codex alimentarius commission





JOINT OFFICE: Viale delle Terme di Caracalla 00100 ROME Tel: 39 06 57051 www.codexalimentarius.net Email: codex@fao.org Facsimile: 39 06 5705 4593

AGENDA ITEM NO. 7

CX/FL 06/34/9

E

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD LABELLING THIRTY-FOURTH SESSION OTTAWA, CANADA, MAY 1 – 5, 2006

PROPOSED DRAFT DEFINITION OF TRANS-FATTY ACIDS (CL 2005/51-FL)

GOVERNMENT COMMENTS AT STEP 3

COMMENTS FROM:

COSTA RICA FIJI

IRAN

JORDAN

MEXICO

NEW ZEALAND

PERU

SOUTH AFRICA

UNITED STATES

EUROPEAN DAIRY ASSOCIATION (EDA)
THE EU OIL AND PROTEINMEAL INDUSTRY (FEDIOL)

INTERNATIONAL DAIRY FEDERATION (IDF)

INTERNATIONAL FEDERATION OF MARGARINE ASSOCIATIONS (IFMA)

PROPOSED DRAFT DEFINITION OF TRANS-FATTY ACIDS (CL 2005/51-FL)

GOVERNMENT COMMENTS AT STEP 3

COSTA RICA:

Regarding the work and the discussion that took place to define the term "trans fatty acids" we welcome the input from the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) and from the Codex Committee on Food Labelling (CCFL).

Costa Rica agrees with the definition proposed by the CCFL for "trans fatty acids" (see text) and believes that this definition should be included in the Codex Guidelines on Nutrition Labelling CAC/GL 2-1985, Rev. 1-1993 and Rev. 1-2003, as that is the only document that includes definitions for nutrient, sugars, dietetic fibber and polyunsaturated fatty acids. Other Codex Standards, such as the General Standard for the Labelling of Prepackaged Foods, do not make reference to those definitions, it is recommended to include the definition of "trans fatty acids" only in the Standard for Nutrition Labelling and to make reference to it in the other standards that mention the term "trans fatty acids". This would help maintaining the uniformity of the terminology being used.

Trans Fatty Acids

"For the purpose of the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated carbon-carbon double bonds in the trans configuration interrupted by at least one methylene group

FIJI:

Fiji supports amendment to the General Standard on Labelling of Prepackaged Foods and the Guideline on Nutrition Labelling to include the following definition for Trans-Fatty Acids:

For the purpose of the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines, trans-fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans-configuration. Changes to the above definition should be initiated at such time as there is sufficient scientific evidence to take into account the health impact of TFA provided by specific foods or food categories e.g. dairy products.

IRAN:

Iran supports amendment of the general standard on Labelling of Prepackaged Foods that was mentioned in: CL 2005/51-FL November 2005.

JORDAN:

We support amendment of the General Standard on Labelling of Prepackaged Foods and the Guidelines on Nutrition Labelling to include the following definition for trans fatty acids: For the purpose of the Codex Guidelines on Nutrition Labeling and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration

MEXICO:

Mexico does not have any comments on Trans Fatty Acids, and consider that the definition should be adopted as it is.

NEW ZEALAND:

New Zealand supports the proposed definition:

For the purpose of the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometric isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration.

From a practical point of view it is our understanding that the food composition analysis appropriate for the above definition of trans fatty acids is not difficult and is routinely used in food composition work internationally, including in New Zealand.

PERU:

Peru agrees with the proposed definition.

SOUTH AFRICA

South Africa has reservations on the current Codex definition for trans fatty acids, since it is a purely chemical definition, which covers a wide range of trans fatty acids stemming from natural origins as well as industrial processes. The definition is not based on biological data or the latest findings in nutrition science. It is our opinion that the present Codex definition is not appropriate or suitable to protect the health of consumers adequately.

The negative effects of certain trans fatty acids derived from the partial hydrogenation of oils and fats in the presence of a suitable catalyst or through raffination/deodorisation of fats and oil applying heat, are well documented in scientific literature. However, naturally occurring trans fatty acids in animal fats, particular dairy fats such as trans vaccenic acid and dairy conjugated linoleic acids (CLA) do not seem to exert undesired health effects. Dairy CLA and trans vaccenic acid might even promote beneficial health effects. It is clear that different trans fatty acids isomers show different metabolic behaviour.

In addition South Africa is concerned about the present lack of reliable and cost-effective methods to differentiate and determine the individual trans isomers in different matrices. Present methodology such as silver ion thin layer chromatography with two or three columns in series and a UV detector is complex, expensive and time consuming and may not be seen as suitable for routine use in nutritional analysis for labelling purposes.

South Africa therefore recommends that a decision by CCFL about the inclusion of the proposed Codex definition for trans fatty acids in the *Codex General Standard for Labelling of Prepackaged Foods* and in the *Codex Guidelines on Nutrition Labelling* be postponed until:

- more extensive research on individual trans fatty acids has been done and the scientific knowledge has improved and are considered conclusive for both the harmful effects and the health benefits of individual trans isomers; and
- a more in-depth investigation is done to improve the analytical methodology required to differentiate between the individual trans isomers. The legislative experience from countries such as Canada and Denmark may be very valuable in this regard.

