European Food Safety Authority

The EFSA Journal (2009) 971, 1-12

SCIENTIFIC OPINION

Project to study alternatives to carcass destruction systems using the bunker system[1]

Scientific Opinion of the Panel on Biological Hazards

(Question No EFSA-Q-2008-713)

Adopted on 21 January 2009

PANEL MEMBERS

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SUMMARY

Following a request from the Spanish Competent Authority, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the Project to study alternatives to carcass destruction systems using the bunker system.

The application concerns an on-farm combination of several steps. The first of these is represented by the hydrolysis process or, alternatively, the crushing and pasteurization of pig carcasses and other pig by-products (placentas and embryos) using a bunker system; the process can be stopped here and the product obtained can be packaged in hermetically sealed containers to be transported from the farm for processing according to the approved methods for Category (Cat.) 2 Animal By-Products (ABPs) as defined in Regulation (EC) 1774/2002[2], as amended. After the processing of the material using one of the two above mentioned processes, the material obtained could be co-treated with pig slurry using separation of the solid and liquid fractions through ionic transfer mediated by a polymer. According to the Applicant, the end product obtained from the latter step is intended to be used for composting or for an undefined "tertiary use".

The BIOHAZ Panel concluded that, on the basis of the documentation submitted, it was not possible to assess the safety of the hydrolysis process applied on Cat. 2 materials before co-

[1] For citation purposes: Scientific Opinion of the Panel on Biological Hazards on a request from the Spanish Competent Authority on the Project to study alternatives to carcass destruction systems using the bunker system. *The EFSA Journal* (2009) 971, 1-12

[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.

treatment with pig slurry. Moreover, insufficient information was provided as regard to the crushing and pasteurisation and the co-treatment with pig slurry steps.

The Panel further concluded that the hydrolysed material, which is referred to as an "intermediate product" in the application, would not pose an additional risk provided it is further processed according to the provisions for Cat. 2 materials of Regulation (EC) 1774/2002[2], as amended.

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 jointly by the Health and Consumer Protection Directorate-General and EFSA[3] 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, Hydrolysis, Pig Carcasses, Bunker System, Safety

[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

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BACKGROUND AS PROVIDED BY THE SPANISH COMPETENT AUTHORITY

1. Background

Article 15 of Royal Decree no 1429/2003 creates Spanish National Commission For Animal By Products Not Intended For Human consumption, as collegiate body for coordination, advising and dialogue regarding ABPs. This Commission is composed by every department with competences regarding ABPs and between its duties, also established in the same royal decree, to suggest carrying out studies or research projects with regards to by-products.

Moreover, annex II of document SANCO/l0060/2006 "Guidelines for applications for new alternative methods of disposal or use of animal by-products under Regulation (EC) no 177412002", lays down the Secretariat of Spanish Commission as the contact points for the applications sent from Spain.

2. Completion of experiments

The main livestock producers for non ruminant species asked the Spanish National Commission for the need to search for alternatives to current fallen stock collecting system, and disposal based on incineration. The main reasons for this proposal *were the* following:

Current systems involve some risks sanitary status, jeopardizing the bio security conditions of farms, related with frequent transit of lorries carrying out the fallen stock collection from farm to farm.

That transit also means some problems related with environmental and public health issues, stemmed from leak risks associated to ABP transport. That system also generates a negative opinion between public opinion

The fallen stock collection system, even as it is partially subsidized by Civil Service, involves a high cost for livestock farmers, hard to transfer to other links within the food chain. Thus, it makes the competitiveness of farms more difficult and its position on that food chain weaker.

The action proposed by main livestock producers for non ruminant species means studying alternatives for use of fallen stock inside the own farm by means of systems allowing an adequate and safe disposal, within environmental and economic sustainability principles. Experiences are based on simple system reproducing the natural carcass rotting conditions, also cutting down on need for collecting carcasses too often, and so on the main inconvenient before related. Thus, three systems were selected as priorities:

Hydrolysis based system on a waterproof vat: hydrolization system does not but accelerate the phases that in natural conditions occur in animal corpses, taking profit of the presence of their natural enzymes, the control of process conditions and the addition of a natural bio activator.

