

A trans European Union difference in the decline in trans fatty acids in popular foods - a market basket investigation.

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Complete List of Authors:	Stender, Steen; Gentofte University Hospital, Clinical biochemistry Astrup, Arne; University of Copenhagen, Human Nutrition Dyerberg, Jørn; Gentofte University Hospital, Clinical Biochemistry
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STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,
6		exposure, follow-up, and data collection
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of
1		selection of participants. Describe methods of follow-up
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of
		case ascertainment and control selection. Give the rationale for the choice of cases
		and controls
		Cross-sectional study—Give the eligibility criteria, and the sources and methods of
		selection of participants
		(b) Cohort study—For matched studies, give matching criteria and number of
		exposed and unexposed
		Case-control study—For matched studies, give matching criteria and the number of
		controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect
		modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was
		addressed
		Cross-sectional study—If applicable, describe analytical methods taking account of
		sampling strategy
		(<u>e</u>) Describe any sensitivity analyses
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Results		
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed
		(b) Give reasons for non-participation at each stage
		(c) Consider use of a flow diagram
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information
data		on exposures and potential confounders
		(b) Indicate number of participants with missing data for each variable of interest
		(c) Cohort study—Summarise follow-up time (eg, average and total amount)
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time
		<i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure
		Cross-sectional study—Report numbers of outcome events or summary measures
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their
		precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and
		why they were included
		(b) Report category boundaries when continuous variables were categorized
		(<i>c</i>) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	18	Summarise key results with reference to study objectives
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.
		Discuss both direction and magnitude of any potential bias
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity
		of analyses, results from similar studies, and other relevant evidence
Generalisability	21	Discuss the generalisability (external validity) of the study results
Other informati	ion	
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,
		for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

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6 7 8	2	A trans European Union difference in the decline in <i>trans</i> fatty acids in
9 10 11	3	popular foods - a market basket investigation.
12 13	4	Steen Stender ¹ , Arne Astrup ² and Jørn Dyerberg ¹
14 15 16	5	
17 18	6	1 Department of Clinical Biochemistry, Copenhagen University Hospital, Gentofte, Niels Andersens
19 20 21	7	Vej 65, DK-2900 Hellerup, Denmark
22	8	
23	9	2 Department of Human Nutrition, Faculty of Life Sciences, University of Copenhagen, Rolighedsvej
24 25 26	10	20 DK 1058 Frederikahara Denmark
26	$\frac{11}{12}$	30, DK-1958 Frederiksberg, Denmark
27 28	12 13	
20 29 30	13 14	Steen Stender (SS) Head of the Department.
31 32 33	15	Arne Astrup (AA) Head of the Department.
33 34 35	16	Jørn Dyerberg (JD) Consultant.
36	17	
37 38	18	Corresponding author:
39 40 41	19	Steen Stender
42 43	20	Department of Clinical Biochemistry Copenhagen University Hospital, Gentofte
45	21	Copenhagen University Hospital, Gentofte
47	22	Niels Andersens Vej 65, DK-2900 Hellerup
48 49 50	23	Denmark
50 51 52	24	email: <u>stst@geh.regionh.dk</u>
53 54	25	Telephone: +45 39 77 31 20
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Key words: 1. Trans fatty acids 2. Fast food 3. Eastern Europe 4. Western Europe 5. Legislation Word count: 2533 (20-3-2012)

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Article summary

Article focus

Are popular foods with high amounts of industrial trans fatty acids still available in EU-countries to the same extent as it was in 2006

Is there a difference in availability of such foods between Western and Eastern EU-countries

Key messages

Industrial trans fatty acids in popular foods in Wester EU-countries have declined considerably since 2005.In

Eastern Europe industrial trans fatty acids in popular foods are in spite of some decline still high

A low average intake of industrial trans fatty acids at the population level does not preclude a high intake among

subgroups

Most EU countries rely on food producers to voluntarily reduce the amounts of industrial trans fatty acids in

foods with varibale results. An effective alternative is legislation so far only used by a few EU-countries

Strengths and limitations

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A strength is the measurement of trans fatty acids in many popular foods in several EU-countries in 2005 and again in 2009

A limitation is that the average daily intake of trans fatty acids was not measured in subgroups of the population, but instead inferred from the popularity of fast food and from the presence of popular foods with high amounts of industrial trans fatty acids in large supermarkets

ABSTRACT

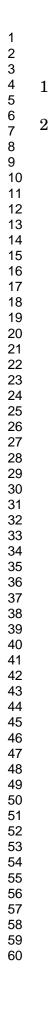
Objectives: To minimize the intake of industrial trans fatty acids(I-TFA) some countries have introduced labelling, while others have introduced legislative limits on the content of I-TFA in food. However, most countries still rely on food producers to voluntarily reduce the I-TFA content in food. The objective of the present study was to investigate the efficiency of these strategies in the EU.

Design: The potential consumption of I-TFA was assessed in a market basket investigation by analysing the I-TFA content in popular foods.

Setting: A standardized purchase methodology was used in 16 EU countries in 2005 and again in 2009.

Samples: 70 servings of French fries and chicken nuggets, 90 packages of microwave popcorn, and 442 samples of biscuits/cakes/wafers with "partially hydrogenated vegetable fat" listed high on the list of ingredients were analysed. A high-trans menu was defined as a large serving of French fries and nuggets, 100 g of microwave popcorn, and 100 g of biscuits/wafers/cakes.

Results: In 2005, a high-trans menu provided above 30 g of I-TFA in five EU countries in Eastern Europe and 20–30 g in eight EU countries in Western Europe. In 2009 the values in Hungary, Poland, and the Czech Republic remained high between 10 and 20 g, whereas they were less than 2 g in Germany, France and the UK. Conclusion: In 2009 contents of I-TFA in popular foods in Western Europe appear low but, in spite of some reduction, still high in Eastern European EU countries. These findings suggest that millions of people in the EU $\mathbf{24}$ still consume I-TFA in amounts that substantially increase their risk of coronary heart disease.