At the same time CCFL should formally requests the WHO/FAO to look into this matter since it is our understanding that a revision of the "WHO/FAO Recommendations on Fats and Oils in Human Nutrition" is presently under consideration.

UNITED STATES:

The United States supports the inclusion of the definition of trans-fatty acids as drafted, on which consensus was reached at the 33rd session of the CCFL, within the Definitions section of the Codex Guidelines on Nutrition Labelling. The United States also supports the use of this definition for the purpose of related Codex texts, such as the Guidelines for Use of Nutrition Claims.

EUROPEAN DAIRY ASSOCIATION (EDA):

The EDA, representing the overall European dairy industry, welcomes the opportunity to comment on the Codex Commission request to the coming Codex Committee on Food Labelling to consider the inclusion of the Codex definition of Trans Fatty Acids (TFA) into both the General Standard for the Labelling of Prepackaged Food and into the Guidelines on Nutrition Labelling.

In this respect, the EDA would like to remind that the present Codex definition on TFA covers isomers present in all type of fats without actually considering the compositional and physiological differences that exist between TFA present in fats of ruminant origin and those found in partially hydrogenated vegetable oils (PHVO)¹.

[•] In animal fats such as ruminant milk fat, TFA are formed from polyunsaturated fatty acids during the biohydrogenation process of rumen anaerobic bacteria. The main TFA in ruminant milk fat is the vaccenic acid (VA), which represents about 43% of the total TFA. This significantly depends on the type of feeding.

TFA are also generated during partial hydrogenation of vegetable oils: in this case, the major TFA isomers are elaidic (EA) and trans-10 octadecenoic acids.

There are methods of analysis that can establish such differences, e.g. high-resolution gas-liquid chromatography or analysis of triacylglycerol profile (methodology already available for authenticity of milk fat). These methodologies could be routinely used for quality control assessment.

This purely chemical definition does therefore not seem to be adequate when it comes to consider the possible introduction of labelling requirements aiming at informing consumers about the nutritional composition of the product they are eating. As a matter of fact, although there are sufficient scientific publications showing the negative effects of certain TFA (notably those from an industrial hydrogenation of oils and fats) there is currently no conclusive scientific evidence about such effects concerning TFA naturally occurring in milk. Moreover, it is important to note here that clinical studies are currently being carried out to better determine human health effects of TFA according to their sources.

Besides this, whereas nutritionists are considering TFA taking into account the total fat consumption and their contribution to the total energy intake, and whereas the contribution of TFA in dietary patterns is minute (they represent roughly 1% of total energy intake), one could question the nutritional relevance of highlighting them in the labelling of foodstuffs.

Considering all these elements and current developments in science, EDA is of the opinion that the Codex Committee on Food Labelling should suspend any premature actions that would risk creating a situation where messages delivered to the consumer might induce a wrong perception about the impact of TFA on health.

To substantiate these comments, EDA invites Codex members to consider the attached scientific consensual paper on evidences of existing compositional and physiological differences between TFA from PHVO and those from dairy fat.

E U R O P E AN D A I R Y A S S O C I A T I ON ASSOCIATION LAITIERE EUROPEENNE EUROPÄISCHER MILCHINDUSTRIEVERBAND

Brussels, July 2005

Evidences of Existing Compositional and Physiological Differences between Trans Fatty Acids from Partially Hydrogenated Vegetable Oils and those from Dairy Fat

Consensual Argumentation Paper of the EDA Expert Panel on TFA

1. Pattern of TFA

The European Food Safety Authority (EFSA) states correctly that there is a considerable overlap of trans-fatty acid (TFA) isomers in fats of ruminant origin and partially hydrogenated vegetable oils (PHVO), with many isomers in common. We would, however, like to draw attention to the differences in the TFA isomer patterns.

The term "ruminant" encompasses TFA from both dairy products and ruminant meat. In ruminant fat vaccenic acid (VA, short name t11-18:1 or 18:1t, n-7) typically accounts for 14-72% (mean value 43.4%, 1765 milk fat samples analyzed) of all trans-18:1 isomers (1). In dairy fat, the distribution pattern of trans-C18:1 depends significantly on the feeding management, e.g. pasture versus barn feeding (2-4). The predominant trans-18:1 isomer in PHVO is t9-18:1, elaidic acid (EA) amounts of which could vary in the range of 15-46 %.(1,5). The t10-18:1 isomer ranks second (mean, 21%), and VA represents on average 13% of total TFA (1,6).

Trans-18:3 isomers are found in PHVO could also be formed during deodorization of oils rich in α -linolenic acid (18:3, n-3) (6). Partially hydrogenated fish oils contain trans-isomers of 16:1,

18:1, 20:1 and 22:1 and other long-chain TFA (7). As long as it is not clarified as to which TFA isomers are responsible for one or all metabolic effects, it is not possible to disregard these differences. Dairy fat contains no trans-18:3 isomers and only traces of trans-16:1 (8-9).

