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Scientific Opinion on a continuous multiple-step catalytic hydro-treatment for the processing of rendered animal fat (Category 1)

EFSA Panel on Biological Hazards (BIOHAZ)

Abstract

An alternative method for the treatment of rendered animal fat (Category 1) intended for the production of renewable fuels by a continuous multi-step catalytic hydro-treatment process was assessed. The alternative method is based on a pre-treatment by degumming and bleaching followed by a hydro-treatment comprising three main processes: catalytic hydro-treatment, stripping and isomerisation. The minimum processing conditions are pressure 30 bar, temperature 265°C and retention time 20 minutes. Based on the outcome of previous EFSA Opinions and the expert evaluation, the BIOHAZ Panel considered that a reduction of six $\log_{10}$ in the transmissible spongiform encephalopathy (TSE) agent by the alternative method is necessary to consider the process at least equivalent, for Category 1 animal by-products, to the processing methods previously approved. Experimental data in the reviewed literature showed that similar processes at temperatures between 160 and 200°C deliver at least a 6 $\log_{10}$ reduction in TSE infectivity in 20 minutes. Thus, at least a similar level of reduction is expected to be produced by the alternative method proposed. This is in addition to the inactivation achieved by the pressure sterilisation method applied prior to the application of the alternative method. The treatment under assessment is considered to achieve the required level of TSE inactivation, as long as the critical limits of key parameters are achieved as specified by the applicant. The minimum retention time is a critical parameter. The applicant's estimate of minimum retention time is based on the reactor size and the flow rate of the material, but the real minimum time in actual processing conditions has not been determined. It should be confirmed that a minimum retention time of 20 minutes is achieved in all parts of Category 1 material under normal operational conditions in order to ensure the effectiveness of the treatment.

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Keywords: animal fat, TSE, hydro-treatment, category 1, rendering

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Summary

Following a request from the Ministry of Agriculture and Forestry of Finland (Competent Authority) on behalf of the company Neste Oil, the European Food Safety Authority (EFSA) Scientific Panel on Biological Hazards (BIOHAZ Panel) was asked to deliver a scientific opinion on an alternative method for the treatment of rendered animal fat (Category 1) intended for the production of renewable fuels by a continuous multi-step catalytic hydro-treatment process.

Under point 5 of Article 20 of Regulation 1069/2009 it is specified that EFSA shall assess whether the alternative method submitted ensures that risks to public or animal health are: (i) controlled in a manner which prevents their proliferation before disposal in accordance with this Regulation or the implementing measures thereof; or (ii) reduced to a degree which is at least equivalent, for the relevant category of animal by-products, to the processing methods laid down pursuant to point (b) of the first subparagraph of Article 15(1).

The alternative method is based on a series of steps. A pre-treatment — independent of the hydro-treatment process — consists of two steps: degumming and bleaching. The hydro-treatment process consists of three main processes: catalytic hydro-treatment, stripping and isomerisation. It is a continuous process during which the feedstock flows from one reactor to the next without intermediate storage. The processing conditions during the different steps indicated would be a minimum pressure of 30 bar and minimum temperature of 265°C. The actual retention time is dependent on the size of the reactors and the flow rate, but an average retention time of 20 minutes is ensured by design, according to the application.

The data used in the assessment were provided by the applicant in a dossier and in an *ad hoc* request for missing information. Two scientific papers which were cited in support of the application were evaluated. A third paper (not provided by the applicant), but by the same authors, that included additional data on the effect of heat treatment in different fat/glycerol/water mixtures on scrapie infectivity was also reviewed.

Based on the outcome of previous EFSA Opinions on the treatment of Category 1 material and the expert evaluation, the BIOHAZ Panel considered that a reduction of 6 log units in transmissible spongiform encephalopathy (TSE) infectivity was at least equivalent, for Category 1 of animal by-products, to the processing methods laid down in the legislation.

The experimental model applied has been thoroughly reviewed in terms of the titration method, the strain and mouse model, the confirmation of the disease, and the interpretation of the results. Although based on experiments conducted in laboratory conditions and not at industrial scale, the model, which was applied on the same raw material and under similar treatment conditions, is scientifically sound, based on a state-of-the-art, well-accepted, experimental model, and can be considered a good indicator of the industrial process. Thus, it can be accepted as a valid model for comparisons.

The experimental data reported showed that similar processes carried out at temperatures between 160 and 200°C deliver at least a 6 $\log_{10}$ reduction in TSE infectivity in 20 minutes. Based on the principles of heat inactivation, it can be expected that any process carried out using more stringent parameters (higher temperature and pressure, longer exposure time) would achieve at least the same or a higher level of reduction, irrespective of whether the inactivation kinetics are linear or non-linear. Thus, at least a similar level of reduction is expected to be produced by the alternative method proposed. This is in addition to the inactivation achieved by the pressure sterilisation method (method 1) applied prior to the alternative method under assessment.

Therefore, the treatment under assessment is considered to achieve the required level of TSE inactivation as long as the critical parameters are kept at all times as specified by the applicant.

It is essential to accurately monitor pressure, temperature and retention time in order to guarantee that the process parameters are maintained.

In relation to retention time, the applicant estimates it taking into account the size of the reactor and the flow rate of the material, which leads to only an estimate of the minimum retention time, as it does not take into account the effect of other factors such as the mixing that will occur in the fluid.

The minimum retention time is the most critical parameter. There is no indication in the application of the real minimum retention time, or of the associated variability. In order to ensure the effectiveness of the treatment, it is of paramount importance that the minimum retention time of 20 minutes is ensured in all parts of Category 1 material under normal operations at industrial scale. An appropriate method to determine the minimum retention time based on experimental trials should be implemented.

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1. Introduction

1.1. Background and Terms of Reference as provided by the Ministry of Agriculture and Forestry of Finland

On 19 February 2015, The European Food Safety Authority (EFSA) received from the Ministry of Agriculture and Forestry of Finland (competent authority) the application (mandate and technical dossier) under Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011, for the evaluation of an alternative method for the treatment of rendered animal fat (Category 1) intended for the production of renewable fuels by a continuous multi-step catalytic hydro-treatment process, submitted on behalf of the company Neste Oil (hereinafter referred to as the applicant).

The application dossier includes a number of supporting documents which have also been listed in the section on Documentation provided to EFSA.

