SCIENTIFIC OPINION

Scientific Opinion on Lime Treatment of Solid Pig and Poultry Manure[1]

EFSA Panel on Biological Hazards (BIOHAZ)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

EFSA's Scientific Panel on Biological Hazards (BIOHAZ) was asked for a scientific opinion on a novel process submitted by a European association as a safe means of disposal of Animal By-Products (ABP) according to Regulation (EC) 1774/2002[4]. The application received describes a lime treatment process for dewatered pig and solid poultry manure which could be operated at two different temperatures (60°C and 70°C). The applicant carried out full scale trials for a batch process (i.e. stockpiles) utilizing quick lime (CaO) and demonstrated that the proposed process inactivated the relevant bacterial pathogens (*Salmonella*) and indicator (*Enterococcus faecalis*) by more than 5 $\log_{10}$ and the relevant virus and parasite eggs by more than 3 $\log_{10}$. The Panel concluded that the information provided by the applicant is sufficient to show that the mixing of dewatered pig and solid poultry manure with quicklime at the requested exposure time of 30 or 60 minutes, respectively for treatment at 70°C and 60°C at pH 12 meets the requirements for Agent Risk Reduction. However, it was highlighted that the assessment provided cannot be extended to different equipments, different types of manure and different incubation conditions than those used in the experimental validation. Moreover, the applicant did not give sufficient information to ascertain that in practice the target temperatures and pH are achieved in all part of the stockpile for the sufficient time period. The BIOHAZ Panel recommended that the proposed processes can be considered able to safely process dewatered pig and solid poultry manure only if certain given conditions are met.

KEY WORDS

Manure, Lime, Animal By-Products, Alternative Methods

1 On request from the European Commission, Question No EFSA-Q-2005-062 adopted on 08 July 2010.

2 Panel members: Olivier Andreoletti, Herbert Budka, Sava Buncic, John D Collins, John Griffin, Tine Hald, Arie Hendrik Havelaar, James Hope, Günter Klein, James McLauchlin, Winy Messens, Christine Müller-Graf, Christophe Nguyen-The, Birgit Noerrung, Luisa Peixe, Miguel Prieto Maradona, Antonia Ricci, John Sofos, John Threlfall, Ivar Vågsholm, Emmanuel Vanopdenbosch. Correspondence: biohaz@efsa.europa.eu

3 Acknowledgement: the Panel wishes to thank the members of the Working Group for the preparatory work for opinion: Christophe Nguyen-thé, Reinhard Böhm and Robert Somerville.

4 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. OJ L 273, 10.10.2002, p. 1-95.

Suggested citation: EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on Lime Treatment of Solid Pig and Poultry Manure. EFSA Journal 2010; 8(7):1681. [16 pp.]. doi:10.2903/j.efsa.2010.1681. Available online: www.efsa.europa.eu

SUMMARY

Following a request from the European Commission, the Panel on Biological Hazards was asked to deliver a scientific opinion on Lime Treatment of Solid Pig and Poultry Manure.

Regulation (EC) No 1774/2002 of the European Parliament and of the Council, laying down health rules concerning animal by-products not intended for human consumption[5], divides Animal By-Products (ABP) into three different Categories and requires them to be disposed of, recycled or used. The Regulation also provides for the possibility to approve other means of disposal and other ways to use ABP after consultation of the appropriate scientific committee (Articles 4(2)(e), 5(2)(g) and 6(2)(i)).

A European association submitted a novel process and asked the European Commission to approve it as a safe means of disposal under Article 5 (2) (g) of Regulation 1774/2002/EC, i.e. as far as Category 2 material are concerned.

The European Commission asked EFSA to i) assess the ability of the process submitted to safely dispose of Category 2 animal by-products and ii) in case the process is considered to present a risk, to advice on the risks of the use of that process and on possibilities for addressing them. After an information exchange with the applicant it was clarified that the terms of reference of the mandate were focused only on pig and poultry solid manure treatment and that the solid pig manure consisted of dewatered manure.

