EFSA Panel on Biological Hazards (BIOHAZ); Scientific Opinion on the „Biomation" application for an alternative method for the treatment of animal-by-products

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SCIENTIFIC OPINION

Scientific Opinion on the 'Biomation' application for an alternative method for the treatment of animal-by-products[1]

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

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

A method alternative to the ones already approved in the current legislation, called 'Biomation' process, for the treatment of Category (Cat.) 2 and 3 Animal By-Products (ABP)[4] was assessed. The process consists of an alkaline treatment. The target parameters are: particle size ≤ 5mm, temperature 70 °C, pH 12.5, exposure time 20 minutes. According to the application received also Cat. 1 ABP can enter the processing plant and it has then to be removed from the rest of the ABP material and treated according to current legislation. The end product generated by the 'Biomation' process is intended to be used as an organic fertiliser and soil improver. According to the legislation in force, before being used as an organic fertiliser, Cat. 2 (and mixes of Cat. 2 and 3) material should be treated with a sterilisation process (i.e. 133 °C / 20 min / 3 bars / 50 mm particle size)[5]. The hazard identification provided by the applicant was not adequately addressed, since the most resistant organisms (including TSE agents) were not properly identified, and an experimental validation with representative test-organisms under practical conditions was not performed. A laboratory experiment was performed but its results were not clear and did not allow a proper assessment of the level of risk reduction of the relevant biological hazards achieved by the process. Moreover, it was noticed that it is not certain that the values of the parameters used in the laboratory experiment would be homogenously reached in all the material under real scale conditions. Major deficiencies were noticed in the HACCP plan provided. It was concluded that there is no evidence that the proposed alternative method is equivalent to the sterilization process defined in the current legislation.

KEY WORDS

Animal By-Products, alternative methods, 'Biomation', equivalence, alkaline treatment

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[1] On request from the Competent Authority of the United Kingdom, Question No EFSA-Q-2011-01166, adopted on 08 March 2012.

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[3] Acknowledgement: The Panel wishes to thank the members of the Working Group on Assessment of Animal By-Products: Avelino Álvarez-Ordóñez, Reinhard Böhm, John Griffin and Christophe Nguyen-The for the preparatory work on this scientific opinion.

[4] Cat. 1, 2 and 3 ABPs are defined in Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009).

[5] Annex IV to Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011).

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SUMMARY

Following a request from the UK Competent Authority, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the 'Biomation' application for an alternative method for the treatment of animal-by-products.

The application received concerns a new method for the treatment of Category (Cat.) 2 and 3 Animal By-Products (ABP) as defined in Reg. 1069/2009[6] (the ABP Regulation).

According to the applicant, fallen stock containing Specified Risk Material (SRM), which is included in the list of Cat. 1 ABP in article 8 of the ABP Regulation, can also enter the processing plant. In this case the fallen animals are received in a separate area and the SRM is removed using the same methods employed in slaughtering plants. The removed SRM is then handled according to the requirements foreseen in the ABP Regulation and on its implementing measures laid down in Reg. 142/2011[7] and incinerated in an approved incineration plant.

The proposed process consists of 6 steps i) mincing the material to a particle size ≤ 5mm; ii) transfer to a refrigerated holding tank; iii) treatment by alkaline hydrolysis by addition of NaOH to a concentration of at least 15% to the material until reaching a pH of at least 12.5 and keeping it at a temperature of 70 °C for 20 minutes; iv) treatment by neutralization by addition of acrylic acid at a temperature of 70 °C and an exposure time of 20 - 30 minutes in order to decrease the pH from 12.5 - 13.2 to 7.0 - 7.7; v) treatment by polymerization by addition of ammonium persulfate 0.5% (w/w) at a temperature of 70 °C and an exposure time of 10 minutes; vi) drying in a drying tunnel at 200 °C - 220 °C.

The end product generated by the process is intended to be used as an organic fertiliser and soil improver.

Following article 13 (d) of the ABP Regulation, in order to be used as organic fertiliser and soil improver, Cat. 2 (and mixes of Cat. 2 and 3) material should be treated according to method 1 as defined in Annex IV to Regulation (EU) 142/2011 (i.e. 133 °C / 20 min / 3 bars / 50 mm particle size).

