European Code to good practice for the collection, transport, storage, trading and industrial manufacture of safe feed/food ingredients

Sector reference document on the manufacturing of safe feed ingredients from biodiesel processing

Version 2.0

Changes are highlighted in grey

Sectors covered by the European Code

The following sector specific sector documents have been developed by the respective European sector organisations in cooperation with EFISC-GTP:

Starch Europe	Sector reference document on the manufacturing of safe feed ingredients from starch processing
FEDIOL	Sector reference document on the manufacturing of safe feed ingredients from oilseed crushing and vegetable oil refining
EBB	**Sector reference document on the manufacturing of safe feed ingredients from Biodiesel processing**
EUROMALT	Sector reference document on the manufacturing of safe feed ingredients from malt production
COCERAL	Sector reference document on the collection, storage, transport and trading of feed/food ingredients

This European Code is open to other manufacturers producing feed ingredients by the development of a sector specific document.

Information on EBB

Please contact:

European Biodiesel Board (EBB)
Boulevard Saint Michel 34
1040 Brussels, Belgium
Tel: +32 (0)2 763 2477
Fax: +32 (0)2 763 0457
E-mail: info@ebb-eu.org
Website: www.ebb-eu.org

Information on EFISC-GTP

Please contact:

EFISC-GTP Aisbl
Avenue des Arts 43 c/o Starch Europe
B 1040 Brussels
Tel.: + 32 (0)2 771 53 30
Fax: + 32 (0)2 771 38 17
E-mail: info@efisc-gtp.eu
Website: www.efisc-gtp.eu

Publishing and copyright information

Version 2.0 14 September 2016 - Effective from: 22 March 2017

Within this Biodiesel Sector document animal fats/waste oils production processes and its' derived feed ingredients are not considered, therefore exempted from this sector document and excluded from EFISC certification

This risk assessment builds on the FEDIOL sector reference document (Appendix 4 of the European Code to good practice for the industrial manufacture of safe feed ingredients) for the manufacturing of the vegetable oils. Therefore it has as a starting point the transport of the incoming material

1. Introduction

The members of the European Biodiesel Board (hereinafter referred to as EBB) produce besides biodiesel, glycerine for animal feeding and for technical purposes. The EBB counts nearly 80 member companies and associations located in 21 EU Member States.

EBB members are committed to manufacture safe feed ingredients and to demonstrate their compliance to European health and safety requirements. In particular in the frame of the Feed Hygiene Regulation 183/2005/EC as well as within the Catalogue of Feed Material (Regulation 2022/1104/EU).

Biodiesel is a renewable fuel, providing a sustainable alternative to fossil fuels. In addition to reducing greenhouse gas emissions in European transportation, biodiesel provides extensive amounts of glycerine used for animal feed and other by-products, used for technical purposes.

The following document intends to support biodiesel facilities in delivering safe feed ingredients. The EBB has conducted risk assessments of the chain of feed materials from the main incoming materials processed by its industry. These assessments offer a tool to the biodiesel manufacturer for the evaluation of their own feed safety management system. They also support these manufacturers in their dialogue on chain control with their customers, suppliers and other stakeholders. The risk assessments mentioning control measures is a further detailing of the concept of HACCP and the supporting Prerequisite Programmes as mentioned in chapter 5 and 6 of the accompanying European Code for the industrial manufacture of safe feed ingredients.

EBB would like to emphasize that companies remain primarily responsible for supplying safe feed and that this risk assessment cannot replace any responsibility.

Table of Contents

List of Abbreviations

FAME: Fatty Acid Methyl Ester
FAE: Fatty Acid Ester
FFA: Free Fatty Acid
MONG: Matter Organic Non Glycerol

2. Listing of feed ingredients

The main raw materials processed by the EU Biodiesel industry are crude or refined rapeseed oil, soybean oil, sunflower seed oil and palm oil in combination with methanol.

The Catalogue of the European Union for Feed Materials provides a common system in the EU for the description and labeling of feed ingredients. The Catalogue includes, for each feed ingredient listed, the name of the product, an identification number, a description of the feed ingredient including - if appropriate - information on the manufacturing process, and the particulars replacing the compulsory declaration for the purpose of article 16 (1) (b) of Regulation (EC) No 767/2009.

