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SCIENTIFIC OPINION

Evaluation of a fluidised catalytic cracking co-processing method for the production of renewable fuels using Category 3 animal fat and used cooking oils

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The declarations of interest of all scientific experts active in EFSA's work are available at https://open.efsa.europa.eu/experts

Abstract

An alternative processing method for the production of renewable fuels from rendered animal fats, pretreated using standard processing methods 1–5 or method 7 and used cooking oils, derived from Category 3 animal by-products, was assessed. The alternative method is based on a fluidised catalytic cracking co-processing treatment with a preheat stage by at least 145°C and a pressure of at least 1.4 barg for at least 13 s, followed by a reactor stage by at least 500°C for 2 s. The applicant selected the use of spores of pathogenic bacteria as primary indicators without carrying out a full hazard identification, which is acceptable as per previous EFSA evaluations. The EFSA BIOHAZ Panel considers that the application and supporting literature contain sufficient evidence to support that the alternative method can achieve a reduction of at least 12 $\log_{10}$ of *C. botulinum* spores and 5 $\log_{10}$ of the spores of other pathogenic bacteria. The Hazard Analysis and Critical Control Point plan contained some inadequacies: the reception of raw materials should be considered a prerequisite (with acceptance criteria) rather than a critical control point and quantitative limits for temperature and holding time at the reactor should be defined. The information provided by the applicant suggests that appropriate corrective actions are in place for dealing with risks associated with interdependent processes and with the intended end use of the products. The applicant also considers as part of the alternative processing method the operation under an unplanned shutdown. EFSA only assesses the alternative processing methods under normal operating conditions. Thus, the procedures under an unplanned shutdown were not assessed as part of the alternative processing method. Overall, the alternative method under evaluation is considered equivalent to the processing methods currently approved in the Commission Regulation (EU) No 142/2011.

KEYWORDS

animal fat, category 3, cracking, renewable fuel, used cooking oil

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SUMMARY

On 7 May 2024, the European Food Safety Authority (EFSA) received from the Dutch Competent Authority (Ministry of Agriculture, Nature and Food Quality, the Netherlands) the application (EFSA-Q-2024-00539) under Regulation (EC) No 1069/2009 referring to the alternative processing method for animal by-products (Category 3 material) submitted by BP Refinery Rotterdam B.V. (referred to as bpRR). The alternative processing method consists of a fluidised catalytic cracking co-processing treatment for the production of renewable fuels. The materials must be exposed to a temperature of at least 145°C and a pressure of at least 1.4 barg for at least 13 s in a preheating system, followed by at least 500°C for 2 s in a reactor. The materials to be treated are rendered animal fats derived from Category 3 materials that have been processed using any of the processing methods 1–5 or processing method 7 (as described in Annex IV of Commission Regulation (EU) No 142/2011) and used cooking oil (UCO) not preprocessed with any of these methods. The BIOHAZ Panel clarified that UCO is considered catering waste and catering waste could be Category 3 or Category 1 animal by-products (ABPs), being the latter in the case of catering waste from means of transport operating internationally, as per Article 10 (p) of Regulation (EC) No 1069/2009. Only Category 3 UCO must be used to produce renewable fuels with the proposed method.

As implemented in previous evaluations for Category 3 ABPs (EFSA BIOHAZ Panel, 2022), the EFSA BIOHAZ Panel considered that, in order to be considered equivalent to the processing methods approved in the legislation, the alternative processing method should 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 $\log_{10}$. If spore-forming pathogenic bacteria are considered relevant in the hazard identification, the required level of inactivation should be a 5 $\log_{10}$ reduction of spores from pathogenic bacteria, with the exception of spores of *C. botulinum*, for which a 12 $\log_{10}$ reduction will be required, as for processing canned pet food. If needed/appropriate, for both spore-forming and non-spore-forming bacteria and viruses, adequately justified alternative non-pathogenic indicator organisms, demonstrating at least a similar level of reduction of all biological hazards possibly present in the Category 3 material, may be used.

Given the possibility of the presence of various pathogens depending on source and location, the applicant used, based on a literature search and due to their high thermal resistance, bacterial spores as the primary indicator for assessing the risk reduction capability of the process. The approach followed by the applicant is consistent with one of the possible scenarios accepted: the selection of bacterial spores as primary indicators to demonstrate a sufficient level of hazard reduction, considering that any process achieving the required level of reduction of bacterial spores will ensure at least a similar level of reduction of any more heat-sensitive biological hazard that may be present in the Category 3 material. The applicant specifically identified spores from Bacillus and Clostridium species as the main targets to demonstrate the method's effectiveness in hazard reduction. This approach included results for a wide range of *Bacillus* and *Clostridium* species, including both pathogenic and non-pathogenic strains. The data also included thermophilic species like *C. thermosaccharolyticum* (now reclassified as *Thermoanaerobacterium thermosaccharolyticum*) and *B. stearothermophilus* (now reclassified as *Geobacillus stearothermophilus*), along with *Desulfotomaculum nigrificans*, a highly heat-resistant spore-forming microorganism.

The applicant presented a body of evidence for the level of hazard reduction based on a non-systematic literature review and the estimation of the $\log_{10}$ reduction after preheating at 145°C for 13 s and at 500°C for 2 s, extrapolated from available data at lower heating temperatures in publicly available studies. However, data extrapolated beyond the interpolation region are not considered in the assessment since the extrapolation analyses exhibit limitations. Considering the evidence available, even if the extrapolation analyses proposed by the applicant are not considered valid, the expected level of reduction achieved for the relevant hazards that may be present is considered equivalent to the reduction required by the standards indicated for Category 3 material.

In the Hazard Analysis and Critical Control Point (HACCP) plan, the reception of animal fats (AF) and used cooking oil (UCO) should be considered a prerequisite (with acceptance criteria) rather than a CCP. The other CCP identified by the applicant, represented by the reactor riser, is considered correct, but quantitative limits for temperature and holding time should have been included in the HACCP plan, along with detailed means of monitoring and corrective actions.

