

SCIENTIFIC OPINION

Scientific Opinion on the capacity of oleochemical processes to minimise possible risks linked to TSE in Category 1 animal by-products¹

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

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ABSTRACT

The capacity of specific oleochemical processes including several steps (i.e. bleaching, fat splitting, hydrogenation, concentration, distillation and refinement) in order to minimise possible risks linked to TSE infectivity in tallow including Category 1 animal by-products (ABP) was assessed. Under the new ABP Regulation (Reg. EC No 1069/2009), the use of Category 1 tallow for oleochemical products may be also authorised, if the processes are proved to be capable of sufficiently inactivating any potential risks linked to TSEs. The processes considered in this opinion are based on different treatment steps in different combination, but with respect to infectivity reduction the major contribution derives from hydrolytic fat splitting and hydrogenation, so to obtain fatty acids and glycerol. It is concluded that if the parameters are fully met as declared by the applicant, certain processes can be considered effective in significantly reducing the TSE infectivity in the end products using Category 1 tallow. However, considering the uncertainties on the TSE infectivity reduction in oleochemical products derived from Cat. 1 material, these products cannot be reliably regarded to be free of infectivity and therefore could pose a risk if they entered the food and feed chain.

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KEY WORDS

Fat splitting, hydrogenation, glycerol, fatty acids, TSE

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SUMMARY

Following a request from the European Commission, the EFSA Scientific Panel on Biological Hazards (BIOHAZ) was asked to provide scientific advice on the capacity of a specific oleochemical processes to minimise possible risks linked to TSE infectivity in tallow including category 1 material.

The current Regulation (EC) No 1774/2002 on animal by-products foresees that rendered fats obtained from Category 2 and Category 3 materials may be used for the manufacture of oleochemical products.

Under the new ABP Regulation (Reg. EC No 1069/2009), the use of Category 1 material in the production of oleochemical products may be also authorised, provided that the manufacturing processes which are applied by the oleochemical industry are capable of sufficiently inactivating any potential risks linked to TSE. This would allow the use of such products in various applications, such as in soaps, cosmetic products and plastics, regardless of the category of animal by-products that are used as starting materials.

The European Oleochemicals and Allied Products Group (APAG), a sector group of the European Chemical Industry Council (Cefic), has submitted scientific evidence to the Commission regarding the capacity of oleochemical processes to inactivate possible risks linked to transmissible spongiform encephalopathies (TSEs) in animal by-products not intended for human consumption (ABPs).

The oleochemical processes considered consist mainly of hydrolytic fat splitting of tallow to obtain fatty acids and glycerol, under the conditions of 200°C, 16 bar of pressure for 20 minutes. The processes can be carried out in a unitower or multitower plant. If saturated fatty acids or hydrogenated tallow are to be obtained, hydrogenation under conditions of 160°C, 12 bar of H₂ pressure for 20 minutes is applied in batch or continuous reactors. Eight different processes, consisting of a combination of different steps, can be used according to the different end products and type of reactors used.

The parameters considered are mainly temperature, time and pressure. In the opinion the reduction effects of the different steps that characterise the processes are assessed and, when possible, quantified. The two steps with experimental evidence that contribute to the TSE risk reduction are the hydrolytic fat splitting and the hydrogenation.

It is concluded that if the critical limits of the specific method considered are met, the reduction of TSE infectivity of certain processes is significant. However, considering the uncertainties on the TSE infectivity reduction in oleochemical products derived from Cat. 1 material, these products cannot be reliably regarded to be free of infectivity and therefore could pose a risk if they entered the food and feed chain.

As for efficacy of hydrogenation step, only batch processes can be compared to validated experiments, continuous processes could not be considered effective due to the lack of critical data (i.e. minimum retention time). As for the splitting step carried out in continuous reactors, the processing time represents a sufficient safety margin compared to the minimum requirement, and therefore it is considered effective.

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BACKGROUND AS PROVIDED BY EUROPEAN COMMISSION

The new Animal By-products Regulation (EC) No 1069/2009 allows the use of animal by-products not intended for human consumption (ABP) of any category, for purposes without direct relevance to the safety of the food and feed chain: if ABP are not used for feeding farmed animals nor for application to land from which such animals are fed, they may be used for the manufacture of derived products as defined in Article 3 No. 2 of the Regulation, under conditions aimed at preventing risks to public and animal health which may be laid down by the Commission. Such conditions may include restrictions related to the starting materials which can be used for a certain manufacturing process (e.g. by restricting the possible starting material for the process to a particular category of ABP) and to the process parameters which can be regarded as appropriate means of mitigating potential health risks, on the basis of available scientific evidence.

Article 5(2) of the new ABP Regulation allows the Commission to determine an end point for derived products which no longer pose any significant risk to public or animal health. Beyond that end point, the derived products are no longer subject to the requirements of the ABP Regulation.

The Commission is currently consulting relevant stakeholders and Member States' experts in order to prepare implementing measures under the new ABP Regulation.

Those measures are to enter into application simultaneously with the revised ABP Regulation, namely on 4 March 2011.

The oleochemical industry uses fats which are obtained from the rendering (or processing) of animal by-products, as a starting material for its products. Those products are used in a wide range of applications, such as in cosmetics and plastics.

Under the current Regulation (EC) No 1774/2002 on animal by-products, rendered fats obtained from Category 2 and Category 3 materials may be used for the manufacture of oleochemical products. Such rendered fats have to be submitted to one of two alternative processes, which are further specified in Chapter III of Annex VI to that Regulation.

Under the new ABP Regulation, the Commission may authorise the use of Category 1 material for the manufacture of oleochemical products. Since such materials include bodies and parts of animals suspected of being infected with a transmissible spongiform encephalopathy (TSE), it is evident that any such authorisation could only be considered provided it can be demonstrated that the manufacturing processes which are applied by the oleochemical industry are capable of sufficiently inactivating any potential risks linked to TSE.

The sector association for the oleochemical industry (APAG) has provided to the Commission a scientific study with data which would suggest that there is evidence for concluding that TSE risks are eliminated by the manufacturing processes used.

