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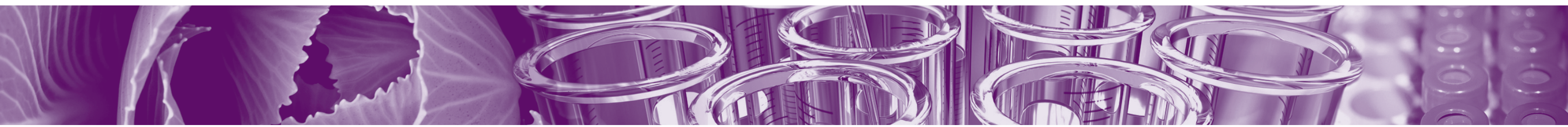

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Summary

Dioxins are chemical compounds that can have toxic effects on humans and animals. In the latest incident, elevated dioxin levels were found in feed in Germany due to the use of technical fats in feed. As a result of this incident, DG SANCO prepared a working document on the monitoring of fats and oils in the feed industry. In most cases, a 100% monitoring of incoming batches is proposed with a maximum batch size of 200 or 1000 tons. The aim of the present project was to determine the most critical steps in the production of fats and oils. First, production processes of vegetable oils, animal fat, fish oil, biodiesel and fat blending were studied and experts from the industry as well as in-house dioxin experts were consulted to identify the most critical steps. Then, monitoring data for vegetable oil, animal fat and fish oil were analysed to determine which products have an increased risk of dioxin contamination.

Vegetable oil production does not result in contamination of dioxins. However, some raw materials, such as bleaching earth, may contain dioxins and should thus be monitored. Drying of oil seeds on open fires using waste material is a risk factor as this may result in dioxin formation. As transport and storage outside the EU may be less well organized, cross-contamination of crude oils in batches from outside the EU can be seen as a risk factor as well. Monitoring data on crude vegetable oils, however, did not show a difference between various crude vegetable oils, except for crude coconut oil. The latter, therefore, should be monitored more frequently than palm, soy, rape and sunflower oil.

Due to the processing of vegetable oils, a concentration of dioxins in some by-products may occur. During chemical refining, concentration of dioxins of up to 300 times may occur in the distillate. Distillates from this production process should, therefore, be used for technical purposes or should be processed further to remove dioxins present. Physical refining is accompanied with a lower concentrating factor between 20-100 times and the fatty acid distillates obtained from crude oils other than coconut oil can be used in animal feed provided that monitoring is applied.

The processing of animal fats normally does not result in increased dioxin levels. Risk for dioxin contamination may occur when contaminated ingredients are used, as was the case in a Belgian incident with contaminated hydrochloric acid (HCl). Random sampling of animal fats is advised as an indicator for Good Manufacturing Practices.

As fish, as a raw material, may contain high levels of dioxins, all incoming batches of crude fish oils should be monitored.

First generation biodiesel produced from crude vegetable oils is subject to the same risk factors as indicated above. Distillates obtained from second generation biodiesel (using waste materials such as cooking oils) should be used for technical purposes only.

Technical fats should be clearly segregated from feed fats using a proper labelling and documentation system, especially when factories produce both fats for feed and technical fats. A Code of Practice should be used for this purpose. Additionally, an indicator, such as glycerol triheptanoate (GTH) may be added to technical fats in order to prevent adulteration

Contents

1 Introduction

Dioxins are environmental pollutants produced by natural and industrial processes. Dioxins and dioxin-like compounds have toxic effects on human and animal health. A number of dioxin-related incidents has occurred over the years with feed ingredients as the main source (see Table 1). Incidents can roughly be categorized as resulting from 1) inadequate drying processes, 2) use of (naturally) contaminated materials, 3) use of wood contaminated with chlorophenols, 4) use of contaminated minerals. This shows that there are many potential sources for dioxin contamination.

Table 1. Overview of dioxin incidents with feed in the last 15 years.

Year	Country	Source
1996	USA	Ball clay in feed for poultry and catfish
1998	The Netherlands, Germany	Contaminated citrus pulp for ruminant feed due to use of contaminated lime
1999	Belgium	Animal feed contaminated with polychlorinated biphenyl oil
1999	Austria, The Netherlands	Use of kaolinic clay in vitamin mixes
2000	Spain	Use of choline chloride mixed with sawdust containing pentachlorophenol
2003	Germany, The Netherlands	Bakery waste dried on open fire of waste wood
2004	The Netherlands	Potato peels contaminated with dioxin containing kaolinic clay
2006	Belgium, The Netherlands	Fat from gelatine production due to contaminated hydrochloric acid
2008	Chile	Use of recycled zinc in pork feed
2008	Ireland	Bakery waste dried on open fire with diesel containing PCB-oil
2009	The Netherlands, Germany	Contaminated corn from the Ukraine, source unknown
2010	Germany	Use of contaminated technical fat from biodiesel production in animal feed

Previous incidents have resulted in strict regulation within the European Union (Lascano Alcoser et al., in press). Two types of legislation can be distinguished in relation to feed (and food) and dioxins: general hygiene legislation and legislation on dioxin contamination.

General hygiene legislation is based on the General Food Law (Regulation EC/178/2002) and is elaborated in the hygiene regulations for food producers (Regulation EC/852/2004), producers of food of animal origin (Regulation EC/853/2002) and for feed producers (Regulation EC/183/2005) (EU, 2002b, 2004a, b, 2005).

Legislation on dioxin contaminants is laid down in maximum levels (EC/2002/32 for Feed, EC/1881/2006 for Food) and methods of sampling and analysis (EC/152/2009 for Feed, EC/1883/2006 for Food) (EU, 2002a, 2006b, c, 2009a). For food, Commission Recommendation (EC/2006/88) has been formulated, which sets action levels for dioxin and dioxin-like PCBs (EU, 2006d). Action levels for feed were incorporated in 2006 into the EC/2002/32 (EU, 2002a, 2006a).

The general hygiene regulations state that the producer is responsible for the safety of the product he puts on the market. The major difference between feed and food producers is that food producers need to be registered, whereas feed producers have to be approved by the national authority. In general, approval means a stricter supervision by the national authority compared to registration. A specific category of raw materials used for feed production are the animal by-products, which are regulated by Regulation EC/1069/2009 (EU, 2009c). Establishments working under this regulation also have to be approved by the national authority.

When food or feed ingredients exceed the maximum levels, they are banned from the use in food and/or feed. Exceeding the action level has the consequence that the producer has to identify sources and pathways of contamination and take measures to eliminate them. Table 2 gives the maximum and action levels for dioxins and dioxin-like polychlorinated biphenyls (dl-PCBs) for food and feed. For comparison, only mixed fats for food are included, although EC/1881/2006 differentiates in dioxin limits between fat from sheep and bovine animals, pigs and poultry. The Table shows that the maximum levels of dioxins and the sum of dioxins and dl-PCBs for vegetable oils and animal fats are the same for food and feed. For fish oil, the levels for food are lower than for feed.

Table 2. Dioxin and dioxin-like PCB limits in oils and fat for food and feed (Directive 2002/32/EC and Regulation EC/1881/2006,(EU, 2002a, 2006b))[a].

	Maximum levels				Action levels			
	Feed		Food		Feed		Food	
	Dioxins	Dioxins and dl-PCBs	Dioxins	Dioxins and dl- PCBs	Dioxins	dl-PCBs	Dioxins	dl-PCBs
Vegetable oil	0.75	1.5	0.75	1.5	0.5	0.5	0.5	0.5
Animal fat (mixed)	2.0	3.0	2.0	3.0	1.0	0.75	1.5	0.75
Fish oil	6.0	24.0	2.0	10.0	5.0	14.0	1.5	6.0

[a] *Maximum content expressed in WHO-TEQ ng/kg relative to a feeding stuff with a moisture content of 12%.*

Exceedances of the legal limits are reported in the RASFF database in case other member states are involved. This database shows that from 1999 to April 2011 106 alerts were issued on dioxins in food and feed. Around 30% of these alerts were related to fats and oils indicating that the majority of alerts were caused by products other than fats and oils. Fish oil was the most frequently reported oil in the RASFF database (24 alerts, mainly cod liver oil); 6 alerts were reported for products of vegetable oils (mainly fatty acid distillates derived from palm oil) and only 1 alert was reported on animal fats. Based on these results, fish oil is the most critical product (77% of alerts on dioxins in oil), followed, to a minor extent, by fatty acid distillates from vegetable oils.

In the latest dioxin incident, the use of contaminated fat resulted in increased dioxin levels in feed. As a result of this, DG SANCO compiled a working document on the monitoring of oils and fat for the feed industry. It lays down monitoring plans for producers of vegetable oils, animal fats, fish oils, oils from biodiesel, fat blends and compound feed. This working document proposes, in most cases, a 100% monitoring of batches of by-products of oils and fats used in the feed industry. Depending on the origin of the oil, the working document maximizes batches at 200 or 1000 tons.

