A Guide to the Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015 (S.I. No. 209 of 2015)

The Guide gives a high level non–exhaustive overview of the Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015.

The Guide is not a legal interpretation of the Regulations.

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Background

Major industrial accidents involving dangerous substances pose a significant threat to humans and the environment; such accidents can give rise to serious injury to human health or serious damage to the environment, both on and off the site of the accident. In Europe, a catastrophic accident in the Italian town of Seveso in 1976 prompted the adoption of legislation on the prevention and control of such accidents.

The so-called Seveso Directive (Directive 82/501/EEC) was later amended in view of the lessons learned from later accidents resulting in the Seveso II Directive (Directive 96/82/EC).

In 2012, the Seveso III (Directive 2012/18/EU) was adopted taking into account, amongst other factors, the changes in EU legislation on the classification of chemicals and the increased rights for the public to access information and justice.

Introduction

The Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015 (the "COMAH Regulations"), implement the Seveso III Directive (2012/18/EU). The purpose of the COMAH Regulations is to lay down rules for the prevention of major accidents involving dangerous substances, and to seek to limit as far as possible the consequences for human health and the environment of such accidents, with the overall objective of providing a high level of protection in a consistent and effective manner.

The intention is to achieve this through tiered controls on the operators of the establishments subject to the Regulations: the larger the quantities of dangerous substances present at an establishment, the more onerous the duties on the operator.

The European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2006 and the European Union (Control of Major Accident Hazards Involving Dangerous Substances) (Amendment) Regulations 2013, which implemented the Seveso II Directive (96/82/EC), have been revoked by S.I. No. 208 of 2015 and replaced by S.I. No. 209 of 2015.

Application

The COMAH Regulations apply to any establishment that presents a major accident hazard because of the presence of dangerous substances in quantities that exceed specified thresholds. The dangerous substances and threshold quantities are specified in Schedule 1 to the Regulations.

Under the COMAH Regulations, dangerous substances are classified using the European Regulation (EC) No. 1272/2008 on the classification, labelling and packaging of substances and mixtures (the "CLP Regulation"). The CLP Regulation adopts the United Nations'

Globally Harmonised System on the classification and labelling of chemicals (UN GHS) across all European Union countries, including Ireland. GHS provides a basis for communicating information on hazards in a uniform way, overcoming differing classification and labelling information requirements for the same chemicals around the world.

The CLP Regulation is amended from time to time in line with technical and scientific development. These amendments are known as 'Adaptations to Technical Progress,' or ATPs, and are usually published at least annually. Therefore any reference to CLP in the COMAH Regulations will always include the latest adaptation to technical progress.

Guide to the Regulations

Part 1 - Preliminary and General

Regulation 1: Citation

The Regulations may be cited as the Chemicals Act (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2015, S.I. No. 209 of 2015.

Regulation 2: Interpretation

This Regulation interprets and defines terms used in the COMAH Regulations. Most of the definitions are directly transposed from the Seveso III Directive, some of which are additional to those that were included in the Seveso II Directive.

Some definitions from the European Communities (Control of Major Accident Hazards Involving Dangerous Substances) Regulations 2006 have also been included and there have been a number of completely new additions.

A number of important new definitions have been added. They include:

- Lower tier establishment
- Upper tier establishment
- Existing establishment
- Other establishment
- The public
- Consultation distance
- Inspection
- The public

You should also note that any reference in the Regulations to the submission of a document "in writing" includes writing which is communicated or kept in electronic form and can be printed.

Regulation 3: Application

The Regulations lay down rules for the prevention of major accidents which involve dangerous substances, and the limitation of their consequences for human health and the environment, with a view to providing a high level of protection in a consistent and effective manner.

The COMAH Regulations do <u>not</u> apply to:

- a) any property occupied by the Defence Forces and any land or premises referred to in section 268(1) of the Defence Act 1954 (No. 18 of 1954);
- 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 establishments defined in Regulation 2(1), 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 defined in Regulation 2(1);
- 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 carried out;
- h) waste land-fill sites, including underground waste storage.

Other changes to note are that:

- i. the term "directly related" is new to paragraph (c) above,
- ii. Regulation 3(3)(g) is an entirely new exemption point (g) above,
- iii. Regulation 3(3)(h) has changed from the Seveso II Directive requirements point (h) above,
- iv. there are additional clarifications added to the exemptions included in Regulation 3(3)(e) and (h) in Regulation 3(4).

The regulations do <u>not</u> apply to the storage of gas at underground offshore sites as defined in (g) above and do <u>not</u> apply to underground waste storage as set out in (h) above.

However, the Regulations <u>do</u> apply to onshore underground gas storage in natural strata, aquifers, salt cavities and disused mines and chemical and thermal processing operations and storage (which involves dangerous substances) related to those operations (Regulation 3(4)).