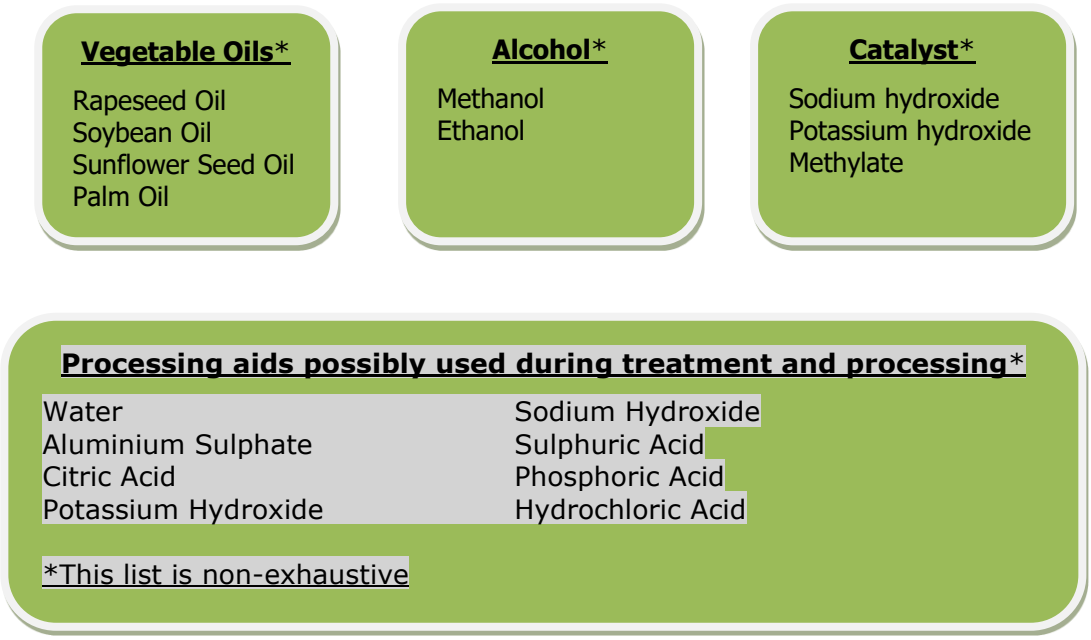
Hereby listed the biodiesel related feed ingredients within Reg. (EU) 2022/1104 (adapted for vegetable origin):

Glycerine, crude	13.8.1	Co-product obtained from: — the oleochemical process of oil/fat splitting to obtain fatty acids and sweet water, followed by concentration of the sweet water to get crude glycerol or by transesterification (may contain up to 0,5 % methanol) of natural oils/fats to obtain fatty acid methyl esters and sweet water, followed by concentration of the sweet water to get crude glycerol; — the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin. Mineral and organic salts might remain in the glycerine (up to 7,5 %). May contain up to 0,5 % methanol and up to 4 % of matter organic non glycerol (MONG) comprising of fatty acid methyl esters, fatty acid ethyl esters, free fatty acids and glycerides; — saponification of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps. May contain up to 50 ppm nickel from hydrogenation
Glycerine	13.8.2	Product obtained from: — the oleochemical process of (a) oil/fat splitting followed by concentration of sweet waters and refining by distillation (see part B, glossary of processes, entry 20) or ion-exchange process; (b) transesterification of natural oils/fats to obtain fatty acid methyl esters and crude sweet water, followed by concentration of the sweet water to get crude glycerol and refining by distillation or ion-exchange process;

		— the production of biodiesel (methyl or ethyl esters of fatty acids) by transesterification of oils and fats of unspecified vegetable and animal origin with subsequent refining of the glycerine. Minimum glycerol content: 99 % of dry matter; — saponification of oils/fats of vegetable or animal origin, normally with alkali/alkaline earths, to obtain soaps, followed by refining of crude glycerol and distillation. May contain up to 50 ppm nickel from hydro-genation

3. Process Description of Biodiesel

Biodiesel consists of Fatty Acid Methyl Esters and is produced by the chemical reaction of Oils and Fats with mono-alcohols, typically methanol. A catalyst, usually sodium or potassium hydroxide and/or methylate, is utilized to accelerate the formation of alkyl esters. This production process is generally known as transesterification.



This section will describe the process of biodiesel production from vegetable oils where the triglyceride oil is broken into alkyl (biodiesel) and glycerine by reaction with a mono alcohol. The biodiesel and glycerine phases are then separated and purified. Production processes contain the same stages, irrespective of the production scale, although the differences in equipment may be significant.

3.1. Reception of Vegetable Oil

Vegetable oils delivered to biodiesel plants are crude or refined vegetable oils. Pre-delivery (as per FEDIOL sector reference document)[1] vegetable oils undergo a number of refining steps to remove various impurities, such as phosphatides, free fatty acids, traces of heavy metals, waxes, tocopherols or colorants, which could impede the biodiesel process reaction and biodiesel quality.