A batch is defined as an identifiable quantity of feed determined to have common characteristics, such as origin, variety, type of packaging, packer, consignor or labelling, and, in the case of a production process, a unit of production from a single plant using uniform production parameters or a number of such units, when produced in continuous order and stored together (EC/767/2009) (EU, 2009b).

The aim of this study was to identify critical steps and products in the production of fats and oils. For this purpose, the various production processes were studied and dioxin monitoring data analysed. The underlying aim was to come to a more risk based proposal for monitoring.

2 Material en methods

A risk based approach was followed applying Hazard Analysis Critical Control Points (HACCP) principles in two steps. First, the various oil production processes were studied to identify critical process steps. Based on available information on production processes and expert opinions, possible risk factors were identified for the categories as mentioned in the DG SANCO working document: vegetable oil refining, animal fat production, fish oil production, biodiesel industry, fat blenders and the compound feed industry. Then, statistical analyses was applied on monitoring data in order to determine the percentage exceeding the action and maximum limits. Based on the risk evaluation in the first step and the statistical analysis in the second step, products were derived that are critical for dioxin levels and need a higher frequency of sampling.

2.1 Identification of critical processes and process steps

2.1.1 Data gathering

Process schemes of the various oil and fat production systems were gathered from the Dutch oil and fat industry, the European Fat Processors and Renders Association (EFPRA), the Product Board for Margarine, Fats and Oils (MVO) and the EU Oil and Protein meal Industry (FEDIOL) together with available risk assessments. For vegetable oil, we focused on those vegetable oils that are produced in largest quantities worldwide: soybean oil, palm oil, rapeseed oil and sunflower oil. Coconut oil was also studied as this was explicitly mentioned in the DG SANCO Working Document. For animal fats, the processes of pig, poultry, ruminant fats as well as poultry and pig gelatine were studied.

Data on production volumes and dioxin monitoring results were obtained from the Dutch industry as well as from the Dutch Food and Consumer Product Safety Authority (VWA) and a Dutch monitoring plan. These data, therefore, are specific for the Netherlands.

2.1.2 Expert consultation

Experts from the Dutch oil and fat industry were consulted for clarification of process schemes and risk assessments. In total 16 experts representing the major processing companies in the Netherlands were consulted, including 8 experts from the vegetable oil industry, 3 experts from the animal fat industry, 1 expert from the fish oil industry, 2 experts from the fat blending industry and 2 experts from the compound feed industry. Apart from industrial experts, two scientific experts from RIKILT were consulted regarding potential sources of dioxins and critical points in the production process.

2.2 Statistical analysis on monitoring data

Data were obtained from industry and from samples analysed by RIKILT. The latter samples either originate from monitoring by the VWA or from a monitoring programme on animal derived products of the Dutch Ministry of Economic Affairs, Agriculture and Innovation (EL&I). As dioxins and dl-PCBs usually are present in low concentrations, an asymmetric distribution is expected. Therefore, all data were log-transformed (using natural logarithms) in order to obtain a normal distribution. The average of the lognormal distribution can be back-transformed to obtain the median of the distribution. The median indicates that 50% of the samples are above and 50% below this value. Using the lognormal distributions of the data, the percentage exceeding the action and maximum limits, as indicated in Table 2, can be estimated.

Depending on the dataset either dioxins or the sum of dioxins and dl-PCBs were used for the statistical analyses. The RIKILT dataset contained both dioxins and the sum of dioxins and dl-PCBs, whereas the data from the vegetable oil industry contained only measurements on dioxins, the data from the animal fat industry contained only measurements on the sum of dioxins and dl-PCBs and the data from the fish oil industry contained both dioxins and dl-PCBs. In case values were indicated as being below the limit of detection (LOD), upper bound values were used as a worst case estimate.

The RIKILT dataset consisted of qualitative as well as quantitative data for 2005-2011: vegetable oils (n= 157), animal fats (n = 194) and fish oil (n= 55). The chemical analysis of the RIKILT samples is performed with two methods. First, a CALUX method is applied in order to determine whether dioxins and dl-PCBs are present above a certain decision limit, in most cases the action limit for dioxins. Once a sample is suspected, the GC/HRMS method is applied in order to confirm and quantify the dioxins and dl-PCBs present. Only these quantitative numbers were used to derive lognormal distributions, which thus results in a worst case approach. In case "oil" was mentioned in this dataset, we assumed this was crude oil.

Data obtained from the vegetable oil industry were obtained for 2005-2011. Two sets of data were obtained: a set of average values (Average) and standard deviations (Stdev) and a set with individual data. Based on the first dataset, average values (LnAverage) and standard deviations (LnStdev) of lognormal distributions could be derived using the following equations:

$LnAverage = Ln(Average)-0.5Ln(1+(Stdev/Average)^2)$

$LnStdev = Sqrt(Ln(1+(Stdev/Average)^2)$, where Sqrt is the square root

Data available were based on 276 samples of crude vegetable oils, 176 samples of refined oils and 476 samples of fatty acid distillates. The second dataset contained individual data on crude vegetable oils (n=85) and fatty acid distillates (n = 35). Lognormal distributions could be derived from these individual data.

Data on animal fat were obtained from various companies and contained individual sample results on the sum of dioxins and dl-PCBs that were log-transformed in order to obtain lognormal distributions. Data were available for the year 2010 and consisted of data on pork (n = 146), poultry (n = 168) and mixed fat (n = 82).

Data of individual samples of fish oil were obtained from January 2010 until April 2011 (n = 21) and contained either unknown fish species or salmon fish oil.

Analysis of variance was performed to determine significant differences between different fat types (e.g. comparing pork, beef, poultry and mixed fat). For this purpose, a significance level of 0.05 was used. Statistical analyses were performed using Genstat for Windows 13th edition (VSN International, 2010).

3 Results

3.1 General

Dioxins can be present in fats and oils due to various contamination routes. They may have an environmental origin and from that source be incorporated into the raw materials for fat, as is the case in fish, in grazing animals and free ranging poultry. Dioxins may also be present in ingredients used in the production process, as was the case in contaminated clay used in animal feed (see Table 1). Apart from the presence of dioxins in ingredients and raw materials due to environmental contamination, they may also be formed during the production process. In that case chloride and aromats are needed in combination with moderate temperatures (200-700 °C). These circumstances may occur, for instance, when waste materials, like preserved or painted wood, are used as fuel for open fires. Apart from natural presence or industrial formation of dioxins, the contaminants may also end up in fats and oils due to cross-contamination or adulteration. The following sections describe possible risk factors for the presence of dioxins in vegetable oil production, animal fat production, fish oil production, biodiesel production, fat blending and compound feed production.

3.2 Vegetable oil production

Production of vegetable oils consists of crushing resulting in crude vegetable oils and refining resulting in refined oil (see Annex I). Mainly crude oils are used for feed production, but in some cases refined oils are used as raw material as well. Table 3 indicates the production of vegetable oils combined with import and export data and use within the Netherlands (total use and use in feed) for the year 2008.

Table 3. Production of vegetable oils and use in feed within the Netherlands in 2008 (x 1000 ton) (FEDIOL, 2008).

	Production	Import	Export	Total use	Use in feed[a]
Palm oil	0	2152	1543	609	92
Palm kernel oil	0	152	50	102	14
Soya oil	572	223	633	162	41
Coconut oil	0	347	195	152	25
Rapeseed oil	336	361	668	29	4
Sunflower oil	127	473	547	53	1

[a] *Data from MVO, 2011.*

Table 4 presents the amount of beans and seeds used within the Netherlands to produce crude oils, the amount of refined oils produced from (imported) crude oils together with the amount of by-products produced on a daily basis.

Table 4. Raw materials processed and production data for the main vegetable oils in the Netherlands in tons/day in 2010 (MVO, 2011).

Raw material	Seeds/beans processed	Crude oil	Refined oil	By-products[a]
Palm	0	0	4700	235
Coconut	0	0	950	48
Soya	6500	1260	1000	38
Rapeseed	34000	1400	830	42
Sunflower	1300	580	620	18

[a] By-products from chemical refining are mainly fatty acids, for physical refining mainly fatty acid distillates (FAD).

Crude palm and coconut oil are mainly produced in the countries of origin. For soy, rapeseed and sunflower either the seeds/beans or the crude oil is imported. As indicated above, drying of seeds on open fires using waste material can result in dioxin formation. This step in the production of crude vegetable oils can, therefore, be seen as a critical step. However, drying of beans and seeds mainly occurs using indirect heating methods, meaning that there is no contact between the product and the fumes from the fire. Palm kernels are mainly dried using heated steam (80-90 °C). Heating of oils using coils with thermal heating oils (THO) is banned within the EU. Several incidents have occurred in the past where the THO, which often contain PCBs, leaked into the consumption oil. Outside the EU, older and smaller factories may still use heating equipment with coils and THO. In case this equipment is used for heating, companies within the Netherlands have the policy to test the oil produced and apply positive release (meaning that the oil is only distributed when monitoring shows that dioxin levels are below the legal maximum limits). Primary production and processing of palm oil is performed on an industrial scale. This is in contrast to the production of coconut oil, where coconuts are dried on a local scale by individual farmers. These farmers use open fires and may burn waste material, which in some cases may result in the formation of dioxins. These conditions can be considered as potentially dioxin increasing activities.

