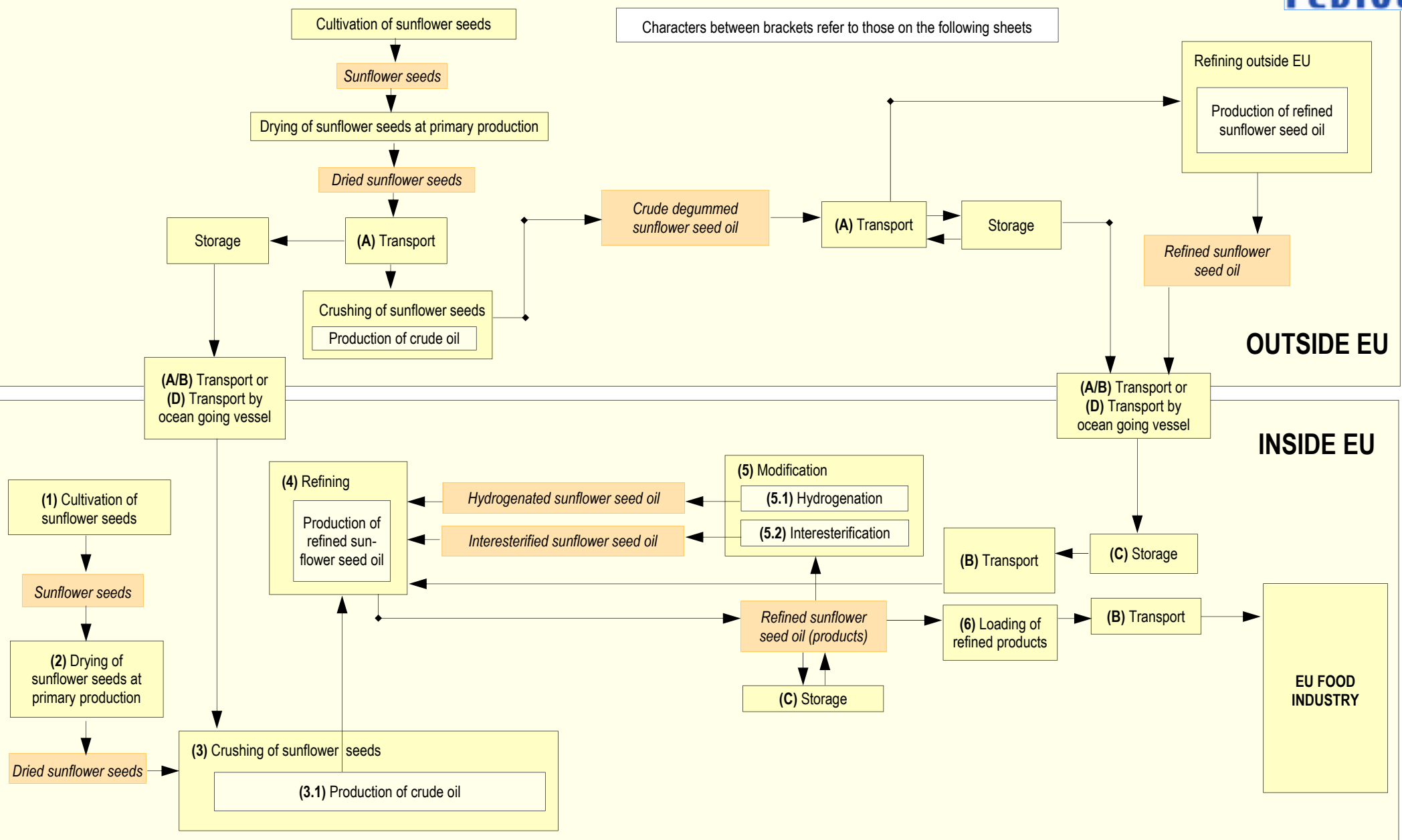


Flow chart of the production chain of sunflower seed products for food application in the EU



Risk assessment of the chain of sunflower oil products

1. Cultivation of sunflower seeds*

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C					Third countries of export of sunflower seeds (Argentina, Hungary, etc) work with positive lists for the use of pesticides during cultivation which, for some substances, may conflict with European pesticide residue legislation. With sunflower seeds, post-harvest use of pesticides appears to be more critical than pre-harvest use of pesticides.	EC Regulation No. 396/2005 prohibits putting into circulation commodities that do not comply with the MRLs set in the annexes. EC Regulation No. 459/2010 amends the annexes II, III and IV listing all pesticide MRLs by products.		