The applicant provided a detailed description of the risks associated with the interdependent processes (storage, transport, disposal) and of the corrective actions that would be implemented for dealing with the risks involved. The end products of the proposed alternative method are renewable fuels. Considering the nature and the expected uses of the final products, no exposure to hazards for humans, animals and the environment, during the normal process, is expected.

The applicant also considered, as part of the alternative processing method, the operation of the fluidised catalytic cracking unit during an unplanned shutdown. EFSA only assesses the alternative processing methods under normal operating conditions. Thus, the BIOHAZ Panel did not assess the procedures during an unplanned shutdown as an alternative method. Any end products produced during an unplanned shutdown should not be considered end products of the alternative method and should be disposed of or used in accordance with Article 13 of Regulation (EC) No 1069/2009. The applicant also developed a HACCP plan for the unplanned shutdown scenario, but this was considered unnecessary. Instead, a corrective action should have been represented in the HACCP plan of the process under normal operating conditions, in case the parameters associated with the identified CCP did not meet the identified quantitative limits.

Overall, the alternative processing method under assessment (which covers only normal operating conditions) can be considered equivalent to the processing methods currently approved in the Commission Regulation (EU) No 142/2011.

1 | INTRODUCTION

On 7 May 2024, the European Food Safety Authority (EFSA) received from the Dutch Competent Authority (Ministry of Agriculture, Nature and Food Quality of the Netherlands) the application (EFSA-Q-2024-00539) under Regulation (EC) No 1069/2009,[1] referring to the alternative processing method for animal by-products (Category 3 material) submitted by bp Refinery Rotterdam B.V. (hereinafter referred to as bpRR).

The applicant submitted an application as required in the procedure for authorisation of an alternative method of use or disposal of animal by-products (ABPs) or derived products, laid down in Article 20 of the Regulation (EC) No 1069/2009. On 12 June 2024, EFSA received the application through the EFSA portal for submission of ABP applications (Portalino) (CR-2024-000174), in line with the new provisions implemented by the Transparency Regulation (EU) 2019/1381.[2]

On 12 August 2024, following the Request for Information sent on 5 August 2024, EFSA received from bpRR the updated application through the Portalino, in line with the new provisions implemented by the Transparency Regulation (EU) 2019/1381.

During the completeness check, performed according to Regulation (EC) No 1069/2009, it was concluded that no information was missing or incomplete. EFSA considered that the application EFSA-Q-2024-00539 was valid on 4 September 2024. According to Regulation (EC) No 1069/2009, EFSA shall respect the deadline of 6 months to deliver the scientific opinion. Therefore, the opinion must be delivered by 4 March 2025.

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,[3] and its amendment by Commission Regulation (EU) No 749/2011.[4] A process flow diagram (Figure 1) and a Hazard Analysis and Critical Control Points (HACCP) plan were included in the application dossier. The report submitted by the Dutch Competent Authority (CA) related to the application was also considered. Relevant scientific papers provided by experts of the WG and previous EFSA opinions were also considered during the assessment.

EFSA carried out a public consultation on the non-confidential version of the application from 12 February to 3 March 2025, for which no comments were received.

2.2 | Methodologies

The EFSA BIOHAZ Panel evaluated the application for an alternative processing method for Category 3 ABPs by individually assessing the following steps as set out in the 'Statement on technical assistance on the format for applications for new alternative methods for animal by-products' (EFSA BIOHAZ Panel, 2010). These steps are:

(i) a full description of the process;
(ii) a full description of the material to be treated;
(iii) hazard identification;
(iv) the level of risk reduction;
(v) the HACCP plan;
(vi) the risk associated with interdependent processes;
(vii) the risk associated with the intended end use of the products.

The applicant is required to document as fully as possible the different aspects of each of these steps.

According to the CA assessment, the application meets the requirements as laid down in the EFSA Statement (EFSA BIOHAZ Panel, 2010).

As set out in subparagraph 5 of Article 20 of Regulation (EC) No 1069/2009, EFSA shall assess whether the method submitted ensures that the risks to public or animal health are:

[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]Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC. GU L 231 del 6.9.2019, p. 1–28.

[3]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 Text with EEA relevance. OJ L 54, 26.2.2011, p. 1–254.

[4]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.

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

According to point 2d, 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 wastewater, 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'*.

According to the EFSA Statement (EFSA BIOHAZ Panel, 2010) and to point 3, Chapter II, Annex VII of Commission Regulation (EU) No 142/2011, validated direct measurements, as referred to above, shall mean:

a. *'measuring the reduction of 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 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*

b. *using a well-characterised test organism or virus introduced in a suitable test body into the starting material'*.

The EFSA Statement (EFSA BIOHAZ Panel, 2010) also asserts 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 also states 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)'*.

*'In case 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'*.

In point 2d, 'Level of risk reduction' of section 2.1.2.1 'Content of applications' of the EFSA Statement (EFSA BIOHAZ Panel, 2010), it is stated that *'in principle, 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*. Although Chapter II of Annex VII of Commission Regulation (EU) No 142/2011 adopted the proposal of the EFSA Statement to use *'the level of risk reduction'* and *'the level of reduction of the most resistant biological hazards*'; interchangeably, it is acknowledged that these are different terms and that the purpose of the evaluation of alternative methods is not the estimation of the level of any risk, but the level of hazard reduction. For the sake of consistency with the legislation, the term 'level of risk reduction' will be used throughout this opinion.

It is acknowledged that the level of reduction described above may result in different levels of safety for humans and animals according to the ultimate end use of the product: renewable fuels, biogas, composted material, organic fertiliser or any other.