The application received describes a lime treatment process for dewatered pig and solid poultry manure which could be operated at two different temperatures (60°C and 70°C). The applicant carried out full scale trials in Belgium utilizing quick lime (CaO). The samples to demonstrate pathogen reduction were tested by the University of Leipzig. The applicant proposes to utilize the two possible treatments to process dewatered pig and solid poultry manure by a batch procedure for covered or uncovered stockpiles and for containers. However, only uncovered stockpiles were used in the experimental protocol to validate the pathogen reduction.

Since the experiments presented by the applicant concerned only dewatered pig and solid poultry manure, the BIOHAZ Panel assessed these treatments only for these kinds of manure and not for all types of Cat. 2 ABP.

The BIOHAZ Panel assessed the application received following the scheme proposed in the "Guidelines for applications for new alternative methods of disposal or use of animal by-products" prepared jointly by the Health and Consumer Protection Directorate-General (DG-SANCO) and EFSA[6].

The Panel concluded that the information provided by the applicant is sufficient to show that the mixing of dewatered pig and solid poultry manure with quicklime at the requested exposure time of 30 or 60 minutes, respectively for treatment at 70°C and 60°C at pH 12 meets the requirements for Agent Risk Reduction according to the EFSA 2005 opinion vis-à-vis biological risks of biogas and compost treatment standards of animal by-products[7]. However, the applicant did not give sufficient

5 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. OJ L 273, 10.10.2002, p. 1-95.

6 EC (European Commission), 2008. Guidelines for applications for new alternative methods of disposal or use of animal by-products. http://ec.europa.eu/food/food/biosafety/animalbyproducts/disposal0604_rev_en.pdf

7 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.

information to ascertain that in practice the target temperatures and pH are achieved in all part of the stockpile for the sufficient time period.

It was highlighted that this assessment cannot be extended to different equipments, different types of manure and different incubation conditions (i.e. continuous process) than those used in the experimental validation.

The BIOHAZ Panel recommended that the proposed processes can be considered able to safely process dewatered pig and solid poultry manure only if certain given conditions are met. In case another mixing device than the one used in the validation is proposed it is recommended to assess its equivalence by a simplified validation procedure based on temperature measurements at representative measuring points in the stockpile. An example of simplified validation procedure was provided in the Appendix of the opinion. In case other types of manure, methods other than stockpiles (i.e. continuous processes or containers) are proposed it was recommended to perform a full validation experiment.

TABLE OF CONTENTS

Abstract 1
Summary 2
Table of contents 4
Background as provided by the European Commission 5
Terms of reference as provided by the European Commission 6
Assessment 7
1. Introduction 7
1.1. Validation of the Process 7
1.1.1. Process description 7
1.1.2. Description of the equipment used in the validation experiment 8
1.1.3. Validation with two manure types (dewatered pig and solid poultry manure) 8
1.1.4. Quality control procedures 8
2. Risk categories 9
3. Identification and characterisation of risk materials 9
4. Agent Risk Reduction 9
5. Risk Containment 10
5.1. The effect of lime treatment depends on the physicochemical properties of the treated material which is different in sewage sludge and animal by-products. 11
6. Identification of interdependent processes 11
7. Intended end use of the products 11
8. Documentary evidence 12
9. Required conditions for practical implementation of the proposed processes 12
Conclusions and recommendations 13
Documentation provided to EFSA 14
References 14
Appendix 15

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

LEGAL BACKGROUND

Regulation (EC) No 1774/2002 of the European Parliament and of the Council, laying down health rules concerning animal by-products not intended for human consumption[8] was adopted on 3 October 2002. It divides animal by-products into three different Categories and requires them to be disposed of, recycled or used as follows:

Category 1 - animal by-products presenting a risk of contamination with BSE or scrapie agent, or with residues of prohibited substances (i.e. hormones used for growth promotion) or environmental contaminants (i.e. dioxins and PCBs) must be totally disposed of as waste by incineration, or co-incineration or landfill after undergoing appropriate heat treatment (Article 4).

Category 2 - animal by-products presenting a risk of contamination with other animal disease agents (i.e. animals which have died on the farm or were killed in the context of disease control measures on the farm) or at risk of residues of veterinary drugs may only be recycled for uses other than animal feed following appropriate heat treatment (Article 5).

Category 3 - parts of slaughtered animals that are not consumed by humans, can only be used in feed for farmed animals if they come from animals declared fit for human consumption following veterinary inspection (Article 6).

