

SCIENTIFIC OPINION

Review of the criteria for acceptable previous cargoes for edible fats and oils¹

Scientific Opinion of the Panel on Contaminants in the Food Chain

(Question No EFSA-Q-2009-00236)

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PANEL MEMBERS

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SUMMARY

The worldwide trade of edible fats and oils in bulk implies their transport by road, railroad, inland waterways and sea. Industry asserts that it is not economically viable to operate a fleet of ships engaged only in the carriage of edible fats and oils as they would have to return empty to their original loading ports. In 1996 and 2003, the Scientific Committee on Food (SCF) assessed the risk to human health arising from potential contamination of oils and fats shipped in tanks which may have been used to transport chemical substances, based on a set of five criteria (SCF criteria). The Codex Committee for Fats and Oils (CCFO) has adopted the Recommended International Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk, which includes the Draft Codex List of Acceptable Previous Cargoes, which did not include criteria for the evaluation of substances. For this purpose, in 2007, four criteria were developed by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) in collaboration with the Dutch National Institute for Public Health and the Environment (RIVM) (FAO/WHO criteria). In 2009, these criteria were amended by CCFO at their 21st session (CCFO criteria) and were forwarded for adoption by the 32nd session of the Codex Alimentarius Committee (CAC).

At the request of the European Commission, the European Food Safety Authority (EFSA) reviewed the criteria for acceptable previous cargoes for edible fats and oils set by the SCF. In doing so, the Panel on Contaminants in the Food Chain (CONTAM Panel) assessed the

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appropriateness of the four CCFO criteria, one by one, by comparing them with those set by SCF for acceptable previous cargoes for edible fats and oils in 1996. The criteria for evaluation of acceptable previous cargoes for edible fats and oils as proposed by the CCFO are not in conflict with any of the five criteria developed by SCF. SCF criteria 1 to 4 are either explicitly or implicitly covered by the CCFO criteria. SCF criterion 5 dealing with the availability of analytical methods is not explicitly addressed in the CCFO criteria. The CONTAM Panel considers that SCF criterion 5 is still important. The CCFO criteria also cover food allergens and compounds that may react with oil and fats. The CONTAM Panel considers these additions relevant.

The CCFO criteria specifically apply to the immediate previous cargo. The CCFO criterion 1 which addresses, among other issues documentation procedures, does not specify for how many previous cargoes records should be kept. This might be particularly important in the event that earlier previous cargoes consist of substances for which an acceptable daily intake (ADI) (or tolerable daily intake (TDI)) has not been established. The CONTAM Panel is of the opinion that records of the three previous cargoes should be kept, in accordance with the Codex Recommended International Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk. With respect to CCFO criterion 2, the CONTAM Panel agrees with the proposed threshold of an ADI (or TDI) of ≥ 0.1 mg/kg body weight (b.w.). The CONTAM Panel considered the situation of second and third previous cargoes and concludes that for non-genotoxic substances their transport as second and third previous cargoes is not of concern, taking into account their very limited carry over. Genotoxic substances, for which a threshold cannot be assumed, would not be acceptable as previous cargoes. Regarding the CCFO criterion 3 on known food allergens, the CONTAM Panel considers the scope of the CCFO criterion too narrow and should apply to all known allergens, not just to known food allergens, given the fact that the same cargo may be sold for cosmetic use. The CONTAM Panel also welcomes the inclusion of a criterion to evaluate the acceptability of substances reacting with the oils or fats.

Key words: criteria, previous cargoes, edible fats, oils, sea transport.

TABLE OF CONTENTS

Panel Members.....	1
Summary	1
Table of Contents	3
Background as provided by the European Commission	4
Terms of reference as provided by the European Commission	5
Acknowledgements	5
Assessment	6
1. Introduction	6
2. Previous assessments of the criteria for acceptable previous cargoes	7
2.1. Scientific Committee on Food Opinion (SCF Criteria)	7
2.2. Joint FAO/WHO Technical Meeting (FAO/WHO Criteria)	8
2.3. 21 st session of the Codex Committee for Fats and Oils (CCFO Criteria)	14
3. Assessment of the SCF criteria and the CCFO criteria	16
Conclusions and Recommendations.....	18
References	19
Abbreviations	21

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Current EU legislation, Commission Directive 96/3/EC², establishes the hygienic rules to be respected as regards the transport of bulk liquid oils and fats by sea.

In April 2003, the Scientific Committee on Food (SCF) produced an opinion on the potential risk to human health arising from the transport in ships' tanks of oils and fats from substances proposed as acceptable previous cargoes.

However, it should be noted that the criteria used at that time related only to the toxicological properties of the substances evaluated.

The Codex Alimentarius Commission (CAC) has adopted the recommended international code of practice for the storage and transport of edible fats and oils in bulk (www.codexalimentarius.net/download/standards/101/CXP_036e.pdf). This Code applies to the handling, storage and transport of all crude or processed edible oils and fats in bulk. The Codex List of Acceptable Previous Cargoes is under development at the CCFO. One of the difficulties in finding agreement on the proposed List of Previous Cargoes at Codex level was the lack of criteria for the evaluation of substances. At the 19th session of the Codex Committee for Fats and Oils, it was agreed that FAO and WHO would provide advice on the establishment of criteria for substances to be included in the Codex List of Acceptable Previous Cargoes.

In response to the request of the CCFO, FAO and WHO requested the collaboration of the Dutch National Institute for Public Health and the Environment (RIVM) to provide advice on this matter.

