

SCIENTIFIC OPINION

FuelCal[®] technology as new alternative method of disposal or use of animal by-products¹

Scientific Opinion of the Panel on Biological Hazards

(Question No EFSA-Q-2007-178)

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PANEL MEMBERS

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SUMMARY

Following a request from the Polish Competent Authority, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the FuelCal[®] technology as a new alternative method of disposal or use of animal by-products.

The application concerns a chemical-physical treatment for Category (Cat.) 2 or Cat. 3 Animal By-Products (ABPs) as defined in Regulation (EC) 1774/2002² as amended, that uses lime as the reagent. The concerned ABPs are initially shredded or milled in order to obtain a homogenous ABP pulp which is then fed by hermetic dosing devices in a mixer together with the reagent (lime). The mixture is then moved to a reaction chamber where heating, sterilization and drying process continue. After that the product is removed from the reaction chamber, cooled and stored. The end product obtained is intended to be used as a fertiliser or in co-incineration.

The BIOHAZ Panel concluded that, on the basis of the documentation submitted, it was not possible to assess the safety of the FuelCal[®] process applied on Cat. 2 and 3 ABPs.

The Panel recommended that the dossiers received by EFSA comply with the “Guidelines for applications for new alternative methods of disposal or use of animal by-products” prepared

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² 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. (OJ L 273, 10.10.2002, p. 1–95). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:273:0001:0095:EN:PDF>.

jointly by the Health and Consumer Protection Directorate-General and EFSA³ in order to contain the relevant information necessary to carry out the requested assessment. In particular, the alternative methods should provide at least the same level of safety as that provided by using the standard method required by Regulation (EC) No 1774/2002 for the category material under consideration.

Key words: Animal By-Products, Alternative Processes, Chemical-physical Treatment, FuelCal[®], Safety

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³ 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

BACKGROUND AS PROVIDED BY THE POLISH COMPETENT AUTHORITY

No background information was provided by the Polish Competent Authority.

TERMS OF REFERENCE AS PROVIDED BY THE POLISH COMPETENT AUTHORITY

The Polish Competent Authority asked EFSA to assess the safety of FuelCal[®] technology as a new alternative method of disposal or use of animal by-products.

ACKNOWLEDGEMENTS

The European Food Safety Authority wishes to thank the members of the Working Group on ABP FuelCal[®] and Bunker System for the preparation of this opinion: John Griffin and Christophe Nguyen-The (Rapporteur).

ASSESSMENT

1. Introduction

The terminology used in this assessment conforms with 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 the European Food Safety Authority (EFSA) (EC, 2008).

The dossier provided by the Applicant consisted of a documentary report, an operational manual and some scientific papers dealing with the technology.

The proposed process technology (FuelCal[®]) is a chemical-physical treatment for Category (Cat.) 2 or Cat. 3 Animal By-Products (ABPs) as defined in Regulation (EC) 1774/2002 (EC, 2002) as amended, that uses lime as reagent. In the documentation provided, it is not clear whether the ABPs that can be used in the process can originate from all material included in the list of Cat. 2 and Cat 3 ABPs. The text in the Risk Categories section of the documentary report indicates that all types of Cat. 2 and Cat. 3 material can be processed. However, in the section of the operational manual describing the process, reference is only made to ABPs from slaughterhouses and meat processing plants.

Two possibilities for processing the material are foreseen: directly on site or outside the slaughterhouse in dedicated processing plants.

The ABPs are initially shredded or milled to sizes below 12 mm. For the material that is to be processed at a dedicated processing plant, the shredding can be done either at the slaughter plants or at the processing plant.

If storage is necessary, the material is collected in storage silos and may be treated with a FeSO₄*7H₂O saturated solution. The aim of this operation is to create conditions protecting the shredded material against biological decay and for odour abatement.

When the ABPs are being processed outside the slaughterhouse, raw animal by-products or shredded homogenous animal by-product pulp are collected in collecting containers or at collecting points, from which they are transported to a shredding unit or to storage facilities in the processing plant, using ABP transport installations (not specified in the dossier).

Raw sludge after mixing in homogenising tanks (when the processing takes place in the slaughterhouse) or in collecting buffer tanks (when processing takes place in a dedicated technical plant) is fed by hermetic dosing devices to the inlet of a double shaft mixer, the initial part of the processing reactor. The reagent, very high-reactivity burned milled lime, is supplied to the processing reactor through the same inlet in an automatically controlled manner. The documentary report states that water present in the animal by-product homogenised pulp undergoes an exothermic reaction with the milled lime. However, the operational manual states that water is added into the system at the double-shaft inlet mixer and that ABP pulp is not added to the system until the target temperature is reached in the processor as a result of the exothermic reaction between the added water and the lime. The target temperature defined as the starting point for the process in the received dossier is 60°C. Moreover, it is not clear at which stage the target temperature is reached, since in the documentary report this is reported to be before the passage to the reaction chamber while in the operational manual this is reported to be directly in the reaction chamber. In addition to an increasing temperature, the pH rises above 12 and NH₃ is generated.