The parameters reported by the applicant as critical for the risk reduction were: particle size ≤ 5mm, temperature 70 °C, pH 12.5, exposure time 20 minutes.

The applicant listed several viral and bacterial pathogens and diseases that regarded as relevant in this context. Since Cat. 1 material is handled at the same plant, cross contamination of the ABP to be treated with TSE agents cannot be excluded. Due to the variety of material intended to be used in the proposed process and on the uncertainty on the cause of the death of the possible fallen animals entering the process, the presence of highly thermo- and chemo resistant hazards cannot be considered negligible. The possibility of the presence of such hazards was not adequately addressed in the application and the biological agent/s which are the most difficult to be inactivated by the critical parameters and which should be retained as the primary target/s for demonstrating the risk reduction achieved by the process were not adequately identified. Moreover, it cannot be excluded that the subsequent polymerisation in this process could possibly lead to the stabilisation of any residual TSE infectivity.

[6] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009).

[7] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011).

No experimental validation of the process in technical or semitechnical scale in order to demonstrate its efficacy in field conditions was performed. The applicant's argumentation on the risk reduction provided by the process was primarily based on data from literature. The only experimental data provided by the applicant were related to a laboratory scale experiment with spores of *Clostridium sporogenes* that were selected as the target to demonstrate the risk reduction achieved by the process. No information was given on the reason why such spores were selected. The methods used in the experiment are not described in detail, the raw data are missing and the results, as described, are not clear and partly improbable.

The applicant provided a HACCP plan that took into account the parameters considered as critical for the process. However, there was no indication on how and were such critical parameters could be monitored and implemented under real scale conditions. It was noticed that the plan provided does not contain clear provisions for the cleaning and disinfection of the means utilised during the process and for ensuring an adequate separation of dirty and clean areas.

The risk associated with interdependent processes was considered by the applicant.

The BIOHAZ Panel concluded that the hazard identification was not adequately addressed, since the most resistant organisms (including TSE agents) were not properly identified, and that no experimental validation with representative test-organisms under practical conditions was done. Moreover, it is not certain that the values of the parameters used in the laboratory experiment would be homogenously reached in all the material under real scale conditions. The results of the laboratory experiments performed are not clear and do not allow a proper assessment of the level of risk reduction of the relevant biological hazards achieved by the process.

Major deficiencies were noticed in the HACCP plan provided.

The Panel further concluded that there is no evidence that the proposed alternative method is equivalent to processing method 1 described under Regulation (EU) 142/2011, in terms of $\log_{10}$ reduction of the relevant hazards, including TSE agents.

To assess alternative methods, the Panel recommended that the relevant hazards and their level of inactivation to be targeted by the processing methods for Cat. 2 animal by-products should be specified in a more precise and detailed way. Moreover, to facilitate the assessment of the alternative methods for the treatment and the specific use of the Cat. 2 material under consideration it was recommended that i) test organisms with defined resistance patterns should be specified; and ii) the required level of quantitative risk reduction of such organisms should also be provided.

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BACKGROUND AS PROVIDED BY THE UK COMPETENT AUTHORITY

An alternative method has been developed by a UK company (Incinerator Replacement Technology Ltd) for the processing of category 2 & category 3 animal by-products (ABPs). In the first stage of this method, which is called the 'Biomation' process, an alkaline mix is introduced to the ABPs (after the ABPs have been reduced in particle size to a maximum of 5 mm) until a temperature of 70˚C is reached by exothermic reaction and heat. This temperature is then maintained for a period of 20 minutes by means of a jacket heater. The minimum pH achieved by the addition of the alkaline mix is 12.5. At this point it is claimed that the derived product has met a 6 log reduction for *Clostridium sporogenes* spores. In the second stage of the manufacturing process acrylic acid is added to the derived product to achieve neutral pH while the temperature continues to be maintained to 70˚C for 20 minutes. Due to the slow addition of acrylic acid the pH of the product is decreasing from 12.5-13.2 to 7.7. In the third and final stage of the manufacturing process ammonium persulfate 0.5% by weight (w/w) is added and mixed with the product to achieve polymerization whilst the temperature is maintained to 70˚C and the pH to 7.7 for 10 minutes. The final derived product of this process is intended to be used as an organic fertiliser/soil improver.