The Joint FAO/WHO Technical meeting, in collaboration with RIVM, has developed the criteria to be used for substances to be included in the Codex List of Acceptable Previous Cargoes.

When assessing the acceptability of previous cargoes for fats and oils, a substance is considered acceptable when it complies with the four criteria listed below:

- 1. The substance is transported/stored in an appropriately designed system, with adequate cleaning routines, followed by effective inspection and recording procedures.*
- 2. Residue of the substance in the subsequent cargo of fat and oil should not result in adverse human health effects. The ADI (or TDI) of the substance should be greater than or equal to 0.1 mg/kg bw/day. Substances for which there is no numerical ADI (or TDI) should be evaluated on a case-by-case basis.*
- 3. The substances should not be a known allergen.*
- 4. Most substances do not react with edible fats and oils under normal shipping and storage conditions. However if the substance does react with edible fats and oils, any reaction products must comply with criteria 2 and 3.*

Recently, at the 21st session of the Codex Committee on Fats and Oils (Kota Kinabalu, Malaysia 16-20 February 2009), the above criteria to be used to determine the acceptability of

² OJ L 21, 27.01.1996 p 42-46

previous cargoes for bulk liquid oils and edible fats transported by sea were slightly modified: see the report at: http://www.codexalimentarius.net/download/report/718/al32_17e.pdf

In particular criteria 1, 3 and 4 were modified as follows:

- 1. The substance is transported/stored in an appropriately designed system; with adequate cleaning routines, including the verification of the efficacy of cleaning between cargoes, followed by effective inspection and recording procedures.*
- 3. The substance should not be or contain a known food allergen, unless the identified food allergen can be adequately removed by subsequent processing of the fat or oil for its intended use.*
- 4. Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any known reaction products must comply with criteria 2 and 3.*

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

EFSA is asked to review and update the criteria set by the previous opinion of the Scientific Committee on Food. In doing so, EFSA is requested to assess the appropriateness of the criteria for acceptable previous cargoes for edible fats and oils in the light of the technical report elaborated by FAO/WHO in collaboration with RIVM and the latest modifications proposed at the 21st session of the Codex Committee on Fats and Oils (Kota Kinabalu, Malaysia 16-20 February 2009).

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ASSESSMENT

1. Introduction

The worldwide trade of edible fats and oils in bulk implies their transport by road, railroad, inland waterways and sea. Regulation (EC) 852/2004³, repealing Council Directive 93/43/EEC⁴, requires the transport of bulk liquid, granulate and powdered foods in receptacles and/or containers/tanks reserved for foodstuff only. Industry asserts that it is not economically viable to operate a fleet of ships engaged only in the carriage of edible fats and oils as they would have to return empty to their original loading ports.

The majority of the global trade in oils and fats is done under contracts of the Federation of Oils, Seeds and Fats Associations (FOSFA), a professional international contract-issuing and arbitral body concerned exclusively with the world trade in oilseeds, oils and fats, which provides a wide range of standard forms covering different methods of transportation and different terms of trade. FOSFA does not require dedicated containers and allows the transport in tanks that have previously been used to transport substances from a positive list. A FOSFA list of banned previous cargoes also exists (FOSFA, 2008).

Commission Directive 96/3/EC⁵ was then developed allowing derogation from certain provisions of Directive 93/43/EEC, later on replaced by Regulation (EC) 852/2004. This permits sea transport of fats and oils in bulk tanks, which have previously been used to transport substances included in a positive list of acceptable previous cargoes. The Directive required the review of the substances included in the list of acceptable previous cargoes to take into account scientific or technical developments. Therefore, in 1996, the Scientific Committee on Food (SCF) assessed the risk to human health arising from potential contamination of oils and fats shipped in tanks which may have been used to transport the substances as given in the Annex of the derogating Directive 96/3/EC (SCF, 1996). In 2003, the SCF issued an update of its previous opinion in the light of new toxicological information, where available (SCF, 2003).

On the basis of the evaluations carried out by the SCF in 1996 and 2003, Commission Directive 2004/4/EC⁶ amended the list of substances acceptable as previous cargoes set out in Annex to Directive 96/3/EC. However, the substances in the list were only considered to be acceptable as long as the provisions of the Hygiene of Foodstuff Directive 93/43/EEC, later on replaced by Regulation (EC) 852/2004, applied, and especially regarding the cleaning and condition of the tanks, as well as the requirement included in the derogating Directive 96/3/EC, where accurate documented evidence related to the three previous cargoes and the efficacy of the cleaning process between cargoes should be kept by the captain of the vessel.

The Codex Alimentarius Commission (CAC) also sets international food standards to protect the health of consumers and ensure fair practices in the food trade. Under the Codex system, the Codex Committee for Fats and Oils (CCFO) has been established to elaborate standards for fats and oils of animal, vegetable and marine origin, including margarine and olive oil. It has adopted the Recommended International Code of Practice for the Storage and Transport of Edible Oils and Fats in Bulk, which includes the Draft Codex List of Acceptable Previous

³ OJ L 139, 30.04.2004 p 1-54

⁴ OJ L 175, 19.07.1993 p 1-11

⁵ OJ L 21, 27.01.1996 p 42-46

⁶ OJ L 15, 22.01.2004 p 25-30 and OJ L 81, 19.03.2004 p 92

Cargoes (CAC/RCP, 1987). This list is currently under development, and the lack of criteria for the evaluation of the substances has been identified as one of the major problems. Thus, the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) were requested to provide scientific advice on acceptable previous cargoes. In collaboration with the Dutch National Institute for Public Health and the Environment (RIVM) a Technical Report on the “Development of criteria for acceptable previous cargoes for fats and oils” was issued in 2007 (FAO/WHO, 2007).