In the refining process, bleaching earth is used to reduce the levels of pigments in the oil. This bleaching earth is recognised as a possible route of dioxin contamination. Therefore, Fediol has developed a code of practice on the purchase of bleaching earths including a maximum limit of dioxins and dl-PCBs of 1.5 ng WHO-PCDD/F-PCB-TEQ/kg (FEDIOL, 2011a). The presence of dioxins is dependent on the geographic origin. Therefore, suppliers of bleaching earth take samples from the mine that is used for producing bleaching earth. At the exploration phase, a dioxin profile of the mine is determined based on drilling samples at various heights. Based on this information, the mine is taken into production and weekly samples are taken and mixed to an aggregate sample every 3 months. The HACCP principle is applied in this case, meaning that monitoring occurs based on the dioxin levels as established in the exploration phase. When both the fresh bleaching earth and the crude oil used in the production process are free of dioxins, the used bleaching earth is reused within the crushing process.

Apart from production during drying and contamination via ingredients, dioxins may end up in the production process due to cross-contamination during transport and storage. For sea ships this is prevented by applying Fediol codes of practice (FEDIOL, 2007, 2011b), FOSFA rules (FOSFA, 2008) and EU Directive 96/3/EC. Documents on previous cargoes are checked upon arrival by independent surveyors. For road transport within the EU, dedicated trucks are used applying GMP+ (GMP+ International, 2010). Before loading, trucks are cleaned and a cleaning certificate is issued as proof. Transport in countries outside the EU can also be according to Codes of Practice. For example, in Malaysia, the Malaysian Palm Oil Board Codes of Practice are used for transport of oils. These codes imply that lorry tankers intended for carrying palm(kernel) oil products should not be used for carrying mineral oil or petroleum products. Lorry tankers are to be inspected before loading and representative samples should be taken and tested as per contract. In order to prevent adulteration, all access points of the lorry tanker should be closed with security seals after loading of crude palm oil.

Apart from introduction of dioxins in the production process as described above, concentration of dioxins in the production process may occur. There are two types of refining: chemical and physical. Tropical oils are mainly refined using physical refining, whereas soy, rapeseed and sunflower oil are mainly produced using chemical refining. Both chemical and physical refining contain a distillation step during which short chain molecules, like fatty acids (FA) and dioxins, are removed first and end up in the distillate. This causes a concentration of 20-100 times for physical refining and up to 300 times for chemical refining. Chemical refining contains a neutralization step prior to distillation. In this step, the oil is treated with an alkali solution (caustic soda) that reacts with the free FA and converts them into salts of fatty acids. During subsequent distillation, the FA are already removed, so mainly the dioxins end up in the distillate, which causes a higher concentration factor as compared to physical refining. The remaining refined oil can be regarded as free of dioxins. Fediol members designate non-processed chemical distillate for technical purposes, whereas physical FA distillate can be used for feed. Chemical distillates may be processed (e.g. using active carbon treatment) in order to remove dioxins present. These processed chemical distillates are always monitored prior to use in food or feed. When physical refining contains a pre-stripping step, steam distillation is used in order to strip the oil from volatile compounds, such as FA, that are sold as a by-product to feed. The by-product of the consecutive distillation step is reported to be sold for technical application, comparable to chemical distillate.

In the Netherlands, the major vegetable oil producers currently focus their monitoring on the raw materials. Every quarter, Fediol members analyse on dioxin per type of bean/seeds or crude oil by independent surveyors. These surveyors also take several samples according to the FOSFA method (FOSFA, 2010). A ship in this case is seen as a batch, containing between 30,000 and 75,000 tons. Crude palm oil (CPO) is also monitored 4 times a year on incoming vessels (capacity ranging between 45,000-75,000 tons). Vessels have different compartments and can be loaded at various harbours (so origins may differ on 1 vessel). Tanks are monitored pre-shipment and samples are sent in for analyses. When samples are cleared, the oil can be loaded on board. Upon arrival, independent surveyors take samples from the vessel according to SOPs. Apart from the raw materials, every batch of fatty acid distillates from physical refining is currently monitored (FEDIOL, 2011c), as dioxins may concentrate in this by-product. Small refineries that refine oil commissioned by customers usually do not monitor the incoming crude oils. Monitoring only occurs when the customer specifies this and is usually done on oils that come from suspicious origins (based on historical data). These refineries usually refine smaller quantities in a variety of products, such as walnut oil or cocoa butter. The distillates (either chemical or physical) that are derived from these smaller factories are all reported to be used for technical applications only.

3.3 Animal fat production

In contrast to vegetable oils, the production and trade of animal fats can be considered as a regional activity, i.e. within Europe and frequently within one (member) state. This is both related to the type of production of animal products (slaughterhouse and cutting/deboning operations) and to the transport costs. Production data for the Netherlands are indicated in Table 5. Around 75% of animal fats are used in feed, 8% is destined for food and 18% for technical purposes.

Table 5. Production data (estimation based on Dutch industry (MVO, 2011)).

	2006	2007	2008	2009	2010
Animal fat production in the Netherlands (1000ton/yr.)	148	163	172	181	183

Production of animal fats for application in feed consists of two (legally) different types of operations. Raw materials used are either slaughter by-products fit for human consumption (Regulation EC/853/2004), such as lard or category 3 animal by-products derived from animals fit for human consumption (regulation EC/1069/2009), such as by-products down-graded for economic reasons. Fats derived from the latter raw materials have to be processed if used in feed. The main processing condition is that the process must guarantee a *Clostridium perfringens* free product (Regulation EC/142/2011, (EU, 2011)). Heating/sterilization is done in the temperature range of 80-130 °C. The fats produced by these establishments can only be used for feed (or technical) purposes. Production schemes of both types of establishments are shown in Annex II. In general, the production processes differ only in the sterilization process that is obligatory under Regulation EC/142/2011 (animal by-products). A specific process that produces animal fat as well, is the production of gelatine from either skins or bones. In the Netherlands, fat production related to gelatine is originating both from bone and skin processing. Fat production is a thermal degreasing process (at approximately 90 °C) from which fat is recovered by centrifuging and decanting. In Belgium, gelatine production from bones uses hydrochloric acid (HCl) in order to degrade the bones. This has led to an incident in 2006, when contaminated HCl was used in the production process. During the process, the dioxins accumulated into the fat, which was formed as a by-product of the gelatine process. The contamination of HCl was caused by incorrect functioning filter systems at the plant producing HCL as a by-product (Hoogenboom et al., 2007).

Storage and transport of animal fats have to be performed in and by food grade dedicated tanks and trucks. Cleaning is performed with water at 82°C, sometimes in combination with detergents and or disinfectants. The chemicals used are the chemicals normally applied in the food industry for cleaning and disinfection purposes.

Historically, monitoring in the Netherlands included one sample per week from a random tank. Since the beginning of 2011, a different procedure is introduced. Daily representative samples are taken, either aggregate samples from continuous production or one random sample per day. This sample is retained for tracing back a possible contamination. The various daily samples are mixed into one aggregate sample that is then analysed for dioxins and dioxin-like PCBs. Frequency of analysis is determined in weeks based on a batch size of 500 or 1000 tons. The frequency then ranges between one aggregated sample per week down to 1 aggregated sample per 4 weeks.

3.4 Fish oil production

Fresh water fish (mainly eel) contains highest concentrations of dioxins and dl-PCBs compared to other seafood. A possible explanation is the high level of these contaminants in certain rivers due to the presence of industries close to those rivers. Besides fresh water fishes, also pelagic marine fishes have high concentrations of PCBs and dioxin-like compounds (Sioen et al., 2009). The fat-soluble properties of dioxins cause them to accumulate in fatty tissues. Herring and salmon are fatty fish that may thus contain high dioxin concentrations (Helsinki Commission, 2004). Other fish with lower fat content, such as cod, accumulate dioxins in their liver. Oil obtained from these livers may thus contain high levels of dioxins as well, as is also frequently reported in the RASFF database. The degree of contamination varies geographically, from year to year, and according to the fat content, the season (highest in the spring), and also with the size and age of the fish (Helsinki Commission, 2004). In industrialized countries, levels are higher than those in less industrialized regions as they are released in by-products from industrial processes such as chlorine bleaching of paper and pulp and the manufacture of some pesticides, herbicides and fungicides (Yu et al., 2010). Fish from the Baltic sea or US Menhaden are higher contaminated than fish from other regions. Typically, dioxin levels in Baltic wild salmon are currently 2-8 ng WHO-TEQ/kg fresh weight (Helsinki Commission, 2004).