2. Analysis of TFA

Authenticity of dairy products and biomarkers of dairy fat intake

EFSA states "at present there are no methods of analysis applicable to a wide range of foods that can distinguish between TFA of natural origin and those formed during processing". However, there are means to distinguish them, using high-resolution gas-liquid chromatography (1,9). These methodologies could be routinely used for quality control assessment.

Another possible approach is to determine the ratio of VA to c9,t11-CLA. This conjugated isomer of linoleic acid is the product of delta-9-desaturation of VA, is essentially present only in ruminant fat and its concentration is therefore strictly correlated to the concentration of VA (10).

Additionally, authenticity of milk fat could be determined by analysing triacylglycerol profile or short chain and branched-chain fatty acids, which are distinct features of milk fat (4,11).

Intake of dairy fat could be easily assessed by analysing the level of pentadecanoic acid in serum lipids (12). This uneven numbered saturated fatty acid is present in dairy fat and is as well incorporated into serum cholesteryl esters and phospholipids (12).

3. Biological effect and metabolic differences

Effect of TFA on factors associated with coronary heart disease risk

Cholesterol and lipoprotein cholesterol levels are established risk indicators for coronary heart disease (CHD), but explain only part of the risk. Consumption of TFA from PHVO increases LDL-cholesterol and lowers HDL-cholesterol (13,14).

The EFSA report indicates that there is a lack of data comparing the health effects of TFA from animal origin and those coming from PHVO or refined vegetable oils, i.e. data on the effect of different TFA under "ceteris paribus" conditions (isoenergetic diets with otherwise identical fatty acid profile). We agree with this statement. Nevertheless, the production of milk fat samples differing mainly in TFA content is feasible (15), Seidel and co-workers observed a decrease of the LDL/HDL ratio and Lipoprotein(a) concentration in humans after a three-week diet with fat-modified dairy products rich in VA, in comparison with other fats (16).

Some unpublished results (Mendy et al., 2005 and Kuhnt et al. 2005) suggest that low levels of VA do not have the same effect as EA on lipid factors associated with cardiovascular disease risks. More results obtained using VA-enriched milk fat will be available in the near future. Additionally, clinical studies comparing the respective effects of EA and VA could be carried out if large amounts of pure EA and VA are prepared by chemical synthesis.

A study was conducted by Meijer et al (17) on the atherogenic effect of EA vs. VA. Hamsters were fed a hyperlipidemic diet (30% of energy) and cholesterol lipoproteins were measured. The results were compared to an oleic acid group (non atherogenic). No significant differences were observed between the EA and VA groups. However, macroscopic liver vacuolisations were observed in each group, including the oleic acid group. The occurrence of hepathic disorders, induced by the hyperlipidemic diets, does not allow concluding about the putative atherogenic effect of VA.

CHD is the consequence of systemic chronic inflammation, and therefore the effect of dietary TFA on markers of inflammation (interleukin-6, IL-6; C-reactive protein, CRP; soluble tumor necrosis factor receptors, sTNF-R; adhesion molecules) deserves attention. High levels of IL-6 and CRP are also linked to adiposity and the metabolic syndrome. TFA consumption increases markers of inflammation (18,19). Butter consumption led to levels intermediate between stick margarine and soy oil (19). This could be explained by its content of saturated fatty acids

(18).

Recent studies concentrated on the association between TFA intake and inflammatory parameters. In the Nurses' Health Study, TFA intake was positively correlated with high levels of CRP, sTNFR-2 and serum adhesion molecules (20) and with serum levels of sTNF-R1 and sTNF-R2 (21). TFA in blood cell membranes were positively correlated with levels of markers of inflammation in patients with established heart failure (22). Again, these studies were carried out in populations with moderate intake of ruminant TFA.

Trans α -linolenic acid (trans-18:3) may be one of the active TFA. A low amount of 1.4g/day from deodorized rapeseed oil increased the ratio of LDL/HDL-cholesterol by 8.1% and of total/HDL-cholesterol by 5.1% (23). Another study found that TFA from partially hydrogenated fish oil have more adverse effects on lipoprotein cholesterol levels than the same amount of TFA from partially hydrogenated soybean oil (24). These compounds are not present in milk fat (8), therefore such data are not relevant when considering biological effect of dairy TFA.

Bioconversion of VA and its biological significance: a distinct feature of ruminant TFA

There is evidence in cells of various origins that VA and EA are different, with respect to fatty acid metabolism and insulin secretion (25-33). Whether this is relevant *in vivo* is not clear, but all effects of VA as compared to EA are considered favourable or at least neutral.

The most prominent characteristic of VA is its conversion to c9,t11-CLA in the human body, at a rate of around 20-30% (34-35). There is strong evidence, both *in vitro* and *in vivo*, that c9,t11-CLA may be beneficial for health.

