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Agenda Item 4 c)

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FATS AND OILS Twenty-second Session Penang, Malaysia, 21-25 February 2011

CODE OF PRACTICE FOR THE STORAGE AND TRANSPORT OF EDIBLE FATS AND OILS IN BULK PROPOSED DRAFT LIST OF ACCEPTABLE PREVIOUS CARGOES COMMENTS AT STEP 3

EUROPEAN UNION

1. Comments on the Proposed Draft List of Acceptable Previous Cargoes in the Code for the Storage and Transport of Edible Fats and Oils in Bulk

The EU strongly supports the principle of establishing a Codex positive list of acceptable previous cargoes. Concerning the Proposed Draft List of Acceptable Previous Cargoes at Step 3, the EU supports progress of this list in the Codex Step procedure subject to the acceptance of the specific comments provided below.

Taking into account the concerns raised by the EU at the 21st session of the Codex Committee on Fats and Oils (CCFO 21), the European Food Safety Authority (EFSA) was asked to deliver a scientific opinion on the evaluation as acceptable previous cargoes for edible fats and oils of the substances included in the Proposed Draft List of Acceptable Previous Cargoes. The EFSA based its evaluation on the criteria used in the latest review of the EU Scientific Committee on Food (2003) and the Proposed Draft Criteria by the CCFO 21. In addition, EFSA took into account impurities of the chemicals shipped as previous cargoes, since they may be more toxic than the chemical substance itself.

This **Scientific Opinion on the evaluation of substances as acceptable previous cargoes for edible fats and oils** can be found on the following Website: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211903078992.htm

As already stated at the CCFO 21, the EU supports that the following substances are kept in the Proposed Draft List:

- ✓ Calcium ammonium nitrate solution (CAS number 6484-52-2),
- ✓ Calcium nitrate (CN-9) solution (CAS number 35054-52-5),
- ✓ Fatty acid methyl esters: Methyl laurate (CAS number 111-82-0), Methyl oleate (CAS number 112-62-9), Methyl palmitate (CAS number 112-39-0) and Methyl stearate (CAS number 112-61-8),
- ✓ Kaolin slurry (CAS number 1332-58-7),
- ✓ 1,3-Propylene glycol (CAS number 504-63-2).

As regards the substances for which the EU had concerns at the CCFO 21 and the new substances proposed for inclusion in the list, the EU would like to provide the following comments:

- At the previous session of the CCFO the EU could not support the inclusion of **iso-Butanol (2-methyl-1-propanol (CAS number 78-83-1))** due to the limited toxicological data to conduct a revised risk assessment for this substance. However, having regarded the above mentioned Scientific Opinion, the EU is now in a position to accept the inclusion of **iso-Butanol (2-methyl-1-propanol (CAS number 78-83-1))** in the list as the criteria for acceptability as previous cargo are met.

- **Hydrogen peroxide** has been evaluated for the first time by the EU as acceptable previous cargo. The results of the EFSA evaluation have shown that its toxicity is not considered to be of health concern. Therefore, the EU considers that it could be maintained in the Proposed Draft List.
- The EU also considered the new proposal to add **Fructose** to the list. The EU is of the opinion that **Fructose** also meets the criteria for acceptability as a previous cargo and consequently the EU would support its inclusion on the list.
- **Unfractionated fatty acid mixture or mixtures of fatty acids from natural oils and fats and Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats:** the EU considers that they would not cause any health concern as previous cargoes, provided their sources are edible types of fats or oils.
- **Unfractionated fatty esters or mixtures of fatty esters from natural oils and fats:** the EU considers that ester mixtures produced from fatty acids and alcohols derived from fats and oils, as well as methanol and ethanol, would not cause any health concern as previous cargoes, provided the sources are restricted such that the fatty acids and the fatty alcohols are from edible types of fats and oils not contaminated with compounds of toxicological concern (e.g. oils from waste collection sites, mineral oils, PCBs).