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INTRODUCTION

 $\mathbf{2}$ Trans fatty acids (TFA) in food originate from industrial hydrogenation of oils and from ruminant sources. Compared to unhydrogenated oils, fats containing industrial *trans* fatty acids (I-TFA) are solid at room temperature, have some technical advantages in food processing, and prolong the shelf life of food. However I-TFA can constitute up to 60% of the fats in certain foods, whereas ruminant fat contains at most 6% TFA.[1] A meta-analysis of four large prospective studies found that an intake of TFA corresponding to 2% of the total energy intake (E%) (approximately 5 g/d) was associated with a 23% increase in the risk of coronary heart disease[2]. Several public health organisations have recommended that I-TFA intake should be lowered as much as possible[3-5]. In 1976, the average intake of TFA in Western Europe was 6 g/d. In 1996, this intake had dropped to 2.6 g/d (range 1.2 to 6.7 g/d, corresponding to 0.5-2.1 E% [6]. Approximately half of this intake was from ruminant TFA and only about 1.3 g was from I-TFA, which constitutes a 78% decrease since 1976[6]. Despite a mean population intake of approximately 1 g of I-TFA per day in Denmark in 2001, it was still possible to consume 20–30 g of I-TFA in a single high-*trans* menu by eating popular food products such as wafers, microwave popcorn, nuggets, and French fries[5]. Among the 5 million Danes, 10,000–50,000 people consumed food from this type of menu several times each week, and got a daily intake of more than 5 g I-TFA[4]. Generalizing to the population in the EU, this corresponds to 1-5 million people.

In 2003, Canada introduced the mandatory labelling of the I-TFA content in pre-packaged food. In the same year, Denmark introduced a legislative limit of 2% I-TFA in fat used for foods. The European Commission initially opposed this legislation but in March 2007 dropped its infringement proceedings against Denmark because of increased scientific evidence on the dangers of *trans* fats[7]. The US introduced mandatory labelling of pre-packaged food in 2006, followed by legislative limits on I-TFA

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in the food served in restaurants in New York City in 2008 and in 2010-11 in the state of California. In 2009, Austria and Switzerland introduced a legislative ban similar to the Danish' to be followed in 2011 by Iceland and Sweden. Of the EU's approximately 500 million inhabitants who consume food that still may contain high amounts of *trans* fat, Denmark's and Austria's populations, representing approximately 14 million people, are the exceptions. In 2005, we assessed by a market basket investigation the availability of a high-*trans* menu (large

servings of French fries and nuggets, 100 g of microwave popcorn and 100 g of biscuits/wafers/cakes) in 15 EU countries, and found that, in spite of a low mean intake, high concentrations of I-TFA were still present in many popular foods. Thus, subgroups of the populations could have an intake that is considerably higher than the recommended upper limit for intake of I-TFA[8]. I-TFA in foods from international fast food providers was an important contributor to the high intake in these subpopulations[9]. Still in 2009, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods. The present study assess the efficiency of that strategy in three Eastern European countries, Hungary, Poland, and the Czech Republic, and in three Western European countries, Germany, France, and the UK.

METHODS

Purchase of food products

Between November 2004 and January 2006, 542 items of foods were purchased in 26 countries. The cities included were partly determined by visits taken by the authors and their colleagues for other purposes, and these visits were supplemented by arranged visits by two of the authors (SS, JD). The tourist office in the city was asked to identify three large supermarkets in the vicinity, preferably chain

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supermarkets with many large shops in the capital and across the country. A written procedure was followed that included details about which products to select and instructions for storage methods until the food could be returned to the laboratory. Fast food items (chicken nuggets and French fries) were obtained from McDonald's and KFC outlets. Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g. In July 2009 to September 2009, the capitals of Poland, the Czech Republic, Hungary, Germany, France, and the UK were revisited and the same procedures for the purchase of food items were followed. If possible, the same stores were revisited and the same brands were bought. Altogether, 602 samples of food in EU countries were purchased **Analysis for TFA** The microwave popcorn was popped before processing. The foods were homogenised, and the fatty acid content was analysed by gas chromatography (GC) on a 100-m highly polar capillary column. Thin layer chromatography on silver nitrate-impregnated silica with renewed GC verified the results[10]. The method is accredited by the Danish Accreditation Authorities (DANAK) according to ISO 17025. Calculation

For comparison, the amounts of I-TFA in the French fries and the chicken nuggets were expressed as the amounts in a serving size equivalent to a large serving from McDonald's in the US. The serving sizes were 171 g of French fries and 160 g of chicken nuggets.

The potential consumption of I-TFA in a given country was defined as the sum of the I-TFA contents provided by a high-*trans* menu that consisted of products with the highest identified amount of I-TFA.

RESULTS

Biscuits, cakes, and wafers

Figure 1 presents data from the products bought in the six EU countries in 2005 and 2009. The products are ranked according to I-TFA content and the combined values for the three Eastern EU countries and for the three Western EU countries are given separately. The highest I-TFA contents (10–15 g) in single 100 g servings in 2005 were found in Hungary, Poland, and the Czech Republic. In France, Germany, and the UK, the I-TFA contents were lower but still considerable (4–7 g) averaging 5 g excluding one outlier.

In 2009 biscuits, cakes, and wafers in the three Eastern EU countries contained a smaller, but still substantial, amount of I-TFA (4–8 g). In contrast, the I-TFA content in products in the three Western EU countries was minimal (< 1 g). The same pattern was observed in each of the countries.

5 Fast food

In 2005, the I-TFA content of the McDonald's servings in EU varied from less than 1 g in Copenhagen
to 7 g in London, UK. For KFC servings, there were even larger differences between the countries,
ranging from less than 1 g in Germany to 24 g in Hungary. 15 percent of the 54 fast food servings

.9 contained more than 10 g per serving, and 50% contained between 5 and 10 g[9].

In 2009, each of the 12 fast food menus, which were collected in France, Germany and the UK in the

1 same locations as in 2005, contained less than 1 g of I-TFA per serving (Figs. 2 and 3).

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1 Popcorn

The highest I-TFA content in a single 100 g serving of microwave oven popcorn bought in each country is presented in the data given for the I-TFA content in the high-*trans* menu for that country (Fig. 2).

In 2009, the microwave oven popcorn samples with the highest amounts of I-TFA, which were from
Hungary, Poland and the Czech Republic, contained the same amounts of I-TFA as the popcorn that we
analysed in 2005. In contrast, the I-TFA in popcorn from Germany, France, and UK was negligible
(Tip. 2)

8 (Fig. 3).

0 A high-*trans* menu

In 2001, the potential consumption of I-TFA by eating a high-*trans* menu was 37 g in Denmark, but by 2005, this potential consumption level was reduced to less than 1 g (Fig. 2). In 2005, by contrast, the potential consumption level via a high-*trans* menu exceeded 20 g in 13 out of the 16 EU-countries, from which foods were investigated. Hungary, the Czech Republic, and Poland ranked among the highest, with values around 40 g per menu. A considerable amount of the I-TFA in the menus was derived from the fast food meal.

Figure 3 demonstrates the time trends for I-TFA in the high-*trans* menu in Hungary, the Czech
Republic, Poland, Germany, France, and the UK. In all of the countries, the contribution values
obtained from McDonald's and KFC meals (nuggets and fries) in 2009 were negligible compared to the
values obtained in 2005.

