



Digestate and REACH

Position Paper

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1. Introduction

Digestate is the fully fermented, mostly liquid remain of a fermentation process. It is generated during operation of biogas plants, in addition to the biogas itself (see in detail regarding the process section 2).

Digestate has excellent properties to serve as fertilizers, and is used for this purpose. Its application is, just as for any other organic fertilizer, subject to requirements of EU Member States' fertilizer regulations. In this context, it is worth mentioning that EU Fertilizer Regulation¹ is currently under revision, *inter alia* with the aim to extend the scope of the Regulation on organic fertilizers, soil improving material and cultural substrates. One aim of the revision is to set out harmonized criteria for limit values for pollutants, labeling, as well as positive lists or negative lists in terms of feedstock for the production of compost and digestate products at European level.

Important to note that biowaste is also in principle a suitable feedstock for biogas process (which legally in this case is considered waste treatment). In the course of the discussions at EU level on the end-of-waste criteria for biodegradable waste subject to biological treatment, the question has been raised whether digestate from certain types of biowaste could, after ceasing to be waste, possibly fall under the requirements of EU REACH Regulation (EC) No 1907/2006 (in the following: "REACH")², and in particular become subject to registration requirements as of Title II of REACH.

In our view, digestate is currently clearly not subject to registration obligations (and in the vast majority of cases, is not falling in the scope of REACH either). To date, we have communicated this position also to the members of our associations. However, it is admitted that this result is the conclusion of a detailed assessment of different cases of exemption from REACH, in line with the understanding expressed by European Chemicals Agency ECHA (see in detail below chapter 3).

The aim of this document is against this background

- a. calling for the Commission's attention to the issue;
- b. asking the Commission to assess whether they can release a statement where the Commission confirms that they share ECHA's opinion that digestate in the cases discussed hereunder is not subject to REACH, or, where applicable, that in cases digestate is subject to REACH, there is no obligation for registration;
- c. suggesting that Commission considers launching a revision process regarding Annex V of REACH, to unambiguously clarify remaining uncertainties regarding digestate.

2. Technical background

Key message 1: Anaerobic digestion of biogenic material is a natural process.

2.1. Introduction

Dead herbal biomass like trees, leaves, grass, are intaken as food by different living beings (cattle, horses, sheep, worms, beetles, microbes, etc.), digested and excreted for the major part as metabolism products. The metabolism products of this process are material (e.g., excrements) and gaseous removals. The same processes occur with the decomposition of all other organic material (e.g., with decay).

- If the decomposition process of biomass (biogenic organic materials) occurs with aerial supply (aerobic conditions), one speaks of composting; the generated products are compost, heat and a CO₂-rich gas.
- If this process occurs without such a supply (anaerobic condition), one speaks of digestion; the generated products are: nutrient rich digestate, and a high-energy methane-containing gas mixture - the biogas.

The conversion or digestion of biomass under anaerobic conditions into fermentation gas and in fermenting products is therefore equivalent to natural microbiological processes, which often occur elsewhere in nature. During each decay or decomposition process natural fermentation gas processes are present in anaerobic zones. Such processes are to be observed for instances in moors and marshes. Once water is saturated, oxygen starvation appears which leads to the natural decomposition of organic material, and allows the generation of peat. Other examples include inundated rice fields, badly aerated soils, eutrophic waters sediments, digestive tracts of animals (in particular cow's rumen), expired food in closed vessels, or decayed pilework of water purification. Also the deposition of organic waste at landfills under oxygen starvation leads to the uncontrolled decomposition processes.

Biogas technology makes use of these natural microbiological processes in which the feedstock is transformed by the different micro-organisms under exclusion of air into large amounts of biogas, a methane-rich gas mixture (fermentation gas) and digestate, rich in nutrient.

Key message 2: For digestate generation from anaerobic digestion, the same feedstock is used as for (aerobic) composting. The resulting products, digestate and compost, are used for the same purpose – as fertilizers and soil improvers.