However, the EU still has concerns on the acceptability of the following substances currently included in the list at Step 3: **2,3-Butanediol (2,3-butylene glycol (CAS number 513-85-9), Cyclohexanol (CAS number 108-93-0) and Cyclohexanone (CAS number 108-94-1).**

- For cyclohexanol and cyclohexanone, there are still uncertainties about the potential carcinogenicity and reproductive toxicity. In addition, the possible toxicity associated with the expected reaction products from cyclohexanone (dioxolane derivatives) needs to be considered. In the case of 2,3-butanediol, there is a lack of chronic and carcinogenicity studies and information about potential genotoxicity is considered insufficient, as well as the potential toxic impurities. **The EU therefore considers that these three substances do not meet the criteria for acceptability as previous cargoes and cannot be included in the Codex List.**
- In the case of **epoxidised vegetable oils**, there is no information about what entities might be covered by the term “epoxidised vegetable oil”. **Epoxidised soybean oil** (ESBO-CAS Number 8013-07-8) is already on the Draft List of acceptable previous cargoes at Step 7.

Epoxidised linseed oil (ELO) is the second most commonly used epoxidised vegetable oil as plasticiser, but there are no toxicological data on this or other epoxidised vegetable oils apart from ESBO. Since these epoxidised vegetable oils as previous cargoes have not been evaluated, the EU is not in a position to accept the inclusion in the list of **Vegetable oil – epoxidised**.

The Proposed Draft List of Acceptable Previous cargoes supported by the EU would be as follows:

PROPOSED DRAFT LIST OF ACCEPTABLE PREVIOUS CARGOES (AT STEP 3)

Substance (synonyms)	CAS Number
Iso-butanol (2-methyl-1-propanol)	78-83-1
Calcium ammonium nitrate solution	6484-52-2
Calcium nitrate (CN-9) solution	35054-52-5
Fatty acid methyl esters, these include for example: Methyl laureate (methyl dodecanoate) (a) 111-82-0 Methyl oleate (methyl octadecenoate) (a) 112-62-9 Methyl palmitate (methyl hexadecanoate) (a) 112-39-0 Methyl stearate (methyl octadecanoate) (a) 112-61-8	
Hydrogen peroxide	
Kaolin slurry	1332-58-7
1,3-propylene glycol	504-63-2

Unfractionated fatty acid mixture or mixtures of fatty acids from natural oils and fats ¹	
Unfractionated fatty alcohol mixture or mixtures of fatty alcohols from natural oils and fats ²	
Unfractionated fatty esters or mixtures of fatty esters from natural oils and fats ³	
Fructose	

Taking into account the importance to ensure consumer's health protection the EU strongly supports that the above Proposed Draft List of Acceptable Previous Cargoes in the Code for the Storage and Transport of Edible Fats and Oils in Bulk at Step 3 is forwarded to the 34th session of the CAC for adoption at Step 5/8

2. Comments on mechanisms and procedures that could be used to apply the criteria to assess the acceptability of substances as previous cargoes using the Working Principles for Risk Analysis.

The EU is of the opinion that it is of the utmost importance to reach consensus in relation to the mechanisms and procedures that should be used to apply the criteria to assess the acceptability of substances as previous cargoes.

The EU considers that, in principle, JECFA should carry out the evaluations for assessing new substances to be included in the list of previous cargoes once the criteria which are under discussion are adopted by the CAC. The EU believes that this task is within the Terms of Reference of the JECFA. As indicated by the JECFA Secretariat at the CCFO 21, specific scientific advice could be requested where a concern has been identified in the risk analysis process. In order to incorporate new substances to the list, all the interested parties should provide JECFA with the necessary data for their assessments.