[1] Fediol Sector Reference Document: appendix 4 to the European Code to good practice for the manufacture of safe feed ingredients:
http://www.efisc.eu/data/1377527038FEDIOL%20-%20version%203.0%20-%20Sector%20ref%20doc%20on%20oilseed%20crushing%20and%20veg%20oil%20refining%20version%203.0.pdf

Most if not all vegetable oils undergo some form of pre-treatment for impurities or free fatty acid (FFA) reduction prior to being utilised as a raw material in the manufacture of biodiesel.

On delivery, the crude or refined vegetable oils are segregated to pre-processing storage tanks. The safety and quality of the incoming material is assessed in line with the EFISC-GTP incoming material requirements (Code §4.3.2).
It should be noted, depending on the biodiesel plant design and organisation, the safety and quality assessment of oils may also occur at an earlier stage (i.e. in cases of integrated plants (crushing/refining/esterification).

The content of free fatty acids, water and non-saponifiable substances are key parameters in achieving high conversion efficiency in the transesterification reaction. The results of the oils parameters will influence the quantity of raw material, alcohol and catalyst ratio in the transesterification process.

3.2. Reaction Stage/ Transesterification:

The objective of the reaction stage is to convert the free fatty acid (FFA) fraction of the feedstock into biodiesel. When the FFA content is high the reaction stage is usually conducted in two steps: esterification and transesterification.

Following the pre-processing analysis of the incoming vegetable oil, the alcohol and catalyst is mixed and sent to the reaction vessel where upon the vegetable oil is added (Figure 1 Flow Chart). This stage is known as esterification and is generally a pretreatment step to the transesterification which reduces the FFA content of the oil.
The complete transesterification process is closed to the atmosphere to prevent any loss of alcohol. Excess alcohol is normally used to ensure total conversion of the oil to its esters.

3.3. Separation Stage

Once the reaction is complete, two major products exist: glycerine and biodiesel. Each has a substantial amount of the excess methanol that was used in the reaction. The reacted mixture is sometimes neutralized at this step if needed. The glycerine phase is much more dense than the biodiesel phase and the two can be gravity separated with glycerine simply drawn off the bottom of the settling vessel. In some cases, a centrifuge is used to separate the two materials faster.

3.4. Acidulation and FFA separation

Typically, the glycerine after the separator is usually 35% glycerine, 30% methanol, 25% water and 10% soap and catalyst. The catalyst is neutralized and soaps are split to free fatty acids and salts. Free fatty acids and methanol are removed and recovered.

3.5. Glycerin neutralization

The glycerine by-product contains unused catalyst and soaps that are neutralized with an acid and sent to storage as crude glycerine.
In

some cases the salt formed during this phase is recovered for use as fertilizer. If so water and alcohol are removed to produce approx. 80% pure glycerine that is ready to be sold as crude glycerine.

3.6. Methyl Ester Wash

Once separated from the glycerine, the biodiesel is sometimes purified by washing gently with warm water to remove residual catalyst or soaps, than dried and sent to storage. In some processes this step is unnecessary.

3.7. Glycerine Refinery

Crude glycerine (Reg. 68/2013/EU; Chapter 13.8.1) can be further purified by a series of process steps (see below) for obtaining refined glycerine by removing water, salts, traces of MONG, color bodies and odors. A glycerine refinery broadly involves three processes (i) drying (ii) distillation and (iii) bleaching.

(i) Crude glycerine is transferred to a drying column and subsequently the de-watered crude glycerine is transferred to at least one desalting unit (distillation, decanting).
(ii) Distillation consists of vaporization, stripping and scrubbing of the glycerine phase; decanting consists of precipitation and removal of salts by settlement.
(iii) Final purification section uses deodorization and activated carbon to remove color and odor and other volatiles.

Refined Glycerine (Reg. 68/2013/EU; Chapter 13.8.2) can be delivered for feed ingredient but is mainly used for other applications (i.e. technical, pharmaceutical and cosmetic applications and food additive).