In 2009, biscuits, cakes, wafers, and microwave oven popcorn were still high in I-TFA in Eastern EU countries. In contrast, only small amounts of I-TFA in these same products obtained in Western EU countries were found.

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DISCUSSION

The data from 2005 show that, despite a mean daily intake of around 1 g I-TFA for the entire population (as it was in Denmark in 2001), it was still possible to consume 30-40 g I-TFA in a high-*trans* menu composed of popular foods. Consequently, a low average intake at the population level does not preclude a very high intake among some subgroups[6]. Following Denmark's 2003 legislation, the I-TFA content of the same menu was reduced to less than 1 g[9-10]. In addition, the data demonstrate that in 2005 it was possible to eat a menu of popular foods with more than 20 g of I-TFA in 13 out of 16 EU countries and up to 40 g in Hungary (Fig. 2). Thus far, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods. The present study demonstrates the difference between Eastern and Western Europe in the efficiency of this strategy. The overall picture regarding the I-TFA content in fast food, biscuit/wafers/cookies and microwave oven popcorn in the EU indicates that I-TFA has disappeared from American-based fast food, such as that from McDonald's and KFC, mainly due to societal pressure[9,11]. The same decline for biscuits and snacks in Western EU countries were observed. In Eastern EU countries, however, the amount of I-TFA in these products is still high. We even observed this difference in products bought at the same retailers in the Eastern and Western EU countries (e.g. Carrefour).

Limitations of the study

The average daily intake of I-TFA was not measured in subgroups of the population, but instead inferred from the popularity of fast food from McDonald's and KFC and from the presence of popular foods with high amounts of I-TFA in large supermarkets. The assumptions are: 1) the analysed brands

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of biscuits, cakes, wafers, and microwave oven popcorn were stocked at the supermarkets because they $\mathbf{2}$ are sold in considerable amounts; 2) the majority of these foods are regularly bought and consumed by the same subgroups of consumers; and 3) the findings in the supermarkets in each capital are representative of the entire country and of adjacent countries in the Eastern and Western Europe. $\mathbf{5}$ Another weakness is that only foods were bought in large supermarkets and from two international fast food providers (McDonald's and KFC). The I-TFA content in foods sold by small, privately owned shops or street vendors was not examined. Fats with high amounts of I-TFA prolong the shelf life of foods, and it is reasonable to assume that this factor is of even higher importance for small, privately owned shops than it is for larger supermarkets. The selective pattern of purchasing may thus have led to an underestimation of the amounts of I-TFA consumed by subgroups of the population.

12 Implications

An intake of above 5 g of TFA daily is associated with a health risk that can be eliminated more easily than many other diet-associated health risks. This issue is particularly relevant to low socioeconomic groups, such as truck and taxi drivers and manual labourers, who, due to other lifestyle factors, already have an increased risk of coronary heart disease partly due to high prevalence of smoking and poor diet, including high intake of I-TFA, and metabolic syndrome[12].

In 2011, EU countries, with the exception of Austria and Denmark, legally allow foods with the maximum concentration of I-TFA in the fat (i.e. 60%) to be sold without any notice as long as the food is unpackaged (as is the case for restaurants and fast food outlets). If the food is pre-packaged, then the law requires the presence of I-TFA to be noted only by the term "partially hydrogenated fat" in the list of ingredients. Most consumers do not appreciate the hazard concealed therein.

Societal pressure on food producers has undoubtedly resulted in a reduction in the population-level $\mathbf{2}$ mean intake of I-TFA from 2005 to 2009, especially in Western EU countries[11]. However, this study demonstrated that a high intake of I-TFA is still possible in Eastern EU countries. This problem will continue as long as popular foods with a high concentration of I-TFA are available. Even though labelling foods with I-TFA contents may further reduce the mean intake of I-TFA, such $\mathbf{5}$ labelling still allows the intake of high amounts of these fatty acids, first because fast food is not labelled and second because consumers might not pay attention to or understand the labelling[14-15]. A further advantage of a legislative limit on I-TFA content is that it does not require the population to learn about the health risks of I-TFA or to pay attention to the labelling of food products. It is also much easier and cheaper to monitor the presence of I-TFA in foods than it is to monitor the actual intake of I-TFA in at-risk population subgroups. In EU Austria and Denmark have shown that the health risk that a high intake of I-TFA causes, can be eliminated for the entire population without any noticeable side effects for consumers. This has the added advantage of creating a "level playing field" for suppliers. All are equally challenged. All can profit from experience of successful and rapid adaptation as in Denmark. It remains to be investigated to what extent the difference of availability of I-TFA in popular foods between and Eastern and

Western EU countries contributes to the much higher mortality of coronary heart disease in Eastern,

than in Western EU-countries (Fig. 4)[10].

20 What this paper adds box

21 WHAT IS ALREADY KNOWN ON THIS TOPIC

A daily intake of approximately 5 g of industrial *trans* fatty acids is associated with a 23% increase in the risk of coronary heart disease.

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3 4 5	1	In the EU Austria and Denmark have shown that a high intake of I-TFA can be eliminated by a
6 7	2	legislative ban, without any noticeable side effects for consumers.
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10 11 12	4	WHAT THIS STUDY ADDS
13 14	5	A decline since 2005 in the amounts I-TFA in popular foods in Western EU countries is observed
15 16	6	In Eastern EU countries, however, the amount of I-TFA in these products is, in spite of some reduction,
17 18 19	7	still high.
20 21	8	A low average intake of I-TFA at the population level does not preclude a very high intake among
22 23 24	9	some subgroups.
24 25 26	10	Most EU countries rely on food producers to voluntarily reduce the amounts I-TFA in foods with
27 28	11	variable results. However, legislation is eminently feasible, and offers a more effective, rapid and
29 30 31	12	equitable approach.
32 33	13	
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36 37 38	15	Contributors: SS obtained funding. SS and JD were both responsible for the concept design of the
39 40	16	study, for collection of food items, registration and labelling. SS and JD produced the first draft of the
41 42 43	17	paper and SS, JD and AA were responsible for critical revision of the manuscript. SS is a guarantor for
43 44 45	18	the study
46 47	19	
48 49 50	20	Acknowledgement: We acknowledge the support from Jenny Vissings Foundation, University of
50 51 52	21	Copenhagen and the Department of Clinical Biochemistry, Gentofte University Hospital.
	22	The study funders had no role in study design, in the collection, analysis and interpretation of data; in
55 56 57	23	the writing of the report and in the decision to submit the article for publication. The researchers' were
58 59 60		13

independent from funders. SS is the head of the department which provided resources for the $\mathbf{2}$ conduction of the investigation. All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis $\mathbf{5}$ Data sharing: no additional data available. Conflicts of interest: None of the authors have any relevant conflicts of interest. The corresponding author had full access to all the data in the study and has the final responsibility for the decision to submit for publication. **Competing Interest** All authors have completed the Unified Competing Interest form at www.icmje.org/coi_disclosure.pdf (available on request from the corresponding author) and declare that none of the authors have relationships with companies that might have an interest in the submitted work in the previous 3 years; Their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) None of the authors have non-financial interests that may be relevant to the submitted work. This study did not require ethics approval