According to the information received on production and processing of fish oil, crude fish oil is mostly imported in the Netherlands. In fish oil processing, a physical separation is practised between oil intended for Human Consumption (HC) and Non-Human Consumption (NHC). All suppliers of HC fish oil have to abide by the EU hygiene standards applicable to fish oil production. NHC oil is obtained from GMP+ certified producers (see paragraph 3.7). Crude oil is either transported by trucks (containing around 25 tons) or by ship (between 100 and 2000 tons). Monitoring of fish oil only takes place on the incoming batches. In case the oil is transported by truck, the supplier of the oil has analysed the tank from which the oil is originating. Transport for NHC purposes occurs according to GMP+ requirements (GMP+ International, 2010). All incoming ships are also analysed for dioxins and dl-PCBs.

Depending on the market, fish oil can be refined using chemical refining. When distillation is applied, the residual distillates are sold for technical purposes only. In case cold filtration is applied, the by-product stearin is sold mostly for technical purposes. The residual filter (activated carbon) is removed as a waste product.

3.5 Biodiesel production

Currently, both first and second generation biodiesels are produced from oil seeds and waste materials, respectively. First generation biodiesel from seeds is produced in two steps. First, crude oil is extracted from the seeds through crushing. This production process is not typical for biodiesel production, but is a general process to obtain crude oil from oil seeds. For the risk categorization of this part of the production process we, therefore, refer to paragraph 3.2. Crude vegetable oil is then used as raw material to produce biodiesel resulting in glycerol as by-product that may go to the feed industry (see Annex III for the production process). As dioxins are hydrophobic, they will not be present in this glycerol fraction. The DG SANCO working document acknowledges this fact and glycerol, therefore, does not need to be monitored. First generation biodiesel is mainly produced from crude vegetable oils, but can also be produced from animal fat.

Risk factors for animal fat are described above. The production of biodiesel from animal fat is the same as from crude vegetable oil and will thus produce the same by-product: glycerol.

Second generation biodiesel is produced from organic waste material from the food industry such as deep-frying fats collected at catering companies. When high percentage of free fatty acids are present, a pre-stripping may be used prior to biodiesel production. By-products from these 2nd generation biodiesels are not used in feed but destined for technical purposes. GMP+, the major feed safety system in the Netherlands, explicitly forbids the use of waste material, such as deep frying fats as a raw material for feed.

3.6 Fat blending

In order to meet specific requirements, fats can be blended based on their fatty acid characteristics. According to the industry, seagoing vessels are monitored for dioxins in the country of origin. On positive release basis (when monitoring results show that dioxin levels are below the legal limits), samples are loaded on board. Vessels may contain between 500 and 2500 tons when they enter the harbour in Rotterdam. Batches coming from EU refineries are not sampled as such. However, when multi-component blends (consisting of oils from various plant sources) are produced, the final product is monitored on dioxins as well and positive release is applied. Dedicated tanks are used for storage and cleaning is applied between batches according to GMP+.

3.7 Compound feed production

In 1992, the GMP+ Feed Safety Assurance (GMP+ FSA) scheme was developed in the Netherlands. This scheme assures feed safety in all steps of the feed chain. In the Netherlands, all feed companies currently are registered and/or certified by GMP+. Suppliers of raw materials for the feed industry either have to be certified by GMP+ as well or need to be subjected to a risk assessment performed by the feed industry prior to delivery. This, therefore, also accounts for the producers of vegetable oils, animal fats or fish oils. In case feed producers buy fats and oils directly from producers in the country of origin, these suppliers should also be covered by GMP+.

Internationally, GMP+ contains 11000 participants in 65 countries. Raw materials used for feeding of food producing livestock should be included in the Feed Safety Database (FSD) using a generic risk assessment. As the focus of this study was the definition of risk factors for the oil and fat industry, the risk assessments as performed by the feed industry were not further examined. Apart from generic risk assessments, the FSD also contains monitoring data, fact sheets on various hazards and limits related to the hazards. Based on the information provided by FSD, companies can perform a company specific HACCP analysis (GMP+, 2011). On top of GMP+ FSA, feed companies in the Netherlands and Belgium wanted to cooperate more closely in order to share knowledge on monitoring and quality management. This resulted in the foundation of TrusQ in 2003 and SAFE FEED in 2005 (Safefeed, 2011; TrusQ, 2011).

TrusQ focuses on the monitoring of raw materials as this is the start of the food and feed chain. TrusQ has performed a risk assessment on the raw materials used in the feed industry to determine the high risk, medium risk and low risk ingredients. This list is combined with the tonnages to be used by the compound feed producers to come to a monitoring plan that is shared with the members. Every year, the members are checked for their compliance to this pre-set monitoring plan and fines are issued in case of non-compliance. For fats and oils, the products that are indicated in the high risk category for dioxins are: animal fats, crude coconut oil and palm fatty acid distillates (PFAD). For these products, the members either monitor on dioxins themselves or they rely on the analytical results provided by the supplier. One of the TrusQ members indicated that they rely on a positive release system for animal fats.

More than 60 Dutch feed mills are cooperating within SAFE FEED representing 50% of the Dutch compound feed producers. SAFE FEED assesses suppliers of raw materials to ensure that detailed specifications are present in agreement with the legislation and GMP+. Suppliers are visited regularly to verify the competence of the supplier. Furthermore, monitoring plans are implemented based on risk assessment.

3.8 Statistical analysis on dioxin monitoring data

3.8.1 RIKILT data

Results of the CALUX method are presented in Table 6. This shows that for crude vegetable oils, soy and palm oil had the highest number of suspected samples. Around 28% of the mixed animal fat samples were suspected using the CALUX method. Fish oil had the highest percentage of suspected samples. It should be stressed that this also depends on the decision limit used for the test, which - at RIKILT - is rather conservative. The suspected samples were analysed further using the GC/HRMS method. Quantitative results from the GC/HRMS method were used to derive lognormal distributions, for which the results are indicated in Tables 7, 9 and 10 for vegetable oils, animal fats and fish oil respectively. As can be seen in Table 6, the percentage of samples exceeding the action limits, using the GC/HRMS method, in most cases was 0.0%. This confirms the fact that the CALUX method is applied in a conservative way. The advantage of the CALUX method is that samples above the action limit have a high probability of being detected (>99%) and it can thus be used as a screening method. The CALUX method is a bioassay that can also detect other dioxin-like compounds with a potential health effect on humans. As such it can be used for detecting emerging risks.

Table 6. Percentage of RIKILT samples that were suspected using the CALUX method.

	N	%suspCALUX[a]	%>AL[b]
Vegetable oils			
Coconut	25	4.0%	0.0%
Palm	32	31.2%	0.0%
Rape	5	0.0%	0.0%
Soy	81	33.3%	0.0%
Sunflower	14	21.4%	0.0%
Animal fats			
Poultry	35	2.9%	0.0%
Beef	40	5.0%	0.0%
Pig	52	3.8%	0.0%
Mix	67	28.4%	1.5%
Fish oils			
Various types	55	89.1%	0.0%

[a] %suspCALUX: number of samples that were suspected based on results of the CALUX (using the action limits for dioxins as decision limits)
[b] %>AL: percentage of samples exceeding the action limit for dioxins (0.5 for vegetable oils, 1.0 for animal fat and 5.0 for fish oil) as measured using the GC/HRMS method.

3.8.2 Vegetable oils

Crude vegetable oils imported in the EU may be used in feed directly or may be used as a raw material to produce refined oils. The DG SANCO working documents only mentions the monitoring of crude vegetable oils. Therefore, the focus of the statistical analyses was on crude rather than on refined oils. Statistical analyses were performed on the log-transformed data for dioxins only, as industrial data did not contain results on dl-PCBs. Results from RIKILT, individual data and average values form industry are presented in Table 7. Based on the RIKILT data, highest percentage of samples exceeding the action and maximum limit were obtained for sunflower oil, which was not confirmed by the industrial data. However, this estimation was based on 3 suspected out of 14 samples. Based on the average industrial data, coconut oil had the highest percentage exceedance of the action and maximum limits, which was not found in the individual industrial nor in the RIKILT data. The latter two datasets consisted of only 3 coconut samples in total, which makes comparison difficult. Furthermore, sampling points are different. The average industrial data are based on samples from incoming ships, whereas the other data are based on samples at the compound feed industry. It is likely that ships containing crude coconut oil exceeding the maximum limits will not be sold as such to the compound feed industry.

Table 7. Results of monitoring data on crude vegetable oils. Indicated are the results for dioxins.