The standard processing methods for the different categories of ABPs are described in Chapter III, Annex IV of Commission Regulation (EU) No 142/2011. There are no hazard reduction standards for proposed alternative methods for biodiesel or renewable fuels production using ABPs. When the starting material is Category 3, the level of risk reduction achieved by the approved methods is not specified, and no definitive standards have been set down either in relation to hazard reduction for alternative methods dealing with Category 3 materials. This was already highlighted by previous EFSA opinions. For example, in the EFSA Statement on technical assistance related to the EFSA Opinion on transformation of ABPs into biogas and compost (EFSA BIOHAZ Panel, 2009), the Panel recommended that *'requirements for the reduction of the representative pathogens or indicators should be defined according to the final use of the different ABP categories to be processed, with the different ABP categories representing different risks of microbiological contamination of the input material'*.

A recent scientific opinion evaluating an application, also by bpRR, of an alternative process for the production of renewable fuels defined these requirements for Category 3 ABPs (EFSA BIOHAZ Panel, 2022). It was stated that: *'In order to be*

*considered at least equivalent to the processing methods approved in the legislation, the alternative methods for Category 3 ABPs should 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} (*EFSA BIOHAZ Panel, 2005*). For chemical treatments, a reduction of viable stages of resistant parasites such as eggs of Ascaris* sp. *by at least 99.9% (3 log_{10}) shall be required. The determination of the relevant pathogenic bacteria and viruses should be defined by the hazard identification, specific to the material to be treated.*

If the hazard identification considers spore-forming pathogenic bacteria to be relevant, the required level of inactivation will also be a 5 log_{10} reduction of spores from these bacteria, with the exception of spores of C. botulinum *for which a 12 log_{10} reduction would be required, as for processing canned petfood. This is the expected reduction in C. botulinum spores after applying 121.1°C for 3 min, the minimum standard of a heat treatment for canned petfood.*

Given their well-described high level of resistance to thermal and chemical treatments, applicants may choose to directly use spores of pathogenic bacteria as primary indicators without carrying out a full hazard identification exercise. If needed/appropriate, for both spore-forming and non-spore-forming bacteria and viruses, adequately justified alternative non-pathogenic indicator or surrogate organisms with at least the same level of resistance may be used, demonstrating an equivalent level of reduction in the substrate of interest.

These reductions should be achieved by the process independently from the reduction provided by the standard processing methods [methods 1–5 or 7 of Commission Regulation (EU) No 141/2011], should these be required'.

These standards will be applied to assess the level of risk reduction in the current application.

The full dossier provided by the applicant is available here: https://open.efsa.europa.eu/questions/EFSA-Q-2024-00539?search=EFSA-Q-2024-00539. Therefore, the current opinion includes only the evaluation performed by the BIOHAZ Panel, with reference to the relevant sections of the original dossier.

3 | ASSESSMENT

3.1 | Generic process description

The following section provides an overall general description of the alternative process.

1. Starting materials

   For this process, the following materials may be used:

   a. Rendered fats derived from Category 3 material, which have been processed using any of the processing methods 1–5 or processing method 7, or used cooking oil (UCO) (catering waste) defined as Annex 1 point 22 of Commission Regulation (EU) No 142/2011;
   b. A hydrocarbon feed stream deemed as a suitable feedstock for a fluidised catalytic cracking process.

   The use of ABPs derived from Category 1 or Category 2 material for this process shall be prohibited.

2. Processing method

   a. The starting materials (namely rendered fats/used cooking oils and hydrocarbon feed) shall be processed simultaneously through a fluidised catalytic cracking process.
   b. The materials must be submitted to a fluid catalytic cracking process which consists of a preheat section followed by a reactor–regenerator section followed by a main fractionator section.
   c. During normal operation of the fluidised catalytic cracking unit, the materials must be exposed to a temperature of at least 145°C and a pressure of at least 1.4 barg for at least 13 s, followed by at least 500°C for at least 2 s at atmospheric pressure or above.

The text above provides a generic description of the process under normal operating conditions. The applicant also considers as part of the alternative method the operation of the fluidised catalytic cracking unit during an unplanned shutdown. However, EFSA only assesses the alternative processing methods under normal operating conditions. Thus, the BIOHAZ Panel did not assess the procedures during an unplanned shutdown as an alternative processing method.

3.2 | Detailed description of the alternative processing method

The raw materials to be co-processed with heavy gasoils in a fluidised catalytic cracker unit (FCCU) are rendered fats derived from Category 3 animal by-products (AF) and used cooking oils (UCO) being catering waste as defined in Article 10 of Regulation (EC) No 1069/2009.

The alternative method has been designed for one fluidised catalytic cracker unit (FCCU) located in the facilities of the applicant in its refinery in Rotterdam (The Netherlands).

Figure 1 illustrates the end-to-end process of the proposed method of co-processing of AF and UCO in the FCCU.

Input material

AF and UCO can be sourced and purchased throughout the entire world. bpRR will receive AF and UCO on site via a barge (inland ship) or sea-going vessel according to international (and national) regulations and standards. AFs and UCOs are all heated with steam coils and are always kept at above 50°C due to their high pour point.

Feed preheat system

The heated AF and UCO (approx. 50°C) will be sent to the feed system of the bpRR FCCU. The feed system will combine various streams of hydrocarbons including those from the AF and UCO but also from other storage tanks as well as other process installation units including the Crude Distillation Units and Vacuum Distillation Unit (VDU). The combined streams will pass through two heat exchangers in series, to further heat the feed to the desired feed temperature.

Under normal operation, when the VDU is running and feeding hot wax to the FCCU, the FCCU feed is heated to minimum of 220°C by the preheat system. When the VDU is not running, the feed is heated to a minimum of 145°C by the preheat system.

'Wax' refers to heavy gasoils (HGOs) that have similar consistency to candle wax or lubricating oil used in an internal combustion engine automobile. When the VDU is running, 'hot wax' is produced by the VDU and enters the FCCU preheat system directly from the VDU at a minimum temperature of 270°C.