The FAO/WHO Technical Report was presented at the 21st session of the CCFO (Malaysia, 16-20 February, 2009). The criteria were amended by CCFO and forwarded for adoption by the 32nd session of the CAC (Italy, 29 June-4 July, 2009).

The European Commission has requested the European Food Safety Authority (EFSA) to review and update the SCF criteria for acceptable previous cargoes for edible fats and oils, in the light of the criteria proposed by the FAO/WHO Technical Report, and the latest modifications proposed at the 21st session of the CCFO (Malaysia, 16-20 February 2009).

2. Previous assessments of the criteria for acceptable previous cargoes

2.1. Scientific Committee on Food Opinion (SCF Criteria)

In 1996, the SCF issued an opinion on the potential risk to human health arising from the transport of oils and fats in ships’ tanks from substances proposed as acceptable previous cargoes (SCF, 1996). The Committee was asked to examine the substances given in the Annex of Directive 96/3/EC and other substances that may be proposed for addition to the list.

The SCF was asked to take into account the information provided by industry concerning (i) the likelihood and potential levels of contamination in the light of the information regarding cleaning procedures, dilution and limits of detection of analytical methods and (ii) the additional processing of oils and fats. The SCF focused its attention on the evaluation of the toxicological properties of the substances without considering other aspects such as the ecotoxicological characteristics, the microbial status or nutritional relevance. The Committee’s view on the acceptability of the substances in the list of acceptable previous cargoes from Directive 96/3/EC was based on the criteria shown in Table 1.

Table 1. Criteria for the inclusion of substances in the list of acceptable previous cargoes according to the SCF (SCF, 1996).

SCF criteria ^(a)	
1.	No toxicological concerns, particularly with regard to their genotoxic and carcinogenic potential, for which a threshold is difficult to establish,
2.	Efficacy of procedures used to clean ships’ tanks between cargoes,
3.	Dilution factor in relation to the potential amount of residue of the previous cargo and any impurity which the previous cargo might have contained and the quantity of oil or fat transported,
4.	Subsequent application of refining processes and solubility relevant to the occurrence of possible contaminating residues,
5.	Availability of analytical methods to verify the presence of trace amounts of residues or the absence of contamination of oils and fats.

(a): Although the SCF criteria have no numbering in the original reference, in the present opinion they have been included for an easier referral throughout the document.

The substances in the list were only considered to be acceptable as long as the provisions of the Hygiene of Foodstuffs Directive 93/43/EEC, later on replaced by Regulation (EC) 852/2004, applied, and especially regarding the cleaning and condition of the tanks, as well as the requirement included in Directive 96/3/EC, where accurately documented evidence related to the three previous cargoes and the efficacy of the cleaning process between cargoes should be kept by the captain of the vessel.

Some of the substances were considered to be acceptable as previous cargoes by the SCF because they are food or food components. A number of other substances were considered acceptable from a toxicological point of view.

For others, the acceptance was considered only provisional considering mainly their unlikely genotoxic potential, their easy removal by tank cleaning procedures, and the very low residues expected as a result of these factors and their likely dilution.

Finally, ten substances were considered as not acceptable for reasons such as inadequate toxicological and/or technical data or because their genotoxic and carcinogenic potential were a reason for concern (SCF, 1996).

In 2003, the SCF was requested to update the list of substances from its previous opinion in the light of new toxicological information, where available (SCF, 2003). Priority was given to those substances provisionally accepted as previous cargoes. As in its previous opinion, the SCF focused on the toxicological properties. The criteria used for re-evaluation were the same as those described in its opinion from 1996 (Table 1). The re-evaluation led to the full acceptance of some substances previously considered as not acceptable or provisionally acceptable in view of the new toxicological information. Others were confirmed to be not acceptable as previous cargoes since the new information did not allow for a re-evaluation of their carcinogenicity or genotoxicity.

2.2. Joint FAO/WHO Technical Meeting (FAO/WHO Criteria)

Scope of the Technical Meeting

Following the request by CCFO, FAO and WHO convened in 2006 a Technical Meeting in collaboration with the RIVM, to establish criteria to be used for substances to be included in the Codex list of acceptable previous cargoes. Storage and land transport of fats and oils is covered by national regulations or legislation and is limited to food-only tanks. Therefore, criteria were developed for the acceptability of previous cargoes for the carriage of edible fats and oils as bulk liquids by sea only. It was proposed that if no other regulations are present, the criteria may also be applicable to land transport systems and storage tanks.

For practical reasons, it was considered that the criteria to assess if a substance is acceptable as previous cargo should be generic, assuming worst case conditions, as it would be impractical to develop a system that would take into account every possible combination of previous cargo, type of tank construction, cleaning regime and further processing of the subsequent fat or oil cargo.

It was also considered that under International Maritime Organisation (IMO) regulations (IMO, 2002; 2006a; 2006b), certain substances (e.g. mineral oils) are not permitted to be transported in types of ships that are suitable for the transportation of edible fats and oils. Therefore, by definition such substances cannot be previous cargoes for fats and oils and safety aspects for these were not further taken into account.