TERMS OF REFERENCE AS PROVIDED BY THE UK COMPETENT AUTHORITY

The UK competent authority asked EFSA to assess the proposed alternative method for the treatment of category 2 and 3 animal by-products in order to produce an organic fertiliser and whether the final derived product has reached an 'end point' in the manufacturing chain.

Clarification of the Terms of Reference

The assessment was performed taking into account the criteria laid down in Art. 20, point 5 of Reg. 1069/2009. The requestor asked also to assess if the final derived product can be considered as reaching an "end point" in the manufacturing chain. This is not under EFSA's remit in this context.

ASSESSMENT

1. Introduction

The terminology used in this assessment conforms to the "Statement on technical assistance on the format for applications for new alternative methods for animal by-products" (EFSA Panel on Biological Hazards (BIOHAZ), 2010). The assessment only considered biological hazards. Other hazards that can occur due to the use or release of chemical substances are not considered.

The assessment of the application received was performed taking into account the criteria laid down in Art. 20, point 5 of Regulation (EC) 1069/2009[8] (the ABP Regulation).

2. Full description of the process

The application received concerns a new method for the treatment of Category (Cat.) 2 and 3 Animal By-Products (ABP) as defined in Reg. 1069/2009. The end product generated by the process is intended to be used as an organic fertiliser and soil improver.

Following article 13 (d) of the ABP Regulation, in order to be used as organic fertiliser and soil improver, Cat. 2 (and mixes of Cat. 2 and 3) material should be treated according to method 1 as defined in Annex IV to Regulation (EU) 142/2011[9] (i.e. 133 °C / 20 min / 3 bars / 50 mm particle size).

According to the applicant, fallen stock containing Specified Risk Material (SRM), which is included in the list of Cat. 1 ABP in article 8 of the ABP Regulation, can also enter the processing plant. In this case the fallen animals are received in a separate area and the SRM is removed using the same methods employed in slaughtering plants. The removed SRM is then handled according to the requirements foreseen in the ABP Regulation and on its implementing measures laid down in Reg. 142/2011 and incinerated in an approved incineration plant.

The applicant reports that former foodstuffs (i.e. foodstuffs which are not longer intended for human consumption) are separated from any packaging prior to processing. However, it is not clear how this operation is performed.

The main equipments where the material is processed in are a macerator for mincing the Cat, 2 and Cat. 3 materials, an intermediate storage tank, a hermetically sealed pressure mixing vessel in which the three steps of the 'Biomation' process are subsequently run and a drying tunnel for evaporating the water.

The whole treatment process is characterized by the following main steps and parameters:

1. Mincing of the material to a particle size ≤ 5mm.

2. Transfer of the material to a refrigerated holding tank (no temperature data are given).

3. Treatment by alkaline hydrolysis by addition of at least 15% NaOH to the material until reaching a pH of at least 12.5 and keeping it at a temperature of 70 °C for 20 minutes.

[8] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009).

[9] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011).

4. Treatment by neutralization by addition of acrylic acid at a temperature of 70 °C and an exposure time of 20 – 30[10] min in order to decrease the pH from 12.5 – 13.2 to 7.0 - 7.7[10].

5. Treatment by polymerization by addition of ammonium persulfate 0.5% (w/w) at a temperature of 70 °C and an exposure time of 10 min.

6. Drying in a drying tunnel at 200 °C - 220 °C.

It is intended that every batch of end product will be sampled (5 samples per batch) and sent to an approved laboratory to be analysed. The applicant reports that a batch of Cat. 2 material has to be tested for *Cl. perfringens* while a batch of Cat. 3 material has to be tested for *Salmonella* spp. and *Enterobacteriaceae*. In case a batch fails the laboratory analysis it has to be sent to disposal. However, the applicant did not provide any critical limit for the laboratory analysis to be performed.

