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Evaluation of the application for a new alternative processing method for animal by-products of Category 3 material (ChainCraft B.V.)

EFSA Panel on Biological Hazards (EFSA BIOHAZ Panel),
Antonia Ricci, Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Lucy Robertson, Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall, Helene Wahlström, Rosina Girones, Avelino Alvarez Ordoñez, John Griffin, Sandra Correia and Pablo Fernández Escámez

Abstract

EFSA received an application from the Dutch Competent Authority, under Article 20 of Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, for the evaluation of an alternative method for treatment of Category 3 animal by-products (ABP). It consists of the hydrolysis of the material to short-carbon chains, resulting in medium-chain fatty acids that may contain up to 1% hydrolysed protein, for use in animal feed. A physical process, with ultrafiltration followed by nanofiltration to remove hazards, is also used. Process efficacy has been evaluated based on the ability of the membrane barriers to retain potential biological hazards present. Small viruses passing the ultrafiltration membrane will be retained at the nanofiltration step, which represents a Critical Control Point (CCP) in the process. This step requires the Applicant to validate and provide certification for the specific use of the nanofiltration membranes used. Continuous monitoring and membrane integrity tests should be included as control measures in the HACCP plan. The ultrafiltration and nanofiltration techniques are able to remove particles of the size of virus, bacteria and parasites from liquids. If used under controlled and appropriate conditions, the processing methods proposed should reduce the risk in the end product to a degree which is at least equivalent to that achieved with the processing standards laid down in the Regulation for Category 3 material. The possible presence of small bacterial toxins produced during the fermentation steps cannot be avoided by the nanofiltration step and this hazard should be controlled by a CCP elsewhere in the process. The limitations specified in the current legislation and any future modifications in relation to the end use of the product also apply to this alternative process, and no hydrolysed protein of ruminant origin (except ruminant hides and skins) can be included in feed for farmed animals or for aquaculture.

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Correspondence: biohaz@efsa.europa.eu

Panel members: Ana Allende, Declan Bolton, Marianne Chemaly, Robert Davies, Pablo Salvador Fernández Escámez, Rosina Girones, Lieve Herman, Konstantinos Koutsoumanis, Roland Lindqvist, Birgit Nørrung, Antonia Ricci, Lucy Robertson, Giuseppe Ru, Moez Sanaa, Marion Simmons, Panagiotis Skandamis, Emma Snary, Niko Speybroeck, Benno Ter Kuile, John Threlfall and Helene Wahlström.

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Summary

On 8 August 2017, the European Food Safety Authority (EFSA) received from the Netherlands Food and Consumer Product Safety Authority, Ministry of Economic Affairs (Competent Authority) an application (mandate and technical dossier) for the evaluation of an application of the company ChainCraft B.V. (hereinafter referred to as the Applicant) for the approval of an alternative method for treatment of Category 3 material, as foreseen in Article 20 of Regulation (EC) No 1069/2009. Category 3 of animal by-products (ABP) is the lowest risk category. It includes parts of animals that have been considered fit for human consumption in a slaughterhouse but which are not intended for human consumption for commercial or other reasons. Category 3 ABP also includes catering waste and products of animal origin, or foodstuffs containing products of animal origin which are no longer intended for human consumption for commercial reasons, or due to manufacturing, or packaging defects or other defects that do not pose a risk to public or animal health.

The proposed alternative method consists of the hydrolysis of Category 3 material to short-carbon chains, resulting in a mixture of volatile fatty acids. The volatile fatty acids are fermented, together with ethanol, to medium-chain fatty acids (MCFA). The MCFA, which are present in their salt form, are separated from the fermentation broth and subsequently purified and dried to form the final product which will be used for animal nutrition. The data used in the assessment were provided by the Applicant as requested in Annex VII of Commission Regulation (EU) No 142/2011 and its amendment by Commission Regulation (EU) No 749/2011. A process flow diagram and a Hazard Analysis and Critical Control Point (HACCP) plan were attached to the application dossier. A report submitted by the Competent Authority, related to the application, was also considered.

The feedstock used in the process is Category 3 material. According to the Applicant, materials referred to in Article 10 (o) of Regulation (EC) No 1069/2009 (i.e. adipose tissue) could be used as feedstock but, according to Article 14 d) (i), that type of material together with subcategories 10 (n) and (p) cannot be used for manufacturing feed for farmed animals other than for fur animals.

The end use of the material from the ChainCraft B.V. process is animal feed and, in this case, a physical process, with ultrafiltration followed by nanofiltration to remove hazards, instead of a thermal or chemical inactivation process, is used. In a physical process based on filtration, all hazards present should be retained by the barrier imposed by the membrane depending on their physical characteristics. Therefore, the efficacy of the process has been evaluated based on the ability of that physical process to remove potential biological hazards present in the material. The level of agent risk reduction published in 2005 EFSA 'Opinion on the safety vis-à-vis biological risks of biogas and compost treatment standards of animal by-products (ABP)' was used for this particular case to consider if the process was equivalent to the processing standards laid down in Regulation (the process applied for treatment shall be capable of reducing the concentration of the relevant pathogenic bacteria by at least $5 \log_{10}$ and the infectious titre of the relevant viruses by at least $3 \log_{10}$). Specific information on the size and physical properties of the various hazards that could be present in the feedstock was not provided by the Applicant. Taking into account their size and considering the filtration properties, viruses and bacterial toxins are the most relevant hazards to be taken into account. The possible presence of small bacterial toxins that could be introduced during the fermentation steps cannot be avoided by the nanofiltration step and this hazard should be controlled by a Critical Control Point (CCP) elsewhere in the process. The ultrafiltration membrane used in the process has a mean pore size of 30 nm according to the technical description provided by the Applicant and probably small viral particles may pass through, e.g. *Parvovirus* and *Circovirus* (18–26 nm) and *Picornavirus* (around 30 nm). Small viruses passing the ultrafiltration membrane will be retained at the nanofiltration step, which represents a CCP in the process. The nanofiltration step of this application has not been validated after inoculation of bacteria or viruses to assess the effectiveness of the process. Nonetheless, the ability of nanofiltration to remove viruses when they are artificially inoculated into laboratory models that mimic industrial-scale nanofiltration conditions has been shown. This CCP requires the Applicant to provide validation and certification for the specific use of the nanofiltration membranes used, in addition to conducting continuous monitoring and membrane integrity tests as control measures described in the risk assessment plan.

The end product mainly contains MCFA, but may also contain up to 1% of hydrolysed protein (polypeptides, peptides and amino acids). The limitations specified in the current legislation and any future modifications in relation to the end use of the product also apply to this alternative process, and no hydrolysed protein of ruminant origin (except ruminant hides and skins) can be included in feed for farmed animals or for aquaculture.

The ultrafiltration and nanofiltration techniques are able to remove particles of the size of viruses, bacteria and parasites from liquids. If used under controlled and appropriate conditions, the processing methods proposed should reduce the risk in the end product to a degree which is at least equivalent to that achieved with the processing standards laid down in the Regulation (EC) No 1069/2009 for Category 3 material.