APAG requests that this evidence would be used for the determination of an end point for ABP which have been processed into oleochemical products.

TERMS OF REFERENCE AS PROVIDED BY EUROPEAN COMMISSION

EFSA is asked to issue an opinion on the capacity of an oleochemical processes as described in the present opinion to minimise possible risks linked to TSE infectivity in tallow including category 1 material.

SUPPORTING DOCUMENTS

- Documents provided by APAG:
 - Process description and risk analysis of oleochemical processes to inactivate possible risks linked to TSE in animal by-products not intended for human consumption provided by APAG (October 2010).
 - Risk evaluation for category 1 tallow processed in oleochemical operations (October 2010).
 - Table about the minimum conditions of exposure to the treatment (October 2010).
 - Documentation about the fate of waste generated during the process (November 2010).
 - Flow diagrams of the processes (December 2010).

ASSESSMENT

1. Introduction

The terminology used in this assessment conforms to 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 dossier provided by the Applicant consisted of (i) a description of the major manufacturing processes involved in TSE infectivity reduction within the oleochemical industry, i.e. the splitting treatment via multitower or unitower plant and/or hydrogenation process; (ii) an analysis of the TSE risks in oleochemical plants along with preventive measures/corrective actions; (iii) a summary of the minimum conditions applied during the manufacturing of oleochemicals.

The aim of the present opinion is to assess the capacity of the oleochemical processes as described in the documentation provided by the applicant to minimise possible risks linked to TSE in animal by-products not intended for human consumption.

The side products of the processes will be also dealt in this opinion.

2. Material to be treated

In the documentation provided, it is explained that tallow entering the processes comes from the rendering process, where meat and bone meal are separated (typically about 50% protein, 35% ash, 8-12% fat, and 4-7% moisture) from the fatty part. Only tallow which has been submitted to treatment at 133°C under 3 bar of pressure (produced by saturated steam) for 20 minutes, as stated by Regulation 1774/2002 (Annex V, Chapter III, method I) can enter the processes. As stated in the new Regulation on ABP, rendered fats derived from ruminant animals must be purified in such a way that the maximum level of remaining total insoluble impurities does not exceed 0.15 % in weight.

It is claimed in the report provided that tallow entering the processes already shows a good degree of safety in terms of BSE risk, showing up to 1000 fold reduction (Appel et al., 2001b; Taylor and Woodgate, 2003). Until now only Cat. 2 and 3 tallow is allowed to be processed. The applicant intends to use Cat. 1 tallow and, as communicated by the applicant at the meeting on 23 November 2010, possibly imported from outside the EU.

3. Thermosensitivity of TSE strains

Most experiments used in this context for describing the risk reduction were carried out with the 263K hamster adapted scrapie strain, but there might be differences in thermosensitivity among the TSE strains.

The infectious agents causing transmissible spongiform encephalopathies (TSEs) are notoriously difficult to completely inactivate or destroy. In a recent study (Somerville et al., 2009) a thermal hydrolysis system was tested, which combines saturated steam heating to 180°C (10 bar), with stirring. The 301V-TSE strain, which has been derived by passage of BSE in mice, was used since it is the most thermostable TSE strain tested so far. All detectable TSE infectivity was destroyed, with a clearance factor of greater than 10^5 ID₅₀.

Varying autoclaving conditions for three TSE strains between 132 and 138 degrees C, and times of exposure between 30 and 120 min, had little or no effect on TSE infectivity, if the hydration state of the TSE agent is not maintained (Fernie et al., 2007). In other studies reflecting the conditions of the rendering procedure, including saturated steam, these experiments showed reduction activity (Fair CT987019, 2001).

Further testing concerned three TSE strains derived from sheep with scrapie (Somerville et al., 2002).

Giles et al. compared several strains after particular treatment using SDS and/or heating, including the hamster Sc237, mouse 301V and BSE prions, and concluded that some strains, in particular BSE strain, were up to 10^6 fold more resistant for some treatment (Giles et al. 2008).

This evidence illustrates the difficulties in interpretation of results obtained with only one TSE strain, in the frame of the assessment of the efficacy of a given process.

4. Description of the processes

The proposed process technology is a chemical treatment of tallow including Category (Cat.) 1 tallow as defined in Regulation (EC) 1774/2002 that consists mainly in a hydrolytic fat splitting of tallow to obtain fatty acids and glycerol.

The general process is composed by the following steps: bleaching (and/or acidic/alkali treatment), fat splitting, hydrogenation, concentration (for glycerol), distillation, refinement.

During the splitting step the triglycerides (fat) molecules are split to give crude fatty acids in the hydrophobic phase and crude glycerol in the hydrophilic phase.

According to the information received by APAG eight different type of processes can be used to process tallow. These types of process lead to the production of different end products.

The eight different types of processes are listed here below considering the end products given and the process conditions:

1. Production of hydrogenated tallow.
2. Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the multitower reactor.
3. Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the unitower reactor.
4. Production of unsaturated fatty acids and glycerol (via distillation) and splitting in the unitower reactor.
5. Production of unsaturated fatty acids and glycerol and splitting in the multitower reactor.
6. Production of hydrogenated fatty acids and glycerol (via distillation) with splitting in the unitower reactor followed by hydrogenation.
7. Production of hydrogenated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor followed by hydrogenation.
8. Production of unsaturated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor.

The above mentioned eight different types of processes are obtained through the combination of different steps. The general description of these steps is provided here below.

4.1. Removal of impurities: bleaching or acidic or alkali treatment

Prior the chemical splitting, the tallow is treated with bleaching earths in order to remove impurities through an adsorption process. This step takes place at 100 – 130°C for at least 40 minutes to two hours under vacuum. The bleaching earth are then disposed through incineration by authorised plants.

Another possible purification treatment is through acidic or alkali treatment with phosphoric acid or strong alkali (10%) at 60-90°C, so to denaturise and precipitate protein impurities. This is followed by filtration, and the filter disposed as for the bleaching earth.

