

Note to REA's members regarding the application of REACH, CLP and COMAH regulations to digestates

Introduction

This note clarifies whether REACH, and CLP regulations apply to digestates. With regard to COMAH discussions are still being held with the HSE to clarify whether digestate falls under the scope of the regulations or not.

The content of this note is based on REA's recent communications with Defra and the HSE.

Please note that Defra reminds us that this material is provided for information only and that only the Courts can give authoritative interpretations of the law.

REACH and digestates

1.1 What is REACH?

REACH is the Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals. It came into force on 1st June 2007.

REACH aims to make the people who place chemicals on the market (mainly manufacturers and importers) responsible for understanding and managing the risks associated with their use.

One of the main requirements set up by REACH is 'Registration'. Companies who manufacture chemical substances or import them into Europe – either on their own or mixed together to make chemical products - have to 'register' a dossier of technical information about each substance they manufacture or import above a tonne a year with the ECHA (European Chemicals Agency) in Helsinki.

1.2 So, does REACH apply to digestates?

Digestate with 'waste' status is not covered by the REACH Regulation.

Digestate with 'product' status (i.e. certified under the Biofertiliser Certification Scheme) is within the scope of this regulation. However, the UK's interpretation of ECHA's guidance is that digestate with 'product' status is exempt from the REACH obligations for registration, evaluation and downstream user provisions, as it falls under one of the categories described in Annex V of the REACH (exempt substances).

For this reason, our understanding is that AD operators do not need to register digestates with ECHA for the purpose of the REACH Regulation.

Please note that Defra and the HSE have confirmed that they agree with this interpretation.

1.3 The UK's interpretation in detail

Despite some non-UK EU stakeholders disagreeing with this interpretation, Defra has confirmed to REA in writing that:

- Annex V to the REACH Regulation lists types of substances that are exempted from the registration requirements. Registration is deemed inappropriate or unnecessary for these substances. The Annex explicitly includes compost and biogas, but not digestates¹.
- Whereas digestate is not mentioned, specifically, in Annex V, this part of the REACH Regulation does include an exemption for "Substances occurring in nature...". Anaerobic decomposition is an entirely natural process and the resulting liquid and solid materials are substances which occur in nature. It could be argued that those who produce digestate are not manufacturing a material but, instead, are managing a natural process. ECHA's guidance for Annex V gives explanations on how to apply the exemption for "Substances occurring in nature..." and includes the following advice:

*"Naturally occurring substances as such: means, substances obtained, for example, from plants, micro-organisms, animals, or certain inorganic matter such as minerals, ores and ore concentrates, or organic matter such as crude oil, coal, natural gas. It should be noted that whole living or unprocessed dead organisms (e.g. yeast (see Attachment 2), freeze-dried bacteria) or parts thereof (e.g. body parts, blood, branches, leaves, flowers etc.) are not considered as substances, preparations or articles in the sense of REACH and are therefore outside of the scope of REACH. The latter would also be the case if these have undergone digestion or decomposition resulting in waste as defined in Directive 2008/98/EC, **even if, under certain circumstances, these might be seen as non-waste recovered materials**".* However, it should be noted that there is a footnote to this text that states:

"This explanation is without prejudice to discussions and decisions to be taken under Community waste legislation on the status, nature, characteristics and potential definition of such materials, and may need to be updated in the future".

There is reference to this exemption in HSE guidance, namely the leaflet REACH and Substances Recovered from Waste.

Defra clarified that "The REACH authorities (the Commission, the European Chemicals Agency, and Member States) in CARACAL² are considering the end of waste interface between REACH and the Waste Framework Directive. This work will probably have some implications for anaerobic digestate. However, an explicit exemption would only be possible through an amendment to REACH Annexes IV or V, and the Commission has no plan to do that at the moment."

¹ According to Defra, one of the reasons for this decision is that, in most EU countries, digestate retains its status as waste and so an exemption was not needed at the time of the Annex V revision. On the other hand compost is widely traded in Europe as a non-waste material and so, to ensure uniformity in those countries in which it is not regarded as waste, compost was included in Annex V.