1.2. Additional information

The working group deemed necessary to have additional information on the alternative method hence proposed to request additional data. Therefore, EFSA asked the applicant to provide:

- details of the verification method(s) used to ensure that the minimum retention time of 20 minutes is respected at all times in the continuous process and in all input raw material,
- if radioactive addition or other measurements are applied, a description of the method(s) used to produce such measurements, including technical parameters and protocol of implementation and frequency,
- if a similar system of monitoring retention time is already in place for the implementation of the approved multi-step catalytic process for Category 2 and Category 3 rendered animal fat, data on the monitoring of this critical parameter,
- if a measurement system is not in place, details on how the applicant will implement the monitoring of minimum retention time in the future, should the method be approved.

The applicant submitted additional information that was considered as part of the application and reviewed during the assessment.

2. Data and Methodologies

2.1. Data

The data used in the assessment were provided from the applicant in a dossier which followed the standard format of applications for alternative methods set out in Annex VII of Commission Regulation (EU) No 142/2011[1] and its amendment by Commission Regulation (EU) No 749/2011.[2] A flow diagram and a Hazards Analysis and Critical Control Point (HACCP) plan were attached to the application dossier. Additional data as described in Section 1.2 were added to the application and reviewed accordingly.

Two scientific papers which were cited in support of the application were evaluated (Müller et al., 2006, 2008). A third paper (not provided by the applicant), by the same authors, that includes additional data on the effect of heat treatment in different fat/glycerol/water mixtures on scrapie

[1] 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.

[2] 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.

infectivity (Müller et al., 2007) was also reviewed. In addition, unpublished data provided by other experts as well as a number of relevant scientific papers were considered during the assessment.

A report submitted by the Competent Authority, in this case the Ministry of Agriculture and Forestry of Finland, related to the application was also assessed.

2.2. Methodologies

As set out in Article 20 of European Union Regulation (EC) No 1069/2009,[3] 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 which is at least equivalent to that achieved by the processing methods that have already been approved for the same category of animal by-products.

This requirement for applications is elaborated in the EU Regulation (EC) No 142/2011 implementing Regulation (EC) No 1069/2009. According to point 2(D), Chapter II, Annex VII of Regulation 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 EFSA Panel on Biological Hazards (BIOHAZ) evaluated whether these requirements were met by the continuous multi-step catalytic hydro-treatment process by following the steps set out in an EFSA scientific opinion on the format for applications for new alternative methods for animal by-products (EFSA BIOHAZ Panel, 2010a). 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 processed;
- risk associated with the intended end use of the product.

Article 12 of EU Regulation 1069/2009 establishes that Category 1 materials shall be disposed as waste by incineration, co-incineration or by burial in an authorised landfill, directly without prior processing or following processing by pressure sterilization. Alternatively, they can be used as fuel for combustion, with or without prior processing, or used for the manufacture of derived products referred to in Articles 33, 34 and 36 of the same EU regulation and placed on the market in accordance with those Articles. The proposed alternative method would be carried out following prior processing of rendered animal fat by pressure sterilisation (method 1) and the end products of the process would be renewable diesel, renewable jet fuel, renewable propane and renewable gasoline.

[3] Regulation 1069/2009 of the European Parliament and od 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.

For Category 1 materials that are destined for disposal, the standard laid down in the Regulation is pressure sterilisation (method 1). No definitive standards have been set down for Category 1 material that is to be used for other purposes. Different opinions have discussed processes where a reduction of 6 $\log_{10}$ in TSE infectivity was reached depending on the process, either including the method 1 treatment or in excess of it, indicating that with such levels of reduction the process could be considered safe for treatment and use of Category 1 material (EFSA, 2003, 2004; EFSA BIOHAZ Panel, 2011). These opinions are further discussed in Section 3.1.

Based on these precedents and on its own expert evaluation, the BIOHAZ Panel decided that a reduction of 6 $\log_{10}$ in TSE infectivity by the alternative method is required to consider it at least equivalent, for Category 1 of animal by-products, to the processing methods laid down in the legislation, and assessed whether the alternative method proposed can achieve such reduction level.

3. Assessment

3.1. Introduction

According to point D, Section 2, Chapter IV, Annex IV of Regulation 142/2011 as amended, a fat fraction derived from animal by-products of all categories may be used for the production of biodiesel. Category 1 or Category 2 materials must be first processed using processing method 1 (pressure sterilisation) as set out in Chapter III.

The EFSA opinion on the use of the high-pressure hydrolysis biogas (HPHB) process as a method for safe disposal of Category 1 animal by-products (ABPs) not intended for human consumption concluded that 'the two processes relevant for the BSE-infectivity reduction provide at least a reduction of six log units'. The two processes referred to in the opinion are pre-processing with method 1 and a subsequent two-step procedure involving heat treatment at a temperature of at least 220°C for at least 20 minutes at a pressure (absolute) of at least 25 bar, first by direct steam injection and, secondly, indirectly in a coaxial heat exchanger (as described in point 2 C, Section 2, Chapter IV, Annex IV, of Regulation 142/2011).

In 2004, the BIOHAZ Panel undertook a reassessment of the safety of Category 1 material for use in the 'Biodiesel process'. The process had previously been considered safe by the Scientific Steering Committee of the European Union for Category 2 and 3 materials. It was stated that the pressure sterilisation step, the trans-esterification step and the hydrolysis step would each give a reduction of 3 $\log_{10}$ units. However, the Panel pointed out that 'experiments have been done on laboratory scale and as the kinetics of prion reduction are not understood at present it is therefore questionable whether these reductions found in all the steps of the process can be added up. However, since the material at the start of the process has already undergone a treatment of 133°C/20 minutes/3 bar rendering it may be concluded that the resulting biodiesel, as well as the by-products, do not carry a TSE risk'. The Opinion added that 'the conclusion on safety is only valid if the technical process reflects the conditions of the experimental report'. In this opinion it was assumed that the validated process designed to produce biodiesel will result in a safe product even if it uses Category 1 animal fat.

The BIOHAZ Panel published a scientific opinion on the application by Neste Oil for a new alternative method of disposal or use of ABPs (EFSA BIOHAZ Panel, 2010b), whereby animal fat of all categories is used for the production of diesel fuel, jet fuel and gasoline. The method was based on a pre-treatment process (degumming and bleaching) followed by continuous multi-step catalytic process (minimum pressure of 20 bar; minimum temperature of 250°C; minimum retention time of 20 minutes). The Panel concluded that the method proposed by Neste Oil could be considered safe for the treatment of Category 2 and Category 3 rendered animal fat since the input materials have already undergone a process ensuring adequate risk reduction. The Panel also concluded that, in principle, the method may be appropriate for the safe destruction of Category 1 material. The applicant provided only minimal data to support this conclusion and, in the absence of adequate supporting data, the method could not be considered safe for the treatment of Category 1 material. It was stated that the applicant did not provide technical details about the pre-treatment and treatment steps (e.g. parameters for centrifugation and filtration, temperature and pressure curves) and adequate monitoring and surveillance procedures (following the HACCP concept). The Panel

recommended that the method is appropriately validated to ensure the safe processing of Category 1 ABPs.