'Cold wax' is heavy gasoil that has been produced at bp Rotterdam or at another oil refinery and has been stored in intermediate storage tanks. Cold wax is fed to the FCCU to supplement the total amount of wax fed to the FCCU when the VDU is running – therefore, when the VDU is running, the flow of cold wax from the tank is low.

The residence time within the preheat section (from the point where the feeds are blended to the exit of the last heat exchanger) is at least of 13 s. The temperature of the feed is increased by approximately 80°C in the preheat section.

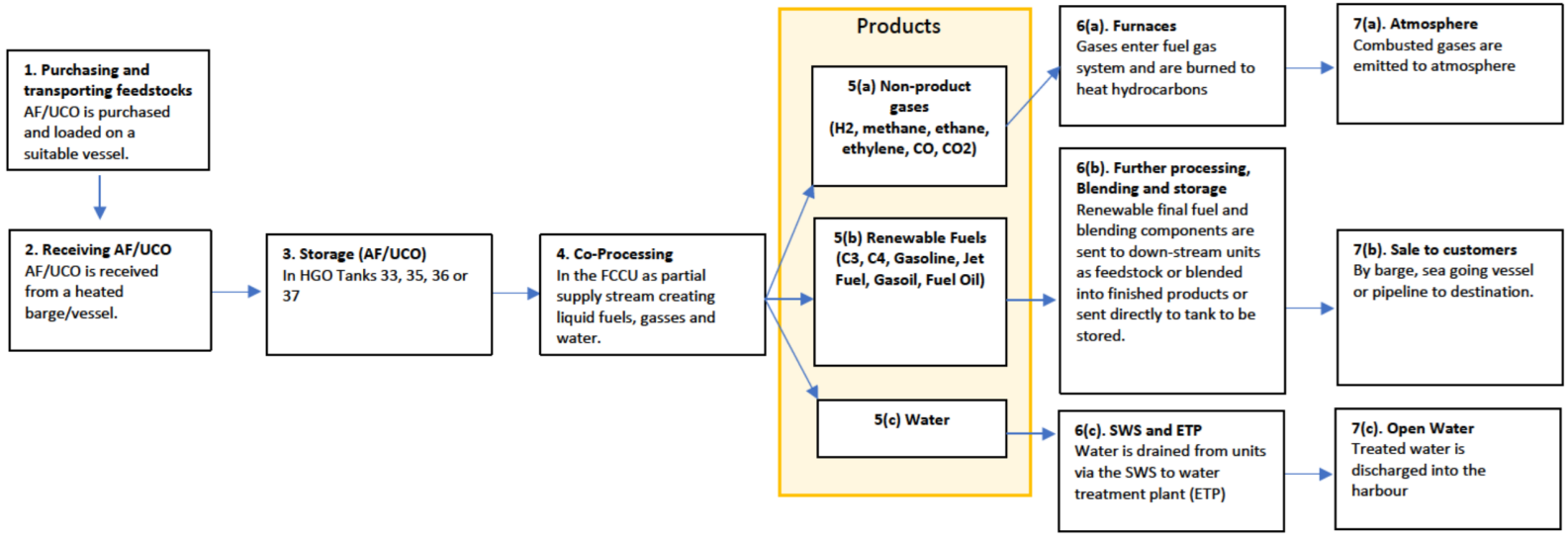

FIGURE 1 Flow diagram of the end-to-end steps of co-processing of AF and UCO as a partial stream to create renewable fuels.

From the exit point of the last heat exchanger to the point where the feed is injected to the reactor, the temperature is maintained at the temperature achieved by the preheat system. The residence time in the section of the line between the last heat exchanger and the reactor is also a minimum of 13 s. The minimum pressure in the entire preheat section up to the point of injection to the reactor is 1.4 barg.

Due to the presence of both hydrocarbons and AF and UCO, the FCCU will simultaneously process all material (co-process).

Table 1 shows a summary of inlet and outlet temperatures in the preheat system, including the residence time, when VDU is on or off.

TABLE 1 Summary of temperature delta over preheat system.

Mode of operation (VDU[a] on or off)	Preheat system inlet temperature	Preheat system outlet temperature	Temperature delta achieved by preheat system	Residence time
VDU on	140°C	220°C	80°C	13 s
VDU off	60°C	145°C	85°C	13 s

[a]VDU: vacuum distillation unit.

Reactor

After the heating stage, the combined streams are injected to the FCCU reactor riser, where > 90% of the combined AF/UCO/hydrocarbon feed will vaporise rapidly upon contact with hot catalyst (c. 700°C) that is being circulated from the FCCU Catalyst Regenerator. Typical oil residence time in the riser is 2 s, and this will also apply to the UCO/AF feeds. A fraction of the feed will react on the circulating catalyst, forming coke which will be burnt off in the regenerator.

Alongside and after vaporisation, the following reactions will occur:

1. Decarboxylation: These reactions will occur in AF and UCO. These molecules are not aromatic but are all long-chained hydrocarbons. Decarboxylation forms 3 n-paraffins, methane, propane, and water. The reaction is shown below.

$$\text{triglyceryls} + H_2 = C_nH_{n+2} + C_3H_8 + H_2O\,/\,CO\,/\,CO_2.$$

2. Thermal and Catalytic Cracking (β-scission): The decarboxylated long-chained hydrocarbons will undergo further reaction in the presence of hot FCCU catalyst, like the reactions of the normal FCCU feedstock. The high temperatures of the process will yield some light gases such as hydrogen, methane and ethane. The reaction products will typically fall in the C_3 to C_{16} range, with the distribution depending on the process conditions.

$$C_nH_{n+2} \xrightarrow{\triangle,\text{zeolite}} H_2 + CH_4 + C_2H_6 + C_2H_4 + C_3H_6 + C_3H_8 + C_nH_n + C_nH_{n+2}$$

3. Hydrogen Transfer, Isomerisation and Cyclation: During the cracking reactions, the hydrocarbons form ionic compounds when interacting with the FCCU catalyst. In this state, the hydrocarbons can undergo additional rearrangement reactions in order to form more stable ions.