The Regulation also provides for the possibility to approve other means of disposal and other ways to use ABP after consultation of the appropriate scientific committee (Articles 4(2)(e), 5(2)(g) and 6(2)(i)).

STATE OF PLAY

The Commission has received a number of applications for approval of alternative methods for the safe disposal of ABP from Member States and from the industry. Seven of these applications were forwarded to the Scientific Steering Committee (SSC) requesting scientific evaluation. The SSC has adopted the following opinions on this subject:

1. Opinion on six alternative methods for safe disposal of animal by-products (adopted by the SSC at its meeting of 10-11 April 2003); and

2. Final opinion and report on a treatment of animal waste by means of high temperature (150 °C, 3 hours) and high pressure alkaline hydrolysis (adopted by the SSC at its meeting of 10-11 April 2003).

For those five methods regarded as safe for ABP of Categories 2 and 3, the SSC concluded that they would probably also have the capacity to safely dispose of ABP of Category 1, but that there was not enough information or data supporting this claim.

Following this conclusion, the applicants of two of these processes forwarded new applications with additional information to the Commission, which were forwarded to the European Food Safety Authority (EFSA). The Panel on Biological Hazards of EFSA adopted an opinion on the "high pressure hydrolysis biogas" process on 26 November 2003 (question no EFSA-Q-2003-028), concluding that under certain conditions the process did not present an additional risk when disposing of ABP of Category 1. Further, the panel adopted an opinion on the "combustion of tallow in a

8 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. OJ L 273, 10.10.2002, p. 1-95.

thermal boiler" on 22 April 2004 and on the "biodiesel process" as a method of safe disposal of category 1 material on 2 June 2004.

LIME TREATMENT OF MANURE AND DIGESTIVE TRACT PROCESS

A European association has submitted a novel process and has asked the Commission to approve it as a safe means of disposal under Article 5 (2) (g) of Regulation 1774/2002/EC, i.e. as far as Category 2 material are concerned. Details of the process and the studies carried out on behalf of this association, as well as further evidence, are contained in the comprehensive submission provided to the Commission.

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

1. To assess the ability of the process submitted by a European association to safely dispose of Category 2 animal by-products.

2. If the process is considered to present a risk, the Commission asks EFSA to advice on the risks of the use of that process and on possibilities for addressing them.

Clarification on the Terms of Reference

After an information exchange with the applicant it was clarified that the terms of reference of the mandate were focused only on pig and poultry solid manure treatment. The solid pig manure consisted of dewatered manure.

ASSESSMENT

1. Introduction

The application received describes a lime treatment process for dewatered pig and solid poultry manure which could be operated at two different temperatures (60°C and 70°C).

Either quick lime (CaO) or slake lime ($Ca(OH)_2$) can be used for liming manure. Liming is a common method for pathogen reduction by elevating the pH value combined, when using quick lime, with an increase in temperature. The reaction between quick lime and the water of the manure is exothermic (1140kJ/kg of CaO) and at the correct dosage rate is sufficient to raise the temperature of the manure undergoing treatment to the target levels. Lime is also alkaline and a saturated solution (1.16g/litre) will impart a pH of 12.4 at 25ºC.

The applicant carried out full scale trials in Belgium on the treatment of dewatered pig and solid poultry manure with quick lime. The samples to demonstrate pathogen reduction were tested by the University of Leipzig.

The experiments presented by the applicant concerned only dewatered pig and solid poultry manure. Accordingly, the BIOHAZ Panel assessed these treatments only for these kinds of manure and not for all types of Cat. 2 Animal By-Products Materials.

The applicant proposes to utilize the two possible treatments to process dewatered pig and solid poultry manure by a batch procedure for covered or uncovered stockpiles and for containers. However, only uncovered stockpiles were used in the experimental protocol to validate the pathogen reduction.

The parameters of the two treatments tested in the protocol are listed below:

Table 1: Parameters of the treatments proposed by the applicant

	Critical limit
Parameter	
Maximum particle size on entering reactor	12 mm
Minimum pH in all reactor material	12
Minimum temperature in all material of the stockpile	1. 60°C 2. 70°C
Minimum sanitization time at target temperature	1. 60 minutes (60°C) 2. 30 minutes (70°C)

1.1. Validation of the Process

1.1.1. Process description

The procedure described in the application was composed by the following steps:

1. Determination of the dry matter content of manure, which must be between 15% and 70%.
2. Determination of amount of lime to be added to manure to reach the target temperatures.
3. Pre-mixing of manure to reduce its particle size followed by mixing with lime.
4. Incubation of the batch in a stockpile until the targets time and temperature are reached.