1 2			
3 4 5	1	Refe	rences
6 7	2	1	Wahle KWJ, James WPT. Isomeric fatty acids and human health. Eur J Clin Nutr 1993;47:828-
8 9	3		39.
10 11 12	4	2	Mozaffarian D, Katan MB, Ascherio A, Stampfer MJ, Killett WC. Trans fatty acids and
13 14	5		cardiovascular disease. N Engl J Med 2006; 354 :601–3.
15 16	6		
17 18 19	7	3	World Health Organization. Population nutrient intake goals for preventing diet-related chronic
20 21	8		diseases. 2003. www.who.int/nutrition/topics/5_population_nutrient/en/index12.html. (Accessed
22 23 24	9		May, 2012)
25 26	10		
27 28 20	11	4	Dietary Guidelines for Americans 2010.
29 30 31	12		www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf (Accessed May, 2012)
32 33	13		
34 35 36	14	5	Stender S, Dyerberg J. The influence of <i>trans</i> fatty acids on health – Fourth edition. A report from
37 38	15		the Danish Nutrition Council. 2003. http://www.meraadet.dk/default.asp?id=1347 (Accessed
39 40	16		May, 2012)
41 42 43	17		
44 45	18	6	van Poppel G on behalf of the TRANSFAIR Study Group. Intake of fatty acids in Western
46 47 48	19		Europe: the <i>TRANS</i> FAIR Study. Lancet 1998; 351 :1099–1106
	20		
51 52	21	7	Stop Press: Commission drops Danish trans fat case. EU Food Law Weekly 2007; 295 (23
53 54 55	22		March).
56 57	23		
58 59 60			15
00			

2 3 4	1	0	Stender C. Dweeten I. Dweten A. Leth T. Astron. A. A. tweeterwood in work Athenesel 2006.
5	1	8	Stender S, Dyerberg J, Bysted A, Leth T, Astrup A. A <i>trans</i> world journey. Atherosclr 2006;
6 7	2		(Suppl 7): P47–52.
8 9 10	3		
11 12	4	9	Stender S, Dyerberg J, Astrup. A. High levels of industrially produced trans fat in popular fast
13 14	5		foods. N Engl J Med 2006; 354 :1650–2
15 16 17	6		
18 19	7	10	Leth T, Jensen HG, Mikkelsen AA, Bysted A. The effect of the regulation on <i>trans</i> fatty acid
20 21	8		content in Danish food. Atherosclr 2006; (Suppl 7):P53-6.
22 23 24	9		
25 26	10	11	Katan MB. Regulation of <i>trans</i> fats: The Gap, the Polder, and McDonald's French fries.
27 28 29	11		Atherosclr 2006; (Suppl 7):P69-71
	12		
33	13	12	Gill PE and Wijk K. Case study of a healthy eating intervention for Swedish lorry drivers. Health
34 35 36	14		Education Research 2004; 19(3) :306-315
37 38	15		
39 40 41	16	13	Legislation relating to the level of industrially produced trans fatty acids in food in: The
42 43	17		influence of <i>trans</i> fatty acids on health – Fourth edition. A report from the Danish Nutrition
45	18		Council. 2003. http://www.meraadet.dk/default.asp?id=1347 (Accessed May, 2012)
46 47 48	19		
	20	14	Consumers find food labelling confusing: http://www.guardian.co.uk/money/2009/may/07/food-
ΰZ	21		drink-health-labels (Accessed May 2012)
53 54 55	22		
	23	15	Borra S. Consumer perspectives on food labels. Am J Clin Nutr 2006;83(5):1235S
59 60			16

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1 2			
2 3 4 5 6 7	1	16	OECD Health Data 2009: Statistics and Indicators.
6 7	2		www.oecd.org/document/56/0,3746,en_2649_34631_12968734_1_1_1_1,00.html.
8 9	3		(Accessed May, 2012)
10 11 12	4		
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Legends

Figure 1

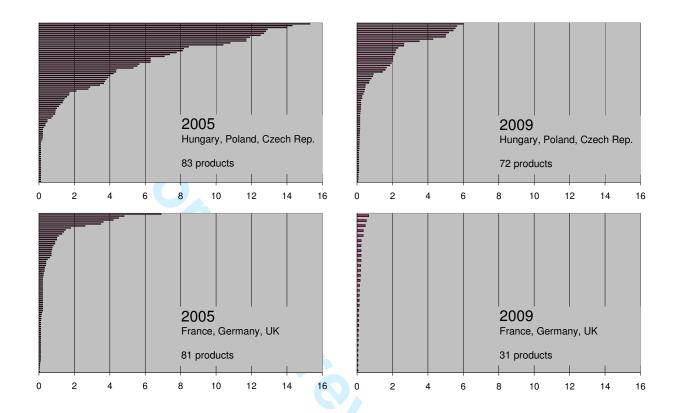
Amounts of industrial trans fatty acids in 100 g of biscuits/cakes/wafers bought in six EU countries in $\mathbf{5}$ 2005 and in 2009. For both groups of countries (three Eastern EU countries and three Western EU countries), the products are ranked according to the concentrations of industrially produced *trans* fatty acids. Products were only bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g. Fewer products in Western EU countries fulfilled the inclusion criteria compared with products in 25 10 Eastern EU-countries. 32 13 34 14 Figure 2 Amounts of industrial *trans* fatty acids in a high-*trans* menu bought in the various countries in 2005. For each country, the product with the highest concentration of industrial *trans* fatty acids in each of the three food categories is shown. Figure 3 46 19 Time trends for the amounts of industrial *trans* fatty acids in a high-*trans* menu bought in three Eastern EU countries in 2005 and 2009 and in three Western EU countries in 2005

53 22 and 2009.