As a result, Regulation (EU) 749/2011 acknowledged the EFSA opinion and stated in its recitals that the multi-step catalytic process should be authorised for rendered fats derived from Category 2 and Category 3 materials, but should be rejected for rendered fats derived from Category 1 material.

The amendment added the new method in point J, Section 2 Chapter IV Annex IV of Regulation 142/2011, as amended: The multi-step catalytic process for the production of renewable fuels using:

(i) rendered fats derived from Category 2 material, which have been processed using processing method 1 (pressure sterilisation);

(ii) fish oil or rendered fats derived from Category 3 material, which have been processed using any of the processing methods 1 to 5 or processing method 7; or in the case of material derived from fish oil, any of the processing methods 1 to 7;

(iii) fish oil or rendered fat which have been produced in accordance with Sections VIII or XII of Annex III to Regulation (EC) No 853/2004,[4] respectively.

The approved processing method consists of a pre-treatment of (i) bleaching of the centrifuged materials by passing them through a clay filter; (ii) removal of remaining insoluble impurities by filtration. The subsequent process, the multi-step catalytic process, consists of a hydro-deoxygenisation step, followed by an isomerisation step. The materials must be submitted to a pressure of at least 20 bar at a temperature of at least 250°C for at least 20 minutes.

It is stated in Regulation (EU) 749/2011 that the use of rendered fats derived from Category 1 material for this process shall be prohibited.

Based on the information provided in the application, the only difference between the alternative method evaluated by the previous EFSA Scientific Opinion and the current one, in terms of treatment conditions, is the minimum temperature and pressure in the hydro-treatment process: 250°C and 20 bar in the previous application and 265°C and 30 bar in the method under evaluation.

The evaluation of different oleochemical processes to inactivate the TSE agent in Category 1 material was conducted by the EFSA's BIOHAZ Panel (2011). The European Oleochemicals and Allied Products Group (APAG), a sector group of the European Chemical Industry Council (Cefic), submitted scientific evidence to the Commission regarding the capacity of oleochemical processes to inactivate possible risks linked to TSEs in ABPs not intended for human consumption. The only processes for which experimental data were produced were the production of hydrogenated tallow and fat splitting in uni-tower or multi-tower reactors. The reduction in TSE infectivity attributed to the process in a uni-tower reactor was based on the evidence published by Müller et al. (2008) whereby hydrogenation treatment under processing parameters of 160°C/12 bar/20 minutes produced an estimated $\log_{10}$ reduction of 5.9. The reduction in TSE infectivity achieved by the process in a multi-tower reactor was based on the evidence published by Müller and Riesner (2005) whereby splitting treatment under processing parameters of 200°C/16 bar/20 minutes produced an estimated $\log_{10}$ reduction greater than 6. The BIOHAZ Panel concluded that, considering the uncertainties on the reduction of TSE infectivity in oleochemical products derived from Category 1 material, these products cannot be reliably regarded to be free of infectivity and could therefore pose a risk if they accidently enter the food and feed chain.

3.2. Full description of the process

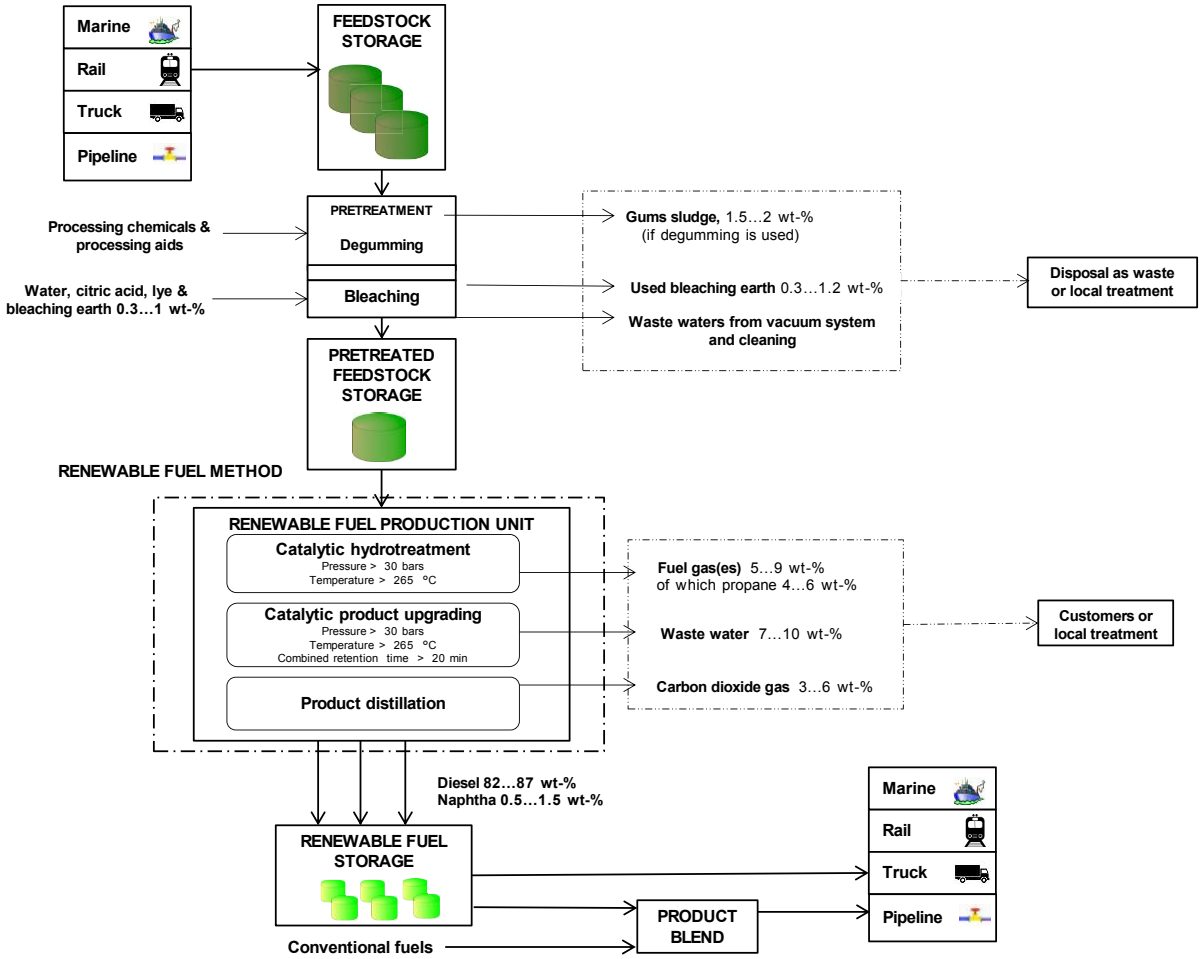
The renewable fuel production process is a continuous multi-step catalytic hydro-treatment process carried out at high pressure and high temperature.

