



European Guide to good practice for the industrial manufacture of safe feed materials

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

Version 1.1
Effective from November 2014



Sectors covered by the European Guide

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

Starch Europe	Sector reference document on the manufacturing of safe feed materials from starch processing
FEDIOL	Sector reference document on the manufacturing of safe feed materials from oilseed crushing and vegetable oil refining
EBB	Sector reference document on the manufacturing of safe feed materials from Biodiesel processing

This European Guide is open to other manufacturers producing feed materials 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: ebb@ebb-eu.org
Website: www.ebb-eu.org

EBB
European Biodiesel Board

Information on EFISC

Please contact :

EFISC 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: <mailto:info@efisc.eu>
Website: www.efisc.eu



Publishing and copyright information

All rights reserved ©EFISC Aisbl

Version 1.1

Effective from: November 2014

Within this Biodiesel Sector document animal fats/waste oils production processes and its' derived feed materials 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 Guide to good practice for the industrial manufacture of safe feed materials) 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, a number of co-products 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 materials and to demonstrate their compliance to European health and safety requirements. In particular in the frame of the Feed Hygiene Regulation 183/2005 as well as within the Catalogue of Feed Material (Regulation 68/2013).

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 materials. 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 further detailing of the concept of HACCP and the supporting Prerequisite Programmes as mentioned in chapter 5 and 6 of the accompanying Community Guide.

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

1. Introduction.....	3
2. Listing of feed materials	5
3. Process Description of Biodiesel	7
3.1. Reception of Vegetable Oil	7
3.2. Reaction Stage/ Transesterification:	7
3.3. Separation Stage.....	8
3.4. Acidulation and FFA separation	8
3.5. Glycerin Neutralization	8
3.6. Methyl Ester Wash.....	8
3.7. Storage.....	8
3.8. Transport	8
6. Biodiesel Production Process Flow Chart	9
7. Risk Assessment	10
7.1. EBB made the following incoming materials subject to feed safety chain risk assessment	10
7.2. Summary of the risk-based approach for the biodiesel sector.....	10
7.3. Risk-based approach for the characterisation of hazards applicable to feed materials coming from biodiesel production.....	11
7.4. Procedure of carrying out risk assessment	12
8. Risk based approach for glycerine	13
9. Minimum Monitoring	23

2. Listing of feed materials

The main raw materials processed by the EU Biodiesel industry are 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 materials. The Catalogue includes, for each feed material listed, the name of the product, an identification number, a description of the feed material 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 materials within Reg. 68/2013 (adapted for vegetable origin):

Glycerine, crude	13.8.1	<p>By-product obtained from:</p> <ul style="list-style-type: none"> – 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 origin. Mineral and organic salts might remain in the glycerine (up to 7,5 %). <p>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;</p> <ul style="list-style-type: none"> – saponifications of oils/fats of vegetable origin, normally with alkali/alkaline earths, to obtain soaps. <p>May contain up to 50 ppm Nickel from hydrogenation.</p>
Glycerine	13.8.2	<p>Product obtained from:</p> <ul style="list-style-type: none"> – 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 origin with subsequent refining of the glycerine. Minimum Glycerol content: 99 % of dry matter; – saponifications of oils/fats of vegetable origin, normally with alkali/alkaline earths, to obtain soaps, followed by refining of crude Glycerol and distillation. <p>May contain up to 50 ppm Nickel from hydrogenation.</p>

2.1 Processing aids possibly used during treatment and processing

Water

Aluminium Sulphate

Citric acid

Ferric Chloride

Hydrochloric acid

Potassium hydroxide

Sodium Hydroxide

Sodium Methoxide

Sulphuric acid

Phosphoric acid

Toluene Sulphonic acid

This list is non-exhaustive

3. Process Description of Biodiesel

Biodiesel consists of Fatty Acid Methyl Esters and is produced by the chemical reaction of Oils and Fats with monoalcohols, typically methanol. A catalyst, usually sodium or potassium hydroxide and/or methyllate, 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 partially 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, waxes, tocopherols or colorants, which could impede the biodiesel process reaction.