4.2. Hydrogenation

If the end products are hydrogenated fatty acids, then tallow is hydrogenated in the presence of a metal catalyst (nickel or palladium), at minimum conditions of 160°C, 12 bar of hydrogen gas (H₂) for 20 minutes at least (although the applicant mentioned other higher minimum times and temperatures in other documents provided). Hydrogenated tallow is filtered to remove the catalyst, and the catalysts treated by authorised plants. Hydrogenation can be done in batch or in a continuous reactor.

4.3. Fat splitting

The tallow is split through hydrolysis into crude fatty acids and crude glycerol in counter current with water and tallow. This step is carried out in a closed system, thus making it impossible for the personnel to get in contact with the processed material.

The fat splitting step can be performed in a multitower or unitower reactor. These two reactor systems differ in the following patterns:

- The multitower reactor is a continuous process carried out with more than one splitting tower in counter current. Tallow is mixed up with water (ratio fat/water: about 60/40) and sent to the splitting columns, where it is worked at 230°C minimum at the corresponding saturated vapour pressure (at least 28 bar) for at least 5 hours.
- Unitower reactor is a continuous process carried out in one splitting tower in counter current. Tallow is mixed up with water (ratio fat/water: about 60/40) and sent to the splitting column, where it is worked at minimum 260°C at the corresponding saturated vapour pressure (at least 50 bar) for 20 minutes minimum (although the applicant mentioned other minimum times in other documents provided).

4.4. Glycerol concentration

The glycerol part is concentrated from 11% to 80% in a multiple effect evaporator at the following minimum conditions of 70 or 120°C, 1.5 bar to 70 mbar vacuum for at least 20 minutes (although the applicant mentioned other higher minimum times in other documents provided).

4.5. Distillation

After splitting the triglycerides, fatty acids are distilled under minimum conditions of 215°C, 25 mbar for at least 30 minutes.

Concentrated glycerol is distilled through addition of alkali at minimum pH 8 in order to saponify residual free fatty acids, then distilled to obtain 99% pure glycerol at 155°C at 4 mbar for 20 minutes. Low boiling and high boiling phases are separated from glycerol.

4.6. Refinement through active carbon

Distilled glycerol is bleached through active carbon.

4.7. Alternative process for refined glycerol via the ion-exchange process

The process permits removal of inorganic salts, fat and soap components, coloured matter, odour causing substances, and other impurities. The process consists of a demineralization unit with cation- and anion-exchangers in series, followed by bleaching columns with activated carbon and a final demineralization with ion exchangers.

4.8. Description of steps for the eight different processes

4.8.1. Production of hydrogenated tallow

Steps:

- Rendering with method 1;
- Bleaching;
- Hydrogenation;
 - End product: hydrogenated tallow used for different purposes.
 - Side products: exhausted bleaching earth and spent catalysts.

4.8.2. Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the multi-tower reactor

Steps:

- Rendering with method 1;
- Bleaching;
- Hydrogenation;
- Splitting in multi-tower reactor;
- Distillation of crude fatty acids;
- Concentration of glycerol
- Distillation of glycerol;
- Purification of glycerol.
 - End products: low boiling fraction of fatty acids and distilled fatty acids, distilled and bleached glycerol.
 - Side products: High boiling fractions of fatty acids distillation, distillation residuals from glycerol, exhausted active carbon, exhausted bleaching earth and spent catalysts.

4.8.3. Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the unitower reactor

Steps:

- Rendering with method 1;
- Bleaching;
- Hydrogenation;
- Splitting in unitower reactor;
- Distillation of crude fatty acids;

- Concentration of glycerol;
- Distillation of glycerol;
- Purification of glycerol;
 - End products: low boiling fraction of fatty acids and distilled fatty acids, distilled and bleached glycerol.
 - Side products: High boiling fractions of fatty acids distillation, distillation residuals from glycerol, exhausted active carbon, exhausted bleaching earth and spent catalysts.

4.8.4. Production of unsaturated fatty acids and glycerol (via distillation) and splitting in the unitower reactor

Steps:

- Rendering with method 1;
- Splitting in unitower reactor;
- Distillation of crude fatty acids;
- Concentration of crude glycerol;
- Distillation of crude glycerol;
- Purification of distilled glycerol.
 - End products: low boiling fraction of fatty acids and distilled fatty acids, distilled and bleached glycerol.
 - Side products: high boiling fractions of fatty acids distillation, distillation residuals from glycerol, exhausted active carbon.

4.8.5. Production of unsaturated fatty acids and glycerol and splitting in the multitower reactor

Steps:

- Rendering with method 1;
- Splitting in multitower reactor;
- Distillation of crude fatty acids;
- Concentration of crude glycerol;
- Distillation of crude glycerol;
- Purification of distilled glycerol.
 - End products: low boiling fraction of fatty acids and distilled fatty acids, distilled and bleached glycerol.
 - Side products: high boiling fractions of fatty acids distillation, distillation residuals from glycerol, exhausted active carbon.

4.8.6. Production of hydrogenated fatty acids and glycerol (via distillation) with splitting in the unitower reactor followed by hydrogenation

Steps:

- Rendering with method 1;
- Splitting in unitower reactor;
- Distillation of crude fatty acids;
- Hydrogenation of distilled fatty acids;
- Concentration of crude glycerol;
- Distillation of crude glycerol;
- Purification of distilled glycerol.
 - End products: low boiling fraction of fatty acids and distilled hydrogenated fatty acids, distilled and bleached glycerol.
 - Side products: High boiling fractions of fatty acids distillation, distillation residuals from glycerol, exhausted active carbon, and spent catalysts.

4.8.7. Production of hydrogenated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor followed by hydrogenation

Steps:

- Rendering with method 1;
- Splitting in unitower reactor;
- Distillation of crude fatty acids;
- Hydrogenation of distilled fatty acids;
- Concentration of crude glycerol;
- Treatment of crude glycerol via ion exchange;
- Purification of treated glycerol.
 - End products: low boiling fraction of fatty acids and hydrogenated fatty acids, distilled and bleached glycerol.
 - Side products: High boiling fractions of fatty acids distillation, waste water from regeneration of ion exchange, exhausted active carbon, and spent catalysts.

