and to participate in such mechanisms at Union level where appropriate.

11 Member States shall ensure that operators 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 this Directive, 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.

Article 21

Information system and exchanges

1 Member States 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 this Directive.

2 By 30 September 2019, and every four years thereafter, Member States shall provide the Commission with a report on the implementation of this Directive.

3 For establishments covered by this Directive, Member States 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.

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The Commission shall set up and keep up to date a database containing the information supplied by the Member States. Access to the database shall be restricted to persons authorised by the Commission or the competent authorities of the Member States.

4 The Commission shall set up and keep at the disposal of Member States a database containing, in particular, details of the major accidents which have occurred within the territory of Member States, for the purpose of:

- a the rapid dissemination of the information supplied by Member States pursuant to Article 18(1) and (2) among all competent authorities;
- b distribution to competent authorities of an analysis of the causes of major accidents and the lessons learned from them;
- c supply of information to competent authorities on preventive measures;
- d provision of information on organisations able to provide advice or relevant information on the occurrence, prevention and mitigation of major accidents.

5 The Commission shall, by 1 January 2015, adopt implementing acts to establish the formats for communicating the information referred to in paragraphs 2 and 3 of this Article from Member States and the relevant databases referred to in paragraphs 3 and 4. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 27(2).

6 The databases referred to in paragraph 4 shall contain, at least:

- a the information supplied by Member States in accordance with Article 18(1) and (2);
- b an analysis of the causes of the accidents;
- c the lessons learned from the accidents;
- d the preventive measures necessary to prevent a recurrence.

7 The Commission shall make publicly available the non-confidential part of the data.

Article 22

Access to information and confidentiality

1 Member States shall ensure, in the interests of transparency, that the competent authority is required to make any information held pursuant to this Directive available to any natural or legal person who so requests in accordance with Directive 2003/4/EC.

2 Disclosure of any information required under this Directive, including under Article 14, 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 points (b) and (c) of Article 14(2) held by the competent authority may be refused by that competent authority, without prejudice to paragraph 2 of this Article, 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 reasons that certain parts of the report or inventory shall not be disclosed. In such cases, and on approval of that authority, the operator shall supply to the competent authority an amended report or inventory excluding those parts.

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Article 23

Access to justice

Member States shall ensure that:

- (a) any applicant requesting information pursuant to points (b) or (c) of Article 14(2) or Article 22(1) of this Directive is able to seek a review in accordance with Article 6 of Directive 2003/4/EC of the acts or omissions of a competent authority in relation to such a request;
- (b) in their respective national legal system, members of the public concerned have access to the review procedures set up in Article 11 of Directive 2011/92/EU for cases subject to Article 15(1) of this Directive.

Article 24

Guidance

The Commission may develop guidance on safety distance and domino effects.

Article 25

Amendment of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 26 in order to adapt Annexes II to VI to technical progress. Such adaptations shall not result in substantial changes in the obligations of the Member States and the operators as laid down in this Directive.

Article 26

Exercise of the delegation

- 1 The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
- 2 The power to adopt delegated acts referred to in Article 25 shall be conferred on the Commission for a period of five years from 13 August 2012. The Commission shall draw up a report in respect of the delegation of power no later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than four months before the end of each period.
- 3 The delegation of power referred to in Article 25 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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4 As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5 A delegated act adopted pursuant to Article 25 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 27

Committee procedure

1 The Commission shall be assisted by the Committee established by Directive 96/82/EC. That Committee is a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 28

Penalties

Member States shall determine penalties applicable to infringements of the national provisions adopted pursuant to this Directive. The penalties thus provided for shall be effective, proportionate and dissuasive. Member States shall notify those provisions to the Commission by 1 June 2015 and shall notify it without delay of any subsequent amendment affecting them.

Article 29

Reporting and review

1 By 30 September 2020, and every four years thereafter, the Commission, on the basis of information submitted by Member States in accordance with Article 18 and Article 21(2) and of information held in databases, as referred to in Article 21(3) and (4), and taking into account the implementation of Article 4, shall submit to the European Parliament and to the Council a report on the implementation and efficient functioning of this Directive, including information on major accidents that have occurred within the Union and their potential impact upon the implementation of this Directive. The Commission shall include in the first of those reports an assessment of the need to amend the scope of this Directive. Any report may, where appropriate, be accompanied by a legislative proposal.