Composting based systems on open and closed conditions: composting systems allows an integral use of farm by-products, obtaining a quality product valued for its application to crops. Those reasons make it one of the most valuated systems of disposing of carcasses throughout the world as, for example, in USA or Canada.

Isolation in a waterproofed pit, with addition of quicklime: it has been one of the most used in Spain traditionally allowing an adequate disposal without health or environmental risks.

There were engaged research teams to carry out with experiences. Those teams were selected based on their independence and wide renown in every single method studied. It was created also a Commission composed by technicians of civil service with competences on ABPs, and

the main livestock sectors representatives. That commission was entrusted to monitor the developing of experiences from an environmental, public health and animal health scope.

Every experience was carried out based on a protocol designed from specialized staff from civil service, with the aim of to blend parameters to study and working methodology.

The experiences were developed from April 2005 to November 2005, and the final reports in which the main results were included were finished 15th November 2005.

Those reports were evaluated at first by the Monitoring Commission, and then were submitted to working groups involved in development of Spanish National ABP Plan on the issues related with fallen stock collection and new technologies regarding ABP transformation. All those groups presented their objections and contributions that were included in the final reports, which were modified, where appropriate.

Nevertheless, publication of document SANCO/10060/2006 "Guidelines for applications for new alternative methods of disposal or use of animal by-products under Regulation (EC) no 1774/2002" meant a new scope in the applications presentation requirements. Since final reports were already finished, it was necessary to adapt that presentation to new requirements pointed by point 3 of aforementioned guidelines. It meant a delay for the submission of the applications.

Once approved from a technician level, the final reports were submitted for approval to Spanish ABPs National Commission, which presented some objections as well to modify the reports before approving them. The first two reports were officially approved by the Spanish ABP Commission during the plenary held on 4 October 2006, with the mandate to send them to European Commission in order to approve them as new alternative methods, asking first to EFSA for a scientific opinion. The present application was approved in the last plenary meeting of the Spanish ABP Commission, held in Madrid on 5 March 2008.

The results of the process above mentioned are the final reports of experiences carried out, in which Competent Authorities have cooperated closely in the beginning of that process, with the design of the protocol in which are based, during the developing of experiences, by means of the Monitoring Commission that evaluated periodically the experiences, and in the end of the process, by means of forwarding the final reports to a technicians composed working groups and submit to Spanish National Commission for its consideration and approval.

Finally, it also collaborated in the development of the new application according to the basic presentation required by point 3 of Guidelines for applications for new alternative methods of disposal or use of animal by-products under Regulation (EC) no 1 774/2002. Thus, Spanish Competent Authorities have followed the recommendations pointed by point 2.2.1 of aforementioned guidelines, cooperating closely with the applicants and giving legal and technical advice always without, on the other hand, reducing independence and scientific criteria of research teams regarding results obtained and main conclusions raised from experiences final reports.

3. Evaluation of the application

The main objective of the method proposed is to demonstrate that the product obtained through a natural hydrolysis of the carcasses could be considerer in the same risk conditions as pig slurry, due to its Physical-chemical specifications and microbiological load. Thus, it can be used in the same way as the pig slurry can, according to point 5.2.e) of the Regulation

(EC) 1774/2002, be used without further processing as raw material in a biogas plant or composting plant or applied to land in accordance with ABP regulation.

The application also describes the use of this product for the co-treatment with pig slurry using ECOPURIN® technology, to separate solid and liquid fraction.

The final product is then homogenised and could be used for the aforementioned fates avoiding any arising risks.

Finally, the process suggests the use of a crushing and pasteurisation process using parameters of method (133°C/20 min./3 bars/50 mm particle size).

