

SCIENTIFIC OPINION

Statement on technical assistance related to the EFSA opinion on transformation of Animal By-Products into biogas and compost¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2,3}

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ABSTRACT

EFSA's Scientific Panel on Biological Hazards (BIOHAZ) was asked by the European Commission to clarify i) whether additional testing for *Clostridium perfringens* of the end product obtained from biogas and compost transformation of Animal By-Products (ABPs) would respond to the concerns expressed in the EFSA 2005 opinion on "the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products" and, should this was not be the case, ii) to indicate if additional testing, according to the model of method 7 of the ABP Regulation, for another pathogen than *Clostridium perfringens* would respond to the recommendations laid down in the above-mentioned opinion. Considering that digestion residues and compost are intended to be applied on land, that land naturally contains bacterial spores and that *Clostridium perfringens* is ubiquitous, the BIOHAZ Panel concluded that the absence of *Clostridium perfringens* is not necessary. The BIOHAZ Panel also concluded that end product testing does not respond to the recommendations given in the previous EFSA opinion, which concerns the validation of the efficacy of a process.

KEY WORDS

Animal By-Products, Biogas, Compost, *Clostridium perfringens*, Technical assistance

1 On request from the European Commission, Question No EFSA-Q-2009-00654, adopted on 21 October 2009.

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3 Acknowledgement: the Panel wishes to thank the members of the Working Group on Technical Assistance EFSA Opinion transformation ABP biogas and compost for the preparation of this statement: Dorte Lau Baggesen, Reinhard Böhm, John Griffin, Christophe Nguyen-The and Maurice Pensaert.

Suggested citation: EFSA Panel on Biological Hazards (BIOHAZ); Statement on technical assistance related to the EFSA opinion on transformation of Animal By-Products into biogas and compost. EFSA Journal 2009; 7(11):1370. [8 pp.]. doi:10.2903/j.efsa.2009.1370. Available online: www.efsa.europa.eu

SUMMARY

Following a request from the European Commission (EC), the Panel on Biological Hazards (BIOHAZ) was asked to deliver a statement on technical assistance related to the EFSA opinion on transformation of Animal By-Products into biogas and compost.

On 7 September 2005 the BIOHAZ Panel adopted an opinion on the safety vis-à-vis biological risks of biogas and compost treatment standards of ABPs⁴. The main objective of the opinion was to advise on possible equivalent standards to the one laid down in the European legislation at the time, for processing ABPs in biogas and composting plants.

Among the recommendations in the opinion, the Panel recommended revising the standards for biogas and compost processes and introducing monitoring of the hygienic situation of the plant where the transformation into biogas or compost takes place, as well as of the processes themselves. Following this opinion the EC modified the parameters for the testing of the end products of both transformation processes by way of Commission Regulation (EC) No 208/2006⁵.

Recently, the European Parliament and the Council of the European Union gave their agreement to an EC proposal for a revised ABP Regulation. The European Fat Processors and Renderers Association (EFPRA) submitted a position paper to the EC criticising the alleged remaining absence of equivalency between the standards applicable to the processing of Category (Cat.) 3 ABPs in processing plants and the transformation of such by-products into biogas or compost. As a possible measure to introduce equivalent standards, EFPRA proposed a supplementary test during thirty days on the final product (digestion residues or compost) which may be applied to land to demonstrate the absence of *Clostridium perfringens*, following the model for the approval of processing method 7 in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002 (the ABP Regulation)⁶.

The BIOHAZ Panel was asked to clarify i) whether supplementary testing for *Clostridium perfringens* would respond to the concerns expressed in the EFSA 2005 opinion and, should this not be the case, ii) to indicate if additional testing, according to the model of method 7 of the ABP Regulation, for another pathogen than *Clostridium perfringens* would respond to the recommendations of the above-mentioned opinion.

The Panel highlighted that, as a risk assessment body, EFSA does not set the safety level required by the European legislation, that its role is strictly restricted to providing scientific advice for the consideration of the European risk manager, and that the present statement is strictly limited to replying to the Terms of Reference as received from the EC. Moreover, it was highlighted that, as stated in the EFSA 2005 opinion, any process for hazard reduction should be validated with representative agents in relation to the reduction target defined.

The BIOHAZ Panel concluded that, considering the final use of digestion residues or compost, the absence of *Clostridium perfringens* is not necessary. Moreover, it was stated that end product testing does not respond to the recommendations given in the previous EFSA opinion, which concern the validation of the efficacy of a process.

4 EFSA (European Food Safety Authority), 2005. Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products (ABP). The EFSA Journal. 264, 1-21.

5 EC (European Commission), 2006. Commission Regulation (EC) No 208/2006 of 7 February 2006 amending Annexes VI and VIII to Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards processing standards for biogas and composting plants and requirements for manure. Official Journal of the European Union, 25-31.