4.8.8. Production of unsaturated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor.

Steps:

- Rendering with method 1;
- Splitting in unitower reactor;

- Distillation of crude fatty acids;
- Concentration of crude glycerol;
- Treatment of crude glycerol via ion exchange;
- Purification of treated glycerol.
 - End products: low boiling fraction of fatty acids and distilled unsaturated fatty acids, distilled and bleached glycerol.
 - Side products: High boiling fractions of fatty acids distillation, waste water from regeneration of ion exchange, exhausted active carbon, and spent catalysts.

5. Risk categories

Tallow including Cat. 1 tallow as defined in the Regulation (EC) 1069/2009, Art. 8.

6. Identification and characterisation of risk materials

In the dossier it is stated that tallow comes from all the streams (healthy slaughtered animal, at risk, eradication). The material may be of extra-EU origin. The only pathogens considered in this opinion are the TSE agents.

7. Agent risk reduction

The maximum permitted level of insoluble impurities in tallow of 0.15% represents a relatively low level of possible TSE infectivity present in the processed material compared to the starting material. If it is assumed that 1% of this material has been accidentally caused by infected SRM in the batch, this infected SRM would approximately represent no more than 1.5×10^{-3} % of the whole material. Based on this worst case scenario, a 5 log reduction is sufficient for the whole treatment procedure (Dormont et al., 2003; Mueller et al., 2008).

In all the processes method 1 has been applied to the material before entering the oleochemical process. This ensures at least 3 log reduction of prion infectivity, including various TSE strains and cattle BSE (Fair CT987019, 2001; Schreuder et al. 1998; Dormont et al., 2003).

In the following sections only the risk reduction steps that have been already validated under experimental conditions are taken into account. **This assessment of the risk reduction is only valid if the conditions indicated at point 7.1 to 7.8 are kept.** Other steps can, however, also contribute to the overall risk reduction given by the proposed processes but the risk reduction for these steps cannot be quantified due to the lack of experimental quantitative data.

It has to be remarked that the applicant indicated that parameters used in the in-plant conditions are stricter (higher temperature, pressure) than the parameters used in the experimental validation studies.

Due to the reason that the experiments to measure the inactivation of TSE infectivity in the treatment steps used in oleochemical processes and rendering have been done in batch processes only the risk reduction for those steps conducted in batches can be quantified. Uncertainties on the minimal retention time for continuous processes remain and prevent accurate quantification of the risk reduction achieved. However, in the case of splitting steps considering the long reaction time (at least 5 hours for the multitower and 3.5 hours for the unitower) when compared to the 20 minutes used in the experimental validation the risk reduction estimated in the experimental validation was applied.

The Table 1 illustrates the log reduction of TSE infectivity according to the various process steps. The additive reduction effect may be not strictly mathematically calculated, since the reactivity and sensitivity of prions may be influenced by several variables (medium, chemical structure, molecular

conformation, etc.) during the different steps. Nevertheless the conditions of temperature, pressure and type of reagents at the different treatment steps are considerably strict and of different physical and chemical nature, so it would be reasonable to assume that they may have a further effect on prions.

It must be taken into account that for the experimentally validated steps only one strain was used (263K). In some cases no reference values/studies are available, indeed some steps have minor contribution to TSE inactivation. For bleaching, distillation, concentration and purification steps some considerations are reported after the Table 1 (chapter 7.1 to 7.8).

Table 1: Estimated log-Reduction of TSE-infectivity in oleochemical processes with different combinations of treatment steps following Method 1 (263K prion strain was used in the experiments in the references reported).

No				
1.	Production of Hydrogenated Tallow (see 4.8.1): Bleaching-Hydrogenation			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
1.1	Bleaching	90°C/40 min (batch)	0	No ref.
1.2	Hydrogenation	160°C/ 12 bar/20 min	5.9	Mueller et al., 2008
1.3	Estimated total (including method 1)		>6	
2.	Production of hydrogenated fatty acids and Glycerol (see 4.8.2): Hydrogenation, splitting in multi-tower reactor, distillation of crude fatty acids, concentration of glycerol			
2.1	Production of hydrogenated fatty acids			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
2.1.1	Bleaching	90 °C/40 min (batch)	-	No ref.
2.1.2	Hydrogenation	160 °C/ 12 bar/20 min	5.9	Mueller et al., 2008
2.1.3	Distillation	210 °C/25 mbar/30 min (continuous)	-	No ref.
2.1.4	Estimated total (including method 1)		>6	
2.2	Production of Glycerol			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
2.2.1	Bleaching	90 °C/40 min (batch)	-	No ref.
2.2.2	Hydrogenation	160 °C/ 12 bar/20 min	5.9	Mueller et al., 2008
2.2.3	Concentration	50 °C/70 mbar/40 min	-	No ref.
2.2.4	Distillation	150 °C/ 10 mbar/20 min	-	No ref.
2.2.5	Purification	Adsorption to active carbon	-	No ref.
2.2.6	Estimated total (including method 1)		>6	
3.	Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the unitower reactor (see 4.8.3): Bleaching, hydrogenation, splitting in unitower reactor, distillation of crude fatty acids, concentration of glycerol, distillation of glycerol, purification of glycerol			
3.1	Production of hydrogenated fatty acids			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
3.1.1	Bleaching	90 °C/40 min (batch)	-	No ref.
3.1.2	Hydrogenation	160 °C/ 12 bar/20 min	5.9	Mueller et al., 2008
3.1.3	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
3.1.4	Distillation	210 °C/25 mbar/30 min (continuous)	-	No ref.
3.1.5	Estimated total (including method 1)		>6	