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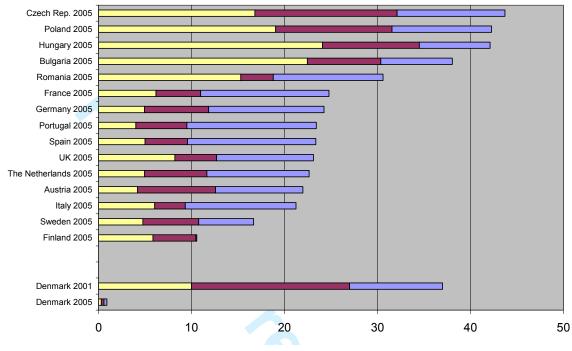
	Figure 4
	Trends in coronary heart disease mortality rates, selected OECD countries, 1980-2006.
•	Source: OECD Health Data 2009. The raw mortality data are extracted from the WHO
:	Mortality Database, and age-standardised to the 1980 OECD population. For 2006 to 2009
	the yearly mortality for Hungary is 228, 215,205 and 204. The corresponding values for
; ;))	Denmark and for OECD-mean have not yet appeared in the OECD Health data 2011.

Fig 1



Grams of industrial trans fatty acids in 100 g of product

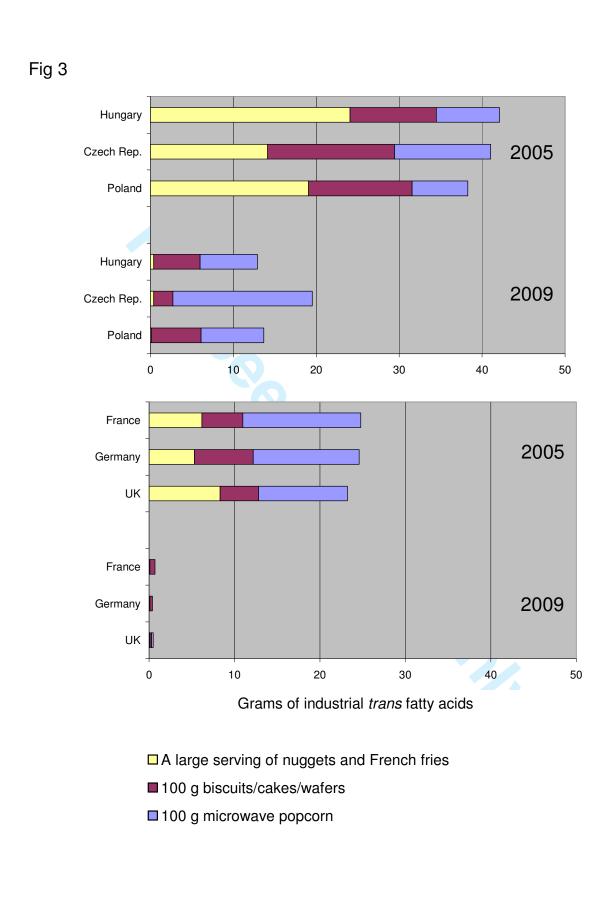
Fig 2

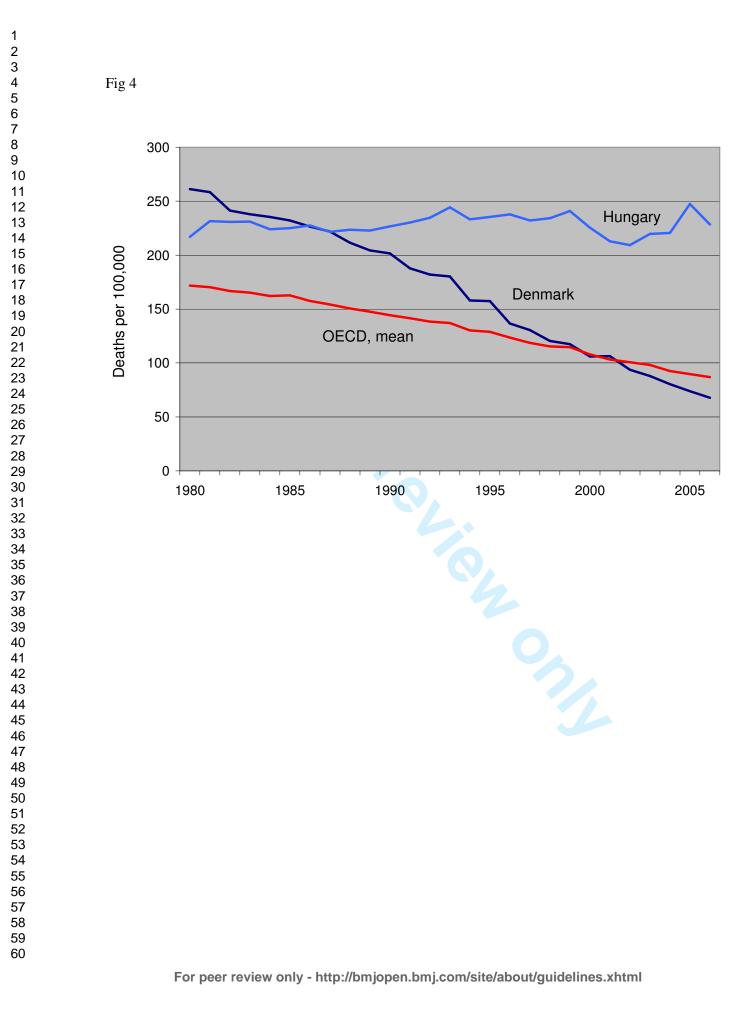


Grams of industrial trans fatty acids

- $\hfill\square A$ large serving of nuggets and French fries
- 100 g biscuits/cakes/wafers
- 100 g microwave popcorn







Reviewer 1 Comments...

Name: S Capewell Position: Chair of Clinical Epidemiology

This is an excellent paper with very important messages for public health in the UK and Europe.

I have no major criticisms, apart from:Figure 3 which is currently a histogram; it needs to be redrawn as a bar chart, to facilitate comparisons with Figure 2.

A new figure 3 has been made according to the reviewer's suggestion

Secondly, I do have a few suggestions to make the paper even better. Mainly by strengthening or revising specific sentences.

These are specified below, with suggested changes IN CAPITALS.

Also, I will endevour to also send the comments as a Word "Track Changes" document, which may be MUCH easier to comprehend.

All numbers refer to line numbers in the pdf document submitted.

A trans European Union difference in the decline in trans fatty acids in popular foods - a basket investigation.