1.1.2. Description of the equipment used in the validation experiment

It is important to note that the ability of the process to inactivate pathogenic microorganisms and infectious agents depends on the adequate mixing of the manure with quick lime to generate heat and to raise pH homogeneously, within the duration of the process. There are no rapid and simple methods to verify the quality of mixing during process functioning. Consequently, the technical devices used for this purpose should be accurately described and should be validated for their ability to produce the proposed time, temperature and pH treatment.

The following information was provided by the applicant as regard to the mixer used in the experimental validation:

- Two screw type mixers with 2 screws per mixer were used, both mixers operated in-line.
- Screw diameter = 0.55m.
- Screw length = 3.5m.
- Power per mixer = 30 kW.
- Rotation speed of the screw = 156 rpm.
- Mean blending duration = approx 2 minutes.
- Treatment capacity per mixer = approx 10 t/h.

1.1.3. Validation with two manure types (dewatered pig and solid poultry manure)

The trials were carried out on poultry manure with an average dry solids content of 40.4% (standard deviation = 3%) and on dewatered pig manure with a dry solids content of 28.5% (standard deviation = 3%) using a granulated quicklime with particle size of 3mm[9].
A total of 16 capsules containing the test organisms were used for the validation study. The tests were done for both types of manure (pig or poultry), both treatment temperatures (60° or 70°C) and exposure times (30 min, 60 min).

1.1.4. Quality control procedures

The procedure provided details for the sampling and measurement of pH, temperature, particle size and dry matter content.

However, little information regarding the variability of the particle size, pH and temperature obtained during the validation experiment was provided. In particular, only five and three continuous temperature records were provided for the treatment temperatures of 60°C and 70°C respectively, and the location of the probes within the stockpiles was not specified. As a consequence, it is not possible to determine the coldest point in the stockpile, and no demonstration of the representative measuring points for pH and temperature in the stockpiles was provided.

The method EN 12880:2000 “Characterization of sludges. Determination of dry residue and water content” is proposed to characterize solid manure.

9 The applicant recommended to use quick lime meeting the specifications laid down in CL 90 in EN 459 – 1 and having medium to high reactivity (i.e. less than 6 minutes to achieve a 40ºC rise in temperature as per the criteria in the Reactivity test 5.10 in EN 459-2:2002) for use in field condition.

2. Risk categories

Manure and digestive tract content, which is part of Cat. 2 ABPs as defined in the Regulation (CE) 1774/2002 (EC, 2002) as amended.

3. Identification and characterisation of risk materials

The material to be treated is dewatered pig and solid poultry manure with dry matter content between 15 and 70%.

The hazards concerned are pathogenic microorganisms and infectious agents that can be present in manure (EFSA, 2005a). They can be both zoonotic agents and animal pathogens. They include bacteria, viruses and parasites. More details concerning the presence and the epidemiology of pathogens in manure can be found in Strauch (1991), DFG (2002), Pell (1997), DFG (2002), Burton and Turner (2003).

This hazard identification does not include chemical and physical hazards.

4. Agent Risk Reduction

In order to assess the disinfectant capacity of the treatment, samples of lime-mixed manure were spiked with a suspension of known aliquots of parasite eggs, bacteria and viruses. After incubation, the sample contents was cultured or incubated in order to test the microorganism survival rate.

The basis for the validation of the agent risk reduction was reported, according to the EFSA opinion vis-à-vis biological risks of biogas and compost treatment standards of animal by-products (2005b), as:

- *Salmonella* Senftenberg 775W (H_2S negative), to show at least a 5 $\log_{10}$ reduction;
- *Ascaris* eggs, to show at least a 3 $\log_{10}$ reduction for the viability of the parasites eggs;
- *Parvovirus*, to show at least a 3 $\log_{10}$ reduction;
- In addition, the effect of the treatment on *Enterococcus faecium* to show at least a 5 $\log_{10}$ reduction was measured.