The process, then is based on two basic considerations:

- The process of hydrolysis can be considered as safe by evaluating the microbiological and environmental risks and the rest of potential risks. Those risks have been evaluated by direct measures, in the case of microbiological and environmental risks, and applying a prevention program based in HACCP principles when considering additional risks.
- The final product obtained of the hydrolysis has equal risk consideration that pig slurry. The co-treatment applied then homogenizes the final product in order to ensure a risk containment, both for pig slurry and hydrolysed carcasses.

TERMS OF REFERENCE AS PROVIDED BY THE SPANISH COMPETENT AUTHORITY

The Spanish Competent Authority asked EFSA to assess the safety of systems based on bunker system process as alternatives to carcass destruction methods.

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 (Rapporteur) and Christophe Nguyen-The.

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).

1.1. Outline of the process

The proposed process is an on-farm combination of several steps:

- Hydrolysis processing of pig carcasses and other pig by-products (placentas and embryos); the process can be stopped here and the product obtained can be packaged in hermetically sealed containers to be transported from the farm for processing according to the approved methods for Category (Cat.) 2 Animal By-Products (ABPs) as defined in Regulation (EC) 1774/2002 (EC, 2002) as amended;

or alternatively

- Crushing and pasteurizing of pig carcasses and other pig by-products (placentas and embryos); the process can be stopped here and the product obtained can be packaged in hermetically sealed containers to be transported from the farm for processing according to the approved methods for Cat. 2 ABPs.

After the processing of the material using one of the two above-mentioned processes the material obtained could be co-treated with pig slurry using separation of solid and liquid fraction through ionic transfer mediated by a polymer. According to the Applicant, the end product obtained from the latter step is intended to be used for composting or for an undefined "tertiary use".

Insufficient information is provided on the crushing and pasteurisation (i.e. particle size, treatment time and temperature) and the co-treatment with pig slurry steps. It is not clear either if crushing and pasteurisation can be combined with hydrolysis, and if so under what conditions. Hence, the following process description concerns only the hydrolysis process alone.

1.2. The equipment

According to the received dossier, the hydrolysis is carried out in a hermetically sealed vat placed outside the installations where the animals are kept.

The vat is divided in four hermetically sealed compartments to be filled in respectively in a specific season of the year (winter, spring, summer and autumn).

Since the hydrolysis is influenced by the external temperature, the compartments have different dimensions according to the season (winter 113.75m^3, spring and autumn 70m^3, summer 56m^3).

It is not clear what happens if the quantity of fallen animals exceeds the storage capacity of a compartment of the vat. Moreover, the mortality rate could be higher in the period for which the smallest compartment is foreseen (summer).

1.3. The raw material

Carcasses from fallen animals, placentas and embryos are collected every day.

A macroscopic presumptive diagnosis is performed in order to rule out the presumptive presence of a notifiable disease.

It is not clear whether the process is intended to be used also in the case of a disease outbreak or in case of risk due to residues of veterinary medicines. The documentary report received from the Spanish Competent Authority says that in case of a communicable disease, the vat concerned can easily be emptied and the carcasses collected and processed according to Regulation (EC) 1774/2002 (EC, 2002) as amended.

1.4. The hydrolysis

Carcasses, placentas and embryos are then placed into the appropriate compartment.

The compartment is then closed and the hydrolysis process can start. In the experiments described in the dossier, the compartments were closed 1.5 to 3 months after filling had commenced.

In the dossier, no target temperatures for the hydrolysis are given.

The minimum retention time foreseen for the hydrolysis process is not clear. In the case of partial emptying of a compartment, this is defined to be 3 months, whereas in the case of total emptying, this is considered to be 9 months. In another section of the dossier, the treatment is said to take between 6 and 9 months. In some experiments described, the last samples were taken before 6 months.