Fractionator

The reactor products enter the FCCU main fractionator in the state of superheated vapour containing molecules across a wide boiling range – spanning from hydrogen to fuel oil. Reactor products (mixed with steam and still containing a small amount of FCCU catalyst) enter near the base of the main fractionator at a temperature exceeding 500°C. The main fractionator is equipped with cooling and condensation systems to reduce the heat of the vapours, producing liquid and allowing fractionation (separation) to take place. Fractionation is a separation process where a column is used to separate a mixture of various gases and products into separate product fractions (similar to distillation).

The bottom liquid product from the main fractionator (MCB) collects in the base of the tower, typically at a temperature of 340–360°C. It is not possible to assign a single temperature or retention time for the main fractionator column. The reactor products cool down from > 500°C to as low as 140°C within a matter of seconds of entering the main fractionator under normal operation.

Products

Fluidised catalytic cracking thus gives a wide range of products compared with processes like hydrogenation, which generally preserve the carbon chain of the feedstock oil. While the primary products from cracking tend to be in the naphtha/

gasoline boiling range, there are significant yields of other products including hydrogen, methane, ethane, ethylene, propane, propylene, butane, butylene, kerosene, gasoil/diesel and fuel oil. Water is also produced as a by-product of the co-processing reactions. A significant portion of the propane/propylene and butane/butylene is recovered for further processing or sale.

Unrecovered gases including hydrogen, methane, ethane/ethylene, propane/propylene, butane/butylene, CO and CO_2 are sent to the existing fuel gas system of the refinery to provide fuel to the furnaces of the units in the rest of the refinery.

The gasoline/naphtha and diesel/gasoil products are separated and further processed and/or blended prior to sale. The fuel oil product is sent to fuel oil tankage for blending and/or sale.

Water is separated from the final products and ultimately is processed by the on-site water treatment plant. The water is further discharged into the harbour.

Gases such as CO and CO_2 will separate and be mixed with the existing fuel gas system and will be emitted to the atmosphere.

Once the FCCU fuel products have been separated into the various fractions in the main fractionator column and in the downstream separation columns of the gas concentration section, they continue to various designated locations within the refinery.

Summary of operating conditions and temperature profile under normal operation

Table 2 contains a summary of the key equipment, minimum operating conditions and minimum retention times in the FCCU under normal operation. As the lowest temperatures are experienced when the VDU is out of service, the conditions during this mode of operation are used to represent the minimum operating conditions.

TABLE 2 Minimum operating conditions of key equipment under normal operation.

Equipment	Min pressure (barg[a])	Min temperature (°C)	Minimum retention time (s)
Preheat system	1.4	60	13
Line from preheat system to reactor	1.4	145	13
Reactor	0.1	500	2
Main fractionator	1	140	< 5

[a]Barg: refers to Gauge pressure, that is the pressure, in units of bars, above or below atmospheric pressure. The 'g' at the end of the word indicates that the measurement is not absolute pressure. Absolute pressure = Gauge Pressure + atmospheric pressure.

3.3 | Assessment by the BIOHAZ panel on the material to be treated

The raw materials to be processed for the production of renewable fuels are AF and UCO. The application states that all AF and UCO provided to the refinery must be in a liquid state free from solids. It shall not contain recycled oils (lubricants), waste oils (hydraulic fluids, sewage sludge), mineral oils (fossil products) or fish oils as this is part of the contaminant control.

The application exclusively focuses on ABP Category 3 materials as described in Article 10 of Regulation (EC) No 1069/2009. As mentioned by the applicant, AF will be derived from a variety of ABPs and from different countries, including those outside the European Union (EU). There is provision for the importation of rendered fats from third countries for the production of renewable fuels in Annex XIV of Commission Regulation (EU) No 142/2011. The conditions are set out in Section 1 and section 9 of Chapter II of Annex XIV. Rendered fats must be processed using any of the processing methods 1–5 or processing method 7. In addition, they must come from an approved third country or part of a third country, from an establishment or plant that is registered and approved by the CA of the third country, and which is on the list of such establishments and plants referred to in Article 30 of Commission Regulation (EU) No 142/2011. Health certification is also required.

The application states that UCO (vegetable/seed/animal oil that has been used to cook foodstuffs) will not necessarily be processed using any of the processing methods 1 to 5 or processing method 7 before being used for the production of renewable fuel. Although it is clearly specified that only Category 3 ABPs will be used to produce renewable fuels with this method, in section 1.2.2 of the application, it is mentioned that UCO is a Category 3 animal by-product, as per point 22 Annex I Commission Regulation (EU) No 142/2011. In fact, point 22 only defines catering waste but it does not mention the risk category. It is in Article 10(p) of Regulation (EC) No 1069/2009 where it is specified that Category 3 ABPs include catering waste other than as referred to in Article 8(f). This latter article declares as Category 1 ABP catering waste from means of transport operating internationally. Therefore, catering waste could be Category 1 or Category 3 ABP. Only Category 3 UCO must be used to produce renewable fuels with the proposed method.

It is not clear if UCO can be imported into the EU for the production of renewable fuels as it is not specifically listed as one of the raw materials that can be imported into the EU for use outside the food chain.

UCO is subjected to a high temperature when it is being used as a cooking oil. This is not the case for AF. However, in contrast with UCO, AF is always pretreated with methods 1–5 or method 7.

3.4 | Assessment of the BIOHAZ panel on the hazard identification

According to the applicant the microbiological hazards that could remain in AF are '*pathogenic bacteria that may include Salmonella, Enterobacteriaceae or spore-forming bacteria such as Bacilli or Clostridia, which may also vary depending on the points of origin of the material*'. However, most of these taxa contain both pathogenic and non-pathogenic representative species.