Table of contents

Abstract.....	1
Summary.....	3
1. Introduction.....	6
1.1. Background and Terms of Reference as provided by the Dutch Competent Authority.....	6
1.2. Interpretation of the Terms of Reference.....	6
1.3. Additional information.....	6
2. Data and methodologies.....	6
2.1. Data.....	6
2.2. Methodology.....	7
3. The new process as provided by the Applicant.....	8
3.1. Pre-treatment of Category 3 material.....	11
3.2. Hydrolysis, acidification and solid/liquid separation.....	11
3.3. Fermentation and Ultrafiltration.....	11
3.4. Concentration via reverse osmosis.....	12
3.5. Nanofiltration.....	12
3.6. Ammonia stripping.....	12
3.7. Evaporation and Drying.....	12
3.8. Water treatment.....	13
4. Assessment.....	13
4.1. Material to be treated.....	13
4.1.1. Categories of ABP as provided by the Applicant.....	13
4.1.2. Assessment of the material to be treated by the BIOHAZ Panel.....	14
4.2. Hazard identification.....	14
4.2.1. Hazard identification as provided by the Applicant.....	14
4.2.1.1. Biological hazards.....	14
4.2.1.2. Chemical hazards.....	15
4.2.1.3. Physical hazards.....	16
4.2.2. Assessment of the hazard identification by the BIOHAZ Panel.....	16
4.3. Level of risk reduction.....	16
4.3.1. Level of risk reduction as provided by the Applicant.....	16
4.3.1.1. Particle size.....	16
4.3.1.2. Temperature and time.....	16
4.3.1.3. Pressures.....	16
4.3.1.4. Microbiological criteria and pH.....	16
4.3.1.5. Hydrolysis of carbon chains, ultrafiltration and nanofiltration.....	17
4.3.1.6. Validation.....	17
4.3.2. Assessment of the level of risk reduction by the BIOHAZ Panel.....	18
4.4. HACCP plan.....	19
4.4.1. HACCP plan and CCP, as provided by the Applicant.....	19
4.4.2. Assessment of the HACCP plan by the BIOHAZ Panel.....	20
4.5. Risk associated with interdependent processes.....	20
4.5.1. Risk associated with interdependent processes as provided by the Applicant.....	20
4.5.2. Assessment of the risk associated with interdependent processes by the BIOHAZ Panel.....	21
4.6. Risk associated with the intended end use of the products from the process.....	21
4.6.1. Risk associated with the intended end use of the products from the process as provided by the Applicant.....	21
4.6.2. Assessment of the risk associated with the intended end use of the products from the process by the BIOHAZ Panel.....	21
5. Uncertainty evaluation.....	22
6. Conclusions.....	22
7. Recommendations.....	22
References.....	22
Abbreviations.....	23

1. Introduction

1.1. Background and Terms of Reference as provided by the Dutch Competent Authority

On 8 August 2017, the European Food Safety Authority (EFSA) received from the Netherlands Food and Consumer Product Safety Authority, Ministry of Economic Affairs (Competent Authority) an application (mandate and technical dossier), under Regulation (EC) No 1069/2009¹ and Commission Regulation (EU) No 142/2011², for the evaluation of an application of the company ChainCraft B.V. (hereinafter referred to as the Applicant). An evaluation of the application by the Competent Authority was also submitted to EFSA.

The Applicant submitted an application for the approval of an alternative method for the treatment of Category 3 ABP material as foreseen in Article 20 of the Commission Regulation (EC) No 1069/2009. This alternative method consists of the hydrolysis of Category 3 material to short-carbon chains, resulting in a mixture of volatile fatty acids. The volatile fatty acids are fermented, together with ethanol, to medium-chain fatty acids (MCFA). The MCFA, which are present in their salt form, are separated from the fermentation broth and subsequently purified and dried to form the final product. The application of the final product is animal nutrition.

Category 3 ABP is defined in Article 10 of Regulation (EC) 1069/2009 as the lowest risk category. It includes parts of animals that have been considered fit for human consumption in a slaughterhouse but which are not intended for consumption for commercial or other reasons. Category 3 ABP also includes catering waste and products of animal origin, or foodstuffs containing products of animal origin which are no longer intended for human consumption for commercial reasons or due to manufacturing or packaging defects or other defects that do not pose a risk to public or animal health. Under Commission Regulation (EU) No 142/2011, catering waste means all waste food, including used cooking oil originated in restaurants, catering facilities and kitchens, including central kitchens and household kitchens.

1.2. Interpretation of the Terms of Reference

EFSA evaluated the alternative method proposed by the Applicant under the frame of Article 20 of Regulation (EU) No 1069/2009.

1.3. Additional information

During the assessment for the evaluation of the alternative method, as set out in Article 20 of Regulation (EU) No 1069/2009, it was deemed necessary to request additional information and data from the Applicant on certain technical aspects of the dossier. In particular, the Applicant was asked about some specific parameters (temperature and time) related to the evaporation and drying process steps. The Applicant replied with a general description of the process without detailed specifications.

2. Data and methodologies

2.1. Data

The data used in the assessment were provided by the Applicant as requested in Annex VII of Commission Regulation (EU) No 142/2011 and its amendment by Commission Regulation (EU) No 749/2011³. A process flow diagram and a Hazard Analysis and Critical Control Point (HACCP) plan were attached to the application dossier as well some technical specifications of the membranes systems and of the analysis certificates.

The report submitted by the Competent Authority (CA) related to the application was also considered.

¹ 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, p. 1–33.

² 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, p. 1–254.

³ Commission Regulation (EU) No 749/2011 of 29 July 2011 amending Regulation (EU) No 142/2011 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 198, 30.7.2011, p. 3–22.

Relevant scientific papers provided by experts of the Working Group (WG) were considered during the assessment.

2.2. Methodology

The EFSA Panel on Biological Hazards (BIOHAZ) evaluated the ChainCraft B.V. process by following the steps set out in the 'EFSA Scientific Opinion on the format for applications for new alternative methods for ABP' (EFSA BIOHAZ Panel, 2010). These steps are:

- full description of the process;
- full description of the material to be treated;
- hazard identification;
- level of risk reduction;
- HACCP plan;
- risk associated with interdependent processes;
- risk associated with the intended end use of the product.

The Applicant is required to document as fully as possible the different aspects of each of these steps and according to the CA, the application meets the requirements as laid down in the above mentioned EFSA Opinion.

As set out in Article 20 of European Union Regulation (EC) No 1069/2009, EFSA is required to assess whether the method submitted ensures that the risks to public or animal health are:

- a) *'controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or*
- b) *reduced to a degree which is at least equivalent, for the relevant categories of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).'*

In essence, point (b) above means that the proposed processing method must reduce the risk to a degree that is at least equivalent to that achieved by the processing methods that have already been approved for the same category of ABP.

This requirement for applications is elaborated in the Commission Regulation (EU) No 142/2011 implementing Regulation (EC) No 1069/2009 and amended by Commission Regulation (EU) No 749/2011. According to point 2(d), Chapter II, Annex VII of Commission Regulation (EU) No 142/2011, any application for the evaluation of alternative methods shall *'show that the most resistant biological hazards associated with the category of materials to be processed are reduced in any products generated during the process, including the waste water, at least to the degree achieved by the processing standards laid down in this Regulation for the same category of animal by-products. The degree of risk reduction must be determined with validated direct measurements, unless modelling or comparisons with other processes are acceptable'*.

