



Minimum specifications for feed fats

GMP+ D 4.12

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GMP+ Feed Certification scheme



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AND THE LIKE” OF MARCH 200149**

3 Introduction

3.1 General

The GMP+ Feed Certification scheme was initiated and developed in 1992 by the Dutch feed industry in response to various more or less serious incidents involving contamination in feed materials. Although it started as a national scheme, it has developed to become an international scheme that is managed by GMP+ International in collaboration with various international stakeholders.

Even though the GMP+ Feed Certification scheme originated from a feed safety perspective, in 2013 the first feed responsibility standard has been published. For this purpose, two modules are created: GMP+ Feed Safety Assurance (focussed on feed safety) and GMP+ Feed Responsibility Assurance (focussed on responsible feed).

GMP+ Feed Safety Assurance is a complete module for the assurance of feed safety in all the links of the feed chain. Demonstrable assurance of feed safety is a 'license to sell' in many countries and markets and participation in the GMP+ FSA module can facilitate this excellently. Based on needs in practice, multiple components have been integrated into the GMP+ FSA module, such as requirements for the quality management system (ISO 9001), HACCP, product standards, traceability, monitoring, prerequisites programmes, chain approach and the Early Warning System.

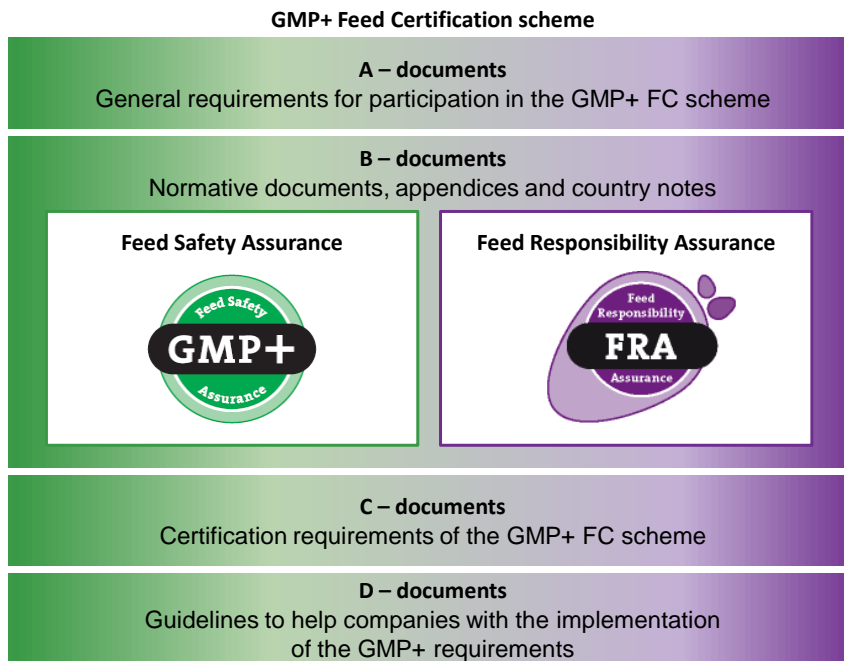
With the development of the GMP+ Feed Responsibility Assurance module, GMP+ International is responding to requests by GMP+ participants. The animal feed sector is confronted with requests on working responsibly. This includes, for example, the use of soy (including soy derivatives and soy products) and fishmeal which are produced and traded with respect for humans, animals and the environment. In order to demonstrate responsible production and trade, a company can get certified for the GMP+ Feed Responsibility Assurance.

Together with the GMP+ partners, GMP+ International transparently sets clear requirements to guarantee feed safety & responsibility. Certification bodies are able to carry out GMP+ certification independently.

GMP+ International supports the GMP+ participants with useful and practical information by way of a number of guidance documents, databases, newsletters, Q&A lists and seminars.

3.2 Structure of the GMP+ Feed Certification scheme

The documents within the GMP+ Feed Certification scheme are subdivided into a number of series. The next page shows a schematic representation of the content of the GMP+ Feed Certification scheme:



All these documents are available via the website of GMP+ International (www.gmpplus.org) .

The present document is referred to as the GMP+ D4.12 *Minimum specifications for feed fats*.

It is not a standard document, but a study at that time carried out in co-operation with the Product Board Animal Feed. In this document use has been made of the original texts from the report. The information from this study can be used for better implementation of the GMP+ FSA standards.

Minimum specifications for feed fats

GMP regulation feed sector

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Preface

On 16 June 1999, the board of the Product Board Animal Feed adopted the 'Plan for the improvement of quality assurance in the feed sector'. The direct reason for this was the Belgian affair with dioxin-contaminated feed fats, although plans to adjust the quality policy were already in preparation.

The main objective of the plan is to reinforce the system of *standard setting, assurance and control & monitoring* in the feed sector in such a way that the desired quality level for feed, in relation to the safety of animal products for consumers, is assured adequately. In addition, the safety of the animals continues to be an objective. The improved and reinforced system must enjoy the permanent confidence of consumers, as well as other partners in the chain of animal production and sales, and the national government.

The focuses of the plan are mainly (i) the integration of the HACCP principle in risk assessment and risk control, (ii) a better assurance of the entire feed chain (including previous links of suppliers of raw materials) and (iii) the development of an early warning system. In addition it has been decided (iv) to recalibrate the desired quality level, also based on the risk assessment, (v) to reinforce the control and enforcement within the framework of self-regulation, and (vi) to improve the communication.

With this plan the feed sector has opted for a system of Quality Assurance (GMP and HACCP) which is also applied in the foodstuffs industry.

The implementation of a risk inventory and risk analysis is part of the development and introduction of the HACCP system in the feed industry. On the basis of such a risk analysis the following things must be established on the sector level as well as on the company level:

The following matters, among others, are established on the basis of the risk assessments of feed materials on the chain level, with a view to risk control:

- the risk factors in the production chain
- the necessary control measures to eliminate or reduce these risk factors and to control them at an acceptable level
- standards and critical (action) limit values for the relevant risk factors
- a measuring strategy (monitoring and verification/control) at the raw materials level and the end product level

This report contains an analysis and proposal in the field of standards and critical (action) limits for relevant risk factors. More in particular with regard to components which may occur in feed fats. This report was prepared by the Core Group Minimum Specifications for Feed Materials, which prepared the general approach in consultation with the Technical Committee Minimum Specifications for Feed Fats (composition mentioned in Appendix 1). We are very grateful to the members of this core group and the technical committee, in particular Dr. L. Vellenga, for the work done and the result delivered.

This report served as a basis for the adjustment of the PDV Decision standards GMP feed sector 1999, which the board of the Product Board Animal Feed decided on 7 November 2001. This has defined more clearly what is considered under GMP circumstances to be healthy and customary commercial quality.

PRODUCT BOARD ANIMAL FEED

J. den Hartog
Secretary

4 Objective

The general objective of the feed legislation is that feed materials must be of a "healthy, good and customary commercial quality, and must not present any risk for the health of humans and animals" (art. 3:1 PDV feed regulation 1998).

Maximum limits have already been established for a number of undesirable substances and products, usually based on incidents in the past. There are no action limits or rejection limits for many risk factors which emerge in the drafting of a risk analysis (in accordance with the HACCP principles).

Reality teaches that it is urgently desired that action and rejection limits are prepared for this, in order to determine whether a feed material is safe and of a healthy, good and customary commercial quality.

It is expected that the European Commission will make the necessary efforts within the framework of the White book, but that it will take quite some time before action and rejection limits can be determined in a European context.

In anticipation of this the Product Board Animal Feed has found it necessary to create a Core Group Minimum Specifications for Feed Materials, which *implements the drafting of action standards and rejection values for the relevant risk factors in feed materials.*

3 Working method

3.1 General

The board of the Product Board Animal Feed consented in March 2000 to the creation of the Core Group Minimum Specifications for Feed Materials. The Core Group will always take the following aspects into account in the assessment of a contaminant and the determination of the action and rejection limit:

- Relevancy of the determination of a maximum standard and an action threshold.
- Avoidance. Is it (technically - economically) (im)possible to repel the risk.
- Background values
- Current standards (national, EU)
- Transfer of feed to animals, to humans and to the environment
- Potential risks to animals, to humans (employees or consumers) and to the environment
- Available (validated) analysis methods
- Missing data

Action and/or rejection limits which are objective and responsible from the viewpoints of animal, environmental and public health and which are technically and economically feasible and are supported and enforceable by GMP, must be determined on the basis of the above data.

The Core Group has itself advised by technical committees (expert panels). The technical committees may submit proposals for action and rejection limits per raw material flow.

3.2 Technical committee on minimum specifications for feed fats

It has been decided to start with the determination of the action and rejection limits of contaminants (problem substances) in **feed fats**. To this end the Technical Committee on Minimum Specification for Feed Fats was created (see appendix for the composition).

In a first exploratory meeting of the Technical Committee the objective and the working method of the Committee were discussed and subscribed to by means of the Project Plan "Drafting action and rejection limits" of the PDV.

The list of possible problem substances (contaminants) which may occur in feed fats was prepared as well. This concerns a selection of the contaminants which have been enumerated in the Risk Analysis Feed Fats (Quality series no.). These are:

- arsenic (relevant only for fish oil products)
- nickel (relevant only for hardened fatty substances)
- chlorinated and other fat-soluble pesticides
- aflatoxin B1, possibly ochratoxin A and zealarenon
- dioxins
- PCBs

- Polycyclic Aromatic Hydrocarbons (PAHs)
- mineral oils (alkanes/hydrocarbons)
- polyethylene
- polymerised/oxidised fatty acids
- methyl esters
- insoluble impurities
- lead
- fluorine
- mercury
- cadmium
- chrome
- selenium

The starting point in the selection of the contaminants for which minimum specifications must be developed is the question of whether certain contaminants occur as such in fatty substances or whether they are formed during certain production processes or of which the concentration is increased during the production process.