According to the applicant the critical steps for the risk reduction are the mincing of the material and the alkaline addition. The alkaline addition is performed in batches.

The parameters reported by the applicant as critical for the risk reduction are:

- particle size ≤ 5mm;
- temperature 70 °C;
- pH 12.5;
- exposure time 20 minutes.

No information is given on the transfer and storage of the minced material into the refrigerated tank and on the transfer of that material from the refrigerated tank to the mixing vessel.

According to the description received steps 3, 4 and 5 take place into the same mixing vessel.

During the process the exhaust air is passed through a filter to remove chemical gases. No clear information is given on the gases generated by the process (the applicant reports that these are mainly water vapours and ammonia) neither on the measure of the effect of such filter in reducing the quantity of gases and biological hazards which may be released into the environment.

The waste water resulting from the cleaning of the equipment is collected in tanks and then disposed of according to current legislation. The fate of the water generated during the drying process is not described.

A flow diagram of the proposed process under commercial conditions is shown in Figure 1.

[10] Divergent data are given in the application.

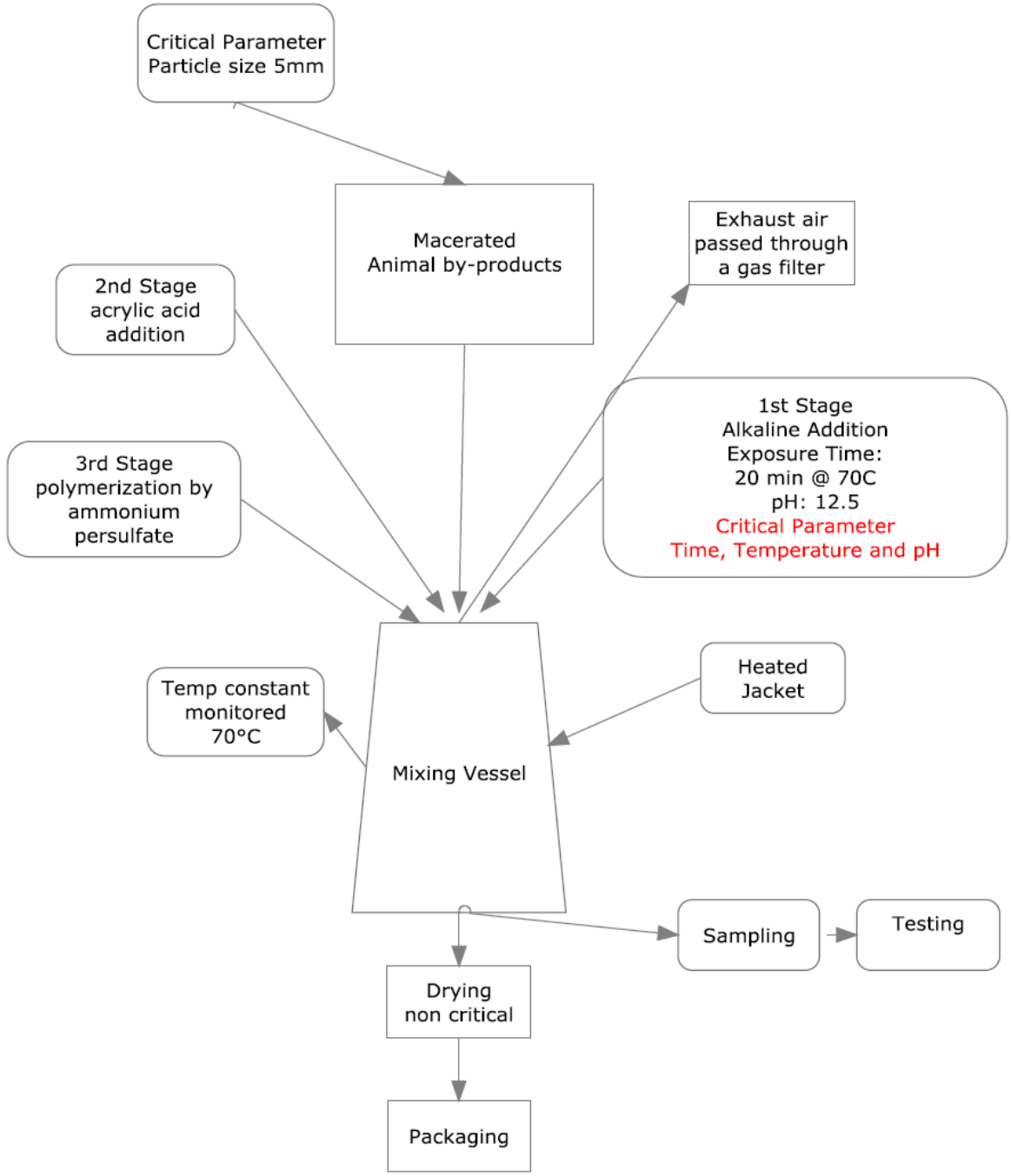

Figure 1: Extract from the applicant's report: Flow diagram of the proposed process

3. Full description of the material to be treated

All type of Cat. 2 and Cat. 3 ABP can enter the processing plant. Since it is intended to process also fallen stock containing Specified Risk Material (SRM), Cat. 1 ABP, will also be handled on the same plant, while the SRM is removed for incineration in an approved incineration plant in a separate area and the remaining material subsequently transferred to the treatment process as Cat. 2 ABP.

4. Hazard identification

The material to be treated is represented by fallen animals of different species and all other kinds of ABP including former foodstuffs. The hazards concerned are pathogenic microorganisms and infectious agents that can be present in fallen animals and other ABP. They can be both zoonotic