Most if not all feedstocks 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 partially refined vegetable oils are segregated to pre-processing storage tanks. The safety and quality of the incoming material is assessed.

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.

¹ Fediol Sector Reference Document: appendix 4 to the Community Guide to good practice for the manufacture of safe feed materials:
http://www.efisc.eu/data/1342020514Sector%20document%20oilseed%20and%20proteinmeal%20industry_version-2-2-1_16-02-11%20update%20hyperlinks%209_7.pdf
EFISC Guide- Sector reference document on the manufacturing of safe feed materials from biodiesel processing

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 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 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 50% glycerine, 40% methanol and 10% soap and catalyst. The catalyst is neutralized and soaps are split to 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. In most cases the salt is left in the glycerine. Water and alcohol are removed to produce approx. 80% pure glycerine that is ready to be sold as crude neutralised glycerine.

Refined Glycerine: Crude glycerine in some cases maybe further refined to pharmaceutical or technical grades or feed grades by removing water and salts by distillation.

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, dried, and sent to storage. In some processes this step is unnecessary. In some systems the biodiesel is distilled. This step is optional and increases biodiesel purity.

3.7. Storage

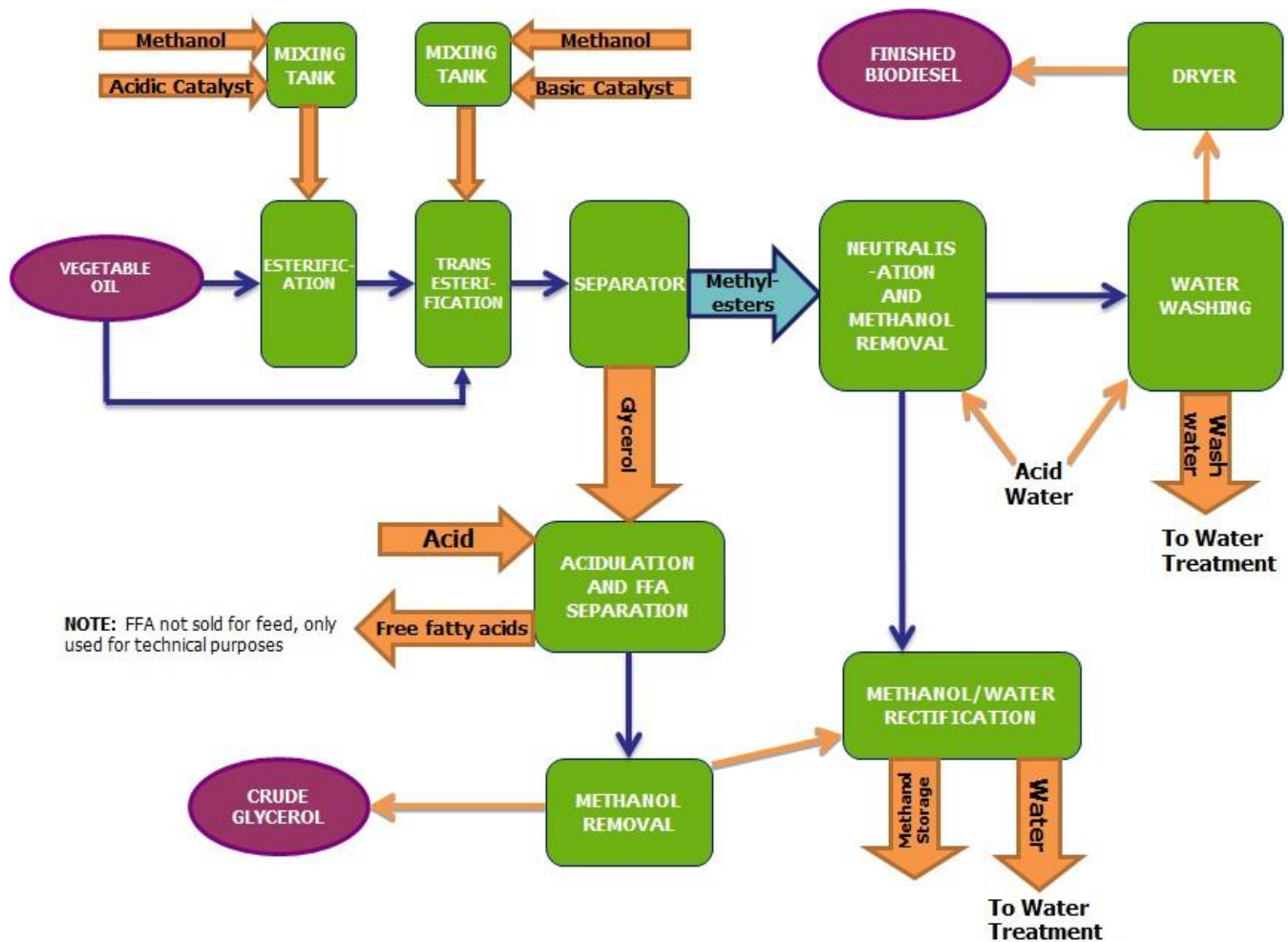
Glycerine is stored in suitable storage tanks.