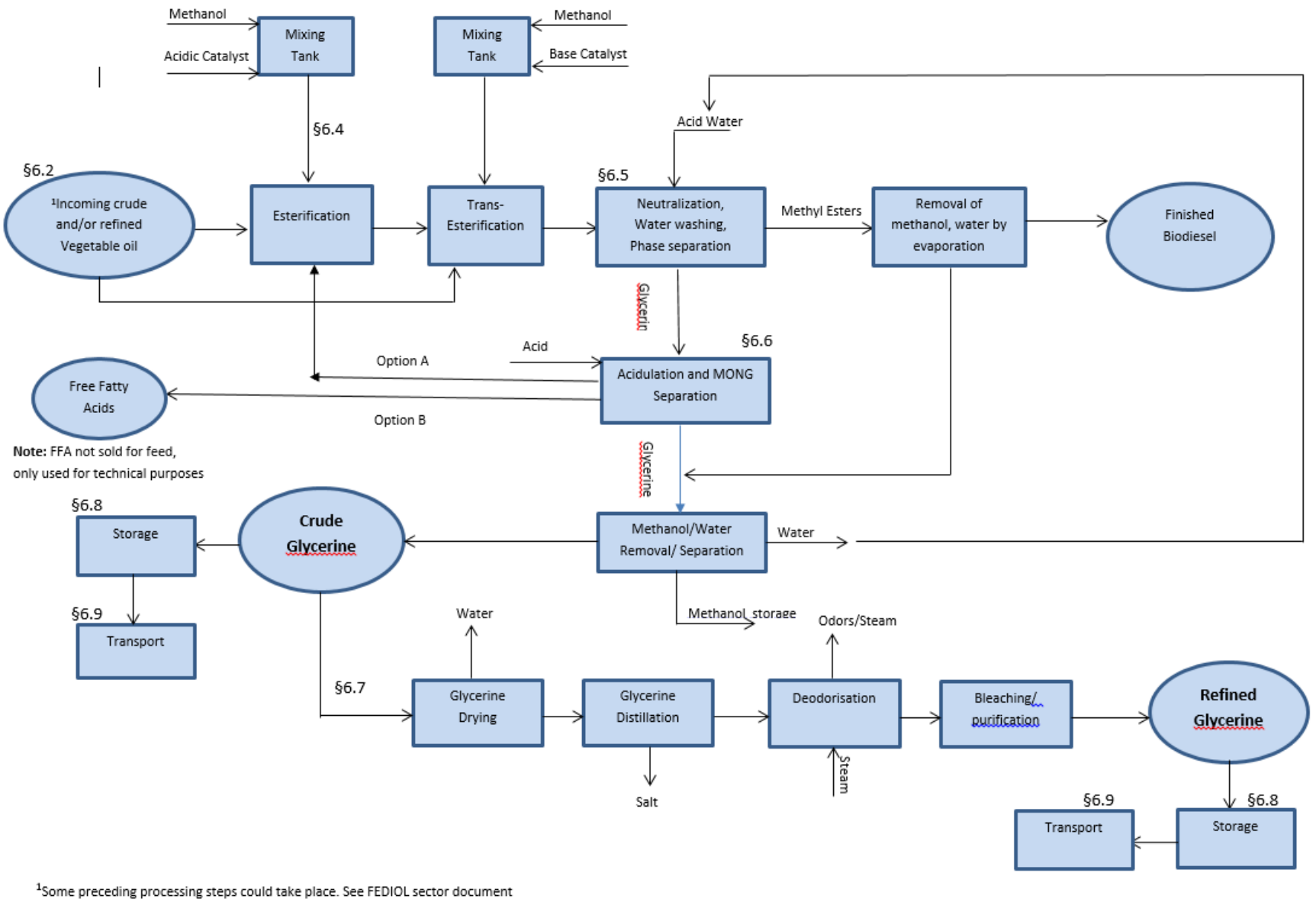
3.8. Storage

Glycerine is stored in suitable storage tanks (in line with the requirements as described in the FEDIOL sector document and EFISC-GTP Code).

3.9. Transport

The transportation of the glycerine has to be in line with EU and National legalisations, the EFISC-GTP Code, customer requirement and the requirements in this code 'Sector reference document on the manufacturing of safe feed materials from biodiesel processing'.

4. Biodiesel Production Process Flow Chart



[1]Some preceding processing steps could take place. See FEDIOL sector document

*This chart describes a general biodiesel process

5. Risk Assessment

5.1. EBB made the following incoming materials subject to feed safety chain risk assessment

Raw Material: Vegetable Oils

In all cases, biodiesel sites are expected to comply with the requirements concerning HACCP implementation including risk assessments. A table of hazards is included in Appendix 1 but individuals should note that this list is not exhaustive and the operator should carry out their own risk assessments. Further information on specific hazards and control measures can be found in relevant HSE publications and EC Regulations in the Risk Assessment tables.