6 EC (European Community), 2002. Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. Official Journal of the European Union, 1-95

In general, the Panel recommended that requirements for the reduction of the representative pathogens or indicators should be defined according to the final use of the different ABP categories to be processed, with the different ABP categories representing different risks of microbiological contamination of the input material. Furthermore, it was recommended that the use of the term “validation” should be defined more precisely (as in the EFSA 2005 opinion) in the ABP Regulation and that “end product testing” should not be used as a synonym for the term “validation”.

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is asked for technical assistance in relation to the opinion of the Scientific Panel on Biological Hazards on "the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products" (Question No. EFSA-Q-2003-097), which was adopted on 7 September 2005.

The opinion recommended revising the current standards for the testing of the final products and introducing monitoring of the hygienic situation of the plant where the transformation into biogas or compost takes place, as well as of the processes themselves.

In response, the Commission has modified the parameters for the testing of the end products of both transformation processes by way of Commission Regulation (EC) No 208/2006 (OJ L 36, 8.2.2006, p.25), in accordance with the advice provided by EFSA.

In addition, the European Parliament and the Council have recently given their agreement to the Commission proposal for a revised Animal By-products Regulation (COM(2008) 345 final of 20 June 2008). According to the revised Regulation, operators who are transforming animal by-products into biogas or compost will need to introduce a permanent procedure of own checks based on the HACCP principles in their establishments.

The European Fat Processors and Renderers Association (EFPRA) has submitted a position paper in which it criticises the alleged remaining absence of equivalency between the standards applicable to the processing of animal by-products in processing plants and the transformation of such by-products into biogas or compost.

As a possible measure to introduce equivalent standards, EFPRA proposes a supplementary test during thirty days of the final product which may be applied to land (digestion residues from biogas or compost) to demonstrate the absence of *Clostridium perfringens*, following the model for the approval of processing method 7 in accordance with Chapter III of Annex V to Regulation (EC) No 1774/2002.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

To clarify whether supplementary testing for *Clostridium perfringens* would respond to the concerns expressed in the EFSA 2005 opinion on "the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products".

Should the pathogen proposed not be suitable, to indicate if additional testing, according to the model of method 7 of the ABP Regulation, for another pathogen than *Clostridium perfringens* would respond to the recommendations of the above-mentioned opinion.

EVALUATION

1. Introduction

On 7 September 2005 the EFSA Scientific Panel on Biological Hazards (BIOHAZ) adopted an opinion on the "Safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products (ABP)" (EFSA, 2005).

The main objective of this opinion was to advise on possible equivalent standards to the one laid down in the European legislation at the time, for processing Animal By-Products (ABPs) in biogas and composting plants.

In this opinion the BIOHAZ Panel concluded that the level of pathogens elimination reached by applying the standard process described for the Category (Cat.) 2 ABPs (i.e. 133°C / 20 minutes / 3 bars):

"...is not fully achieved by the current treatment conditions applied for ABP's of category 3 (70°C/60 min). Therefore, if ABP of category 3 were pressure-cooked before use in any biogas or compost process, potential hazards could be eliminated."

and that, for other processes:

"Any process for hazard reduction should be validated with representative agents in relation to the reduction target defined..."

Furthermore, in section 5.1 of the opinion the BIOHAZ Panel stated that:

"Using end-product monitoring alone to validate a process is likely to provide a false sense of security that the process is capable of controlling the relevant hazards in the final product."

On 7 February 2006 the European Commission (EC) adopted the Regulation (EC) N° 208/2006 (EC, 2006) amending Annexes VI and VIII to Regulation (EC) No 1774/2002 – the ABP Regulation - (EC, 2002) of the European Parliament and of the Council as regards processing standards for biogas and composting plants and requirements for manure. This Regulation did not change the standard treatment conditions for biogas and compost processing of Cat. 3 ABPs, but opened the possibility for process parameters other than those already described in Regulation (EC) No 1774/2002 (EC, 2002), provided that the reduction of biological risk is demonstrated by a validation.

In its position paper submitted to the EC, EFPPA criticises the presumed absence of equivalency between the standards applicable to the processing of Cat. 3 ABPs in processing plants and the transformation of such material into biogas and compost.

As a risk assessment body EFSA does not set the safety level required by the European legislation but its role is strictly restricted to providing scientific advice for consideration of the European risk manager.

The present statement is strictly limited to replying to the Terms of Reference (ToR) as received from the EC.

2. Discussion on the EFPR proposal

2.1. The EFPR position

According to the information received, the EFPR position is:

- Methods for rendering (such as methods 2 to 5 and 7 in the ABP Regulation as amended) have a high level of safety because they provide inactivation of bacterial spores.
- The methods used in biogas and composting plants are not equivalent to the ones used by the rendering industry for Cat. 3 ABPs to be used as soil improver or organic fertilisers.