The validation requirements are further elaborated on in the 2010 EFSA Opinion. According to the Opinion and to section 2, Chapter III, Annex V of Commission Regulation (EU) No 142/2011 (point 1 (c)), the *'validation of the intended process can be performed by measuring the reduction of viability/infectivity of:*

- i) *endogenous indicator organisms during the process, where the indicator is:*
 - *consistently present in the raw material in high numbers,*
 - *not less resistant to the lethal aspects of the treatment process, but also not significantly more resistant than the pathogens for which it is being used to monitor,*
 - *relatively easy to quantify and relatively easy to identify and to confirm; or*
- ii) *a well-characterised test organism or virus introduced in a suitable test body into the starting material.'*

The Opinion states that *'results should be accompanied by evidence'*. Such evidence *'includes, for measurements, information on the methodology used, nature of samples that have been analysed and evidence that samples are representative (e.g. number of samples, number of tests performed and selection of measuring points)*. *If several treatment steps are involved, an assessment should be performed on the degree to which individual titre reduction steps are additive, or whether early steps in the process may compromise the efficacy of subsequent steps. In any case it is necessary to provide*

the sensitivity and specificity of the detection methods applied. Data on the repeatability and statistical variability of the measures obtained during the experiments should also be presented.' It states also that *'Generally, the level of risk reduction for human and animal health which can be achieved by the process should be evaluated on the basis of direct measurements (validation).'*

Should *'no direct measurements of the risk reduction be available (i.e. no validation as defined above is feasible), modelling or comparison with other processes may be acceptable if:*

- i) the factors leading to the risk reduction are well known;*
- ii) the model of risk reduction is well established; and*
- iii) continuous direct measurements of the factors leading to the risk reduction are provided for the full-scale process which demonstrate that these factors are homogeneously applied throughout the treated batch.'*

The standard processing methods are described in Chapter III, Annex IV of Commission Regulation (EU) No 142/2011. The degree of risk reduction achieved by these methods is not specified and no definitive standards have been set down in relation to risk reduction for alternative methods dealing with Category 3 materials. The 2010 EFSA Opinion states that the *'standard already approved for validation of composting processes for Category 3 ABPs can be used as a benchmark for other treatment processes for comparable input material and potential end use.'* In the present assessment, the same rationale for agent risk reduction published in the 2005 EFSA Opinion is used: the process applied for treatment shall be capable of reducing the concentration of the relevant pathogenic bacteria by at least 5 log₁₀ and the infectious titre of the relevant viruses by at least 3 log₁₀ (EFSA, 2005a).

The end use of the material from the ChainCraft B.V. process is animal feed and a physical process based on filtration is used to remove biological hazards. In a filtration process all hazards present should be retained by the barrier imposed by the membrane depending on their physical characteristics (size, charge, membrane affinity, etc.). Therefore, the efficacy of the process has been evaluated based on its ability to remove potential biological hazards, irrespective of the levels of hazards present in the raw material.

The Applicant describes the raw material as Category 3 material and the final product as MCFA that may contain up to 1% of hydrolysed protein. Therefore, the following Regulations concerning the raw materials and the end use of these final products have been considered in the assessment: Regulations (EC) No 1069/2009, Commission Regulations (EU) No 142/2011 and Regulation (EC) No 999/2001 and their amendments.

3. The new process as provided by the Applicant

The description presented in the current chapter has been extracted verbatim from the application, with minor editorial changes for clarity purposes.

The 'alternative method consists of the hydrolysis of Category 3 material', e.g. food waste, 'to short-carbon chains, resulting in a mixture of volatile fatty acids. The volatile fatty acids are fermented, together with ethanol, to MCFA. The MCFA, which are present in their salt form, will be separated from the fermentation broth and subsequently purified and dried to the final product. The application of the final product is animal nutrition.'

'ChainCraft developed a platform technology in order to produce chemical building blocks that are now being produced from crude palm kernel oil or petrochemical sources. This unique patented technology can be integrated into the existing infrastructure of the agri-food industry and uses different types of organic product streams, including Category 3 material, as feedstock.

The process can be divided into seven important steps. The first step is the pre-treatment of Category 3 material. When former foodstuffs are used as feedstock, the products are unpacked. Subsequently the particle size of the feedstock is reduced. In the second step the organic feedstock is hydrolysed and acidified by a mixed culture of bacteria. During the hydrolysis and acidification phase, long carbon chains in the biomass are biodegraded into short chain fatty acids. At the end of the second step, solid particles are removed. In a third step the short chain fatty acids are coupled with ethanol via fermentation to longer chains: the MCFA. At the end of this step, the product is filtered by ultrafiltration. The product is then concentrated by reverse osmosis. In the next step, the product passes through a nanofiltration membrane, which guarantees that all molecules have a molecular weight below 10,000 dalton and no microorganisms and proteins can be present. Subsequently, ammonia is removed by stripping, after which the product flow will pass an evaporation step and drying step, in which the product is dried to a solid powder of fatty acid salts. The application of the

final product is animal nutrition. According to Regulation (EC) No 767/2009, the product can be considered as feed material, suitable for all animal species.'

The process with its main seven steps can be visualized in Figure 1 below.

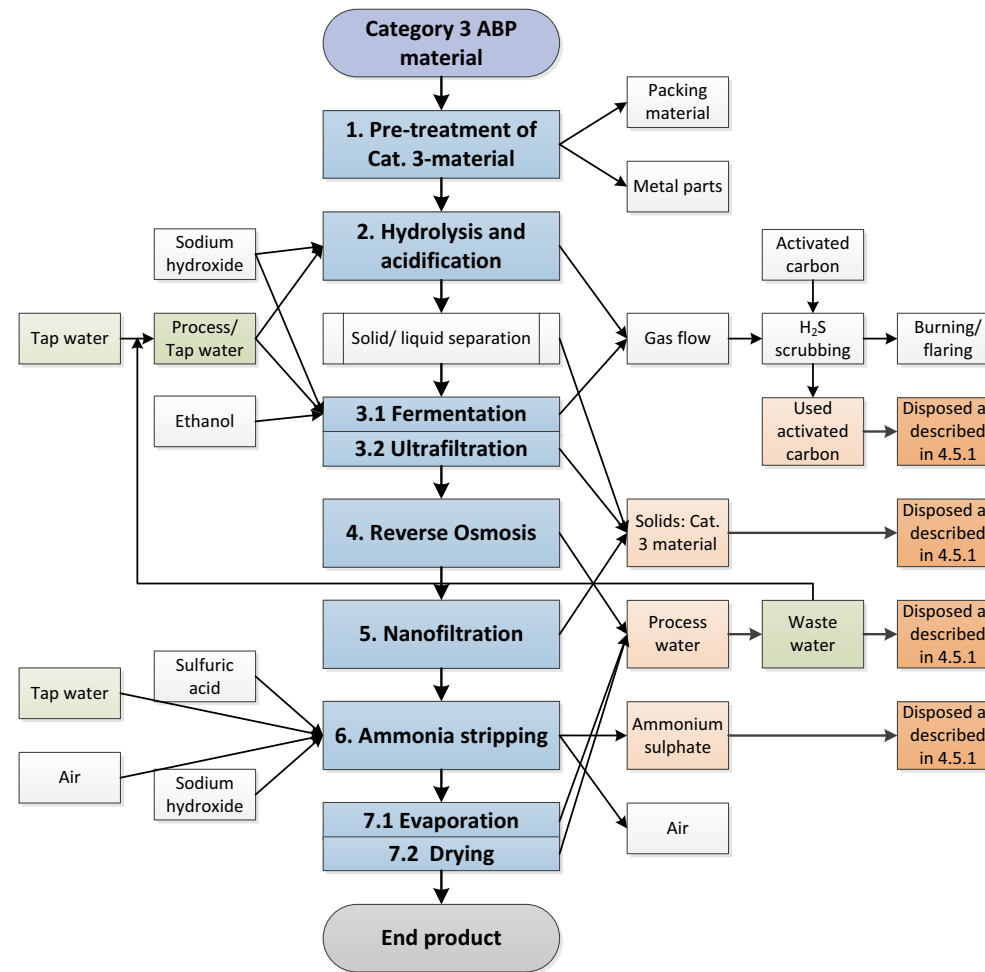


Figure 1: Process flow diagram of a new alternative processing method for Category 3 ABP material (ChainCraft B.V.)