The following description of the manufacturing process has been extracted verbatim from the application. Some generic sentences have been added for ease of reading.

[4] Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin. OJ L 139, 30.4.2004, p. 55–201.

The multi-step catalytic process can, depending on feedstock mix, be preceded by a separate feedstock pre-treatment step. The objective of the pre-treatment step is to remove impurities that can be harmful and detrimental to the catalytic processes. These impurities include any solid particles present in the vegetable oils and/or animal fats used as feedstock as well as, for example, metals that are naturally present in the vegetable oils and/or animal fats at trace levels. Operating conditions in the pre-treatment processes are typically mild compared with the severe processing conditions used in the multi-step catalytic hydro-treatment process.

A flow diagram of the manufacturing process is shown in Figure 1.



Note: the flow diagram submitted by the applicant has been modified in order to improve its readability. The information included in it has been respected. The terminology used in the renewable method does not coincide with the one used in Section 3.2.3.

Figure 1: Flow diagram of the manufacturing process. Category 1 animal fat entering the process has been previously treated according to processing method 1.

3.2.1. Feedstock reception

The raw material, Category 1 animal fat previously treated according to processing method 1, can be received over water or land (trucks/trains). The animal fat will be discharged through flexible hoses/unloading arms and/or fixed pipes and pumped through this closed system to the receiving storage tanks. Before unloading the connection is tested for leaks. After unloading and before disconnecting, the whole system is flushed with nitrogen in order to empty the hoses/unloading arms and pipes.

The animal fat is stored in feedstock tanks. There are no dedicated tanks for animal fat since all tanks are interconnected with pipes and contents can be mixed with other raw materials, e.g. vegetable oils. Therefore, the content of all feedstock storage tanks will be considered to be Category 1 material.

3.2.2. Pre-treatment

The pre-treatment is performed in a unit in a closed building where the degumming and bleaching sections are contained. Both processes are based on physical separation and the process conditions have no quantified effects on the remaining risks of the rendered Category 1 animal fat. The operating temperature indicated is around 90°C and the retention time is about one hour.

The pre-treatment should be considered independent from the hydro-treatment process and consists of two steps: degumming and bleaching. Depending on the quality of the feedstock, either degumming and bleaching or only one of them will be applied to remove impurities.

Degumming

In the degumming section, the feedstock is mixed with acid and caustic solutions in order to remove phospholipids and other impurities, such as metals, from the feedstock by forming gums. The gums are separated from the feedstock by centrifugation. The cleaned feedstock will go either to the bleaching section for additional pre-treatment or to the hydro-treatment process. The by-products generated by the degumming are gums and waste water from cleaning.

Bleaching

In the bleaching section, the feedstock is mixed with bleaching earth in order to remove remaining contaminants and impurities through an adsorption process followed by filtration. The impurities will attach to the bleaching earth, which is filtered out of the feedstock. The cleaned feedstock will go to the hydro-treatment process. The by-products generated by bleaching are bleaching earth with impurities and waste water from cleaning.

3.2.3. Hydro-treatment process

The hydro-treatment process consists of three main process steps/reactors: catalytic hydro-treatment,[5] stripping[6] and isomerisation.[7] This process is a continuous process during which the feedstock flows from one reactor to the next without intermediate storage. The reactors are fixed-bed reactors specially designed to withstand the high pressure and temperatures needed for the process.

The processing conditions during the different steps indicated would be a minimum pressure of 30 bar and minimum temperature of 265°C. The actual retention time is dependent on the size of the reactors and the flow rate, but a minimum retention time of 20 minutes is ensured, according to the application.

Catalytic hydro-treatment

Since the reaction in this first step is exothermic, it creates enough heat for normal operations. The feedstock structures are first catalytically decomposed in the presence of hydrogen (i.e. catalytic hydro-treatment). The main structures in the vegetable oils and/or animal fats used as feedstock are tri-, di- and monoesters of fatty acids and glycerol (i.e. tri-, di- and monoglycerides) as well as free fatty acids.

In the first catalytic step, these structures are cracked into short and long hydrocarbons, water and carbon oxides. The long chain hydrocarbons are separated from the short chain hydrocarbons, the water and the carbon oxides. The short chain hydrocarbons are mainly propane, which will be used as a fuel. The by-product generated by this step of the process is water as result of the chemical reaction:

[5] Referred to in the application as 'hydro-treatment process'.
[6] Referred to in the flow diagram as 'catalytic product upgrading'.
[7] Referred to in the flow diagram and in the application as 'product distillation' or 'distillation'.

$$C_{57}H_{102}O_6 + 16H_2 \rightarrow 6H_2O + C_3H_8 + 3C_{18}H_{38}$$

Stripping

For start-up and isomerisation, additional heat is provided by a hot oil heater in a closed system. The hot oil has no contact with the feedstock or (intermediate) products. The water formed is separated from the hydrocarbons by decantation after the water is stripped from light hydrocarbons, H_2S and hydrogen in a stripping column. The long-chain hydrocarbons are further processed in a second catalytic process step to enhance the fuel properties of the hydrocarbon fraction. The by-products generated by this step of the process are carbon oxides, decanted water, H_2S and hydrogen.

Isomerisation

In the third step, isomerization, the hydrocarbon mixture is finally fractionated by distillation into the different fuel products in accordance with the boiling point ranges for gasoline, jet and diesel fuels.

The end products are renewable fuels chemically composed of iso- and n-paraffinic hydrocarbons. The by-products generated by this step of the process are propane-rich light gases, pure water and CO_2.

3.2.4. Storage of the end product

The end products (renewable diesel, renewable jet fuel, renewable propane and renewable gasoline) are stored in product tanks. The tanks are all equipped with advanced, automated, level controls to prevent overfilling. At high level, the pumps will automatically stop the filling.

The storage systems, piping and pumps for unloading feedstock and loading the end-product are completely separated. Therefore re-contamination of the end-product is not possible.

