

REA briefing: applicability of COMAH Regulations to AD plants

Anaerobic digestion (AD) operators must consider if the [Control of Major Accident Hazard \(COMAH\) Regulations 2015](#) apply to their activities.

The [Seveso III Directive](#), and by extension the COMAH Regulations 2015 which implement the Directive, place duties on those who use, store, manufacture or otherwise process dangerous substances to classify those substances, identify the hazards and comply with the appropriate duties. It is basically about controlling hazards that have major accident potential, and any substance that falls under the categories and thresholds in Annex 1 of the Directive, bring the site into scope of the arrangements under Seveso.

The HSE (Competent Authority for COMAH regulations) said it is not the place of the Competent Authority to determine whether or not the Regulations apply to a site or a substance beyond giving advice on how to use and interpret the Regulations. This responsibility lies with the operator.

Important notes to read prior to reading this briefing note

This note does not include all hazardous substances and it is for the operator to determine all applicable hazardous substances on their site that need to be considered.

In addition, hazardous substances cannot be considered individually, they need to be considered together and the combined quantity needs to be considered via the aggregation rule set out in note 4 of [Schedule 1](#) of COMAH Regulations 2015 (copied for convenience in the Annex 1 to this briefing note. Annex 2 to this briefing note includes examples of how the aggregation rule could apply to AD plants).

Biogas

[Schedule 1](#) of COMAH Regulations 2015, Parts 1 and 2, include the quantities of dangerous substances on site that determine whether the site falls under the scope of COMAH and whether Lower Tier or Upper Tier requirements apply.

We show below the sections of the schedule relevant to biogas.

SCHEDULE 1 Dangerous substances, PART 1 - Categories of Dangerous Substances

Column 1	Column 1	Column 1
Hazard categories in accordance with the CLP Regulation	Qualifying quantity in <u>tonnes</u> of dangerous substances for the application of:	
	Lower tier requirements	Upper tier requirements
P2 FLAMMABLE GASES Flammable gases, Category 1 or 2	10	50

This means that if the quantity of biogas stored on site is above 10 tonnes, the AD plant will need to comply with lower tier requirements. If the quantity is greater than 50 tonnes, the site will need to comply with upper tier requirements.

In addition, with reference to upgraded biogas, note 19 of the regulations states:

As highlighted already, hazardous substances cannot be considered individually, but together and the combined quantity needs to be considered via the aggregation rule set out in note 4 of Schedule 1 of the regulations (see Annex 1). For example, if an AD plant only stored 9.99 tonnes of biogas at any one time, that wouldn't necessarily be sufficient to conclude that the plant does not fall under the scope of COMAH Regulations.

(19) Upgraded biogas.

For the purpose of these Regulations, upgraded biogas may be classified under entry 18 of Part 2 of this Schedule 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.

HSE Guidance Document L111 "A guide to the Control of Major Accident Hazards Regulations (COMAH) 2015", states:

398 Upgraded biogas would include any biogas for which dispensation has been granted to transport using the natural gas network. Raw biogas which requires further processing before being suitable for the natural gas network would not be covered by entry 18 of Part 2 of Schedule 1.

399 For the purposes of note 19, the entry for natural gas includes whether liquefied or not.

SCHEDULE 1 PART 2 - Named Dangerous Substances (section relevant to upgraded biogas)

Column 1	Column 1	Column 1
Dangerous substances	Qualifying quantity in <u>tonnes</u> of dangerous substances for the application of:	
	Lower tier requirements	Upper tier requirements
18. Liquefied flammable gases, Category 1 or 2 (including LPG) and natural gas (see note 19)	50	200

Propane

Note that for propane stored on site, the thresholds specified under entry 18 above will also apply.

Digestate

Digestate may be classed as an aquatic pollutant under COMAH, depending on its characteristics.

The '[CLP Regulation](#)' (Reg. (EC) No 1272/2008, with amendments under Reg. (EU) No 286/2011), includes requirements in relation to the classification, labelling and packaging of (active) 'substances' and 'mixtures' (i.e. formulated products). The criteria for classifying a substance as an aquatic hazard, taken from the CLP Regulation, are shown in the table below.