	N	Average[a]	LnAverage[b]	LnStdev[c]	%>AL[d]	%>ML[e]
RIKILT						
Coconut	1	0.17	-1.77	-	-	-
Palm	10	0.23	-1.51	0.23	0.02%	0.00%
Rape	0	-	-	-	-	-
Soy	27	0.22	-1.54	0.24	0.03%	0.00%
Sunflower	3	0.34	-1.09	0.25	5.82%	0.08%
Industry individual data						
Coconut	2	0.23	-1.49	0.09	0.00%	0.00%
Palm	40	0.26	-1.37	0.26	0.48%	0.00%
Rape	-					
Soy	28	0.25	-1.44	0.27	0.24%	0.00%
Sunflower	-					
Industry average data						
Coconut	68	0.68	-0.58	0.63	56.85%	32.00%
Palm	118	0.21	-1.62	0.29	0.07%	0.00%
Rape	38	0.12	-2.14	0.27	0.00%	0.00%
Soy	27	0.13	-2.13	0.42	0.03%	0.00%
Sunflower	25	0.18	-1.75	0.12	0.00%	0.00%

[a]*Average: average value for the non-transformed data*
[b]*LnAverage: average values for the log-transformed data*
[c]*LnStdev: standard deviations for the log-transformed data*
[d]*%>AL: estimated percentage of samples from the lognormal distribution exceeding the action limit (0.5 for dioxins, -0.693 on log scale)*
[e]*%>ML: estimated percentage of samples from the lognormal distribution exceeding the maximum limit (0.75 for dioxins, -0.288 on log scale)*

Analysis of variance was performed on the average data from industry as this was based on the largest number of samples. This showed that crude coconut oil was significantly different ($p < 0.05$) from the other vegetable oils and that there was no significant difference between the various refined oils (data not shown). Vegetable oils from different plant origins were combined in case they were not significantly different and are presented in Table 8, together with the results for fatty acid distillates. Based on the available data on average values and standard deviations, the derived lognormal distributions resulted in highest exceedances of the action and maximum limits for crude coconut oil, followed, to a much lower extent, by fatty acid distillates.

Table 8. Overall results for crude vegetable oils, coconut oil, refined oil and fatty acid distillates.

	N	Average[a]	LnAverage[b]	LnStdev[c]	%>AL[d]	%>ML[e]
Crude coconut oil	68	0.68	-0.58	0.63	56.85%	32.00%
Crude vegetable oils (palm, rape, soy, sunflower)	208	0.18	-1.77	0.29	0.01%	0.00%
Refined oils (coconut, palm, rape,soy, sunflower)	176	0.14	-2.10	0.53	0.41%	0.03%
Fatty acid distillates	476	0.32	-1.19	0.36	8.13%	0.56%

[a]Average: average value for the non-transformed data
[b]LnAverage: average values for the log-transformed data
[c]LnStdev: standard deviations for the log-transformed data
[d]%>AL: estimated percentage of samples from the lognormal distribution exceeding the action limit (0.5 for dioxins, -0.69 on log scale)
[e]%>ML: estimated percentage of samples from the lognormal distribution exceeding the maximum limit (0.75 for dioxins, -0.29 on log scale)

3.8.3 Animal fats

Results of statistical analyses on the log-transformed monitoring data of animal fats are indicated in Table 9. The RIKILT data show that based on the lognormal distribution derived for the GC/HRMS data, 3.5% of the beef samples was above the action limit, and 0.2% above the maximum limit. However, these percentages are based on only 2 measurements on the GC/HRMS, whereas 38 samples were below the action limit. No data on beef were available from the animal fat industry. The industrial data show that only mixed fat exceeded the action and maximum limit with a percentage of 1.6 and 0.01% respectively. Significant differences were seen between fats of various origins ($p < 0.05$) with highest levels for mixed fat and beef fat followed by poultry fat and pig fat.

Table 9. Results of monitoring data on animal fats. Indicated are the sum of dioxins and dl-PCBs.

	N	Average[a]	LnAverage[b]	LnStdev[c]	%>AL[d]	%>ML[e]
RIKILT						
Poultry	1	0.49	-0.71	-	-	-
Beef	2	0.70	-0.36	0.50	3.46%	0.20%
Pig	2	0.34	-1.06	0.02	0.00%	0.00%
Mix	18	0.71	-0.34	0.30	0.16%	0.00%
Industry						
Poultry	168	0.66	-0.43	0.22	0.00%	0.00%
Beef	-					
Pig	146	0.56	-0.60	0.19	0.00%	0.00%
Mix	82	0.86	-0.22	0.36	1.60%	0.01%

[a]Average: average value for the non-transformed data
[b]LnAverage: average values for the log-transformed data
[c]LnStdev: standard deviations for the log-transformed data
[d]%>AL: estimated percentage of samples from the lognormal distribution exceeding the action limit (1.75 for dioxins and dl-PCBs, 0.56 on log scale)
[e]%>ML: estimated percentage of samples from the lognormal distribution exceeding the maximum limit (3.0 for dioxins and dl-PCBs, 1.10 on log scale)

3.8.4 Fish oil

In most cases, the fish species involved was unknown, therefore, data were combined for all fish oils. Statistical analysis on the log-transformed monitoring data showed that part of the samples exceeded the action and maximum limits (Table 10). Due to the fact that the standard deviation for the industrial data is larger, the percentage of samples that exceed the action and maximum limits are higher than for the RIKILT data.

Table 10. Results of monitoring data on dioxins and sum of dioxins and dl-PCBs in fish

	N	Average[a]	LnAverage[b]	LnStdev[c]	%>AL[d]	%>ML[e]
RIKILT						
Dioxins	49	1.57	0.36	0.50	0.59%	0.20%
Dioxins+dl-PCBs	49	6.95	1.85	0.52	1.80%	0.55%
Industry						
Dioxins	21	1.50	0.03	1.04	6.43%	4.51%
Dioxins+dl-PCBs	21	5.70	1.43	0.90	4.65%	2.62%

[a]Average: average value for the non-transformed data
[b]LnAverage: average values for the log-transformed data
[c]LnStdev: standard deviations for the log-transformed data
[d]%>AL: estimated percentage of samples from the lognormal distribution exceeding the action limit (5.0 for dioxins and 19.0 for dioxins and dl-PCBs, resp. 1.61 and 2.94 on log scale)
[e]%>ML: estimated percentage of samples from the lognormal distribution exceeding the maximum limit (6.0 for dioxins and 24.0 for dioxins and dl-PCBs, resp. 1.79 and 3.18 on log scale)

4 Discussion en conclusions

4.1 Critical steps in the production processes of fats and oils

Dioxins and dl-PCBs may enter vegetable oils due to drying, storage or transport processes but also chemicals used during production. Once dioxins are present in the crude vegetable oil, a 300 times concentration may take place during chemical refining. This can, therefore, be seen as a critical step for dioxin levels in vegetable oil production. Fediol members either designate chemical distillates for technical purposes or apply distillation or active carbon treatment to remove the dioxins. These processed distillates may be used in feed, provided that safety is demonstrated. Processed chemical distillates may be included in the European Feed Catalogue (EU, 2010) as "deodistillates, processed", in order to distinguish them from non-processed distillates that are not fit for feed purposes. For physical refining, the concentration factor is lower, but still a factor of 20-100 times. Besides, fatty acid distillates have been shown to cause a few alerts in the RASFF database. Therefore, the fatty acid distillate obtained may be used for the feed industry provided that it is monitored on dioxins as is currently done by Fediol members. Bleaching earth used in the production of vegetable oil is currently monitored for dioxins and this, therefore, does not pose a risk for dioxin contamination. The production process of vegetable oils, in general, does not seem to include process steps that may introduce dioxins in the final product or by-products destined for feed. Exceptions are the drying of seeds on open fires using waste material as can be the case in the production of coconut oil and also in the production of cocoa butter, which recently resulted in a contamination found in cocoa butter fatty acids. Depending on the type of fuel used, this drying process may thus introduce dioxins in the product and is, therefore, a risk factor in the production process. As for cross-contamination, transport within the EU occurs according to GMP+ requirements. Outside the EU, codes of practices for transport may be applicable as well, such as applied in Malaysia. It is, however, unclear whether all palm oil producers apply these practices. Furthermore, transport of other oils from outside the EU (such as coconut oil) may not have comparable codes of practice. Therefore, cross-contamination during transport and storage of raw materials from outside the EU can be seen as a risk factor as well.

The production process of animal fats normally does not pose any risks for further dioxin contamination. However, an incident in Belgium has occurred when HCl, that is used for gelatine production from bones in some production processes, was contaminated with dioxins. This incident showed that processing aids, in general, should be subject to a HACCP analysis and critical ingredients should be monitored. In contrast to vegetable oil production, no concentration occurs during production of animal fats. Since the raw materials used for animal fat are derived from animals fit for human consumption, it is unlikely that these raw materials have a higher dioxin contamination than animal products fit for human consumption. Materials for animal fat production come from healthy animals that are regularly checked on dioxins by food producers. In case raw materials exceed the legal limits, they are indicated as category 1 material (Regulation 1069/2009/EC, (EU, 2009c)). Increased dioxin levels in animal fat can only occur when the animals have been fed with feed containing elevated levels of dioxins or through environmental contamination (when animals are grazing on polluted soils). The dioxins from the feed are taken up by the animals and stored in their fat tissue. Over time, dioxins may accumulate in the fat tissues as is the case for all living species. Part of the accumulated amount in dairy cows and laying hens is depleted due to lactation and via egg production.