Regulation 4: Establishment of the competent authorities

This Regulation covers the designation of competent authorities by the appropriate Ministers.

The Health and Safety Authority is identified here as the Central Competent Authority (the term "CCA" is extensively used in this guide for Central Competent Authority) and its coordinating role is set out in paragraph (1)(a).

The procedure for the designation of the local competent authorities (the term "LCAs" is extensively used in this guide for local competent authority), responsible for the external emergency plan aspects, is also specified.

Designations that were in place under the 2006 Regulations will continue to have effect under the new Regulations.

Regulation 5: Commencement

The commencement date for the Regulations is 1st June 2015.

Regulation 6: Amendments

Amendments to the Chemicals Act consequent to the implementation of these Regulations are set out here, including the designation of the CCA as a national authority under the Chemicals Act, for the purposes of the Seveso III Directive.

In addition, the definition of a chemical under Section 2 of the Act has been updated to include a reference to the Seveso III Directive.

Part 2 – General Duties

Regulation 7: General duties of operators

Regulation 7 sets out the duties imposed on all operators: it applies to the operators of all establishments and there is no differentiation between the operators of upper-tier and lower-tier establishments.

Under this Regulation an operator¹ is obliged to take all necessary measures to prevent major accidents and to limit their consequences for both human health and the environment and to comply with the Regulations.

An operator is required to provide the relevant competent authority with all the assistance necessary to enable that authority to carry out any function under the Regulations, including inspections and investigations carried out by the CCA.

The operator must also assist the competent authority to fully assess the likelihood of a major accident and determine the scope of any increase in probability and in the provision of information for the preparation of the external emergency plan.

An operator must provide appropriate evidence (which includes documentation) at the request of the CCA, to demonstrate that:

- the major accident hazards for the establishment have been identified, and
- all necessary measures have been taken to prevent major accidents and to limit their consequences for human health² and the environment.

An operator must be able to prove that all necessary measures have been taken to comply with their obligations under the Regulations. Paragraph (2) of this Regulation goes on to list more specific examples of what "all necessary measures" includes.

Regulation 8: Notification

All operators are required to submit a notification to the Central Competent Authority. The notification must contain the information specified in paragraph (1) of this Regulation:

(a) the name and, where different, the 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 subparagraph (a);

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

¹ Regulation 2(1) contains the definition of 'operator'

² The COMAH Regulations now refer to "human health and the environment" throughout rather than "people and the environment".

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

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

(g) the immediate environment of the establishment, and factors likely to cause a major accident or to aggravate the consequences thereof including, where available, details of neighbouring establishments, of sites that fall outside the scope of these Regulations, areas and developments which could be the source of or increase the risk or consequences of a major accident and of domino effects within the meaning of Regulation 9(1).

The time limits for sending the notification to the Central Competent Authority are set out in this table:

Establishment Type	Notification Submission Timeline
New	No later than 3 months prior to start of construction or operation or the modification (Regulation 8(2)(a))
Other	1 year from when the COMAH Regulations apply to the establishment (Regulation 8(2)(b))
Existing	By June 01, 2016 (Regulation 8(2)(b))
Update	Every 5 years <u>and</u> prior to any modification (Regulation 8(2)(c))
Transitional Arrangements for Existing Establishments	If the information in the existing notification meets the requirements of these Regulations ³ , there is no requirement to submit a new notification until the routine 5-year notification update is due (Regulation 8(3))

An operator will also be required to notify the Central Competent Authority in writing, before any of the following:

- any significant increase or decrease in the quantity or significant change in the nature or physical form of the dangerous substances present, from that provided in the notification referred to above, or a significant change in the processes using those dangerous substances;
- modification of an establishment or an installation which could have significant consequences in terms of major accident hazards;
- the permanent closure of the establishment or its decommissioning;
- changes to the name and/or trade name of the operator and the full address of the establishment or the registered place of business, or of the name or position of the person in charge.

The Health and Safety Authority will put a downloadable electronic notification form to be on its website. **The CCA will accept only notifications made using this form**.

³ The CCA view is that in most situations this is unlikely to be the case.

The form will also be used to collect the information:

- to be provided to the public (as required by Regulation 25) and
- for the development of technical land-use planning advice (as required by Regulation 24).

Regulation 9: Domino effects

A "domino group" is a group 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 to each other. These effects are referred to as "domino effects".

The Regulation applies to both upper and lower-tier establishments and a domino group could consist of a mixture of upper and lower-tier sites or of all upper or all lower-tier sites.

Domino groups are identified by the CCA from either the information contained in the notification and safety report or through information obtained from inspection.

When the operator of an establishment is informed by the CCA that the establishment has been identified as part of a domino group, the operator must cooperate with, and provide information to, the other operator(s) within the domino group.