agents and animal pathogens. They include bacteria, fungi, viruses and parasites. Food waste spoilage organisms and other contaminants as well as toxins must be taken into account too. The applicant listed several viral and bacterial pathogens and diseases (Rabies virus, Influenza virus, *Salmonella* spp., *Campylobacter* spp., coliforms, *Enterobacteriaceae*, *E. coli* O157, *Erysipetothrix rhusiopathiae*, *Listeria monocytogenes*, tuberculosis, brucellosis, anthrax, *Cl. botulinum*, *Cl. perfringens*, trichinella, toxoplasma, taeniasis, swine fever virus, parvovirus, foot and mouth disease virus, *Staphylococcus aureus*, *Mycoplasma* spp., viruses and Clostridia spp.) that were regarded as relevant in this context. Since Cat. 1 material is handled at the same plant, cross contamination of the ABP to be treated with TSE agents cannot be excluded.

However, due to the variety of material intended to be used in the proposed process and on the uncertainty on the cause of the death of the possible fallen animals entering the process, the presence of highly thermo- and chemo resistant hazards cannot be considered negligible. In particular method 1 as defined in the current legislation, is able to minimise the risks due to unidentified agents, such as bacterial spores, thermo resistant viruses and in particular TSE agents. The possibility of the presence of such hazards was not adequately addressed in the application and the biological agent/s which are the most difficult to be inactivated by the critical parameters and which should be retained as the primary target/s for demonstrating the risk reduction achieved by the process were not adequately identified. Moreover, it cannot be excluded that the subsequent polymerisation in this process could possibly lead to the stabilisation of any residual TSE infectivity.

5. Level of risk reduction

The applicant refers to the first treatment step of alkaline hydrolysis as the only part of the process relevant for risk reduction but no experimental validation of this step in technical or semitechnical scale was performed in order to demonstrate its efficacy in field conditions. The applicant's argumentation concerning risk reduction, including TSE agents, due to the process applied is primarily based on data from literature (e.g. Appendix 1 and 11 to the application dossier). The only experimental data given in the application has been elaborated in two different sets of laboratory scale experiments performed by the applicant and by an external laboratory with different spore preparations of *Clostridium sporogenes* and minced meat. Those experiments seem to have more the character of range finding experiments, than of a pre-validation study. No reasons were given, why *Clostridium sporogenes* spores were identified by the applicant as the target to demonstrate the risk reduction achieved by the process.

Since these are the only experimental data presented in the context of the application, some methodological details will be given below.