² http://ec.europa.eu/enterprise/sectors/chemicals/reach/caracal/index_en.htm

Defra has reassured REA that the UK's position remains to rely on REACH Annex V and the ECHA guidance on the exclusions covered by that Annex. They highlighted that if the issue of further exemptions should be re-opened by the Commission, then the UK will be engaged fully in the debate, and support any reasonable Commission proposal to include digestate in Annex V. Defra confirmed that if Member States are called upon to discuss the status of digestates under REACH, then the UK will develop an appropriate negotiating position based on its current view, and any position taken by the Commission or ECHA on the subject.

CLP and digestates

2.1 What is CLP?

REACH & CLP are two independent pieces of chemical legislation in EU.

CLP stands for the Regulation (EC) No 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures. CLP introduces the United Nations globally harmonized system (UN GHS) for classification and labelling of chemicals into Europe. CLP entered into force on 20th January 2010.

According to CLP, companies that manufacture, import, use or distribute chemical substances or mixtures must classify, label and package any substance or mixture, regardless of its annual tonnage, in accordance with the CLP Regulation before these are placed on the EU market. Placing on the market of a substance or mixture means making it physically available to third parties, whether in return for payment or free of charge.

A manufacturer or importer is required under CLP to:

- classify substances that are subject to registration or to notification in line with Article 7 or 9 of REACH, even if these are not placed on the market; and
- notify hazardous substances that are placed on the market on their own or contained in hazardous mixtures above certain applicable concentration limits, regardless of the annual tonnage manufactured or imported, as well as substances subject to registration under REACH and that are placed on the market, to the Classification & Labelling Inventory established at the Agency. However, if the substance is not subject to registration under REACH and does not meet the criteria for classification as hazardous, there is no notification obligation.

2.2 So, does CLP apply to digestates?

Waste is not considered to be a substance, article or mixture under the CLP Regulation. Therefore, waste digestate is not covered by the CLP Regulation.

Residues which are recovered as substances or mixtures do fall under the scope of CLP. Therefore product digestate is within the scope of the CLP Regulation. However categories of substances or individual substances listed in the Annex V of the REACH Regulation must be notified to the Classification and Labelling inventory **only when exhibiting hazardous properties.**

For this reason, our understanding is that AD operators do not need to notify digestate to the Classification and Labelling Inventory.

Please note that the HSE has confirmed that they agree with this interpretation.

2.3 ECHA's guidance in more detail

ECHA's website states: "Where a substance is exempted from registration under REACH, CLP requires it to be notified to the C&L Inventory if it is classified as hazardous and is placed on the market either on its own or contained in a hazardous mixture above specified concentration limits. On the other hand, substances which are exempted from registration under REACH and which are not classified as hazardous and placed on the market do not have to be notified to the C&L Inventory"³.

It also states: "Annex V to REACH lists categories of substances as well as individual substances, e.g. certain naturally occurring substances, fatty acids and glass, which are exempted from registration under REACH as registration is deemed inappropriate or unnecessary. For certain categories, the absence of classification is a pre-condition for the exemption from registration. Other substances which are included in Annex V may have hazardous properties and therefore need to be notified according to CLP whenever they are placed on the market. **However, as long as a manufacturer or importer concludes that it is inappropriate to classify a specific substance covered by Annex V, he does not need to notify information on that substance to the C&L Inventory.**"

The JRC's Technical Proposals for End of Waste for composts and digestates⁴ conclude that:

"Compost fulfilling end-of-waste criteria (e.g. will not lead to overall adverse environmental or human health impacts) does not exhibit any hazardous properties, and thus has not to be labelled according to CLP since it is not classified as hazardous according to CLP.

³ <http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/topic/clp>

⁴ Hans Saveyn & Peter Eder, 2014. End-of-waste criteria for biodegradable waste subjected to biological treatment (compost & digestate): Technical proposals

For end-of-waste digestate exempt from REACH obligations for registration according to the stipulations in Annex V, the same reasoning on the hazardous properties would be valid and it would hence be excluded from the CLP obligations as well. However, it appears that end-of-waste digestate subject to REACH might be subject to the obligations of the CLP."