2 In the context of relevant Union legislation, the Commission may examine the need to address the issue of financial responsibilities of the operator in relation to major accidents, including issues related to insurance.

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Article 30

Amendment of Directive 96/82/EC

In Directive 96/82/EC, the words ‘(d) heavy fuel oils’ are added to the heading ‘Petroleum products’ in Part 1 of Annex I.

Article 31

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31 May 2015. They shall apply those measures from 1 June 2015.

Notwithstanding the first subparagraph, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 30 of this Directive by 14 February 2014. They shall apply those measures from 15 February 2014.

They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

2 Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.

Article 32

Repeal

1 Directive 96/82/EC is repealed with effect from 1 June 2015.

2 References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table set out in Annex VII.

Article 33

Entry into force

This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

Article 34

Addressees

This Directive is addressed to the Member States.

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Done at Strasbourg, 4 July 2012.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

A. D. MAVROYIANNIS

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LIST OF ANNEXES

Annex I	— Dangerous substances
Annex II	— Minimum data and information to be considered in the safety report referred to in Article 10
Annex III	— Information referred to in Article 8(5) and Article 10 on the safety management system and the organisation of the establishment with a view to the prevention of major accidents
Annex IV	— Data and information to be included in the emergency plans referred to in Article 12
Annex V	— Items of information to the public as provided for in Article 14(1) and in point (a) of Article 14(2)
Annex VI	— Criteria for the notification of a major accident to the Commission as provided for in Article 18(1)
Annex VII	— Correlation table

ANNEX I

DANGEROUS SUBSTANCES

Dangerous substances covered by the hazard categories listed in Column 1 of Part 1 of this Annex 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 Annex 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 Article 3(10) 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	50	200

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TOXICITY – SINGLE EXPOSURE STOT SE Category 1		
Section ‘P’ – PHYSICAL HAZARDS		
P1a 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
P1b EXPLOSIVES (see note 8) Explosives, Division 1.4 (see note 10)	50	200
P2 FLAMMABLE GASES Flammable gases, Category 1 or 2	10	50
P3a 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)
P3b 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)	5 000(net)	50 000(net)
P4 OXIDISING GASES Oxidising gases, Category 1	50	200

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<p>P5a FLAMMABLE LIQUIDS</p> <ul style="list-style-type: none"> — 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 ≤ 60 °C, maintained at a temperature above their boiling point (see note 12) 	10	50
<p>P5b FLAMMABLE LIQUIDS</p> <ul style="list-style-type: none"> — 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 ≤ 60 °C where particular processing conditions, such as high pressure or high temperature, may create major-accident hazards (see note 12) 	50	200
<p>P5c FLAMMABLE LIQUIDS</p> <p>Flammable liquids, Categories 2 or 3 not covered by P5a and P5b</p>	5 000	50 000
<p>P6a SELF-REACTIVE SUBSTANCES AND MIXTURES and ORGANIC PEROXIDES</p> <p>Self-reactive substances and mixtures, Type A or B or organic peroxides, Type A or B</p>	10	50

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P6b 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
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

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PART 2

Named dangerous substances

Column 1		CAS number ^a	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)	—	5 000	10 000
2.	Ammonium nitrate (see note 14)	—	1 250	5 000
3.	Ammonium nitrate (see note 15)	—	350	2 500
4.	Ammonium nitrate (see note 16)	—	10	50
5.	Potassium nitrate (see note 17)	—	5 000	10 000
6.	Potassium nitrate (see note 18)	—	1 250	5 000
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

a The CAS number is shown only for indication.

b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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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

a The CAS number is shown only for indication.

b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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20.	Ethylene oxide	75-21-8	5	50
21.	Propylene oxide	75-56-9	5	50
22.	Methanol	67-56-1	500	5 000
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	2 000
26.	2,4 -Toluene diisocyanate	584-84-9	10	100
	2,6 -Toluene diisocyanate	91-08-7		
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
32.	Polychlorodibenzofurans and	—		0,001

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b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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	polychlorodibenzodioxins (including TCDD), calculated in TCDD equivalent (see note 20)			
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
34.	Petroleum products and	—	2 500	25 000

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b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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	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)			
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

a The CAS number is shown only for indication.