3.3. Full description of the material to be treated

The feed for the production of the renewable diesel is a mixture of vegetable oils, animal fats and free fatty acids (originating from the refining of edible oils, fat and biodiesel, acid oils from soap stocks and deodorizer distillates) with an expected average content of Category 1 animal fat of 15%.

3.4. Hazard identification

This application is specifically aimed at using Category 1 animal fat, a high-risk material due to the potential presence of TSE agents. The renewable fuel method proposed by the applicant is suitable for all kinds of animal fats and/or plant oils as a feedstock. Besides TSE agents, Category 1 material can hold other hazards caused by contamination of the material, which were taken into account.

3.5. Level of risk reduction

Given the high resistance to destruction, and in particular the high thermo-stability, of the infectious agents causing TSEs (Somerville et al., 2009), it is assumed that if the alternative method ensures the inactivation of the TSE agent, then all microorganisms, including spore-forming bacteria and thermo-resistant viruses, will be completely inactivated. Therefore, the focus will be on the risk reduction in relation to TSE agents.

Before the feedstock is accepted into the process, it will be ensured that the animal fat derived from animal by-products is first processed using processing method 1 (pressure sterilisation) as set out in Chapter III of Annex IV of Commission Regulation (EU) No 142/2011. During transport, storage and pre-treatment there will be no further inactivation of the prions.

During the hydro-treatment process, the prions will be inactivated by both physical and chemical destruction.

3.5.1. Physical inactivation

Physical inactivation of the TSE agent depends on the combined effects of pressure, temperature and retention time during the different sections of the total treatment (at least 30 bar at a temperature of at least 265°C for no less than 20 minutes).

As stated by the applicant, the pressure in the hydro-treatment process is no lower than 45.9–51.4 barg and in the isomerisation section is 30–40 barg. This is continuously monitored and logged in the automated process control system. It is assumed that the hydro-treatment process refers to the first step of the hydro-treatment process, which is the catalytic hydro-treatment. Barg refers here to the gauge pressure, i.e. pressure reading relative to current atmospheric pressure.

As stated by the applicant, the temperature in the catalytic hydro-treatment section is 265–340°C, and the temperature in the isomerisation section is 306–347°C. Temperature is continuously monitored and logged in an automated process control. If the temperature drops below normal[8] the operation temperature reaction will be incomplete and the end products will be off specification. In that case, they will be either collected in the designated tank or directly re-routed to the top of the reactor for re-processing.

As stated by the applicant, this is a continuous process and all reactors are in line without intermediate storage. Retention time is not monitored but is calculated based on reactor sizes in the catalytic hydro-treatment and isomerisation sections, and on the feed rate. The lower the fresh feed intake rate into the unit, the longer the retention time. The way that the retention time was calculated in the application is shown in Table 1.

[8] It is assumed that the normal operation temperature is at least 265 °C.

Table 1: Retention time calculations for the different plants

		Hydro-treatment section[(a)]				Isomerisation section[(b)]				Total
Plant name	Fresh feed rate t/h	Liquid volume (m^3)	Max flow rate (kg/h)	Min flow density (kg/m^3)	Min retention time (minutes)	Liquid volume (m^3)	Max flow rate (kg/h)	Min flow density (kg/m^3)	Min retention time (minutes)	Min retention time (minutes)
NExBTL Porvoo 1	33	34.8	150 142	614	8.5	15.2	30 141	614	18.6	***27.1***
NExBTL Porvoo 2	33	34.8	150 142	614	8.5	18.3	30 141	614	22.4	***30.9***
WS NExBTL	114	120.3	620 600	530	9	98.2	120 100	522	21.5	***30.5***

(a): It is assumed that the Hydro-treatment section refers to the first step, which is the catalytic hydro-treatment process.
(b): It is assumed that the Isomerisation section refers to the second and third steps which are catalytic product upgrading and product distillation, as in Figure 1.

3.5.2. Chemical inactivation

In addition to the physical inactivation of TSE agents, the applicant suggested that chemical inactivation will occur during the proposed treatment, based on the destruction of the prion molecule due to hydrogenolysis, as shown in Figure 2. Proteins are decomposed due to the cleavage of C–O, C–N and C–S bonds, producing, respectively, carbon monoxide and dioxide, ammonia and hydrogen sulphide.

It was indicated that the presence of remaining prions after hydrogenolysis can be detected by nitrogen analysis. The nitrogen concentration of the intermediate product from the hydro-treatment reactor is analysed. If the nitrogen concentration is too high, the intermediate product is returned to the hydro-treatment reactor for reprocessing.

This was only qualitatively indicated, and no experimental evidence of the effectiveness of this process was provided, nor of the sensitivity of the proposed method to determine prion viability. Since no quantitative evidence of the level of chemical inactivation was provided, its impact on the reduction of infectivity could not be considered.

Both physical and chemical inactivation occur simultaneously during the hydro-treatment.

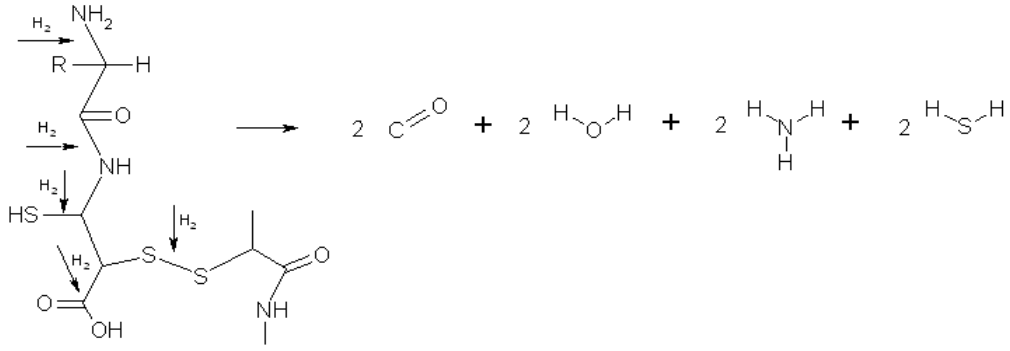


Figure 2: Chemical reaction showing bond cleavage of the prion protein, as provided by the applicant

The applicant estimated the level of risk reduction based on extrapolations from the information available in the literature. In particular, it used research articles by Müller et al. (2006, 2008). According to the applicant, Müller et al. (2006) studied the inactivation of prions after processing fats by heat and pressure during hydrolytic fat splitting. They found that a treatment at 200°C, 10 bar, for 20 minutes resulted in an infectivity reduction factor (RF) of 7 $\log_{10}$. Based on this result, Müller et al. (2006) concluded that hydrolytic fat splitting is an effective process for reducing TSE contamination to an acceptable minimum. In a further study, Müller et al. (2008) evaluated the effect of hydrogenation of fats on prion decontamination. They reported that hydrogenation at 160°C and 12 bar for 20 minutes resulted in an RF of six $\log_{10}$. Based on the experimental data from Müller et al. (2006, 2008), the applicant estimated that the level of TSE reduction as a function of the pressure or the treatment temperature would be greater than 10 $\log_{10,}$ assuming that a linear relationship exists in both cases.