3.2 Production of Glycerol				
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
3.2.1	Bleaching	90 °C/40 min (batch)	-	No ref.
3.2.2	Hydrogenation	160 °C/ 12 bar/20 min	5.9	Mueller et al., 2008
3.2.3	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
3.2.4	Concentration	50 °C/70 mbar/40 min	-	No ref.
3.2.5	Distillation	150 °C/ 10 mbar/20 min	-	No ref.
3.2.6	Purification	Adsorption to active carbon	-	No ref.
3.2.7	Estimated total (including method 1)		>6	
4. Production of unsaturated fatty acids and glycerol (via distillation) and splitting in the unitower reactor (4.8.4): Rendering with method 1, splitting in unitower reactor, distillation of crude fatty acids, concentration of crude glycerol, distillation of crude glycerol , purification of distilled glycerol				
4.1 Production of unsaturated fatty acids				
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
4.1.1	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
4.1.2	Distillation	210°C/25 mbar/30 min (continuous)	-	No ref.
4.1.3	Estimated total (including method 1)		>6	
4.2 Production of glycerol				
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
4.2.1	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
4.2.2	Concentration	50°C/70 mbar/40 min	-	No ref.
4.2.3	Distillation	150°C/ 10 mbar/20 min	-	No ref.
4.2.4	Purification	Adsorption to active carbon	-	No ref.
4.2.5	Estimated total (including method 1)		>6	
5. Production of unsaturated fatty acids and glycerol and splitting in the multitower reactor (4.8.5): Rendering with method 1, splitting in multitower reactor, distillation of crude fatty acids, concentration of crude glycerol, distillation of crude glycerol, purification of distilled glycerol				
5.1 Production of unsaturated fatty acids				
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
5.1.1	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
5.1.2	Distillation	210°C/25 mbar/30 min (continuous)	-	No ref.
5.1.3	Estimated total (including method 1)		>6	
5.2 Production of glycerol				
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
5.2.1	Splitting	200°C /16 bar/20min	≥6	Mueller and Riesner, 2005
5.2.2	Concentration	50°C/70 mbar/40 min	-	No ref.
5.2.3	Distillation	150°C/ 10 mbar/20 min	-	No ref.
5.2.4	Purification	Adsorption to active carbon	-	No ref.
5.2.5	Estimated total (including method 1)		>6	

6.	Production of hydrogenated fatty acids and glycerol (via distillation) with splitting in the unitower reactor followed by hydrogenation (4.8.6): Rendering with method 1, splitting in unitower reactor, distillation of crude fatty acids, hydrogenation of distilled fatty acids, concentration of crude glycerol, distillation of crude glycerol, purification of distilled glycerol			
6.1	Production of hydrogenated fatty acids			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
6.1.1	Splitting	200°C /16bar/20min	≥6	Mueller and Riesner, 2005
6.1.2	Distillation	210°C/25 mbar/30 min (continuous)	-	No ref.
6.1.3	Hydrogenation	160°C/ 12 bar/20 min	5.9	Mueller et al., 2008
6.1.4	Estimated total (including method 1)		>6	
6.2	Production of glycerol			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
6.2.1	Splitting	200°C /16bar/20min	≥6	Mueller and Riesner, 2005
6.2.2	Concentration	50°C/70 mbar/40 min	-	No ref.
6.2.3	Distillation	150°C/ 10 mbar/20 min	-	No ref.
6.2.4	Purification	Adsorption to active carbon	-	No ref.
6.2.5	Estimated total (including method 1)		>6	
7	Production of hydrogenated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor followed by hydrogenation (4.8.7): Rendering with method 1, splitting in unitower reactor, distillation of crude fatty acids, hydrogenation of distilled fatty acids, concentration of crude glycerol, treatment of crude glycerol via ion exchange, purification of treated glycerol			
7.1	Production of hydrogenated fatty acids			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
7.1.1	Splitting	200°C /16bar/20min	≥6	Mueller and Riesner, 2005
7.1.2	Distillation	210°C/25 mbar/30 min (continuous)	-	No ref.
7.1.3	Hydrogenation	160°C/ 12 bar/20 min	5.9	Mueller et al., 2008
7.1.4	Estimated total (including method 1)		>6	
7.2	Production of glycerol			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
7.2.1	Splitting	200°C /16bar/20min	≥6	Mueller and Riesner, 2005
7.2.2	Concentration	50°C/70 mbar/40 min	-	No ref.
7.2.3	Ion exchange		-	No ref.
7.2.4	Purification	Adsorption to active carbon	-	No ref.
7.2.5	Estimated total (including method 1)		>6	

8	Production of unsaturated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor (4.8.8): Rendering with method 1, splitting in unitower reactor, distillation of crude fatty acids, concentration of crude glycerol, treatment of crude glycerol via ion exchange, purification of treated glycerol			
8.1	Production of unsaturated fatty acids			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
8.1.1	Splitting	200°C /16bar/20min	≥6	Mueller and Riesner, 2005
8.1.2	Distillation	210°C/25 mbar/30 min (continuous)	-	No ref.
8.1.3	Estimated total (including method 1)		>6	
8.2	Production of glycerol			
	Processing steps	Process Parameter	Estimated log₁₀ reduction	Reference
8.2.1	Splitting	200°C/16bar/20min	≥6	Mueller and Riesner, 2005
8.2.2	Concentration	50°C/70 mbar/40 min	-	No ref.
8.2.3	Ion exchange		-	No ref.
8.2.4	Estimated total (including method 1)		>6	

* If batch hydrogenation (reduction not quantified in case of continuous reactor).

7.1. Potential of hydrogenation to reduce TSE infectivity

This is the only processing step which had been validated in laboratory scale experiments (Mueller and Riesner, 2005; Mueller et al, 2008).

The process parameters given by APAG in the process description are 160°C – 220°C for 20 minutes at a pressure of 12 bar of hydrogen gas. In the APAG paper “Minimum conditions to be applied for oleochemical processes”, a minimum temperature of 160°C at a pressure of 12 bar is given and no minimum exposure time.