The category 3 fats (AF) that bpRR receives are already rendered following one of the standard methods 1–5 or 7 as described in annex IV of Commission Regulation (EU) No 142/2011. These *processes applied ensure an important decimal reduction in biological hazards, thereby reducing the probability of remaining bacteriological contamination*.

Since it is difficult to predict which (and when and where) pathogens may be present, the argumentation for microbial inactivation in the bpRR FCCU process was based by the applicant on a review of literature addressing the heat inactivation of vegetative cells as well as spores from different *Bacillus* and *Clostridium* species, including key pathogenic and spoilage species, known for their ability to produce highly temperature-resistant spores (Gomez-Jodar et al., 2015; Le Marc et al., 2022).

UCOs are vegetable/seed/animal oils and fats that have been used to cook or fry foodstuff (products of animal origin) for human consumption. Frying processes are carried out at temperatures of between 140°C and 200°C. bpRR considers the remaining bacteriological risk in UCOs low due to the following reasons:

- Cooking oils and fats have already gone through various manufacturing processes prior to being used as a medium for cooking foodstuffs.
- Since these oils and fats are used to cook meat or other products fit for human consumption, the exposure of humans to biological hazards is not expected.
- The frying processes are carried out at high temperatures of between 140°C and 200°C.

According to the applicant, given that AFs and UCOs from various sources can be used as feedstock, a broad range of biological hazards may be present in the material to be treated. For AFs, only rendered fats classified as Category 3 and pretreated with methods 1–5 or method 7, as outlined in Annex IV of Commission Regulation (EU) No 142/2011, will be used as raw materials. This considerably reduces the risk of contamination by hazardous biological agents. Similarly, UCOs originate from restaurants, catering facilities and kitchens as a by-product of cooking foodstuffs at high temperatures, which ensures an important decimal reduction in biological hazards, thereby reducing the probability of remaining bacteriological contamination.

The dossier does not provide a comprehensive, detailed list of all relevant biological hazards for human and animal health based on the origin and category of the material to be processed. Instead, it focuses on a few potential biological hazards, specifically mentioning *Salmonella*, pathogenic *Enterobacteriaceae* and spore-forming pathogenic bacteria like *Clostridium perfringens*. Bacterial spores were then selected by the applicant as the primary target for assessing the risk reduction capability of the process due to their high heat resistance. The applicant specifically identified spores from *Bacillus* and *Clostridium* species as the main targets to demonstrate the method's effectiveness in hazard reduction. This approach included heat inactivation data for a wide range of *Bacillus* and *Clostridium* species, including both pathogenic and non-pathogenic strains. This dataset also included thermophilic species like *C. thermosaccharolyticum* (now reclassified as *Thermoanaerobacterium thermosaccharolyticum)* and *B. stearothermophilus* (now reclassified as *Geobacillus stearothermophilus*), along with *Desulfotomaculum nigrificans*, a highly heat-resistant spore-forming microorganism. The approach followed by the applicant is consistent with one of the possible scenarios accepted: the selection of bacterial spores as a primary target to demonstrate a sufficient level of hazard reduction, considering that any process achieving a significant level of inactivation of them will ensure a sufficient level of reduction of any more heat-sensitive biological hazard that may be present in the Category 3 material.

Chemical and physical hazards may also be present in the material to be treated; however, these are not addressed in this assessment.

3.5 | Assessment of the BIOHAZ panel on the level of risk reduction

To determine whether an acceptable level of risk reduction will be met, the applicant collected and reviewed various scientific studies describing the heat inactivation of vegetative cells and spores of different *Bacillus* and *Clostridium* species under conditions as close as possible to the expected conditions of the bpRR alternative process during normal operation. Although none of these studies reproduced the exact conditions of bpRR's existing temperatures, pressures and retention times, the applicant aimed to demonstrate that the process will lead to at least the required reduction of potential microbial hazards.

The applicant provided scientific data collected with a focus on results from high temperature studies. Available data describing the inactivation of vegetative cells at the high temperature of the bpRR process is very limited due, at least partially, to their higher sensitivity compared to spores. Spores are of critical concern, and significant differences in heat sensitivity are shown not only between different species but also between strains or isolates of the same species.

A list of D-values (at temperatures ranging from 95°C to 140°C) and z-values was provided for spores of different species (*Bacillus subtilis*, *Bacillus cereus*, *Bacillus macerans, Bacillus megaterium, Geobacillus stearothermophilus, Clostridium*

botulinum, Clostridium sporogenes, Clostridium perfringens) in oil-like fluids. D-values (at temperatures ranging from 95°C to 140°C) and *z*-values were also provided for spores of different species (*Bacillus subtilis, Geobacillus stearothermophilus, Clostridium botulinum, Clostridium sporogenes, Clostridium thermosaccharolyticum, Desulfotomaculum nigrificans*) subjected to wet heat treatments. Where studies reported data from multiple strains or isolates, the data captured by the applicant represented the most conservative values. Additionally, the applicant also presented data on $\log_{10}$ reductions achieved for spores of *Bacillus subtilis* and *Bacillus anthracis* in very short (sub-second) air-dry heat treatments at temperatures ranging from 300°C to 500°C.

The applicant extrapolated from the collected D- and z-values to predict $\log_{10}$ reductions expected after preheating at 145°C for 13 s, since these conditions slightly exceeded the range of the experimentally tested data. For fluidised catalytic cracking in the riser at 500°C for 2 s, estimates were obtained by interpolation within the experimental data range. With this approach, it was concluded that preheating of an oil product will induce limited inactivation of bacterial spores, but only 2 s in the riser (considered as a wet heat treatment) are sufficient to induce more than a hundred $\log_{10}$ reductions.