Given the same input substrates and the same application possibilities of the products (digestate and compost), uniform regulations on the end-of-waste criteria for both products are elaborated at European level. Indeed, the only differences are identified in the procedure technology, including the specific demands for temperature etc., and the permitted additives. Products, digestate and compost, serve as organic full fertilizers of the plant food and the soil, the latter by the supply of carbon.

2.2. Feedstock for biogas plants

Currently, predominantly energy crops and liquid manure are used as feedstock for biogas production. However, in principle, all organic materials are suitable as feedstock for instance separately collected organic waste, fat separators, food leftovers and expired food, animal by-products, as well as agricultural products like grass silages.

2.3. Description of digestion process

The conversion of biomass to biogas and digestate is a complex biochemical process. Four phases can be distinguished as follows:

1. In the first step, the *Hydrolysis*, polymers components of the feedstock (among other things carbon hydrates, proteins, fat) are disassembled into lower molecular organic compounds (*inter alia* amino acids, sugar and fatty acids). The hydrolytic micro-organisms involve release hydrolytic enzymes, which decompose the material biochemically.
2. The produced intermediates are degraded during *Acidogenesis* by acidogenic bacteria to lower fatty acids (acetic acids, propionic and butyric acid) as well as to carbon dioxide and hydrogen. Besides, also lactic acid and alcohols are produced, mostly in small quantities.
3. The intermediates subsequently are transformed during *Acetogenesis* by acetogene bacteria to acetic acid, hydrogen and carbon dioxide.
4. In the last phase, the *Methanogenesis*, methane and carbon dioxide are formed, by archaea.

Beside bacteria and eukaryotes, archaea are one of three domains into which all cellular living beings are classified. Archaea belong to the oldest living beings on earth, which originated around three to four milliards years, long before the atmosphere was formed.

For the optimisation of the process additives can be used in certain cases to offer nutrients for the micro-organisms and for further treatment of the generated products (biogas and digestate). These are usually required only in very small quantities (less than 2% in share of the feedstock). The following categories of additives are usually used:

- Flocculation agents and flocculation aids,
- Trace elements,
- Precipitants,
- Enzymes,
- Free or immobilized archaea, prokaryotic and eukaryotic biomass,
- Emulgators,
- Antifoaming agents,
- Complexing agents,
- Antiscalants,
- Macronutrients (Na, Mg, Ca, Carbonate and Phosphate).

2.4. Properties and use of digestate

Digestate is a high-quality fertilizer, richly in humus forming materials and nutrients. It is used as an organic fertilizer either in liquid form (about 5-10% dry matter), or separated and dried, in agriculture, in landscaping and horticulture as well as in private gardens, in a similar way as compost, liquid manure or peat. An amount of around 80 million tonnes of digestate is generated in Europe in about 13,000 biogas facilities.

The nutrients that were contained in the feedstock remain in the digestate. Only carbon, hydrogen and in marginal quantities nitrogen, sulphur and oxygen can leave the process during gas phase. Therefore, the used feedstocks determine directly the composition of the generated digestate. The relevant nutrients are predominantly nitrogen, phosphorus, potassium and the organic carbon content.

The following table gives an overview on results of analyses of about 1,800 collected digestate samples during the time frame 2009-2012, in several Member States of the EU.

	unit	n	10 % quantil	arithmetical average	90 % quantil
DM content	[%]	1875	2,7	5,7	9,1
organic matter in % of DM	[%]	1709	55,2	69,3	82,4
ph value		1856	7,5	7,9	8,3
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N	[% of DM]	1652	4,9	10,4	18,1
NH4-N	[% of DM]	1822	1,6	6,0	12,6
K2O	[% of DM]	1294	2,2	5,3	8,8
P2O5	[% of DM]	1292	1,9	3,8	5,5
CaO	[% of DM]	1136	2,1	4,7	8,1
Mg	[% of DM]	1133	0,3	0,7	1,3
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Cr	[mg/kg DM]	1091	6,5	15,1	25,9
Cd	[mg/kg DM]	1068	0,2	0,4	0,6
Pb	[mg/kg DM]	1081	2,1	5,8	9,6
Zn	[mg/kg DM]	1095	157,4	311,1	494,0
Cu	[mg/kg DM]	1095	34,9	87,5	151,6
Hg	[mg/kg DM]	1071	0,0	0,1	0,2