3.5.3. The assessment of the experimental model by the publications by Müller et al.

No evidence of the level of inactivation under real-life conditions using industrial equipment was provided by the applicant. The two papers submitted by the applicant (Müller et al., 2006, 2008) were assessed by the Panel, as well as a third paper (not provided by the applicant) but by the same authors that included additional data on the effect of heat treatment in different fat/glycerol/water mixtures on scrapie infectivity (Müller et al., 2007). Additional papers from the literature were evaluated but experimental conditions were not similar to those of the process under evaluation and therefore were not considered further.

In the experiments described by Müller et al. (2006, 2007, 2008) a laboratory inactivation model for PrP^{Sc} was used that closely replicates the conditions applied in the industrial application submitted by the applicant. In this respect, the experimental outcomes regarding PrP^{Sc} infectivity or degradation can be considered a good indicator of the industrial process.

The titration method

The experimental model used by Müller et al. (2006, 2007, 2008) was based on the measurement of infectivity using the incubation time interval assay (ITIA) method, a well-established and widely used method introduced by Prusiner et al. (1982). According to the ITIA method, incubation periods (IPs) are recorded after bioassaying serial dilutions of a TSE strain (Sc263 in this case). The IPs are then plotted against the dilution factor and equations can be derived from the best-fit curves of the plot. The same strain (in this case Sc263) is subjected to specified treatments (i.e. inactivation regimes as described in the papers) and the product of each treatment is bioassayed in the same animal species. The mean incubation period for each treatment is calculated.

The titre of each treatment is calculated with the equations derived from the plots, as above mentioned. Compared with the end point dilution (EPD) method, ITIA uses fewer animals and is more economical. Although there is no consensus on this point, the ITIA may not be as precise or sensitive as the EPD.

Müller et al. (2006, 2007, 2008) used the ITIA method for titre calculations. Neither the plot nor the data that derived from the serial dilutions of the strain are shown in the papers. Instead, there is a reference to Prusiner et al. (1982). In this respect, the initial plot/data from the dilution series should have been generated and presented, as it is the case in other papers presenting similar approaches, e.g. Somerville et al. (2009) and Yoshioka et al. (2013). It is therefore assumed that Müller et al. (2006, 2007, 2008) used the curve or equations produced by Prusiner et al. (1982). There is no certainty that the animals used by Müller et al. (2006, 2007, 2008) in their studies behaved similarly to those used 24 years earlier by Prusiner et al. (1982). Genetic drifts that may affect bioassay parameters can occur even within the same breeding unit.

The strain and mouse model

The selected experimental model is based on the use of the scrapie strain Sc263K inoculated intra-cerebrally into Syrian hamsters. This is not a model that uses transgenic mice expressing the PRNP gene of a susceptible species and no data are available on direct comparison between the heat resistance of this strain and that of bovine spongiform encephalopathy (BSE)-field strains.

Although the experimental model did not use a BSE strain, it did use a TSE source that is very resistant to heat inactivation. This model has been favoured 'because it is accepted as a well-validated, highly sensitive model' (Müller et al., 2006). However, it is not known if the scrapie strain used by Müller et al. behaves similarly to the BSE strain under the specific inactivation conditions, which is known to be highly resistant to decontamination methods. This is acknowledged by the authors: 'prion strains may differ with regard to specific inactivation procedures' (Müller et al., 2006). It is not possible, therefore, to assess how the BSE strain would behave under similar conditions.

Confirmation of the disease

Müller et al. (2006, 2007, 2008) do not explicitly mention if TSE was confirmed in the hamsters using a statutory diagnostic laboratory method. It cannot be excluded that the TSE diagnosis was based purely on clinical signs (e.g. the animals 'were examined for the development of clinical neurological disease …' (Müller et al., 2006, 2008). Clinical evaluation alone is not a very reliable method and is subject to large inter- and intra-observer variability and should always be confirmed by demonstration of vacuolation or detection of PrP^{Sc} (the abnormal isoform of the prion protein resulting) in the brain of experimental animals.

It is possible that conditions other than TSE may cause neurological clinical signs. This could provide an alternative explanation of the anomaly observed at 200°C and the inconsistent data obtained from the EPD for heat treatment at 90°C, 20 minutes, in 90% fat and 10% water mixture, as reported by Müller et al. (2007).

Interpretation of the results

The ITIA method was used to assess the titre only for bioassays with a mean IP of less than 140 days (Müller et al., 2006, 2007, 2008). Bioassays with longer IPs 'were not included in the calculation of the inactivation factors. Instead, the bioassay detection limit of 2 $\log_{10}$ ID_{50} was used' (Müller et al. 2006). This clarifies how the titration estimates shown in this paper for the fatty acid regime at 110°C, 140°C and 170°C were derived. The authors mention that 'this is a conservative treatment to avoid an overestimation of the reduction achieved', but they do not explain how they reached this conclusion.

According to Müller et al. (2006, 2007) 'the inactivation of prion infectivity is always achieved much more effectively than the degradation of PrP27–30 occurs'. Prion degradation was assessed using Western blot (Müller et al. 2006, 2007, 2008). There is a body of research indicating that, compared with Western blot, infectivity is a far more sensitive parameter in detecting TSE. This is why prion misfolding cyclic amplification was developed: because a prion detection method that was at least as, or even more, sensitive than bioassay was required. In addition, there is not always a direct quantitative correlation between the amount of TSE infectivity and the PrP^{Sc} levels detected biochemically (Gonzalez et al., 2012).

In the fatty acid regime applied in the studies, there was a correlation between increasing temperature and decreasing PrP^{Sc} infectivity up to 170°C. Paradoxically, this relationship was not consistent at 200°C. At this temperature, an increase in infectivity was observed. This seems to be an actual result as it is presented in the Müller et al. (2006) and repeated in the 2007 publication. This result is an oddity, as a more aggressive treatment would be expected to achieve an increased reduction in infectivity.