3.8. Transport

Transportation is required for the processed co-product glycerine. The transportation of the co-product has to be in line with EU and National legalisations, existing transportation codes, customer requirement and the requirements in this code 'Sector reference document on the manufacturing of safe feed materials from biodiesel processing'.

6. Biodiesel Production Process Flow Chart

This chart describes a very general biodiesel process



7. Risk Assessment

7.1. 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 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.

7.2. 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)
- 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 (68/2013/EC).
- The Regulation regards the approval of establishments placing on the market, for feed use, products derived from vegetable oils and blended fates as regards the specific requirements for production, storage, transport and dioxin testing of oils, fats and products derived thereof (225/2012/EC).

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

Biological hazards

- Relevant Vegetative Pathogens according to the GMP feed regulation and associated microbiological criteria.

Potential Chemical hazards

- Process chemicals, processing aids e.g. and antioxidants,
- Mycotoxin
- Heavy metals
- Pesticides residues
- PCB, Dioxins
- Polycyclic aromatic hydrocarbons (PAH)
- Lubricants (non- food grade)
- Pest control chemicals

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 guide.

Physical contamination hazards

- Physical contamination, e.g. metal, glass

Radioactivity hazard

- Radionuclides (after a nuclear accident)

7.3. 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 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.

7.4. Procedure of carrying out risk assessment

EBB followed the methodology as described in the Guide – chapter 6 – HACCP

- 7.4.1. 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 transesterification, washing, further refining of glycerine to end product of biodiesel and crude glycerine feed material, storage and transport
- 7.4.2. 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.
- 7.4.3. 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.
- 7.4.4. 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.

- 7.4.5. EBB justified the risk assessment
- 7.4.6. EBB checked whether EU legislation or trade standards limits for respective standards for the respective hazard, and if so, listed them

8. 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 in the production of biodiesel.	According to Regulation 183/2005/EC water used during the manufacture of feed shall be of suitable quality.	Apply suitable water of drinking quality. Dedicate water circuits	
Cleaning agents	C	Low	Medium	2	Cleaning come into contact with the product.		Cleaning agents used in the production system should be flushed. Cleaning agents used must be evaluated and appropriate measures taken to bring risk to acceptable levels.	Not a common risk as most productions facilities are continuous process
Flying in birds	B	Low	Medium	2				Closed building can prohibit this hazard
Toxins from pest control materials	C	Very low	High	2	Poison bait from open boxes could cause cross contamination		A pest control programme must be applied. Appropriate measures should be taken to minimise risk	
Lubricants	C	Low	High	3			Use of lubricant should be evaluated before use and appropriate measures be taken to bring risk to acceptable levels	Purchasing specifications. Risk is low as oils are checked before use
Insects and rodents	B	Medium	Low	2			Building proofing, cleaning programs and pest control system as part of the pre requisite programme	