Taking into account that JECFA meets twice a year, and that the interval between CCFO meetings is two years, the EU is of the opinion that the lists could be updated within a reasonable timing and using the Codex accelerated procedure if no objections are raised. The EU would like to stress the fact that under Section 2.1.3 of the Code of Practice for the Storage and Transport of Edible fats and Oils in Bulk (CAC/RCP 36-1987) it is clearly stated that "*Previous cargoes not on the Codex List of Acceptable or Banned cargoes are only to be used if agreed upon by competent authorities of the importing countries*". Therefore, if a substance is not in the Codex List of Acceptable Previous Cargoes it does not mean that the substance cannot be used if an agreement is reached.

The EU is open to consider any other proposals which may contribute to speed up the updating of the Codex lists.

MALAYSIA

The 21st Session of the Codex Committee on Fats and Oils (CCFO) in 2009 agreed to circulate for comments in CL 2009/6-FO, the Proposed Draft Criteria to Assess the Acceptability of Substances for Inclusion in a List of Acceptable Previous Cargoes at Step 5 (para. 55, Appendix III, ALINORM 09/32/17) and the Proposed Draft List and Draft List of Acceptable Previous Cargoes in the Code of Practice for the Storage and Transport of Edible Fats and Oils in Bulk at Step 3 and Step 7 respectively (para. 71, Appendix V, ALINORM 09/32/17).

The 21st CCFO also agreed to seek government comments on the mechanisms and procedures that could be used to apply the criteria discussed under Agenda 4a) to assess the acceptability of substances as previous cargoes using the *Working Principles for Risk Analysis*, including the evaluation of substances without ADI, a "modus operandi" to address this issue in a timely manner and the process for inclusion of new substances based on proposals from Members arising from new scientific information and data.

¹ provided their sources are edible types of fats or oils

² provided their sources are edible types of fats or oils

³ provided the sources are restricted such that the fatty acids and the fatty alcohols are from edible types of fats and oils not contaminated with compounds of toxicological concern

The 22nd Session of the CCFO scheduled from 21-25 February 2011 will further discuss the above matters based on written comments submitted in response to the CL 2009/6-FO, and it is hoped that these long standing issues will be resolved at this coming session of the CCFO.

In general we strongly support the advancement of **both the Proposed Draft List at Step 3 and the Draft List at Step 7 to Step 8**. We note that considerable time and effort have been taken to thoroughly deliberate on these lists. There is merit in seeing the conclusion of this effort in the form of a consolidated list which will not impede world trade of fats and oils. With regard to the **mechanisms and procedures that could be used to apply the criteria**, our proposals are as follows:-

In order to facilitate the work of CCFO at the plenary, it is proposed that a Working Group (WG) be established. Recognising that there is a need for the list to be updated on a timely basis in order not to disrupt world trade, it is proposed that an Expert Group (EG) be established.

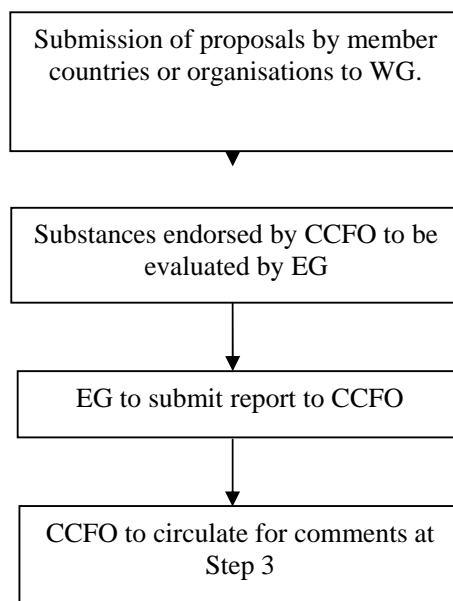
The terms of reference of the WG are as follows:-

- a) To receive proposals for addition of new substances in a standardised format.
- b) To prepare report of the WG as a CRD in English for CCFO.

The terms of reference of the EG are as follows:

- a) To serve as the risk assessor in evaluating the proposed addition of new substances and advise CCFO accordingly.