ABSTRACT

Line 8 Objectives: Trans fatty acids (TFA) are produced when liquid vegetable oil is industrially hydrogenated to make it solid fat. A daily intake of approximately 5 g of TFA is associated with a 23% 9 increase in the risk of CORONARY heart disease. In order to minimize the intake of TFA some countries 10 have introduced labelling, while others have introduced legislative limits on the content of TFA in 11 food INCLUDING AUSTRIA, DENMARK AND SWITZERLAND. HOWEVER , but most countries still rely on food producers to voluntarily reduce the TFA content in food. The 12 objective of the present study was to investigate the efficiency of these strategies in the EU. 13 Design: The potential consumption of TFA was assessed in a basket

1	
2	
3 4	
5	investigation by analysing the TFA CONTENT in popular
6	14 foods in 16 EU countries in 2005 and AGAIN in 2009 USING A STANDARD
7	METHODOLOGY.
8	15 Samples: 70 servings of French fries and chicken nuggets, 90 packages of
9	microwave popcorn, and
10	16 442 samples of biscuits/cakes/wafers with "partially hydrogenated vegetable
11	fat" listed on the label
12 13	17 high on the list of ingredients were analysed. A "high-trans menu" was
14	
15	DEFINED AS a large serving of French fries
16	18 and nuggets, 100 g of microwave popcorn, and 100 g of biscuits/wafers/cakes.
17	19 Results: In 2005, a high-trans menu provided above 30 g of TFA in five EU
18	countries in Eastern
19	20 Europe (SPECIFY) and 20-30 g in eight EU countries in Western Europe
20	(SPECIFY WHICH). In 2009 the values in Hungary, Poland,
21 22	21 and the Czech Republic REMAINED HIGH (between 10 and 20 g), whereas they
23	were less than 2 g. in Germany,
24	
25	22 France and the UK,
26	
27	Conclusion:
28	In 2009 the content of TFA in popular foods in 1 Western European APPEARS LOW
29 30	but not in
31	Line 2 Eastern European EU countries. THESE FINDINGS suggest that millions of
32	people in the EU still consume TFA in
33	3 amounts that SUBSTANTIALLY increase their risk of CORONARY heart disease.
34	The Austrian, Danish, and Swiss experiences
35	
36	4 with legally limiting TFA content in human food, demonstrate that this risk
37	can be eliminated, with no
38 39	5 noticeable effect on the availability, price, or quality of food.
40	
41	INTRODUCTION
42	Line 2 Trans fatty acids (TFA) in food originate from industrial hardening of
43	oils and from ruminant sources.
44	3 Compared to unhydrogenated oils, fats containing industrially produced TFA
45	are solid at room
46 47	
48	4 temperature, have some technical advantages in food processing, and prolong
49	the shelf life of food. HOWEVER,
50	5 TFA can constitute up to 60% of the fats in certain foods, whereas ruminant
51	fat contains at most 6%
52	6 TFA. A meta-analysis of four large prospective studies found that an intake
53	of INDUSTRIAL TFA corresponding to
54 55	7 2% of the total energy intake (E %) (approximately 5 g/d) was associated
55 56	with a 23% increase in the
57	8 risk of CORONARY heart disease1. Several public health organisations have
58	o have been been and the sease of the sease
59	
60	

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therefore recommen	nded that INDUSTRIAL TFA intake
9 should be lowered INDUSTRIAL TFA ir	l as much as possible2-4. In 1976, the average intake of western
10 Europe was 6 g/ 6•7 g/d), correspon	d. In 1996, this intake had dropped to $2 \cdot 6$ g/d (range $1 \cdot 2$ to ding to
	pproximately half of this intake was from ruminant TFA, and
	hich constitutes a 78% decrease since 19765. Despite a
	g of industrial TFA per day in Denmark in 2001, it was
-	SINGLE high-trans menu by eating popular food products
	ench fries4. Among the 5 million Danes, 10,000–50,000 peop
	u several times each week, and got a daily intake of more
17	
18	
	troduced the mandatory labelling of the TFA content in pre-
packaged food. In t	ne nark introduced a legislative limit of 2% industrial TFA in
fat used for foods.	
	ission initially opposed this legislation but in MARCH 2007
dropped its infringe	ment
21 proceedings aga dangers of trans fat	inst Denmark because of increased scientific evidence on the s6.The
-	andatory labelling of pre-packaged food in 2006, followed by
23 TFA in the food s	served in restaurants in New York City in 2008 and in 2010-
11 in the state of	
similar 1 to the Dan	Austria and Switzerland introduced a legislative ban hish' TO BE FOLLOWED IN 2011 BY ICELAND AND SWEDEN. On ly 500 million inhabitants who consume food that still may ts of
3 trans fat, Denmar 14 million people, a	k's and Austria's populations, representing approximately
4 exceptions.	ssed by a basket investigation the availability of a high-
trans menu (large s	
	nuggets, 100 g of microwave popcorn and 100 g of

1 2	
3	
4 5	biscuits/wafers/cakes) in 15 EU
6	7 countries. , and found that, i In spite of a low mean intake, high
7	concentrations of industrial TFA were still
8	8 present in many popular foods. Thus, subgroups of the populations could have
9 10	an intake that is
11	9 considerably higher than the recommended upper limit for intake of TFA7. TFA
12	in foods from
13	10 international fast food providers was an important contributor to the high
14 15	intake in these sub11
16	populations8. Still in 2009, EU countries (with the exception of Austria and
17	Denmark) rely on food
18	12 producers to voluntarily reduce the amounts of TFA in foods. The present
19	study assess the efficiency of
20 21	13 that strategy in three Eastern European countries, Hungary, Poland, and the
22	Czech Republic, and in
23	14 three Western European countries, Germany, France, and the UK.
24	
25 26	METHODS
27	In July 2009 to September 2009, the capitals of Poland, the Czech Republic,
28	Hungary, Germany,
29	Line 7 France, and the UK were revisited and the same procedures for the
30 31	purchase of food items WERE FOLLOWED. If
32	8 possible, the same stores were revisited and the same brands were bought.
33	Altogether, 602 samples of
34	9 food in EU countries were purchased
35	
36 37	Calculation
38	18 For comparison, the amounts of TFA in the French fries and the chicken
39	nuggets were expressed as the
40	19 amounts in a serving size equivalent to a large serving from McDonald's in
41 42	the US: . The serving sizes were 171 g of French fries and 160 g of chicken
43	nuggets.
44	nuggets.
45	RESULTS
46 47	Line 2
48	Biscuits, cakes, and wafers
49	
50	3 Figure 1 presents data from the products bought in the six EU countries in
51	2005 and 2009. The
52 53	4 products are ranked according to TFA content and the combined values for the
54	three Eastern EU
55	5 countries and for the three Western EU countries are given separately.
56	IN 2005, THE highest TFA contents (10–
57 58	6 15 g) in single 100 g servings were found in Hungary, Poland, and the Czech
59	
60	