b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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39.	Bis(2-dimethylaminoethyl)(methyl)amin	3030-47-5	50	200
40.	3-(2-Ethylhexyloxy)propylamin	5397-31-9	50	200
41.	Mixtures ^b 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 Annex I.		200	500
42.	Propylamine (see note 21)	107-10-8	500	2 000
43.	Tert-butyl acrylate (see note 21)	1663-39-4	200	500
44.	2-Methyl-3-butenitrile (see note 21)	16529-56-9	500	2 000
45.	Tetrahydro-3,5-dimethyl-1,3,5-thiadiazine-2-thione (Dazomet)	533-74-4	100	200

a The CAS number is shown only for indication.

b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

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	(see note 21)			
46.	Methyl acrylate (see note 21)	96-33-3	500	2 000
47.	3-Methylpyridine (see note 21)	108-99-6	500	2 000
48.	1-Bromo-3-chloropropane (see note 21)	109-70-6	500	2 000

a The CAS number is shown only for indication.

b Provided that the mixture in the absence of sodium hypochlorite would not be classified as Aquatic Acute Category 1 [H400].

NOTES TO ANNEX I

- Substances and mixtures are classified in accordance with Regulation (EC) No 1272/2008.
- 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.
- The qualifying quantities set out above relate to each establishment.

The quantities to be considered for the application of the relevant Articles 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.

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

This Directive 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 Annex,

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 Annex.

This Directive 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 Annex,

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 Annex.

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 this Directive 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 this Directive.
6. In the case of dangerous substances with properties giving rise to more than one classification, for the purposes of this Directive 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 this Directive. If the quantity of the explosive substance or mixture contained in the article is not known, then, for the purposes of this Directive, the whole article shall be treated as explosive.

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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)⁽¹⁹⁾ identifies the substance or mixture as potentially having explosive properties.
10. If Explosives of Division 1.4 are unpacked or repacked, they shall be assigned to the entry P1a, 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⁽²⁰⁾ (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 (5 000 / 10 000): 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 %⁽²¹⁾ and 24,5 %⁽²²⁾ 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⁽²³⁾,
- 15,75 % by weight or less and unrestricted combustible materials.

14. Ammonium nitrate (1 250 / 5 000): 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 %⁽²⁴⁾ 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 / 2 500): 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 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 Annex which do not fulfil the requirements of Annex III-2 to Regulation (EC) No 2003/2003.

17. Potassium nitrate (5 000 / 10 000)

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 (1 250 / 5 000)

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 this Directive, upgraded biogas may be classified under entry 18 of Part 2 of Annex 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		

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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 P5a Flammable liquids or P5b Flammable liquids, then for the purposes of this Directive the lowest qualifying quantities shall apply.

ANNEX II

Minimum data and information to be considered in the safety report referred to in Article 10

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 Annex III.

2. Presentation of the environment of the establishment:
- description of the establishment and its environment including the geographical location, meteorological, geological, hydrographic conditions and, if necessary, its history;
 - identification of installations and other activities of the establishment which could present a major-accident hazard;
 - on the basis of available information, identification of neighbouring establishments, as well as sites that fall outside the scope of this Directive, areas and developments that could be the source of, or increase the risk or consequences of a major accident and of domino effects;
 - description of areas where a major accident may occur.
3. Description of the installation:
- 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 this Directive, 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;

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

ANNEX III

Information referred to in Article 8(5) and Article 10 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:

- (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.

ANNEX IV

Data and information to be included in the emergency plans referred to in Article 12

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;
 - (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;

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- (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 this Directive in accordance with Article 9 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.

ANNEX V

Items of information to the public as provided for in Article 14(1) and in point (a) of Article 14(2)

PART 1

For all establishments covered by this Directive:

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 this Directive and that the notification referred to in Article 7(1) or the safety report referred to in Article 10(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 Annex 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 Article 20(4), 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 Article 22.

7. Details of where further relevant information can be obtained, subject to the requirements of Article 22.

PART 2

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

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.

ANNEX VI

Criteria for the notification of a major accident to the Commission as provided for in Article 18(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 Annex 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 1 000.

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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 Member States regard 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.