Fish oil often contains higher levels of dioxins than animal fats or vegetable oils. This is due to the fact that environmental dioxins accumulate in fatty fish such as salmon and herring and also in the livers of lean fish. The raw materials for fish oil production, therefore, may contain high levels of dioxins. Alerts on dioxin presence in fats and oils are mainly related to fish oil in the RASFF database. Therefore, according to the industry, all crude fish oil used in the Netherlands is analysed for dioxins and only oils containing levels below the legal maximum limits are used in the production process. The crude oil may be used in feed as such or can be chemically refined or filtrated using cold filtration with activated carbon. The chemical distillate obtained is used for technical purposes only.

The crushing of oils from seeds for biodiesel production is identical to the production of crude vegetable oil as described above. Critical steps, therefore, are identical. As no high temperatures are involved, the production process of biodiesel from the crude oil does not pose any additional risks for dioxin contamination. When biodiesel is produced from waste materials (such as deep-frying fats), the raw materials used may contain dioxins. However, by-products from these 2nd generation biodiesels are destined for technical purposes only and should not enter the feed chain.

The fat blending process does not contain process steps, like highly elevated temperatures, that may increase dioxin levels in the final product. A positive release system is applied for all vegetable oils transported over sea as well as for final products that consist of multi-components. Oils obtained from EU countries, however, are not monitored.

4.2 Maximum batch size for sampling of fats and oils

As indicated in the introduction, the definition of a batch can have a range of characteristics (EU, 2009b). In the oil and fat industry, definition of batches can be difficult, as the refining process usually is a continuous process. In the animal fat industry this is resolved by taking daily samples and mixing them until the production volume reaches a total batch size of 500 or 1000 tons. This may be achieved within one week or within 4 weeks, depending on the company capacities. During transport, batches can have a great variation in sizes. For example, ships with vegetable oils may contain between 30,000 and 75,000 tons. Batch sizes in the oil industry differ between factories and between production processes. Definition of a maximum batch size for monitoring, therefore, does have its problems. Using the definitions as posed in the current DG SANCO document implies that from a ship containing 75,000 tons of palm oil, 75 samples would need to be analysed for dioxins. Ships may contain loading decks containing oil from various locations and origins. However, upon arrival the content of the ship is loaded into a land tank where mixing of the origins occurs. As oils and fats for the most part are liquids, and loading and unloading is performed by pumping the material, it can be assumed that dioxins will be distributed homogenously along a batch. In case ships are loaded into one tank, this can then be seen as one batch. When large vessels are pumped into several land tanks, the batch size should be defined as the size of a land tank. Aggregate samples can be taken from one batch (a ship or a tank) that is composed of several incremental samples per loading deck. The number of incremental samples and the size of the aggregate sample to be analysed is laid down in EC/152/2009 (EU, 2009a). When aggregate samples are taken, there is a risk that one (or more) highly contaminated incremental sample is diluted by the other non-contaminated incremental samples. For example, in the animal fat industry the daily samples are mixed into one aggregate sample that is analysed. In case dioxin levels are elevated on one of the production days, it is possible that the aggregate sample does not exceed the action or maximum dioxin levels. Therefore, when dioxin levels found in the aggregate samples are above the usual average levels found, it is recommended to analyse the incremental samples individually. Based on available monitoring data, the industry may define a decision level (e.g. the average + 2 times the standard deviation), above which further actions are required. This level may be lower than the action limits currently established in regulation 2002/32/EC.

4.3 Monitoring frequency for fats and oils

Comparison between RIKILT and industrial data is difficult as the analytical approach followed differs. The RIKILT samples are first screened using the CALUX method and only samples that are suspected (exceeding the action limit) are quantified using GC/HRMS. This resulted in few quantitative samples. The industrial samples contained more quantitative data and distributions derived from these data are, therefore, more realistic. However, it should be kept in mind that the results of the statistical analyses as presented in paragraph 3.8 are based on upper bound values in case results were indicated as being below the detection limit (<LOD). This, therefore, is a worst case approach.

Based on the results of the monitoring data, crude palm, soy, rape and sunflower oil hardly showed any exceedances of the action or maximum limits. Increased monitoring frequency for these crude vegetable oils, therefore, does not seem to be justified. Import of crude oil from outside the EU was indicated as a possible risk factor (see paragraph 4.1). However, as zero per cent of the crude palm oil samples exceeded the maximum limits over the past five years, the quality of this non-EU product, is comparable to the other crude vegetable oils. Coconut oil, as expected, had a higher percentage of samples exceeding the action and maximum limits. This product should, therefore, be monitored more frequently than the other crude vegetable oils. Fatty acid distillates showed higher percentage of samples above the action and maximum limits than crude vegetable oils and should thus have a higher monitoring frequency than crude vegetable oils.

Data on animal fats from the industry show that only 0.01% of the mixed fat samples exceeded the maximum limit. Increased monitoring for poultry, pig and mixed fats, therefore, is not justified. A higher percentage was found for beef samples from the RIKILT (3.8%), although this percentage was based on only two suspected samples out of 40 samples. EFSA also determined percentages exceeding the action limits. However, these percentages were partly based on contamination incidences and, therefore, do not indicate normal dioxin levels found in oil and fat (EFSA, 2010). Although more data are needed for beef fat to determine its monitoring frequency, European data on beef products and beef fat do not indicate that increased monitoring is needed for this product (SCF, 2000; EFSA, 2010).

Around 5% of the fish oil samples exceeded the action or maximum limit. This is expected, as fish oil is the most frequently reported product in alerts on dioxins and dl-PCBs in fats and oils in the RASFF database. Fish may be contaminated by pollution of the aquatic environment. As fish has the highest maximum limits for dioxins and dl-PCBs and in some cases exceeds these limits, it may be seen as a critical product and should, therefore, be monitored more frequently than crude vegetable oils or animal fats.

The current datasets as analysed in this report were not sufficient for statistically deriving the number of samples to be monitored in order to achieve a pre-set level of compliance. For such an analysis, the variation between countries of origin, between companies, between analytical techniques used and variation over the years needs to be known. Individual companies may perform such analysis based on their own raw data. This may be taken up as part of a company's risk assessment.

5 Recommendations

Based on the inventory of the critical production processes and on the monitoring data of the various fats and oils, we come to the following recommendations:

Based on a HACCP approach, bleaching earth used in vegetable oil production should be monitored for dioxin levels, as is currently done by industry. Only bleaching earth with levels of dioxins and dl-PCBs below 1.5 ng/kg (WHO-PCDD/F-PCB-TEQ) should be used in the production process. Used bleaching earth may be reused in the production process when the fresh bleaching earth and the crude oils used contain dioxins and dl-PCBs below the legal limit.

The frequency of monitoring of incoming batches of crude vegetable oil should be based on statistical analyses on company's raw data. As crude coconut oil is more likely to exceed the maximum limits than other crude vegetable oils, a 100% monitoring is advised.

Two types of distillates are produced in the refinement of crude vegetable oils: chemical and physical distillates. Non-processed chemical distillates from vegetable oils should only be used for technical purposes. Processed chemical distillates (where e.g. active carbon treatment is used to remove dioxins) should be monitored prior to use in food or feed in order to demonstrate its safety. In order to distinguish between processed and non-processed distillates, an extra definition may be taken up in the EU Feed Catalogue (EU, 2010). It should be determined to what extent competent authorities can audit these processes. Physical fatty acid distillates from vegetable oils may be used by the feed industry on the condition that they are checked for dioxin levels. As crude coconut oil showed highest exceedances of the action and maximum limits, the physical distillates derived from this raw material should not be used in feed, unless monitoring results demonstrate that they are below the legal limits or further processing is applied to remove dioxins present.

Production of animal fats, normally, does not contain any steps that may lead to dioxin formation, except when contaminated ingredients (such as HCl) are used as processing aids. A HACCP analysis should thus be applied on processing aids and critical ingredients, such as HCl, should be monitored for dioxins. Monitoring of final products is not necessary. However, as in the past, adulteration of animal fats has occurred, random monitoring of final products can be considered as an indicator for good practices.

As fish as a raw material may contain high levels of dioxins, incoming batches of crude oils should be monitored. According to the fish industry this is, currently, done on every incoming batch. Non-processed chemical distillates from fish oil should not be used in feed.

The current DG SANCO working document proposes random sampling of technical fats indicating that 2% of the batches should be monitored. As technical fats are not meant to be used for the production of feed, monitoring of these fats is actually superfluous. Physical segregation of feed and technical product streams is recommended. Furthermore, a good labelling and documentation system is essential, especially when factories produce both technical and feed fats (for example when both chemical and physical refining is applied). Such a system needs to be checked regularly. It is advisable to use a Code of Practice for this purpose such as suggested by Fediol (FEDIOL, 2011d). On top of this, the addition of an indicator, such as glycerol triheptanoate (GTH) to technical fats will have a precautionary effect on mistakes or adulteration. GTH is currently used as a marker for products of Category 1 animal by-products according to Regulation 1069/2009/EC (EU, 2009c). GTH is a transparent liquid with three C7-fatty acids esterified with glycerol, which is currently applied in the food industry (e.g. marking of butter). It meets the requirements of the legislation, and in addition, could be used in the animal by-product industry as it withstands extreme sterilisation conditions. It can be measured using gas chromatography coupled to mass spectrometry (GCMS) or coupled to flame ionisation. An implementation study at ten European rendering plants has been conducted demonstrating that GTH is a suitable marker for animal by-products from category 1 and 2 (Boix et al., 2006). Although Regulation 1069/2009/EC does not apply to vegetable oils and their derivatives, the use of a marker such as GTH should be seriously considered for batches exceeding dioxin and PCB limits. If the use of a permanent marker is introduced for non-feed/food fats and oils, it will logically have the consequence that positive release into the feed/food chain has to be applied for critical products. As this is a measure with potentially large logistical and financial consequences for the food/feed industry, an impact assessment of such a measure has to be considered.