The mixture is then moved to a reaction chamber where the heating, sterilization and drying process continues. The minimum retention time is not clear since in one part of the documentary report it is stated to be 8 minutes while in another part this is stated to be 4 minutes. It is not clear how the minimum retention time is reached in case of a continuous process.

After that, the product is removed from the reaction chamber, cooled and stored.

In the documentary report it is not defined whether the procedure is a batch or continuous process. However, in the operational manual, it is stated that this could be either a batch or a continuous process.

The vapours emitted during pulp processing are condensed in a cooling chamber and then collected in a dedicated collecting tank where they are neutralised to a pH ranging from 6.5 to 7.5 with a FeSO₄*7H₂O saturated solution. According to the received dossier, this creates Mohr's salt and gypsum. Mohr's salt after drying can be used as fertiliser additive or added to the final product. Gypsum can be used as an additive to fertiliser.

The condensate after neutralisation is free from gypsum and only has a negligible ammonia content. The measures of this ammonia content are not provided.

According to the dossier the condensate is then redirected to slaughterhouse waste-water treatment plant.

The dossier claims that all odour generating processes are blocked and that, if necessary, the emitted gases are purified using filters with active carbon.

The end product is intended to be used as a fertiliser or in co-incineration.

2. Risk categories

Cat. 2 and Cat. 3 ABPs as defined in the Regulation (CE) 1774/2002 (EC, 2002) as amended.

3. Identification and characterisation of risk materials

In the documentation provided, it is not clear whether the ABPs that can be used in the process can originate from all material included in the list of Cat. 2 and Cat. 3 ABPs or from slaughterhouses and meat processing plants or only from slaughterhouses.

In the absence of any accurate description of the ABPs intended to be processed in the dossier, all ABPs of Cat 2 and 3 must be considered.

The relevant pathogens are not identified.

4. Agent risk reduction

This point is not satisfactorily addressed in the dossier.

No experimental validation on the reduction of relevant pathogens or indicators is provided. There is no experimental evidence in the dossier to demonstrate that the process in fact achieves the conditions proposed to inactivate pathogens (i.e. temperature higher than 60°C, for at least 8 min at pH above 12).

According to Regulation (EC) 1774/2002 (EC, 2002) as amended, Cat. 2 ABPs intended to be composted to produce fertilisers should be treated with method 1 (133°C / 20 min / 3 bars / 50 mm particle size). Therefore, the proposed process should achieve an equivalent risk reduction.

The Applicant proposes to follow method 7 of Regulation (EC) 1774/2002 (EC, 2002) as amended, which does not indicate any physical or chemical treatment. With this method, verification is required over one month on a daily basis that the end product from the method complies with some microbiological criteria. Method 7 does not permit the risk reduction to be assessed as it does not require the measurement of the level of the relevant hazards in the starting material.

The provided literature review is mainly concerned with treatment of substrates other than ABPs from slaughterhouses or meat processing plants (e.g. sewage sludge, municipal and industrial wastes) under different conditions compared to the ones in operation during the proposed process. In addition, some of the relevant pathogens potentially present in the material to be treated are not considered in the literature provided.

5. Risk containment

The dossier states that members of staff taking care of the process (supervising processing operations or dealing with ABP pulp) have no possibility of contact with any other category materials in the slaughterhouse.

The dossier claims that there are no possibilities for the material to bypass the different steps of the process. However, no procedures capable of demonstrating this are provided.

The dossier states that the same chemical agents used at slaughterhouses are used as decontaminants for the elements used in loading/re-loading phases, which are washed at the end of the operations.

The dossier states that the washing and sterilization procedures are similar to the ones prescribed for slaughterhouses. These procedures are not described. Any spent liquid or spilled material should be added to fresh homogenised pulp for re-processing.

In the documentary report, there is no information given on the minimum size of the shredded material and on the homogenisation procedure. However, in the operational manual the maximum particle size is defined to be <12mm. It is not clear how this parameter is monitored. The documentary report states that the responsibility for this belongs to the shredding system suppliers.

The dossier states that a temperature above 60°C is reached in the double shaft mixer. The temperature is measured continuously, and registered in a computer disk for documentation, at the outlet from the double shaft mixer to the inlet of the reactor chamber. It is not clear at which stage the target temperature is reached, since in the documentary report this is reported to be before the passage to the reaction chamber while in the operational manual this is reported to be directly in the reaction chamber.

