

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
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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	
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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