Aquatic hazard classification	Criteria for hazard classification for 'substances' and 'mixtures'	GHS09 Pictogram	Signal word	Hazard statement ###	Precautionary statements ***
'Acute category 1' #	Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7-14 day ErC50: ≤ 1 mg /L		'Warning'	H400 'Very toxic to aquatic life'	P273, P391 & P501.
'Chronic category 1' #	i) Chronic toxicity data available for substance /mixture and not 'rapidly degradable'. Chronic NOEC for fish, crustacea, algae or other aquatic plants < 0.1 mg /L ii) Chronic toxicity data available for substance /mixture and 'rapidly degradable'. Chronic NOEC for fish, crustacea, algae or other aquatic plants < 0.01 mg /L iii) Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF > 500 (or in absence of data $\log K_{ow} > 4$); Criteria as for 'Acute category 1'		'Warning'	H410 'Very toxic to aquatic life with long lasting effects'	P273, P391 & P501.
'Chronic category 2'	i) Chronic toxicity data available for substance /mixture and not 'rapidly degradable'. Chronic NOEC for fish, crustacea, algae or other aquatic plants > 0.1 to < 1 mg /L ii) Chronic toxicity data available for substance /mixture and 'rapidly degradable'. Chronic NOEC for fish, crustacea, algae or other aquatic plants > 0.01 to < 0.1 mg /L iii) Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF > 500 (or in absence of data $\log K_{ow} > 4$); Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7 day ErC50: > 1 mg /L to ≤ 10 mg /L		No 'signal word' required	H411 'Toxic to aquatic life with long lasting effects'	P273, P391 & P501.
'Chronic category 3'	i) Chronic toxicity data available for substance /mixture and 'rapidly degradable'. Chronic NOEC for fish, crustacea, algae or other aquatic plants > 0.1 to < 1 mg /L ii) Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF > 500 (or in absence of data $\log K_{ow} > 4$); Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7 day ErC50: > 10 mg /L to ≤ 100 mg /L	Not required	No 'signal word' required	H412 'Harmful to aquatic life with long lasting effects'	P273 & P501.
'Chronic category 4' ('Safety net' classification)	Applies when data does not allow classification under above criteria but where there are 'some grounds for concern'. Includes for example poorly water soluble compounds (< 1 mg/L) for which effects are less than 50% at up to limit of solubility but which are: not 'rapidly degraded' and which have a fish BCF ≥ 500 (or in absence of data $\log K_{ow} \geq 4$); unless 'other scientific evidence' shows 'classification to be unnecessary' e.g. chronic NOECs $>$ water solubility or > 1 mg/L or where other evidence of 'rapid degradation' exists (i.e. using methods not included in the standard definition)	Not required	No 'signal word' required	H413 'May cause long lasting harmful effects to aquatic life'	P273 & P501.

It should be noted that in 2015 European Biogas Association (EBA) was involved in some R&D work to verify whether digestates should be classified as aquatic pollutants. Preliminary results on ecotoxicity indicated that digestate would not be classified under the point H14 of the Water Framework Directive as an eco-toxic substance. We are in the process of checking with EBA whether they made further progress with this testing at the time and what the conclusions were. We will update this note in due course with the relevant information.

If a confirmed pollutant, then digestate is either classed as E1 (Acute 1 or Chronic 1) or E2 Hazardous to the Aquatic Environment (Chronic 2). The relevant thresholds for lower tier and upper tier establishments are shown in the table below, from Schedule 1 Part 1 of the regulations.

SCHEDULE 1 Dangerous substances, PART 1 - Categories of Dangerous Substances

<i>Column 1</i>	<i>Column 1</i>	<i>Column 1</i>
Hazard categories in accordance with the CLP Regulation	Qualifying quantity in <u>tonnes</u> of dangerous substances for the application of:	
	Lower tier requirements	Upper tier requirements
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

CNG Services' COMAH calculator

Member of the REA CNG Services have developed a comprehensive calculator that can help determining whether the site falls under COMAH and whether is a lower tier or an upper establishment. This can be provided by CNG Services upon request.

Requirements for lower tier and upper tier establishments

The latest HSE's guidance on the COMAH Regulations 2015 (L111, Third edition) can be found [here](#).

Duties for lower and upper tiers

The HSE [Guidance](#) for new entrants include information on all the requirements.

COMAH regulation 5 requires every COMAH operator to prepare and keep a document setting out their **major accident prevention policy (MAPP)**. For lower-tier COMAH sites it is a standalone document but for top-tier COMAH sites the MAPP may be included in the safety report rather than as a separate document.