Heavy metals such as cadmium, mercury and lead, are found only incidentally in fats. As national or international standards are already in existence for these contaminants, the Technical Working Party on Minimum Specifications does not find it necessary to pay extra attention to this. As no problems with selenium, chrome and fluorine are known from the past and in reasonableness are not to be expected in the future either, it has been decided not to discuss these substances in greater detail. Aflatoxin has been discussed in the working party, but as this substance is soluble in water, it is not relevant for fatty substances.

3.3 Action and rejection limits

The current background levels have been taken into account in the determination of the maximum contents of the contaminants in certain cases. In order to urge all parties involved to continue to limit as much as possible the presence of undesirable substances, the instrument of the action threshold has been used by the Technical Committee.

The **action limit** of undesirable substances is significantly lower than the determined maximum content (**rejection limit**).

If the action limit is exceeded, an investigation needs to be conducted into the cause of the contamination and measures must be taken to eliminate or reduce the cause of the contamination.

4 The potential contaminants

4.1 Arsenic

4.1.1 Relevancy

Arsenic occurs in nature all over the world. The sources include: volcanic eruptions, mining industry and arsenic-containing pesticides and (animal) medicaments. Normally speaking, arsenic occurs in foodstuffs in very small quantities only. In reality arsenic occurs in fish oil only. Because of the refinery of raw fish oil a tenfold enrichment of arsenic takes place in the fatty acids.

4.1.2 Avoidance

A world-wide ban has been imposed on the use of arsenic-containing fungicide preparations and arsenic-containing growth promoters. In this way the quantity of arsenic which is present in foodstuffs has already been reduced substantially.

4.1.3 Transfer from feed to animals, humans and environment

The average daily intake therefore depends on the quantity of fish consumed. In Ballin (1994) it is stated that 95% of the arsenic originates from the organic arsenic-betain. This arsenic-betain is inert in the human body and is excreted by the body almost entirely with the urine. The half-life value lies between 6 and 24 hours. Research has demonstrated no biotransformation in humans after the consumption of sea fish or after the intake of a dose of synthetic arsenic-betain in experiments on animals. Exact toxicological data are hardly available. The acute toxicity of arsenic-betain has been investigated in male mice. After an oral dose of 10 g/kg no genotoxic, mutagenic or lethal effects were found. Arsenic may also occur in products such as poultry meat and rice. In poultry meat the arsenic content depends on the share of fish meal in the ration of the animals. In analysis results the arsenic content is expressed almost always in total arsenic (PTW) (Codex, 1995 and Codex, 1996)

4.1.4 Potential hazard for animals, humans and environment

In the past (inorganic) arsenic was used as rat poison. Organic arsenic (which occurs in fish) is far less toxic. This does not alter the fact that arsenic can cause a range of disease symptoms in animals and humans. Among these can be mentioned: acute diarrhoea and tonic and clonic cramps. If arsenic is ingested for an extended period of time, anaemia, paralysis and gangrene of hands and feet may occur. In humans arsenic accumulates in hairs and nails. Inorganic arsenic is carcinogenic.

In 1983 the WHO mentioned in its advice a provisional tolerable daily intake (PTDI) of inorganic arsenic of 2 µg/kg of body weight.

Because of the absence of sufficient toxicological data, this was not done for organic arsenic. The daily oral intake of arsenic may vary rather widely. This depends on the quantity of fish which a person eats. However, the quantity remains almost always below the PTWI.

4.1.5 Background values

The background values which are found in the various fish species (such as herring and mackerel) vary from 4 – 13.5 mg/kg. Refined oil actually contains no arsenic. In the fatty acid fraction, however, the arsenic contents may reach too high values. Fediol is of the opinion that fish fatty acids, fish oil distillates and fish fatty acid distillates no longer ought to be supplied to the feed industry (Fediol, 2001).

4.1.6 Current standard

For simple feed raw materials (referred to below as: feed materials) a maximum arsenic content of 2 mg/kg (ppm) applies in the EU, with the exception of fish or other marine animals for which a maximum arsenic content of 10 mg/kg (ppm) applies.

4.1.7 Available (validated) analysis methods

There is no standard for determining arsenic in oil. The NEN does state however that arsenic can be determined in water with the NEN 6432 method. That method can then be applied to an oil sample as well after the arsenic has been brought into an aqueous environment by means of a destructive step. For the sake of clarity the proposal is to apply NEN 6432 with a preliminary destruction step.

4.1.8 Missing data

None.

4.1.9 Proposed action and rejection limit

	Plant and animal fats and oils	Fish oil
Action limit:	2 mg/kg	10 mg/kg
Rejection limit:	2 mg/kg	10 mg/kg

4.2 Nickel

4.2.1 Introductory remark

The underlying documents which have been consulted often fail to mention explicitly whether metallic nickel (Ni^0), poorly soluble nickel (for example NiO_2) or easily soluble nickel (Ni^{2+} in, for example, NiCl_2 and NiSO_4) is concerned.

Actually, making a distinction between these three categories of nickel is essential because of the varying physical-chemical properties and therefore also the biological/toxicological 'end points' to be expected for these three groups (for example absorption in the digestive tract and intrinsic toxicity or 'hazard'. This is mentioned explicitly wherever possible. If a concentration (mg/kg) or exposure (mg/kilogram of body weight/d) is mentioned, this is expressed, unless stated otherwise, as mg of nickel (MW 58,7).

4.2.2 Relevancy

Nickel occurs naturally in small quantities in some foodstuffs. A discussion is going on whether nickel is an essential element. RIVM and ATSDR think differently about this (RIVM, 2000; ATSDR, 1997). It would have a function in the action mechanism of certain enzymes. The difference between the daily intake which is considered to be necessary and the intake level at which toxicity may occur is rather small.

Nickel does not occur naturally or does not occur naturally in relevant quantities in oils and fats, but it is used as a catalyst for hardening. Ni^0 is used for this purpose and both NiO_2 and Ni^{2+} can be formed. This means that theoretically Ni^0 , NiO_2 and Ni^{2+} (for example as nickel oleate) can occur as contaminants. The occurrence of Ni^0 , NiO_2 and Ni^{2+} has been confirmed from the sector.

4.2.3 Avoidance

The industry has developed techniques to remove nickel from oils and fats. With these techniques the concentration of total nickel can be reduced by refining to a level which is 'acceptable' according to the sector ('guarantee value') of 0.2 mg of total Ni/kg.

4.2.4 Background exposure

The total daily intake (Ni^0 and/or Ni^{2+}) via foodstuffs in the Netherlands is estimated at 0.004 mg/kilogram of body weight/d (RIVM, 2000).

4.2.5 Current standard

There is no EU standard for nickel. This subject was discussed in the EU context a few years ago in response to imports of fatty substances into Denmark from the Far East, and this after the Danish delegation had notified the European Commission of this. The sector itself uses in accordance with the 'Guarantee values for product characteristics of refined oils and fats' a guarantee value of 0.2 mg/kg for refined oils and fats for foodstuffs for human consumption.

4.2.6 Transfer from feed to animals, humans and environment

Transfer to animals can take place via ingestion of nickel by farm animals from feed which has been prepared (partly) with nickel-contaminated feed materials.

Transfer to humans may occur through consumption of foodstuffs of animal origin which have been contaminated in this way. Transfer to the environment is left out of consideration here. For a rough estimate of the quantities that may find their way into foodstuffs of animal origin, use has been made of data such as these have been supplied by the sector, among other bodies (see exposure).

4.2.7 Risks for humans, animals, environment and image

4.2.7.1 Potential risk (hazard)

The most frequently mentioned toxicological effects after repeated oral exposure to Ni²⁺ in nickel salts such as nickel sulphate, nickel chloride, nickel acetate, nickel sulphide and nickel nitrate are effects on the blood image and on organ weights, but also skin reactions. The most critical 'No Observed Adverse Effect Levels (NOAL)' that have been found, all in the administration of NiCl₂ to rats, were NOAEL <0.38 mg/kilogram of body weight/d (Lowest Observed Adverse Effect Level (LOAEL) 0.38 mg/kilogram of body weight/d) for reduced growth; 0.38 mg/kilogram of body weight/d (LOAEL 0,75 mg/kilogram of body weight/d) for increase in leukocytes; 1.2 mg/kilogram of body weight/d (LOAEL 8,6 mg/kilogram of body weight/d) for, among others, ataxia and hypothermia. The lowest once-only dose resulting in dermatitis was 0.009 mg/kilogram of body weight/d. In ATSDR 1997 not even a 'safe value' was derived because application of the customary safety factors on the LOAEL of 0.009 mg/kilogram of body weight/d would result in a safe intake below the normal daily intake. Nevertheless there are limit values, from other reports not consulted. For nickel (Ni⁰ and/or Ni²⁺) a Reference dose (RfD) of 0.02 mg/kilogram of body weight/d (EPA, 1996 in ATSDR, 1997) and a limit value for drinking water of 0.1 mg/l (IRIS 1996 in ATSDR, 1997) apply in the United States. In the Netherlands the RIVM has derived for 'nickel' a TDI of 0.05 mg/kilogram of body weight/d (RIVM, 2000).

The WHO (IARC, 1990 and ATSDR, 1997) has classified nickel compounds (Ni²⁺) as carcinogenic for humans and metallic nickel (Ni⁰) as possibly carcinogenic for humans (not demonstrated but still to be treated as if it were a carcinogen for humans).