In the context of the FAO/WHO Technical Meeting, the term “edible” includes fats and oils, which are destined for the oleo-chemical industry for use in personal care products (e.g. soaps, creams) and therefore, the potential for both oral and dermal allergenicity of a previous cargo should be taken into account.

Only safety implications of the presence of residues from previous cargoes for human health were considered. Contamination of fats and oils with foodstuffs and food additives, including flavouring and colouring substances, were considered to be changes in food quality and therefore beyond the scope of the document. With respect to other possible changes in quality, it was recognised that edible fats and oils should comply with the quality criteria as indicated in the Codex Standards.

Outcome of the Technical Meeting

The following issues were discussed:

1. Efficacy of cleaning procedures between cargoes;
2. Toxicological properties, including genotoxic and carcinogenic potential;
3. Dilution factor in relation to the potential amount of residue of the previous cargo and any impurity which the previous cargo might have contained, and the volume of fat or oil transported;
4. Solubility of possible contaminating residues;
5. Subsequent refining/processing of the fat or oil;
6. Availability of analytical methods for the detection of trace amounts of residues or for verifying the absence of contamination;
7. Allergenicity;
8. Reactivity of edible fats and oils with contaminating residues, where appropriate;
9. Organoleptic changes
10. Microbiological contamination
11. Homogeneity
12. Previous cargoes

The following text addressing these issues is taken from the Joint FAO/WHO Report of the Technical Meeting (FAO/WHO, 2007).

Ad 1) Efficacy of cleaning procedures

“Tank cleaning was considered to be particularly important in the consideration of acceptable previous cargoes and the meeting identified this as a criterion.

All cleaning agents used on board chemical tankers are evaluated by the Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection (GESAMP) Committee for IMO (International Maritime Organization). The effect on sea life and the threat posed to seafarers by the cleaning agents is a major consideration. The meeting considered contamination by cleaning agents to be outside the scope of the meeting.

It is possible for some residue to remain in the tank and its associated pipework after cleaning. Chemical carrier tanks are constructed either of stainless steel or of mild steel coated with a suitable material to protect it from corrosion. The level of contamination depends upon the type of tank employed. The main difference between the two tank types is the degree of absorption of the previous cargo being carried in coated tanks compared to hardly any absorption in stainless steel tanks. The absorbed material is desorbed or displaced at various rates into subsequent cargoes, thus contaminating them. To achieve a worst-case situation, coated tanks were used to estimate the quantity of the previous cargo which could be present in the subsequent cargo of edible fats and oils.

It was considered that any contamination from a previous cargo in seagoing vessels after cleaning is unlikely to be greater than 10 mg/kg of fat or oil, and is generally in the order of 1 mg/kg of fat or oil for stainless steel tanks (Hancock, 2006). However, contamination from previous cargoes carried in coated tanks could be as high as 100 mg/kg of fat or oil (Chemserve, 2006; Coutts, 1991; Woods, 2000). The meeting considered that the worst-case maximum concentration of residue after cleaning would be 100 mg/kg of fat or oil. This value was based on possible contamination levels in coated tanks or in relatively small tanks. This estimate is used in the derivation of the toxicological criterion, i.e. criterion 2”.

Ad 2) Toxicological properties

“The toxicological aspects of the substances were considered to be particularly important when considering acceptable previous cargoes and the meeting identified this as a criterion.

The meeting concluded that it was possible to identify a criterion based on the ADI (acceptable daily intake) or TDI (tolerable daily intake) concept, and proposed that this would provide adequate human health protection even taking into account possible exposure to the same substance from other sources. The meeting noted that the ADI (or TDI) is developed to evaluate lifetime exposures, but also noted that it was highly unlikely that an individual would consume the same type of fat or oil contaminated with a particular residue of a previous cargo on a regular basis. Given that acute toxic effects may occur, the need for a criterion based on an acute reference dose (ARfD) was discussed. Taking into account that an ADI (or TDI) can be based on the effects of relatively short-term exposure (e.g. toxic effects during pregnancy), and that the ARfD is developed to evaluate exposure on a single day but that the possibility of repeated exposure to the chemicals could not be excluded, it was considered necessary to refer to the ADI (or TDI) in order to be sufficiently protective of public health.

For estimation of exposure to a previous cargo contaminant in edible fats and oils, the meeting estimated a dietary intake of 25 g/day of a single type of fat or oil. This value is based on the rounded maximum intake estimate for one single type of fat or oil (i.e. refined soybean oil) of 22 g/person per day. This estimate is taken from the WHO GEMS/Food (Global Environment Monitoring System/Food Contamination Monitoring and Assessment Programme) Consumption Cluster Diets, which are based on imports/exports and use quantities of various fats or oils in 13 regional clusters, divided by the number of inhabitants in each separate cluster. Although food consumption data as generated by the United Kingdom or the Netherlands, for example, would be more appropriate, it is recognized that such data are only available for a very limited number of countries. For this reason, preference is given to the WHO GEMS/Food Consumption Cluster Diets (WHO, 2006).

In a worst-case scenario, a previous cargo residue could be present at a concentration of 100 mg/kg of fat or oil (see efficacy of cleaning procedures). Assuming an individual eats on average a maximum of 25 g of fat or oil from a single type of fat or oil per day, this concentration would result in a residue intake of about 0.04 mg/kg of bodyweight (bw) per day in a 60 kg adult. However, this calculation is based on consumption data for adults. As a result of their higher caloric intake per kg bw, dietary exposure of children to contaminants is frequently 2.5 times that of adults. A factor of 2.5 would also cover high-intake consumers. The meeting therefore agreed that for the evaluation of previous cargoes, an ADI (or TDI) of 0.1 mg/kg bw/day would be the minimum requirement to provide sufficient protection for children and high-intake consumers.