Table 1: Results of analyses of digestate in Europa (2009 – 2012), source: EBA

Hereinafter, results of analyses of composts from Germany are enclosed. In comparison to digestate, it is obvious that the biggest difference between composts and fermenting products is in terms of water content. Where digestate is usually liquid, and also is used predominantly in liquid form, compost does contain substantially higher dry matter content and is applied in solid form. Essential results from the investigation and comparison between composts and digestate are also included in the current draft of the JRC report on the end-of-waste criteria for biodegradable waste subject to the biological treatment.³

	unit	n	10% quantil	arithmetic average	90 % quantil
DM content	[%]	2795	51,7	63,5	75,8
organic matter in % of DM	[%]	2795	25,7	38,3	51,3
ph value		2795	7,8	7,5	8,2
N	[% of DM]	2795	0,8	1,4	1,9
NH4-N		2795			
K2O	[% of DM]	2795	0,6	1,2	1,7
P2O5	[% of DM]	2795	0,4	0,7	1,0
CaO	[% of DM]	2795	2,0	4,8	8,2
Mg	[% of DM]	2795	0,4	0,8	1,3
Cr	[mg/kg DM]	2795	13,6	24,2	36,8
Cd	[mg/kg DM]	2795	0,2	0,4	0,6
Pb	[mg/kg DM]	2795	18,8	35,3	54,0
Zn	[mg/kg DM]	2795	114,0	172,3	240,0
Cu	[mg/kg DM]	2795	25,2	42,7	65,0
Hg	[mg/kg DM]	2795	0,1	0,1	0,2

Table 2: Results of analyses of compost in Germany (2012), source: Bundesgütegemeinschaft Kompost e.V.

3. Legal assessment: Placing digestate on the market and obligations under REACH

3.1. Is digestate in the scope of REACH?

3.1.1. Starting point: Definition and concept of the term “substance” under REACH

REACH lays down provisions for manufacture, placing on the market and use of *substances*, on their own, in mixtures or in articles (Article 1(2) REACH).

The term “*substance*” is defined as

“a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition“ (Article 3(1) REACH).

Digestate is within the scope of REACH if it is either to be considered a substance on its own, or a mixture which contains substance/s.

3.1.2. “Organism”-exemption of “substance” concept

In the Guidance for Annex V of REACH / exemptions from the obligations to register⁴, European Chemicals Agency ECHA has specifically addressed results of digestion process of certain materials and the “*substance*” concept under REACH. ECHA points out that

“[...]It should be noted that whole living or unprocessed dead organisms (e.g. yeast [...] 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 [...]”

Following this approach, it can be assumed that as long as only whole living or unprocessed dead organisms are used as feedstock in the biogas process, the result of the digestion/decomposition process – i.e. the digestate! – is not considered a substance or mixture in the sense of REACH. Even if applying the concept “whole living or unprocessed dead organisms” is not without difficulties, it is obvious from the illustrative examples ECHA uses here that in any case and without doubt, renewable raw materials and other crude remains from agriculture and forestry or from food industry, as typical feedstocks, are covered.

Note that in a public presentation⁵, German competent authority BAuA has held the position that in a similar way also manure is no substance / no mixture under REACH.

The addition of additives to the digestion process does not change the result of assessment whether this concept applies to the case of digestate – there is no restriction within the view of the ECHA in

terms of *how* the digestion process should be done, it depends alone on the fact *that* a digestion process has occurred.