The most documented benefit is its carcinogenesis preventive property against breast cancer (36). Some animal studies have found that this isomer inhibits atherogenesis and promotes atherosclerotic lesion regression (37), and attenuates inflammation (38). In humans, c9,t11-CLA decreased mitogen-induced activity of lymphocytes (39) and showed beneficial effects on serum lipids (40).

Reports (41-42) reinforce the notion that the conversion of VA acid to c9,t11-CLA is as important for mammary cancer prevention as dietary c9,t11-CLA itself, at least in the rat studies. The conversion of dietary VA to c9,t11-CLA dose-dependently increased the accumulation of c9,t11-CLA in mammary fat, accompanied by a parallel decrease of tumor formation (42). On the contrary, EA promoted carcinogenesis in the large intestine of rats (43). In addition, c9,t11-CLA does not induce fatty liver and insulin resistance (44-46).

At present, it is too early to have a definitive opinion on the health effects of CLA. More intervention studies in humans comparing the major CLA isomers should thus be stimulated.

4. Epidemiological data

All prospective studies listed by EFSA found that increasing intake of TFA increases CHD risk. All were carried out in populations with a moderate intake of animal TFA. Several of them also showed a significant (47) or non-significant inverse association of CHD risk with intake of animal TFA (48) or at least no increased risk with increasing intake animal TFA (49). Only the Zutphen Elderly Study (50) observed a positive (apparently non-significant) association between ruminant TFA intake and CHD risk. This is surprising, as ruminant TFA intake in this study population was as low as in most other prospective studies, on average 1.7g/day or 16% of total TFA, against a background of high TFA intake from PHVO and other sources (on average 8.8g/day).

Of the studies not mentioned by the EFSA report, one observed a significant positive association of CHD risk with margarine, and a non-significant inverse association with butter intake (51). A cross-sectional study in an U.K. population found in men no increased CHD risk with increasing total TFA intake, but a significant inverse association with ruminant TFA intake (52). In this population, TFA intake from ruminant fat was on average 4.9g/day, from other sources was 7g/day.

Weggemans and co-workers (53) recently reviewed the epidemiological data available on the

relationship between TFA intake from both sources, PHVO (industrial) and ruminant, and CHD risk. The authors conclude that due to the scarcity of literature, thorough comparison of the adverse health effects of ruminant versus industrial TFA is not achievable.

5. Conclusions and perspectives

There is evidence of unfavourable effects of TFA from PHVO on LDL, HDL and other risk factors associated with cardiovascular disease. However, clinical or epidemiological data on the potential unfavourable effect of the prevailing TFA in milk, VA, on cardiovascular disease risk factors are seldom.

There are means to track the origin of TFA in foods based on the fatty acid pattern. Individual TFA isomers do have different physiological effects. Preliminary data and recently published results suggest that dairy TFA do not have same effect on factors associated with CHD risk compared to TFA from PHVO.

The EFSA report mentions that the current CLA intake from natural sources is too low to show beneficial health effects. On that point, it is important to underline that there are natural ways to significantly increase the CLA content of ruminant products.

Furthermore, as we know too little about long-term effects of low doses of natural TFA, and possibly synergy effects with other diet ingredients, it is not justified to exclude such a beneficial effect at this point.

To address the lack of scientific evidence, several studies are currently under way in Europe and in the US to investigate the effects of TFA and CLA on human health, for example the EU6FP project and the project entitled TRANSFACT, involving the Nestlé Research Centre, the INRA and CNIEL and the project BIOCLA within the EU5FP

(http://www.teagasc.ie/research/dprc/biocla/index.htm). It would be advisable to take the results of these studies into account when evaluating the potential health effects of ruminant TFA.

6. References

01 PRECHT D. AND MOLKENTIN J: Trans fatty acids: implications for health, analytical methods, incidence in edible fats and intake Die Nahrung 39,343-374, 1995.

02 BAUMAN DE, GRIINARI JM: Nutritional regulation of milk fat synthesis. Annu Rev Nutr. 23: 203-227, 2003.

03 JAHREIS J, FRITSCHE J AND STEINHART H: Conjugated linoleic acid in milk fat - high variation depending on production system. Nutr Res 17: 1479-1484, 1997.

04 KRAFT J, COLLOMB M, MOECKEL P, SIEBER R, JAHREIS G: Differences in CLA isomer distribution of cow's milk lipids. Lipids 38: 657-664, 2003.

05 WOLFF RL, COMBE NA, DESTAILLATS F, BOUE C, PRECHT D, MOLKENTIN J, ENTRESSANGLES B: Follow-up of the delta4 to delta16 trans-18:1 isomer profile and content in French processed foods containing partially hydrogenated vegetable oils during the period 1995-1999. Analytical and nutritional implications. Lipids, 35:815-25, 2000.

06 DE GREYT W, RADANY O, KELLENS M, HUYGHEBAERT A: Contribution of trans-fatty acids from vegetable oils and margarines to the Belgian diet. Fett/Lipid, 1:30-33, 1996.

