

ANNEXE 2 : BENCHMARK DE L'APPLICATION DE LA REGLEMENTATION SUR LES SOUS-PRODUITS ANIMAUX DANS 5 PAYS DE L'UNION EUROPEENNE

I. GUIDE D'ENQUÊTE

Context of this study :

Like every European country, France must apply EU Animal By-product Regulation. A sanitary approval is required for biogas plants at farm or industry level when they use biowaste before running.

After several years of negotiation, the EU ABP Regulation has been transposed in the French law. The National Decree (April 2018) describes precisely in what case derogation from pasteurisation (70°/1hr) can be obtained. Theoretically, slurry and manure are part of the positive list of animal by-products that can be digested without pre-treatment. Despite this text, French administration has recently (summer 2018) started to require pasteurisation for all substrates upstream from the digester when it comes to centralized biogas plants (above 30 000t/y or >10 farms). French authorities consider that the risk of dissemination is too high for centralized plants.

Standard Method for pasteurization (1hr/70°c/<12mm) is a cost expansive and energy consuming process and this situation could put the break on the biogas development in France.

In order to enlighten Administrations about alternative sanitation procedures, and initiate additional studies, French gas operators asked AILE to benchmark European countries with centralized biogas Plants. (UK, Germany, Netherlands, Denmark, Belgium-Flanders)

1. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

- a) *What are the main obligations for sanitary approval? Which are the steps to be carried out?*
- b) *How is the digestate sanitary quality controlled? (for landspreading, without exportation)*
 - *Who makes the control? (Administration? Certifying body?)*
 - *How often ?*
 - *What kind of analyses? Which indicator organisms have to be analysed? Limit max?*
 - i. *E.Coli ?*
 - ii. *Salmonella ?*
 - iii. *Other ?*

1. Alternative time-temperature regimes for sanitation

- a) *What kind of ABP must be pasteurized? How?*
- b) *In what situation should manure be pasteurized? How ? (upstream? downstream ?)*
- c) *In your country, has alternative method been validated?*
 - *Minimum guaranteed retention time (MGRT) :*
 - *Temperature :*
 - *Is it before or after digestion?*
 - *Other constraints?*

2. Additionnel ressources

- a) *Publication, website.. (english) to be read ?*
- b) *Other contact or expert to be reached for further details?*

II. ALLEMAGNE

First Name, last Name :

Organisation :

2. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

c) How must the biogas plants be approved by sanitary authorities?

The Regulation 1069/2009 has been transposed in the German Law. Application Law : Tierische Nebenprodukt-Beseitigungsgesetz (TierNebG) and a Decree : Tiersiche Nebenprodukte-Beseitigungsverordnung (TierNebV).

=> All biogas plants using manure or other ABP cat 3 or 2 must be approved by sanitary authorities = Federal Ministry for Food and Agriculture.

The procedure for sanitary approval is simple : Joint request for permit construction and environmental permits to the LALLF (Landesamt für Landwirtschaft, Lebensmittelsicherheit und Fischerei) , with regards from the Veterinary administration

The veterinary administration must check =

- Type and origin of substrates*
- Process*
- Become of outgoing products*
- Hygiene procedures*

To be noticed: In Germany, the digestate is not considered as a waste but as a product. There is a quality assurance system for digestate RAL (dry and liquid) => Digestate can be certified, but it is not mandatory :

RAL GZ 245 for bio-wastes + 2) RAL GZ 246 for renewable energy crops

d) How is the digestate sanitary quality controlled? (for landspreading, without exportation)

Question : is this only for biogas plants with pasteurisation or for all biogas plants with C2/C3, including manure?

- Who makes the control? (Administration? Certifying body?) Biogas Plants choose their own laboratory, no accreditation is needed, but laboratory must be regulatory checked by administration*
- How often ?*
- What kind of analyses? Which indicator organisms have to be analysed? Limit max?*
 - i. E.Coli/Enterococcaceae + Salmonella ? YES*

E. coli oder Enterococcaceae: n = 5; m = 1000, M = 5000 in 1 g

Salmonellen in 25 g nicht nachweisbar

ii. Other ?