The oral absorption of nickel depends on the various ligands (protein binding) and ions (for example sulphate, chloride) that are present, therefore on the matrix, but also on the shape and the valence (Ni⁰, NiO₂ or Ni²⁺). For example, 27% and 0.7% respectively have been reported for Ni²⁺ from Ni²⁺ SO₄ in water and from foodstuffs (ATSDR, 1997). The current assessment reckons, with the impossibility to specify this for the various forms of nickel, with, therefore, an arbitrary percentage of oral absorption of 25% for the transfer from feed to foodstuffs of animal origin.

Recently an RfD of 0.008 mg/kilogram of body weight/d for additional exposure on top of the 'natural' exposure via foodstuffs was proposed recently (Haber e.a., 2000). The difficulty here is that the 'natural' exposure already includes the exposure which is the result of human actions. For this reason this RfD is not used in the current assessment.

As it is assumed that the RIVM evaluation is valid, a Total Daily Intake (TDI) of 0.05 mg/kilogram of body weight/d (RIVM, 2000) or 3.1 mg/person/day at a body weight of 62 kg is assumed. For an assessment of the possible risks for cattle it is assumed that the various species have the same sensitivity as humans.

Exposure

The RIVM estimated the total daily intake (Ni⁰ and/or Ni²⁺) in the Netherlands at 0.004 mg/kilogram of body weight/d (RIVM, 2000). An American report estimated the daily exposure as slightly lower, namely 0.002-0.0024 mg/kilogram of body weight/d (ATSDR, 1997). This corresponds with a recent estimation for Ni²⁺ of 0.002 mg/kilogram of body weight/d via foodstuffs and 0.00003 mg/kilogram of body weight/d via the drinking water (Haber e.a., 2000).

For the calculation of the exposure as a result of contamination of feed materials use has been made for the 'unavoidable' transfer of the 'guarantee value' of 0.2 mg/kg for secondarily refined oils and fats. However, hardened oils, fats and fatty acids without secondary refining are used as well. Higher contents occur in these raw materials. For example, <0.5 mg/kg is mentioned as 'typical' for Ni²⁺. As it has been reported from the sector that even contents of 5 mg Ni⁰/kg of raw material and 20 mg Ni²⁺/kg of raw material may occur, risk indices are calculated with these contents as the upper limit.

Animals

By means of data supplied with regard to mixing percentages etc. and the limit value of 0.2 mg total Ni/kg of raw material it has been calculated that the intake of nickel by cattle can increase to approximately 0.002 mg/kilogram of body weight/d. With the higher contamination levels of 5 mg Ni⁰/kg of raw material and 20 mg Ni²⁺/kg of raw material it has been calculated that this intake may increase to 0.04 mg Ni⁰/kilogram of body weight/day and 0.2 mg Ni²⁺/kilogram of body weight/d.

Humans

The intake of nickel by humans is estimated in a comparable way. It appears from this that by including the consumption of contaminated foodstuffs of animal origin, the intake may increase to 0.018 mg/d at the above-mentioned contamination level of 0.2 mg/kg of raw material and to 2.2 mg Ni²⁺/d at the highest contamination level of 20 mg Ni²⁺/kg raw material.

4.2.7.2 Risks

For an estimation of the possible risks to health, the estimated intake (exposure) at a chosen level of contamination is compared with the toxicological limit value (0.05 mg/kilogram of body weight/d or 3,1 mg/person/day). The unitless result is called the risk index.

Animals

With a number of assumptions the highest risk index for animals appears to be 3.2 (calculated with the total of the highest reported contamination with Ni⁰ and Ni²⁺). This highest risk index is found for contamination of feed for fattening pigs with 20 mg Ni²⁺/kg. If the guarantee value of 0.2 mg/kg is used for the calculation, the intake and thus also the risk index will be lower by a factor 30. In a calculation with 5 mg Ni⁰⁺/kg all risk indices remain below 1.0.

Considering the 'worst case' assumptions (prolonged presence of 20 mg/kg of raw material) and the safety margin already taken into account in the TDI used (0.05 mg/kilogram of body weight/d) the risk indices for animals are considered to be acceptable.

Humans

Once again with a number of assumptions, risk indices of, at the most, 0.7 can be derived for humans as well. This highest risk index applies to the consumption of contaminated pig kidneys. It appears moreover that, if the guarantee value of 0.2 mg/kg is used, the intake and thus also the risk indices will be lower by a factor 30. On the basis of the calculated provisional risk indices ('worst case' assumptions) it is concluded that effects on the health of humans and animals, as a result of the presence of nickel on levels at or below 20 mg/kg of raw material, are not expected.

In addition to the 'preface' it has to be noticed that the principal uncertainties reside in the potential risk (hazard). It cannot be concluded unambiguously from the consulted sources to which form of nickel the RfD relates. It also remains unclear which is the maximum content of NiO₂, which is possibly the most potent form of nickel from a toxicological point of view.

4.2.8 Available (validated) analysis methods

NEN 6371 (replaced, incidentally, by NEN-EN-ISO 8294:1999) for total nickel.

4.2.9 Missing data

Data concerning the contents of NiO₂. Specification of toxicological limit values for the three main forms in which nickel may occur.

4.2.10 Proposed action and rejection limit

Action limit: 20 ppm (fat basis)

Rejection limit: 50 ppm (fat basis)

4.3 Chlorinated and other fat-soluble pesticides

4.3.1 Relevancy of current list standards in fatty substances for feed

The current Dutch standard, which is based on the standards from Directive 1999/29/EU, can still be deemed to be relevant. Copying applicable standards or standards that can be derived for other pesticides from the foodstuffs regulations is not strictly necessary from the viewpoint of risk control.

4.3.2 Avoidance

As far as we know, the greater part of residues of pesticides that may still occur that have been standardised for feed, will concern an unavoidable residue which originates from environmental pollution.

These substances are so persistent that the pollution may remain present in relevant quantities for decades. Therefore it may be necessary incidentally to reckon with avoidable situations of serious local environmental pollution, especially risky raw materials, possibly avoidable use or abuse of banned products.

4.3.3 Transfer from feed to animals, humans and environment

The well-known transfer factors give in most cases no reason for concern about standards being exceeded in animal products if the standards relating to feed are enforced. However, one must reckon with the fact that, strictly speaking, the standard for endrin in feed is not low enough to guarantee the enforcement of the rather low standards that apply for this in poultry products, considering the transfer factor of 10 which has been mentioned for this in the literature.

However, it will be difficult to lower the standard in feed because of the detection limit of the method. In reality, however, there are hardly any problems to be expected here because of the rare occurrence of these residues.

4.3.4 Background values

Only limited data are available about the contents found in the Netherlands in fats for feed preparation. The research program aimed at this of the Product Board Animal Feed (PDV) was downsized because of the low frequency with which the standard was exceeded over the years. The annual reports reveal that in 1999 no residues were found on the 12 examined samples of feed (of which 6 fats, consisting of 2 vegetable fats, 3 animal fats and a sample of fat residues). In 1998 and 1997 residues were demonstrated in most fats examined (15 respectively 26 samples), usually low residues for DDT and sometimes also endosulphan, HCB and the various HCHs and in 1998 the standard for endosulphan in animal fat was exceeded once.

The National Inspection Service for Livestock and Meat (RVV) has also begun monitoring pesticides in feed and raw materials for feed, including fats. It appears from this monitoring that no residues were found, except for endosulphan in soya oil.

It can be concluded from the results that a reasonable degree of monitoring of this group of pesticides is still desirable, and that especially endosulphan in animal and vegetable oils and fats needs to be monitored.

The Federation of the European Oils and Fats Industry (FEDIOL) has had 84 analyses performed for the levels of the 11 pesticides from Directive 1999/29, in crude oils and fats, distillates from the chemical refinery and fatty acids from the physical refinery. Two samples per country of origin were analysed for soya oil, sunflower oil, rapeseed oil, palm (kernel) oil, coconut oil, peanut oil and fish oil. In 38 samples contents just above the detection limit were measured (circa 10% of the standard). Two samples of sunflower oil distillates from the Ukraine and a sample of sunflower oil from Russia exceeded the standard for lindane and HCB. Endosulphan was found as well in the sample from Russia. Pesticides can accumulate in the soil and can be found in the crops many years after the use has been stopped.

4.3.5 Potential risks

Potentially there still is a (very small) risk that the standard is exceeded in the fats, the feed and also in the animal products as a result of this. In reality the real risks have become small (only incidental problems to be expected), and at any rate the consequences for the health of humans have been reduced to nearly zero from this route. This may be different locally in developing countries.

4.3.6 Current standard

Revision does not seem to be necessary for the time being. However, the developments need to be monitored in the setting of standards for foodstuffs and the admissible use, respectively information about contamination (for example with regard to endosulphan).

In the EU the following maximum contents of pesticides have been determined for fats and other feed, based on the detection limits at the moment of establishment (see EU Directive 1999/29).

Undesirable substance	Feed material	Maximum content in mg/kg (ppm) of the feed material, reduced to a moisture content of 12%
Aldrin + dieldrin	Feed materials with the exception of: Fats	0.01 0.2
Chlorinated camphene (toxaphene)	All feed (including feed materials)	0.1
Chlordane	Feed materials with the exception of: Fats	0.02 0.05
DDT	Feed materials with the exception of: Fats	0.05 0.5
Endosulphan	All feed Oil-containing seeds	0.1 0.5
Endrin	Feed materials with the exception of: Fats	0.01 0.05
Heptachlorine	Feed materials with the exception of: Fats	0.01 0.2
HCB	Feed materials with the exception of: Fats	0.01 0.2
HCH Alpha-isomer	Feed materials with the exception of: Fats	0.02 0.2
HCH Beta-isomer	Feed materials with the exception of: Fats	0.01 0.1
HCH Gamma-isomer (lindane)	Feed materials with the exception of: Fats	0.2 2.0

4.3.7 Available (validated) analysis methods

There are suitable measures with which pesticide residues in fats can be measured with a sufficient accuracy. With regard to feed the standard is sometimes on the border of what can still be measured.