For substances which are both mutagenic and carcinogenic, or which are mutagenic and for which no carcinogenicity data are available, ADIs (or TDIs) cannot be allocated and these substances are excluded as acceptable previous cargoes.

The meeting recognized that persistence and bioaccumulation are implicitly covered by the ADI (or TDI).

Account was taken of the fact that there are potential previous cargoes for which insufficient toxicity data are available to derive an ADI (or TDI). In an attempt to cover this, the TTC (threshold of toxicological concern) approach was considered, but it was decided that this approach was not helpful in the evaluation. Therefore, substances where there are insufficient data should be evaluated on a case-by-case basis. This could lead either to a request for further toxicity data or to an evaluation of well-documented toxicity data for structural analogues of the previous cargo under consideration. Any such evaluation should be undertaken by JECFA”.

Ad 3) Dilution factor

“The dilution factor regards the remainder of the previous cargo left after unloading but before tank cleaning. In a worst-case scenario, it was estimated that the maximum residue level of the previous cargo would be 100 mg/kg of fat or oil after tank cleaning – also applicable to relatively small tanks. Given that cleaning is an essential criterion (criterion 1), it is not necessary to include the dilution factor as a criterion”.

Ad 4) Solubility of possible contaminating residues

“Removal of residues of previous cargoes is facilitated by high solubility in water and high vapour pressure. Both parameters are relevant for cleaning and refining processes. Solubility and vapour pressure are taken into account when deciding on the appropriate cleaning procedures, and therefore they are implicitly taken into account in the worst-case estimate for contamination of edible fats and oils (i.e. 100 mg/kg fat or oil). As refining was considered to be outside the scope of the discussion, solubility and vapour pressure are not included in the criteria”.

Ad 5) Subsequent refining/processing of the fat and oil

“To meet consumer acceptance, fats and oils are further refined (usually post shipment) to remove products of oxidation and hydrolysis. The vast majority of vegetable oils shipped by

sea are refined on arrival to meet food-grade specifications. Water soluble compounds, colour pigments, gums and free fatty acids are removed by degumming, neutralization and the use of bleaching clays. The final step in the manufacture of an edible oil is deodorization. This is a steam distillation process taking place at temperatures above 220°C and under vacuum. Thus, a wide range of substances, even some with a saturated vapour pressure as low as 1 mPa, are easily removed during the deodorization step.

However, it was noted that some oils are not refined (e.g. virgin olive oil), while others are transported by sea after refining (e.g. palm oil); therefore, as a worst-case scenario, it was decided not to take refining into consideration in the estimation of possible exposure to previous cargo residues. Omission of the refining step is implicitly taken into account in the worst-case estimate for contamination of edible fats and oils (i.e. 100 mg/kg fat or oil)”.

Ad 6) Availability of analytical methods

“Suitable analytical methods are available to determine residues in the range of the assumed maximum concentration, consistent with a residue level of 100 mg/kg of previous cargo in fats or oils.

It was acknowledged that contamination can occur; the meeting developed an approach (i.e. the criteria) to ensure that such contamination will not pose a toxicological risk when the criteria are met. It is not proposed or considered necessary to set maximum levels (MLs) to support these criteria; as a result, analytical methods for the determination of previous cargoes in fats and oils are not included in the criteria”.

Ad 7) Allergenicity

“Exposure to allergenic substances in pre-sensitized individuals may trigger severe adverse reactions, even at very low levels. Allergenicity of the previous cargo was considered to be particularly important in the consideration of acceptable previous cargoes and the meeting identified this as a criterion”.

Ad 8) Reactivity with edible fats and oils

“The reactivity of the previous cargo with edible fats and oils was considered to be particularly important in the consideration of acceptable previous cargoes and the meeting identified this as a criterion.

Edible fats and oils are chemically quite inert under normal handling conditions. Reactions likely to occur during transport are oxidation and hydrolysis. Elevated temperature, moisture and the presence of catalysts such as copper promote hydrolysis and/or oxidation. However, small changes in oil quality are anticipated and are dealt with during further refining. Standard practices, such as loading from the bottom of the tank, the addition of antioxidants prior to loading, or the nitrogen blanketing of high-quality oils during carriage, may reduce the deterioration of quality parameters.

However, consideration must be given to the possibility that the chemical substance can react with edible fats and oils under transport conditions. Possible reactions covered by normal quality aspects are oxidation (peroxidation), hydrolysis and saponification. However,

reactions with triglyceride or fatty acid impurities in the fat or oil (e.g. methylation or ethylation) must be evaluated on a toxicological basis (i.e. criteria 2 and 3)."

Ad 9) Organoleptic changes

"Changes in oil which may result in a deterioration of organoleptic quality (e.g. oxidation, hydrolysis) were discussed as a possible criterion, but were dismissed because such affected oils were considered unlikely to enter the food-chain without further refining. Quality aspects were considered to be outside the scope of the discussion."

Ad 10) Microbiological contamination

"Chemical previous cargoes are not a potential source of microbiological contamination of subsequent cargoes of edible fats and oils. Furthermore, edible fats and oils are poor substrates for the growth of microorganisms. For these reasons, the meeting considered that microbiological contamination was not a potential health risk and hence not a criterion."