The schematic diagram of the flow of work is as below:-



With regard to the standardised format, it is proposed that the CCFO deliberates on the information to be included in the format at the 22nd Session of the CCFO

PHILIPPINES

The Philippines is adopting the position to wait for the adoption of the Draft Criteria to Assess the Acceptability in a List of Acceptable Previous Cargoes before a position on these lists is made.

FOSFA

As reported in Alinorm 09/32/REP, the Commission has adopted the Proposed Draft Criteria to Assess the Acceptability of Substances for Inclusion in a List of Acceptable Previous Cargoes at Step 5. Although the criteria may be amended slightly following their recent use by the European Food Standards Authority, FOSFA International supports the full adoption of the criteria. It now needs to be considered as to how the criteria could be used by Codex to modify the lists following applications from Governments, Trade Associations or individual commercial companies to add or remove certain substances.

At the meeting in February, CCFO agreed to retain at Stage 7 the Draft List of Acceptable Previous Cargoes which comprises almost 100 substances. The Committee also agreed to return to Step 3 the Proposed Draft List of Acceptable Previous Cargoes which comprises 15 substances which almost entirely made up of those substances which are on the trade acceptable lists (FOSFA and NIOP) but are not on the EU List of acceptable previous cargoes.

The European Commission recently asked their Food Safety Authority (EFSA) to review the criteria for acceptable previous cargoes as proposed at the CCFO, and EFSA published its scientific opinion on this issue in May 2009 (EFSA, 2009). Essentially, EFSA found that the Codex criteria were not in conflict with any of the five criteria previously developed within the EC. Recently, EFSA has been requested by the European Commission to (re)evaluate the substances on the CCFO Proposed Draft List of acceptable previous cargoes for edible fats and oils, in the light of new technical and toxicological information, if available, and considering all the criteria reviewed in the EFSA's Scientific Opinion. Thus, it is likely that some of these substances will be agreed by EFSA as suitable for addition to the acceptable previous cargo list.

This being the case, it should be possible for CCFO to agree to add these substances which have undergone scrutiny using the CCFO criteria to the list which has already been agreed at Step 7. This amended list would then be very similar to the trade lists and would go a long way to harmonising the trade and Codex procedures. FOSFA believes that the list at Step 7 with the addition of any substances that have been agreed by the European Food safety Authority should be adopted as the Codex Acceptable List and included in the Code of Practice, together with the Criteria when they are adopted.

The majority of the substances which are currently not on the Draft List at Step 7 are those which have been added to the trade lists since 1996. Thus, there have been about two substances each year suggested by various companies for inclusion in the lists. In fact, the number of applications is reducing as the generation of the data required by the Trade committees to evaluate the substances is increasing. We feel that there will be no more than three applications in the two years between CCFO meetings and that if the industry provides the data and the assessment criteria are accepted, then this should not be a burdensome task for JECFA or another comparable body to perform. Since the average time for an application to be agreed by CCFO will thus be about one year, we feel that this is also not unreasonable for the maintenance of the lists.

In summary, FOSFA proposes that the Code of Practice should be revised to include the enhanced acceptable list and to include the criteria for assessment of additions to the list. We believe that the few modifications to the list can be considered by JECFA in their normal course of business and that this allows the removal from the Code of Practice of any reference to products on neither of the lists to be considered by individual country administrations.

BACKGROUND INFORMATION ON THE USE OF THE BANNED AND ACCEPTABLE LISTS OF PREVIOUS CARGOES WITHIN WORLD TRADE

The Mechanics of World Trade

It is estimated that over 85% of the international trade in oilseeds and oils and fats is carried out using FOSFA contracts. This has the benefit of allowing traders to discuss the three major issues of quantity, date of delivery and price, while leaving the details to their contract execution departments. The details (such as who organises the ship, who insures the cargo, sampling and analysis of the cargo etc) do not usually change and are well understood by both companies, being already documented and established globally.