3.1. Pre-treatment of Category 3 material

'Category 3 material is used as feedstock. Initially, ChainCraft will process former foodstuffs (as described in Article 10(f) of Regulation (EC) No 1069/2009). All subcategories of Category 3 material, other than materials referred to in Article 10(m), (n), and (p) of Regulation (EC) No 1069/2009, may be used as feedstock.

The category 3 material is supplied by vendors who are authorized according to Regulation (EC) No 1069/2009. The former foodstuffs are unpacked and the particle size of the Category 3 material is reduced with a hammer mill or other suitable milling equipment. Unpacking and milling can be done by the supplier.

The particle size after the pre-treatment is usually smaller than 12 mm.'

3.2. Hydrolysis, acidification and solid/liquid separation

'The Category 3 material is hydrolysed and acidified by an anaerobic mixed culture (mesophilic or thermophilic) fermentation. Naturally occurring endogenous microorganisms are used (no specific bacterial culture is added to the process). Recycled water coming from the reverse osmosis and/or evaporation step is added. Sodium hydroxide is added for acidity/pH control. Mixing in the reactors occurs via stirring or nitrogen bubbling. The resulting main process flow is a fermentation broth containing water and mainly dissociated volatile fatty acids (VFA) and some ethanol.

The resulting gas flow from the fermentation contains nitrogen, hydrogen sulphide, hydrogen, methane and carbon dioxide. This gas is treated by a scrubber where the hydrogen sulphide is removed by activated carbon. The remaining gas will be burned in the steam engine for steam production or will be flared, all within permit boundaries. Periodically, the used activated carbon will be reactivated by the supplier.

The remaining solids and liquids in the main process flow are separated from each other by a centrifuge decanter and/or disk bowl centrifuge. The solids, which are considered as untreated Category 3 material, will be disposed of via one of the routes described in the application' (see Section 4.5.1).

'Characteristics of the main process flow:

- [REDACTED]
- Temperature: mesophilic or thermophilic
- Pressure: atmospheric
- Exposure time: up to 8 days
- [REDACTED]
- Particle size after solid/liquid separation: maximum 0.5 mm'

3.3. Fermentation and Ultrafiltration

'The dissociated VFA in the main process flow will be fermented, together with ethanol, to dissociated medium-chain fatty acids (MCFA).' According to the Applicant, 'the fermentation is mesophilic and the dominant prevailing fermenting organism is *Clostridium kluyveri*. Natural occurring endogenous microorganisms are used (no specific bacterial culture is added to the process). Sodium hydroxide is added for acidity/pH control. The resulting main process flow is a fermentation broth containing mainly water, dissociated MCFA, and sodium ions.

The remaining solids and liquid in the main process flow are separated from each other by membrane filtration (ultrafiltration).' The Applicant claims that 'the ultrafiltration will remove all microbiological species, viruses and parasites. The membranes have a pore size of maximum 30 nm' (according to the technical annex provided by the Applicant, membranes have a mean pore size of approximately 30 nm). 'The permeate fraction is the main process flow. The retentate is the flow containing the solids. This stream is a Category 3 material that will be disposed of following one of the routes described in the application' (see Section 4.5.1).

'The resulting gas flow from the fermentation contains nitrogen, hydrogen sulphide, hydrogen, methane, and carbon dioxide. This gas is treated by a scrubber where the hydrogen sulphide is removed: the remaining gas will be burned in the steam engine for steam production or will be flared, all within permit boundaries. The used activated carbon will be periodically reactivated by the supplier.

Characteristics of the main process flow:

- █ [REDACTED]
- Temperature: mesophilic
- Pressure: atmospheric
- Exposure time: maximum 2 days
- █ [REDACTED]
- Particle size after ultrafiltration: maximum 30 nm'

3.4. Concentration via reverse osmosis

'The remaining main process flow will be split via reverse osmosis (R.O.) into a permeate flow containing clean water and a concentrated retentate. The major part of the process water will be used for recirculation. The surplus is wastewater (or vapour). The main process flow will be a concentrated retentate flow containing mainly water and concentrated dissociated MCFA. The pressure of the R.O. system is dependent on the desired product concentrations in the retentate flow.

Characteristics of the main process flow:

- █ [REDACTED]
- Pressure: 25–40 bar, depending on the desired product concentration
- █ [REDACTED]
- particle size: maximum 30 nm'

3.5. Nanofiltration

'In the previous steps (hydrolysis, acidification, and fermentation), the feedstock is mainly converted into MCFA salts. In addition, the main process flow may contain small amounts of polypeptides, peptides, amino acids, and minerals.

To guarantee that all molecules in the main stream have a molecular weight that does not exceed 10,000 dalton, the main process flow passes through a nanofiltration membrane with a cut-off of 5,000 dalton.

Characteristics of the main process flow:

- Process type: continuous
- Temperature: 25–50°C
- Pressure: 5–10 bar, depending on flow rate and type of membrane
- pH: 5–8
- Particle size: maximum 10,000 dalton'

3.6. Ammonia stripping

'The main process flow, containing mainly water and dissociated MCFA, will be stripped from remaining ammonia by air stripping. Subsequently, the air (containing ammonia) will be stripped of ammonia by addition of sulphuric acid (H_2SO_4). Ammonium sulphate ($(NH_4)_2SO_4$) and air will remain.

Characteristics of the main process flow:

- █ [REDACTED]
- Particle size: maximum 10,000 dalton'

3.7. Evaporation and Drying

Evaporation

The main process flow, containing mainly water and dissociated MCFA, will be concentrated via evaporation. The resulting water flow will be partly recycled and re-used. The surplus is wastewater.

Characteristics of the main process flow:

- [REDACTED]
- Particle size: maximum 10,000 dalton
- [REDACTED]

Drying

The main process flow, containing mainly dissociated MCFA and water, will be concentrated and dried with an appropriate drying device (e.g. agitated thin film dryer or spray drier). The resulting water flow will be partly recycled and re-used. The surplus is wastewater.

Characteristics of the main process flow:

- [REDACTED]
- Particle size: maximum 10,000 dalton
- [REDACTED]

3.8. Water treatment

'Process water is collected from the reverse osmosis step and arises as condensate from the evaporation and drying processes of the final product.

The condensate from the evaporation and drying processes is stored at a minimum temperature of 85°C. If necessary, the water is heated in order to reach this temperature. The hot process water is mainly reused in the hydrolysis and acidification process.

The process water from the reverse osmosis step is stored at a temperature of 25–40°C. Due to the anaerobic storage conditions and the large flow rate of process water, bacterial growth is unlikely. If desired, the water can be filtered or treated with UV light. This process water is mainly reused in the fermentation process.

Process water can also be used for cleaning purposes. In order to prevent recontamination, only tap water is used in the process steps after the ultrafiltration step.

For the surplus process water, the processing plant has a wastewater disposal system which meets the requirements set out by the Competent Authority in accordance with EU legislation.'

4. Assessment

4.1. Material to be treated

4.1.1. Categories of ABP as provided by the Applicant

The description of the material to be treated, presented in the current section, has been extracted verbatim from the application with minor editorial changes for clarity purposes.