The incubation period for the fatty acid treatment at 200°C was 116–117 days post inoculation (dpi); this was significantly shorter than the IP for the same treatment at 110°C, which was 146 dpi (Müller et al., 2006).

Müller et al. (2007) attributed the infectivity observed at 200°C to increased amounts of aggregate mixtures with higher molecular mass (> 60 kDa). Regrettably, these important data have not been provided by the applicant. In addition to specific PrP^{Sc} bands, non-specific bands can be visualised on Western blot gels. The fact that a band is revealed after application of a PrP^{Sc} antibody does not necessarily mean that it is PrP^{Sc}-specific, as the antibodies can show affinity to molecules other than PrP^{Sc}.

It is possible that during treatment at 200°C other products may be generated, one of which could have neurotoxic effects, or that appreciable amounts of glycerol are produced, which may have a protective effect on the heat stability of prions. If the TSE status of the animals cannot be confirmed, the possibility that the animals in the 200°C treatment group died from a neurological disease unrelated to TSE cannot be unequivocally excluded. It is also unlikely that at 200°C PrP^{Sc} infectivity increases to levels which are associated with detectable PrP^{Sc} using Western blot yet no PrP^{Sc} was detected in the final product.

It is not clear if this oddity is an experimental artefact due to the difficulties of measuring infectivity, or is attributable to a biological factor, for example the increased production of glycerol at high temperatures.

3.5.4. Outcome of the assessment

The method under assessment is very similar to the one approved in 2010 for Category 2 and Category 3 materials. Temperature and pressure conditions are higher than those in the previous method and, in this case, a quantitative estimate of the risk reduction level for Category 1 material was provided.

According to point 2(D), Chapter II, Annex VII of Regulation 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'.

Although based on experiments conducted in laboratory conditions and not at industrial scale using the same equipment as in a processing plant, the model applied by Müller et al. (2006, 2008) under various treatment conditions of bovine edible tallow (fat hydrogenation under stirring conditions at 160°C, 12 bar, for 20 minutes (2006), and 200°C, 12 bar, for 20 minutes (2008)) is scientifically sound, based on a state-of-the-art and well-accepted experimental model, and can be considered a good indicator of the industrial process. Thus, it can be accepted as a valid model for comparisons. Müller et al. (2006, 2008) use similar raw material (bovine edible tallow) and an analogous process (fat hydrogenation). The drawbacks of the model were identified and discussed above.

According to Müller et al. (2006), 'due to the availability of high-infectivity titre prion rods and a bioassay detection limit of 2 $\log_{10}$ ID_{50}, infectivity assays could be performed even under industrial temperatures as high as 200°C, an infectivity reduction factors of up to 6.9 $\log_{10}$ ID_{50} could be detected'. This detectable reduction would be in addition to the inactivation achieved by the pressure sterilisation method applied prior to the process proposed by the applicant. Based on the principles of heat inactivation, it can be expected that any process that uses more stringent parameters (higher temperature and pressure and/or longer exposure time) would achieve at least the same or a higher level of reduction, irrespective of whether the inactivation kinetics are linear or non-linear.

Although there are no agreed standards on the level of TSE inactivation required to render safe a processed Category 1 material, as discussed in Section 2.2, the Panel considered that at least a reduction of 6 $\log_{10}$ in the infectivity titre would be at least equivalent, for Category 1 material, to the processing methods previously approved.

Despite the reduction in infectivity achieved by the treatment applied in Müller et al. (2006, 2008), manifested by extended IPs and lower infectivity titres, it is important to note that in all cases infectivity remained after the treatment, as shown by high attack rates. The inoculation route (intra-cerebral) does not represent the normal exposure route to the TSE agent in natural conditions (oral) and always results in higher transmission rates (EFSA BIOHAZ Panel, 2015).

There are experimental data showing that similar processes carried out at temperatures between 160 and 200°C deliver a reduction in TSE infectivity of at least a 6 $\log_{10}$ in 20 minutes. A similar if not higher level of reduction is expected to be achieved by the alternative method proposed. Therefore the treatment under assessment can be considered at least equivalent to the processing methods previously approved for Category 1 animal fat as long as the critical parameters are kept at all times as specified by the applicant.

It is essential to accurately monitor pressure, temperature and retention time in order to guarantee that the process parameters are maintained.

In relation to retention time, the applicant calculated it taking into account the reactor size and flow rate, which only leads to an estimate of the minimum retention time, as it does not take into account other factors, such as the effect of mixing that will occur in the fluid. Therefore, no indication of the real minimum retention time of 20 minutes achieved was provided nor of the associated variability. An appropriate method to determine the minimum retention time based on experimental trials should be implemented.

3.6. HACCP plan

A detailed HACCP plan was provided by the applicant. The temperature, pressure and flow rate of the hydro-treatment process were designated as critical parameters to set limits in order to establish Process Criteria. A few improvements are necessary:

- information should be provided on verification procedures and documentation;
- parts of the validation section of the HACCP plan are not clear. For example, in the section dealing with the effect of pressure on prion inactivation, the relevant temperature is not provided.

- some items are incorrectly listed as hazards in the hazards analysis table, e.g. inadequate treatment: temperature < 265°C. This should be corrected.

3.7. Risk associated with interdependent processes

Point 5(a), Chapter II, Annex VII of Regulation (EU) 142/2011 requires that the applicant provides information on the risks associated with interdependent processes. In particular, the applicant is required to provide information on the outcome of an evaluation of possible indirect impacts, which may: (i) influence the level of risk reduction of a particular process; or (ii) arise from transport or storage of any products generated during the process and from the safe disposal of such products, including waste water.

In the HACCP plan accompanying the application, measures are set out to mitigate any risks that may arise during transport and storage of the material. For example, during unloading of the feedstock measures are in place to prevent spillage. A procedure for dealing with spills is set out. The effects are mitigated by cleaning the jetty/road and disposing the resulting waste as Category 1 material. In the event of a release to surface water (sea), the spilled material will be removed by suction. If needed, spreading is avoided by using oil booms. The collected material will be disposed as waste using the methods described in Chapter IV of Annex IV of Commission Regulation (EU) No 142/2011.

All solid by-products of the process will be disposed of as waste using the methods described in Chapter IV of Annex IV of Commission Regulation (EU) No 142/2011.

Point 1(a), Section 3, Chapter IV, Annex IV of Regulation (EU) 142/2011 states that products derived from the processing of Category 1 material shall be:

(i) disposed in accordance with Article 12(a) or (b) of Regulation (EC) 1069/2009;

(ii) disposed of by burial in an authorised landfill;

(iii) transformed into biogas, provided the digestion residues are disposed of in accordance with points (i) or (ii), or

(iv) further processed into fat derivatives for uses other than feeding.