Note: The provided experimental validation scheme did not cover inactivation of bacterial spores, which is not required for the treatment of manure and digestive tract content to be used as organic fertilisers.

According to the experimental evaluation the treatment proposed was able to reduce the infective agents at the levels indicated in all the samples processed, for both target temperatures (60°C or 70°C) and exposure times (60 and 30 minutes respectively).

However, a number of deficiencies were noticed in the recording of the physical and chemical parameters reached during the experiments (e.g. temperature records at representative measuring points in the stockpiles). The capsules containing the test organisms were inserted in the stockpiles once the target temperature was reached at the point of insertion. No continuous temperature measures over the treatments were done on the stockpiles in which the capsules were inserted[10]. Therefore, the experiment validates that the desired risk reduction is obtained when the lime-manure

10 The continuous temperature records were done on a different stockpile than the ones used to insert the capsules containing the pathogens and indicators.

mixture reaches the target pH, temperature and time, but does not provide indication on the control measures to be implemented in practice, *i.e.* place and number of monitoring points for pH and temperature, total elapsed time from initiation of the treatment (*i.e*. start of the incubation as defined in 1.1.1) until the minimum target temperature has been reached in all part of the stockpile.

5. Risk Containment

Risk might arise from the accidental release of improperly processed manure. The HACCP scheme described in the application proposed to isolate and retreat batches for which proper mixing of lime with manure and target time, temperature, pH values are not achieved.

However, the applicant proposed to extend the HACCP scheme to a wider range of processing conditions than those validated experimentally.

The HACCP scheme proposed by the applicant mentioned the possibility to treat manure in continuous reactors, although only batch treatment was validated. Because continuous reactors introduce an additional critical parameter for the success of the treatment (i.e. the range of resident times of the material in the reactor), compared to batch treatments, the validation done on batches (stockpiles) by the applicant cannot be extended to continuous reactors. The HACCP scheme should clearly indicate that the process is carried out in batches (i.e. the process is not continuous).

In addition, the HACCP protocol should introduce a critical control point on size and geometry of the stockpiles. Since the validation was done on stockpiles of approximately 2 tonnes the minimum size for acceptable stockpiles should be at least 2 tonnes. Smaller stockpiles may not keep heat as efficiently.

The HACCP scheme mentioned the diversity of mixing devices and diversity of manure. The success of the lime treatment depends on the adequate mixing of lime and manure, which is a function of the manure “texture” and lime granularity. Therefore, changing these conditions from those used in the experimental validation could affect the success of the treatment. The HACCP scheme should be limited to the manure type (dewatered pig and solid poultry manure) and mixing conditions used in the experimental validation.

The proposed HACCP scheme lacks accuracy in several important aspects:

- The draft HACCP scheme proposes to put the temperature probes in positions that demonstrate the target temperature is achieved even in the least favourable (least insulated/most exposed) parts of the treated material. However, in the validation provided there was no indication on the location of the points where temperature curves have been recorded. Therefore, it is not possible to deduce from the experimental validation the representative points to measure the process temperature (e.g. “coldest point”, “hottest point”).

- There is no information given on how many temperature probes should be installed and on how many samples for pH measurements should be taken in relation to the amount of the material processed.

- The HACCP scheme should also specify the type and the minimum technical specifications for the mixing equipment (performance data e.g. rotations per minute). The particle size of the material (e.g. leaving the mixer) is proposed in the HACCP scheme as a parameter of successful mixing. However, the particle size *per se* is useful but not a good indicator of mixing because it could be reached before the mixing due to a pre-treatment (a pre-mix phase of the raw material for size reduction is proposed in the flow diagram of the HACCP scheme at the beginning of the process). Increasing temperature and pH indicate good mixing but this requires a sufficient number of measuring points placed in representative parts of the stockpile.

- The HACCP scheme proposes to retain as critical limits for the success of the treatment 60 minutes at 60°C or 30 minutes at 70°C and pH above 12. The validation protocol supported the proposed critical limits for temperature and pH, but the HACCP scheme does not indicate the methodology to monitor these critical parameters. The HACCP scheme should accurately define the number and location of the points to monitor pH and time/temperatures during the treatments, using the information obtained during the experimental validation. However, few temperature records were provided in the experimental validation, only some of them were continuous records and the latter were not obtained in the same experiment that was used to validate the process against the pathogens and indicators. Similarly, few pH measures were given and their locations were not specified.