The MAPP will need to include:

- 1) your policy setting out your aims and principles of action concerning the prevention of major accidents; and
- 2) a description of your safety management system for achieving these aims. Note that in the context of COMAH, 'safety' includes environmental protection. The MAPP will usually be a

short and simple document setting down what is to be achieved but it should also include a summary and further references to the safety management system that will be used to put the policy into action. The key areas are:

- organisation and personnel;
- identification and evaluation of major hazards;
- operational control;
- planning for emergencies;
- monitoring, audit and review.

The amount of detail should be proportionate to the level of the hazards present – the greater the hazards the more detail you will have to provide. The MAPP can refer to other relevant documentation for the establishment.

Usually it won't be necessary to prepare any special documents to comply with this regulation. For top-tier establishments the safety report, emergency plans, hazardous substances consent and planning permissions should provide sufficient evidence. For lower-tier establishments the MAPP, hazardous substances consent and planning permissions will normally be sufficient. Establishments that are already subject to environmental regulation may have relevant information for managing risk to the environment, although further detail may be required to address major accident hazards.

Upper tiers

Regulation 7 requires all top-tier COMAH operators to prepare a safety report and send it to the CA as part of their demonstration that all measures necessary have been taken to prevent major accidents and to limit the consequences to people and the environment of any that do occur.

Regulation 9 requires top-tier COMAH operators to ensure that the consequences of a major accident at a COMAH site are minimised through the provision of effective on-site emergency planning and response arrangements and where necessary, dovetailing with the off-site emergency plans prepared by the local authorities under COMAH or civil contingencies legislation.

Changes to sites

Please note that there are similar (but different) rules for Hazardous Substances Consent which need to be taken into account when planning changes / new sites. You can read further information [here](#).

Note: Please ensure you read the HSE relevant [guidance](#) in full to understand all the requirements of the regulations, as this briefing note only represents a summary.

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Annex 1: excerpt from Note 4 to Schedule 1 of COMAH Regulations 2015 (the 'aggregation rule')

Please note that further detail on how the aggregation rule applies can be found in the HSE L111 [Guidance](#).

"4. The following rules governing the addition of dangerous substances, or categories of dangerous substances, 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 quantity, the following rule must be applied to determine whether these Regulations apply to the establishment.

An establishment is an upper tier establishment if the sum:

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

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

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

An establishment is a lower tier establishment if the sum:

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

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

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

This rule must 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.

These Regulations apply where any of the sums obtained by (a), (b) or (c) is greater than or equal to 1."

Annex 2 – excerpt from EA’s [consultation](#) on Appropriate measures for the biological treatment of waste, paragraph 136, page 62

136. You must determine if the COMAH regulations 2015 apply to your activities. This will depend on the quantity of dangerous substances you store on site. Raw biogas is classified as a category 1 flammable gas (extremely flammable), which has a lower tier COMAH limit of 10 tonnes. If your site stores less than 10 tonnes, you must apply the aggregation rule. Biogas is aggregated with other flammable gases or liquids, such as Liquid Petroleum Gas (LPG) (Propane or butane), or diesel. These have individual lower tier COMAH limits of 50 tonnes and 2500 tonnes respectively. If the aggregation is greater than 1 then COMAH applies. Here are 2 examples.

Example 1: injecting gas to grid

AD sites which inject biogas to the national gas grid would need to consider the quantity of both:

- biogas in the headspaces and storage facilities on site
- liquefied flammable gases stored

Example:

8 tonnes of raw biogas (lower tier limit is 10)

25 tonnes of LPG (lower tier limit of 50)

Aggregation for COMAH assessment is: $8 \div 10 = 0.8$ $25 \div 50 = 0.5$ $0.8 + 0.5 = 1.3$ therefore above 1 and COMAH regulations applies

Example 2: biogas burnt onsite to generate electricity

AD sites which use gas to generate electricity, with a store of diesel for back up would need to consider the quantity of both:

- biogas in the headspaces and storage facilities on site
- diesel stored.

Example: 9.4 tonnes raw biogas (lower tier limit is 10)

600 tonnes diesel (lower tier limit of 2500)

Aggregation for COMAH assessment: $9.4 \div 10 = 0.94$ $600 \div 2500 = 0.24$ $0.24 + 0.94 = 1.18$ therefore above 1 and COMAH regulations applies

Operators should contact the HSE for more information on COMAH.