The consequence is that for the digestate for which only energy crops and / or liquid manure were used as feedstocks, no obligations exist under REACH. The same applies to possible duties which arise from CLP Regulation (EC) No 1272/2008⁶, because under CLP Regulation, an identical concept of “substance” is used as under REACH.

3.1.3. “Waste”-exemption of substance concept (Article 2(2) REACH)

If biowaste – i.e. for example separately collected organic fractions or food waste – is used as feedstock for the biogas process, it needs to be assessed, whether the digestate itself is still considered waste, and thereby according to Article 2(2) REACH is not considered a substance or mixture under REACH.

Waste is in this context defined in line with the definition of EU Waste Framework Directive 2008/98/EC⁷ to which REACH makes reference:

“any substance or object which the holder discards or intends or is required to discard”

The question under which conditions biowaste treated in biogas facilities is legally not considered waste any more, is to be assessed according to Article 6 of Waste Framework Directive: As long as criteria are set at EU level for certain specified waste streams, those criteria apply; otherwise the Member States decide case-by-case, taking into account applicable case-law. Since no criteria have been set so far at EU level, the decision currently lies within the Member States.

As far as the waste status of digestate, generated from waste, continues to exist at the time of its marketing, following Article 2(2) of REACH it is to be assumed that the digestate is not considered a substance or mixture under REACH, and hence, in this respect no obligations apply under REACH.

Because according to its Article 1(3), waste is not considered a substance or mixture under CLP Regulation either, no obligations would be applied under CLP Regulation.

3.1.4. Intermediate result, remaining cases of doubt and future perspective

As far as one of the two exemptions discussed above (3.1.2 and 3.1.3) applies, no obligations under REACH are in place for the marketing of digestate.

Uncertainties may arise (only) if the following three aspects appear cumulatively:

- biowaste was used as feedstock,
- end-of-waste status was achieved, and
- regarding the used biowaste, it is not unambiguous to what extent it can be considered as “whole living or unprocessed dead organisms”.

Such uncertainties could arise more frequently in the future once the envisaged EU Regulation on End of Waste for digestate from waste streams has been adopted. The mentioned JRC document³ discusses in this respect the example of residues from the production of fruit jam as one element possibly triggering registration obligation for digestate, in contrast to fruit waste.

In those limited cases digestate could fulfil the substance concept of REACH (probably UVCB substance). In that case, in principle all obligations under REACH would be applicable, unless REACH itself contains an exception. Thus, as a mean of alternative assessment, for those cases it is checked below whether REACH itself may contain exceptions from certain obligations, namely exceptions from the obligation to register.

3.2. Alternative assessment: If certain types of digestate are subject to REACH, are these types exempted of obligations under REACH?

3.2.1. Exemptions from the obligation to register, Article 2(7) (b) / Annex V REACH

Article 2(7) REACH contains the following exemption:

“The following shall be exempted from Titles II, V and VI:
(b) substances covered by Annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation“

In particular the obligation for registration, which is laid down in Title II of REACH Regulation, is addressed with this exemption.

3.2.1.1. Article 2(7) (b) / Annex V, entry 8 REACH (naturally occurring substances)

The wording of entry No 8 of Annex V reads as follows:

“Substances which occur in nature other than [...Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal], if they are not chemically modified, unless they meet the criteria for classification as dangerous according to or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).”

The entry has three preconditions:

- A substance occurs in nature;
- which was not changed chemically;
- which fulfils certain classification criteria (e.g. not dangerous).

Case-by-case, this entry may apply to digestate and lead to the exemption from the obligation to register. In our opinion, the entry has no particular importance with a view on the general exemption for living or unprocessed dead organisms from the concept of substance, as discussed in section 3.1.2.

3.2.1.2. *Article 2(7) (b) / Annex V, entry 12 REACH (compost and biogas)*

The wording of the entry reads as follows:

“Compost and Biogas“

This entry, particularly with a view on the wording where the two terms “compost and biogas” are used in combination, should in our view also apply to digestate from biogas facilities.