This exchange of information will enable the domino group operators to assess the nature and extent of the overall hazard of a major accident arising from the group and they can then take this into account in their MAPPs, safety reports, emergency plans and so on.

Operators of upper-tier establishments within a domino group are required to co-operate with each other in informing the public (as required under Regulation 25) and the local competent authorities for the preparation of external emergency plans (under Regulation16).

Establishments of all tiers should cooperate in informing other neighbouring sites that fall outside the scope of the Regulations.

Part 3 – Major Accident Prevention Policy and Safety Report

Regulation 10: Major Accident Prevention Policy

All operators (it applies to both upper and lower-tier establishments) are required to prepare a major accident prevention policy document (the term "MAPP" is widely used in this guide for major accident prevention policy) and submit it to the CCA. Upper-tier establishments include their MAPP in the safety report.

The MAPP must be reviewed, and when necessary updated, at least every 5 years and the update submitted to the CCA without undue delay.

The policy must:

- be designed to guarantee a high level of protection of human health and the environment;
- include the operator's overall aims and principles of action and a commitment to ensure a high level of protection of human health and the environment;
- include the role and responsibility of management in ensuring its proper implementation;
- include a commitment towards continuously improving the control of major accident hazards;
- take account of the principles specified in Schedule 2 to the Regulations

The operator must properly implement the policy by appropriate means, structures and a safety management system (or by other appropriate means, structures and management systems in the case of a lower tier-establishment), in accordance with the second Schedule to the Regulations. These should be proportionate to the major accident hazards and the complexity of the organisation or the activities of the establishment.

The 'monitoring performance' section of Schedule 2 has been strengthened and now includes a definite requirement for performance indicators.

The time limits in relation to the preparation of a MAPP and its submission to the CCA are set out in the table below:

Establishment Type	MAPP Submission Timeline
New	No later than 1 month prior to when the COMAH Regulations apply (Regulation 10(6)(a))
Other	1 year from when the COMAH Regulations apply (Regulation 10(6)(b))
Existing	Before 1 st June 2016 (Regulation 10(4))
Review and Update	Prior to any modification <u>and</u> every 5 years (Regulation 10(2))
Transitional Arrangements for Existing Establishments	If the MAPP prepared under the 2006 Regulations complies fully with the requirements of the COMAH Regulations 2015, it can be submitted before 1 st June 2016 (Regulation 10(5))

Regulation 11: Safety Report

This Regulation applies only to the operators of upper-tier establishments.

The requirements of the Regulations in relation to safety reports are essentially unchanged, but there are important new timelines to be observed, which are aimed at ensuring that the assessment of the safety report is completed within a reasonable period of time. (You should also refer to Regulation 21, which addresses the functions of the CCA, in this regard).

The operator is required to prepare and submit a safety report, in writing, to the Central Competent Authority, for the purposes that are set out in paragraph (1) of this Regulation.

One hard copy of the safety report is required along with a complete and easily searchable electronic version.

The safety report is required to contain at least the data and information that is specified in Schedule 3 to the Regulations, as well as the name(s) of the relevant organisations involved in the drawing up of the report.

The time limits for sending the safety report to the CCA are set out in this table:

Establishment Type	Safety Report Submission Timeline
New	No later than 4 months prior to start of construction, operation, or the modification (Regulation 11(3)(a)).
Other	2 years from the date from which the COMAH Regulations apply (Regulation 11(3)(c)).
Existing Establishments	Operator should submit an update by 1 st June 2016 (to be considered as an update rather than a 5-year review and the original 5 year review date given under the 2006 Regulations applies) (Regulation 11(3)(b)).
Review and Update	Every 5 years <u>or</u> following a major accident <u>or</u> at any other time where necessary (Regulation 11(7) and (8)).
Transitional Arrangements for Existing Establishments	If the safety report submitted under the 2006 Regulations complies with the requirements of the 2015 COMAH Regulations then an update does not have to be sent to the CCA and the original 5 year review date (given under the 2006 Regulations) applies (Regulation 11(4)).

The operator of a new establishment cannot begin construction or operation or implement modifications that would lead to a change in the inventory of dangerous substances that would cause it to become an upper-tier establishment, until the Central Competent Authority, following its examination of the safety report, has given its conclusions and permission.

The Regulations require the CCA to communicate its conclusions from the examination of the safety report to the operator, or to seek further information, within four months of the safety report submission date⁴. At this time the operator may be requested to provide the Central Competent Authority with any further information it requires to complete the assessment of the safety report (Regulation 21 (4)).

When it does so, the operator has one month from the date of the request to supply this information, or the CCA may specify a longer period in writing where it considers this is justified (Regulation 11(5)).

Following the receipt of the additional information, the CCA must complete the assessment within a reasonable period of time but in any case within a further two months (see Regulation 21(5)).