The aim of the application is to demonstrate that after the hydrolysis process the material can then be considered to pose the same biological risk as pig slurry.

1.5. End product

When the hydrolysis phase is considered to be completed, the material can:

1. be treated as an “intermediate product” and collected in hermetically sealed containers. In this way, the hydrolysed material can be transported outside the farm and processed and used according to the provisions of Regulation (EC) 1774/2002 (EC, 2002) as amended, for Cat. 2 material; or
2. be added to pig slurry for co-treatment using separation of solid and liquid fraction through ionic transfer mediated by a polymer.
3. According to the dossier received, the product of the co-treatment can eventually be used for composting or for an undefined “tertiary use”. However, according to the documentary report provided by the Spanish Competent Authority the end-use of the product of the co-treatment is represented by Article 5.2 (e) of Regulation (EC) 1774/2002.

2. Risk categories

Cat. 2 material as defined in the Regulation (EC) 1774/2002 (EC, 2002) as amended.

3. Identification and characterisation of risk materials

In the dossier presented, it is not clearly stated what kind of pig material can undergo the process.

However, in the documentary report provided by the Spanish Competent Authority it is stated that the materials to be processed are pig slurry, pig carcasses, pig placentas and embryos.

A physico-chemical characterisation of the materials to be processed (for pig carcasses during the storage phase in the vat and from pig slurry) was performed.

Although the microbiological analyses (for pig carcasses during the storage phase in the vat and from pig slurry) took into account aerobic mesophilic bacteria, Clostridium sulphite reducing bacteria, *Escherichia coli*, fungi, *Salmonella spp.*, *Shigella spp.* and Porcine Parvovirus, not all the relevant pathogens were identified.

4. Agent risk reduction

Generally, Cat. 2 material, which includes the carcasses of animals that die on-farm, should be treated according to method 1 of Annex V of Regulation (EC) 1774/2002 (EC, 2002) as amended (i.e. 133°C / 20 min / 3 bars / 50 mm particle size) before being used in composting or biogas plants (Article 5. 2 (c) of the regulation). However, pig slurry, also a Cat. 2 material, can be directly used in composting and biogas treatment plants, according to the EC regulation (Article 5. 2 (e)). Therefore, before being co-treated with pig slurry as proposed in the dossier, carcasses of pigs dead on the farm should be treated according to method 1 of Annex V of Regulation (EC) 1774/2002 (EC, 2002) as amended, or with a process (hydrolysis in the dossier) giving the same risk reduction. Alternatively, the whole process, including both the pig carcasses hydrolysis and the co-treatment with pig slurry, should achieve the same risk reduction as method 1.

In addition, the Regulation (EC) 1774/2002 (EC, 2002) as amended states for Cat. 2 materials in Annex VI that “Samples of processed products destined for biogas or composting plants or landfill, taken directly after heat treatment, must be free from heat-resistant pathogenic bacteria spores (*Clostridium perfringens* absent in 1 g of the products)”. The end product after co-treatment of hydrolysed carcasses and pig slurry should therefore meet this requirement.

It must be remembered that the risk reduction can only be measured if the agent is present in sufficiently high numbers in the material before treatment.

In general, considering the hydrolysis process, the samples taken did not show an appropriate risk reduction.

This is due to the fact that either the microbiological parameters taken did not show a real reduction (e.g. Aerobic mesophilic bacteria, Clostridium sulphite reducing bacteria, fungi) or the identified indicators were not present (or present at very low concentration) at the start of the process (e.g. *Shigella spp.*, *E. Coli*).

A certain reduction was shown for *Salmonella spp*. (in the spring bunker vat) and for Porcine Parvovirus. However, the reduction shown for *Salmonella spp*. was only in the order of magnitude of 3 $\log_{10}$, and for Porcine Parvovirus the performed analysis was only a presence/absence assessment and did not permit the level of reduction achieved to be measured.