5.2. Summary of the risk-based approach for the biodiesel sector

In establishing the list of potential hazards, an operator should take due consideration of:

- The Directive of undesirable substances in feed (2002/32/EC).
- The Regulation on genetically modified food and feed (1829/2003/EC).
- The Placing on the market Regulation (767/2009/EC)
- Laying down requirements for feed hygiene (183/2005/EC)
- The Regulation on maximum residues levels of pesticides in or on food and feed of plant and animal origin (396/2005/EC).
- The Regulation Catalogue of Feed Materials (2022/1104/EU).
- The Regulation amending Annex II to Regulation (EC) No 183/2005 of the European Parliament and of the Council as regards the dioxin testing of oils, fats and products derived thereof (2015/1905/EU)

See EFISC-GTP Code chapter 7 Reference documents

The following list of examples is non-exhaustive and should be adapted according to the circumstances.

Biological hazards

- Relevant Vegetative Pathogens according to the feed hygiene regulation (183/2005/EC) and associated microbiological criteria.

Potential Chemical hazards*

- Process chemicals, processing aids and antioxidants,
- Mycotoxin
- Heavy metals
- Pesticides residues
- PCB, Dioxins
- Polycyclic aromatic hydrocarbons (PAH)
- Lubricants and mineral oils

- Pest control chemicals

*This list is not exhaustive

The use of processing aids is included in the hazards analysis developed by the operator according to the requirements of the section 6 of the EFISC-GTP Code.

Physical contamination hazards

- Physical contamination, e.g. metal, glass, plastics

5.3. Risk-based approach for the characterisation of hazards applicable to feed materials coming from biodiesel production

The following tables present the characterisation of hazards applicable to products, coming from biodiesel production, sold as feed materials. For more understanding of the following risk assessment tables please see EFISC-GTP main text, chapter 6 HACCP system.

Those risks cannot be considered as complete and may differ amongst biodiesel producers based on individual and specific manufacturer's processing conditions.

Biodiesel manufacturers have refined the risks to a level appropriate to their specific operating conditions.

Three categories of hazards were considered:

- Biological hazards;
- Chemical hazards; and,
- Physical hazards.

5.4. Procedure of carrying out risk assessment

EBB followed the methodology as described in the EFISC-GTP Code – chapter 6 – HACCP

5.4.1. Biodiesel Process: EBB constructed a flow chart covering all stages of biodiesel production: from transport and reception of raw materials, storage, application of processing aids, separation of materials following transestification, washing, further refining of glycerine, to the end product which is biodiesel and crude or refined glycerine feed ingredient, storage and transport.

5.4.2. For processing steps: utilities-related hazards were commonly described. A safety hazard is a biological (B), chemical (C) or physical agents (P) in, or condition of, a product that makes it injurious to human or animal health.

5.4.3. In the elements of the chain that directly relate to the professional activity of the EBB members within the production process a risk based assessment per hazard was conducted.

5.4.4. As previously described, those risks cannot be considered as complete and may differ amongst biodiesel producers based on individual and specific manufacturer's processing conditions

Moreover, in these tables, no operational prerequisite programme (OPRP) or critical control point (CCP) is listed due to the fact that the decision leading to the establishment of such OPRP or CCP should be consistent with the actual operating conditions in each plant or processing line.

5.4.5. EBB justified the risk assessment

5.4.6. EBB checked whether EU legislation or trade standards sets limits for the respective hazard, and if so, listed them

6. Risk based approach for glycerine	1. General risk: Biodiesel Processing							
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS**	**CONTROL MEASURE**	**REMARKS**
Quality of water	C/B/ P	Low	High	3	Water is used for the purification of biodiesel.	According to Regulation 183/2005/EC water used during the manufacture of feed shall be of suitable quality EFISC-GTP Code section 4.2.9 Water, steam and air supply	Apply suitable water quality Water used, and re-used, in feed materials manufacture shall be of suitable quality at all stages. The management must be sure that the water which is used in the production of the feed materials is safe for animals. Dedicate water circuits in order to avoid the risk of contamination.	Boiler chemicals used for water conditioning needs to be evaluated and risk assessed
Cleaning agents	C	Low	Medium	2	Cleaning agents may come into contact with the product	EFISC-GTP Code 4.2.6 Cleaning, disinfection and sanitation	Cleaning agents used in the production system should be flushed. Evaluated and appropriate measures taken to bring risk to acceptable levels. Cleaning agents and disinfection agents used shall be suitable for its purpose, food grade when needed and authorised in the country of use.	Not a common risk as most productions facilities are continuous and processes
Flying in birds	B	Low	Medium	2	Risk of bird drops/ microbiological contamination	EFISC-GTP Code 4.2.3.2. Requirements for loading, storage, production areas and other feed material related facilities	Building maintenance/ closed windows and doors when applicable. Bird control. Biodiesel processing is a closed process	