4.3.8 Analysis of organic chlorinated pesticides in oil and fat:

After homogenisation of the sample an aliquot is weighed and an internal standard is added. The sample is dissolved in ethylacetate/cyclohexane (1:1 V/V) and is then purified over a High Performance Gel Permeation Chromatography (HP-GPC) system.

The pesticide-containing fraction is isolated and is measured after concentration on a gas chromatograph linked to a mass spectrometer (GC-MS).

It is determined on the basis of retention time and spectral information if the sample to be examined is contaminated with a certain pesticide. After a positive identification the content in the sample can be quantified.

4.3.9 Missing data

A derivative of the standards which are applicable to endosulphan in the vegetable fats (on the basis of the standards for oil seeds) can be useful.

4.3.10 Supplementary research

Supplementary research is not desired.

4.3.11 Proposed rejection limit

The applicable standards of EC Directive 1999/29 can be maintained for this purpose. As said, standards which are suitable for endosulphan in the fat must be derived from the standard for oil seeds.

4.4 Dioxins and polychlorinated biphenyls (PCBs)

4.4.1 Relevancy

Dioxins is a collective name for two subgroups of chlorinated tricyclic aromatic components which have similar chemical, physical and biological characteristics. These are the polychlorinated benzo-p-dioxins (PCDDs) and the polychlorinated-dibenzophuranes (PCDPs).

The total number of chlorine atoms may vary from 1 to 8, so that 75 PCDD congeners and 135 PCDP congeners are possible. There is no technical use for dioxins and therefore they are not produced intentionally (with the exception of scientific research).

Dioxins can be formed in all sorts of combustion processes in, among others, waste incineration plants, cable incineration plants, etc.

Furthermore the presence of PCDD/Ps has been demonstrated in various pesticides, among which 2,4,5-T; 2,4-D; pentachlorinated phenol; hexachlorophene and diphenyl esters, etc.

When PCBs are heated/incinerated in the presence of oxygen, PCDPs can be formed, and these have been demonstrated in commercial PCB mixtures. In addition to the PCDPs formed, traces of PCDDs can also be formed in that PCB mixtures are often polluted with chlorobenzenes which can be converted to the PCDDs. More than 1 million tons of PCBs have been produced since 1929 for electrical, chemical and industrial applications. Production declined strongly after 1980 and in 1984 France and Spain were the only countries in the EU that still produced PCBs. The production of PCB's is based on the chlorination of biphenyls at an increased temperature and in the presence of a catalyst.

A chlorination of 20 to 68 % is achieved, depending on the conditions. The product formed is a mixture of several congeners. Commercial products are purified even more by means of filtration and distillation. Unfortunately some traces of PCDPs (concentration 10-50 ppt), among other substances, always remain behind. PCBs are used mostly in electrical components such as condensers, transformers and a heat exchangers and in various kinds of plastic. The PCBs in condensers have been replaced with mineral oil, silicone oil, etc., since the end of 1970. The emission into the environment used to be caused mainly by the use in plastics and by spillage from industrial systems and/or illegal dumping. The total emission has declined strongly in the last decade.

The "Belgian" dioxin crisis was caused through the fat used in the preparation of feed being polluted with a PCB mixture which in turn was polluted with dioxins (mainly PCDPs).

The toxicity of dioxins and the dioxine-like PCBs is determined by the activity of the various PCDD/Ps on the immune system. It appears that the activities of the various congeners differ rather strongly from one another, this has resulted in a selection of 17 PCDD/Ps which show the highest toxicity and are therefore the most toxic. The relative activity of these 17 congeners has been determined in respect of 2,3,7,8-TCDD, this is the congener with the highest activity on the immune system.

4.4.2 Avoidance

There are a number of sources that may be of relevance for animal products. In addition to the concentrate, a possible contamination of the surface water and of the grass / hay / silage is of relevance for dairy cattle. By improving the processes used in the waste incineration plants, for example separate incineration, higher temperatures, building special filters into chimneys, etc., the industry has succeeded in drastically reducing the emission of dioxins in most situations. This has resulted in a substantial reduction of the dioxin content in milk.

The emission of dioxins and, combined therewith, the direct contamination of agricultural products obviously plays a role as well in the feed used. In addition, it has appeared that the use of recycled material may result in increased values.

Examples of these are destruction fats, clay minerals, limestone, choline chloride, etc.

A number of feed raw materials such as fish oil and fish meal make a permanent contribution to the increase of the background contamination with dioxins as well as PCBs. In addition, some production processes, such as the drying of grass, also make a contribution to the dioxin content. This often happens because the material to be dried is brought into direct contact with polluted flue gases.

The background content of dioxins in animal products can also be reduced by using raw materials which are unsuspected (for example fish oil / fish meal from South America) and by omitting the processing of residual or recycled materials or by controlling these flows adequately.

Production processes must also be checked for critical points. Natural gas must be used as a fuel for drying processes. The use of PCB-containing oil in technical systems for the production of feed materials has to be banned.

4.4.3 Transfer from feed to animals, humans and environment

Research has demonstrated that the dioxin content in milk increases rapidly after the animals had been given dioxin-contaminated feed. After lightly contaminated citrus pulp pellets (CPP) had been given for two weeks, the standard of 6 pg i-WHO TEQ/gram of fat was exceeded already.

4.4.4 Background values

Analyses were performed within the context of FEDIOL to determine the dioxin contents in crude oils and fats, distillates from the chemical refinery and fatty acids from the physical refinery. In the crude oils, dioxin is found only in fish oil (10.7 and 5.73 pg/g). In the 6 samples of distillates values are measured between 0.32 and 5.54 pg/g with fish fatty acids as a peak with a content of 212.6 pg/g. After analysis of the five corresponding crude oil samples, the dioxin appeared to migrate from the bleaching earth used to the oil (crude oil contents 0.11-0.32 pg/g).

It was then decided to accept only bleaching earth with a maximum content of 1 µg/g from then on.

4.4.5 Potential risk

The Scientific Committee for Animal Nutrition has prepared a report with the title:

“Dioxin Contamination of feedingstuffs and their contribution to the contamination of food of animal origin”. This English-language report can be found on the website of the European Commission:

http://europa.eu.int/comm/food/fs/sc/scan/out55_en.pdf

4.4.6 Current standard

Dioxins

In accordance with the national legislation the content of dioxins in feed fats is not allowed to be higher than 6 picograms per gram 2,3,7,8-TCDD equivalent.

PCBs

The Fats in Feed Regulation of 21 January 2000 (LNV), reference TRCJZ/2000/697 stipulates that the content of PCBs in frying oils and fats intended for feed is not allowed to be higher than 0.2 mg/kg (ppm). For the other oils and fats the standards have been laid down in the PDV Decision on GMP Feed Sector 1999 amendment of 18 October 2000: animal fats with the exception of fish oil: 0.25 mg/kg (on the basis of fat, rejection limit);

4.4.7 Available (validated) analysis methods

The quantitative determination of polychlorobiphenyls has been the subject of a large number of studies in recent years.

After extraction and purification the final measurement takes place by means of a gas chromatograph which is equipped with an Electron Capture Detector (ECD) or with a mass spectrometer. The study is concerned with the presence of the 7 indicator PCBs (CB 28; 52; 1001; 118; 138; 153 and 180).

Systems that combine purification and measuring have now become available. In this way the analysis of the seven indicator PCBs has been automated to a high degree and large series can be measured in a relatively short period of time.

The quantitative determination of dioxins and dioxin-like PCBs is very complicated and time-consuming and expensive standards are needed. With the exception of the environmental samples, the analysis focuses on the determination of the seventeen most toxic congeners. These are the congeners of which the hydrogen atom has been replaced at least in the 2,3,7,8 position with a chlorine atom.

At first a known quantity of the seventeen congeners to be determined, but then labelled ^{13}C , must be added to the sample to be examined. Next an extraction takes place, if necessary, followed by extensive purification. The purification is aimed at removing possibly interfering compounds such as PCBs, pesticides and naturally occurring relatively small molecules which may be present in a 10^4 to 10^6 higher concentration than the dioxins themselves and which may drastically disturb the eventual determination. Next the measurement must be performed on a gas chromatograph which is connected to a high resolution mass spectrometer.

The analysis yields contents per measured congener (therefore of the seventeen 2,3,7,8 substituted compounds) expressed in pg/gram of fat or product. The contents of the individually measured congeners are then multiplied by the corresponding Toxicity Equivalent Factors (TEF). In this way the content of each congener is expressed as if it were the 2,3,7,8-TCDD, this being the most toxic congener. Next all these converted values are totalled and the content is expressed in pg i-TEQ/gram of fat or gram of product and is tested against the proposed standard.

In addition to the PCDD/Ps there are also a number of dioxin-like chlorobiphenyls which must be included in the future in the assessment whether a product is suitable for human consumption or is allowed to be used as feed (see Appendix 2)

In addition to these so-called reference methods, there are also a number of manufacturers who offer screening tests. A number of tests are based on immunological techniques.

Because of the limited sensitivity, these are suitable only for screening relatively highly contaminated environmental samples. In addition, two firms are introducing a bio-assay in the market, the so-called CALUX test.

The CALUX assay is a fast screening assay with which dioxins and related substances are traced on the basis of their toxic effect. Specially developed cells are exposed to extracts and react to dioxins by creating the enzyme luciferase. The concentration of luciferase is thus a measure for the quantity of dioxins. The processing of samples is much simpler and quicker than that for the GC/MS method and can take place in large series. As the test can also react, in principle, to a limited number of other substances, there is a small chance of false-positive results and positive results must be confirmed by means of a GC/MS.