'The feedstock used in the process described in this application is Category 3 material. Initially, ChainCraft will process former foodstuffs (as described in Article 10(f) of Regulation (EC) No 1069/2009). All subcategories of Category 3 material, other than materials referred to in Article 10(m), (n) and (p) of Regulation (EC) No 1069/2009 may be used as feedstock. The Category 3 material may contain animal proteins from ruminants.

In addition, the following processing aids are used:

- Sodium hydroxide;
- Ethanol;
- Water;
- Sulphuric acid.

All these processing aids are authorized as feed materials (according to Regulation (EC) No 767/2009) or as feed additives (according to Regulation (EC) No 1831/2003). The products are appropriate for the purpose for which they are used and comply with the legislation on undesirable substances (Directive 2002/32/EC).⁴

4.1.2. Assessment of the material to be treated by the BIOHAZ Panel

According to the application, materials referred to in Article 10(o), i.e. adipose tissue, may be used as feedstock. However, this is not in line with the legislation. According to Article 14 d) (i) of Regulation (EC) No 1069/2009, all subcategories of Category 3 material, other than materials referred to in Article 10(n),⁴ (o)⁵ and (p)⁶ of Regulation (EC) No 1069/2009, may be used as feedstock.

Point (b) of paragraph 2 of Article 11 of Regulation (EC) No 1069/2009 prohibits the 'feeding of farmed animals other than fur animals with catering waste or feed material containing or derived from catering waste.' This prohibition is reflected in Article 14 d) (i).

4.2. Hazard identification

4.2.1. Hazard identification as provided by the Applicant

The description of the biological, chemical and physical hazards, presented in the current section, has been extracted verbatim⁷ from the application, with minor editorial changes for clarity purposes.

4.2.1.1. Biological hazards

'The application concerns the processing of Category 3 material. According to the EFSA Statement on technical assistance on the format for applications for new alternative methods for animal by-products (EFSA Journal 2010; 8(7):1680), the new proposed process should be able to reduce the amount of the most resistant biological hazards associated with the category of the material to be processed for a defined final use to an acceptable level. This principle will apply to pathogens relevant for Category 3 material.

The EFSA 2005 opinion⁸ on the safety vis-à-vis biological risks of biogas and compost treatment standards of ABPs (...) categorizes biological hazards as follows:

- *"Zoonotic agents: include bacteria, parasites, fungi and possibly some viruses. Zoonotic agents are agents transferred from animals to man and may cause disease in humans.*
- *Animal pathogens: specific animal pathogens (viral, bacterial and parasitic) may be present and may cause animal disease.*
- *Toxins and degradation products: within ABPs several biological processes may occur, including growth of toxigenic microorganisms, which can result in the production of microbial toxins and other potentially toxic metabolites.*

Factors of importance in relation to the above hazards:

- *Initial concentration in raw materials: The initial concentration of the agent causing the hazard can vary greatly. Some agents, e.g. viruses, can cause infections in animals and can then occur in very high concentrations in animal tissues. Relatively high concentrations of viruses may also occur even in the absence of clinical and pathological signs. (...)*
- *Multiplication: viruses, which need living cells, are unable to multiply in animal by-products. Bacteria and fungi are able to survive and sometimes multiply in ABPs leading to high concentrations and/or toxin production.*

⁴ Hides and skins, hooves, feathers, wool, horns, hair and fur originating from dead animals that did not show any signs of disease communicable through that product to humans or animals, other than those referred to in point (b) of this Article;

⁵ Adipose tissue from animals which did not show any signs of disease communicable through that material to humans or animals, which were slaughtered in a slaughterhouse and which were considered fit for slaughter for human consumption following an ante-mortem inspection in accordance with Community legislation;

⁶ Catering waste other than as referred to in Article 8(f).

⁷ The text taken verbatim from the EFSA (2007) opinion is enclosed in quotation marks and the parts where text has been excluded are indicated with an ellipsis.

⁸ Text included by the Applicant was extracted from the EFSA (2007) opinion which refers to the 2005 opinion and slightly amends the content of the "Hazard identification" chapter from the 2005 opinion. The correct reference is to the EFSA (2007) opinion, not the 2005 opinion.

- *Storage and initial processing: ABPs consist of substrate for enzymatic processes or microbiological deterioration, with enzymes that can break down protein, fat or carbohydrates, and micro-organisms that can produce toxins and enzymes. Metabolites of protein deterioration, such as ammonia and biogenic amines, can be produced in high amounts, but the fate of these products during aerobic and anaerobic treatment is uncertain. Storage conditions should minimize multiplication and prevent formation of toxins.*
- *During processing: the hazards identified above, if present, must be inactivated effectively.*

Conditions for reduction of the identified hazards:

- *Viruses: inactivation can occur as a result of storage, although some resistant viruses (e.g. Parvovirus) can survive for weeks to months in the environment, particularly when embedded in organic material (Gorham et al., 1976). Viruses can be inactivated by heat treatment in temperature ranges of 50–100°C. For some thermostable viruses, temperatures above 70°C are necessary if the required reduction is to be achieved in a reasonable time (EFSA, 2005b). All viruses are inactivated by high pH (pH > 11), and most are inactivated by low pH values, although some are resistant to low pH conditions, even at pH values as low as 2 to 3.*
- *Non-spore forming bacteria: this group of micro-organisms can be inactivated by heating in the temperature range 50–100°C. Inactivation rates increase with increasing temperature. Other inactivation procedures (e.g. lime treatment) can also be applied to non-spore forming bacteria.*
- *Spore-forming bacteria: spores are more resistant to heating than vegetative bacteria. To eliminate spores, processing at temperatures above 100°C is required. The temperature/time relationship necessary for their inactivation depends on the type of organism, the substrate in which they are embedded and the moisture content. In general, for microorganisms and viruses, heat resistance increases with decreasing water activity.*
- *Parasites: Helminth eggs are sensitive to heat (about 50°C is lethal); however, those of some species (e.g. Ascaris eggs) are tolerant to extreme pH values (e.g. lime). Giardia and Cryptosporidium cysts are fairly tolerant to heat. To obtain several log₁₀ scale inactivation in water, 2 min at 64.2°C and 10 min at 70°C were necessary for respectively Cryptosporidium parvum and Giardia lamblia cysts (Ongerth et al., 1989; Fayer, 1994).*
- *Toxins: Bacterial toxins that may be present in animal by-products are of protein origin. Some (e.g. toxins of the Clostridium botulinum group) can be inactivated by heating. Others (e.g. enterotoxins of Staphylococcus aureus), are difficult to denature by heating, but can be inactivated by chemical processes.”*

Reduction of hazards by ultrafiltration and nanofiltration

Above is discussed that biological hazards can be eliminated or reduced by heat. The ChainCraft process uses ultrafiltration and nanofiltration to control biological hazards. Bacteria and viruses are removed by ultrafiltration. Additionally, nanofiltration is applied in order to remove particles greater than 10,000 dalton.

Prions have a mass of about 30,000 dalton.’ The Applicant claims that ‘carbon chains, including amino acids and peptides with a molecular weight no larger than 10,000 Da are regarded as safe in feed for ruminants (Office International des Epizooties, Paris, France).

4.2.1.2. Chemical hazards

In the application the main focus is on biological hazards. Chemical hazards are briefly addressed.

When referring to chemical hazards, this particularly concerns undesirable substances (heavy metals, dioxins, PCBs, etc.) and pesticides as defined in Directive 2002/32/EC⁹ and Regulation (EC) No 369/2006. As the Category 3 material processed by ChainCraft is derived from former foodstuffs or from animals slaughtered for human consumption. Due to its origin, it may be assumed that these products meet the requirements for chemical hazards. This aspect shall be evaluated’ by the Applicants’ own HACCP study.