Ad 11) Homogeneity

"Consideration was given to whether there was a possibility of inhomogeneity of residue levels in more viscous edible fats and oils, giving rise to regions of elevated concentrations of residue of the previous cargo. Edible fats and oils are shipped at 10°–15°C above their melting points to ensure low viscosity. It was concluded that inhomogeneity of edible fats and oils cargoes during shipment is not likely to occur, due to efficient mixing caused by pumping during loading and discharge, convection currents and the ship's movements. Therefore, the estimated maximum residue level of 100 mg/kg of fat or oil will apply to all subsamples within a tank load."

Ad 12) Previous cargoes

"The meeting discussed whether immediate, second or third previous cargoes need to be considered. The estimated maximum residue level of 100 mg/kg of fat or oil applies to the immediate previous cargo. Residue levels from second and third previous cargoes will be lower and therefore all previous cargoes (immediate, second or third) are implicitly taken into account in the worst-case estimate for contamination of edible fats and oils (i.e. 100 mg/kg fat or oil)."

List of criteria proposed to CCFO by the Technical Meeting

When assessing the acceptability of substances as previous cargoes for fats and oil, a substance is considered acceptable when it complies with the four criteria listed in Table 2.

Table 2. Criteria for the assessment of acceptable previous cargoes as proposed by the FAO/WHO Technical Meeting (FAO/WHO, 2007).

FAO/WHO Criteria
1. The substance is transported/stored in an appropriately designed system; with adequate cleaning routines, followed by effective inspection and recording procedures.
2. Residues of the substance in the subsequent cargo of fat or oil should not result in adverse human health effects. The ADI (or TDI) of the substance should be greater than or equal to 0.1 mg/kg b.w./day. Substances for which there is no numerical ADI (or TDI) should be evaluated on a case by case basis.
3. The substance should not be a known allergen.
4. Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any reaction products must comply with criteria 2 and 3.

2.3. 21st session of the Codex Committee for Fats and Oils (CCFO Criteria)

The FAO/WHO Report of the Technical Meeting (FAO/WHO, 2007) was presented and initially discussed during the 20th session of the CCFO (London, 19-23 February, 2007). At the following CCFO meeting (21st session of the CCFO) in February 2009, the criteria as presented in 2007 were further discussed. Some amendments were included during this meeting and subsequently CCFO agreed to advance the CCFO Criteria (Table 3) as a Proposed Draft Amendment to section 2.1.3 of the Code of Practice for the Transport of Fats and Oils in Bulk, for adoption at Step 5 by the 32nd Session of the CAC. For further details on the history of the discussions in CAC and CCFO the reader is referred to the Joint FAO/WHO Technical Report (FAO/WHO, 2007) and to the report of the 21st CCFO meeting (CCFO, 2009).

Table 3. Criteria proposed for immediate previous cargoes by the CCFO during their 21st meeting (CCFO, 2009). The modifications from the criteria proposed in the Joint FAO/WHO Technical Meeting (Table 2) are shown in italics.

CCFO Criteria
1. The substance is transported/stored in an appropriately designed system; with adequate cleaning routines, <i>including the verification of the efficacy of cleaning between cargoes</i> , followed by effective inspection and recording procedures.
2. Residues of the substance in the subsequent cargo of fat or oil should not result in adverse human health effects. The ADI (or TDI) of the substance should be greater than or equal to 0.1 mg/kg b.w./day. Substances for which there is no numerical ADI (or TDI) should be evaluated on a case by case basis.
3. The substance should not be <i>or contain</i> a known <i>food</i> allergen, <i>unless the identified food allergen can be adequately removed by subsequent processing of the fat or oil for its intended use</i> .
4. Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any <i>known</i> reaction products must comply with criteria 2 and 3.

The following text is taken from the report of the 21st session of the CCFO (CCFO, 2009) regarding the amendments introduced to the FAO/WHO criteria.

Criterion 1

“The Committee agreed to retain Criterion 1 with some amendments to clarify the text and reflect that the efficacy of cleaning between cargoes should be verified”.

Criterion 2

“Some delegations expressed the view that the requirement for a numerical ADI or TDI greater or equal to 0.1 mg/kg would exclude several substances currently proposed for inclusion in the lists of previous acceptable cargoes. The Committee noted a proposal to replace the specific ADI or TDI value with a requirement for a risk assessment, but agreed to retain the numerical value as this was the main element to assess the acceptability of substances. The Committee therefore retained this criterion as currently drafted and noted that its application would be considered further when examining the substances on the lists under Agenda Item 4b).”

Criterion 3

“The Committee amended the text to clarify that the substance transported as cargo might be allergenic or contain an allergen. It was noted that when food allergens were involved, as in the case of peanut oil or soybean oil, refined oil would not be transported after crude oil and that previous cargoes were more likely to be chemicals than foods.

The Committee discussed whether the criterion should refer to allergens in general or to food allergens. Some delegations expressed the view that all types of allergenic reactions originating from oil contamination, such as inhalation or contact with cosmetics, should be taken into account. The Representative of FAO indicated that the experts had considered this issue in the Technical Meeting.

Other delegations proposed to address only food allergens in view of the mandate of Codex and the overall purpose of the Code to ensure food safety, as it was not the responsibility of the Committee to consider allergens that might be present in non food products. After some further discussion, the Committee agreed to refer to “food allergen” as the Code should address the contamination of oils intended for human consumption.