07 ARO A, VAN AMELSVOORT J, BECKER W, VAN ERP-BAART MA, KAFATOS A, LETH T, VAN POPPEL G: Trans fatty acids in dietary fats and oils from 14 European countries: The TRANSFAIR study. J Food Comp Anal, 11:137-149, 1998.

08 DIONISI F, GOLAY PA, FAY, LB: Influence of milk fat presence on the determination of trans fatty acids in fats used for infant formulae. Anal-Chim-Acta. 465:395-407, 2002.

09 DESTAILLATS F, WOLFF RL, PRECHT D, MOLKENTIN J. Study of individual trans- and cis-16:1 isomers in cow, goat, and ewe cheese fats by gas-liquid chromatography with emphasis on the trans-delta3 isomer. Lipids. 35:1027-1032, 2000.

10 PRECHT D. AND MOLKENTIN J: Frequency distributions of conjugated linoleic acid and trans fatty acid contents in European bovine milk fats. Milchwissenchaft 55:687-691, 2000.

- 11 ISO/DIS 17678 / IDF 202 Detection of foreign fats by gas chromatographic analysis of triglycerides (Reference method)
- 12 SMEDMAN AE, GUSTAFSSON IB, BERGLUND LG, VESSBY BO: Pentadecanoic acid in serum as a marker for intake of milk fat: relations between intake of milk fat and metabolic risk factors. Am J Clin Nutr, 69:22-29, 1999
- 13 ZOCK P.L., KATAN M.B: Hydrogenation alternatives: effects of trans fatty acids and stearic acid versus lineleic acid on serum lipids and lipoproteins in humans. J. Lipid Res. 1992 33:399-410, 1992.
- 14 MENSINK R.P.; ZOCK P.L.; KESTER A.D.; KATAN M.B., Effects of dietary fatty acids and carbohydrates on the ratio of serum total to HDL cholesterol and on serum lipids and apolipoproteins: a meta-analysis of 60 controlled trials, Am. J. Clin. Nutr. 77:1146-1155, 2003.
- 15 BAUMAN DE, BARBANO DM, DWYER DA, GRIINARI JM: Production of butter with enhanced conjugated linoleic acid for use in biomedical studies with animal models. J Dairy Sci., 83:2422-2425, 2000.
- 16 SEIDEL C, DEUFEL T, JAHREIS G: Effects of fat-modified dairy products on blood lipids in humans in comparison with other fats. Ann Nutr Metab. 49:42-48, 2005.
- 17 MEIJER GW, VAN TOL A, VAN BERKEL TJ, WESTSTRATE JA: Effect of dietary elaidic versus vaccenic acid on blood and liver lipids in the hamster. Atherosclerosis 157:31-40, 2001.
- 18. BAER DJ, JUDD JT, CLEVIDENCE BA, TRACY RP: Dietary fatty acids affect plasma markers of inflammation in healthy men fed controlled diets: a randomized crossover study. Am J Clin Nutr, 79:969-973, 2004.
- 19 HAN SN, LEKA LS, LICHTENSTEIN AH, AUSMAN LM, SCHAEFER EJ, MEYDANI SN: Effect of hydrogenated and saturated, relative to polyunsaturated, fat on immune and inflammatory responses of adults with moderate hypercholesterolemia. J Lipid Res, 43:445-452, 2002.
- 20 LOPEZ-GARCIA E, SCHULZE MB, MEIGS JB, MANSON JAE, RIFAI N, STMPFER MJ, WILLETT WC, HU FB: Consumption of trans fatty acids is related to plasma biomarkers of inflammation and endothelial dysfunction. J Nutr, 135:562-566, 2005.
- 21 MOZAFFARIAN D, PISCHON T, HANKINSON S, RIFAI N, JOSHIPURA K, WILLETT WC, RIMM EB: Dietary intake of trans fatty acids and systemic inflammation in women. Am J Clin Nutr, 79:606-612, 2004a.
- 22 MOZAFFARIAN D, RIMM EB, KING IB, LAWLER RL, MCDONALD GB, LEVY W (2004) Trans fatty acids and systemic inflammation in heart failure. Am J Clin Nutr, 80:1521-1525, 2004b.
- 23 VERMUNT SHF, BEAUFRÈRE B, RIEMERSMA RA, SÉBÉDIO JL, CHARDIGNY JM, MENSINK RP, TransLinE investigators: Dietary trans a-linolenic acid from deodorised rapeseed oil and plama lipids and lipoproteins in healthy men: the TransLinE Study. Br J Nutr, 85:387-392, 2001.
- 24 ALMEDINGEN K, JORDA O, KIERULF P, SANDSTAD B, PEDERSEN JI: Effects of partially hydrogenated fish oil, partially hydrogenated soybean oil, and butter on serum lipoproteins and Lp[a] in men. J Lipid Res, 36:1370-1384, 1995.
- 25 LAWSON LD, KUMMEROW FA: β-Oxidation of the coenzyme A esters of vaccenic, elaidic, and petroselaidic acids by rat heart mitochondria. Lipids, 14:501-503, 1979.
- 26 ROSENTHAL MD, DOLORESCO MA: The effects of trans fatty acids on fatty acid D5 desaturation by human skin fibroblasts. Lipids, 19:869-874, 1984.
- 27 AWAD AB, HERRMANN T, FINK CS, HORVATH PJ: 18:1 n7 fatty acids inhibit growth and decrease inositol phosphate release in HT-29 cells compared to n9 fatty acids. Cancer Lett, 91:55-61, 1995.
- 28 VAN GREEVENBROEK MMJ, ROBERTUS-TEUNISSEN MG, ERKELENS DW, DE BRUIN TW: Lipoprotein secretion by intestinal Caco-2 cells is affected differently by trans and cis unsaturated fatty acids: effects of carbon chain length and position of double bond. Am J Clin Nutr, 68:561-567, 1998.
- 29 WOLDSETH B, RETTERSTOL K, CHRISTOPHERSON B: Monounsaturated trans fatty acids, elaidic acid and trans vaccenic acid, metabolism and incorporation in phospholipid molecular species in hepatocytes. Scan J Clin Lab Invest, 58:635-645, 1998.
- 30 ALSTRUP KK, BROCK B, HERMANSEN K: Long-Term exposure of INS-1 cells to cis and trans fatty acids influences insulin release and fatty acid oxidation differentially. Metabolism, 53:1158-65, 2004.
- 31 SAUER LA, DAUCHY RT, BLASK DE, KRAUSE JA, DAVIDSON LK, DAUCHY EM, WELHAM KJ, COUPLAND K: Conjugated linoleic acid isomers and trans fatty acids inhibit fatty acid transport in hepatoma 7288CTC and