⁹ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. OJ L 140, 30.5.2002, p. 10.

4.2.1.3. Physical hazards

Physical hazards can be present as a result of the presence of packing materials, which must be removed in an adequate manner. Other potential physical hazards, including wood, metal parts and glass are removed by sieving and filtration steps.'

4.2.2. Assessment of the hazard identification by the BIOHAZ Panel

A general categorization of possible hazards present in the material to be treated, as described above in Section 4.2.1, is provided by the Applicant, although a list of specific pathogens for humans and animals potentially present was not provided. Taking into account that Category 3 material of different subcategories may be used as feedstock, a wide range of biological hazards may be present in the material to be treated.

Usually the most resistant microorganisms are identified in order to focus the risk reduction assessment on those particular hazards. In the past, the selection of the most resistant microorganisms has been conducted based on their resistance to high temperature. For the new application where filtration systems work as a physical barrier, size and other physical properties, rather than heat resistance of the hazards, are the key aspects to be considered.

The Applicant refers to a definition of the World Organization for Animal Health/Office International des Epizooties (OIE) for carbon chains with a molecular weight no larger than 10,000 dalton. However, this reference alone cannot be used to state that hydrolysed protein is safe. The EU ABP legislation and, in particular, the principle of categorisation, should be taken into account.

As stated by Maya et al. (2010), helminth eggs are sensitive to heat and heating for 70°C for 2 h is considered to be lethal.

Specific information on the size and physical properties of the various hazards that could be present in the feedstock was not provided by the Applicant.

Taking into account their physical properties, and particularly their small size, viruses and bacterial toxins are the most relevant hazards to be considered.

4.3. Level of risk reduction

4.3.1. Level of risk reduction as provided by the Applicant

The description presented in the current section has been extracted verbatim¹⁰ from the application with minor editorial changes for clarity purposes.

4.3.1.1. Particle size

'In the pre-treatment (process step 1) the particle size of the Category 3 material is reduced to maximum 12 mm. The particle size is further reduced by hydrolysis and fermentation, sieving, decantation, centrifugation, ultrafiltration and finally nanofiltration. Because of these steps later in the process, the reduction of particle size in the pre-treatment is not a critical point.'

4.3.1.2. Temperature and time

'During evaporation and drying, the temperature will be raised to a level at which micro-organisms are reduced. These heating steps occur in the process after the nanofiltration and do not have any effect on the microbiological parameters of the product.'

4.3.1.3. Pressures

'Different stages of the process are not carried out at atmospheric conditions. Ultrafiltration takes place at a pressure of approx. 3 bar and the reverse osmosis at approx. 40 bar. Since the temperature in these process steps is not higher than 50°C, the pressure in ultrafiltration and reverse osmosis has no effect on risk reduction.'

4.3.1.4. Microbiological criteria and pH

'According to Chapter I of Annex X of Regulation (EU) No 142/2011, the following microbiological standards shall apply to derived products:

¹⁰ The text taken verbatim from the 2010 EFSA opinion is enclosed in quotation marks and the relevant parts of the text that have been excluded are indicated with an ellipsis.

Samples¹¹ of the final products taken during or upon withdrawal from storage at the processing plant:

- Salmonella absent in 25 g: $n = 5$, $c = 0$, $m = 0$, $M = 0$
- Enterobacteriaceae: $n = 5$, $c = 2$, $m = 10$, $M = 300$ in 1 g'

The Applicant claims that 'the ultra and nanofiltration and the nature of the end product guarantee the absence of microbiological activity. Besides that, the nature of the product (mixture of salts of organic acids) makes it very unlikely that microorganisms will survive.

Methods and results of analysis on the presence of Salmonella spp. and Enterobacteriaceae in the samples of the final product can be found in' the application.

4.3.1.5. Hydrolysis of carbon chains, ultrafiltration and nanofiltration

'During the process, the Category 3 material is hydrolysed to short-carbon chains, resulting in a mixture of volatile fatty acids. The fatty acids are fermented together with ethanol to form dissociated MCFA.

In order to control the molecular size of the final product, the product passes subsequently through ultrafiltration and nanofiltration membranes.

The ultrafiltration membrane has a pore size of maximum 30 nm.' The Applicant claimed that 'all possible microorganisms present (bacteria, viruses and parasites) are separated by this filter. The operation of ultrafiltration is monitored by periodic checks of the total aerobic and total anaerobic plate counts' on samples of the main process flow.

'Subsequently, the product is subjected to nanofiltration, which separates all particles with a molecular size > 5,000 dalton. Batches after nanofiltration are only released based on batch by batch analysis on the molecular weight of the main process flow after nanofiltration or by continuous in-line measurement.

The nanofiltration membrane will be cleaned periodically due to fouling that will cause the flow over the membrane to decrease (when the pressure on the membrane is kept equal), or the pressure on the membrane to increase (when the flow over the membrane is kept equal). Regarding particle size, a membrane with fouling of the surface can result in a decrease of the maximum particle size passing through the membrane. An increase in the particle size that can pass the membrane is not possible.

Clean-In-Place (CIP) will be performed when the pressure in the system reaches a determined threshold value (at equal flow over the membrane), or when the flow reaches a determined threshold value (at equal pressure on the membrane). 'According to the Applicant, in 'the unlikely event of a crack in the membrane, samples' taken 'after nanofiltration will be analysed for the presence of particles > 10,000 dalton. Samples will be analysed by GPC (Gel Permeation Chromatography), SEC (Size exclusion Chromatography) or other comparable validated methods. The data will be checked for the presence of particles with a molecular size > 10,000 dalton.

Non-compliant batches will be reprocessed or discarded to an authorized processor.

In the HACCP-plan the operation of the nanofiltration is identified as a CCP.'

4.3.1.6. Validation

'According to the EFSA Statement on technical assistance on the format for applications for new alternative methods for animal by-products (EFSA BIOHAZ Panel, 2010), "the validation of the intended process can be performed by measuring the reduction in viability/infectivity of:

- endogenous indicator organisms during the process, where the indicator is:
 - consistently present in the raw material in high numbers;
 - not less resistant" (...) ¹² "than the pathogens for which it is being used to monitor;
 - relatively easy to quantify and relatively easy to identify and to confirm;

or

¹¹ Two-class sampling plans designed to decide on acceptance or rejection of a lot consist of:

N: number of sample units to be chosen independently and randomly from the lot;

M: a microbiological limit (i.e. in CFU/g); a sample is defined to be positive, if its microbial content exceeds this limit;

C: maximum allowable number of sample units yielding a positive result (presence/absence testing) or exceeding the microbiological limit m; for pathogens c is usually set to 0.

¹² The following text from the 2010 EFSA opinion is not included in the application: "to the lethal aspects of the treatment process, but also not significantly more resistant".