* Assessment of risks in this part of the chain is out of the scope of this document. See the methodology document paragraph 2.3 for more information.

Risk assessment of the chain of sunflower oil products

2. Drying of sunflower seeds at primary production*

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Contaminants caused by drying									
- dioxin	C						Code of Practice for the prevention and reduction of dioxin and dioxin-like PCB contamination in foods and feeds (Codex CAC/RCP 62-2006).		<p>Good Manufacturing Practices recommend using fuels which are not generating dioxins and dioxin-like compounds and other harmful contaminants.</p> <p>In case of direct heating, proper burners should be used. Monitoring is regarded necessary to ensure that drying or heating processes do not result in elevated levels of dioxins and dioxin-like PCBs. No use of waste products as a fuel for direct drying.</p>
- PAHs	C					PAHs may be found in crude sunfloweroil due to bad drying practices.			<p>JECFA (Joint FAO/WHO Expert Committee on Food Additives) recommends replacing direct drying by indirect drying. In case of direct heating, Good Manufacturing Practices recommend not to use waste products as a fuel for direct drying. Temperature and time should be controlled to avoid PAH formation. The equipment has to be kept clean and well maintained.</p> <p>EC Regulation No. 1881/2006 sets a 2.0 µg/kg limit for BaP in oils and fats intended for direct human consumption or use as an ingredient in foods.</p>

* Assessment of risks in this part of the chain is out of the scope of this document. See the methodology document paragraph 2.3 for more information.

Risk assessment of the chain of sunflower oil products

			Utilities: sunflower seeds crushing, oil refining and processing.						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Hydraulic oils or lubricants from equipment	C	low	high	3	PRP	Hydraulic oils and lubricants may contain toxic compounds.		The prerequisite programme should assure that the contamination of product with non-food grade hydraulic oils or lubricants is avoided and that the risk of contamination of the product with food grade hydraulic oils and lubricants is minimised. The prerequisite programme could involve recording of the quantities used.	
Quality of water	C	low	high	3	PRP	Water is used in the crushing and refining process.		Apply water of suitable quality.	
Cleaning agents and boiler chemicals	C	medium	medium	3	PRP	Cleaning agents and steam (using boiler chemicals) come into contact with the product.		Cleaning agents used in the production system should be flushed. Cleaning agents and boiler chemicals must be suitable for use in the food industry.	
Thermal heating fluids (THF) from equipment	C	medium	high	4	CCP	THF may still be used by non-FEDIOL members.	According to the FEDIOL Code of Practice on the Heating of Edible Oils during Processing, the use of THF is not allowed*.	Use hot water or steam heating. Otherwise, a control measure should assure that the contamination of product with thermal heating fluids is avoided.	

Risk assessment of the chain of sunflower oil products

			3. Crushing of sunflower seeds						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Toxins from pest control materials	C	low	high	3	PRP	Poisoned grain from open boxes could end up in the food chain.		A pest control programme must be applied that is suitable for use in the food chain.	
Toxic compounds from hexane	C	low	high	3	PRP	Industrial hexane may contain toxic compounds.	Directive 2009/32 sets purity criteria for the use of hexane during the crush of oilseeds.	Food grade hexane must be used.	
Foreign material like glass, wood, metals, etc.	P	medium	medium	3	PRP	Foreign material may be present		A system should be in place that removes foreign material.	

Risk assessment of the chain of sunflower oil products

			3.1 Production of crude oil						
HAZARD	CAT.	CHANGE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Contaminants from filter aids	C	low	high	3	PRP	The crude oil can potentially wash contaminants out of the filter aid.		Use of filter aids that are suitable for the food industry.	
Mineral oils from a failing recovery system	C	low	high	3	PRP	Mineral oils may contain toxic compounds. It is in the interest of the crusher to recover as much hexane as possible, and to thus maintain the recovery system well.		Mineral oil of the recovery system must be of food grade quality. The prerequisite programme should assure that the contamination of product with non-food grade oils is avoided and that the risk of contamination of the product with food grade oils is minimised. The prerequisite programme could involve recording of the quantities used.	
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	medium	medium	3	PRP	Regular monitoring of pesticide residues on sunflower seeds shows that residue levels remain within legal limits. Asynchronous MRL policies EU versus third countries from which sunflower seeds are imported.	EC Regulation No. 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. EC Regulation No. 459/2010 amends the annexes II, III and IV listing all pesticide MRLs by products. FEDIOL contract for purchasing sun seeds from the Black Sea area (contains a clause on compliance with EU MRL legislation).	Check incoming material (depending on the origin).	