- inguinal fat pads in buffalo rats. J Nutr, 134:1989-1997, 2004.
- 32 WOLDSETH B, RETTERSTOL K, CHRISTOPHERSON B: Monounsaturated trans fatty acids, elaidic acid and trans vaccenic acid, metabolism and incorporation in phospholipid molecular species in hepatocytes. Scan J Clin Lab Invest, 58:635-645, 1998.
- 33 ROSENTHAL MD, WHITEHURST MC: Selective effects of isomeric cis and trans fatty acids on fatty acyl delta 9 and delta 6 desaturation by human skin fibroblasts. Biochim Biophys Acta, 753:450-9, 1983.
- 34 SALMINEN I, MUTANEN M, ARO A: Dietary trans fatty acids increase conjugated linoleic acid levels in human serum. J Nutr Biochem, 9:93-98, 1998.
- 35 SANTORA JE, PALMQUIST DL, ROEHRIG KL: trans-Vaccenic acid is desaturated to conjugated linoleic acid in mice. J Nutr, 130: 208-215, 2000.
- 36 IP C, DONG Y, IP MM, BANNI S, CARTA G, ANGIONI E, MURRU E, SPADA S, MELIS MP, SAEBO A: Conjugated linoleic acid isomers and mammary cancer prevention. Nutr Cancer, 43:52-8, 2002.
- 37 KRITCHEVSKY D, TEPPER SA, WRIGHT S, CZARNECKI SK, WILSON TA, NICOLOSI RJ: Conjugated linoleic acid isomer effects in atherosclerosis: growth and regression of lesions. Lipids, 39:611-616, 2004.
- 38 CHANGHUA L, JINDONG Y, DEFA L, LIDAN Z, SHIYAN Q, JIANJUN Y: Conjugated linoleic acid attenuates the production and gene expression of proinflammatory cytokines in weaned pigs challenged with lipopolysaccharide. J Nutr, 135:239-244, 2005.
- 39 TRICON S, BURDGE GC, KEW S, BANERJEE T, RUSSELL JJ, GRIMBLE RF, WILLIAMS CM, CALDER PC, YAQOOB P: Effects of cis-9,trans-11 and trans-10,cis-12 conjugated linoleic acid on immune cell function in healthy humans. Am J Clin Nutr, 80:1626-1633, 2004.
- 40 TRICON S, BURDGE GC, KEW S, BANERJEE T, RUSSELL JJ, JONES EL, GRIMBLE RF, WILLIAMS CM, YAQOOB P, CALDER PC: Opposing effects of cis-9,trans-11 and trans-10,cis-12 conjugated linoleic acid on blood lipids in healthy humans. Am J Clin Nutr, 80:614-620, 2004.
- 41 BANNI S, ANGIONI E, MURRU E, CARTA G, MELIS MP, BAUMAN D, DONG Y, IP C: Vaccenic acid feeding increases tissue levels of conjugated linoleic acid and suppresses development of premalignant lesions in rat mammary gland. Nutr Cancer, 41:91-97, 2001.
- 42 CORL BA, BARBANO DM, BAUMAN DE, IP C: cis-9, trans-11 CLA derived endogenously from trans-11 18:1 reduces cancer risk in rats. J Nutr, 133:2893-2900, 2003.
- 43 HOGAN ML, SHAMSUDDIN AM: Large intestinal carcinogenesis. I. Promotional effect of dietary fatty acid isomers in the rat model. J Natl Cancer Inst, 73:1293-1296, 1984.
- 44 CLEMENT L, POIRIER H, NIOT I, BOCHER V, GUERRE-MILLO M, KRIEF S, STAELS B, BESNARD P: Dietary trans-10,cis-12 conjugated linoleic acid induces hyperinsulinemia and fatty liver in the mouse. J Lipid Res, 43:1400-1409, 2002.
- 45 RISÉRUS U, ARNER P, BRISMAR K, VESSBY B: Treatment with dietary trans10, cis12 conjugated linoleic acid causes isomer-specific insulin resistance in obese men with the metabolic syndrome. Diabetes Care, 25:1516-1521, 2002a.
- 46 RISÉRUS U, BASU S, JOVINGE S, FREDRIKSON GN, ÄRNLÖV J, VESSBY B: Supplementation with conjugated linoleic acid causes isomer-dependent oxidative stress and elevated C-reactive protein. A potential link to fatty acid-induced insulin resistance. Circulation, 106:1925-1929, 2002b.
- 47 PIETINEN P, ASCHERIO A, KORHONEN P, HARTMAN AM, WILLETT WC, ALBANES D, VIRTAMO J: Intake of trans fatty acids and risk of coronary heart disease in a cohort of Finnish men. Am J Epidemiol, 145:876-887, 1997.
- 48 WILLETT WC, STAMPFER MJ, MANSON JE, COLDITZ GA, SPEIZER FE, ROSNER BA, SAMPSON LA, HENNEKENS CH: Intake of trans fatty acids and risk of coronary heart disease among women. Lancet, 341:581-585, 1993.
- 49 HU FB, STAMPFER MJ, MANSON JE, RIMM E, COLDITZ GA, ROSNER BA, HENNEKENS CH, WILLETT WC: Dietary fat intake and the risk of coronary heart disease in women. New Engl J Med, 337:1491-1499, 1997.
- 50 OOMEN CM, OCKÉ MC, FESKENS EJM, VAN ERP-BAART MAJ, KOK FJ, KROMHOUT D: Association between trans fatty acid intake and 10-year risk of coroanry heart disease in the Zutphen Elderly Study: a prospective population-based study. Lancet 357:746-751, 2001.
- 51 GILLMAN MW, CUPPLES LA, GAGNON D, MILLEN BE, ELLISON RC, CASTELLI WP: Margarine intake and subsequent coronary heart disease in men. Epidemiology 8:144-149, 1997.