At first, digestate in the perception and the use of the general public is often considered as "compost" – being part of the joint higher category “result of a biological-organic decomposition process”. This understanding should be made as a basis for the understanding of entry 12, and not the technical expert understanding which distinguishes between compost and digestate, as confirmed by the following considerations:

Firstly, the combination of "compost" with "biogas" in the same entry suggests that the legislator had the intention to cover all products arising from the processes, including by-products.

Secondly, to take the technical understanding of the text as a basis instead of the common usage of language would essentially lead to an unequal treatment of digestate with other fertilizers which could not be justified and would not comply with the basic principle of equal treatment recognized by the EU. In particular, an interpretation where compost would be exempted from the obligation to registration under REACH whereas digestate – with nearly identical properties – would not be exempted, would raise serious questions of equal treatment. An objective justification of such an unequal treatment seems hardly possible to justify against the aim of the exemption as laid down in Article 2(7) REACH:

“registration is deemed inappropriate or unnecessary for these substances and their exemption from these Titles does not prejudice the objectives of this Regulation”.

There is further to be asked to what extent the general aims of REACH

“[...] to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation”

would justify charging the marketing of digestate with the bureaucratic burden of registration under general chemicals law. Note that requirements for feedstock as well as for properties and conditions of the use, which the JRC has developed in the course of the development of the end-of-waste-criteria for biodegradable waste subject to biological treatment, are identical for digestate and compost.

3.2.2. Intermediate result

For the remaining cases of digestate, not excluded from REACH in general since they are not considered as a “substance” under REACH, no obligation to registration under REACH exists if in case one or several of the exceptions are fulfilled as discussed in this chapter.

The exception of Article 2(7) (b), Annex V No 8 REACH is applicable for digestate on a case-by-case basis.

The exception of Article 2(7) (b), Annex V No. 12 REACH excludes in general all digestate from the obligation to register.

4. Conclusions

- Digestate is not subject to REACH. It is no "substance" and no "mixture" in the sense of REACH, because
 - it is either "whole living or unprocessed dead organism", having undergone digestion or decomposition, or because
 - it is considered as waste.
- It is obvious that this result, with a view on the variety of possible feedstock for the biogas process, may need a detailed justification in particular cases.
- Additionally, regarding the specific case of treatment of biowaste, after adoption of the planned EU Regulation on end-of-waste criteria for biodegradable waste subject to biological treatment which is currently discussed, the situation may further change and create uncertainties. On this occasion, in our opinion Article 2(7) (b) / Annex V, entry 12 REACH applies, exempting digestate from the obligation to register under REACH.
- Against this background, we would be grateful to receive a statement from the Commission Services, expressing with their authority that the assessment made in this position paper corresponds to the view of the Commission.
- We are further making the suggestion that the Commission considers launching a revision process regarding Annex V, entry 12 of REACH, modifying the wording of this entry and ambiguously clarifying remaining uncertainties regarding the status of digestate. A change of this entry could occur, according to Article 131 REACH, in the Committee procedure addressed in Article 133 (4) REACH.

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¹ Regulation (EC) No 2003/2003 of the European Parliament and of the Council of 13 October 2003 relating to fertilisers (OJ L 304, 21.11.2003, p. 1), as amended.

² Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1), as amended.

³ JRC/IPTS, Study report on End-of-waste criteria for Biodegradable waste subjected to biological treatment (Draft Final Report, July 2013), available at <http://susproc.jrc.ec.europa.eu/activities/waste/>.

⁴ ECHA, Guidance for Annex V - Exemptions from the obligation to register. (Version 1.1, November 2012). Available at echa.europa.eu/documents/10162/13632/annex_v_en.pdf

⁵ BAuA, Recycling unter REACH: Fragen und Antworten (2008) (in German), available at http://www.reach-clp-biozid-helpdesk.de/de/Veranstaltungen/pdf/2008/081104/081104-04Knietsch.pdf?__blob=publicationFile&v=2

⁶ 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, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1), as amended.

⁷ Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3), as amended.