Food



Risk assessment of the chain of sunflower oil products

			4. Refining						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Processing aids	C	medium	medium	3	PRP	Processing aids come into contact with the product.		Processing aids that directly come into contact with the oil must be for food use or of food grade quality.	
Foreign materials like glass, wood, metals, etc.	P	medium	medium	3	PRP	Foreign materials may be present.		Filter before loading	

Risk assessment of the chain of sunflower oil products

4. Refining (continued)

HAZARD	CAT.	CHANGE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Dioxin and dioxin-like PCBs	C	low	high	3	PRP	A potential source of dioxin contamination for oil is drying of sunflower seeds and bleaching earth. Nevertheless, the dosage level of bleaching earth during refining is only 1-3%.	EC Regulation No. 1881/2006, for vegetable fats and oils sets a dioxin limit of 0.75 ng/kg (WHO-PCDD/F-TEQ) and one for the sum of dioxin and dioxin-like PCBs of 1,5 ng/kg (WHO-PCDD/F-PCB-TEQ). FEDIOL has developed a Code of Practice on the purchase conditions of fresh bleaching earth for oil refining, which includes a maximum limit for dioxin and dioxin-like PCBs of 1,5 ng/kg (WHO-PCDD/F-PCB-TEQ) as upperbound value.	Source fresh bleaching earth from suppliers that fulfil the FEDIOL specifications on fresh bleaching earth.	
Pesticide residues above the MRL, i.e. residues of herbicides, insecticides, fungicides or rodenticides above the MRL.	C	low	medium	2		Regular monitoring of pesticide residues on sunflower seeds shows that residue levels remain within legal limits.	EC Regulation No. 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. EC Regulation No. 459/2010 amends the annexes II, III and IV listing the MRL for pesticides.		
Microbiological contamination	B	low	medium	2		Moisture content (i.e. water activity) in refined oils is too low for bacteria to grow.			
Adventitious presence of allergens (from lecithin, peanuts, nuts, sesame seeds and products thereof)	C	low	high	3	PRP	Potential cross contamination. Allergic reactions may occur at very low levels.	Directive 2000/13/EC as amended by Directive 2003/89/EC requires the mandatory labelling of ingredients known to trigger allergies or intolerances. FEDIOL Code of Practice on the production and labelling of certain oils in connection with allergy.	Prerequisite programme to prevent cross contamination.	

Risk assessment of the chain of sunflower oil products

PAHs	C	medium	high	4	CCP	BaP may be found in crude sunflower seed oil due to bad drying practices. BaP is an indicator for PAHs.	EC Regulation No. 1881/2006 sets a 2.0 µg/kg limit for BaP in oils and fats intended for direct human consumption or use as an ingredient in foods.	Use of active carbon to verify compliance with EU legislation.	Occurrence depends on origin of seeds.
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Risk assessment of the chain of sunflower oil products

			5. Modification (general)						
HAZARD	CAT.	CHANGE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Foreign materials	P	medium	medium	3	PRP	Foreign materials may be present.		Filter before loading.	
Processing aids	C	medium	medium	3	PRP	Processing aids come into contact with the product.		Processing aids that directly come into contact with the oil must be for food use or of food grade quality.	

Risk assessment of the chain of sunflower oil products

			5.1 Hydrogenation						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Contamination with high nickel levels	C	medium	medium	3	PRP	Nickel used as a catalyst may be incompletely removed after filtration.		Proper post-refining or post-bleaching.	

Risk assessment of the chain of sunflower oil products

			5.2 Interesterification						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
No hazards in addition to those listed under 5. Modification (general)									

Risk assessment of the chain of sunflower oil products

6. Loading of refined products

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Foreign matter	P	low	high	3	PRP	Foreign bodies may be present.	FEDIOL Code of working practice for bulk road and tank container transport of fats and oils for direct food use	Filter before loading. A quality plan should require the loading of tank cars with refined oils under a roof.	
Microbiological contamination	B	low	medium	2		Moisture content (i.e. water activity) in refined oils is too low for bacteria to grow.			
Misuse of additives	C	low	medium	2		Misuse or overdosing of additives may occur.	Directive 89/107/EEC.		
Adventitious presence of allergens (from lecithin, peanuts, nuts, sesame seeds and products thereof)	C	low	high	3	PRP	Potential cross contamination. Allergic reactions may occur at very low levels.	Directive 2000/13/EC as amended by Directive 2003/89/EC requires the mandatory labelling of ingredients known to trigger allergies or intolerances. FEDIOL Code of Practice on the Production and Labelling of certain oils in connection with allergy.	Prerequisite programme to prevent cross contamination.	