The above mentioned recommendations on monitoring for dioxins may lead to increased monitoring with additional costs for the oil and fat industry. It is worthwhile to relate these additional costs to the financial impact of a dioxin crisis. For this purpose, incidents from the past should be analysed to determine economic losses (Lascano Alcoser et al., in press).

Batch sizes differ in the oils and fat industry. It is, therefore, difficult to determine a maximum batch size. Batch sizes may be defined on the presumption of homogeneity. Incoming ships containing crude oils may, for example, be seen as one batch, as the various loading decks are pumped into one or more land tanks resulting in homogenisation of the cargo. Definition of batch sizes should be based on a risk assessment performed by individual companies as a general definition for the oil and fat industry is not feasible. Aggregate samples may be taken from a defined batch consisting of a mixture of incremental samples. Based on historical data, decision levels need to be established by industry. In case aggregate samples show dioxin levels above the decision levels, it should be possible to trace back the source of the contamination. For incoming ships, incremental samples may thus be taken and stored per loading deck. The frequency of sampling should be defined by industry and should be based on a risk based approach using historical data. National authorities may then verify the approach followed.

Recommendations on dioxin monitoring are recaptured in the following bullet points. These recommendations are valid both for all industry importing or processing oils and fats within the EU:

- Bleaching earth should be monitored based on a HACCP approach
- Used bleaching earth may be re-used provided that the fresh bleaching earth and the crude oils are free of dioxins
- A 100% monitoring of crude coconut oil is advised
- Non-processed physical distillates from crude coconut oil and non-processed chemical distillates from crude vegetable oils should be applied for technical purposes only
- Processed chemical distillates may be used in feed using 100% monitoring and a definition for this by-product should be incorporated in the EU Feed Catalogue (EU, 2010)
- Physical distillates from sources other than coconut oil should be monitored regularly

- A HACCP analysis should be applied on any (new) processing aids used and critical ingredients (such as HCl) should be monitored
- Random monitoring of final products of animal fats is recommended
- 100% of incoming ships carrying fish oil should be monitored
- By-products from 2nd generation biodiesel should only be used as technical fat
- Batch sizes and monitoring frequencies should be defined by individual companies based on a risk based approach using historical data
- In case aggregate samples are used, industry should define a decision limit based on historical monitoring data (e.g. the average + 2 times the standard deviation).
- Physical segregation of feed and technical product streams is recommended
- A Code of Practice should be used for labelling and checking fats for feed and technical fats
- A marker like GTH can be used as indicator in technical fats to prevent mistakes and adulteration

6 Acknowledgements

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Annex I
Production of vegetable oils (aAf and FeDIOL, 2010)

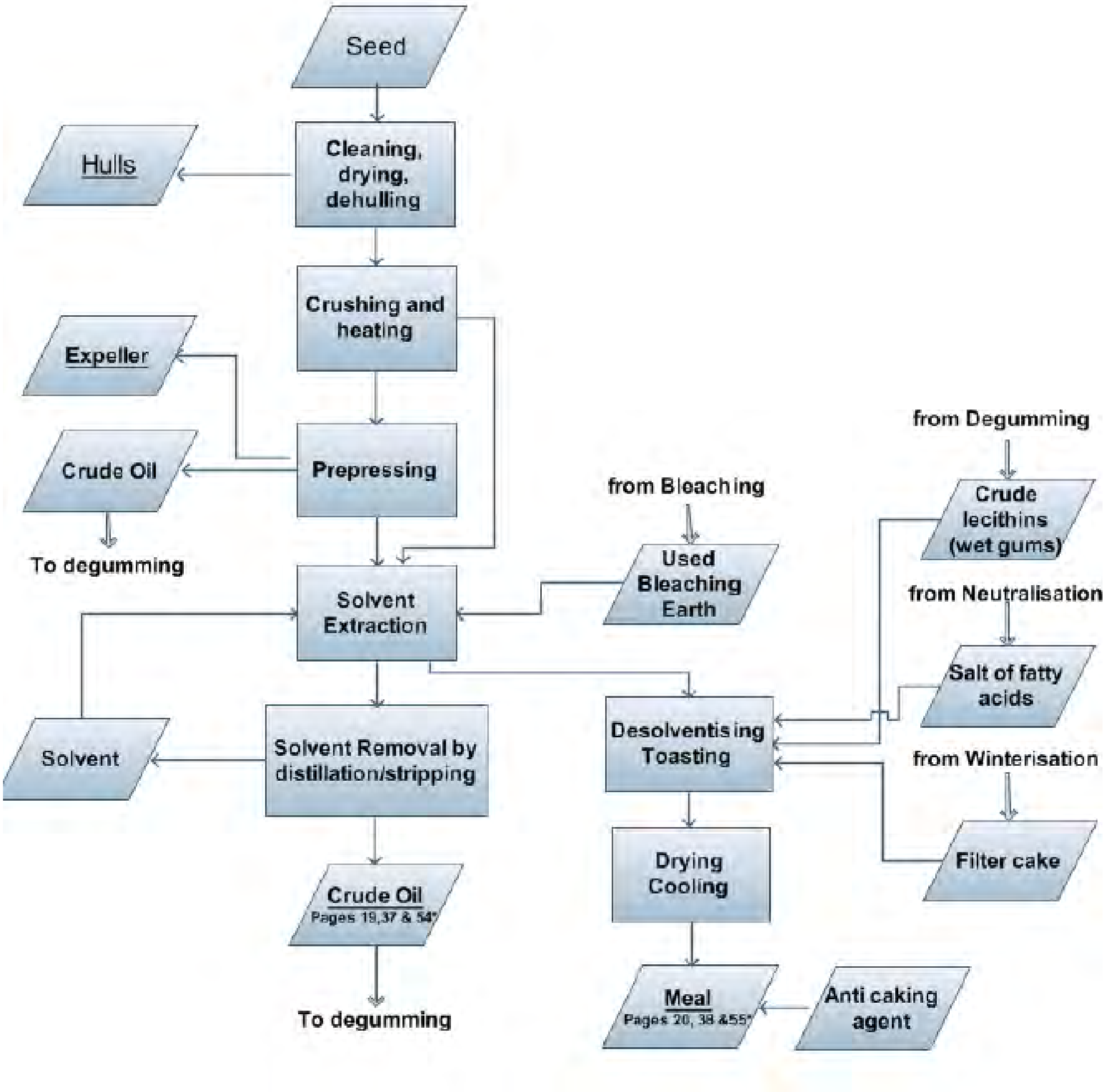


Figure I.1. Flow chart of oilseed crushing.