ANNEX VII

CORRELATION TABLE

Directive 96/82/EC	This Directive
Article 1	Article 1
Article 2(1), first subparagraph	Article 2(1) and Article 3(2) and (3)
Article 2(1), second subparagraph	Article 3(12)
Article 2(2)	—
Article 3(1)	Article 3(1)
Article 3(2)	Article 3(8)
Article 3(3)	Article 3(9)

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Article 3(4)	Article 3(10)
Article 3(5)	Article 3(13)
Article 3(6)	Article 3(14)
Article 3(7)	Article 3(15)
Article 3(8)	Article 3(16)
—	Article 3(2) to (7), Article 3(11) and (12) and Article 3(17) to (19)
Article 4	Article 2(2), first subparagraph, points (a) to (f) and (h)
—	Article 2(2), first subparagraph, point (g) and Article 2(2), second subparagraph
—	Article 4
Article 5	Article 5
Article 6(1)	Article 7(2)
Article 6(2), points (a) to (g)	Article 7(1), points (a) to (g)
Article 6(3)	Article 7(3)
Article 6(4)	Article 7(4), points (a) to (c)
—	Article 7(4), point (d)
Article 7(1)	Article 8(1)
—	Article 8(2), points (a) and (b)
Article 7(1a)	Article 8(2), point (a)
Article 7(2)	Article 8(5)
Article 7(3)	—
—	Article 8(3)
—	Article 8(4)
—	Article 8(5)
Article 8(1) and (2)	Article 9(1) and (2)
—	Article 9(2)
Article 9(1)	Article 10(1)
Article 9(2), first subparagraph	Article 10(2)
Article 9(2), second subparagraph	—
Article 9(3)	Article 10(3)
Article 9(4)	Article 10(6)
Article 9(5)	Article 10(5)
Article 9(6)	—

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—	Article 10(4)
Article 10	Article 11
Article 11(1), points (a) and (b)	Article 12(1), points (a) and (b) and Article 12(2)
Article 11(1), point (c)	Article 12(1), point (c)
Article 11(2)	Article 12(3)
Article 11(3)	Article 12(4) and (5)
Article 11(4)	Article 12(6), first subparagraph
Article 11(4a)	Article 12(6), second subparagraph
Article 11(5)	Article 12(7)
Article 11(6)	Article 12(8)
Article 12(1), first subparagraph	Article 13(1)
Article 12(1), second subparagraph	Article 13(2)
Article 12(1a)	—
Article 12(2)	Article 13(3)
—	Article 13(4)
Article 13(1), first subparagraph	Article 14(2), first subparagraph, point (a), and Article 14(2), second subparagraph, second sentence
Article 13(1), second subparagraph, first and third sentences	Article 14(2), second subparagraph, last sentence
Article 13(1), second subparagraph, second sentence	Article 14(1)
Article 13(1), third subparagraph	Article 14(2), second subparagraph, first sentence
—	Article 14(1), second sentence
Article 13(2)	Article 14(3)
Article 13(3)	Article 14(4)
Article 13(4), first sentence	Article 14(2), point (b)
Article 13(4), second and third sentences	Article 22(3), first and second subparagraphs
Article 13(5)	Article 15(1)
Article 13(6)	Article 14(2), point (c)
—	Article 15(2) to (7)
Article 14(1)	Article 16
Article 14(2)	Article 17
Article 15(1), points (a) to (d)	Article 18(1), points (a) to (d) and Article 18(2), first subparagraph

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Article 15(2), first subparagraph	Article 18(1), point (e) and Article 18(3)
Article 15(2), second subparagraph	Article 18(2), second subparagraph
Article 15(3)	Article 18(4)
Article 16	Article 6(1)
—	Article 6(2) and (3)
Article 17	Article 19
Article 18(1)	Article 20(1) and (2)
Article 18(2), point (a)	Article 20(4)
Article 18(2), points (b) and (c)	Article 20(7)
Article 18(3)	Article 20(11)
—	Article 20(3),(5),(6), (8), (9) and (10)
Article 19(1)	Article 21(1)
Article 19(1a), first subparagraph	Article 21(3), first subparagraph
Article 19(1a), second subparagraph	Article 21(3), second subparagraph
Article 19(2), first subparagraph	Article 21(4)
Article 19(2), second subparagraph	Article 21(6)
Article 19(3)	Article 21(7)
—	Article 21(5)
Article 19(4)	Article 21(2)
Article 20(1), first subparagraph	Article 22(1)
Article 20(1), second subparagraph	Article 22(2)
Article 20(2)	—
—	Article 23
—	Article 24
Article 21(1)	Article 25
Article 21(2)	Article 21(5)
Article 22	Article 27
Article 23	Article 32
Article 24	Article 31
Article 25	Article 33
Article 26	Article 34
—	Article 26 and Articles 28 to 30
—	Annex I, introductory paragraphs
Annex I, Introduction, paragraphs 1 to 5	Annex I, notes to Annex I, notes 1 to 3