In the case of processing temperature failure, the ABP dosing system is automatically stopped and the reagent supplying continues with the extraction valve closed until the target temperature conditions are reached. The documentation indicates that there are temperature measures only at the outlet from the double shaft mixture and in the reactor chamber. Consequently, processing temperature failure can only be detected after the material has entered the reactor chamber. In addition, the steps at which the temperature is measured along the process are not consistently described throughout the dossier. It is not clear what procedures are in place to ensure that such material is processed at the required temperature for the appropriate time period.

It is not clear what is the minimum retention time, since in the dossier two different values (8 and 4 minutes) are given. It is not clear how the retention time is measured if pulp is added during stabilised processing conditions in the reaction chamber and if the process is run continuously.

In the case of reagent feeding failure, the system automatically stops. It is not described how this can be achieved.

The dossier states that products not meeting the standards of production are collected separately and re-processed together with fresh ABP material. It is not clear how the standards of production are controlled.

In the reaction chamber, the pH raises above 12 and NH₃ is generated. However, in the documentation provided there is no description of how, and how frequently pH and NH₃ are measured.

The operational manual states that the processing line is operated automatically only with stable pulp quality while the documentary report indicates that the entire reaction process is fully automated.

To prevent the emission of ammonia gases, the vapours emitted during pulp processing are condensed in a cooling chamber and then collected in a dedicated collecting tank where they are neutralised to a pH ranging from 6.5 to 7.5 with a FeSO₄*7H₂O saturated solution.

According to the dossier, the condensate is then redirected to slaughterhouse waste-water treatment plant. It is not clear what happens when the processing plant is not placed in a slaughterhouse plant.

The dossier reports that, if necessary, the emitted gases are purified using filters with active carbon. It is not clear whether this treatment is needed or not.

The dossier claims that all odour generating processes are inactivated.

The operational manual states that the chemical reactions continue after the product is extracted from the reaction chamber. It is not clear where and for how long the product should be kept before being commercialised.

6. Identification of interdependent processes

Although the dossier states that the material is supplied directly from the slaughterhouse, a storage phase (container) is described. It is not clear how long it will remain in the silos and whether or not it will be treated with the $\text{FeSO}_4 \cdot 7\text{H}_2\text{O}$ saturated solution, since in one part of the dossier this treatment seems to be necessary whereas in other parts it seems to be necessary only in case of temporary storage or in case of long storage periods.

Moreover, the threshold for a long storage period is not defined.

The dossier states that the material is strictly separated from external environment and Cat. 1 material.

When the material is processed in dedicated processing plants, a transport phase is not considered. The risk of spillage is addressed and the dossier states that unloading or re-loading facilities are equipped with devices (pumps, conveyors) to transfer back the spilled material to the temporary storage tank. No decontamination procedures are described.

7. Intended end-use of the products

Fertiliser or co-incineration.

8. Documentary evidence

A flow diagram is provided to illustrate the functioning of the process. However, the Applicant states that this should be regarded as an example only, since the processing line configuration reflects local conditions.

No HACCP procedures are provided.

No results of parameter monitoring (temperature, pH, ammonia, time) are presented. Target values are given for temperature, pH, time of treatment, but not for ammonia concentration, although the latter is presented as contributing to the inactivation of pathogens.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- The application concerns treatment of Animal By-Products of Category 2 and 3, as defined in the Regulation (CE) 1774/2002 (EC, 2002) as amended. The end products are intended to be used as fertilisers or to be co-incinerated.
- The relevant biological hazards are not properly identified.
- The origin and nature of the raw material is not clearly defined. Some aspects in the description of the process are unclear.
- Because of a lack of information in the report, it is not possible to determine the degree of risk reduction of pathogenic agents achieved by the process.
- Some deficiencies were noted by the Panel in relation to the risk containment and in the procedures for identifying and dealing with risks arising from interdependent processes.
- Therefore, on the basis of the documentation submitted, it is not possible to assess the safety of the FuelCal[®] process applied on Category 2 and Category 3 Animal By-Products.

RECOMMENDATIONS

The dossiers received by EFSA should comply with 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 and the European Food Safety Authority in order to contain the relevant information necessary to carry out the requested assessment. In particular, the alternative methods should provide at least the same level of safety as that provided by using the standard method required by Regulation (EC) No 1774/2002 for the category material under consideration.

DOCUMENTATION PROVIDED TO EFSA

1. Letter and Application submitted by the Polish Competent Authority on 11 September 2007.
2. Letter and English translation of the Application mentioned in point 1. submitted by the Polish Competent Authority on 19 February 2008.
3. Letter and additional documentation submitted by the Polish Competent Authority on 15 September 2008.
4. Letter and additional documentation submitted by the Polish Competent Authority on 23 October 2008.

REFERENCES

- 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. (OJ L 273, 10.10.2002, p. 1–95). <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:273:0001:0095:EN:PDF>.
- 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.