

SCIENTIFIC OPINION

Scientific Opinion on the Neste Oil Application for a new alternative method of disposal or use of Animal By-Products¹

EFSA Panel on Biological Hazards (BIOHAZ)^{2, 3}

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ABSTRACT

EFSA's Scientific Panel on Biological Hazards (BIOHAZ) was asked for a scientific opinion on a novel process developed by the Neste Oil Company as a safe means of disposal of animal by-products (ABP) according to Regulation (EC) 1774/2002. It is proposed that the method, known as the "Renewable Fuel" method, will be used for the treatment and disposal of Category 1 and Category 2 rendered animal fat obtained from animal by-products that have been produced according to processing method 1 as referred to in Annex V, Chapter III of Commission Regulation (EC) 1774/2002 and for the treatment of Category 3 rendered animal fat that has been produced according to any of the processing methods 1 to 7 as referred to in the same Annex. The proposed process technology consists of a pre-treatment and of a continuous multiple step catalytic process. The main steps of interest for this assessment are called hydrodeoxygenation and isomerisation by the applicant. The production process can utilize a mixture of vegetable-oil and animal fat as feedstock. The Panel concluded that, in principle, the "Renewable Fuel" method may be appropriate for the safe destruction of BSE/TSE infectivity in animal waste. However, the company provided minimal data to support this conclusion (e.g. no quantitative estimate of the risk reduction level for Cat. 1 material was given). In the absence of such supporting data, the "Renewable Fuel" method cannot be considered safe for the treatment of such Category 1 wastes. The process proposed by Neste Oil can be considered to be safe for the treatment of Cat. 2 and 3 rendered animal fat since the input materials have already undergone a process ensuring adequate risk reduction.

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KEY WORDS

Animal by-products, alternative methods, tallow, Neste Oil, "Renewable Fuel" method

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3 Acknowledgement: The Panel wishes to thank the members of the Working Group on Neste Oil Application: Reinhard Böhm, John Griffin, Christophe Nguyen-The, Zbigniew Paluszak and Robert Somerville for the preparatory work on this scientific opinion.

SUMMARY

Following a request from the Finnish Competent Authority, the Panel on Biological Hazards (BIOHAZ) was asked to deliver a scientific opinion on the Neste Oil Application for a new alternative method of disposal or use of Animal By-Products (ABPs).

In its dossier, the Neste Oil Company asked for approval of a method, known as the “Renewable Fuel” method, for the treatment and disposal of Category 1 and Category 2 rendered animal fat obtained from animal by-products that have been produced according to processing method 1 as referred to in Annex V, Chapter III of Commission Regulation (EC) 1774/2002⁴ and for the treatment of Category 3 rendered animal fat that has been produced according to any of the processing methods 1 to 7 as referred to in the same Annex.

According to the applicant, the proposed process technology consists of a pre-treatment and of a continuous multiple step catalytic process. The main steps of interest for this assessment are called hydrodeoxygenation and isomerisation by the applicant. The production process can utilize a mixture of vegetable-oil and animal fat as feedstock.

The BIOHAZ Panel assessed the application following the scheme proposed in the “Guidelines for applications for new alternative methods of disposal or use of animal by-products” prepared jointly by the Health and Consumer Protection Directorate-General (DG SANCO) and EFSA⁵.

The Panel concluded that, in principle, the Neste Oil “Renewable Fuel” method may be appropriate for the safe destruction of BSE/TSE infectivity in animal waste. However, the company has provided minimal data to support this conclusion (e.g. no quantitative estimate of the risk reduction level for Cat. 1 material was given). In the absence of such supporting data, the “Renewable Fuel” method cannot be considered safe for the treatment of such Category 1 wastes. The process proposed by Neste Oil can be considered to be safe for the treatment of Cat. 2 and 3 rendered animal fat since the input materials have already undergone a process ensuring adequate risk reduction.

The BIOHAZ Panel recommended that the Neste Oil “Renewable Fuel” method should be appropriately validated for ensuring the safety of processing Cat. 1 ABPs.