Toxins from pest control materials	C	Very low	High	2	Poison bait from open boxes could cause cross contamination	EFISC-GTP Code 4.2.7 Pest control	A pest control programme must be applied. Appropriate measures should be taken to minimise risk	
Contamination by lubricants	C	Low	High	3	Contamination of lubricant with the glycerine due to leakage	EFISC-GTP Code 4.2.5 Maintenance	Use of lubricant should be evaluated before use and appropriate measures be taken to bring risk to acceptable levels. Use of food/feed grade where applicable. Monitoring of the use of lubricants. Maintenance procedures in place	Purchasing specifications food/ feed grade.
Insects and rodents	B	Medium	Low	2	Possible contamination of the glycerine with insects or rodents/ faeces.	EFISC-GTP Code 4.2.3.2. Requirements for loading, storage, production areas and other feed material related facilities EFISC-GTP Code 4.2.7 Pest control	Building proofing, cleaning programs and pest control system as part of the pre requisite programme. Biodiesel production is a closed process.	
Boiler water treatment chemical contamination of refined glycerine	C	medium	medium	3	Contamination of intermediate product by chemical containing in steam in the glycerine-deodorizing step.	EFISC-GTP Code 4.2.9 Water steam and air supply	Water, steam and air used and re- used, in feed materials manufacture shall be of suitable quality at all stages.	Used boiler water treatment chemicals do not move into steam phase.
Foreign materials	P	Low	Medium	2	Foreign materials may be present.	EFISC-GTP Code 4.3.2 Incoming materials requirements	Dedicated buildings and circuits filters, staff hygiene, glass and hard plastics procedure, good maintenance practices, closed process	

Microbiological contamination	B	Low	Medium	2	Closed process. No grow conditions during manufacturing	EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	

6. Risk based approach for glycerine

2. Incoming crude and/or refined vegetable oil

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS	CONTROL MEASURE	REMARKS
Contamination by the previous cargo during the transport by truck or barge or ocean going vessel	C	Low	High	3	Transport of vegetable oils takes place in accordance with 183/2005/EC	852/2004/EC FEDIOL Code previous cargo's EFISC-GTP Code 4.3.3 Handling of incoming materials	Risk must be evaluated and appropriate measures must be taken to bring this risk to acceptable levels.	Visual checks
Foreign materials	P	Low	Medium	2	Foreign materials may be present.	EFISC-GTP Code 4.3.2 Incoming materials requirements	Dedicated buildings and circuits filters, staff hygiene, glass and hard plastics procedure, good maintenance practices, closed process	

Contamination with undesirable substances	C	Low	High	3	In general the contaminants listed below do not concentrate in the glycerine but remain in the biodiesel.	Directive 2002/32/EC on undesirable substances on feed materialsEFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	Contamination with undesirable substance normal cases CHANCE is LOW – if manufacturer purchases a raw material of lower quality the risk elevates to medium
- Dioxins and dioxin like PCB's	C	Very Low	High	2	In general the dioxins like PCB's do not concentrate in the glycerine but remain in the biodiesel.	Directive 2002/32/EC and EU regulation 2015/1905/EU EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	EU Regulation of 2015/1905/EU on Dioxins mentions for certain incoming products the 100 % monitoring on Dioxin
- Nickel	C	Very Low	High	2	Starting vegetable oil is crude or refined vegetable oil and does not contain nickel. Nickel is not used in biodiesel production but for the hydrogenation of refined vegetable oil.	EU Regulation 68/2013/EU Catalogue of Feed Materials EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	If hydrogenated vegetable oil is used, a defined monitoring plan is needed .	In case hydrogenated vegetable oil would be used, nickel would concentrate in the glycerine and so the chance would be high.
- non Dioxin like	C	Very Low	High	2	Starting vegetable oil is	Directive 2002/32/EC	Monitoring plan	