In the experimental study carried out by the applicant, the spore suspension used was prepared by the laboratory of the applicant itself. 1200 g of minced meat (5 mm particle size) for petfood was inoculated and mixed with a *Cl. sporogenes* spore suspension to reach a concentration of 6.3 – 6.8 $\log_{10}$ spores per gram of meat.

The total amount of inoculated material was then divided in 12 beakers with 100g of material in each of them.

In order to assess the risk reduction reached by the proposed process the applicant measured the reduction of the number of viable spores at different points in time in two sets of experiments, respectively at 60 °C and 70 °C, with sodium hydroxide concentrations of 0, 5, 10, 15, 20 and 25% (w/w). The applicant reported that the temperature never dropped below 60 and 70 °C in the two set of experiments.

The reduction of the number of viable spores achieved in the two sets of experiments as reported by the applicant is listed in table 1 and 2.

Table 1: Log CFU/g of Cl. sporogens spores at 60 °C in various sodium hydroxide concentrations within 20 minutes (Mean value=5±Standard Deviation) [sic].

	0 min	5min	10 min	15 min	20 min
0%	6.8±6.3	6.8±6.5	6.8±6.0	6.8±6.3	6.8±6.2
5%	6.8±6.2	5.7±4.9	5.5±4.6	5.0±4.3	4.7±3.8
10%	6.8±6.2	4.6±3.7	4.4±3.6	4.0±3.1	3.9±3.0
15%	6.8±6.0	3.7±2.8	3.9±2.9	3.7±2.8	3.4±2.5
20%	6.8±5.9	3.3±2.5	3.2±2.3	3.1±2.1	2.9±2.0
25	6.8±6.4	3.3±2.4	3.1±2.2	2.9±2.0	2.8±1.8

Table 2: Log CFU/g of Cl. sporogens spores at 70 °C in various sodium hydroxide concentrations within 20 minutes (Mean value=5±Standard Deviation) [sic].

	0 min	5 min	10 min	15 min	20 min
0%	6.8±6.2	6.8±6.2	6.8±6.0	7.1±6.3	6.0±5.4
5%	6.3±5.5	4.8±3.9	3.9±3.1	3.6±2.6	3.0±2.2
10%	6.8±6.0	4.6±3.7	3.5±2.7	3.0±2.0	2.9±1.9
15%	6.8±6.3	2.8±1.9	2.3±1.4	2.0±1.0	0.0±0.0*
20%	6.8±6.2	2.8±1.8	2.0±1.2	1.8±1.0	0.0±0.0*
25%	6.8±6.4	2.8±2.0	1.7±0.8	1.3±0.5	0.0±0.0*

The presentation of the data is confusing (e.g. it is doubtful that the standard deviation of the control is in the same range as the mean bacterial count). The methods used in the experiment are not described in detail, the raw data are missing and the results, as described, are not clear and partly improbable.

For example, according to the applicant 5% NaOH can lead to 3 $\log_{10}$ reduction of *Cl. sporogenes* spores within 20 minutes at 60 and 70 °C. However, the results from table 1 and 2 do not support this conclusion. Moreover, according to the applicant any concentration of NaOH above 15% (pH of at least 12.5) at 70 °C for 20 minutes leads to the total destruction of spores (> 6$\log_{10}$ reduction). However, given that as reported by the applicant the detection limit for the method for counting the *Cl. sporogens* spores is 10 CFU/ml, the 6 $\log_{10}$ reduction is not really measured.

The exact temperature at which the experimental validation was performed was not provided in the applicant´s report and could also have been higher than the critical temperature proposed for the process under real scale conditions.

Moreover, the measure of one of the critical parameters according to the applicant (pH) was not presented for the laboratory trial. In this trial only the concentration of NaOH is reported. The applicant associated 15% concentration of NaOH with a pH of 12.5 without providing any supporting data.

According to the applicant these experiments were then validated by an external laboratory (as reported in Appendix 10 to the application dossier). In those experiments 0.1 ml of a spore suspension ($5x10^7$ CFU//ml) prepared out of a freeze dried preparation were added to 10 g of minced meat ($5x10^5$ spores per gram of meat) and heated in the water bath for 10 minutes. 1g of this mixture was transferred into 9ml of saline solution and NaOH was added to reach final concentrations between 5% and 25%. Samples heated at 70 °C were taken after 5 min to 20 min, immediately neutralized with HCl, heat shocked and the CFU of surviving spores were determined. According to their experiments, treatments with NaOH at concentrations of 10%, 15%, 20% and 25%, completely inactivate all spores after an exposure time of 5 min.