Although D-values and *z*-values can be used to estimate reductions at conditions different from the experimental ones, the risk of extrapolation has been indicated in the scientific literature (Diao et al., 2014; Peleg, 2021). Therefore, any thermal death time determined by extrapolation can lead to underestimation or overestimation of the lethality of the thermal process. Valdramidis et al. (2005) also stated that calculations falling out of the microbial experimental region (as the maximal heating temperature) should be taken with caution. Data extrapolated beyond the interpolation region should be considered on a case-by-case basis, taking into account the model used to fit the data and the magnitude of the extrapolation (how far the experimental region is). Following the same approach taken in previous opinions (EFSA BIOHAZ Panel, 2022), extrapolated data have not been considered in this assessment. The only assumption considered valid was that if, for a given treatment time, heating at a fixed temperature provides a certain level of risk reduction, higher temperatures will provide, at least, the same level of reduction.

In a meta-analysis of the heat resistance of *C. botulinum* and *C. sporogenes* (a non-pathogenic indicator), authors included 911 D-values collected from 38 studies (Diao et al., 2014). Average D-values of 0.19 and 1.28 min at 121.1°C, respectively, were reported. At the highest temperature for which a D-value was measured for *C. botulinum* (140°C), considering the upper 95% credibility interval boundary of the study, a D_{140} of approximately 0.01 min was reported. The revision of scientific references provided by the applicant indicates inactivation of spore-forming bacteria after very short treatments at temperatures close to or up to 500°C. In a study by Xing et al. (2014), exposure to rapid dry heating at 500°C, generated by a conductive heating system, reached an inactivation of *B. anthracis* spores of between 2 and 3 $\log_{10}$ in 0.1 s of exposure. Additionally, Grinshpun et al. (2010) exposed spores of *B. subtilis* to an axially heated air flow system and found that temperatures of 400°C or above achieved more than 5 $\log_{10}$ reductions for exposure times of 0.3 to below 1s (as a conservative estimation). Being *B. subtilis* a good surrogate for pathogenic *Bacillus* spores, as demonstrated in various decontamination studies, including thermal processes (Montville et al., 2005; Soni et al., 2022), this evidence indicates that temperatures in the range of 400–500°C induce inactivation of *Bacillus* spores that would exceed 5 $\log_{10}$ reduction, considering also that dry heat is less effective inactivating spores than wet heat. Overall, considering a minimum retention time of 13s, at temperatures of 140°C or higher, plus 2s at 500°C in the reactor riser, all the evidence collected and analysed supports an inactivation that exceeds the requirements (12 $\log_{10}$ reductions for *C. botulinum* spores and 5 $\log_{10}$ reductions of spores of other pathogenic bacteria), not taking into consideration data extrapolation.

Therefore, considering the evidence available, even if the extrapolation analyses proposed by the applicant are not considered valid, the expected level of reduction achieved for the relevant hazards that may be present is considered to be at least equivalent to the reduction required by the standards indicated for Category 3 material.

3.6 | Assessment of the BIOHAZ panel on the HACCP plan

The applicant presented a HACCP plan based on the identification of critical control points for bpRR's process. The HACCP plan included prerequisite programmes, which are part of the Operating Management System (OMS) and enable the ISO 9001 and 14,001 certifications. The relevant biological, chemical and physical hazards in the material to be treated were identified by the applicant.

The first step considered by the applicant is the reception of AF and UCO and is identified as a CCP. The hazard indicated by the applicant for this step is microbiological (i.e. existence of pathogens for entry to site) but then the applicant states, as parameter to control the hazard, the 'content of insoluble impurities'. In the dossier, the content of insoluble impurities is listed as acceptance criteria for all feedstocks (and products) in the prerequisite program, and therefore, the reception of raw materials cannot be considered a CCP. At the point of arrival, Category 3 AF must have already been processed by methods 1–5 or 7, as described in Chapter 3 of Annex IV of Commission Regulation (EU) No 142/2011, and the content of the insoluble impurities must be below [redacted]. If the values are higher the feedstock must be rejected, and the material must be returned and reprocessed until it meets the specification.

The applicant states that the content of insoluble impurities should be below [redacted] w/w, which is higher than the maximum value (0.15% w/w) of the alternative 'D. Biodiesel production process' included Annex IV of Commission Regulation (EU) No 142/2011.

The second step is the pre-blending/storage. This step is not identified as a CCP by the applicant, and this is considered correct. The third step is the feed blending system and is not identified as a CCP. This is considered correct. The fourth

step is the feed preheat section and is not identified as a CCP. Although this step can certainly contribute to inactivate microbiological hazards, because it occurs at a minimum temperature of 145°C for 13 s, the applicant recognised that there are following steps in the process reaching much higher temperatures. Therefore, this step is not considered a CCP. The fifth step is the reactor and is identified as a CCP. This is considered correct, but clear quantitative critical limits for both the target temperatures and holding time should be stated in the HACCP plan (monitoring of the CCP). The sixth step is the fractionator bottom, which is not identified by the applicant as a CCP. This is considered correct. The last step of the process, represented by the renewable fuel storage and export, is not identified as a CCP, and this is considered correct.

All in all, the reception of AFs and UCOs should be considered a prerequisite (with acceptance criteria) rather than a CCP. The other CCP identified by the applicant, represented by the reactor riser, is considered correct, but clear quantitative limits for temperature and holding time must be included in the HACCP plan along with detailed means of monitoring and corrective actions.

The applicant also developed a HACCP plan for the unplanned shutdown scenario. This is considered unnecessary. Instead, a corrective action should have been represented in the HACCP plan of the process under normal operating conditions, in case the parameters associated with the identified CCP do not meet the identified quantitative limits.

3.7 | Assessment of the BIOHAZ panel on the risk associated with interdependent processes

The applicant states that the material to be processed has to meet certain specification criteria. If those specifications are not attended to, the material must be pretreated. The pretreatment process of the by-products (degumming, bleaching and deodourisation) would occur at other facilities and not at bpRR. Those facilities would pretreat the materials with permitted methods to carry out the necessary steps before the material arrives at bpRR for processing. Once the material has been pretreated, it will be sent to bpRR and will be checked against the acceptance criteria.