52 BOLTON-SMITH C, WOODWARD M, FENTON S, BROWN CA: Does dietary trans fatty acid intake relate to the prevalence of coronary heart disease in Scotland? Eur Heart J, 17:837-845, 1996.

53 WEGGEMANS R.M., RUDRUM M, AND TRAUTWEIN E.A: Intake of ruminant versus industrial trans fatty acids and risk of coronary heart disease – what is the evidence? Eur. J. Lipid Sci. Technol. 106:390–397, 2004

THE EU OIL AND PROTEINMEAL INDUSTY (FEDIOL):

The EU Oil and Proteinmeal Industry, fully supports the inclusion of the TFA definition² agreed by Codex, in the Section on Definitions of the General Standard for the Labelling of Prepackaged Food and Guidelines on Nutrition Labelling.

INTERNATIONAL DAIRY FEDERATION (IDF):

Summary

The present Codex definition is a purely chemical definition covering a wide range of Trans Fatty Acids stemming from very different origins and processes – industrial and natural. It is not based on biological data or the latest findings in nutrition science. Therefore, the present Codex definition is <u>not</u> appropriate or suitable for the establishment of horizontal Codex labelling requirements for all foods in the context of protecting the health of the consumers and ensuring fair practices in the food trade.

At present, there is no conclusive scientific evidence that proves that the Trans Fatty Acids that occur naturally in milk (as the product of the formation of intermediates during rumen biohydrogenation) have any negative health effects. Therefore, the introduction of Codex labelling requirements that would apply to the Trans Fatty Acids that occur naturally in milk would create an arbitrary discrimination against the consumption of milk and milk products.

The decision on the inclusion of the proposed Codex definition of Trans Fatty Acids in the Codex General Standard for Labelling of Pre-packaged Foods and in the Codex Guidelines on Nutrition Labelling should be postponed until there is improved scientific knowledge on Trans Fatty Acids.

Current knowledge about Trans Fatty Acids

It is well documented that there are scientific publications showing negative effects of certain Trans Fatty Acids, particularly those that are part of food products derived from the hydrogenation of oils and fats in the presence of a suitable catalyst or through raffination/deodorisation of oils and fats applying heat³. In contrast, there is no conclusive

For the purpose of the Codex Guidelines on Nutrition Labelling and other related Codex Standards and Guidelines, trans fatty acids are defined as all the geometrical isomers of monounsaturated and polyunsaturated fatty acids having non-conjugated, interrupted by at least one methylene group, carbon-carbon double bonds in the trans configuration.