3.7.1. Waste water handling

According to Section 2, Chapter I, Annex IV, of Regulation (EU) 142/2011, plants processing Category 1 material shall have a pre-treatment process for the retention and collection of animal material as an initial step in the treatment of waste water. The equipment used in the pre-treatment process shall consist of drain traps or screens with apertures with a filter pore or a mesh size of no more than 6 mm in the downstream end of the process or equivalent systems that ensure that the solid particles in the waste water passing through them are no larger than 6 mm. No grinding, maceration or other processing or application of pressure that could facilitate the passage of solid animal material through the pre-treatment process shall be carried out. All animal material retained in the pre-treatment process in premises as referred to above shall be collected and transported as Category 1 material, as appropriate, and disposed of in accordance with Regulation (EC) No 1069/2009, which includes in Article 12 the obligation to dispose Category 1 material by incineration or co-incineration with or without prior processing, use as fuel for combustion, and in certain circumstances, by burial in an authorised landfill.

According to the applicant, waste water consists of water from the pre-treatment and chemically formed water in the hydro-treatment process. The chemically formed water will not contain any contaminations related to animal fats due to the process conditions in the hydro-treatment unit.

This waste water in the unit results from (a) condensation from steam used in the process and for cleaning of filters and equipment with steam and (b) water from other cleaning activities. It will be in contact with the crude feedstock, including the Category 1 animal fat. The applicant states that measures will be in place to ensure that small particles possibly present in the animal fat feedstock will not be present in the waste water. This is achieved by either a strainer already in the feedstock feed line the pre-treatment unit (PTU) and/or a strainer in the waste water sewer system from the pre-treatment unit. Oil will be separated from the waste waters by fat traps. The procedures for

dealing with waste water meet the requirements set out in Section 2, Chapter I Annex IV, of Regulation (EU) 142/201.

3.8. Risk associated with the intended end use of the process

According to Point 5(a), Chapter II, Annex VII, of Regulation (EU) 1142/2011 (i) the risks associated with the intended end use of any products generated during the process must be specified; (ii) the likely risks for human health and animal health and possible impacts on the environment must be assessed on the basis of the risk reduction estimated in accordance with point 2(d).

The end products resulting from the alternative method are renewable diesel, renewable jet fuel, renewable propane and renewable gasoline. The end-products are chemically composed of iso- and n-paraffinic hydrocarbons. Considering the nature of the final product and the end use of the process, no additional risk associated with the intended use is foreseen.

4. Conclusions

- The method under assessment is very similar to the one approved in 2010 for Category 2 and Category 3 materials. Temperature and pressure are higher than in the previous method: 250°C and 20 bar in the previous application and 265°C and 30 bar in the method under evaluation. The retention time is the same.
- The experimental model presented by the applicant is based on the results of two scientific papers, Müller et al. (2006, 2008), using the same raw material and similar treatments. The experimental model to measure TSE inactivation has been thoroughly reviewed. Limitations and inconsistencies of the model have been identified and are detailed in the opinion.
- Despite the limitations and uncertainties identified, the experimental model is scientifically sound and can be accepted as a valid model for comparisons.
- There are no agreed standards on the level of TSE inactivation required to render safe a processed Category 1 material. Previous EFSA opinions (2003, 2004) established that at least a reduction of 6 $\log_{10}$ in the TSE infectivity should be achieved in order to be at least equivalent, for the relevant category of animal by-products (Category 1), to the processing methods previously approved.
- According to Müller et al. (2008), hydrogenation of animal fat at 160°C and 12 bar for 20 minutes produced a detectable RF of 6 $\log_{10}$.
- Based on the principles of heat inactivation, it can be expected that any process using more stringent parameters (higher temperature and pressure and/or longer exposure time) would achieve at least the same or higher level of reduction, irrespective of whether the inactivation kinetics are linear or non-linear. This is in addition to the inactivation achieved by the pressure sterilisation method (method 1) applied prior to the alternative method under assessment.
- The treatment under assessment can be considered at least equivalent, to the processing methods previously approved for the treatment of Category 1 animal fat as long as the critical parameters (265°C, 30 bar and 20 minutes) are maintained at all times.
- It is essential to accurately monitor pressure, temperature and retention time in order to guarantee that the process parameters are maintained. The applicant estimates retention time taking into account the reactor size and flow rate, which leads to only an estimate of minimum retention time, as it does not take into account other factors, such as the effect of mixing that will occur in the fluid. Therefore, no indication of how the real minimum retention time of 20 minutes will be guaranteed at all times is provided, nor of the variability associated with this critical parameter.

5. Recommendations

- The estimation of the retention time is based on the size of the reactor and the flow rate of the material but the real minimum time in actual processing conditions has not been established. This is a critical parameter. It should be determined and validated that a

minimum retention time of 20 minutes is achieved in all parts of Category 1 material under normal operation at industrial scale in order to ensure the effectiveness of the treatment.

Documentation provided to EFSA

1. Report of the competent authority related to the application of Neste Oil. 19 February 2015. Submitted by the Ministry of Agriculture and Forestry (Finland).

2. Application Neste Oil. 19 February 2015. Submitted by the Ministry of Agriculture and Forestry (Finland).

3. Renewable fuel flow diagram. 19 February 2015. Submitted by the Ministry of Agriculture and Forestry (Finland).

4. '2015-04-17 HACCP plan Neste Oil'. 28 April 2015. Submitted by Neste Oil.

5. 'EFSA AF 28.4.2015'. 28 April 2015. Submitted by Neste Oil.

6. 'EFSA 31.7.2015'. 31 July 2015. Submitted by Neste Oil

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Abbreviations

ABP	Animal by-product
APAG	European Oleochemicals and Allied Products Group
BIOHAZ	EFSA Panel on Biological Hazards
BSE	bovine spongiform encephalopathy
Cefic	European Chemical Industry Council
dpi	days post inoculation
EFSA	European Food Safety Authority
EPD	End point dilution
EU	European Union
HACCP	Hazard Analysis and Critical Control Points
HPHB	High-pressure hydrolysis biogas
IP	Incubation period
ITIA	Incubation time interval assay
kDa	Kilodalton
PrP^{Sc}	Abnormal isoform of prion proteins (PrP) resulting from a post-translational modification of the cellular prion protein (PrP^{C})
PTU	Pre-treatment unit
RF	Reduction factor
TSE	Transmissible spongiform encephalopathy