

# codex alimentarius commission



FOOD AND AGRICULTURE  
ORGANIZATION  
OF THE UNITED NATIONS



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Agenda Item 6

CX/FO 03/7

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

### CODEX COMMITTEE ON FATS AND OILS

Eighteenth Session

London, United Kingdom, 3 – 7 February 2003

### PROPOSED DRAFT LIST OF ACCEPTABLE PREVIOUS CARGOES

#### GOVERNMENT COMMENTS AT STEP 3

The following comments have been received from Brazil and FOSFA International in response to CL 2001/4-FO.

#### BRAZIL

Brazil questions the reason why the substance **Nonane (CAS nr 111-84-2)**, reprovved by European Community, does not appear on the list of the APPENDIX VI of ALINORM 01/17. This substance doesn't appear in any list.

Justification: The approved substances by FOSFA and NIOP, even though reprovved by European Community, were listed in the APPENDIX VI of the ALINORM 01/17, for further evaluation by the Host Countries, aiming the subsequent addition and or elimination of the same in the Lists of Acceptable Previous Cargoes and Banned Immediate Previous Cargoes.

Brazil considers important the inclusion of the substances **Hexane (Technical) – CAS nr 64742-49-0** (reprovved by FOSFA) and **Wine lees – CAS nr 868-14-4** (reprovved by NIOP) in the referred list in the APPENDIX VI of the ALINORM 01/17.

Justification: Despite the fact of the harmonization need among the lists proposed by FOSFA, NIOP and European Community, in a way to avoid future fetter in the international trade, it is considered important that these substances be listed in the APPENDIX VI of ALINORM 01/17 for further evaluation by the Host Countries, as done with the substances reprovved only by European Community.

Brazil questions the reason of referring the substance **Hydrogen Peroxide** in the list of the APPENDIX VI of ALINORM 01/17.

Justification: The reprovved substances by more than one international organization (FOSFA, NIOP, European Community) were eliminated from the 'positive list' proposed by Codex, as well as they were not included in the proposed list, presented on the APPENDIX VI of ALINORM 01/17, for further evaluation by the Host Countries. However, even though reprovved by the organizations above mentioned, it is part of the list of the APPENDIX VI.

## **FOSFA INTENTIONAL**

In circular CL 2001/4-FO dated March 2001, the CAC requested governments and international organisations to provide comments and information on the Proposed Draft List of Acceptable Previous Cargoes. FOSFA International, as the contract issuing and arbitral body of the world trade in oils and fats, submits the following information for consideration by the Commission CCFO.

The notes which are included in Appendix III of Alinorm 01/17 have been taken into account, and the submission has the following format.

- A general document, Appendix I, in which the criteria which can be addressed by common information for all substances carried by ship are considered.
- A further document, Appendix II, which summarises the uses and important properties for each substance listed in Appendix VI which was proposed by the Federation at the February 2001 Meeting. Also, nonane (CAS No.111-84-2) has been included as this substance is present in the trade list but was overlooked on our part at the February 2001 Meeting.
- Finally, dossiers of supporting information e.g. toxicological, carcinogenic, safety, legal status etc., are provided for each substance. These include data from reference books, reports from internationally recognised risk evaluation bodies, and material safety data sheets provided by manufacturers. These are given at Annex 2A<sup>1</sup>.

### **Appendix I – general issues**

Appendix III of Alinorm 01/17 lists several factors which should be taken into consideration during the risk assessment of substances being proposed for inclusion in the List of Acceptable Previous Cargoes. There are some general points which can be made concerning these factors, which are described below.

### **CLEANING PROCEDURES**

FOSFA has been a forum for the worldwide trade in fats and oils for many years. This experience has led to the development of an infrastructure which protects the interests of all areas of the trade, including the consumers. This infrastructure includes the application of several codes of practice which are accepted throughout the world and which ensure that any risks inherent in the trade are reduced to a minimum. This includes the area of cleaning and inspection of all ships' tanks and lines prior to loading with oils and fats.

The procedure for tank cleaning is rigorous and generally includes the following stages

Pre-cleaning (spraying with cold water) .  
Cleaning (spraying with hot water or water and detergents)  
Rinsing (spraying with water)  
Flushing (with fresh water)  
Steaming  
Draining  
Drying

The high pressure spraying apparatus (Butterworth Machine) utilised by the vessels is of a special design which ensures full coverage of all of the surfaces of the tank. The pumping, filling and emptying lines are cleaned simultaneously, in a similar manner, ensuring a positive pressure is maintained. The trade uses a recognised tank cleaning guide\* which defines, for each individual substance, the cleaning regime (detergents, temperatures, times etc) to be used prior to loading oils and fats.