PCB's					crude and/or refined vegetable oil. Non Dioxin like PCBs does not concentrate in the glycerine but remain in the biodiesel.	on undesirable substances on feed material EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Defined monitoring frequency	
PAH	C	Low	High	3	Does not concentrate in the glycerine but remain in the biodiesel.	EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	
Pesticide residues above the maximum residue levels (MRL), i.e. Residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	*Low	Medium	2	Regular monitoring of pesticide residues on crude oil or oil seeds shows that residue levels remain within legal limits.	Regulation 396/2005/EC sets limits for residues of pesticides. This regulation allows using a processing factor for authorised pesticides into processed products, providing food safety is assured. EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and	Monitoring plan Defined monitoring frequency	Most pesticides are not water soluble and will not move to the glycerine water phase *Certain origins of vegetable oil or oil seeds can have a medium chance of exceeding the MRL

						analysis See Section 7 Biodiesel Sector Document		
Unauthorised pesticides residues as listed in EU Directive 2002/32 for undesirable substances in feeding stuff	C	Very low	High	2	Some of the banned pesticides may be present in the environment. The chance of finding them in crude vegetable oils, however, is very low.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff. EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	Most pesticides are not water soluble and will not move to the glycerine water phase. If water soluble the pesticides are removed in the crude oil refining steps. Risk level might vary depending on the country of origin.

6. Risk based approach for glycerine				**3. Storage of the incoming material**				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS**	**CONTROL MEASURE**	**REMARKS**

Cross contamination resulting from equipment malfunction or operator accident	C	Low	Medium	2	Sources of risk include equipment malfunction and operator accident. Extremely low frequency of occurrence. Preventative measures to reduce impact include automated safety mechanisms, filters, spill containment, site security, restricted site access.	EFISC-GTP Code 4.3.4 Measures for the prevention of cross contamination	Closed process and storage facilities. Storage procedure in place	

6. Risk based approach for glycerine				4. Stage 1 of 3 – Trans esterification (Reaction stage)				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS**	**CONTROL MEASURE**	**REMARKS**
Contaminants in Processing aids (alkali solution, acids)	C	Low	Medium	2	Processing aids come into contact with the product.	EU Regulation 68/2013/EU Catalogue of Feed Materials EFISC-GTP Code 4.3.6 Processing	Processing aids that directly come into contact with the oil must be suitable for use in the food/feed industry. The use of the processing aid evaluated and appropriate measures taken	Processing aids in direct contact must be suitable for food/ feed quality

						Aids and Technological Additives	to bring risk to acceptable levels. Product specification Inline process monitoring, correct labelling of the chemical containers	
Contamination caused during addition of methanol	C	Low	Medium	2	Undesirable substances in the methanol	EFISC-GTP Code 4.3.6 Processing Aids and Technological Additives	Apply methanol of suitable food/feed quality Described in the product specification In line process monitoring, correct labelling of the chemical containers	In very small scale operations, the handling of dangerous chemicals may pose a greater risk to the operator if these chemicals are manually transferred and employed in a batch process versus an automated system.
Contamination caused during addition of Catalyst	C	Low	Medium	2	Undesirable substances in the catalyst	EFISC-GTP Code 4.3.6 Processing Aids and Technological Additives	Apply catalyst of suitable quality In line process monitoring, correct labelling of the chemical containers	

6. Risk based approach for glycerine				5. Stage 2 of 3 – Trans esterification (Separation stage)				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS**	**CONTROL MEASURE**	**REMARKS**
Methyl ester remaining in glycerine	C	Low	High	3	Separation of biodiesel from coproducts - stage 1	EU Regulation 68/2013/EU mentions: May contain up to 4% of Matter Organic Non Glycerol (MONG) comprising of Fatty Acid Methyl Esters, Fatty Acid Ethyl Esters, Free Fatty Acids and Glycerides	Monitoring plan and process follow up	Continuous monitoring
Methanol in crude glycerine	C	Medium	High	4		EU Regulation 68/2013/EU mentions: May contain up to 0,5 % methanol	Control by process parameters and/or continuous monitoring	

6. Risk based approach for glycerine				6. Stage 3 of 3 - Acidulation and MONG separation				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS**	**CONTROL MEASURE**	**REMARKS**
Contaminants in processing aids (alkali solution, acids)	C	Low	High	3	Processing aids come into contact with the product. Risk of overdoses	Regulation 68/2013/EU set limits for maximum contents of chemical impurities resulting from manufacturing process or from processing aids EFISC-GTP Code 4.3.6 Processing Aids and Technological Additives EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Processing aids that directly come into contact with the oil must be suitable for use in the food/feed industry. Product specifications. The use of the processing aid evaluated and appropriate measures taken to bring risk to acceptable levels. Inline process monitoring of the usage, correct labelling of the chemical containers	
Contamination with processing aids due to salt recovery process (at Glycerine Neutralisation)	C	Low	Low	1	NaCl (salt) is almost always dissolved in the crude glycerine and not a solid by-product	EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Process control when applied. Periodic monitoring	Possibility of salt recovery for use as a fertilizer