4 Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. OJ L 273, 10.10.2002, p. 1-95.

5 EC (European Commission), 2008. Guidelines for applicants for new alternative methods of disposal or use of animal by-products. http://ec.europa.eu/food/food/biosafety/animalbyproducts/disposal0604_rev_en.pdf

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BACKGROUND AS PROVIDED BY THE FINNISH COMPETENT AUTHORITY

Under Regulation (EC) No 1774/2002 on animal by-products not intended for human consumption of 3 October 2002, alternative methods of disposal or use of animal by-products may be approved by the Commission after consultation of EFSA. The Finnish Oil Company Neste Oil has prepared an application for Community approval of an alternative method for renewable fuel production to be added to Commission Regulation (EC) 92/2005. Instead of a national approval a community approval is needed, because the new method would be used also outside Finland in Rotterdam and in Singapore.

TERMS OF REFERENCE AS PROVIDED BY THE FINNISH COMPETENT AUTHORITY

The Finnish Competent Authority asked EFSA to assess the safety of the Neste Oil method as a new alternative method of disposal or use of animal by-products.

ASSESSMENT

1. Introduction

The terminology used in this assessment conforms with the “Guidelines for applications for new alternative methods of disposal or use of animal by-products” prepared jointly by the Health and Consumer Protection Directorate-General (DG-SANCO) and the European Food Safety Authority (EFSA)(EC, 2008).

The applicant and the Finnish Competent Authority provided respectively the application and a documentary report. Moreover, the applicant was invited to present the proposed method to a meeting of the *ad hoc* working group in charge of assessing the application that was held on 21 May 2010. Additional information was received on 25 May 2010 and on 16 June 2010.

In its dossier, the applicant asked for approval of a method, known as the “Renewable Fuel” method, for the treatment and disposal of Category 1 and Category 2 rendered animal fat obtained from animal by-products that have been produced according to processing method 1 as referred to in Annex V, Chapter III of Commission Regulation (EC) 1774/2002⁶ and for the treatment of Category 3 rendered animal fat that has been produced according to any of the processing methods 1 to 7 as referred to in the same Annex.

The applicant also asked for approval of the products obtained by the “Renewable Fuel” method in plants located in a third country where classification of the animal fat is not performed in accordance with the Commission Regulation (EC) 1774/2002.

It is outside the remit of EFSA to assess alternative processing method that are used outside the EU which do not necessarily use input material conforming to the EU legal framework. Consequently, this part of the application was not considered further.

2. Process description

According to the applicant, the proposed process technology consists of a pre-treatment and of a continuous multiple step catalytic process. The main steps of interest for this assessment are called hydrodeoxygenation and isomerisation by the applicant. The production process can utilize a mixture of vegetable-oil and animal fat as feedstock.

The pre-treatment process is deemed to purify the material to be used in the multiple step catalytic process and consists of an acid hydrolysis followed by a centrifugal step to remove precipitates (degumming), then an absorption step with clay (bleaching) followed by filtration to remove the remaining impurities that may disrupt the main process (e.g. proteins). According to the information provided by the applicant on 21 May 2010, the operating conditions are: temperature about 90°C, pH 2, time 1 hour. The by-products generated by the pre-treatment are i) sludge, containing oils, phosphates and metals, ii) exhausted clay (used bleaching earth) with an oil content ranging from 30 to 50% iii) waste water, to be treated in waste water plant. Sludge and used clay are dried and, in case of use of Cat. 1 material, incinerated.

In the multiple step catalytic process, the feedstock is first decomposed in the presence of hydrogen (i.e. hydrodeoxygenation). The main structures in the 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

6 Regulation (EC) No 1774/2002 of the European Parliament and of the Council of 3 October 2002 laying down health rules concerning animal by-products not intended for human consumption. OJ L 273, 10.10.2002, p. 1–95

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 long chain hydrocarbons are further processed in a second catalytic process step (isomerisation) to enhance the fuel properties of the hydrocarbon fraction.

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 chemically composed of iso- and n-paraffinic hydrocarbons.