Experimental data are existing concerning the hydrogenation step elaborated by using the 263K hamster adapted scrapie strain. Titration had been done by blotting (Appel et al., 2001b) and by bioassay (Müller et al. 2008). The detection limit in the bioassay was less than 2 log ID₅₀ and a reduction in infectivity was determined which was more than 5.9 log ID₅₀ at an exposure time of 20 minutes in a 300 ml laboratory scale reactor run at 160°C. Determination of a higher log reduction was not possible, because the starting titre was 7.96 ± 0.5 log ID₅₀. However APAG did not provide evidence of guaranteeing the minimum time in the continuous process. It is important for the efficacy to keep the minimum time under real conditions.

7.2. Potential of splitting to reduce TSE infectivity

This process step can be judged on already performed validation studies under comparable conditions. In the process description by APAG, for the multitower process, the practical conditions given are 230°C for 5 to 12 h at a pressure of up to 28 bar saturated steam (Process description, October 2010). For the unitower process, the practical conditions range between 240°C to 250°C at an exposure time ranging from 3,5 to 5 hours at a pressure of 50 bar is given (APAG process description, October 2010). In the APAG table “Minimum conditions to be applied for oleochemical processes” a minimum condition of 200°C at corresponding saturated vapour pressure for at least 20 minutes is indicated, and no distinction is made between unitower and multitower processes. Experimental data are existing concerning the high pressure high temperature treatment by using the hamster adapted scrapie strain 263K. Titration had been done by blotting and confirmation by bioassay. In those experiments the maximum reduction rate which could be measured had been 6 log ID₅₀ (Mueller and Riesner, 2005). According to the APAG documentation (December 2010), the minimal exposure time due to the

process effectiveness is in the unitower process 3,5 h and in the multitower process 5h. It is important for the efficacy to keep the minimum time under real conditions.

7.3. Potential of bleaching to reduce TSE infectivity

No experimental data are available on inactivation of TSE agents under the conditions described here.

The temperature range given by the applicant in the process description is 100°C – 130°C for 40 minutes up to 120 min, whereas in the documentation about minimum conditions to be applied for oleochemical processes, a minimum temperature of 90°C is given and no minimum exposure time. Even a batch process like this could be effective in destroying TSE-infectivity, but it is difficult to estimate the reduction rate without clear time and temperature relationships.

Moreover it must be questioned if temperature alone in a lipid matrix without water in a vacuum will lead to comparative inactivation rates as could be expected during autoclaving at high pressure. It may be expected that proteins might be much more resistant to denaturation in a lipid matrix as suggested by some data from autoclaving experiments by Appel et al. (2001). The lowest temperature tested in this experiments was 100°C and a 0,5 log reduction could be measured in 20 min. Although those data are based on a limited number of replicates they may lead to the conclusion that a treatment at 100°C at atmospheric pressure for 40 minutes will result in a 1 log reduction of recombinant prion protein rPrP(90±231) from Syrian hamster in the lipid fraction as long as the minimum conditions are fixed to 100 °C and 40 min. No bioassay for titration of infectivity was performed by the authors.

7.4. Potential of distillation of crude fatty acids to reduce TSE infectivity

Distillation processes work on the separation of substances with different molecular weight on the base of their vapour tension. Therefore, in principle, large molecules such as proteins should not be present in the distilled material. However the applicant did not provide experimental evidence for the absence of proteins in the distilled glycerol and fatty acids.

The process parameters given by APAG are 215°C for 20 minutes at a vacuum of 25 mbar. In the APAG flow sheets a range of 210°C – 260°C at an exposure time of 30 minutes at a vacuum of 25 mbar is given.

If the process is a batch process under pressure in an autoclave the given temperature/time relationship would be effective in destroying more than 5 log of TSE infectivity but it is unknown how long the first molecule of a fresh fed fatty acid requires to reach the vapour phase and what is the starting temperature in the distillation process.

Moreover it is unknown how prion protein will behave in this process under vacuum conditions in a hydrophobic matrix since it can be expected, that it will bind to lipids due to hydrophobic interactions (Appel et al., 2001b; Hunter et al., 1972). Thus parts of the lipid fraction passing the process after a short exposure time or at low temperatures during distillation may serve as a vector for the residual prion protein as well it is not known if vacuum will stabilize the structure and the binding to the lipid fraction.

On the other hand the distillation process is running at temperatures around 200°C, the lowest measured temperature from the data collected by one company was 178 °C, so an additional safety by this process step could be expected, but quantification is impossible due to missing experimental data.

7.5. Potential of concentration of glycerol to reduce TSE infectivity

No experimental data are available on inactivation of TSE – agents under the conditions described for this treatment step (glycerol-water-mixture).

The process parameters given by APAG are 70°C to 120°C (average 100°C) for 40 minutes (minimum 20 min) at a pressure ranging from 1.5 bar to 70 mbar (average 100 mbar), whereas in the APAG

paper “Minimum conditions to be applied for oleochemical processes”, a minimum temperature of 50°C and no data for minimum pressure or minimum exposure time are listed in the table. In the APAG flow sheets a range of 70°C – 120°C at an exposure time of 40 minutes is given.

No major reduction of TSE-infectivity can be expected at temperatures below 100°C. Experimental data are not available on thermoresistance of prions in glycerol/water mixtures.

7.6. Potential of distillation of glycerol to reduce TSE-infectivity

No experimental data are available on inactivation of TSE – agents under the conditions described for this treatment step (glycerol-sodium soap-mixture).

The process parameters given by APAG in the process description are 155°C to 158°C for 20 minutes at a pressure of 4 mbar for multitower system and 165°C to 168°C for at least 1h at a pressure of 10 mbar to 15 mbar for unitower system. In the APAG paper “Minimum conditions to be applied for oleochemical processes”, a minimum temperature of 150 °C and a minimum pressure of 25 mbar but no minimum exposure time are listed in the table.

Since temperature, pressure and availability of water are the main factors leading to the destruction of the infectious prion molecule no reliable quantitative assessment can be done how the structure will be influenced in the vacuum in a hydrophilic matrix in the presence of a sodium soap-mixture.