Finished product Free Fatty Acid – correct labelling		Low	High	3	Contaminants might be present in the free fatty acids (FFA)	See EFISC-GTP Code 6.4 Incoming material and feed material specifications EFISC-GTP Code 4.3.4 Measures for the prevention of cross contamination	If free fatty acids are delivered as a by-product, ensure labelling as "nonfeed/nonfood" in order to assure this is not used in feed sector	Free fatty acids containing methyl esters collected after methanol recovery at a biodiesel production, are prohibited for feed purposes

6. Risk based approach for glycerine				7. Glycerine Refinery				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS**	**CONTROL MEASURE**	**REMARKS**
Methanol in refined glycerine	C	Very low	High	2	EU Regulation 68/2013: Minimum glycerine content: 99% dry matter	EFISC-GTP Code 4.4.3 Inspection, sampling and analysis		Methanol is evaporated in the initial drying step
Dioxin, Dioxinlike PCB, Non- dioxine like PCB, PAH, Salmonella, Heavy metals (Pb, Cd, As, Hg), and Pesticides in refined glycerine	C	Very low	High	2	The risk is already low for crude glycerine. Further refining reduces the risk	EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	
PAH	C	Very low	High	2	Does not concentrate in the glycerine but remain in the biodiesel.	EFISC-GTP Code 4.3.2 Incoming materials requirements EFISC-GTP Code 4.4.3 Inspection, sampling and analysis	Monitoring plan Defined monitoring frequency	

6. Risk based approach for glycerine				8. Storage				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS**	**CONTROL MEASURE**	**REMARKS**
Contamination due to lack of segregation	C	Low	High	3		Regulation 852/2004/EC EFISC-GTP Code 4.3.10 Storage 4.3.5 Measures for the prevention of contamination	Storage procedures in place to reduce the risk of cross contamination. Dedicated tanks	
Cross contamination resulting from transfer materials	C	Medium	Medium	3		EFISC-GTP Code 4.3.4 Measures for the prevention of cross contamination	Dedicated circuits and storage tanks. Storage procedure in place	

6. Risk based approach for glycerine				9. Transport of glycerine				
HAZARD	**CAT.**	**CHANCE**	**SERIOUSNESS**	**RISK CLASS.**	**JUSTIFICATION**	**LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS**	**CONTROL MEASURE**	**REMARKS**
Contamination by previous cargo	P/C/B	Low	Medium	2		EFISC-GTP Code 4.3.11 Transport	Control of the three previous cargoes Visual control of the loading compartment	
- Tank cars, rail tanks,barges and ocean vessels	C	Low	High	3	Transport of glycerine based on customer requirements	EC Regulation No. 183/2005/EC setting rules in the transport of feed ingredients EFISC-GTP Code 4.3.11 Transport	Check previous cargoes via IDTF database Transport suitable for feed ingredients as described in the European Code for the industrial manufacturing for safe feed ingredients	Follow instructions in IDTF database
Contamination by cleaning agents	C	Low	High	3		EFISC-GTP Code 4.3.11.3 Transport operation bulk feed ingredient	Cleaning agents used must suitable for use in the food grade/ feed industry, evaluated for potential risks and appropriate measures taken to bring risk to acceptable levels. Check the IDTF database for the relevant cleaning protocol Not a common risk as dedicated transportation containers are in most cases utilized	

Foreign bodies	P	Low	High	3		EFISC-GTP Code 4.2.3.2. Requirements for loading, storage, production areas and other feed ingredient related facilities	Operator should conduct a risk assessment to control foreign bodies. Use of a filter/sieve during loading/unloading.	

7. Minimum Monitoring

EFISC-GTP system participants shall implement a monitoring plan as described in the EFISC-GTP Code §4.4.3.

In case insufficient data is available for a risk assessment the following minimum monitoring requirements shall apply. The minimum number of analysis will depend on the volume of feed materials in tons manufactured in one location as shown in the table below.

Minimum Monitoring plan Glycerine as by-product of the processing of vegetable oil

Table A Glycerine and Crude Glycerine.

Annual production in t Parameter	**≤10,000t**	**> 10,000t - ≤20,000t**	**> 20,000t**
Dioxin	2	4	4
Dioxinlike PCB	2	4	4
Non- dioxine like PCB	2	4	4
PAH	2	4	4
Salmonella	2	3	4
Heavy metals (Pb, Cd, As, Hg	2	3	4
Pesticides	2	2	2
Methanol*	2	3	4

*Examinations of methanol only for crude glycerine