According to the applicant, the typical operating conditions in the processes are temperatures above 250°C, pressures above 20 bar and total residence time longer than 20 minutes for both the hydrodeoxygenation and isomerisation steps. The by-products generated by the process are i) waste water which is first neutralised and then treated in a waste water plant, ii) propane and off-gases which are burned in the refinery fuel gas network and iii) CO₂ which is cleaned and released to the atmosphere. The by-products are removed after the hydrodeoxygenation step and therefore are submitted to one treatment of at least 250°C, 20 bars, 20 minutes.

A flow diagram describing the proposed process has been provided by the applicant.

3. Risk categories

Cat. 1, Cat. 2 and Cat. 3 ABPs as defined in the Regulation (CE) 1774/2002 as amended.

4. Identification and characterisation of risk material

Animal fats deriving from Cat. 1, Cat. 2 and Cat. 3 ABPs. There is a potential TSE risk inherent to Cat. 1 ABPs.

5. Agent risk reduction

In the case of Cat. 1 and 2 ABPs, the input material is purchased by the applicant after treatment according to processing method 1 as defined in the ABPs Regulation.

In the case of Cat. 3 ABPs, the input material is purchased by the applicant after treatment according to any of the processing methods 1 to 7 as defined in the ABP Regulation.

The applicant extrapolated the risk reduction achieved by the multiple step catalytic process by comparison with other methods of processing ABPs (namely process method 1 as defined in the ABPs Regulation and the Biodiesel process according to Reg. (EC) 92/2005)⁷.

The applicant claims that the proposed process conditions (temperatures above 250°C, pressures above 20 bar and total residence time longer than 20 minutes) are more severe than the ones of already approved methods to process Cat. 1 ABPs and that the final products can be regarded as safe, regardless of the origin and the category of the animal fat to be processed.

⁷ Regulation (EC) No 92/2005 of 19 January 2005 implementing Regulation (EC) No 1774/2002 of the European Parliament and of the Council as regards means of disposal or uses of animal by-products and amending its Annex VI as regards biogas transformation and processing of rendered fats. OJ L 19, 21.1.2005, p. 27–33

In theory the end products (i.e. diesel fuel, jet fuel and gasoline) obtained by the multiple step catalytic process can be considered to be safe for the intended use for the following reasons:

- due to the type of pre-treatment, it can be assumed that some of the TSE infectivity present in the input material will be transferred to the by-products generated by the pre-treatment;
- it is known that the proposed treatment at the given time, temperature and pressure relationships should inactivate further TSE infectivity in addition to the treatment with method 1;

Additional risk reduction, again in theory, is given due to the fact that:

- the product itself is burned in a process at temperatures destroying the any remaining TSE infectivity;
- the character of the product is as such that transmission of any remaining TSE infectivity to man or animal is highly unlikely.
- Since the by-products generated in the multiple step catalytic process are submitted to one treatment of at least 250°C, 20 bars, 20 minutes they can be considered to be safe as well.

However, the applicant did not provide any information about the level of risk reduction in the treatment steps and enough technical details and measuring data about the functioning of treatment steps.

In the case of Cat. 1 material, the by-products generated by the pre-treatment (waste water, sludge and exhausted clay) may still contain TSE infectivity. Sludge and exhausted clay are incinerated but not enough information is given concerning the effectiveness of separation of remaining solids and fats from the waste water and the disposal of the latter. This is particularly important in this case since the possible TSE infectivity present in the material to be processed is likely to be carried over into the by-products (including waste water) generated by the pre-treatment.

The treatment of Cat. 2 and 3 materials can be regarded as safe since the input materials have already undergone a process ensuring adequate risk reduction.

6. Risk containment

6.1. Pre-treatment

The disposal of the exhausted clay and the sludge appears to meet the requirements of current regulation. However, the parameters allowing a good separation of sludge and exhausted clay from waste water are not specified. Moreover, it is not clear what happens to the waste water generated during the pre-treatment and how the possible remaining TSE infectivity, in case of processing of Cat. 1 material, is removed.