In the UK digestate with product status is currently considered exempt from the REACH, thus it is excluded from the CLP obligations as well. Given the above considerations, REA's current understanding is that AD operators do not need to notify digestate to the Classification and Labelling Inventory.

REA will continue to liaise with Defra, the HSE and European trade bodies EBA and ECN to keep informed on the discussions held in Europe and seek further clarification on whether there is still any risk that AD operators may be caught by this set of regulations in future.

REA will endeavour to inform promptly and provide guidance to its members if the UK position changes.

COMAH regulations and digestate

The Health and Safety Executive has been recently consulting on new proposed regulations, titled 'The Control of Major Accident Hazards (COMAH) Regulations 2015' to implement all but the land use planning aspects of Council Directive 2012/18/EU (Seveso III Directive) on the control of major-accident hazards involving dangerous substances. These will replace COMAH 1999.

The Seveso III Directive entered into force on 13th August 2012 and aims to prevent on-shore major accidents involving dangerous substances and limit the consequences to people and/or the environment.

COMAH is enforced by HSE and the relevant environment agencies – the Environment Agency (EA), the Scottish Environment Protection Agency (SEPA), and Natural Resources Wales (NRW) - working together as the COMAH Competent Authority (CCA).

REA's response to the HSE consultation can be downloaded [HERE](#). The position of the REA, highlighted in our response, is that AD sites should not be included in the COMAH Regulations.

There are references to biogas within Seveso III, whereas digestate is not specifically mentioned. However there is a possibility that digestate could be classified as aquatic pollutant and therefore fall within the scope of the Directive. This would mean that expensive conditions which should relate only to large scale chemical hazards would be imposed on the AD industry.

HSE's initial advice:

REA sought clarification from the HSE on whether digestate is covered. The HSE's initial advice was that the revised COMAH regs would not apply to digestate. HSE clarified to REA that:

"Digestate is a fertiliser similar to compost and as such it wouldn't be expected to have any hazardous properties, unless the waste material being digested was hazardous in which case the digestate wouldn't be suitable for use as a

fertiliser. If it's being sold (and maybe if it's a waste product itself) then CLP/REACH would require it to be classified/self classified, which would then determine whether it was in scope of Seveso/COMAH Regulations 2015. It would be more likely the biogas which would attract COMAH, if above threshold quantities, not the digestate."

The HSE informed REA that they will develop a Q&A on this issue which will feature on the [Seveso III website](#). It is possible to subscribe to the Seveso e-bulletin via this link, which will keep you up to date about implementation.

HSE's more recent update (2nd September)

More recently, the HSE clarified to REA that as of now HSE is not able to provide a definitive answer and continues to work on the issue. This work includes interacting with some of the European Member States and with DEFRA to come to a solution and they will keep REA and other interested trade bodies informed of the progress. They are also planning to have a face to face meeting with REA and other interested parties (ADBA) in the coming months.

The issue arises from Note 5 to Annex 1 of the Directive (which will be copied out in the new Regulations) which - paraphrased - says that where dangerous substances are present on a site, even if they are not covered by the CLP Regulation, they must be assigned to the most appropriate category or named dangerous substance and treated accordingly. So, if the digestate has hazardous properties it has to be classified on the basis of those properties even if the CLP Regulation doesn't consider it to be a substance.

As it is the responsibility of the user to classify any materials that they hold it would fall to the industry, if the specific composition of the digestate differs from site to site then it would be specific users, to consider whether the digestate has hazardous properties that bring it into line with a Seveso III / COMAH 2015 category. The main concern appears to be whether it may be E1 Hazardous to the Aquatic Environment Acute 1 or Chronic 1. If it does, and the site holds over the qualifying quantity, then the Regulations would apply.

With regard to biogas, whilst biogas is mentioned in the revised Seveso directive, the thresholds are rather high and most sites "should" be exempt (biogas is unlikely to be "stored" on site at the volumes triggering COMAH).

Based on the most recent update from the HSE, REA is currently unable to clarify whether COMAH regulations will apply to digestates or not. We are currently liaising with the HSE. Work may need to be done to identify whether digestate falls under the acute or chronic toxicity descriptions for an aquatic pollutant. We will let you know as soon as we have an update.

V1, 3rd September 2014