The Committee recognised that allergens might be present in the cargoes but could be removed by subsequent processing and clarified the text accordingly.”

Criterion 4

“The Committee agreed to limit this criterion to only include “known” reaction products, as it was important to focus on known reactions.”

3. Assessment of the SCF criteria and the CCFO criteria

The Panel on Contaminants in the Food Chain (CONTAM Panel) assessed the appropriateness of the CCFO criteria as described above, one by one by comparing them with those set by SCF for acceptable previous cargoes for edible fats and oils in 1996.

CCFO criterion 1: The substance is transported/stored in an appropriately designed system; with adequate cleaning routines, including the verification of the efficacy of cleaning between cargoes, followed by effective inspection and recording procedures (CCFO, 2009).

Adequate cleaning procedures between cargoes, verification of these, inspection and recording procedures form the basis for acceptability of previous cargoes for edible fats and oils. The current CCFO criterion is not in conflict with the SCF criteria on the cleaning procedures and covers similar ground to that in SCF criteria numbers 2, 4 and 5 (Table 1).

Since the first SCF opinion in 1996 the cleaning procedures and their control have become much more tightly controlled. Codes of practice addressing these issues have been developed and more widely applied, including the Recommended International Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk by CAC (CAC/RCP, 1987) and the Qualifications and Operational Procedures for Ships Engaged in the Carriage of Oils and Fats in Bulk for Edible and Oleo-Chemical Use by FOSFA (FOSFA, 2007).

The CCFO criterion 1 does not specify for how many previous cargoes records should be kept. However, conditions for acceptability of substances as previous cargoes as set by the SCF included adherence to the provisions of the Hygiene of Foodstuffs Directive 93/43/EEC, later on replaced by Regulation (EC) 852/2004, and accurate documentation related to three previous cargoes to be kept by the captain of the vessel. This might be particularly important in the event that earlier previous cargoes consist of substances for which an acceptable daily intake (ADI) (or tolerable daily intake (TDI)) has not been or cannot be established.

The CONTAM Panel noted that the preamble in the CCFO criteria states that they apply to the immediate previous cargo. However, the Codex Recommended International Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk (CAC/RCP, 1987) states that *“The three previous cargoes carried in a ship's tank should be declared to the charterer and the records made available to all parties involved. The provision should be part of all shipping contracts. In addition, authorities may wish to see evidence of previous cargo details”*. Therefore, the CONTAM Panel is of the opinion that accurate documentation related to the three previous cargoes should be kept because of the need to know the identity of second and third previous cargoes (see below).

CCFO criterion 2: Residues of the substance in the subsequent cargo of fat or oil should not result in adverse human health effects. The ADI (or TDI) of the substance should be greater than or equal to 0.1 mg/kg b.w./day. Substances for which there is no numerical ADI (or TDI) should be evaluated on a case by case basis (CCFO, 2009).

The proposed threshold of an ADI (or TDI) ≥ 0.1 mg/kg body weight (b.w.) is derived using a conservative scenario, assuming an exposure of 25 g/day of fat or oil from a single type plus an additional factor of 2.5 to cover for children and high-intake consumers (see chapter 2.2. Ad 2). The CONTAM Panel considers this to be adequate to ensure that human health effects

of previous cargoes are avoided. Because of a possibility of repeated exposure, the rationale of using the ADI (or TDI) rather than the acute reference dose (ARfD) is valid.

This CCFO criterion 2 would take into account the dilution factor (SCF criterion 3) and also SCF criterion 1 (Table 1).

The CONTAM Panel notes that this criterion 2 allows for a case-by-case evaluation of substances as **immediate previous cargoes** for which a numerical ADI (or TDI) is not available. Three types of cases can be distinguished:

1. Substances which have been evaluated as acceptable for use in food based on their low anticipated toxicity. These would be acceptable as previous cargoes.
2. Substances which have not been evaluated in the context of their presence in food and not been assigned an ADI (or TDI). These may be acceptable when considered on a case-by-case basis.
3. Substances with a genotoxic mode of action, for which a threshold cannot be assumed. These substances would not be acceptable as previous cargoes.

However, the CONTAM Panel notes that CCFO criterion 2 does not address the issue of **second and third previous cargoes**. A worst case carry over for each previous cargo would be 0.01 %, based on a maximum concentration of residue after cleaning of 100 mg/kg of fat or oil (see Chapter 2.2. Ad 1). For second and third previous cargoes it can be calculated that substances would have to have an ADI (or TDI) < 0.01 µg/kg b.w. (second cargo) or < 0.001 ng/kg b.w. (third cargo), in order for them to present any health concern. The Panel considers that substances with such low ADIs (or TDIs) are extremely unlikely to be previous cargoes, noting that very toxic substances should be carried in IMO tanks type 1 and not in IMO tanks type 2 or 3, in which edible fats and oils are transported (IMO, 2002; 2006a; 2006b).

The CONTAM Panel notes that by application of CCFO criterion 2 some substances will turn out to be unacceptable as previous cargoes. This could include substances with ADI (or TDI) < 0.1 mg/kg b.w. or substances with genotoxic activity. The Panel considers that the exclusion of such substances as previous cargoes is appropriate.

CCFO criterion 3: The substance should not be or contain a known food allergen, unless the identified food allergen can be adequately removed by subsequent processing of the fat or oil for its intended use (CCFO, 2009).

The CONTAM Panel notes that the issue of allergenicity was not covered in the SCF criteria. Inclusion of this aspect in the criteria is relevant.