Cross contamination due to previous product handled	C/B/ P	Low	High	3	Cross – contamination is low in case the operator has proven that implemented flushing and cleaning procedures are effective		A strict protocol outlined in HACCP plan (i) an acceptable duration of operation on new oils and (ii) audited by a third party must be entered into	Multi-feedstock plant which wishes to operate on fresh oils after a period of processing Category 1 or Category 2 animal fats or used cooking oils from catering waste
--	-----------	-----	------	---	--	--	---	--

8. Risk based approach for glycerine				2. Reception of feedstock 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 usually takes place in dedicated transport vehicles		Risk must be evaluated and appropriate measures must be taken to bring this risk to acceptable levels. Dedicated transport, control of the three previous cargos.	Visual checks
Foreign materials	P	Low	Low	1	Foreign materials may be present.		Dedicated buildings and circuits filters, staff hygiene, glass procedure, good maintenance practices	
Contamination with undesirable substances	C	Low	High	3	In general the contaminants listed below do not concentrate in the glycerine but in the FAME	EU Regulation 32/2002 on undesirable substances on feed materials	Monitoring plan	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		Directive 2002/32/EC and EU regulation	Monitoring plan	EU Regulation of 225/2012 on Dioxins

						225/2012		mentions for certain incoming products the 100 % monitoring on Dioxin
- Nickel	C	Low	High	3		EU Regulation 68/2013 Catalogue of Feed Materials	Monitoring plan	Nickel in most cases not used in biodiesel production
- non Dioxin like PCB's	C	Very Low	High	2		Directive 2002/32/EC on undesirable substances on feed material	Monitoring plan	
- PAH	C	Low	High	3			Monitoring plan	
Pesticide residues above the minimal risk 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 shows that residue levels remain within legal limits.	Regulation 396/2005 sets limits for residues of pesticides. This regulation allows using a transfer factor for authorised pesticides into processed products, providing food safety is assured.	Monitoring plan	Most pesticides are not water soluble and will not move to the glycerine water phase
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 soybean oil, however, is very low. The use of endosulfan is allowed on soybeans. Monitoring data show that its residue in crude oil remains within the legal limit.	Directive 2002/32/EC sets limits for a number of pesticides residues in feeding stuff.	Monitoring plan	Most pesticides are not water soluble and will not move to the glycerine water phase

Microbiological contamination		Low	Medium	2			Monitoring plan	
--------------------------------------	--	-----	--------	---	--	--	-----------------	--

8. Risk based approach for glycerine				3. Storage of the incoming material				
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS	CONTROL MEASURE	REMARKS
Contamination by cleaning agents	C	Low	Medium	3	This risk classification applies to terminals that store both chemicals and vegetable oils. Operators may not be using cleaning agents that are suitable for use in the food industry. For tank terminals in the EU that apply HACCP and that keep the storage of vegetable oils and chemicals separated, the chance of using the wrong cleaning agents is very low.		Cleaning agents used must be evaluated and appropriate measures taken to bring risk to acceptable levels.	
Thermal heating fluids from failing equipment	C	Low	High	3	Toxic thermal heating fluids may still be used. However, due to the relatively low heating temperatures applied during storage, the chance of leakage of thermal heating fluids into the product is low.		Documentation on nett losses and analyse accordingly, if necessary.	The use of water and steam heating is recommended. Thermal heating fluids are not commonly used
Cross contamination	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, spill containment, site security, restricted site access.		Storage procedure in place	

8. 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 Catalogue of Feed Materials	Processing aids that directly come into contact with the oil must be evaluated and appropriate measures taken to bring risk to acceptable levels. Inline process monitoring, correct labelling of the chemical containers	
Contamination caused during addition of Catalyst (Methanol)		Low	Medium	2	Undesirable substances in the Methanol		Apply methanol of suitable quality Described in the contract specification Online 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.