3. Alternative time-temperature regimes for sanitation

d) What kind of ABP must be pasteurized? How? (upstream? downstream ?)

Biogas plants with hygiénisation units = ca. 200 plants = units with Cat3 material = pasteurisation (only for C3 substrates) at 70°C/1 hour/12mm. Before or after digestion possible.

Exceptions for : Manure, rumen content, milk C3 and derivatives, colostrum C3 and derivatives

Questions : is there still exceptions for catering and household waste ?

e) In what situation should manure also be pasteurized?

Manure digestion in Germany in more 7500 plants without pasteurization.

f) *In your country, has alternative method been validated? A priori not*

- *Minimum guaranteed retention time (MGRT) :*
- *Temperature :*
- *Is it before or after digestion?*
- *Other constraints?*

4. Additionnel ressources

c) *Publication, website.. (english) to be read ?*

d) *Other contact or expert to be reached for further details?*

III. PAYS-BAS

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3. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

e) What are the main obligations for sanitary approval? Which are the steps to be carried out?

The EU ABP is generally in place.

Off course you know the EU EC Implementing Regulation for animal by-products <http://eur-lex.europa.eu/eli/reg/2011/142/> It states that output is hygienization:

1. *60 min at 70°C or*
2. *has undergone another controlled thermal or chemical treatment which has been shown in a special investigation ('validation') to kill pathogens to an adequate degree*

On some point member state are allowed to deviate from the EU ABP, which is regulated for NL in the Dutch regulation for ABP <http://wetten.overheid.nl/BWBR0032462/2017-01-01>

Then we have the Dutch Technical Agreement describing how to validate the processes if you deviate from #1: NTA 8777 Validation of processes in facilities transforming manure and/or other animal by-products into biogas or compost -Method including material spiked with Enterococcus faecalis <https://www.nen.nl/NEN-Shop/Norm/NTA-87772011-en.htm>

f) How is the digestate sanitary quality controlled? (for landspreading, without exportation)

- *Who makes the control? (Administration? Certifying body?) The NVWA (Netherlands Food and Consumer Product Safety Authority, part of the Ministry of Agriculture, Nature and Food Quality).*

EVERY digester should be registered with the NVWA to get the recognition, "conversion to biogas", but if the input is only manure, and or all listed on the white list, sanitation is not required. The digestate output gets the label "not validated".

- *How often ? Once at the start of operation*
- *What kind of analyses? Which indicator organisms have to be analysed? Limit max? A minimal 5log10 reduction for Salmonella (775 H2S negative) or Enterococcus faecalis. In case thermo resistant viruses are identified as relevant hazard. Also a reduction of 3log10 of heat resistant viruses such as Parvovirus shall be demonstrated.*
 - i. *E.Coli ?*
 - ii. *Salmonella ?*
 - iii. *Other ?*

5. Alternative time-temperature regimes for sanitation

g) What kind of ABP must be pasteurized? How?

h) In what situation should manure be pasteurized? How ? (upstream? downstream ?)

Because of the excess of nutrients in NL, most larger digesters are built specifically to treat and export the digestate. In most plants, the digestate is sanitized 1hr @ 70°C, and either separated and granulated, or further processed into fertilizers. There are installations that are validated, meaning the digestion process itself is proved to kill pathogens to an adequate degree. Most of these digesters are operated thermophilic, at 55°C.

i) In your country, has alternative method been validated?

- *Minimum guaranteed retention time (MGRT) :*
- *Temperature :*
- *Is it before or after digestion?*
- *Other constraints?*

It is possible to get the process validated. A certified company makes a complete analyses of the process and checks the break down of micro-organisms like E.Coli an Salmonella . It the reduction meets the standards, the process is validated. Extra measures like sanitation are not necessary. The validation process is repeated every year.

6. Additionnel ressources

e) Publication, website.. (english) to be read ?

f) Other contact or expert to be reached for further details?