The Environmental Protection Agency (the "EPA") has a strengthened involvement in the safety report assessment process and may be consulted by the CCA on the risks of a major accident to the environment. The EPA will, within two months of receipt of such a request, advise the CCA on the relevant major accidents to the environment and on the best practicable means for their prevention and mitigation (Regulation 21(10)).

⁴ These timelines are in Regulation 21

Regulation 12: Modification of an installation, establishment or storage facility

This Regulation implements Article 11 of the Directive and as such it is linked to the land-use planning regulation (Regulation 24) and is also linked to planning and development legislation that implements the land-use planning and public participation aspects of the Directive.

It is worth noting here that there has been a change in the modifications which must now be notified to the CCA in advance, such as a lower-tier establishment becoming an upper-tier establishment (or the other way round), or a change in the physical form of the dangerous substance.

The operator is required to review, and where necessary update:

- the notification,
- MAPP and safety management system, and
- the safety report (for an upper-tier establishment)

in advance of the listed modifications.

The operator is required to do this in a sufficient time that will allow the CCA to carry out its functions under Regulation 24, which in this context are to decide if additional technical measures are required before the modification can proceed or whether it should be referred to the planning authority for a decision (see also Regulation 24).

Part 4 – Emergency Plans for Upper-tier Establishments

Regulation 13: Objectives of emergency plans

The objectives of emergency plans, which relate to upper-tier establishments only, are addressed in this Regulation.

Emergency plans created under these Regulations must contain the information that is specified in Schedule 4 to the Regulations, which has separate sections that address both internal emergency plans (an operator duty) and external emergency plans (a local competent authority function).

Regulation 14: Implementation of emergency plans

An emergency plan created under the Regulations must be put into effect by the operator and, if necessary, by the relevant local competent authority without delay when a major accident occurs or if an uncontrolled event occurs which could reasonably be expected to lead to a major accident.

Regulation 15: Internal emergency plans

The operator of an upper-tier establishment is required to prepare an internal emergency plan ("IEP").

It must be prepared in consultation with the relevant people working inside the establishment as well as the relevant local competent authorities, which will usually be the local authority fire service, the Health Service Executive and An Garda Síochána and such other persons as appear to the operator to be appropriate.

The plan should address the measures to be taken inside the establishment if uncontrolled events occur that have the potential to lead to a major accident.

The timelines for the preparation of an Internal Emergency Plan are given in this table:

Establishment Type	Internal Emergency Plan Preparation Timeline
New	No later than 1 month prior to start of construction or operation or the modifications leading to a change in the inventory of dangerous substances (Regulation 15(3)(b)).
Other	1 year ⁵ from the date from which the COMAH Regulations apply (Regulation 15(3)(c)).
Existing	By 1 st June 2016 (Regulation 15(3)(a)).
Review and Update	Every 3 years or more frequently as circumstances may require it (Regulation 15(4)).
Transitional Arrangements for Existing Establishments	If the IEP under the 2006 Regulations complies with the requirements of the COMAH Regulations 2015, the original 3 year review date applies (Regulation 15(3)(a)).

The timelines for testing the IEP are:

Establishment Type	Test of the Internal Emergency Plan Timeline
All	At least every 3 years
Transitional Arrangements for Existing	3 years from the date of the last test under
Establishments	the 2006 Regulations (Regulation 15(5)).

Regulation 16: External emergency plans

The Central Competent Authority will notify the relevant local competent authority of an upper-tier establishment in its functional area (or that could affect its functional area). The LCA is then required to prepare an external emergency plan (the term "EEP" is extensively used in this guide for external emergency plan) for that upper-tier establishment.

The local competent authorities (LCAs) can prepare EEPs separately for each LCA or they can collectively prepare the plan.

The operator of the upper-tier establishment is required to supply the necessary information to the local competent authority to enable it to prepare the EEP.

The CCA may decide (under Regulation 21(9)(a)), after the examination of the safety report, that an EEP is not necessary, in which case it will notify the LCA of this in writing and give

 $^{^{5}}$ The timeline is different to that set out in the Directive: this is to remain closer to the timelines set out in the 2006 COMAH Regulations

reasons for the decision. This exemption can also be withdrawn by the CCA (Regulation 21(9)(b)).

The timelines for the <u>operator to provide information</u> to the local competent authority are set out in this table:

Establishment Type	Provision of External Emergency Plan Information Timeline	
New	<u>No later than 1 month prior to start of operation</u> , or modification (Regulation 16(2)(a)).	
Other	6 months from the date from which the COMAH Regulations apply (Regulation 16(2)(c)).	
Existing	By 1 st June 2016 (Regulation 16(2)(b)).	
Transitional Arrangements for Existing Establishments	g Do not have to supply information under this Regulation if the plan drawn up under the 2006 Regulations and the related information remains unchanged and complies with this Regulation and Regulation 13 (Regulation 16(2)(b)).	