A negative result points at concentrations of dioxins below the normal background contamination. So far no substances are known that are capable of suppressing the response of the test and thus of creating of a false-negative result. Research on milk fat and citrus pulp supports this assumption.

A positive result in the CALUX assay points at the possible presence of dioxins or certain PCBs (with a dioxin-like action). However, the possibility always exists that a still unknown substance is present which may not necessarily have to be an environment contaminant. Therefore confirmation with the reference method is necessary to obtain a conclusive result.

The test is very sensitive to fats as well as feed and shows clear and reproducible differences between a blank pulp sample and a sample in which 500 pg i-TEQ/kg has been measured with the GC/MS method.

The test also shows clear differences between a blank fat (animal or vegetable) and a sample in which 2 to 3 pg i-TEQ/g of fat has been measured with the GC/MS method.

Reporting will take place in the first instance in terms of negative, slightly increased or suspect.

Next to the actually measured signal can be compared in the QA samples and in the suspect samples with the GC-HRMS results. A downside of the CALUX test is that no information is obtained about the dioxin pattern.

4.4.8 Missing data

The SCAN report indicates that no unambiguously validated analysis method exists yet that has been tested by means of a ring test in several laboratories. Suitable reference material is lacking for performing a quality inspection by laboratories. Nor has it been established which congeners contribute to which degree to the toxicity.

4.4.9 Proposed rejection limit

An unambiguous, widely applicable, validated analysis method to determine the dioxin content in vegetable oils and fats does not exist yet. It is advised to develop such a method first before standards are adopted. In addition, the analysis method must be accompanied by a calculating method for the degree in which the various congeners are weighed in the calculation of the toxicity.

There is no reason to deviate from the existing, recently introduced standards for PCBs. It is recommended, however, to pursue harmonisation on a European level.

As far as dioxin standards are concerned, the European Commission has made a proposal for dioxin standards for a number of foodstuffs and feed materials. For feed fats these are:

- animal fat 2 pg WHO-PCDD/F-TEQ/g, with the exception of fish oil.
- fish oil 6 pg WHO/PCDD/F-TEQ/g
- vegetable oils and by-products: 0.75 pg WHO/PCDD/F-TEQ/g

During voting rounds in June 2001 in the Standing Committee on Foodstuffs and the Standing Committee on Feed, respectively, there appeared to be no qualified majority.

4.5 Polycyclic aromatic hydrocarbons (PAHs)

4.5.1 Relevancy

PAH contamination is relevant for soya oil, rapeseed oil, sunflower oil, coconut oil and its by-products and fish oil and its by-products.

4.5.2 Avoidance

The main products are, among others, products that have been contaminated by direct emission. For the agricultural sector especially the deposit on grass is of relevance, as well as the deposit on large-leaved crops (spinach, curly cabbage, etc.).

As far as feed is concerned, the risk resides mainly in those raw materials which have been obtained after drying, such as grass pellets, citrus pulp, copra etc.

Another possible source is the use of technical fats that may have been contaminated with PAHs as a result of a treatment. The background content of PAHs in animal products can be reduced by using raw materials which are unsuspected and by omitting the processing of residual or recycled materials or by controlling these flows adequately.

Production processes must also be checked for critical points. Natural gas must be used as a fuel for drying processes.

4.5.3 Transfer from feed to animals, humans and environment

Data concerning the transfer of PAHs from feed to animal products are not available. Available data in kinetics and metabolism of PAHs in mammals are extremely scarce and qualitative only. PAHs are absorbed well from the gastrointestinal tract; in laboratory animals the absorption is > 50 %. Although PAHs are rather lipophile (so that a certain accumulation could be expected), they are metabolised relatively quickly into hydroxylated products and conjugates, which are excreted via urine and/or of faeces. The WHO concluded in 1998 that the turnover of PAHs in the body is quick and that no accumulation occurs.

Considering the problems which have arisen, it seems to make sense to study the transfer of PAHs in lactating bovines. To that end bovines will have to be fed with contaminated materials, after which contents in the milk can be determined with a recently developed, very sensitive GC/MS method. In addition the degradation of a number of PAHs can be investigated by means of liver microsomes (possibly liver slices).

4.5.4 Background values

To be supplied by Fediol (see also Missing data)

4.5.5 Transfer

RIKILT and RIVM have made an estimation of the exposure to and risks of intake of PAHs through the consumption of foodstuffs.

The ("worst case" for the average consumer) estimated intake of benzo(a)pyrene equivalents (BaPEQ) as a consequence of the consumption of contaminated milk and milk products of 2.9 ng/kilogram of body weight/day results, at a lifelong average consumption of this milk and milk products, to an additional risk of cancer of 0.6 per 10⁶ (namely 2.9/5 per 10⁶).

The more realistic estimation on the basis of the MilCons model leads, at a lifelong average consumption, to an additional risk of cancer of 0.2 per 10⁶ (namely 1.1/5 per 10⁶).

The actual risk will be smaller because:

- the assumption is justified that the exposure of the bovines takes place during a limited period only;
- bovines which have consumed PAH-contaminated feed for some time, will have metabolised and excreted these PAHs within a few days after the termination of the exposure, so that the animal products, including the milk, will no longer be contaminated;

The actual exposure of the consumer will therefore be limited to a few weeks at the most.

Under these circumstances the contribution of this consumption to the occurrence of cancer can be considered to be negligible.

4.5.6 Potential risk

See transfer

4.5.7 Current standard

There are no standards for PAHs at this moment. One of the reasons for this is that the carcinogenicity studies published so far are unsuitable for a quantitative risk assessment. For this reason the Dutch RIVM recently conducted an oral chronic study with benzo(a)pyrene in rats. A provisionally derived standard, achieved by linear extrapolation and based on 1 extra case of cancer per one million people at a lifelong exposure corresponds with 5 ng/kg of body weight per day.

Residue limits might be established on the basis of this standard, but this has not been done yet. On the other hand, directive values of 1, 5 and 25 µg/kg of product for benzo(a)pyrene, heavy PAHs and total PAHs, respectively, are currently being used for fats and oils intended for human consumption. Taking into account the strong degradation of these substances, a standard of 50 µg/kg could be assumed for the time being for feed and feed materials. In addition, an action limit of 15 µg/kg could be applied. If the action limit is exceeded, a further investigation is started into the cause of the contamination. In order to further substantiate the standard, research would have to be conducted into the behaviour of PAHs and toxicologically relevant degradation products in farm animals.

4.5.8 Available (validated) analysis methods

In the Belgian-Dutch consultations a detailed description of the GCMS and HPLC methods in the analysis for PAHs (see appendix 3) has been elaborated. Standards have been formulated in the meantime which will be sent to the European Commission for notification before long.

4.5.9 Missing data

Within the framework of FEDIOL it has been arranged to perform joint analyses for the contents of PAHs in crude oils and fats, distillates from chemical refinery and fatty acids from physical refinery. For these oils and fats (including by-products), two samples will be taken (per origin). The purpose of the study is to determine to what extent an enrichment of these components has taken place in fatty acids or distillates versus the crude oils / fats.

For this part of the FEDIOL study the results of the Dutch/Belgian experts' consultation on PAHs in fats or fatty acids were awaited first, so that the validated method can be used. The analyses will be carried out per mid-2001.

4.5.10 Proposed action and rejection limit

Action limit 15 µg BAPEQ/kg (on fat basis)

Rejection limit 50 µg BAPEQ/kg (on fat basis)

Appendix 3 contains a list of proposed TEF values for polycyclic aromatic hydrocarbons.

4.6 Polyethylene

4.6.1 Relevancy

The risk inventory and risk analysis with regard to fats and oils as a raw material for feed (TNO report V 99.858, 2000) have demonstrated that polyethylene standards are relevant for those fat flows that make use of synthetic packing materials. This is the case of the production of animal fats and of the processing of recycling fats (frying fats, faulty productions, returned products).

4.6.2 Avoidance

The content of polyethylene (PE) can be very low if the packing materials are removed carefully. A supplier of fats to the feed and food industry must not process prepacked (returned) meat and meat products and the animal waste packed in plastic as a whole, but must carefully remove the packing material. Obviously this also goes for the prepacked (returned) other fats and oils (margarine tubs, packed frying fat, etc.).

4.6.3 Background values

In a recently performed inventory-taking study (KDD, 2000) the polyethylene content was examined in different kinds of fat. No polyethylene was found at all in vegetable fatty acids and in vegetable fat. Very small quantities were found in vegetable oil (22 mg/kg) and in frying fat (12 mg/kg).

The polyethylene content in the other samples of fat intended for feed varied from 11.5 to 1455 mg/kg (average 357 mg/kg).

It appears from data from Dutch rendering plants that the PE contents of the animal fat produced oscillate around 100 ppm. It is indicated by the oils and fats branch that fats of foreign origin may contain high PE levels fairly often.

4.6.4 Current standard

In the GMP regulation feed sector a maximum limit value of 500 mg/kg of fat basis applies. There is no EU legislation for polyethylene.

4.6.5 Transfer from feed to animals, humans and environment

In the early 1980's some experiments were carried out in poultry to explore the consequences of the oral intake of PE. In the processing of fat with 275 mg/kg of polyethylene, 25 mg/kg of polyethylene was found in broiler feed (Anonymous 1980). In the muscular tissue, the (sub)cutis and cloaca fat of the chickens (which had been given the PE feed for four weeks) no polyethylene could be found. In another experiment polyethylene-containing (17 mg/kg, 170 mg/kg on fat basis) meal for laying hens was fed to laying hens for 2 weeks. Indiscernible contents of polyethylene were found in the egg yolks (Anonymous 1982).

The conclusion is that in poultry no intestinal resorption of polyethylene takes place after oral administration thereof during a number of weeks.

4.6.6 Potential risks for humans, animals, environment and image

It can also be concluded from the above-mentioned experiments that oral absorption of small quantities of polyethylene in poultry has not resulted in health aberrations.