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<sup>1</sup> Note by Secretariat: Annex 2 A was distributed in a electronic form to each Codex Contact Point.

The FOSFA Code of Practice for Superintendents requires that the cleaned ships' tanks are inspected by authorised and independent superintendents prior to the loading of the vessel with oil. They complete a Tank Cleanliness Certificate which also includes a section on the suitability of the tank to receive the oil. This certificate is sent to both the seller and buyer of the oil and ensures that the cleaning has been carried out to a satisfactory standard. Unclean tanks, or tanks which are in a poor condition are rejected in accordance with contractual obligations.

Our industry and the ship owners are proactive in the maintenance of quality throughout the food chain. The procedures and codes have been developed over the years in the light of experience. It should be noted that no problems have been encountered cleaning tanks which have contained any of the substances which are proposed for inclusion in the Codex List.

#### **DILUTION FACTOR**

The cleaning procedure described above ensures that, in the unlikely event of a contamination, the level of contamination will be very low. A possible cause of contamination is the entrapment of some of the substance behind any blisters or loose tank coating material. It is the duty of a superintendent to investigate any blisters to make sure that they are empty of any previous cargo.

As previously stated, the ships' tanks are closely inspected after cleaning. Experience has shown that a superintendent will identify any amount of entrapment of the previous cargo greater than 5-10 kg. the tanks used for the bulk transport of edible oils and fats vary in size but are generally between 750 and 2,000 tonnes, with an average of about 1,000 tonnes. Thus, any contamination from a previous cargo is unlikely to be greater than 10 parts per million, and any possible risk should be evaluated at this concentration, not at the 100% pure substance level, in our opinion.

The materials listed in Appendix VI all have a low viscosity, which means that they are easily diluted and removed by spraying during the wash cycle.

#### **SOLUBILITY**

As water is used during several of the cleaning stages, the solubility of the previous cargoes in water will aid the removal of any of the substances. The majority of the substances being considered in Appendix VI are readily soluble in water. The individual solubility/miscibility data is shown for each substance in the attached data.

#### **REMOVAL OF THE SUBSTANCES DURING DEODORIZATION**

Deodorisation is a necessary step in the manufacture of an edible oil or fat for sale to food manufacturers or the consumers. Deodorisation almost always takes place at temperatures above 220° C and at a very low vacuum. All the substances listed for consideration are easily removed during the deodorization step, without any detriment to the oil.

Our industry has readily accepted the responsibility of "due diligence". The protection of brands and brand "image" means that the principles of HACCP are applied equally to the area of transport and storage within the food chain as well as the manufacturing processes and distribution.

#### **DETECTION AND IDENTIFICATION**

Rigorously developed and internationally approved (ISO) methods of analysis are available to determine whether any of the substances in Appendix VI are present in the oil or fat. The level of contamination can also be determined. This is one of the primary reasons why the reputable Trade Bodies, FOSFA (global trade), PORAM (Malaysian trade), NIOP (USA trade) and FEDIOL (European trade) agreed to the inclusion of these substances amongst others (some 100 substances) on their respective Acceptable Previous Cargo Lists. The declaration of the identity of previous cargoes is an integral component of sales/contractual documentation under FOSFA terms.

## REACTIVITY WITH FATS AND OILS

There has been no research work on the reactivity with oils and fats for any of the substances listed in Appendix VI, although other, more noxious substances have been evaluated. The substances in the Appendix have been considered as non-toxic or of such a nature that any reaction product formed with an oil or fat is likely to have very low or zero toxicity. The industry has adopted this position for these substances since their introduction to the trade lists in 1995, that is, after evaluation by the European Union. Since their introduction, there have been no reported incidents where these substances have occurred as the previous cargo.

Chemical Laboratory "Dr A Verwey", Tank Cleaning Guide (Sixth Edition), ISBN: 90 -800904 -1 -7

## Appendix II – Summaries

### **2,3-Butanediol (2,3-Butylene Glycol)**

**CAS No.513-85-9**

This substance is derived from corn sugar by acid hydrolysis and also from the fermentation of sugar ) beet molasses. It is used in resins and as a solvent for dyes. The substance is very water soluble and, thus, will be easily removed from the tanks and lines during the cleaning process. It is a colourless liquid with a boiling point of 180°C, which means it will be easily removed during the further processing stage of deodorisation.

### **Iso-Butanol**

**CAS No.78-83-1**

This substance is approved by the Joint FAO/WHO Expert Committee on Food Additives (JECFA report no.251 ) as a flavouring agent and for use in the manufacture of esters for fruit flavouring essences. The substance is slightly soluble in water and, thus, any residue left in the tanks will be removed during the cleaning process. It has a boiling point of 108 °C, which means it will be easily removed during the further processing stage of deodorisation. The EPA has set an ADI of 0.3 mg/kg bw/day based on a NOEL of 316 mg/kg bw/day and a 1 ,000 fold safety factor following a 90-day )study.