Risk assessment of the chain of sunflower oil products

			A. Transport outside EU*						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Microorganisms	B					Due to residual water in a tank.			
Contamination by previous cargo	C					Tank cars and barges may have been used for non-food grade approved products such as petrochemicals.			Tank cars and barges that are not dedicated to the transport of foodstuff should have undergone a proper cleaning procedure.
Contamination by cleaning agents	C					<p>Increased risk at cleaning stations that clean both food and chemical tanks at one site.</p> <p>In third countries few cleaning stations exist. However, those that exist may have limited facilities and may also be used for cleaning non-food tank cars. Used cleaning water may be re-used.</p>			Cleaning agents must be suitable for use in the food industry.
Heating or cooling fluids from equipment									
- Tank cars	C					The tanks are heated with cooling water from the motor through a system of double walls (and not internal coils).			Use of tank cars that use coils for heat transfer should be banned. Instead tanks that are equipped with double walls have to be used.
- Barges	C					Toxic thermal heating fluids may still be used. However, due to the relatively low heating temperatures applied during transport, the chance of leakage of thermal heating fluids into the product is low.			If thermal heating fluids have been used, the transporter of the oil must provide for documentation on possible net losses and analyse accordingly if necessary. The use of hot water or steam heating is recommended.
Adulteration	C/P/B					Adulteration can cause harm.	EU Regulation No. 1151/2009 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil. Sets a maximum limit of 50 ppb (external mineral oil). FEDIOL Code of Practice on Sampling		Proper sealing system should be applied.

Risk assessment of the chain of sunflower oil products

							and Analysis on sunflower seed oil from Ukraine. FEDIOL Code of Practice on Sampling and Analysis of all imported crude vegetable oils in bulk by ship into the EU		
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* Assessment of risks in this part of the chain is out of the scope of this document. See the methodology document paragraph 2.3 for more information.

Risk assessment of the chain of sunflower oil products

B. Transport inside EU

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Microorganisms	B	Low	high	3	PRP	Residual water in a tank can make microorganisms grow.		Control drying process after cleaning.	
Contamination by previous cargo									
Tank cars, rail tanks and barges	C	low	high	3	PRP	Transport of oils is foodstuff dedicated	EC Regulation No. 852/2004 implies the transport of liquid food stuffs by tank cars, rail tanks and barges to be dedicated. FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	Check previous cargoes via FEDIOL practical guide to previous cargo(es) for means of transport and tank lining.	
Tank coasters	C	low	high	3	PRP	Tank coasters carrying oils and fats during short sea voyages in the EU must have as an absolute minimum as the immediate previous cargoes a product that is either a foodstuff or a product appearing on the EU list of accepted immediate cargoes of Directive 96/3/EC.	FEDIOL Code of Practice for the transport in bulk of oils and fats into or within the European Union.	Check previous cargoes via FEDIOL practical guide to previous cargo(es) for means of transport and tank lining.	
Contamination by cleaning agents									
Tank cars, rail tanks and barges	C	medium	medium	3	PRP	Increased risk at cleaning stations that clean both food and chemical tanks on one site	FEDIOL Code of Practice for the transport in bulk of oils and fats into or within the European Union. FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	Include safeguards to preclude contamination of the food grade cargo tanks and equipment by steam, water and cleaning agents used in the cleaning of non-food grade cargo tanks.	FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use includes good practices for cleaning of tanks.
Tank coasters	C	medium	medium	3	PRP	Increased risk in case coaster is not dedicated to food stuff.		Selected cleaning stations must have an implemented HACCP-system. Demand a signed cleaning certificate before loading.	