8. 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 68/2003 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	
Methanol in crude glycerine	C	Medium	High	4		EU Regulation 68/2013 mentions: May contain up to 0,5 % methanol	control by process parameters	

8. Risk based approach for glycerine				6. Stage 3 of 3 - Acidulation and FFA 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 set limits for maximum contents of chemical impurities resulting from manufacturing process or from processing aids	Processing aids that directly come into contact with the oil must be must be evaluated and appropriate measures taken to bring risk to acceptable levels. Inline process monitoring (consumption rates)	
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	Low	Low	1	Regular monitoring of pesticide residues shows that residue levels remain within legal limits. Pesticides do not concentrate in the glycerine	Regulation 396/2005 sets limits for residues of pesticides.		
Contamination 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 byproduct			Possibility of salt recovery for use as a fertilizer
Delivery of Fatty Matter – correct labelling		Medium	High	4			If fatty matter is delivered as a byproduct, label fatty matter as “nonfeed/nonfood” in order to assure this is not used in feed sector	Fatty acids with methyl esters (also called fatty matter) collected after methanol recovery at a biodiesel production, are prohibited for feed purposes, since lipophile additives, used in biodiesel production, concentrate in fatty acids.

8. Risk based approach for glycerine				7. 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			Storage procedures in place to reduce the risk of cross contamination. Dedicated tanks	
Contamination by cleaning agents	C	Low	Medium	2	This risk classification applies to terminals that store both chemicals and vegetable oils. They may abstain from using cleaning agents that are suitable for use in the food industry. For tank terminals in the EU that apply HACCP and that keep the storage of vegetable oils and chemicals separated, the chance of using the wrong cleaning agents is very low.		Cleaning agents used must be evaluated and appropriate measures taken to bring risk to acceptable levels	
Thermal heating fluids from failing equipment	C	Low	High	3	Toxic thermal heating fluids may still be used. However, due to the relatively low heating temperatures applied during storage, the chance of leakage of thermal heating fluids into the product is low.		If thermal heating fluids have been used, the storage company must provide for documentation on nett losses and analyse accordingly, if necessary.	The use of water and steam heating is recommended. Thermal heating fluids are not commonly used
Cross contamination	C	Medium	Medium	3			Dedicated circuits and storage tanks. Storage procedure in place	

8. Risk based approach for glycerine				8. 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			Control of the three previous cargoes	
- Tank cars, rail tanks and barges	C	Low	High	3	Transport of glycerine based on customer requirements	EC Regulation No. 183/2005 setting rules in the transport of feed materials	Check previous cargoes via IDTF database Transport suitable for feed materials as described in the European Guide for the industrial manufacturing for safe feed materials	
Contamination by cleaning agents	C	Low	High	3			Cleaning agents used on transportation containers for glycerine should be removed by thorough flushing. Cleaning agents used must be evaluated for potential risks and appropriate measures taken to bring risk to acceptable levels. Not a common risk as dedicated transportation containers are in most cases utilized	
Tank cars	C	Low	Little	1	Stainless steel tanks are used which are heated with cooling water from the motor through a system of double walls (and not coils).			
Foreign bodies	P	Low	High	3			A quality plan should require the loading of tank cars with glycerine under a roof.	
Pest	B	Medium	Medium	3			PRP program for pest control	Check on pest activity

9. Minimum Monitoring

EFISC system participants shall implement a monitoring plan as described in the EFISC 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	<10,000 t	> 10,000t - <20,000t	> 20,000 t
Dioxin	2	4	4
Dioxinlike PCB	2	4	4
Non- dioxine like PCB	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



*EFISC Guide- Sector reference document on the manufacturing of safe feed materials
biodiesel processing*