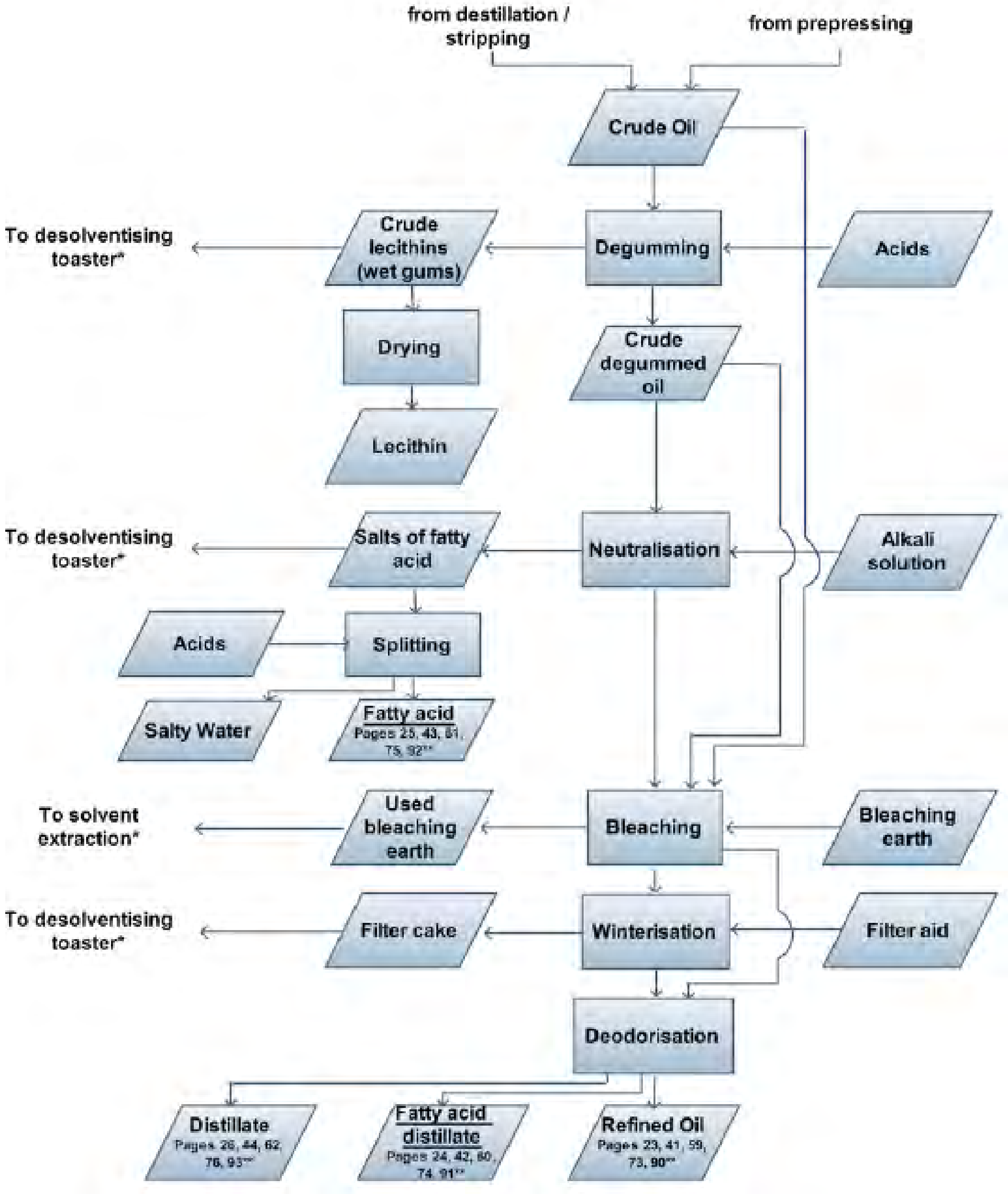
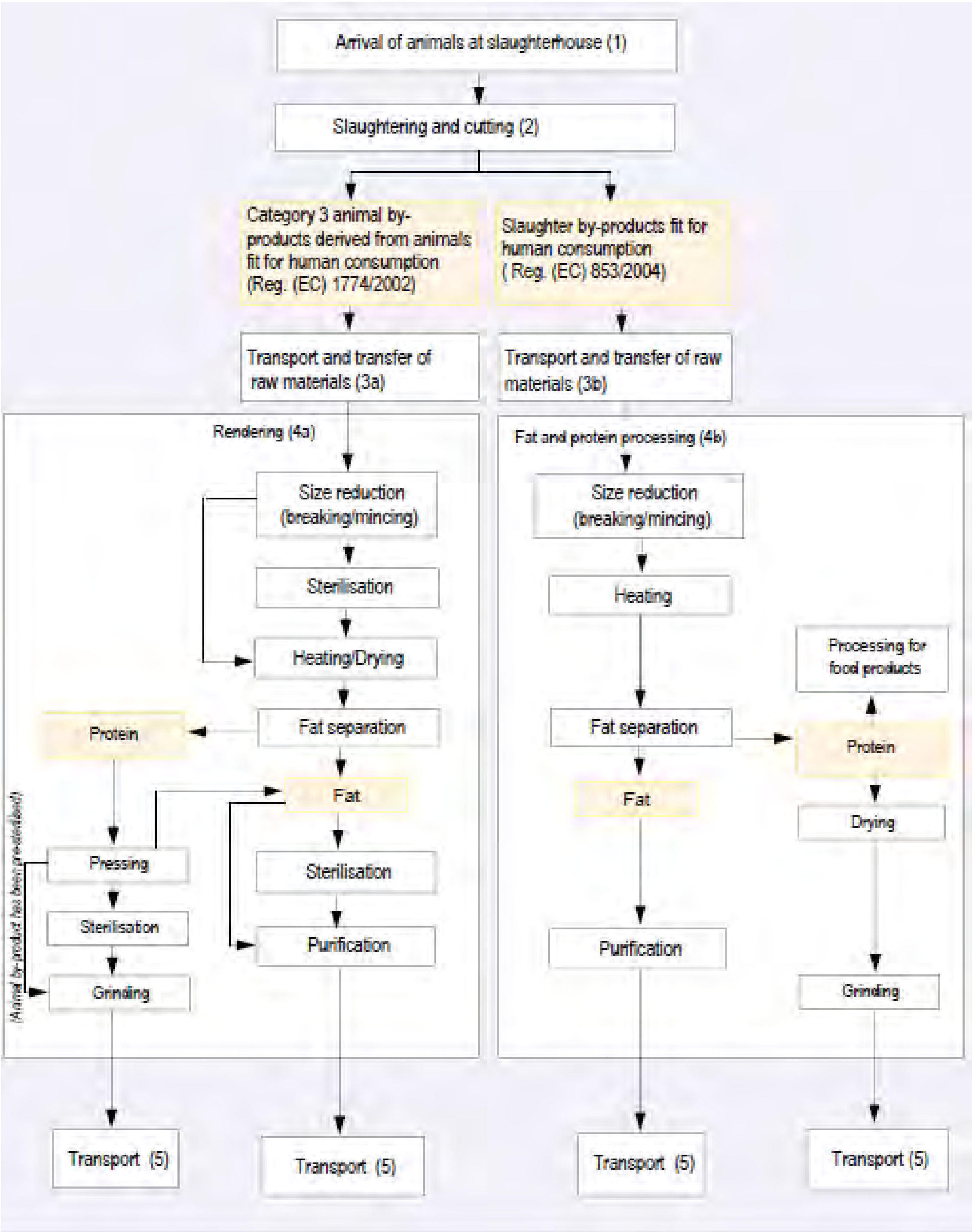
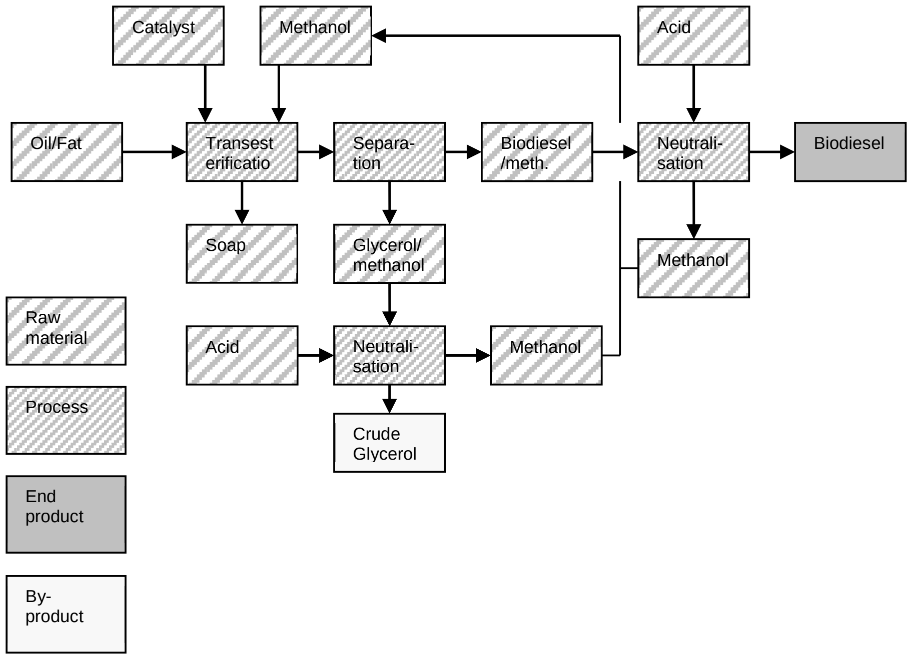


Figure I.2. Flow chart of refining.

Annex II
Production process of animal fats (MVO, 2007)



Annex III
Production process of biodiesel from crude vegetable oils (Van Thuijl et al., 2003)



RIKILT - Institute of Food Safety is part of the international knowledge organisation Wageningen UR (University & Research centre). RIKILT conducts independent research into the safety and quality of food. The institute is specialised in detecting and identifying substances in food and animal feed and determining the functionality and effect of those substances.

RIKILT advises national and international governments on establishing standards and methods of analysis. RIKILT is available 24 hours a day and seven days a week in cases of incidents and food crises.

The research institute in Wageningen is the National Reference Laboratory (NRL) for milk, genetically modified organisms, and nearly all chemical substances, and is also the European Union Reference Laboratory (EU-RL) for substances with hormonal effects.

RIKILT is a member of various national and international expertise centres and networks. Most of our work is commissioned by the Dutch Ministry of Economic Affairs, Agriculture and Innovation and the new Dutch Food and Consumer Product Safety Authority. Other parties commissioning our work include the European Union, the European Food Safety Authority (EFSA), foreign governments, social organisations, and businesses.

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