The relevant local competent authorities must prepare the EEP for new and other establishments within six months of the date for the receipt of the necessary information from the operator, but in any case no later than one year following the date they were notified of the requirement by the Central Competent Authority.

Local competent authorities must also provide, at the request of an operator of an uppertier establishment, any relevant information on the EEP that may be necessary for the operator to draw up the internal emergency plan. It is important that the IEP and EEP are consistent and where necessary that each takes account of the other.

The LCAs must consult with the specified stakeholders and take account of any observations received when creating, substantially modifying or revising the EEP.

The public must also be given an early opportunity to submit observations on the draft plan.

LCAs can appoint authorised officers to enter an establishment within its area at all reasonable times and to require the operator to provide the necessary information for the EEP to be prepared or amended.

Following a major accident, LCAs will have to inform the 'persons likely to be affected' (see Regulation 25(4)) of the accident and, where necessary, of the measures that have been taken to mitigate its consequences.

Regulation 17: Review, testing and reporting of external emergency plans

External emergency plans have to be reviewed and, where necessary, updated as often as the circumstances require, but in any event at intervals not exceeding 3 years.

The LCAs, when they are reviewing an EEP, must take into account changes that have occurred in the establishment to which the plan relates or changes within the LCAs, new technical knowledge and knowledge concerning the response to major accidents.

External emergency plans must be tested at a maximum interval of three years.

If a local competent authority is of the view that the cooperation of one or more other local competent authorities is required to adequately test the plan, it can request this cooperation in writing. Where an LCA receives such a request, it must cooperate (Regulation 17(4)).

Where an EEP has been tested under the 2006 Regulations, the maximum test interval of 3 years will apply from the date of that last test (Regulation 17(2)).

LCAs must submit a report to the CCA on their activities under Regulations 16 and 17 within 2 months of the end of each calendar year. The CCA will provide guidelines to the LCAs on the information to be covered by the report (Regulation 17(5)).

Part 5 – Reporting of Major Accidents

Regulation 18: Information to be supplied by the operator and actions to be taken following a major accident

Following a major accident an operator must, as soon as is practicable, inform the CCA of the accident which has occurred. The operator must also provide the CCA with specific information on the circumstances of the accident and the dangerous substances that were involved. In addition, the operator has to provide information on the emergency measures that have been taken, as well as data to assist the CCA in the assessment of the effects on human health, the environment and property.

The operator must also advise the CCA of the steps it plans to take to mitigate the medium and long-term effects of the major accident and to prevent a recurrence. If further investigation by the operator reveals additional facts which alter the information already provided or the conclusions initially drawn, the operator must provide the updated information to the CCA.

The scene of a major accident should only be disturbed to mitigate the effects of the major accident or otherwise only with the consent of an inspector of the CCA.

Regulation 19: Action to be taken by the Central Competent Authority following a major accident

Following a major accident the Central Competent Authority must ensure that any urgent, medium and long-term measures which are necessary are taken.

It must collect by inspection, investigation or other appropriate means, the information necessary for a full analysis of all aspects of the accident and take appropriate action to ensure the operator puts in place the necessary remedial measures.

The CCA must also make recommendations on future preventative measures.

Where the major accident meets the criteria set out in Schedule 6 to the Regulations, the CCA must provide the European Commission with a report, within a year, with the specified information on the accident.

Regulation 20: Notifiable incident

Operators are required to inform the CCA of certain incidents and 'near-misses' as set out in this Regulation and in Schedule 7 to the Regulations.

It should be noted that operators may, as employers, have a duty to report incidents to the Health & Safety Authority under other national legislation.

Part 6 – Enforcement and Regulation

Regulation 21: Functions of the Central Competent Authority

The functions of the CCA are described in this Regulation. A number of these functions have already been referred to when describing the impact of Regulations 1 to 20 and some more will be highlighted when addressing other Regulations further on in this guide.

A number of the functions relate to the requirement to make reports to the European Commission (Regulation 21(1)). One function covers the making of a submission to the Commission based on information received from an operator, where it supports the case that a particular dangerous substance does not present a major accident hazard. If successful, the Directive may be found, in whole or in part, not to apply to the substance.

The CCA must determine whether operators belong to a domino group and then notify each operator within the group of this ((Regulation 21(2)).

As already alluded to under Regulation 11, the CCA must communicate its conclusions on the safety report within a four-month timeframe.

The CCA may prohibit, and in certain specific circumstances it must prohibit, certain actions by an operator. It may prohibit for a failure to submit a notification or other information required by the Regulations, within the specified period. It must prohibit the use or bringing into use of any establishment, or any part of it, where the measures taken by the operator are seriously deficient or where there has been a serious failure to take the necessary actions identified in an inspection report.

The CCA must notify the relevant LCA of its conclusions in relation to a safety report (Regulation 21(8)).