All final products are stored in individually designated tanks which adhere to Dutch environmental regulations (PGS-29) in terms of design, operation and maintenance. The applicant indicates the possibility of environmental risk, risk to human or animal health due to spills or leaks during storage, maintenance or cleaning activities, together with other hazards (toxic gases, confined spaces, energy isolation or oxygen deficient atmosphere). The applicant states further precautionary health and safety measures are in place for the avoidance of any incidents, but it is not specifically mentioned what procedures are undertaken in compliance with the requirements.

The applicant also describes the transport of the end products as it has a similar path to that of materials to be treated (AF and UCO). The delivery of the end products should occur either via a pipeline, barge or tanker that is built according to standard operational procedures of the applicant. The applicant states that in the case of fuel discharge or leaking, procedures for spill response are in place, but it is not specifically mentioned what measures are undertaken in compliance with the requirements. Still, exposure to pathogens from the fuel is not expected.

The applicant provided a detailed description of the disposal of by-products (wastewater and gases). Both by-products are generated after the AF or UCO are processed in the reactor, being exposed to the high temperatures associated with the alternative process. Thus, both water waste and gases should be free of any pathogens. Afterwards, the wastewater is sent via the sewers to the effluent treatment plant for processing and discharged into the local harbour. The gases will be used as fuel for combustion. Exposure to pathogens via these routes is also not expected.

The applicant also provided a detailed description of the corrective actions related to possible adverse scenarios and the procedures that would be implemented in dealing with risks. Thus, bpRR has developed the Rotterdam Operating Management System (ROMS) which is a set of procedures that address all necessary elements and practices that are defined in the OMS system to ensure that preventive measures are taken when it comes to human, animal and environment safety. The measures should provide an acceptable level of protection against biological and other hazards.

During the evaluation of the fluidised catalytic cracking co-processing treatment, only the process under normal operating conditions was considered. The process during an unplanned shutdown was not assessed. Consequently, any end products produced during an unplanned shutdown should not be considered end products of the alternative method and should be disposed of or used in accordance with the various options described in Article 13 of Regulation (EC) No 1069/2009. In order to be considered as end products of the alternative method, these products would need to be processed under normal operating conditions.

3.8 | Assessment of the BIOHAZ panel on the risk associated with the intended end use of the products

According to the dossier, the primary products from the alternative method tend to be in the naphtha/gasoline boiling range. There are significant yields of other products including H_2, methane, ethane, ethylene, propane, propylene, butane and butylene, kero, gasoil/diesel and fuel oil. A significant portion of the propane/propylene and butane/butylene is recovered for further processing or sale. The applicant describes a possible risk of exposure to the main products in the form of liquid fuels of humans and animals through oral or subcutaneous routes, but the probability is very low. Considering the safety measures applied during storage, transport and sale, and because of the implemented corrective actions, no exposure to hazards for humans, animals and the environment, during normal process, is expected.

4 | CONCLUSIONS

- The alternative processing method consists of a fluidised catalytic cracking co-processing treatment for the production of renewable fuels. The materials must be exposed to a temperature of at least 145°C and a pressure of at least 1.4 barg for at least 13 s in a preheating system, followed by at least 500°C for 2 s in a reactor.
- The raw materials to be processed by the proposed alternative processing method are rendered animal fats (AF) and used cooking oil (UCO), derived from Category 3 ABPs. AF would be pretreated using methods 1–5 or method 7, whereas UCO would not be preprocessed using any of these methods.
- The applicant selected the use of spores of pathogenic bacteria as primary indicators without carrying out a full hazard identification exercise, which is acceptable as per previous EFSA evaluations. It is considered that any process achieving the required level of reduction of bacterial spores will ensure at least a similar level of reduction of all biological hazards possibly present in the Category 3 material.
- Despite the limitations highlighted in the assessment in relation to the analyses performed by the applicant, the dossier and additional literature contain sufficient evidence to support that the proposed alternative processing method can achieve a sufficient level of hazard reduction, i.e. at least 12 $\log_{10}$ of *C. botulinum* spores and 5 $\log_{10}$ of spores of other pathogenic bacteria.
- The presented HACCP plan contained some inadequacies: the reception of AFs and UCOs should be considered a prerequisite (with acceptance criteria) rather than a CCP. The other CCP identified by the applicant, represented by the reactor, is considered correct, but quantitative limits must be included in the HACCP plan along with means of monitoring and corrective actions.
- The information provided by the applicant suggests that appropriate corrective actions are in place for dealing with risks associated with interdependent processes and with the end use of the products.
- The applicant considers, as part of the alternative processing method, the operation of the fluidised catalytic cracking unit during an unplanned shutdown. EFSA only assesses the alternative processing methods under normal operating conditions. Thus, the BIOHAZ Panel did not assess the procedures during an unplanned shutdown as an alternative method. Any end products produced during an unplanned shutdown should not be considered end products of the alternative method and should be disposed of or used in accordance with Article 13 of Regulation (EC) No 1069/2009. The applicant also developed a HACCP plan for the unplanned shutdown scenario, but this was considered unnecessary. It can only represent a corrective action in the HACCP plan of the process under normal operating conditions, in case the parameters associated with the identified CCP do not meet the identified quantitative limits.
- Overall, the alternative processing method under assessment (which covers only normal operating conditions) can be considered equivalent to the processing methods currently approved in the Commission Regulation (EU) No 142/2011.

ABBREVIATIONS

ABP	Animal By-Product
AF	Animal Fats
BIOHAZ	EFSA Panel on Biological Hazards
bpRR	bp Rotterdam Refinery
CA	Competent Authority
CCP	Critical Control Point
FCCU	Fluidised Catalytic Cracker Unit
HACCP	Hazard Analysis Critical Control Point
HGO	Heavy Gasoil
OMS	Operating Management System
UCO	Used Cooking Oil
VDU	Vacuum Distillation Unit

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