Elsinga Beleidsplanning en Innovatie [www.beleidsplanning.nl]

IV. DANEMARK

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4. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

g) *What are the main obligations for sanitary approval? Which are the steps to be carried out?*
Biogas plants in Denmark must be approved by the Food and Veterinary Administration in accordance with Article 24 (2) of the Regulation on animal by-products. 1, g). Biogas plants must comply with the general provisions of the Regulation and the Implementing Regulation in Denmark – all regulations are in line EU regulation.

h) *How is the digestate sanitary quality controlled? (for landspreading in the National Country, without exportation)*

Sampling : producer himself

To be analysed : Salmonella and Enterococcaceae / E. coli

Test methods

For Salmonella: EN ISO

For Enterobacteriaceae: EN ISO

For E. coli: EN ISO

any of the sub-samples contains more than 5,000 E.coli colonies per gram

2 or more sub-samples contain more than 1,000 E.coli colonies per gram

7. Sanitation Requirement

j) *Without treatment*

ABP that don't need to be pasteurized :

- manure

- Digestive tract content that is separated from the digestive tract.

- Milk, milk-based products, colostrum and colostrum-based products.

As a rule, all Category 2 material and Category 3 material can be used as OGJ, provided it meets the respective processing requirements.

Category 1 material can not be used as OGJ, with the exception of category 1 glycerin. Here are a number of very specific terms and conditions

If there is a risk of spreading a serious reportable contagious disease, there will be special restrictions or prohibitions on handling or using OGJ.

k) *What kind of ABP must be pasteurized? How?*

Category 3 ABPs that are not catering waste

Category 2 ABPs that has first been pressure rendered at an approved site

EU constraints :

- treat ABPs at 70°C for 1 hour with a maximum particle size of 12mm*
- sterilise Category 2 ABPs at 133°C with 3 bar pressure, for 20 minutes at an approved plant, prior to treatment*
- compost in a closed vessel system approved (as part of your site approval) by APHA*
- include a pasteurisation stage in anaerobic digestion of Category 3 ABPs*

l) *In what situation should manure be pasteurized? How ? (upstream? downstream ?)
When other Category 3 ABP are treated (see list of exception in c)*

m) *In your country, has alternative method been validated?*

Yes, the biogas plant must meet UK Standards if all you treat is category 3 catering waste and the following category 2 ABPs:

- *manure*
- *digestive tract and its content*
- *dairy products or colostrum*
- *eggs or egg products*

V. FLANDRES (Belgique)

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+ Christophe Boegearts, VLACO

5. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

i) What are the main obligations for sanitary approval? Which are the steps to be carried out?

The installation needs an environmental permit (permit for the activity and the involved buildings)

Registration as 1069 installation at OVAM (waste) or VLM Mestbank ('manure bank', in case the mainly manure is treated. In that case OVAM gives advice on the waste part) – the registration is based on a form, in which the operator answers the following questions:

- *Description of activity*
- *Legal information about the company*
- *Permit*
- *Map of installations*
- *Description of control scheme*
- *Emergency plans*
- *Procedure for calibration of the measurement units*
- *Hygiene description (how are the procedures for recipients and trucks)*
- *How are the input/output streams monitored and traced*
- *If applicable, convictions in past years*

*If Digestate is exported, full 1069 recognition is needed: Pasteurization of the input streams and/or digestate: 70 °C for 1 hour, or **validated** alternative, in case of manure. Other
If only manure is digested and the digestate is used in Flanders (no export), a light recognition is needed – no pasteurization is needed in that case, but the larger digestion plants always co-digest manure with other streams.*

How is the digestate sanitary quality controlled? (for landspreading, without exportation)

If the digestate is used as fertilizer or soil conditioner in Flanders (no export), the digestate must follow VLAREMA conditions and is certified by VLACO if organic biological waste streams are used as input: <https://www.vlaco.be/en>. If the digestate is put in trade, it also needs a exemption from the Royal resolution 28/01/2013 by the FOD Volksgezondheid, Bescherming van de voedselketen en Leefmilieu (<https://www.health.belgium.be/en?ie2Term=ontheffing&ie2section=83>) and FAVV.

- *Who makes the control? (Administration? Certifying body?)*

Use as fertilizer/soil conditioner, VLACO: <https://www.vlaco.be/en>, by means of samples and company audits. VLACO has a ECN-QAS-label.