- The HACCP plan should clearly set out procedures for ensuring the requested processing parameters are achieved for the target time. The few temperature continuous records showed a broad diversity in the time needed to reach the target temperatures at 60° or 70°C (e.g. approximately 4 hours of difference between the first and the last measuring point to reach 60° and 70°C). In addition these temperatures were recorded only in one type of manure with a specific dry matter content. The expected diversity of the manure to be treated likely increases the potential diversity in the temperature profiles within the batch treated. Therefore, due to these uncertainties on the extent of the variability, the HACCP scheme should integrate a margin of safety in the definition of the critical limits (e.g. to extend the holding time).

- All the methods needed to successfully perform the treatments, as in the experimental validation, should be annexed to the HACCP scheme (manure characterisation, calculation of the amount of lime to be added to the manure, …).

5.1. The effect of lime treatment depends on the physicochemical properties of the treated material which is different in sewage sludge and animal by-products.

Several factors are influencing the microbicidal and antiparasitic activity of lime. The dosage-temperature relationships given in the table provided by the applicant cannot always be found under practical conditions even in sewage sludge which is often referred to in the application. Ostertag (1987) recommends a dosage of 200g CaO/1000g dry matter in sewage sludge and exposure time of 24h at a pH value of at least 12.5 for a safe hygienization of sewage sludge. Schirm (2005) describes the treatment of sewage sludge and several other substrates with quicklime using three different mixing devices: a rotating drum mixer, a plough mixer and a paddle mixer. The different substrates and mixer devices did not always give equivalent results.

Since there is an influence of the matrix as well as of the mixing devices it is always necessary to set a safety margin for the process to be used e.g. by prolonging the exposure time.

6. Identification of interdependent processes

This protocol leads to gas emissions (ammonia). Scrubbing of these emissions is not described. Due to environmental reasons, the ammonia emissions should be avoided, therefore this could be a limiting factor for licensing the procedure due to national legislation.

7. Intended end use of the products

Land spreading of the treated material as fertilizers.

8. Documentary evidence

The results of the experimental evaluation of the effects of liming in solid manure on parasitic eggs, bacteria and viruses were provided, including microorganism concentration before and after the treatment.

The application provided some pH, temperature and particle size measures obtained in a full scale validation trial. However, some weaknesses were noticed in the recording of the experimental conditions under which the validation procedure was performed:

- No indication on the location of the points were temperature and pH values were recorded.
- Few temperature records provided, only part of them were continuous records and the latter were not obtained in the same experiment that was used to validate the process against the pathogens and indicators.
- Few pH records provided.

The HACCP plan provided by the applicant is considered inadequate and should be improved considering the observations laid down under section 5 ("Risk Containment") of this opinion.

A process diagram was provided where the functioning of the treatment plant is shown. However, the notes attached to the flow diagram indicate that other processes and conditions (continuous reactors, any type of mixer and manure) than those experimentally validated could be used, which are not covered by the validation experiment.

9. Required conditions for practical implementation of the proposed processes

Since the proposed processes should not be implemented under conditions which have not been validated the following conditions should be met for practical implementation (in addition to the parameters listed in Table 1):

- The processes should be conducted in batches.
- The minimum size for the stock piles should be 2 tonnes.
- The same type of machine and protocol for mixing as the one described in the experimental validation should be used.
- The same types of manure as described in the experimental validation should be processed.
- The quicklime used should comply with the specification proposed by the applicant (as described in section 1.1.3).
- The total exposure time in the stockpiles should be at least 6 hours. Within these conditions the minimum target temperatures of 70°C must be maintained for at least 30 minutes and of 60°C must be maintained for at least 60 minutes at the coldest point of the stockpile.

Moreover, the HACCP scheme should be improved as recommended under section 5 ("Risk containment") of this opinion. In particular, the stockpiles should be monitored to demonstrate that the minimum target temperature is reached and maintained for the required time throughout the stockpile. To determine the coldest point in the stockpile the procedure described in section Appendix should be followed.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- The information provided by the applicant is sufficient to show that the mixing of dewatered pig and solid poultry manure with quicklime at the requested exposure time of 30 or 60 minutes, respectively for treatment at 70°C and 60°C at pH 12 meets the requirements for Agent Risk Reduction according to the EFSA 2005 opinion vis-à-vis biological risks of biogas and compost treatment standards of animal by-products.