Republic. In 2005 in 7 France, Germany, and the UK, the TFA contents were lower but still considerable (4-7 g). AVERAGING 5G EXCLUDING ONE OUTLIER 8 In 2009 biscuits, cakes, and wafers in the three Eastern EU countries contained a smaller, but still 9 substantial, amount of TFA (4–6 g in Figure 3). In contrast, the TFA content in products in the three Western EU 10 countries was minimal (< 1 g). The same pattern was observed in each of the countries. Fast food Line 13 In 2005, the TFA content of the McDonald's servings in EU varied from less than 1 g in Copenhagen 14 to 7 g in London, UK. For KFC servings, there were even larger differences between the countries, 15 ranging from less than 1 g in Germany to 24 g in Hungary. 15 percent of the 54 fast food servings 16 contained more than 10 g per serving, and 50% contained between 5 and 10 g8. (Figure 2) 17 In 2009, each of the 12 fast food menus, which were collected FRANCE, GERMANY AND THE UK in the same locations as in 2005, 18 contained less than 1 g of TFA per serving (Figure 3). Popcorn Line 21 The highest TFA content in a single 100 g serving of microwave oven popcorn bought in each country IN 2005 22 is presented in the data given for the TFA content in the high-trans menu for that country (Fig. 2), 6-12g In 2009, the microwave oven popcorn samples with the highest 1 amounts of TFA, which were from 2 Hungary, Poland and the Czech Republic, contained the same similar amounts of TFA as the popcorn that we 3 analysed in 2005, 8-16q. In contrast, the TFA in popcorn from Germany, France, and UK in 2005 (10-13g) was negligible by 2009 (Fig. 3). 6. A high-trans menu Line 7 In 2001, the potential consumption of TFA by eating a high-trans menu

Page 33 of 40	BMJ Open
1	
2	
3	
4	was 37 g in Denmark, but by
5 6	8 2005, this potential consumption level was reduced to less than 1 g (Fig.
7	2). In 2005, by contrast, the
8	9 potential consumption level via a high-trans menu exceeded 20 g in 13 out of
9	the 16 EU-countries,
10 11	10 from which foods were investigated. Hungary, the Czech Republic, and Poland
12	ranked among the
13	11 highest, with values being around 40 g per menu. A considerable amount of
14	the TFA in the menus was
15 16	12 derived from the fast food meal.
17	13 Figure 3 demonstrates the time trends for TFA in the high-trans menu in
18	Hungary, the Czech Republic,
19	14 Poland, Germany, France, and the UK. In all of the countries, the
20	contribution values obtained from
21 22	15 McDonald's and KFC meals (NUGGETS AND FRIES) in 2009 were negligible
23	compared to the values obtained in 2005.
24	16 In 2009, biscuits, cakes, wafers, and microwave oven popcorn were still
25	high in TFA in Eastern EU
26 27	17 countries. In contrast, only small amounts of TFA in THESE SAME products
28	obtained in Western EU countries
29	18 were found.
30	19
31 32	
33	Implications
34	7 An intake of above 5 g of TFA daily is associated with a health risk that
35	can be eliminated more easily
36 37	8 than many other diet-associated health risks. This issue is particularly
38	relevant to low-income groups
39	9 such as taxi and truck drivers AND MANUAL LABOURERS who, due to other
40	lifestyle factors, already have an increased risk of CORONARY HEART DISEASE
41 42	10 and who may also more frequently eat foods with a high TFA content.
43	
44	11 In 2011, EU countries, with the exception of Austria and Denmark, legally allow foods with the
45	
46	12 maximum concentration of TFA in the fat (i.e. 60%) to be sold without any
47 48	notice as long as the food is
49	13 unpackaged (as is the case for restaurants and fast food outlets). If the
50	food is pre-packaged, then the
51 52	14 law requires the presence of TFA to be noted only by the term "partially
52 53	hydrogenated fat" in the list of
54	15 ingredients. MOST CONSUMERS DO NOT APPRECIATE THE HAZARD CONCEALED
55	THEREIN. (REF)
56	16 Societal pressure on food producers has undoubtedly resulted in a reduction
57 58	in the population-level
59	
60	

17 mean intake of TFA from 2005 to 2009, especially in Western EU countries.
(ref)
18 However, this study demonstrated that a high intake of TFA is still
possible in Eastern EU countries.
19 This problem will continue as long as popular foods with a high
concentration of TFA are available.
20 Even though labelling foods with TFA contents may further reduce the mean
intake of TFA, such
21 labelling still allows the intake of high amounts of these fatty acids,
first because fast food is not
22 labelled and second because consumers might not pay attention to the
labelling OR UNDERSTAND.
A further advantage of a legislative limit on TFA content is that it does 1
not require the population to
2 learn about the health risks of TFA or to pay attention to the labelling of
food products. It is also MUCH easier
3 and cheaper to monitor the presence of TFA in foods than it is to monitor
the actual intake of TFA in
4 at-risk population subgroups.
5 Austria and Denmark have shown that the health risk that a high intake of
industrially produced trans
6 fatty acids causes can be eliminated for the entire population without any
noticeable side effects for
7 consumers.
THIS HAS THE ADDED ADVANTAGE OF CREATING A "LEVEL PLAYING FIELD" FOR
SUPPLIERS. ALL ARE EQUALLY CHALLENGED. ALL CAN PROFIT FROM EXPERIENCE OF
SUCCESSFUL AND RAPID ADAPTATION AS IN DENMARK. (refs) It remains to be investigated to what extent the difference of availability of TFA in popular
8 foods between and Eastern and Western EU countries contributes to the much
higher CHD mortality
9 in CENTRAL EUROPE, than in Western EU-countries (Fig. 4) 10.
10
11 What this paper adds box
12 WHAT IS ALREADY KNOWN ON THIS TOPIC
13 A daily intake of approximately 5 g of industrially produced trans fatty
acids (TFA) is associated with
14 a 23% increase in the risk of CORONARY heart disease.
15 In the EU Austria and Denmark have shown that a high intake of TFA can be
eliminated by a
16 legislative ban, without any noticeable side effects for consumers.
17
18 WHAT THIS STUDY ADDS

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53 54

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2	
3 4	
5	A DECLINE SINCE 2005 IN THE AMOUNTS TFA IN POPULAR FOODS IN WESTERN EU COUNTRIES IS OBSERVED.
6	
7	23 IN EASTERN EU COUNTRIES, HOWEVER, THE AMOUNT OF TFA IN THESE PRODUCTS IS
8 9	STILL HIGH
10	
11	A low average intake TFA at the population level does not preclude a very
12	high intake among some
13 14	20 subgroups.
15	21 Most EU countries rely on food producers to voluntarily reduce the amounts
16	TFA in foods, WITH VARIABLE RESULTS.
17	22
18	However, legislation is eminently feasible, and offers a more effective, rapid
19 20	and equitable approach.
20	
22	Fig 1
23	Line 32 Grams of industrially produced trans fatty acids in 100 g of
24 25	product
25 26	
27	We need some figures for 2009
28	
29	Figure 3
30 31	HISTOGRAM LOOKS ODD. IT NEEDS TO BE CHANGED INTO A BAR CHART, TO FACILITATE
32	COMPARISON WITH FIGURE 2
33	The figure has been changed as suggested
34	
35 36	Figure 4
36 37	HUNGARY TRENDS LOOK ODD. MORTALITY FALLS ARE NOW OCCURRING THERE TOO.
38	We have added the new available figures for 2007, 2008, and 2009
39	We have dated the new available rightes for 2007, 2000, and 2005
40	In conclusion we have followed all of the suggestions from this reviewer and we appreciate his
41 42	thorough work with our manuscript
43	thorough work with our manuscript
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46 47	
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51 50	Reviewer 2 Comments