The CCA may decide an external emergency plan is not required and will communicate this to the relevant LCAs in writing (Regulation 21(9)).

It must consult with the EPA on the information in a safety report concerning risks of a major accident to the environment (Regulation 21(10)).

It must accept information submitted by operators under other EU legislation, provided it complies with the requirements of the Regulations (Regulation 21(11)).

Regulation 22: Inspections and Investigations

The CCA must, under its powers under Part 4 of the Chemicals Act, implement a national system of inspections covering all establishments.

Inspections have to be appropriate to the establishment being inspected and they must be sufficient for a planned and systematic examination of the systems in place at the

establishment, so as to ensure that the operator can demonstrate that the appropriate measures have been taken for the prevention of major accidents and the limitation of their consequences.

Inspections must also be used to verify safety report (or other report) information and to confirm that the public information (under Regulation 25) has been supplied.

The CCA must prepare an inspection plan that contains a list of all the establishments and includes inspection procedures and programmes and frequencies for inspections.

The maximum interval between inspections is set at one year for an upper-tier establishment and three years for a lower-tier establishment.

However the CCA can vary this where the inspection is based on a systematic appraisal of the major accident hazards – in which case the interval between inspections will relate to the major accident impacts of the establishment and the previous compliance record of the operator.

The findings of an inspection must be communicated to the operator within four months of the inspection and the operator must comply with them in a reasonable period of time (Regulation 22(7)). Where significant non-compliance is found, an additional inspection must be conducted within six months (Regulation 22(8)).

Non-routine inspections must be carried out on foot of serious complaints and near misses (Regulation 22(6)).

Inspections must, where possible, be coordinated with inspections under other European Union legislation and combined, where appropriate (Regulation 22(9)).

Regulation 23: Inspectors

This Regulation covers the appointment of inspectors for the purposes of the Regulations. Such appointments are made pursuant to Section 11 of the Chemicals Act and in particular Parts 4 to 6.

The CCA may appoint consultants, advisers or others as inspectors under Section 11 of the Act.

Part 7 – Land Use Planning

Regulation 24: Technical advice on land-use planning

The CCA will advise the relevant planning authority of a consultation distance for an establishment, following the receipt of a notification from the operator. It will periodically review and update the consultation distance as necessary.

The CCA has to be consulted for technical advice as appropriate by planning authorities, on the types of development listed in paragraph (2) of this Regulation.

The CCA will provide technical advice to a planning authority in response to a request under this Regulation and the timelines for doing so are set out in paragraphs (9) and (10).

Where proposed modifications at an establishment do not constitute development as defined in Section 3 of the Planning & Development Act and there is no increase in offsite risk (including through use of additional technical measures by the operator), then only the permission of the CCA⁶ will be required. Operators may not proceed with the modification until this permission has been received.

If in the opinion of the CCA, a proposed modification is considered to be a significant change, the CCA will refer it to the planning authority for a determination on whether the proposed modification is or is not development or is exempted development.

Where the planning authority issues a declaration indicating that the proposed modification is not development or is exempted development then the proposal will be referred back to the CCA for it to address under paragraph (4), in accordance with the land-use planning principles set out in the Directive.

The CCA must inform the operator whenever it has referred a proposed modification to a planning authority. In such cases, the operator must not carry out the modification until a declaration has been received from the planning authority or planning permission has been obtained in respect of the proposed modification.

Operators are required to provide sufficient information to the CCA, as part of a notification (Regulation 8) and when planning a modification (Regulation 12) or following a request at any time from the CCA, on the risks arising from an establishment, to enable the CCA to fulfil its functions under this Regulation, and in particular to ensure that technical advice on those risks is available for land-use planning purposes.

⁶ A decision by the Central Competent Authority to deal with a proposed modification under paragraph (4) of this Regulation and not to refer it to a planning authority under paragraph (5) is not a conclusive determination that planning permission is not required for the proposed modification; such a determination is a matter for the relevant planning authority or An Bord Pleanála on review under Section 5 of the Planning and Development Act 2000. Operators must consider these Regulations and any requirements related to planning in the Planning and Development Act 2000 to ensure they comply with all the relevant provisions.

Part 8 – Information and Confidentiality

Regulation 25: Provision of information to the public

The CCA must make certain information relating to each establishment permanently available to the public. The nature of this information is set out in Schedule 5 to the Regulations: Part 1 relates to all establishments, while Part 2 is specifically for upper-tier establishments.

The CCA must ensure the information to be provided is made available electronically within a reasonable period of time from when the establishment becomes subject to these Regulations.

Note that the safety report and inventory of dangerous substances (upper-tier establishments only) can be made available to the public only on request, but subject to the provisions of Regulation 26

All operators are required to provide relevant information to the CCA for this purpose (Regulation 25(1)). The operator is also required to provide the CCA with any updates to the information, without being requested, and to comply with any request from the CCA in connection with the preparation of the information (Regulation 25(10)).