Under overpressure at 150°C and a minimum exposure time of 20 minutes at least a 3 log reduction could be expected, but the described processes does not totally meet this criteria.

7.7. Potential of refinement step through active carbon to reduce TSE infectivity

No experimental data are available to what extent TSE agents are adsorbed to active carbon. It is highly probable, that up to a certain degree, infective prion protein can bind to the carbon, but quantification is not possible. Possible remaining TSE-agents would be removed from glycerol and remain in the active carbon, which is disposed separately as special waste by external companies.

7.8. Potential of ion-exchangers to reduce TSE infectivity

No experimental data are available to what extend TSE agents are bound to anion- and/or cation-exchangers. It is highly probable, that under certain conditions infective prion protein can bind to the charged structures, but quantification is not possible. Possible remaining TSE-agents would be removed from glycerol and remain in the ion-exchanger. There are some studies showing clearance of infectivity using ion exchangers (Taylor, 1985).

8. Risk containment

Information concerning waste disposal and safety of work environment was provided by the applicant, but the information provided on HACCP plan was not adequate. Even though the applicant provided a HACCP concept, this did not contain complete detailed and quantitative information about the risk containment of the TSE hazards.

In the main steps of risk containment, i.e. hydrogenation and splitting, detailed data, measuring control points and corrective actions are missing. In particular, in the continuous processes there are discrepancies in the information provided with respect to verifying the minimum retention time.

For example, in case of the continuous hydrogenation reactor, no proof was provided that all the material is treated for at least 20 minutes, and which corrective measure would be taken. There is no verification that, on the basis of the quality of the end product (99% hydrogenation of fatty acids), all parameters to achieve the 6 log reduction in TSE infectivity are met during the process.

Although the minimum retention time in the splitting process in the continuous reactor has not been experimentally measured, the treatment times of 3.5 h (unitower) and 5 h (multitower) required for

sufficient end product quality, contain a sufficient safety margin compared to the 20 minutes minimum exposure time experimentally validated.

It is not documented that, if Cat. 1 tallow is processed, the separation between clean and unclean part of the factory is assured according to the EU legislation on ABP.

9. Identification of interdependent processes

9.1. Disposal of by-products generated by the process itself

9.1.1. High boiling fractions (bottom fractions) from fatty acids distillation

These substances are stored in closed storage tanks and kept there. They are transferred to closed tank trucks, unloaded using closed pipelines and stored in closed silos.

The final destination can be as follows:

- These substances can be sold on the market as raw materials or additives for producing (bio)fuels or sold to be directly burnt to produce energy. From the oleochemical company to the working/burning company they are kept in closed systems. All Safety Procedures in place for handling chemicals have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen.
- The distillation residues can be considered as wastes because of Ni content (possible when obtained from the distillation of hydrogenated fatty acids). The EU main reference laws regulating wastes apply:
 - Decision 2000/532/EC.
 - Decision 2001/118/EC.
 - Decision 2001/119/EC.
 - Decision 2001/573/EC.

The EWC (European Waste Catalogue) numbers used are: 07 06 08*; 07 06 99.

In this case they will only be burnt in authorized incineration ovens. From the oleochemical company to the disposal company they are kept in closed systems. All Safety Procedures in place for handling wastes have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all the cycle.

9.1.2. Bottom residues from crude glycerol distillation

These substances are stored in closed storage tanks. They are transferred to closed tank trucks, unloaded using closed pipelines and stored in closed silos.

When they are considered wastes, EWC numbers are 07 06 08; 07 06 99.

In both cases, the final destination could be:

- Burnt in authorized incineration ovens. From the oleochemical company to the disposal company they are kept in closed systems. All Safety Procedures in place for handling wastes have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all their lifecycle.

- Used in biogas plants to feed bacteria. Insoluble/indigestible parts are spread on land. From the oleochemical company to the destination company they are kept in closed systems. All Safety Procedures in place for handling chemicals have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all the cycle.

9.1.3. Spent catalyst

9.1.3.1. Nickel catalyst

Once the catalyst is exhausted, depending on the EU country:

- I. It can be considered as waste, stored in closed containers and delivered to a recovering company. Here it is melted at temperatures higher than 1500°C and used to recover Ni for further applications (e.g. stainless steel) or to prepare salts that find an application mainly in paints. The EWC codes used in this case are 16 08 02*; 16 08 03. From the oleochemical company to the recovering company it is kept in closed systems. All Safety Procedures in place for handling wastes have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all its lifecycle.
- II. In some EU Countries this can be considered as a raw material, although undergoing the same recovering path described before. From the oleochemical company to the recovering company it is kept in closed systems. All Safety Procedures in place for handling classified materials (R40: possible risks of irreversible effects; R43: it may cause sensitization by skin contact) have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all the cycle.

9.1.3.2. Palladium catalyst

This is a precious metal, so that it is handled with care, as its cost is very high. It is considered a waste (EWC code: 16 08 01).

Once exhausted, it is packed in closed containers and sent back to the supplier for regeneration at temperatures higher than 500°C, than used again.

From the oleochemical company to the recovering company it is handled in closed systems. All Safety Procedures in place for handling classified materials (R17: spontaneously combustible in air; R22: harmful when swallowed; R 36/37/38: Irritating to eyes, respiratory organs and hands) have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all its lifecycle.

9.1.4. Bleaching earths

This material is a residue only for those companies carrying out the bleaching process. Exhausted bleaching earths are considered waste. EWC code are 07 06 10* or 15 02 03 or, alternatively, 16 03 06.

Since they may be in contact with Cat. 1 material and leave the factory before being submitted to splitting and/or hydrogenation steps, the bleaching earths have to be treated as a dangerous material and it can only be disposed off by incineration in an authorised waste combustion plant.

From the oleochemical company to the destination company they are kept in closed systems. All safety procedures in place for handling wastes have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all the cycle.

9.1.5. Active carbon

It is considered as waste. EWC code: 19 09 04 or 07 01 99 or 07 06 99 or 16 03 06 or 15 02 03.