- ii) *a well-characterised test organism or virus introduced in a suitable test body into the starting material.*"

The process will be validated at two levels:

- 1) *The effect of ultrafiltration on the presence of endogenous microorganisms will be validated via direct measurement according to method i) as presented in chapter 2.d. in the EFSA Statement on technical assistance on the format for applications for new alternative methods for animal by-products' (EFSA BIOHAZ Panel, 2010). 'Samples of the main process flow before and after the ultrafiltration are tested for the aerobic and anaerobic mesophilic plate counts. After the ultrafiltration the limit for the aerobic and anaerobic mesophilic plate counts is < 10 CFU/g. Methods and results' were provided by the Applicant.*
- 2) *'The effect of nanofiltration on the particle size cannot be validated via direct measurement until sufficient main process liquid is produced by normal operation that will allow testing the nanofiltration membrane on a representative scale (pilot scale). This process step can be validated once the full scale process has been installed.*

According to chapter 2.d. in the EFSA Statement on technical assistance on the format for applications for new alternative methods for animal by-products' (EFSA BIOHAZ Panel, 2010), 'the request for exception is justified as follows:

- i) *"The factors leading to risk reduction are known".
A 5,000 dalton nanofiltration membrane is a physical barrier. Prions have a mass of about 15,000–30,000 dalton. Carbon chains, including amino acids and peptides with a molecular weight no larger than 10,000 dalton are regarded as safe in feed for ruminants (Office International des Epizooties, Paris, France).*
- ii) *"The model of risk reduction is well established."
The application of nanofiltration membranes is a widely established method for the separation of particles based on their molecular weight. (...)*
- iii) *"Continuous direct measurements of the factors leading to the risk reduction are provided for the full-scale process which demonstrates that these factors are homogeneously applied throughout the treated batch."
The direct measurements can be provided once the production process is operational.'*

4.3.2. Assessment of the level of risk reduction by the BIOHAZ Panel

The Applicant carried out microbiological analyses (aerobic and anaerobic mesophilic plate counts) to assess the removal of microbial species by the ultrafiltration unit to a level below 10 CFU/g, by comparing the counts between the flow entering and leaving the unit. These tests showed that mesophilic plate counts were below 10 CFU/g after the ultrafiltration process. Microbial analyses were performed to confirm the absence of certain bacterial groups (including Enterobacteriaceae, *Clostridium perfringens* and *Salmonella* spp.) after this step.

No validation of the ultrafiltration, as described by the Applicant in step 3.2 of the process, was performed to check for the absence of viruses. Furthermore, no inoculation of bacteria or viruses to assess the effectiveness of the filtration processes was done. The ultrafiltration membrane used in the process has a pore size of 30 nm approximately according to the technical description provided by the Applicant and small viral particles may pass through, e.g. *Picornavirus* (22–30 nm), *Parvovirus* (20–26 nm) (Granoff and Webster, 1999) and *Circovirus* (15–25 nm) (ICTV, online). The Applicant states that the operation of ultrafiltration is monitored by periodic checks of total aerobic and total anaerobic plate counts on samples of the main process flow; however, this periodicity should be defined as for the nanofiltration (step 5), analysing at least each batch to check the performance of the membrane.

The nanofiltration (step 5) has not been validated by the Applicant in a laboratory model or at pilot plant and the Applicant relies on the information provided by commercial suppliers. The technical information described in the application shows the nanofiltration membrane as a polyethersulphone membrane with a cut-off of 5,000 dalton, and the Applicant presents this membrane as a guarantee of the removal of compounds smaller than 10,000 dalton, although no validation information is included in the technical data sheet for this membrane. See Figure 1 for the steps.

The nanofiltration is a very important CCP and requires the Applicant to provide certification and validation for the specific use of the 5,000 dalton nanofiltration membranes, in addition to continuous

monitoring and membrane integrity tests as control measures described in the risk assessment plan and proposed in the operational production process. These documents are necessary elements in the safety control plans of the process.

Small viruses passing the ultrafiltration membrane will be retained at the nanofiltration step, which represents a CCP in the process. The ability of nanofiltration to remove viruses when they are spiked into laboratory models that mimic industrial-scale nanofiltration conditions has been shown (Jorba et al., 2014).

According to the Applicant, the nanofiltration process prevents particles of > 10,000 dalton passing through the filter. Therefore, if correctly executed, all parasites, vegetative bacteria, spores, and viruses will be retained and will not be present in the end product, assuming that cross-contamination after nanofiltration does not occur. Most bacterial toxins should also be retained in the filtration steps. On the other hand, some small toxins, with a size < 10,000 dalton (10 kDa), if present, might cross the filters (e.g. *Bacillus cereus* emetic toxin (cereulide) with < 10 kDa, a 4.1 kDa toxin (EAST1) produced by Enteroaggregative *Escherichia coli* (EAEC), *E. coli* heat-stable enterotoxin a (2 kDa), or delta toxin from *S. aureus* (approximately 3 kDa) (Sears and Kaper, 1996). The presence of bacterial toxins cannot be controlled by the nanofiltration step in the case of small bacterial toxins and therefore, a CCP should be included to control this process. The processing conditions during the hydrolysis and fermentation (step 2) should be managed so as to not allow their possible introduction or production even for prolonged fermentation times (2–8 days) by undefined bacteria present in the starting material, as occurs in the process described by the Applicant.

The Applicant indicates that '*the nature of the product (mixture of salts of organic acids) makes it very unlikely that microorganisms will survive*', but no data are provided to support this statement. It is unknown whether inactivation or inhibition will occur in the final product as a result of conditions within the product.

Although prions are mentioned by the Applicant, they were not considered in this assessment which only considers Category 3 material. In addition, according to the prohibitions and derogations described in Article 7 and Annex IV of Regulation (EC) No 999/2001, no hydrolysed protein of ruminant origin (other than from ruminant hides and skins) can be included in feed for farmed animals or for aquaculture. The limitations specified in the current legislation and any future modifications in relation to the raw materials that may be used as feedstock would apply to this alternative process.

4.4. HACCP plan

4.4.1. HACCP plan and CCP, as provided by the Applicant

A HACCP plan was provided by the Applicant with the principles in accordance with the Codex Alimentarius General Principles of Food Hygiene included, as well as the main hazards identified and the risk associated with each of them (considering the likelihood of occurrence and the severity of the possible impact). A specific control measure was also included which contained the interventions/steps considered to be a CCP according to the Applicant. Finally, a proposed corrective action to be taken when monitoring indicates that CCPs are not under control was included.

In point 4 of chapter II of Annex VII of Commission Regulation (EU) No 142/2011, explicit critical process parameters are described which are, according to the Regulation, relevant to obtain risk reduction. These are in particular:

- temperature;
- pressure;
- time;
- pH;
- microbiological criteria.

These parameters play a role in the ChainCraft B.V. process but, as it is apparent from the HACCP plan, were not identified as the most critical for achieving a risk reduction.

ChainCraft B.V. uses ultrafiltration and nanofiltration to control biological hazards. Therefore, the following critical parameters were mentioned:

- particle size;
- the molecular weight of the carbon chains present in the final product.

The relevance of these parameters will be evaluated in the assessment of the HACCP plan.

4.4.2. Assessment of the HACCP plan by the BIOHAZ Panel

The Applicant provides a HACCP plan, which considers the main control points associated with the process. However, the following items have not been included in the HACCP plan: biological hazards are not specifically identified as hazards in the HACCP plan; instead, the HACCP plan mentions physical and chemical hazards. CCPs are determined by the Applicant, based on a decision tree developed by the Codex Alimentarius. The process has only one CCP, which occurs at the nanofiltration step. No information is provided on the verification procedures to confirm that the HACCP system is working efficiently. In addition, there is no information or documentation concerning procedures and records.

Information related to corrective actions in case of failure of the CCP should be more detailed. In addition, in the case of the closed system being opened by accident/explosion, a plan should exist detailing how to protect the workers and the environment.

Given the dependence on the system to cease operation if critical conditions are not met, Good Manufacturing Practices must be followed by the Applicant to ensure that the system is functioning as per design.