It has been accepted for many years that the biggest risk to food safety within this international trade is the transporting of the cargo by sea from the producing country to the consuming country. The management of this risk area forms a major part of all FOSFA contracts and is described in the document 'Qualifications and Operational Procedures for Ships Engaged in the Carriage of Oils and Fats in Bulk for Edible and Oleo-Chemical Use'. It is accepted by most countries that the use of dedicated freight space is both uneconomic and inefficient and thus, other cargoes may be carried as previous cargoes before the loading of edible oils.

Over the decades of modern trade, it had been found that some cargoes should not be allowed as previous cargoes due to their extreme toxicity, their intense bad flavour/smell characteristics, the difficulty in cleaning them from the tanks and other problematic properties. Thus, when the international contracts were revised in the mid-1980s with the increased awareness of food safety, a list of these products was drawn up and designated as 'the banned list'. Under these standard 'banned list' terms of contract, the receiver would accept the cargo as long as the previous cargo was not on the banned list.

However, with the increase in the sophistication of consumers together with the increased value of branding and the fear of litigation, some companies wished to reduce the risk of the consequences of a contamination from a previous cargo. To this end, a list of common previous cargoes which would not cause too many problems if there were any carry-over was drawn up within FOSFA and other trade bodies. These were cargoes which were typically very water soluble or highly volatile, very easily cleaned, were not toxic and were easily detectable by chemical analysis. This list became known as 'the acceptable list' of previous cargoes. Thus, by the addition of an optional clause to the contract, it became an 'acceptable list' terms contract where the receiver would accept delivery of the cargo as long as the previous cargo was one included in the acceptable list.

Thus, the two lists are never applied together within a contract. Depending on the terms of the contract as agreed by the trading parties, either the banned list applies or the acceptable list applies.

In 1993, the European Union decreed that all foodstuffs must be transported in dedicated freight. However, in 1996, after representation from the industry and various producing countries, oils and fats were given derogation to this rule, but at the same time, it was decided that to ensure a reduced risk, all previous cargoes for imports into the EU must be on an EU acceptable list. At that time, EU food experts reviewed the FOSFA acceptable previous cargo list and accepted the majority of the substances for the EU list. Since then, FOSFA has added some new cargoes and in 2004, the EU carried out a further review and confirmed or removed some further substances to/from the list. In 2009, the European Commission asked the European Food Safety Authority to evaluate/re-evaluate the items which are on the Codex list at step 3 and also on the FOSFA list but not on the EU list, and to consider using the criteria proposed by Codex for this review. The results of this review are on the EFSA website.

No other region has yet adopted the same type of legislation as the EU for oils and fats. However, it should be noted that the trading rules used extensively for imports into the USA (the National Institute of Oilseed Products, NIOP, rules) also require that all previous cargoes are on the NIOP List of acceptable previous cargoes, which is essentially the same as the FOSFA list. But this is not USA legislation.

In summary, while it is not FOSFA's role to dictate the terms of trade between parties, the contracts do offer them a system by which they can reduce the risk of serious consequences from contamination of their products by previous cargoes. There are obviously many products which do not appear on either list. In general, these products are more toxic than those on the acceptable, and may be more reactive with oils and fats and will not be removed by further processing, but nevertheless, with good management of the ships' tanks (cleaning, inspection loading etc) they will cause no problems during the shipping part of the supply chain, and allow greater flexibility in ship utilisation and voyage planning. It is also worth noting that the quality of the fleet used by the edible oils industry has recently been upgraded via the revision of their rules by the International Maritime Organisation.

APPLICATION OF THE LISTS WITHIN THE CODEX CODE OF PRACTICE

Within the Codex Code of Practice CAC/RCP 36, contamination is mentioned only in the general introduction as a type of deterioration which can occur in the storage and transport of edible fats and oils,

with the lists as appendices. As currently written, FOSFA feels that paragraph 2.1.3 is rather unclear in some areas, and somewhat misleading in others. In particular we would comment as follows.