It can be:

- I. Treated in ovens at 800°C min, till full combustion of organic substances included, than recovered.
- II. Regenerated with hot steam for at least 24 hours.

Final destination of regenerated Carbon could be wastewater depuration. For this treatment it can be delivered to authorised Companies or sent back to the supplier for regeneration. From the oleochemical Company to the recovering Company it is kept in closed systems. All Safety Procedures in place for handling wastes have to be followed. This means that no inhalation, contact with skin or ingestion is foreseen during all the cycle.

9.1.6. Wastewater (ion exchange process)

The waste water is sent to the wastewater treatment, undergoes a biological (digestion with bacteria), chemical and physical treatment before water is released. Waste water going out from industry has to comply mainly with the following EU laws:

- Directive 2001/42/EC.
- Directive 85/337/EC.
- Directive 97/11/EC.
- Directive 2003/35/EC.
- Directive 96/61/EC.
- Directive 2000/60/EC.
- Directive 2004/35/EC.

Limits for all pollutants are fixed by Member states.

10. Intended end use of the products

The end products are glycerol, unsaturated and saturated fatty acids, and hydrogenated tallow. The end use of the fatty acids and glycerol are destined to industrial purposes as follows:

Table 2: Industrial end use of fatty acids and glycerol produced with the oleochemical processes considered (as provided by the applicant)

Fatty acids	Glycerol
Feedstock for chemical conversion	Feedstock for Chemical Conversion
Food and feed*	Cellulose films
Lubricants and greases	Cosmetics / Toiletries
Paper chemicals	De-icing / Anti-freeze
Personal care ²	Esters
Plastics	Food and drink *
Protective coatings and resins	Nitration
Rubber and tyre industry	Paper
Soaps & Detergents	Pharmaceuticals
	Polyols / Polyurethanes
	Resins
	Tobacco

*Solely food-grade feedstock

11. Documentary evidence

- Several flow diagrams were provided to illustrate the functioning of the processes and highlighting the CCP⁴.
- Process description and risk analysis of oleochemical processes to inactivate possible risks linked to TSE in animal by-products not intended for human consumption provided by APAG⁴.
 - Risks evaluation for category 1 tallow processed in oleochemical operations.
 - Minimum conditions to be applied for oleochemical processes.
 - Documentation about fate of waste generated during the processes.
- In the dossier there is no measure of the reduction of viability/infectivity of endogenous pathogens or test pathogens, but it is referred to literature studies (Appel et al., 2001a; Mueller et al., 2006).
- Records of parameter monitoring from two companies with multitower system and two companies with unitower system were provided. The parameters used in the in-plant conditions are stricter (higher temperature, pressure, longer time, etc.) than the parameters used in the experimental validation studies, so to assure a safer margin⁴.
- Literature provided by the applicant:
 - Appel, T., Wolff, M., von Rheinbaben, F., Heinzl, M., Riesner, D. (2001) Heat stability of prion rods and recombinant prion protein in water, lipid and lipid-water mixtures. *J Gen Virol* 82, 465-473
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⁴ not attached for confidentiality reasons

CONCLUSIONS

- The maximum permitted level of insoluble impurities in tallow of 0.15% represents a relatively low level of possible TSE infectivity present in the tallow used by the oleochemical industry compared to the untreated ABP.
- Rendering tallow according to method 1 as described in the Regulation (EC) 1774/2002 contributes significantly (≥ 3 log reduction) to the overall risk reduction obtained through the described processes. This infectivity reduction was validated for a large panel of TSE agents (including classical BSE).
- Other steps of oleochemical processes (splitting, hydrogenation) were validated at lab scale using the 263K strain. Their effect on infectivity reduction of other TSE agents cannot be quantified at this stage. Thus the present calculations of prion inactivation bear considerable uncertainty.
- Several steps of the proposed process (distillation, ion exchange, bleaching...) were not supported by experimental data for prion inactivation. However these steps contribute to physical elimination of impurities, and therefore are expected to significantly reduce the level of infectivity.
- For the splitting step a treatment time of at least 3.5 hours for the unitower process and at least 5 hours for the multitower process as proposed by the applicant has to be guaranteed and verified.
- For hydrogenation experimental data is lacking about the retention time under practical conditions in a continuous system. Therefore it is not possible to finally judge the extent of TSE inactivation in such a system.
- The processes assumed to reduce significantly infectivity in tallow originating from Cat. 1 material are:
 - Production of hydrogenated tallow by batch hydrogenation.
 - Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the multitower reactor.
 - Production of hydrogenated fatty acids and glycerol (via distillation) with hydrogenation first and splitting in the unitower reactor.
 - Production of unsaturated fatty acids and glycerol (via distillation) and splitting in the unitower reactor.
 - Production of unsaturated fatty acids and glycerol and splitting in the multitower reactor.
 - Production of hydrogenated fatty acids and glycerol (via distillation) with splitting in the unitower reactor followed by hydrogenation only for fatty acids.
 - Production of hydrogenated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor followed by hydrogenation only for fatty acids.
 - Production of unsaturated fatty acids and glycerol (via ion exchange) with splitting in the unitower reactor.
- If all the relevant parameters of the specific ABP treatment considered in this opinion are met as indicated by the applicant, the processes listed above can be considered to reduce significantly TSE infectivity.

- The considerations made so far refer only to the specific oleochemical process of tallow of Category 1 considered in this opinion, and in no case can be generalised to other oleochemical treatments and/or to other raw material.
- The conclusions in relation to the above mentioned process can only be considered to be valid if the complete separation between incoming material and end products is assured according to the EU legislation on ABP.
- Considering the uncertainties on the TSE infectivity reduction in oleochemical products derived from Cat. 1 material, these products cannot be reliably regarded to be free of infectivity and therefore could pose a risk if they entered the food and feed chain.

RECOMMENDATIONS

Efforts should be made to compare the efficacy of the continuous processes to the validated batch processes, including critical control points for TSE reduction in the different steps.

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