4.6.7 Available (validated) analysis methods

Within the GMP regulation for the feed sector it is indicated that regulation NEN 6355 (1985) can be used to analyse polyethylene. NEN 6355 (1985) has also been accepted by the NNI (the Dutch Standardisation Institute) as a Dutch standard.

4.6.8 Missing data

None.

4.6.9 Proposed action and rejection limit

Rejection limit: 500 ppm (on fat basis)

The risks of polyethylene for animals, humans and the environment do not or hardly exist. However, because of the fact that the occurrence of polyethylene is (technically) avoidable and the presence of polyethylene in feed materials may harm the image of the feed sector, a strict action limit has been chosen. In this way the producer of feed fats is urged to avoid and restrict the presence of polyethylene as much as possible.

4.7 Methyl esters

4.7.1 Relevancy

Methyl esters occur in transesterified fats.

4.7.2 Avoidance

Many esters, including methyl esters, are found in nature as aromatic and flavouring substances. Methyl esters as referred to in this document are formed in a refinery operation as a by-product of the transesterification process of oils and fats. As such they might find their way into the food chain via the raw materials for feeds. The composition is a reflection of the fatty acid composition of the transesterification mixture. This is based usually on (hardened) talc, palm oil, coconut oil and palm kernel oil. This concerns more than 15 saturated and unsaturated, especially C12-C22, methyl esters. This therefore means a large range of saturated and unsaturated methyl esters of various chain lengths (SDAMEC (2000) and communications from the sector).

Methyl esters are also released by the deodorisation of various products (by means of distillation). The consequence is that enrichment of methyl esters takes place in remaining fatty acids and distillates (communications from the sector).

4.7.3 Background values

Although no data are available about contents of methyl esters in fatty acids and distillates, it is indicated by the sector that this may lie between not demonstrable and the 10% methanol/fatty acid mass ratio.

4.7.4 Current standard

There is no national or EU legislation in this field. However, the Scientific Committee for Food (SCF) suggested in 1996 to the European Commission to exclude four methyl esters from the list of admissible previous cargoes for the bulk transport by sea of edible oils and fats. These were methyl laurate (C12), methyl palmitate (C14), methyl stearate (C16) and methyl oleate (C18). The European branch organisation for oleochemistry (APAG) then sent a 'position paper' to the Commission, in which the safety of methyl esters was discussed (APAG 1997). It has been heard from the sector in the meantime (2001.01.05) that the SCF has renounced its proposal (see also 'Potential risk').

4.7.5 Transfer from feed to animals, humans and environment

These methyl esters can find their way into the food chain through contamination of feed materials with methyl esters via the sources which have been mentioned above. There are no quantitative data about this transfer (see also 'Potential risk').

4.7.6 Transfer from feed to animals, humans and environment

Potential risk (hazard)

Not much more is known currently than that two completely saturated methyl esters have been admitted by the U.S. FDA as flavouring agents (methyl laurate and methyl myristate) and that two partially unsaturated methyl esters (methyl linolate and methyl linolenate) have the GRAS status. It has been written about methyl oleate that after topical administration there are weakly mutagenic properties and a weak tumour promoter activity for skin tumours (SDAMEC, 2000). The intrinsic toxicity of completely saturated methyl esters is possibly small. Unsaturated methyl esters on the other hand might have a relatively higher intrinsic toxicity.

The reason for the proposal to exclude methyl esters from the list of admissible previous loads for bulk transport by sea of edible oils and fats (for human consumption) seems to be the absence of data rather than the availability of indications for unacceptable risks.

It has to be noticed that it is expected that methyl esters will hydrolyse rather easily in the gastrointestinal tract or in the blood of farm animals into methanol and a fatty acid residue (all sorts of esterases). It is therefore expected that the systemic exposure of farm animals will mainly concern methanol and fatty acids.

In the literature a human exposure of 20 mg/kilogram of body weight/d is qualified for methanol as a non-significant risk (EHC, 1997). Under the assumption that humans and animals do not differ in sensitivity, this value is used in this document as a reference value.

4.7.7 Exposure

Animals

The systemic exposure to methanol is considered to be the most relevant. On the basis of weight this would mean, under the assumption that the methanol/fatty acid ratio is approximately 1/10 is, that raw materials eventually contain, by weight, approximately $1/10 * 10\%$ (w/w) = 10 g of methanol equivalents/kg. Further calculations with mixing percentages, feed consumption, etc., teaches that, expressed per kg of body weight, the highest intake is to be expected in fattening pigs, namely 80 mg methanol/kilogram of body weight/day.

Humans

The exposure of humans is nil because methyl esters are degraded completely via catabolism in the exposed farm animals.

In order to obtain a very general impression of the situation, the highest possible, above-mentioned intake of 80 mg methanol/kilogram of body weight for fattening pigs has been compared with the reference value. This leads to a risk index of 4.0.

The systemic exposure of farm animals as a result of the intake of methyl esters will consist mainly of fatty acids and methanol. The possible exposure to methanol is considered to be the most relevant from the viewpoint of health. In a 'worst case' assumption a maximum exposure is expected of 80 mg of methanol/kilogram of body weight/day for fattening pigs. Considering the 'worst case' assumptions and the probably incidental character of this exposure scenario, the calculated risk index of 4 is considered to be acceptable.

Humans

The risk for humans is nil because the exposure will be nil.

4.7.8 Available (validated) analysis methods

No validated analysis methods are available to our knowledge. The analysis of fatty acids for methyl esters is performed by means of gas chromatography with reference compounds or by means of mass spectrometric detection.

4.7.9 Missing data

None.

4.7.10 Proposed action and rejection limit

On the basis of the calculated 'worst case' risk indices it is not necessary from the viewpoint of animal or human health to determine action or rejection limits below 10% (w/w) for feed materials. Higher values do not occur in reality. Moreover, no validated method is available. Therefore no standards are imposed for methyl esters.

4.8 Hydrocarbons C10-C40

4.8.1 Relevancy

Hydrocarbons consist mainly of alkanes, aromatics and other unsaturated hydrocarbon compounds. The entire series of hydrocarbons does not normally occur in fats. However, the fats can be contaminated with hydrocarbons originating from, for example, mineral fuels, used engine oils or transformer oils. Pollution during transport by unacceptable previous cargoes constitutes the greatest risk in this respect.

Hydrocarbons may be present in feed because of the use of contaminated (recycled) animal and vegetable fat or oil. This is undesirable because it possesses toxic properties, whether or not because of the presence of specific ingredients (PAHs, nitrosamines, chlorinated paraffins, and formaldehyde) (Hard, 2000). The non-substituted hydrocarbons probably constitute the least toxic component of the waste product.

4.8.2 Avoidance

Hydrocarbons such as mineral fuels do not occur naturally in edible oils and fats. However, alkanes which are also characteristic for mineral products do occur naturally in fats. Also other hydrocarbons (squalane, squalene, degradation products of betacarotene, etc.) occur in edible oils and fats.

4.8.3 Background values

Alkanes (hydrocarbons) occur naturally in fats.

The nutrition contains hydrocarbons as a result of the biosynthesis of hydrocarbons in crops on the land and in the water and in animal species and as a result of the pollution of foodstuffs such as fish and sea fruits as a result of geological activities, drilling for oil, oil and petroleum leaks, and the combustion of petroleum and other fossil fuels. Saturated and unsaturated n-alkanes with a chain length of C15, C17, and C21 are predominant in marine organisms, whereas saturated n-alkanes with a chain length of C27, C29, and C31 are typical for crops on the land (SCF, 1995).

The greater part of the hydrocarbons occurring naturally consists of olefins (alkenes). In natural products paraffins with an odd number of carbon atoms occur much more frequently than paraffins with an even number of hydrocarbons (Grob e.a., 2001).

TNO Nutrition has analysed 144 monsters of vegetable and animal fats/oils of different origins for the presence of alkanes that are characteristic for mineral oil (Van Rooijen, 2000). This concerned 'non-polluted' samples, to determine the naturally occurring contents of alkanes in the various fats. Fats which are used in feed include crude vegetable oils/fats, melted animal fats, fatty acid distillates originating from the chemical and physical refinery of vegetable oils/fats, vegetable and animal fatty acid residues originating from oleochemistry and used frying fats.

It is observed that, in addition to the fatty acids produced nationally, relatively large quantities of mixed fatty acids are imported and used in feed.

In some countries the use of paraffin oil is allowed for the preparation of mixtures of minerals and chemicals as additives (Grob e.a., 2001).

4.8.4 Current standard

There is no EU or national legislation for hydrocarbons (or mineral oils in particular) in feed materials.

4.8.5 Transfer from feed to animals, humans and environment

Because of the possible presence of hydrocarbons in fats intended for feed production, a transfer of substances which may occur in (waste) mineral oils to farm animals, to products of animal origin and to humans is possible.

4.8.6 Risks for humans, animals, environment and image

Because of the possible presence of hydrocarbons in fats intended for feed production, a transfer of substances which may occur in (waste) hydrocarbons to farm animals, to products of animal origin and to humans is possible.

Potential risk (hazard)

Lubricating oils have a laxative effect when ingested orally (IPCS, 1982). Absorption of hydrocarbons from the gastrointestinal tract is low. Almost the complete quantity of ingested 'food-grade' hydrocarbons leaves the body unchanged in de faeces. Only 1-5% is absorbed as such via the intestinal wall (IPCS, 1982).

Mineral oils have a low acute oral toxicity (Clayton and Clayton, 1994; IPCS, 1982).