1. In the first paragraph of 2.1.3, the Code states:

"Contamination is avoided ... by the carriage of oils in segregated tank systems in which the previous cargoes are included in the Codex List of Acceptable Previous Cargoes at Appendix 2 of this Code."

This is not correct. Contamination is not avoided by the carriage of previous cargoes which are on any acceptable list. This merely reduces the risk to consumers of the oil if a contamination occurs.

2. In the second paragraph, it states:

"Contamination is also avoided by the rejection of tanks which have carried as a last cargo products which are included on the Codex List of Banned Immediate Previous Cargoes at Appendix 3 of this Code."

This is true and should be the first consideration when selecting tanks for the carriage of edible oils and fats. However, the code does not say that tanks which have carried banned list cargoes must not be used to carry oils and fats as the next cargo.

3. In the third paragraph, it states:

"Previous cargoes not on the Codex Lists of Acceptable or Banned cargoes are only to be used if agreed upon by competent authorities of the importing countries."

From the two points above, it can be seen that the risks associated with the three types of previous cargo are as follows:

Cargoes on the banned list	– high risk
Cargoes not on either list	– medium to low risk
Cargoes on the acceptable list	– low or minimal risk

Thus, as currently written, this third paragraph implies that a trading company may use a tank with a high risk (previous cargo on the banned list) without reference to competent authorities whereas they must refer to competent authorities for a medium risk product (previous cargo on neither list), which is not logical.

The third paragraph brings into question the status of the Code of Practice and its possible effect on world trade. The title of the document states that the code is 'recommended'. This is fine for paragraphs one and two in that they state how contamination can be avoided or the consequences minimised. However, the third paragraph states that tanks with previous cargoes not on the acceptable list are only to be used if agreed upon by the competent authorities of the importing countries. As described above, this is not the current practice in world trade, and we feel that the code would not be agreed by many non-European countries if Codex delegates understood that it would cause major difficulties world trade and a significant increase in price of their oils and fats imports (tanks with acceptable previous cargoes are more expensive as there are fewer of them in general ocean trade).

In commercial terms, the Code is saying in the third paragraph that the standard banned list terms contract may only be used by a buyer if their government agrees that the previous cargo, which is not on the acceptable list, is acceptable! There are hundreds of these products in the medium risk category and we do not believe that many countries would set up the internal mechanisms/group of experts that would decide upon this category to allow importation of vegetable oils into their countries. Moreover, we feel that the development of the criteria for evaluating previous cargoes has eliminated the need to include this sentence referring to the "competent authorities of the importing countries".

It is suggested that the third paragraph is removed from the code, and from the reference in Appendix 3. The code would then recommend that tanks which have carried a banned list product are not used for the carriage of oils and fats as the next cargo and that if an importing country felt that the risk from contamination should be reduced even further, then it may legislate that only cargoes on the acceptable list may precede an edible oil. This reflects the current trade practices and also the legislation of the European Union which is the only 'region' in the world which has demanded, in legislative terms, this low risk provision for previous cargoes. We have attached our proposal of the revised paragraph 2.1.3 and Appendix 3 of the Code.

In summary, we are suggesting:

1. CCFO agree the Criteria as proposed or slightly amended.
2. CCFO agree to add the substances approved by the European Food Safety Authority (December 2009) using these criteria, which are currently at Step 3, to the Draft Approved List at Step 7.
3. This revised list at step 7 can then be approved by the CCFO to become the Codex List of Acceptable Previous Cargoes as it has been investigated and approved at least twice by competent authorities (EFSA and its predecessor committee).
4. CAC agrees that any requests or removal or addition of any substances from/to both lists are referred to JECFA and their decision is considered by CCFO. Experience has shown that there are about two substances each year for which review is required.
5. The Code of Practice is modified as suggested above to remove the requirement for individual countries to change the lists depending on their own evaluation. Of course they may legislate for lower risk imports, as per the EU, if they so desire.

These changes would mean that the Codex Code of Practice mirrored current trade practice and would become more useful for future international trade development.