² Trans Fatty Acids

³ Oh et al *Am J Epidemiol* (2005). Dietary Fat Intake and Risk of Coronary Heart Disease in Women: 20 Years of Follow-up of the Nurses' Health Study 161(7):672-9.

Oomen CM et al *Lancet* (2001). Association between *trans* fatty acid intake and 10-year risk of coronary heart disease in the Zutphen Elderly Study: a prospective population-based study. 357:746-51.

scientific evidence proving that Trans Fatty Acids occurring naturally in milk as the product of formation of intermediates during rumen biohydrogenation cause negative health effects⁴.

In 2005, Lock et al.⁵ reviewed the available prospective cohort and case control studies. These clearly show either negative associations or no association between the intake of ruminant Trans Fatty Acids and risk of CHD. In contrast, the studies show a positive association with the total Trans Fatty Acids (mainly from industrial sources). Weggemans et al.⁶ also reviewed these data and their figures are comparable to those of Lock, although their conclusions are convoluted.

More fundamentally, the basic knowledge on the specific biological effects of "families" of *trans* isomers is only at its early acquirement stage. Research studies are in progress that will provide information about the biochemical and the biological significance of some well-defined TFA isomers. In his studies, Kramer⁷ used the basis of bioconversion pathways to "hypothesize that most if not all the "*t*11" double bond containing FA in ruminant fats may prove to be equally beneficial to monogastric animals and humans".

It should be noted that the present legislation in Denmark limits the use of partially hydrogenated vegetable oils in industrially prepared food to reduce exposure of population to Trans Fatty Acids. This legislation does not apply to naturally occurring Trans Fatty Acids in animal fats, which takes into account current scientific knowledge. Similarly, the Trans Fatty Acids Bill C-220 to amend the Food and Drugs Act in Canada also provides an exception for naturally occurring Trans Fatty Acids. ⁸

IDF would like to draw attention to the fact that clinical studies were initiated in 2005 aimed at gathering a better understanding on the differences between sources, individual isomers and their specific effects on human health. The results of the project, which is also known as TRANSFACT study, are expected to appear in the format of a peer-reviewed publication towards mid 2006 ⁹.

IDF recommendations

The decision about the inclusion of the proposed Codex definition of Trans Fatty Acids in the Codex General Standard for Labelling of Prepackaged Foods and in the Codex Guidelines on Nutrition Labelling should be postponed.

The scientific knowledge on Trans Fatty Acids must be improved before moving forward with the inclusion of a Codex definition of Trans Fatty Acids for horizontal labelling purposes.

Pietinen et al Am J Epidemiol (1997). Intake of fatty acids and risk of coronary heart disease in a cohort of Finnish men. 145:876-87.

⁴ "Trans Fatty Acids: Scientific Progress and Labelling", Bulletin of the IDF N° 393/2005 (download available free of charge from: http://www.fil-idf.org/

⁵ Lock, A.L. et al. (2005), The biology of trans fatty acids: implications for human health and the dairy industry. Aus. J. Dairy Tech. **60**, 134-142

⁶ Weggemans & al.(2004), Intake of ruminant versus industrial trans fatty acids and risk of coronary heart disease – what is the evidence? Eur. J. Lipid Sci. Technol. **106**, 390-397.

⁷ Kramer J.K.G, (2004). Letter to the editor, Lipids **39**, 601-603

⁸ House of commons (2004), Bill C-220 An act to amend the Food and Drugs Act (*trans* fatty acids)

⁹ Chardigny J.M. & al. (2005) Rationale and design of the TRANSFACT Project Phase I: a study to assess de effect of the two different dietary sources of *trans* fatty acids on cardiovascular risk factors in humans. Contemp. Clin. Trials (*submitted for review*)

Based on the expected outcome of the TRANSFACT study, Codex may wish to consider requesting the independent scientific view of WHO/FAO. In this context, it should be noted that a revision of WHO/FAO Recommendations on Fats and Oils in Human Nutrition¹⁰ is already under consideration.

Should it be decided to move forward with the introduction of the present Codex definition, an amendment should be made to section 5.3 (or as a new section 5.4) of the present Codex Guidelines on Nutrition Labelling referring to the need for periodic review of the definition of Trans Fatty Acids in the light of newer developments.

IDF is pleased to share with Codex delegates the IDF publication on "Trans Fatty Acids: Scientific Progress and Labelling" - Bulletin of the IDF N° 393/2005. It is available for free download from the IDF Internet website: http://www.fil-idf.org/content/default.asp?PageID=381

INTERNATIONAL FEDERATION OF MARGARINE ASSSOCIATIONS (IFMA):

The International Federation of Margarine Associations would like to express full support for the request laid down in CL 2005/51- FL.

Following the adoption of a TFA definition by CCNFSDU in November 2004 and following the endorsement by CCFL in May 2005, that definition should now be included in the Section on Definitions of the General Food Labelling Standard and in the Guidelines on Nutrition Labelling.

¹⁰ FAO Food and Nutrition Paper no. 57, 1994