CCFO criterion 3 is sufficient to cover “known food allergens”. The original criterion 3 of the Joint FAO/WHO Technical Report (FAO/WHO, 2007) was more restrictive, covering “known allergens”, and according to the report, this criterion was developed to prevent also dermal allergens entering the cosmetic chain. The CONTAM Panel considers that the scope of the amended CCFO criterion is too narrow and should apply to all known allergens, not just to known food allergens, , given the fact that the same cargo may be sold for cosmetic use.

Although there are known methods for the removal of some allergens, it is difficult to foresee whether it would be possible to comply with this in practice.

CCFO criterion 4: Most substances do not react with edible fats and oils under normal shipping and storage conditions. However, if the substance does react with edible fats and oils, any *known* reaction products must comply with criteria 2 and 3 (CCFO, 2009).

The CONTAM Panel notes that the issue of reaction products is very important, e.g. toxic oil syndrome (Gelpí *et al.*, 2002; Patterson and Germolec, 2005), and was not covered in the SCF criteria, and endorses its inclusion.

SCF criteria not explicitly stated in the CCFO criteria

SCF criterion 3: Dilution factor in relation to the potential amount of residue of the previous cargo and any impurity which the previous cargo might have contained and the quantity of oil or fat transported (SCF, 1996).

As mentioned above, the CONTAM Panel is of the opinion that this SCF criterion is covered by the CCFO criterion 2.

SCF criterion 4: Subsequent application of refining processes and solubility relevant to the occurrence of possible contaminating residues (SCF, 1996).

The CONTAM Panel considers that the application of the CCFO criterion 2 overrides the necessity to consider further refining of fats and oils and the need for SCF criterion 4.

SCF Criterion 5: Availability of analytical methods to verify the presence of trace amounts of residues or the absence of contamination of oils and fats (SCF, 1996).

The CONTAM Panel considers that it should be ensured that analytical methods are available to verify the cleaning procedures and the absence of unacceptable contamination. This issue is not explicitly addressed by the CCFO criteria.

CONCLUSIONS AND RECOMMENDATIONS

The criteria for evaluation of acceptable previous cargoes for edible fats and oils as proposed by Codex Committee for Fats and Oils (CCFO) are not in conflict with any of the criteria developed by the Scientific Committee on Food (SCF) in 1996.

SCF criteria 1 and 2 are covered by the CCFO criteria, whereas SCF criteria 3, 4 and 5 were not explicitly addressed. However, SCF criterion 3 was implicitly covered by the CCFO criterion 2, while SCF criterion 4 became superfluous.

SCF criterion 5 dealing with the availability of analytical methods is not explicitly addressed in the CCFO criteria. The Panel on Contaminants in the Food Chain (CONTAM Panel) considers that SCF criterion 5 is still important. The CCFO criteria also cover food allergens and compounds that may react with oil and fats. The CONTAM Panel considers these additions relevant.

In addition, the CONTAM Panel makes the following remarks to the CCFO criteria:

- The CCFO criteria specifically apply to the immediate previous cargo. The CCFO criterion 1, which addresses among other issues, recording procedures does not specify for how many previous cargoes records should be kept. This might be particularly important in the event that earlier previous cargoes consist of substances for which an acceptable daily intake (ADI) (or tolerable daily intake (TDI)) has not been established. The CONTAM Panel is of the opinion that accurate documentation related to the three previous cargoes should be kept, in accordance with the Codex Recommended Code of Practice.
- With respect to CCFO criterion 2, the CONTAM Panel agrees with the proposed threshold of an ADI (or TDI) of ≥ 0.1 mg/kg body weight (b.w.). For substances for which there is no numerical ADI (or TDI) a case by case evaluation is needed. The Panel also considered the situation of second and third previous cargoes and concludes that for non-genotoxic substances their transport as second and third previous cargoes is not of concern, taking into account their very limited carry over. However, the CONTAM Panel notes that genotoxic substances would not be acceptable as previous cargoes.
- Also in relation to CCFO criterion 2, the CONTAM Panel notes that as consequence of the above some substances will turn out to be unacceptable as previous cargoes. This could include substances with ADI (or TDI) < 0.1 mg/kg b.w. or substances with genotoxic activity. The Panel is of the opinion that the exclusion of such substances as previous cargoes is appropriate.
- CCFO criterion 3 is sufficient to cover “known food allergens”. However, the CONTAM Panel considers that the scope of the CCFO criterion is too narrow, and should apply to all known allergens, not just to known food allergens, given the fact that the same cargo may be sold for cosmetic use.
- The CONTAM Panel endorses CCFO criterion 4 without any further remarks.

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ABBREVIATIONS

ADI	Acceptable Daily Intake
ARfD	Acute Reference Dose
b.w.	Body weight
CAC	Codex Alimentarius Commission
CCFO	Codex Committee for Fats and Oils
CONTAM Panel	Panel on Contaminants in the Food Chain
EFSA	European Food Safety Authority
FAO	Food and Agriculture Organization of the United Nations
FOSFA	Federation of Oils, Seeds and Fats Associations
GEMS	Global Environment Monitoring System
GESAMP	Group of Experts on the Scientific Aspects of Marine Environmental Protection
IMO	International Maritime Organisation
JECFA	Joint FAO/WHO Expert Committee on Food Additives
RIVM	Dutch National Institute for Public Health and the Environment
SCF	Scientific Committee on Food
TDI	Tolerable Daily Intake
WHO	World Health Organization