However, the description of the protocols and the results of the two experiments differs. This raises doubts about the experimental procedure really applied and the reliability of the results provided.

None of the involved laboratories had characterized the resistance of the spore preparation used and validated the microbiological methods applied. Hence, it cannot be excluded that this fact was the reason for the high variations in the zero values (exposure time 0 min and 0% NaOH) in both studies.

Concerning the microbiological safety of waste water from the process, the applicant also tested the sterility of the water extracted from the wet material during the drying process by placing 100g of the treated material in a round flask connected to a condenser. The flask was heated to dry the end product. The condensed water was collected and passed through a microbiological filter. The filter was placed on a nutrient agar plate and cultivated at 37 °C for 3 days. No colonies were detected.

6. HACCP plan

Although the applicant reports that "*any batch (or process load) not meeting the critical parameters for the process will be sent for disposal*" and the HACCP plan provided has listed the critical parameters in the description of the process, is not clear and there is no indication on how and where the critical parameters for the process (particle size, temperature, pH and exposure time) can be monitored and implemented under real scale conditions.

The HACCP plan does not contain clear provisions for the cleaning and disinfection of the means utilised during the process and for ensuring an adequate separation of dirty and clean areas.

7. Risk associated with interdependent processes

The applicant considered different steps that could influence the level of risk reduction achieved by the process.

The SRM removed is handled according to the requirements foreseen in the ABP Regulation and on its implementing measures laid down in Reg. 142/2011 and subsequently sent for incineration in an approved incineration plant.

The exhaust air generated by the process is passed through a filter to remove chemical gases. However, no clear information is given on the gases generated by the process (the applicant reports that these are mainly water vapours and ammonia) neither on the measure of the effect of such filter in reducing the quantity of gases and biological hazards which may be released into the environment.

The waste water resulting from the cleaning of the equipment is collected in tanks and then disposed of according to current legislation.

The fate of the water generated during the drying process is not described.

8. Risk associated with the intended end use of the product

According to the applicant, since the end product is sterile, there is no risk for human and animal health and the environment.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- The application concerns treatment of Animal By-Products of Category 2 and 3, as defined in the Regulation (CE) 1069/2009, for organic fertilisers. The standard processing method to be used for this purpose, called method 1, is specified under Regulation (EU) 142/2011.
- The hazard identification was not adequately addressed since the most resistant organisms (including TSE agents) were not properly identified.
- The process proposed by the applicant has not been properly validated experimentally under real scale conditions. Moreover, it is not certain that the values of the parameters used in the laboratory experiment would be homogenously reached in all the material under real scale conditions.
- The results of the laboratory experiment performed are not clear and do not allow a proper assessment of the level of risk reduction of the relevant biological hazards achieved by the process.
- Major deficiencies were noticed in the HACCP plan provided.
- There is no evidence that the proposed alternative method is equivalent to processing method 1 described under Regulation (EU) 142/2011, in terms of $\log_{10}$ reduction of the relevant hazards, including TSE agents.

RECOMMENDATIONS

- To assess alternative methods, the relevant hazards and their level of inactivation to be targeted by the processing methods for Cat. 2 animal by-products should be specified in a more precise and detailed way.
- To facilitate the assessment of the alternative methods for the treatment and the specific use of the Cat. 2 material under consideration i) test organisms with defined resistance patterns should be specified; and ii) the required level of quantitative reduction of such organisms should also be provided.

DOCUMENTATION PROVIDED TO EFSA

1. 'Biomation' application. November 2011. Submitted by the Animal Health and Veterinary Laboratories Agency, London, UK.

REFERENCES

EFSA Panel on Biological Hazards (BIOHAZ), 2010. Statement on technical assistance on the format for applications for new alternative methods for animal by-products. EFSA Journal, 8(7), 12 pp.