- However, the applicant did not give sufficient information to ascertain that in practice the target temperatures and pH are achieved in all part of the stockpile for the sufficient time period.

- This assessment cannot be extended to different equipments, different types of manure and different incubation conditions (i.e. continuous process) than those used in the experimental validation.

- Since the BIOHAZ Panel has to assess a treatment process and not a treatment principle the whole process to be assessed has to be described in all relevant technical details. Therefore, in the case where several technical solutions for a treatment step are possible, the parameters are essential. In case another mixing device is to be used, specific recommendations were made and can be found in the Annex to this opinion.

- Several weaknesses were noticed in the HACCP scheme proposed by the applicant and specific information were given to implement the process in practice.

RECOMMENDATIONS

- The two proposed processes described in the experimental validation can be considered able to safely process dewatered pig and solid poultry manure if the conditions described in section 9 of the opinion are met.

- If another mixing device than the one used in the validation is proposed it is recommended to assess its equivalence by a simplified validation procedure based on temperature measurements at representative measuring points in the stockpile. An example of simplified validation procedure is provided in the Appendix to this opinion.

- If other types of manure, methods other than stockpiles (i.e. continuous processes or containers) are proposed it is recommended to perform a full validation experiment.

DOCUMENTATION PROVIDED TO EFSA

1. Request for an opinion on the safety of a lime treatment of manure and digestive tract content. April 2005. Letter (ref. D(2005)TG/cm/420351) from the European Commission, Health & Consumer Protection Directorate-General (DG SANCO).

2. Documentation on the application for approval by a European association as a safe means of disposal of ABPs as submitted to the Commission (1 folder).

3. EFSA assessment of the application on Lime treatment for Manure and Digestive Tracts Contents. Letter from the applicant dated 5 October 2007 providing information on the validation protocol.

4. Letter from the applicant dated 18 June 2008 providing information on the test protocol used, validation results and a revised version of the HACCP scheme and asking to change of reference of the mandate.

5. Letter from the applicant dated 3 November 2008 providing information on the substrate and process parameters.

6. Letter from the applicant dated 31 August 2009 providing further information on the application.

7. Letter from the applicant dated 26 January 2010 providing technical information on the mixing device used during the validation experiment.

REFERENCES

Burton CH and Turner C, 2003. Manure Management-Treatment strategies for sustainable agriculture. Editor. Silsoe Research Institute, Wrest Park, Silsoe, Bedford, UK,

DFG (Deutsche Forschungsgemeinschaft), 2002. Potentially harmful organisms and substances in feedstuffs and animal faeces. Report 5.

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 10/10/2002, p. 1-95.

EFSA (European Food Safety Authority), 2005a. Opinion of the Scientific Panel on biological hazards (BIOHAZ) on the biological safety of heat treatment of manure. The EFSA Journal, 265, 1-16.

EFSA (European Food Safety Authority), 2005b. 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.

Ostertag S, 1987. Mikrobiologisch – hygienische Untersuchungen über die Anwendung von Branntkalk und Löschkalk zur Klärschlammentseuchung. Vedewa Schriftenreihe, 4,

Pell AN, 1997. Manure and microbes: public and animal health problem? J Dairy Sci, 80, 2673-2681.

Schirm V, 2005. Entwicklung einer sicheren Methode zur Bioabfallhygienisierung mit Kalk. Vet. med. Diss., Justus Liebig Universität Giessen,

Strauch D, 1991. Survival of pathogenic micro-organisms and parasites in excreta, manure and sewage sludge. Rev Sci Tech, 10, 813-846.

APPENDIX

A. RECOMMENDED PROCEDURE TO VALIDATE OTHER MIXING DEVICES

If another mixing device than the one used in the validation is proposed its equivalence can be assessed by a simplified validation procedure based on temperature measurements at representative measuring points in the stockpile. The procedure could follow the scheme proposed here below.