4.8.7 Exposure

De EU Scientific Committee for Food (SCF, 1995) indicates that it appears from the available data on animals and humans that certain mineral hydrocarbons and synthetic oils and waxes accumulate when doses are received repeatedly and cause effects which are not limited to local reactions but which also point at systemic toxicity in animals. The various oils and waxes show a similar toxicity pattern (effects mainly on liver and lymph nodes), but differ in the intensity of the effects. All tested mineral oils and waxes caused a significant effect in rats at a concentration of 20 g/kg of diet, some products already caused effects at 200 mg/kg of diet effects and a few already at 20 mg/kg of diet. In the tested mineral and synthetic hydrocarbons which accumulated, the accumulation was usually the highest in the substances with the strongest toxicity and the lowest in the substances with low or no toxicity. The SCF (1995) concluded that the quantity of short-chain substances with a low molecular weight which is stored and which is excreted only slowly by the body, will eventually be decisive for the occurrence or non-occurrence of toxicity. All studies show that female rats are more sensitive than male rats (SCF, 1995).

Semichronic, oral studies with repeated exposure to strongly purified white hydrocarbons showed no adverse effects in dogs (Beagle) and rats (Long-Evans) up to the highest dose (1500 mg/kg of diet) (Smith e.a., 1995).

In a study by Firriolo¹⁷ e.a. (1995) with a paraffin white oil with a low viscosity, NOAELs of < 2 g/kg (weight and histopathology mesenteric lymph nodes and liver) and 2 g/kg (inflammation cells liver at 20 g/kg) were determined for Fischer-344 and Sprague-Dawley rats, respectively. Diet studies with mineral white oils and waxes show inflammation effects in Fischer 344 rats, but not in other rat species or dogs (Miller e.a., 1996). F344 rats turn out to be more sensitive to mineral hydrocarbons than other rat species. However, there is no information about whether humans are more sensitive or less sensitive to mineral hydrocarbons than F344 rats (SCF, 1995).

Various Ames tests with cycloalkane mineral oils (with a high viscosity) or with lubricants or with recycled products gave a limited degree of mutagenity (Granella e.a., 1995).

No data are available about the embryotoxicity and teratogenicity of mineral oils (IPCS, 1982).

In a carcinogenicity study with a liquid paraffin with an average viscosity in Fischer 344 rats (Shoda e.a., 1997) no test substance-related tumours were found. In an oral chronic study (14 months), in which 0.2 mg of highly purified diesel engine lubricating oil/rat/day was given (40 rats), only 2 rats developed colon mucosa hyperplasia and 1 rat developed an adenocarcinoma in the colon (IPCS, 1982). In an oral chronic study (500 days) with 'food-grade' hydrocarbons in rats (2% w/v), no toxicologically relevant effects were found (IPCS, 1982). The IARC (1987) 24 has classified mineral oils as 'carcinogenic for humans' when untreated or lightly treated oils are concerned and as 'not classifiable as far as its carcinogenicity for humans is concerned' in the case of highly purified oils (ACGIH, 1991).

This classification is based on findings after dermal and inhalatory exposure to mineral oils.

Fat pneumonia was found in humans after a prolonged oral intake of mineral oils (Hard, 2000).

The SCF has determined a temporary group ADI for human consumption of white paraffin oils with 25 C-atoms or more (at the 5% boiling point), a molecular weight of 480 or more (corresponding with C₃₂), and a viscosity of no less than 8.5 mm²s⁻¹ (centistokes) at 100°C. This ADI is 0 – 4 mg/kilogram of body weight/day (SCF, 1995 and 1997). Insufficient data are available to substantiate the safety of other mineral oils (SCF, 1995). Considering, however, the nature of the toxicity of other mineral oils, it is not expected that low residue levels will result in health problems (SCF, 1997).

4.8.8 Missing data

None

4.8.9 Available (validated) analysis methods

Various descriptions are available of methods for determining alkanes that may be indicative for the presence of hydrocarbons in fats.

These methods are essentially similar and make use of purification by shaking with silica followed by GC-FID analysis (Schonewille, 2000) or the purification of the fat takes place over alumina columns followed by GC-FID analysis (CCL, 1999)¹ or a GC-MS method (Schonewille, 2000).

4.8.10 Proposed action and rejection limit

Mineral oils do not occur naturally in vegetable or animal fats. The analysis method for determining fat samples that may be contaminated with hydrocarbons is based on the measurement of alkanes. However, alkanes that may be characteristic for hydrocarbons may also occur naturally in fats. To determine the background values of alkanes in vegetable and animal fats, the naturally present alkane contents in 'not-polluted' samples were determined and converted to fictitious contents of hydrocarbons (% m/m) (Van Rooijen, 2000). On the basis of the calculated levels of hydrocarbons in the not-polluted samples, limit values have been determined above which a sample is considered as actually contaminated.

As mineral oils do not normally occur in fats and as there are no reasons to tolerate contamination of feed with mineral oils, it is proposed to put the action limit on a par with the rejection limit. Considering the fact that for animal fat (with the exception of crude fish oil) and vegetable oil (with the exception of sunflower oil) the hydrocarbon contents remained below the detection limit, an action/rejection limit of 0.04 % (m/m) is proposed.

For vegetable fatty acids (with the exception of sunflower fatty acids), mixtures of fatty acids and crude fish oil, an action/rejection limit of 0.3 % (m/m) is proposed. For sunflower oil and sunflower fatty acids an action/rejection limit of 0.1% (m/m) is proposed.

Because of the fact that in none of the samples of used frying fat hydrocarbon contents are determined that are above the detection limit of 400 mg/kg, it is proposed to use an action and rejection limit of 400 mg/kg.

Table: Proposed action and rejection limits for crude oils and fats for the feed sector

Group of substances	action/rejection limit (% m/m)	action/rejection limit (mg/kg)
Animal fat (with the exception of fish oil)	0.04	400
Vegetable oil (with the exception of sunflower oil)	0.04	400
Vegetable fatty acids (including mixtures of fatty acids)	0.3	3000
crude fish oil	0.3	3000
Sunflower oil and sunflower fatty acids	0.1	1000

4.9 Insoluble impurities

4.9.1 Relevancy

Insoluble impurities (dirt) are only relevant in reality for melted fats originating from ruminants and their by-products such as fatty acids.

Incidentally, it is true that the definition is determined especially by the analysis method. For animal fat the content of insoluble impurities is determined by means of NEN-EN-ISO 663.

4.9.2 Avoidance

An adequate purification process, by means of the well-known process techniques such as filtration and/or centrifugation and/or coagulation, results in acceptable levels of insoluble impurities of max 0.15%.

4.9.3 Transfer from feed to animals, humans and environment

By means of precaution, specified high risk material (SRM) is not brought into the feed chain (2000/418/EC). The use of carcasses in feed has been banned in the entire EU since 1-3-2001 (2001/25/EC).

4.9.4 Background values

See Transfer from feed to animals, humans and environment

4.9.5 Potential risk

The processing of contaminated bovines involves potential risks. In order to exclude these risks, SRM originating from bovines is excluded from the feed chain. In addition, animal fats which are produced in the EU for processing in feed, originate exclusively from animals approved by veterinarians.

4.9.6 Current standard

A maximum content of 0.15% for melted fats originating from animal by-products of ruminants has applied for insoluble impurities since 1 January 2001 (see Council Order 1999/534/EC).

4.9.7 Available (validated) analysis methods

The content of insoluble impurities in animal fat is determined in accordance with NEN-EN-ISO 663 'Animal and vegetable fats and oils -Determination of insoluble impurities content' (1995), with the exception of the defatting of the filter. This is done by means of a Soxhlet apparatus as described in NEN 1046. For this purpose it is necessary to use a slightly larger filter (diameter 185 mm). Furthermore, to increase the accuracy of the test result, the filter (with and without dirt) is weighed up to a reading accuracy of 0.1 mg (rather than up to 1 mg) and the weighing box with filter (with and without dirt) is cooled down in an exsiccator for a fixed period of time.

4.9.8 Missing data

None

4.9.9 Proposed rejection limit

Enforcing the current standard (see current standard setting).

4.10 Polymers

There is no immediate reason to formulate standards for polymers. It is recommended, however, to conduct further research. TNO Nutrition has been asked to submit a proposal for a literature study in order to determine which components are formed and to which degree these have an adverse effect on health.

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Abbreviations

AAFCO	Association of American Feed Control Officials
ADI	Acceptable Daily Intake
ATSDR	Agency for Toxic Substances and Disease Registry
AVI	Waste Incineration Plant
CPP	Citrus pulp pellets
EHC	Environmental Health Criteria
GRAS-status	Generally Regarded as Safe
IARC	International Agency for Research on Cancer
KDD	Feed sector quality department
LOAEL	Lowest Observed Adverse Effect Level
MVO	Product Board for Margarine, Fats and Oils
NOAEL	No Observed Adverse Effect Level
PDV	Dutch Feed Product Board
RfD	Reference Dose
RIVM-CSR	Dutch State Institute for Public Health and Environment
RVV	Dutch State Institute for the inspection of Cattle and Meat
SDAMEC	The Soap and Detergent Association Methyl Esters Consortium
TDI	Tolerable Daily Intake
WHO	World Health Organisation

Appendix 1: Composition of Technical Working Party for Minimum Specifications for Feed Materials

L. Vellenga	Product Board Animal Feed (Chairman)	
Mrs T. van Acker	Product Board for Margarine, Fats and Oils (MVO) (Secretary)	
	[until 31 May 2000]	
A. Baars	RIVM	
F. Bergmans	Product Board MVO	
C. Blomsma	Product Board MVO (Secretary)	[as of 1 August 2000]
G. van den Bosch	CCL (Compound Feed Industry)	
Mrs C.N. Groeneveld	TNO Nutrition	
W. de Groot	Unimills (VERNOF)	
R. Hiel	Product Board MVO	
A. Hinze	Uniqema (Oleochemical industry)	
G. Houben	TNO Nutrition	
C. Meershoek	VERNOF	
M. Mengelers	Rikilt	
J. Spek	ADM Europoort (VERNOF)	
W. Spring in 't Veld	Handelsonderneming Technivet (NWWW)	
R. Sijtsma	Nutreco (Mixed feed industry)	
H. van Toor	Cargill Hardingsdivisie (VERNOF)	
W. Traag	Rikilt	
J. van der Veen	Ten Kate Holding Musselkanaal (BOVED)	
Mrs C. van Vuure	Rendac (VND)	

Appendix 2: Determination of dioxin-like chlorobiphenyls.