Trade: FOD, <https://www.health.belgium.be/en?ie2Term=ontheffing&ie2section=83> imposes product standards (communicated as a exemption from the royal resolution 18/01/2013) and FAVV (Federal Agency for safety of the food chain): recognition of companies who produce fertilizers or soil conditioner, controls the compliance to these standards.

- *How often ? 'Keuringsattest' = certification as fertilizer/soil conditioner : Yearly*

Exemption is 5 years valid

Yearly control of installation of FAVV controller

- *What kind of analyses? Which indicator organisms have to be analysed? Limit max?*

Application for 'keuringsattest' – certification by VLACO :

Maximum limits according to VLAREMA Annex 2.3.1.A: <https://navigator.emis.vito.be/mijn-navigator?wold=44701>

Maximum use limits according to VLAREMA Annex 2.3.1.B

Yearly control of heavy metals, dry matter, pH, organic matter, nitrogen and P2O5, monocyclic aromatic hydrocarbons

Application of exemption : composition and origin of product, description of production process, agricultural value, analyse report of relevant parameters, applicability and dosage, copy of the certification by VLACO, model of the product label on the packaging

8. Alternative time-temperature regimes for sanitation

*In function of the application and the origin of input material, specific hygienisation rules can be applicable. Next to the obligated hygienisation of animal by-products as manure, also other types of hygienisation can be obligated, F.E. **digestate** from nature- and roadside mowings and/or vegetable, fruit and garden waste, need to be composted to reach hygienisation requirements.*

- a) *What kind of ABP must be pasteurized? How?*

Manure: 70 °C for 1 hour; others need in theory to be sterilized unless VLM/OVAM validates alternatives as equally safe (THOMAS)

Christophe Boegarts, VLACO :

Regarding digestate: all ABP that are subject to the ABP Regulation and are allowed for use in composting and AD plants are to be pasteurised as well. Not only cat 2 manure and digestive tract content, but also cat 3 material is allowed in treatment. All these ABP should comply with the requirements of the ABP regulation. In rule, the material is treated following the standard parameters (1h 70°C, max particle size 12mm). Pasteurisation may be before or after digestion.

As foreseen in Annex V of 142/2011, the competent authority may authorise the use of parameters other than the standard transformation parameters, provided that the applicant for such use demonstrates that such parameters ensure adequate reduction of biological risks. That demonstration includes a validation, carried out in accordance with the prescribed requirements.

- b) *In what situation should manure be pasteurized? How ? (upstream? downstream ?)*

See above, manure should be pasteurized if the digestate is exported.

For use within Flanders digestate from only manure (in case of no veterinary restraints) (and some cat 3 materials (milk, eggs, ...)) is not required to be pasteurised. It is then considered as untreated in the sense of ABP regulation.

- c) *In your country, has alternative method been validated?*

1h 70°C is followed by most co-digesting plants (manure and organic waste) in Flanders, and all but one perform pasteurisation after the digestion process.

In Flanders there has been validation of

- sites composting biowaste (in particular VFG-waste incl kitchen-waste (whether or not pre-digested))
- some thermophile digestion-biogas plants(*): site-specific hygienisation process validated (CCP (critical control points)) e.g. duration, temperature parameters, etc to be respected

To our knowledge there has been no validation regarding manure composting.

- Minimum guaranteed retention time (MGRT) :
- Biogas plant-specific (*)
- Temperature :
- Biogas plant-specific (*)
- Is it before or after digestion?
- After
- Other constraints?

FYI:

The Fertiliser regulation (upcoming and possibly entering into force as of 2021) stipulates hygienisation requirements for digestate/composts

- Thermophilic fermentation at 55°C, min 24h, HRT min 20d

- Thermophilic fermentation at 55°C + pasteurisation

- Thermophilic fermentation at 55°C + post composting (65°C for at least 5 days, or - 60°C for at least 7 days, or - 55°C for at least 14 days)

- Mesophilic fermentation at 37-40°C + pasteurisation

- Mesophilic fermentation at 37-40°C + post composting (65°C for at least 5 days, or - 60°C for at least 7 days, or - 55°C for at least 14 days)

- n) What kind of ABP must be pasteurized? How?
Manure: 70 °C, 1 hour ,others need to be sterilized unless VLM/OVAM validates alternatives as equally safe.
- o) In what situation should manure be pasteurized? How ? (upstream? downstream ?)
See above, if the digestate is exported. If only manure is digested and the digestate is used in Flanders, no hygienisation is needed.
- p) In your country, has alternative method been validated?
- Minimum guaranteed retention time (MGRT) :
 - Temperature :
 - Is it before or after digestion?
 - Other constraints?