6.2. Treatment

The nitrogen content is monitored after the hydrodeoxygenation step, since a content higher than 0.1 ppm may disrupt the isomerisation step. The applicant claims that the low nitrogen content can be regarded as an indicator of the absence of prions and of the achievement of the target values (temperature, pressure and time) for the proposed process but no experimental evidence for such a claim was provided.

According to the applicant in case of a nitrogen content above the specified level no product is withdrawn from the production process. However, it is not clear what would be the fate of an end-product not fulfilling the quality specification. The applicant did not declare whether such product should be destroyed or reprocessed.

The applicant reports that any product or by-products obtained after the multiple step catalytic hydrotreatment process shall be regarded as safe.

6.3. Monitoring and surveillance procedures

The applicant did not provide detailed and quantitative information about the risk containment of the biological hazards generated by the pre-treatment and treatment steps.

No critical control points were identified, no validated critical limits were provided, no corrective actions were identified.

Moreover, technical details about the pre-treatment and treatment steps are missing (e.g. parameters for centrifugation and filtration, temperature and pressure curves).

7. Identification of interdependent processes

The applicant claims that the sourcing, transport and storage of the animal fat to be utilized as feedstock is done in a manner that fulfils all the relevant regulations (i.e. the ABPs Regulation and its amendments and as well as all other relevant Community legislation).

The main products (diesel fuel, jet fuel and gasoline) are stored and transported according to the regulations in place for the relevant product classes (according to their flammable properties). According to the applicant these regulations enforce closed storage systems to be used including e.g. full containments of the storage tanks to avoid any uncontrolled spillage in case of leakage.

The applicant claims that the by-products will be treated according to the relevant legislation and following the guidelines given by the competent authority. No by-products are intended for any end-use that would be part of the animal feed or human food chain and they are separated from any material intended to be used as animal feed through out the logistical chain.

8. Intended end-use of the products

Diesel fuel, jet fuel and gasoline.

9. Documentary evidence

The application, including a flow diagram was provided, together with the documentary report of the Finnish Competent Authority. Additional information was received on 25 May 2010 and on 16 June 2010.

As described in section 6 of this document (Risk containment) there were several deficiencies in the documentation provided. In particular, no quantitative estimate of the risk reduction level for Cat. 1 material was given and no adequate HACCP scheme according to the CODEX Alimentarius definition was provided.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

- In principle the Neste Oil “Renewable Fuel” method may be appropriate for the safe destruction of BSE/TSE infectivity in animal waste. However, the company has provided minimal data to support this conclusion (e.g. no quantitative estimate of the risk reduction level for Cat. 1 material was given). In the absence of such supporting data, the Neste Oil “Renewable Fuel” method cannot be considered safe for the treatment of such Category 1 wastes.
- Since it can be assumed that Cat. 1 material may have residual infectivity after treatment with method 1 the pre-treatment has to be regarded at the most critical step in the Neste Oil “Renewable Fuel” method. In this respect, it is not clear how this method ensures the safe disposal of waste water.
- 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 process proposed by Neste Oil can be considered to be safe for the treatment of Cat. 2 and 3 rendered animal fat since the input materials have already undergone a process ensuring adequate risk reduction.

RECOMMENDATIONS

- The Neste Oil “Renewable Fuel” method should be appropriately validated for ensuring the safety of processing Cat. 1 animal by-products.

DOCUMENTATION PROVIDED TO EFSA

1. Letter (ref. n. 2040/23/2009 dated 10/09/2009) and Application from the Finnish Competent Authority with a request to assess the safety of the Neste Oil method as a new alternative method of disposal or use of animal by-products.
2. Documentary report from the Finnish Competent Authority ((ref. n. 2040/23/2009 dated 29/01/2010).
3. Letter from Neste Oil dated 20 May 2010 providing further information.
4. Letter from Neste Oil dated 11 June 2010 providing additional information.

REFERENCES

EC (European Commission), 2008. Guidelines for applications for new alternative methods of disposal or use of animal by-products.