Introduction

About 10 years ago the dioxin affair in the Dutch Lickebaert polder gave reason to draft a standard for the presence of dioxins in milk fat.

The calculation of the standard was based on the tolerable daily intake (TDI) recommended by the WHO of 10 pg i-TEQ/kilogram of body weight. Assuming an average body weight of 65 kg and a presumed average food consumption pattern, the Dutch government then established a standard of 6 pg i-TEQ/gram of milk fat.

The interpretation of an analysis is as follows:

The analysis yields contents per measured congener (therefore of the seventeen 2,3,7,8 substituted compounds) expressed in pg/gram of fat or product. On the basis of the toxicity factors a total content is then calculated which is expressed in pg i-TEQ/gram of fat or product which is then tested against the established standard.

In the interpretation of analysis results the RIKILT uses the "Lower bound" principle for the biological samples. This means that for unidentified congeners a value 0 is filled in; in other words: these do not contribute to the total content. For the analysis of, for example, citrus pulp we use the "upper bound" principle. This means that for unidentified congeners the detection limit is filled in which, obviously, is then multiplied again by the corresponding TEF value. The "lower bound" principle therefore gives per definition a lower value than, or, if all congeners have been identified, an equal value to the value when the "Upper bound" principle is applied.

The prefix i indicates that the TEF values used have been accepted internationally.

On the basis of new toxicological insights, the WHO has issued a new advice in which the following matters are of relevance.

- 1) A number of TEF values of dioxins have been adjusted; this will lead in general to a slightly higher value for the sum parameter. If all congeners are detected, circa 10% higher.
- 2) The TDI is 1-4 pg WHO-TEQ/kilogram of body weight. Actually a value of 1 is preferred, but because of practical objections a range is proposed for the time being.
- 3) The proposed TDI of 1-4 pg WHO-TEQ/kilogram of body weight is based on the intake of not only dioxins but also of the dioxin-like chlorobiphenyls.

PCBs can be subdivided into two groups:

- a) Chlorobiphenyls with dioxin-like effect.
- b) other.

Re a)

This group can be subdivided in turn into two groups.

The first group are those chlorobiphenyls of which the hydrogen atom has been replaced at one orthoposition with a chlorine atom. These are the so-called Mono-Ortho substituted chlorobiphenyls (MO-CBs).

The second group are those chlorobiphenyls of none of the hydrogen atoms has been replaced at the orthoposition with a chlorine atom. These are the so-called Non-Ortho substituted chlorobiphenyls (NO-CBs).

The first group contains the following congeners: CB 105, 114, 118, 123, 156, 157, 167 and 189.

The second group contains the following congeners CB 77, 81, 126 and 169.

Re b)

The other ones therefore total $(209-12) = 197$ chlorobiphenyls of which seven have been selected in the past by the RIKILT (on the basis of analytics and occurrence). These are the so-called indicator PCBs: 28,52, 101, 118, 138, 153 and 180.

Current situation

In the current analysis the NO-CBs have been measured simultaneously with the dioxins for quite some time.

The measurement consists roughly of the following steps

- * Extraction of the fat from the matrix
- * Spiking the fat with ^{13}C labelled standards (currently only the dioxins and NO-CBs)
- * Separation of fat and components to be determined by means of GPC
- * Extra removal of traces of fat by means of Al_2O_3
- * Separation between dioxins, NO-CBs and other components by means of PGC
 - fraction A contains MO-CBs plus the other CBs
 - fraction B contains dioxins and NO-CBs
- * Measurement of fraction B by means of GC-HRMS

Future

In order to arrive at a complete analysis of all dioxins and dioxin-like CBs it is necessary to measure, in addition to fraction B, also fraction A by means of GC-HRMS. It goes without saying that the methods to be used must be validated.

Appendix 3: Summary of draft Rikilt report “ Polycyclic Aromatic Hydrocarbons (PAHs) in feed, animal fats, vegetable oils / fats, fatty acids and the like” of March 2001

In response to the pollution of palm oil by diesel oil, expedited provisional standards have been established in Belgium for PAHs in fats and fatty acids intended for feed. Next a working party was created, consisting of Belgian and Dutch analytical and toxicological experts, in order to arrive at a better standard setting and to draft a uniform measuring method. An important starting point in the standard setting is the use of so-called TEF values with which, in analogy with the dioxins, the content of the toxicologically relevant PAHs is projected backwards to benzo(a)pyrene. As standard for PAHs in fats and derived products intended for feed, **50 µg BAPEQ/kg** was chosen, and in addition an action limit of **15 µg BAPEQ/kg**. In the ideal situation this standard would have to be based either on toxicological knowledge or on ALARA principles. Unfortunately no data are available about the transfer of PAHs from feed to, for example, milk, although it is expected that the greater part will be degraded. It is not known whether this will result in harmful metabolites in cows. The standard setting is based on the following compounds:

Substance	Proposed TEF
Benzo(a)pyrene	1
Dibenzo(a,h)anthracene	1
Benzo(a)anthracene	0.1
Benzo(b)fluoranthene	0.1
benzo(k)fluoranthene	0.1
indeno(1,2,3-c,d)pyrene	0.1
chrysene	0.01
acenaphtylene	0.01
fluoranthene	0.01
acenaphtene	0.001
phenanthrene	0.001
pyrene	0.001

Table List of proposed TEF values for polycyclic aromatic hydrocarbons

Proposals for norms for the measuring methods to be used as well as the reporting method are described in this report.

The working party has studied a number of analysis methods and has made proposals for uniform measuring methods. These measuring methods have in the meantime been tested by the various laboratories, by means of circulated samples.

The measurement by means of HPLC/FI is not suitable for the determination of all selected compounds; especially the volatile compounds cannot be determined quantitatively and the actual value is underestimated. Results obtained by means of HPLC/FL must therefore be considered as indicative.

As it has in the meantime become clear from recent measurements that PAHs are also formed during all sorts of drying processes and for that reason also occur in other feed materials such as dried grass, lucerne, citrus pulp and copra, it is to be expected that at some time standard setting will be required for this kind of products as well.

Appendix 4: Summary of proposal for standards for feed fats

	Contaminant	Action limit	Rejection limit	Source	Remarks
1.	Arsenic	not applicable	2 mg/kg	99/29/EC implemented in feed legislation the Netherlands part 1 (Appendix IX to Chapter 8 Undesirable substances and products)	All fats, excluding fish oil; maintain existing standard
		not applicable	10 mg/kg	99/29/EC implemented in feed legislation the Netherlands part 1 (Appendix IX to Chapter 8 Undesirable substances and products)	Only for fish oil; maintain existing standard
2.	Nickel	20 mg/kg	50 mg/kg		Proposal for introduction of action and rejection limit
3.	chlorinated and other fat-soluble pesticide <ul style="list-style-type: none"> • Aldrin + dieldrin • Chlorocamphene • Chlordane • DDT • Endosulphan (oil-containing seeds) • Endrin • Heptachlorine • HCB • HCH Alpha-isomer • HCH Beta-isomer • HCH Gamma-isomer (lindane) 	not applicable	mg/kg <ul style="list-style-type: none"> 0.2 0.1 0.05 0.5 0.5 0.05 0.2 0.2 0.2 0.1 2.0 	99/29/EC implemented in feed legislation the Netherlands part 1 (Appendix IX to Chapter 8 Undesirable substances and products)	Maintain existing standards
4.	dioxins	not applicable	6 pg/g 2,3,7,8 –TCDD eq	Regulation concerning dioxin contents in fats and feeds, LNV 18 June 1999	Proposal by European Commission: Animal fat 2 pg/g WHO Teq Fish oil 6 pg/g WHO Teq Vegetable oil 0.75 pg/g WHO Teq
5.	PCBs <ul style="list-style-type: none"> • Animal fats • <i>Frying fat</i> 	not applicable not applicable	250 ppb 200 ppb	PDV decision on standards in feed sector 1999 article 4A <i>Regulation on fats in feed, LNV 21 Jan. 2000</i>	Maintain existing standards

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	Contaminant	Action limit	Rejection limit	Source	Remarks
6.	Polycyclic Aromatic Hydrocarbons (PAHs)	15 µg/kg BaPEQ	50 µg/kg BaPEQ	Consultation between Belgian and Dutch governments	Proposal for action and rejection limit
7.	Hydrocarbons <ul style="list-style-type: none"> • Animal fat (with the exception of fish oil) • vegetable oil (with the exception of sunflower oil) • Vegetable fatty acids (including mixtures of fatty acids) • crude fish oil • sunflower oil and fatty acids 	not applicable	mg/kg 400		Proposal for new standard
		not applicable	400		
		not applicable	3000		
		not applicable	3000		
		not applicable	1000		
8.	polyethylene	250 mg/kg	500 mg/kg	PDV decision on feed sector standards 1999 appendix 2 supplementary standards for feed materials and moisture-rich mixtures article 2.6 packing materials	Proposal for introduction of action limit
9.	Methyl esters	not applicable	not applicable		Irrelevant
10.	insoluble impurities	not applicable	0.15%	99/534/EC implemented VWS regulation concerning thermal treatment systems and end products	For fat from ruminants; maintain existing standard

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