The carcass hydrolysis product contains a considerable population of Clostridium sulphite reducing bacteria, the fate of which during the co-treatment with pig slurry is not presented in the dossier.

5. Risk containment

The dossier addresses this point in detail for each step of the process, also if not in the context of a formal HACCP analysis.

Concerning the raw material, the dossier proposes to avoid treatment of animals that die from a notifiable disease, but this is not described in the risk containment analysis.

Appropriate corrective measures are not always identified and, in particular, no corrective measures are identified for the hydrolysis phase. Similarly, corrective measures to be taken whenever the quantity of fallen animals exceeds the capacity of the system are not given.

No parameters for the hydrolysis phase are given except for time. However, the minimum retention time foreseen is not clear. In case of partial emptying of a compartment, this is defined to be of 3 months, whereas in case of total emptying this is considered to be 9 months. In particular, the influence of temperature on the process is not described and no target temperatures for the hydrolysis are given. It is not clear how external temperatures could influence the fate of the hydrolysis process to be carried out in the vat. This poses a question regarding the suitability for application of the process outside the Spanish region (Murcia) in which the experiment was performed (e.g. Nordic countries).

Gas emissions are controlled using chimneys with active carbon filters.

As regard to the crushing and pasteurisation step, although the documentary report provided by the Spanish Competent Authority states that the parameters of method 1 of Regulation (EC) 1774/2002 (EC, 2002) as amended (133°C / 20 min / 3 bars / 50 mm particle size) are used, no such information is given in the dossier. On the contrary, at the end of the introduction, the dossier mentioned, for crushing and pasteurisation: "the total elaboration of the process will depend on the size of the particle, the temperature and the pressure applied", indicating that conditions are not fixed. Moreover, the basis on which the choice of crushing and pasteurisation, versus hydrolysis, is made is not explained

6. Identification of interdependent processes

The possible storage and transport of hydrolysed material as an “intermediate product” is not explicitly identified. However, this is addressed in a certain way in the dossier provided as being part of the risk containment.

7. Intended end-use of the products

The dossier claims that the hydrolysed material:

- can be further processed, as an “intermediate product”, according to the provisions of Regulation (EC) 1774/2002 (EC, 2002) as amended for Cat. 2 material; or
- can be added for co-treatment to pig slurry to be used for composting or for an undefined “tertiary use”. However according to the documentary report provided by the Spanish Competent Authority, the end-use of the product of the co-treatment is represented by Article 5.2 (e) of Regulation (EC) 1774/2002.

8. Documentary evidence

A flow diagram was provided to illustrate the functioning of the process.

No precise information was provided regarding the crushing and pasteurization step.

The co-treatment process of hydrolysed carcasses with pig slurry was not presented and it is not clear whether this process could contribute to risk reduction.

A proper HACCP analysis was not provided.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- The application concerns treatment of Animal By-Products of Category 2, as defined in the Regulation (CE) 1774/2002 as amended, one of the purposes being the co-treatment with pig slurry. Several aspects in the description of the process are unclear. Some usages of the end products obtained after co-treatment are not fully defined.
- The identification and characterisation of the risk material is not properly addressed in the trial and a comprehensive list of possible risks is not provided.
- Because of a lack of information in the report, it is not possible to determine the degree of risk reduction of pathogenic bacterial, viral and parasitological agents achieved by the process.
- Some deficiencies were noted by the Panel in relation to the risk containment and 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 process applied on Category 2 materials before co-treatment with pig slurry.
- Insufficient information is provided on the crushing and pasteurisation and the co-treatment with pig slurry steps.
- The hydrolysed material, which is referred to as an "intermediate product" in the application, would not pose an additional risk provided it is further processed according to the provisions for Category 2 materials of Regulation (EC) 1774/2002 as amended.

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, Documentary Report and Application submitted by the Comisión National de Subproductos Animales No Destinados A Consumo Humano on 24th September 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.

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