### **Calcium Ammonium Nitrate Solution**

**CAS No.6484-52-2**

### **Calcium Nitrate (CN-9) Solution**

**CAS No.35054-52-5**

These substances are both fertiliser products which are applied directly to the soil as supplemental or ) secondary nitrogen sources. The calcium supplement which is provided by both of these products is required for "high cash crops" such as vegetables and fruit trees. The difference between the two products is that the CN-9 fertiliser is a more concentrated solution used for the "higher en, high cash crops". Owners currently handling CAN-17 and CN-9 have advised that the ship's tank cleaning procedures are relatively simple since each product is 24% and 42% water, respectively. The information gathered does not categorise calcium, calcium nitrate or ammonium nitrate as toxic or carcinogenic. This result should be expected as these fertiliser products are currently an important link in the present food chain. The permitted level of nitrates in drinking water is given as between 10-20 ppm.

### **Cyclohexanol**

**CAS No.108-93-0**

This substance is used in the manufacture of nylon. It is listed in Title 21 of the Code of Federal Regulations, Food and Drugs as a carrier solvent for the use in adhesive, which may come into contact with Foodstuffs. Cyclohexanol is not listed as a carcinogen or an anticipated carcinogen in the US Government's Annual Report on Carcinogens from the National Toxicology Program (NTP). It is not listed as a carcinogen by the Agency for Toxic Substances and Disease Registry or by the International Agency for Research on Cancer (IARC).

## CAS No.108-94-1

### Cyclohexanone

This material has a similar use to cyclohexanol in the manufacture of nylon. According to data reported and an evaluation in an IARC monograph (Vol. 47 last updated 13 April 1999), cyclohexanone was tested for carcinogenicity by oral administration in the drinking-water in one strain of mice and one strain of rats. In mice, there was a slight increase in the incidence of tumors that occur commonly in this strain. In rats, a slight increase in the incidence of adrenal cortical adenomas occurred in males treated with the low dose. No significant systemic toxicity was reported in humans or experimental animals. No significant prenatal toxicity was observed in mice. Cyclohexanone is slightly soluble in water and it has a boiling point of 167°C and will thus be removed during deodorisation.

### Fatty Acid Methyl Esters

These products are generally derived from fats and oils by further processing. They have been extensively evaluated by the Scientific Committee for Food of the EU and at their 10th Meeting (1997) it was concluded that on the basis of the information provided by APAG (The European Oleochemicals & Allied Products Group), these products should be transferred into the EU list of acceptable previous cargoes. The information that was provided for this evaluation is included as a dossier with this submission.

### Hydrogen Peroxide

## CAS No.7722-84-1

Hydrogen Peroxide is a mild disinfectant and is useful in counteracting various microorganisms. Because of their antiseptic action, dilute hydrogen peroxide solutions (3% or less) are frequently used to treat open wounds and can be used to gargle or mouthwash. It has FDA GRAS status as a bleaching agent. Hydrogen peroxide has been evaluated by JECFA (published in FNP 34 (1986)) and is a permitted preservative and sterilising agent. It has also been the subject of a report by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE -report attached) which concluded that further testing was unlikely to reveal any specific developmental effects. Hydrogen Peroxide is non-combustible. It has a boiling point of 110°C and would be easily removed during the deodorisation process.

### Kaolin Slurry

## CAS No.1332-58-7

Kaolin or China Clay Slurry (Hydrated Aluminium Silicate) is a naturally occurring substance which is chemically inert. It has been evaluated by JECFA (Report TRS 733-JECFA 29/24) and is a permitted anti-caking food additive. It has also been approved by the FDA (CFR 178.3297) as a permitted additive in the manufacture of coatings used as the food contact surface of articles used in food manufacture and packaging. It is considered a hazard only when in powder form, via inhalation. Kaolin slurry usually contains biocides, but the manufacturers have agreed that only FDA approved additives will be used.

### 1,3-Propylene Glycol

## CAS No.504-63-2

This material is used in the manufacture of polyesters. There is little data but it appears to be of low toxicity. It is soluble in water. It has a boiling point of 210 °C and will thus be removed during deodorisation.

### Nonane

## CAS No.111-84-2

The uses of Nonane include organic synthesis and the manufacture of biodegradable detergents. It is described as mildly toxic by inhalation, and irritating to the respiratory tract. It has a boiling point of 151 °C and will thus be removed during deodorisation.