The CCA will specify in writing the format for the information and the means by which it is to be provided to the CCA (Regulation 25(11)).

Operators of upper-tier establishments are also specifically required to ensure that 'all persons likely to be affected' by a major accident originating at the establishment receive clear and intelligible information on safety measures and what they should do in the event of a major accident. This information must be supplied to all buildings and areas of public use, including schools and hospitals and, in the case of domino groups, to all neighbouring establishments (Regulation 25(4)).

The operator will be notified by the CCA of the area within which the information is to be supplied (Regulation 25(8)).

The information should be kept under regular review and updated as necessary. It must be supplied at least every 5 years. For new or other establishments it is to be supplied within six months of when the Regulations apply.

Where the information to persons likely to be affected by a major accident originating at the establishment has been supplied under the 2006 Regulations and it meets the requirements of these Regulations, then the existing 5 year review and update timeframe remains in place (Regulation 25(7)).

The operator must consult with the LCAs on the suitability of this information to ensure it is consistent with the advice to be given and actions to be taken under the EEP (Regulation 25(9)).

Regulation 26: Access to information and confidentiality

Information received by the CCA for the purpose of the Regulations comes within the scope of the European Communities (Access to Information on the Environment) Regulations 2007 (S.I. No. 133 of 2007), as amended by the European Communities (Access to Information on the Environment) (Amendment) Regulations 2011 (S.I. No. 662 of 2011) and it will be made available to any natural or legal person who requests it, in accordance with the provisions of those Regulations (Regulation 26(1)).

However, disclosure of that information may be refused or restricted by the competent authority where the conditions laid down in the Access to Information on the Environment Regulations apply (Regulation 26(2)).

The operator of an upper-tier establishment may request that specific information in a safety report or inventory of dangerous substances should not be disclosed for these reasons and the competent authority, taking account of the operator's submission or based on its own assessment, can decide that the restricting conditions in the Access to Information on the Environment Regulations do apply, and an amended form of the safety report or inventory of dangerous substances can then be made available by the operator to the competent authority, for supply in response to public requests for information under paragraph (1) of the Regulation (Regulations 26(3)-(5)).

Information supplied to other competent authorities or public bodies for the purpose of the Regulations must be treated as confidential by those who receive it. Requests for this information under the Access to Information on the Environment Regulations will have to be made to the originating competent authority (Regulation 26(6)-(7) and Regulation 26(10)).

A safety report under assessment will be treated as confidential until the CCA has communicated its conclusions to the operator (Regulation 26(8)).

Technical LUP advice provided to planning authorities under Regulation 24 will be treated as public information (Regulation 26(9)).

Part 9 – Charges for services

Regulation 27: Charges for Services

This regulation deals with the charging of fees by the Central Competent Authority and the local competent authorities.

Paragraph (1) sets out what the CCA may charge for and this includes the assessment of safety reports, MAPPs and notifications. Inspections, investigations and special reports, attendance at external emergency plans, providing the permanent electronic information to the public and technical LUP advice under Regulation 24 are also included.

The current scale of fees will continue until the Minister approves a new scale.

Paragraph (2) addresses the activities that may be subject to charges by the local competent authorities and the approval mechanism for their introduction by the appropriate Minister.

Part 10 - Offences

Regulation 28: Regulations subject to penal provisions

This Regulation lists the Regulations subject to penal provision.

Regulation 29: Offences, prosecution and penalties

The Regulation states that a failure to comply with any of the Regulations identified within Regulation 28 will be an offence and will be prosecuted under the Chemicals Act and that on conviction, the court, in deciding on penalties, will take account of the Directive's requirement that they be effective, proportionate and dissuasive.

Following conviction, the CCA will be entitled to seek costs and expenses for the investigation, detection and prosecution of the offence under Section 30(3) of the Chemicals Act.

Schedules to the Regulations

Schedule 1: Application of the Regulations

This Schedule transposes Annex I of the Directive. The arrangement of parts has been changed from Seveso II and the categories of dangerous substance now constitute Part 1, which of course now also reflects the new CLP generic classifications.

There are now 21 categories in this part, under the groups of:

- Health Hazards,
- Physical Hazards,
- Environmental Hazards, and
- Other Hazards.

Part 2 now contains the named dangerous substances: most of the named substances and mixtures, and their respective thresholds, are identical to those contained in Part 1 of Annex I of Directive 96/82/EC. Part 2 does have a number of new additions, and there are now 48 named substances.

The addition rules and other notes that assist with determining qualification are included in this Schedule.