Risk assessment of the chain of sunflower oil products

B. Transport inside EU (continued)

HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Heating or cooling fluids from failing equipment									
Tank cars	C	low	high	3	PRP	Stainless steel tanks are used which are heated with cooling water from the motor through a system of double walls (and not coils).	FEDIOL Code of Practice for the transport in bulk of oils and fats into or within the European Union.		
Rail tanks, tank barges and coasters	C	low	high	3	PRP	Toxic thermal heating fluids may still be used. However, due to the relatively low heating temperatures applied during transport, the chance of leakage of thermal heating fluids into the product is low.	FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	Heating coils of rail tanks must be of stainless steel (FEDIOL). If thermal heating fluids have been used, the transporter of the oil must provide for documentation on possible nett losses and analyse accordingly if necessary.	
Foreign bodies	P	low	high	3	PRP		FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	A quality plan should require the loading of tank cars with refined oils under a roof.	FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use includes good practices for loading and unloading.
Adulteration	C/P/B	low	high	3	PRP	Adulteration can cause harm.	FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	Application of minimum mandatory requirements in FEDIOL code of working practice for bulk road and tank container transport of fats and oils for direct food use.	Sealing of tanks where possible.

Risk assessment of the chain of sunflower oil products

			C. Storage						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Contamination due to lack of segregation (contamination from previous cargoes, use of incorrect joinings, shared equipment)	C	low	high	3	PRP	This risk classification applies to terminals that store both chemicals and vegetable oils. Less risk is involved when the tank terminal applies the EU list of acceptable previous cargoes during sea transport to the storage of vegetable oils. Least risk is involved when the vegetable oils are stored in tanks that are dedicated to the storage of foodstuffs.	Terminals in the EU that store oils and fats for food application are obliged to apply HACCP (EC Regulation No. 852/2004)	Food or feed dedication of storage tanks. Otherwise, storage tanks must at least adhere to the EU rules on previous cargoes that have been set up for sea transport in Directive 96/3/EC.	
Contamination by cleaning agents	C	low	high	3	PRP	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 must be suitable for use in the food industry.	
Solvent from coating	C	low	high	3	PRP	Solvents from virgin coatings migrating to the oil, which may end up in the fatty acid distillates during refining		Use stainless steel tanks or in case of use of tanks with virgin coating, do not feed the FAD	
Thermal heating fluids from failing equipment	C	low	high	3	PRP	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 net losses and analyse accordingly, if necessary.	The use of water and steam heating is recommended.

Risk assessment of the chain of sunflower oil products

			D. Transport by ocean going vessel						
HAZARD	CAT.	CHANCE	SERIOUSNESS	RISK CLASS.	PRP or CCP	JUSTIFICATION	LEGISLATION, INDUSTRY STANDARDS AND/OR CONTRACT TERMS	CONTROL MEASURE	REMARKS
Transport contamination - Contamination by previous cargoes present in tanks or pipes	C	medium	medium	3	PRP	Ocean going vessels carrying oils and fats for edible use into the EU must have as an absolute minimum that the immediate previous cargoes is a product that is either a foodstuff or a product appearing on the EU list of accepted immediate cargoes of Directive 96/3/EC.	Directive 96/3/EC (Derogation to EC Regulation No. 852/2004) requires that previous loads have to be checked. FOSFA contracts oblige the seller to inform the buyer what the three preceding cargoes have been during the sea transport of oils and fats. FEDIOL Code of Practice for the transport in bulk of oils and fats into or within the European Union.	Before loading, FOSFA recognised superintendents need to check whether tanks are sufficiently cleaned. Before unloading, FOSFA recognised superintendents need to check the ship's logbook on compliance with previous cargo lists. The use of dedicated pipe lines at loading and unloading.	
- Contamination by cleaning agents	C	low	high	3	PRP	Usually maritime business sticks to good practice.		Check ship log-book.	
Solvent from coating	C	low	high	3	PRP	Solvents from virgin coatings migrating to the oil, which may end up in the fatty acid distillates during refining		Use stainless steel tanks or in case of use of tanks with virgin coating, do not feed the FAD	
Thermal heating fluids (THF) from equipment	C	low	high	3	PRP	Toxic thermal heating fluids may still be used. However, due to the relatively low heating temperatures applied during transport, the chance of leakage of thermal heating fluids into the product is low.		If thermal heating fluids have been used, the transporter of the oil must provide for documentation on possible net losses and analyse accordingly if necessary.	The use of water and steam heating is recommended.
Hydraulic oils from portable pumps	C	low	high	3	PRP	Hydraulic oils from portable pumps may be toxic.		The use of portable pumps with clear separation of hydraulic motor from pump. If not, hydraulic oils of food grade quality must be used.	Hydraulic motors that are directly linked to the pump allow for unwanted leakages of hydraulic oil into the vegetable oil in case of seal failure.