2.2. The EFPR proposal

EFPR proposed:

- To demonstrate the absence of *Clostridium perfringens* in digestion residues from Cat. 3 ABPs processed in biogas and composting plants following the model for the approval of processing method 7 in accordance with Chapter III of Annex V to the ABP Regulation (EC, 2002) as amended.

2.3. Discussion

Biogas and compost are produced through a microbiological process, which cannot achieve the sterility of the product; hence the latter cannot inactivate bacterial spores.

Digestion residues and compost are intended to be used as organic fertilisers or soil improvers.

The land naturally contains bacterial spores and, since *Clostridium perfringens* is relatively ubiquitous, among these there is also the presence of *Clostridium perfringens* spores.

Hence, the absence of *Clostridium perfringens* in digestion residues or compost to be applied to land as organic fertilizers or soil improvers is irrelevant.

In contrast, in the current ABP Regulation (EC, 2002) as amended, the output of rendering plants processing Cat. 3 ABPs is not specifically limited to use on land application. Therefore the end product requirements are different.

Except for alternative methods for biogas and composting plants, the ABP Regulation (EC, 2002), as amended, does not explicitly specify the reduction targets for relevant hazards according to the final use of the ABP material to be processed.

The BIOHAZ Panel does not consider method 7 of the current ABP Regulation (EC, 2002), as amended, as a proper validation of the capacity of a process to reduce the level of a hazard since it measures only the hazards in the end product without considering their level in the input material,

which may differ for different categories of ABPs (and other added material(s) where relevant). According to section 5.1 of the previous EFSA opinion (EFSA, 2005):

“Using end-product monitoring alone to validate a process is likely to provide a false sense of security that the process is capable of controlling the relevant hazards in the final product.”

3. Answer to the Terms of Reference

3.1. To clarify whether supplementary testing for *Clostridium perfringens* would respond to the concerns expressed in the EFSA 2005 opinion on "the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products".

In the previous EFSA opinion (EFSA, 2005) it was concluded that:

1. *By applying the standard process described for the category 2 ABP's (133°C/20 min/3 bar) relevant micro-organisms, viruses and most of the toxins can be eliminated. This level of elimination is not fully achieved by the current treatment conditions applied for ABP's of category 3 (70°C/60 min). Therefore, if ABP of category 3 were pressure-cooked before use in any biogas or compost process, potential hazards could be eliminated.*
2. *The criteria in the current legislation relating to composting of ABP do not adequately address the identified hazards and do not realistically reflect the conditions pertaining during processing (e.g. temperature, humidity distribution etc...).*

The BIOHAZ Panel concluded that testing the end product for the proposed microbiological indicator (*Clostridium perfringens*) would not respond to the concerns expressed in the previous EFSA opinion (EFSA, 2005) since, as indicated in section 5.1 of the opinion:

“Using end-product monitoring alone to validate a process is likely to provide a false sense of security that the process is capable of controlling the relevant hazards in the final product.”

Considering the final use of digestion residues and compost, the absence of *Clostridium perfringens* is not necessary.

3.2. To indicate if additional testing, according to the model of method 7 of the ABP Regulation, for another pathogen than *Clostridium perfringens* would respond to the recommendations of the EFSA 2005 opinion on "the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products".

Testing for another pathogen or indicator, according to the model of method 7, has no scientific basis because the material being tested, in this case digestion residues from biogas or compost, originates from ABP material with an undefined level of microbiological hazards.

End product testing does not respond to the recommendations given in the previous EFSA opinion (EFSA, 2005), which concern the validation of the efficacy of a process.

Therefore, in general, the BIOHAZ Panel recommends that requirements for the reduction of the representative pathogens or indicators should be defined according to the final use of the different ABP categories to be processed, similar to those set out in Point 13a, Chapter II of Annex VI to Regulation (EC) No 1774/2002 (EC, 2002) as amended, with the different ABP categories representing different risks of microbiological contamination of the input material.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- Considering the final use of digestion residues and compost, the absence of *Clostridium perfringens* is not necessary.
- End product testing does not respond to the recommendations given in the previous EFSA opinion, which concern the validation of the efficacy of a process.

RECOMMENDATIONS

In general, the BIOHAZ Panel recommends that:

- Requirements for the reduction of the representative pathogens or indicators should be defined according to the final use of the different ABP categories to be processed, similar to those set out in Point 13a, Chapter II of Annex VI to Regulation (EC) No 1774/2002 as amended, with the different ABP categories representing different risks of microbiological contamination of the input material;
- The use of the term “validation” should be defined more precisely (as in the EFSA 2005 opinion on the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products) in the ABP Regulation;
- “End product testing” should not be used as a synonym for the term “validation”.

DOCUMENTATION PROVIDED TO EFSA

1. Letter (ref. n. SANCO/D1/TG/cg (2009) D/41/0817 dated 29/05/2009) from the European Commission with a request for technical assistance related to the EFSA opinion on transformation of animal by-products into biogas and compost.

REFERENCES

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