The hydrolysis and acidification phase (that involves fermentation) (step 2) and the fermentation phase (step 3.1), which are dominated by natural microflora under anaerobiosis and a wide range of possible conditions, should be considered as additional CCPs. The critical parameters associated with the process steps where bacterial toxins could be produced require a monitoring procedure as those toxins in some cases, may not be controlled by nanofiltration (step 5).

The ultrafiltration (step 3.2) is not identified by the Applicant as a CCP because of the later nanofiltration in the process, although some small viruses could pass the ultrafiltration membrane. The periodicity of the controls of the ultrafiltration membrane checking the total aerobic and anaerobic plate counts should be defined, analysing at least each batch. The nanofiltration (step 5), with a cut-off of 5,000 dalton removing compounds larger than 10,000 dalton, is an important CCP, as described by the Applicant, and should retain all viruses. This CCP requires the Applicant to have certification and validation for the cut-off of the nanofiltration membrane used, in addition to the continuous monitoring and membrane integrity tests as control measures described in the HACCP plan. See Figure 1 for the steps.

4.5. Risk associated with interdependent processes

4.5.1. Risk associated with interdependent processes as provided by the Applicant

According to point 5, Chapter II, Annex VII, of Commission Regulation (EU) 142/2011, the Applicant must provide information on the risks associated with interdependent processes, including those that arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.

The Applicant provided information on the by-products and waste streams that arise from the production process, as well as on the destination of these by-products and waste streams, using the following Table 1 (extracted verbatim).

Table 1: Authorized applications of the by-products and waste of the ChainCraft B.V. process

'By-product or waste product	Status of the product	Authorized applications
Solids from solid/liquid separation after hydrolysis and acidification	Category 3 material	Biogas or composting plant, according Annex V of Regulation (EU) No 142/2011; Incineration, according Annex III of Regulation (EU) No 142/2011. Feed material for pet food or furred animals; Authorized processor of Category 3 material
Solids from ultrafiltration, after fermentation		
Solids from nanofiltration and reverse osmosis		
Process water from reverse osmosis, evaporation and drying	Waste water	Waste water treatment according to section 2 of Chapter I of Annex IV of Regulation (EU) No 142/2011
Ammonium Sulphate (NH ₄) ₂ SO ₄ from ammonia stripping	By-product	Fertilizer
Used activated carbon	Waste	Reactivation by supplier'

The HACCP plan provided by the Applicant also contained information on risks associated with interdependent processes.

4.5.2. Assessment of the risk associated with interdependent processes by the BIOHAZ Panel

In general, adequate information is provided by the Applicant on interdependent processes with some exceptions. Detailed information is provided by the Applicant on the handling of water. All the water produced during the process is either reused or disposed of through a wastewater disposal system meeting the requirements set out by the Competent Authority in accordance with EU legislation. The procedure for dealing with wastewater meets the requirements set out in Commission Regulation (EU) No 142/2011.

No information is provided on the storage and transport of the by-products. The methods of reuse or disposal of the by-products as described in the Table 1 above are in line with the requirements set out in Commission Regulation (EU) No 142/2011.

4.6. Risk associated with the intended end use of the products from the process

4.6.1. Risk associated with the intended end use of the products from the process as provided by the Applicant

The description presented in the third and fourth paragraph of the current section has been extracted verbatim from the application with minor editorial changes for clarity purposes.

According to Point 5(b), Chapter II, Annex VII, of Commission Regulation (EU) No 142/2011, *'the risks associated with (i) the intended end use of any products generated during the process must be specified by the Applicant; (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed'* by the Applicant *'on the basis of the risk reduction estimated in accordance with point 2(d).'*

According to the Applicant, *'the final product is a solid powder of fatty acid salts. These fatty acid salts are obtained by hydrolysis and fermentation of Category 3 material (mainly former foodstuffs) or other feed grade biomass. The final product is a mixture of sodium, calcium, magnesium, phosphate and potassium salts of medium chain fatty acids. The product contains up to 1% of polypeptides, peptides, amino acids, and minerals with molecular weights below 10,000 dalton.'*

According to the Applicant, the final product will be used for animal nutrition. *'Potentially, there are also other technical applications for the final product, such as application as feedstock for herbicides, preservatives and disinfectants.'* The Applicant was of the view that the end product met the requirements set out in Regulation (EC) No 767/2009 and Commission Regulation (EU) No 68/2013 for use *'as a feed material, suitable for all animal species. Due to this classification'*, the Applicant was of the view that *'the product can be considered as safe for human health, animal health and the environment.'*

4.6.2. Assessment of the risk associated with the intended end use of the products from the process by the BIOHAZ Panel

Processed Category 3 material is currently allowed to be fed to farmed animals under Regulation (EC) 1069/2009 (except materials referred to in Article 10 (n), (o) and (p)). As mentioned in Section 4.1.2, according to the application, material referred to in Article 10 (o) may be used as feedstock, but this is prohibited for use as feed. There are also a number of other prohibitions. Article 11, paragraph 1 of the Regulation prohibits the feeding of terrestrial animals of a given species other than fur animals with processed animal protein derived from the bodies or parts of bodies of animals of the same species. In addition, under the prohibitions and derogations described in Article 7 and Annex IV of Regulation (EC) No 999/2001, no hydrolysed protein of ruminant origin (other than from ruminant hides and skins) can be included in feed for farmed animals or for aquaculture. Although the end product contains up to 1% of hydrolysed proteins, this prohibition would apply to the present application. Therefore, the evaluation of the process does not affect limitations to the potential use of the end product covered by the Regulations applicable at the moment of production.

Based on the information provided by the Applicant, the Biological Hazards Panel is of the opinion that provided that the end use is in line with regulatory requirements, no additional risks to animal health,

public health and the environment should arise from the intended end use of the products from the process under consideration compared with end uses currently approved for Category 3 material ABP.

5. Uncertainty evaluation

To meet the general requirement for transparency, all scientific risk assessments undertaken by EFSA must consider uncertainty. For this particular assessment, the uncertainty is limited to the conditions around the validation and control of the entire process as appear in the conclusions and recommendations. Therefore, the impact of the uncertainty on the conclusions is negligible.

6. Conclusions

- The ultrafiltration and nanofiltration techniques are able to remove particles of the size of viruses, bacteria and parasites from liquids. If used under controlled and appropriate conditions the processing methods proposed should reduce the risk in the end product to a degree which is at least equivalent to that achieved with the processing standards laid down in the Regulation for Category 3 material.
- The possible presence of small bacterial toxins that could be introduced during the fermentation steps cannot be avoided by the nanofiltration one and this hazard should be controlled by a CCP elsewhere in the process.
- The nanofiltration is a very important CCP and requires the Applicant to provide certification and validation for the specific use of the nanofiltration membranes, in addition to continuous monitoring and membrane integrity tests as control measures described in the risk assessment plan.

7. Recommendations

- Monitoring procedures should be implemented to ensure that the processing conditions during fermentation will not allow the introduction or production of bacterial toxins in the final product.
- The HACCP Plan should be revised and the terminology harmonized. A control verification plan on the end product should be in place.

References

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Abbreviations

ABP	animal by-product
BIOHAZ	EFSA Panel on Biological Hazards
CA	Competent Authority
CAC	Codex Alimentarius Commission
CCP	Critical Control Point
CFU	colony-forming unit
CIP	Clean-In-Place
EAEC	Enteroaggregative <i>Escherichia coli</i>
HACCP	Hazard Analysis and Critical Control Points
MCFA	medium-chain fatty acids
OIE	World Organization for Animal Health/Office International des Epizooties
SEC	size exclusion chromatography
TOR	Terms of Reference
VFA	volatile fatty acid
WG	working group