9. Additionnel ressources

g) Publication, website.. (english) to be read ?

h) Other contact or expert to be reached for further details?

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Christophe Bogaerts, VLACO: [Christophe Boogaerts <Christophe.Boogaerts@vlaco.be>](mailto:Christophe.Boogaerts@vlaco.be)

VI. ROYAUME-UNI

Sources :

<https://www.gov.uk/guidance/using-animal-by-products-at-compost-and-biogas-sites>

+ contacts with : **Ollie More** | Head of Policy | The Anaerobic Digestion and Bioresources Association (ADBA)

And Rachel Smith <RachelS@severnwye.org.uk>

6. Generalities about ABP Regulation application for biogas plants (CE)1069/2009 and (EU)142/2011

- j) *What are the main obligations for sanitary approval? Which are the steps to be carried out?*
An approval from the the Animal and Plant Health Agency (APHA) is required.
- k) *How is the digestate sanitary quality controlled? (for landspreading, without exportation)*
Your samples must pass 12 consecutive tests for each bacteria before your site is validated.
You must have 4 clear test results from your first 4 batches before you can start to sell your product

	Salmonella	Enterobacteriaceae	Clostridium perfringens	Escherichia coli (E.coli) or Enterococcaceae
Biogas, compost or manure processing facility	Yes			Yes
Facilities applying for approval for a new (method 7) processing method	Yes	Yes	Yes	
Any other ABP processing facility (rendering plants, pet food and fertiliser factories, blood processors, biodiesel plants, milk processors)	Yes	Yes		

Sampling : producer himself – a backup must be stored

Samples must be sent to a laboratory accredited by the United Kingdom Accreditation Service (UKAS).

Test methods

For Salmonella: BS EN ISO 6579:2017

Your sample will fail if any sub-sample contains any Salmonella colonies

For Enterobacteriaceae: BS EN ISO 21528-2:2017

For Clostridium perfringens: BS EN ISO 7937:2004

For E. coli: BS EN ISO 16649-1 or 16649-2:2001

any of the sub-samples contains more than 5,000 E.coli colonies per gram

2 or more sub-samples contain more than 1,000 E.coli colonies per gram

10. Alternative time-temperature regimes for sanitation

- q) *What kind of ABP must be pasteurized? How?*

Category 3 ABPs that are not catering waste

Category 2 ABPs that has first been pressure rendered at an approved site

EU constraints :

- treat ABPs at 70°C for 1 hour with a maximum particle size of 12mm*
- sterilise Category 2 ABPs at 133°C with 3 bar pressure, for 20 minutes at an approved plant, prior to treatment*
- compost in a closed vessel system approved (as part of your site approval) by APHA*
- include a pasteurisation stage in anaerobic digestion of Category 3 ABPs*

r) In what situation should manure be pasteurized? How ? (upstream? downstream ?)
When other Category 3 ABP are treated (see list of exception in c)

s) In your country, has alternative method been validated?

Yes, UK Standards if all you treat is category 3 catering waste and the following category 2 ABPs:

- manure
- digestive tract and its content
- dairy products or colostrum
- eggs or egg products

UK Standards :

System	Minimum temp	Minimum time at minimum temp	Maximum particle size
Composting (closed reactor)	60°C	2 days	400mm
Biogas	57°C	5 hours	50mm
Composting (closed reactor) or biogas	70°C	1 hour	60mm
Composting (housed windrow)	60°C	8 days (during which windrow must be turned at least 3 times, at no less than 2 day intervals)	400mm

In England or Wales, external heat can be used for heating

11. Additionnel ressources

i) Publication, website.. (english) to be read ?

All the information are :

<https://www.gov.uk/guidance/using-animal-by-products-at-compost-and-biogas-sites>

j) Other contact or expert to be reached for further details?

Our contacts at ADBA are:

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