The starting point for applying Schedule 1 is the classification of the dangerous substance. If there is a 'harmonised classification' under CLP then operators must use it. Dangerous substances which are not listed as having a harmonised classification must be classified by the operator in accordance with the self-classification rules in the CLP Regulation. For these Regulations, 'dangerous substance' includes intermediates and wastes with the relevant hazard characteristics.

The CCA will put a spreadsheet calculator on its website to assist operators in applying the addition rules.

Schedule 2: Information on the safety management system and the organisation of the establishment with a view to the prevention of major accidents referred to in Regulation 10 and Regulation 11

This Schedule transposes Annex III of the Directive and sets out the elements to be taken account of for the implementation of the safety management system.

The safety management system applies to both lower-tier and upper-tier establishments.

It must be proportionate to the hazards, industrial activities and complexity of the organisation in the establishment and be based on assessment of the risks.

Schedule 2 includes some important new elements:

- measures to raise awareness of the need for continuous improvement,
- involvement of employees/subcontractors only if important from the point of view of safety,
- inclusion of subcontracted activities when identifying/evaluating major hazards,
- the need to take into account information on best practices,
- risks associated with ageing equipment,
- strategy and methodology for monitoring and control,
- provision of follow-up actions and countermeasures,
- an obligation for monitoring procedures to cover the system for reporting major accidents or near misses,
- the necessity for these monitoring procedures to include performance indicators and
- the obligation to consider and include necessary changes indicated by the audit and review.

Schedule 3: Minimum data and information to be considered in the safety report referred to in Regulation 11

This Schedule transposes Annex II of the Directive and details the minimum information that operators must provide in a safety report.

All the information set out in the schedule has to be provided.

New or expanded elements to be included in the safety report include:

Paragraph 2(c): information related to the identification of domino effects.

Paragraph 3(b): information related to the description of processes and the need to take into account available information on best practices when doing so.

Paragraph 4: includes two important new elements of information to be included in the safety report, related to the obligation to further describe the causes that may trigger accident scenarios and the need to also include a review of past accidents and incidents.

Paragraph 5: includes examples of the types of equipment that should be included in the description in 5(a) and adds an important element to be included in the safety report, related to the technical and non-technical measures taken to reduce the impact of a major accident.

Schedule 4: Data and information to be included in the emergency plans referred to in Regulation 13

Emergency Plans prepared under Regulation 13 must contain the information specified in this Schedule.

Part 1 of the Schedule addresses Internal Emergency Plans, which is an operator duty. It remains largely unchanged from the previous Regulations with the exception of the addition of "where necessary" in (f) relating to arrangements for staff training.

Part 2 covers External Emergency Plans, the implementation of which is a function of the local competent authority.

The main changes to this Schedule include:

- the arrangements for off-site mitigatory action should include responses to majoraccident scenarios, and consider domino effects including those having an environmental impact and
- the plans should also provide for informing neighbouring establishments or sites identified for possible domino effects

Schedule 5: Items of information to the public as provided for in Regulation 25

There have been a number of changes to this Schedule, which addresses information which must be provided to the public.

The CCA must make specified information relating to each establishment permanently available to the public. Therefore all operators are required to provide the CCA with the information listed in Part 1 of the Schedule.

Part 1 applies to all establishments; this is an essential element of the new Directive.

An operator is required to provide a description, in simple terms, of the hazardous properties relating to the relevant dangerous substances on the establishment which could give rise to a major accident.

The operator is also required to provide information relating to the appropriate behaviour to take in the event of a major accident and an indication of where the information may be available electronically.

The date of the last site inspection and information on where more detail on inspection related activity can be found must also be set out.

Part 2 of the Schedule sets out the additional information operators of upper-tier establishment must provide.

This now requires the operator to provide general information relating to the nature of the major accident hazards including the potential effects on human health and summary details of the main types of major accident scenarios and the control measures to address them.

Relevant information from the EEP is now also required to be provided to the public.

Where there is a possibility of a major accident with trans-boundary effects, this must be indicated.

Schedule 6: Criteria for the notification of a major accident to the European Commission as provided for in Regulation 19(2)

This Schedule transposes Annex VI of the Directive.

It sets out the criteria for a notifiable major accident, and is the same as the Schedule contained in the 2006 Regulations.

Schedule 7: Criteria for the notifiable incident referred to in Regulation 20

Operators are required to inform the CCA of certain incidents and 'near-misses' as set out in this Schedule.

There are changes to this Schedule, compared to the 2006 Regulations, in that the first paragraph now specifically relates to an explosion or fire involving a dangerous substance that may result in suspension of normal work in the establishment for more than 24 hours.

In relation to the uncontrolled or accidental release or the escape of any dangerous substance in an establishment, the operator is required to notify the CCA if the release had the potential to cause serious injury consequences to human health, serious damage to the environment or damage to property, of the type described in the sixth Schedule.

This should capture 'near-misses' and ensure that they are notified to the Central Competent Authority.