1. GENERAL DESCRIPTION

The experiment to assess the equivalency with the validated mixing device should aim at measuring the diversity of the temperature/time profiles within the stockpile. It should therefore encompass the potential sources of diversity: location in the stockpile and external temperature during the treatment. Therefore it is proposed to performed at least two experiments, during separate periods of time of at least 30 days. One period must be in the cold season (December until February).

2. DETERMINATION OF MEASURING POINTS FOR CONTINUOUS MEASURING OF TEMPERATURE

In order to assess the maximum temperature variability in the stockpile, the measuring points could be located at three different regions: 4 in the basal zone at the basis (maximum 10 cm above ground and 10 cm below surface), 1 in the middle half way between basis and crown and 4 in the marginal zone at the top of the pile (maximum 10 cm below surface and 10 cm below crown of the pile) according to the schemes provided in figures 1, 2 and 3.

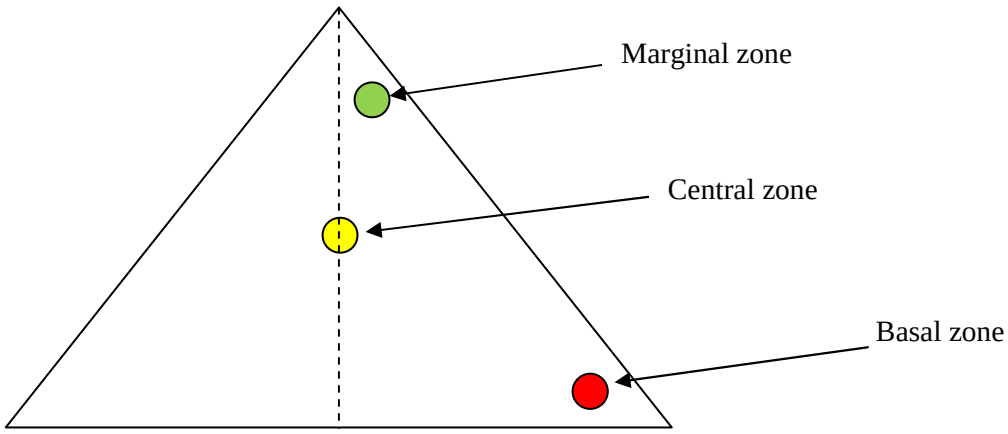

Figure 1: Vertical section of the stockpile: scheme of exposure of the temperature probes according to the three different regions in the stockpile

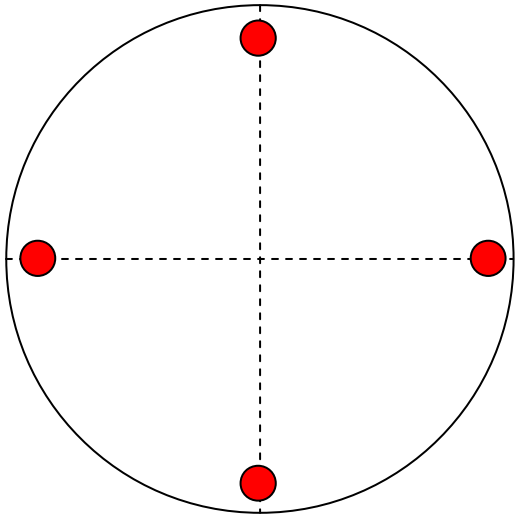

Figure 2: Horizontal section of the stockpile: scheme of exposure of the temperature probes in the basal zone

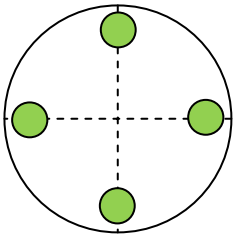

Figure 3: Horizontal section of the stockpile: scheme of exposure of the temperature probes in the marginal zone

Temperatures have to be recorded all over the measuring period and filed for supervision by the competent authority.

3. INTERPRETATION OF THE RESULTS

Equivalency with the process assessed in the current opinion will be considered demonstrated if the target temperatures are achieved at all measuring points in the stockpile within the same period of time as for the process validated and assessed in the present opinion.

Based on the results provided by the applicant, the time/temperature targets (60°C for 60 min or 70°C for 30 min) should be achieved at every measuring point within a total exposure time of 6 hours.