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Annex I, Introduction, paragraphs 6 and 7	—
Annex I, Part 1	Annex I, Part 2
Annex I, Part 1, notes to Part 1, Notes 1 to 6	Annex I, notes to Annex I, notes 13 to 18
Annex I Part 1, notes to Part 1, Note 7	Annex I, notes to Annex I, note 20
—	Annex I, notes to Annex I, note 7
Annex I, Part 2	Annex I, Part 1
Annex I, Part 2, notes to Part 2, note 1	Annex I, notes to Annex I, notes 1, 5 and 6
Annex I, Part 2, notes to Part 2, note 2	Annex I, notes to Annex I, notes 8 to 10
Annex I, Part 2, notes to Part 2, Note 3	Annex I, notes to Annex I, notes 11.1, 11.2 and 12
Annex I, Part 2, notes to Part 2, Note 4	Annex I, notes to Annex I, Note 4
Annex II, Parts I to III	Annex II, points (1) to(3)
Annex II, Part IV, point A	Annex II, point 4(a)
—	Annex II, point 4(a) items (i) to (iii)
Annex II, Part IV, point B	Annex II, point 4(b)
—	Annex II, point 4(c)
Annex II, Part IV, point C	Annex II, point 4(d)
Annex II, Part V, point A to C	Annex II, point 5(a) to (c)
Annex II, Part V, point D	—
—	Annex II, point 5(d)
Annex III, introductory paragraph and points (a) and (b)	Annex III, introductory paragraph and point (a) Article 8(1) and (5)
Annex III, point (c), items (i) to(iv)	Annex III, point (b), items (i) to (iv)
Annex III, point (c), items (v) to(vii)	Annex III, point (b), items (v) to (vii)
Annex IV	Annex IV
Annex V, point 1	Annex V, Part 1, point 1
Annex V, point 2	—
Annex V, points 3 to 5	Annex V, Part 1, points 2 to 4
Annex V, point 6	Annex V, Part 2, point 1
Annex V, points 7 and 8	Annex V, Part 1, point 5
—	Annex V, Part 1, point 6
Annex V, points 9 and 10	Annex V, Part 2, points 2 and 3
Annex V, point 11	Annex V, Part 1, point 7
—	Annex V, Part 2, point 4

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Annex VI, I	Annex VI, Part I
Annex VI, II	Annex VI, Part II
—	Annex VII

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- (1) [OJ C 248, 25.8.2011, p. 138.](#)
- (2) Position of the European Parliament of 14 June 2012 and decision of the Council of 26 June 2012.
- (3) [OJ L 10, 14.1.1997, p. 13.](#)
- (4) [OJ L 326, 3.12.1998, p. 1.](#)
- (5) [OJ L 183, 29.6.1989, p. 1.](#)
- (6) [OJ 196, 16.8.1967, p. 1.](#)
- (7) [OJ L 200, 30.7.1999, p. 1.](#)
- (8) [OJ L 353, 31.12.2008, p. 1.](#)
- (9) [OJ L 143, 30.4.2004, p. 56.](#)
- (10) [OJ L 124, 17.5.2005, p. 1.](#)
- (11) [OJ L 108, 25.4.2007, p. 1.](#)
- (12) [OJ L 334, 17.12.2010, p. 17.](#)
- (13) [OJ L 55, 28.2.2011, p. 13.](#)
- (14) [OJ C 369, 17.12.2011, p. 14.](#)
- (15) [OJ L 26, 28.1.2012, p. 1.](#)
- (16) [OJ L 197, 21.7.2001, p. 30.](#)
- (17) [OJ L 41, 14.2.2003, p. 26.](#)
- (18) [OJ L 156, 25.6.2003, p. 17.](#)
- (19) 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.](#)).
- (20) [OJ L 147, 9.6.1975, p. 40.](#)
- (21) 15,75 % nitrogen content by weight as a result of ammonium nitrate corresponds to 45 % ammonium nitrate.
- (22) 24,5 % nitrogen content by weight as a result of ammonium nitrate corresponds to 70 % ammonium nitrate.
- (23) [OJ L 304, 21.11.2003, p. 1.](#)
- (24) 28 % nitrogen content by weight as a result of ammonium nitrate corresponds to 80 % ammonium nitrate.