Reviewer 2 Comments... Name: Andrew Odegaard PhD, MPH Position: Research Associate COMMENTS FOR THE AUTHOR

The authors have carried out what appears to be a case study that aims to examine the efficiency of relying on producers to voluntarily reduce TFA in foods with historically high TFA content. Indeed, the authors have an extensive and noteworthy background on this public health area.

They found major fast food corporations seem to be self-regulating overall in Europe, biscuits/crackers makers to an extent in Eastern and certainly in Western Europe, where microwave popcorn is self-regulated in Western, but not Eastern Europe. Essentially, 4.5 of the possible 6 areas of possible TFA reduction occurred with self-regulation. (those 1.5 areas being only a partial reduction in TFA in biscuits/crackers and no evident change in popcorn in Eastern EU).

They also report that legislation worked in Denmark to essentially eliminate TFA.

This work is certainly original in that it provides a snap shot, to some extent, on TFA in foods with traditional high levels of TFA, and is probably most relevant to policy makers, since that is what the author's are arguing for.

That said, there are a number of points that could be sharpened to improve this as a scientific research article as it currently reads as more of a hybrid of original research and advocacy paper or editorial.

I've provided general and specific comments below that I hope are helpful.

General

The focus should emphasize "industrial" TFA throughout the paper.

Some readers may quibble with the use of "ischemic" instead of Coronary Heart Disease, but this is immaterial if defined specifically using and ICD code for example.

We have replaced the word ischemic with coronary heart disease as also suggested by reviewer 1

Given the study design and approach- was the follow up assessment in 2009 planned in 2004/5 or was this opportunistic use of data? Either way, it provides interesting results from a number of perspectives.

I think the title may be misleading – the aim seems to have been to assess a high-TFA menu based on items from three different avenues of processed foods that are likely widely available. There is no evidence provided that these are actually popular items or the per capita consumption is high.

We assume the popularity of these products because they were stocked at the supermarkets. They are only stocked there because they are sold in considerable amounts. This is mentioned in the manuscript.

The competition between food producers of having their products on the shelves in large supermarkets is fierce. Only products with a sufficient turnover are allowed to be there.

The popularity of foods from McDonald and KFC in large cities is inferred from the same argumentation.

As well, the abstract conclusion could use more nuance- the fast food reported in Eastern EU was self regulated according to your results.

We have modified the conclusion by adding the sentence "in spite of some reduction" (in Eastern Europe)

Introduction:

-The sentence beginning in line 5 needs a reference for the values provided. We have provided the following reference:Wahle KWJ, James WPT. Isomeric fatty acids and human health.

Eur J Clin Nutr 1993; 47: 828-39.

-An estimate of 0.2-1.0% of the Danish population eats this way according to data provided. Is this a public health issue if similar percentages of these other countries are doing the same? An approach aiming to show this would strengthen the article for the audience. This also relates to the title (popular foods).

We have in line17 page 4 added the sentence: "Generalizing to the population in the EU, this corresponds to 1-5 million people"

-Are readers going to be confused on what a "basket investigation" is? If there is an actual definition- this essentially seems to be a case study

We have now replaced the word basket with the words "market basket" In PubMed.com the search term "market basket" generates 20 titles using the term in the title and 155 papers using the term in the text. Most of the papers deal with the content of toxic components in foods.

Reviewer 2 finds the study to be a case study. We report however 600 cases, which are the number of foods, analysed for TFA

Pg 5 line 11- Earlier it was noted that Switzerland also had introduced a

legislative ban on TFA, which one is it?

The sentence in the paper reads: "Still in 2009, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods." Switzerland is not an EU country.

The legislative ban in Switzerland is similar to the legislative ban in Denmark and is mentioned in the text.

Methods

How were the countries chosen- at random or based on available data?

As mentioned in the text: "The cities included were partly determined by visits taken by the authors and their colleagues for other purposes, and these visits were supplemented by arranged visits by two of the authors (SS, JD)."

In 2005 (fig 2) we intended to include as many EU countries as economically feasible. In 2009 we revisited the 3 eastern EU-countries that had the highest values for the high *trans*menu: Czech Republic, Poland and Hungary and decided to compare with 3 large western EU countries: Germany, France, and UK.

Is there any estimate to the prevalence of said "high density" TFA foods in the supermarkets, for example, what % of microwave popcorn was in this range?

We did not count the total number of different brands of micro wave popcorn or of biscuits. We used the inclusion criteria as given in the text: "Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g."

Is there any data on the frequency of consumption of these popular products?

Not to our knowledge. As already mentioned we rely on the assumption that when the products are present in large supermarkets, they have a considerable turnover. We have considered using the term "availability of food with high content of trans fatty acids". However this term does not reflect that the foods were bought only in large supermarkets.

Results

Were fewer products purchased in Western Europe due to availability? Or what was the reason there is the large sample difference?

In Western Europe we were in 2009 not able to find the same number of foods that fulfilled the inclusion criteria: "Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g."

The number of different brands was probably more or less the same, but in Western Europe most of them were in 2009 not any longer labelled with the term "partially hydrogenated fat" or a similar and when they were, the products contained only small amounts of trans fat. In the legend to fig 1 we have added the following sentences: "Products were only bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g". Fewer products in Western EU countries fulfilled in 2009 the inclusion criteria compared with the situation in Eastern EU-countries.

Limits

Line 4, pg 10- the selective pattern of purchasing could also have led to an overestimate of amounts of TFA in subgroups

Our argumentation supports an underestimation.

Implications

A reference should be provided on the point related to "low income groups", and other lifestyle factors.

We wrote: low-income groups.. who due to other lifestyle factors, already have an increased risk of coronary heart disease and who may also more frequently eat foods with a high I-TFA content

We have added the following reference: Gill PE and Wijk K Case study of a healthy eating intervention for Swedish lorry drivers Health Education Research 2004 vol. 19 no.3:306-315

Same with the statement regarding regulation of TFA in the EU.

We have added the following reference: Legislation relating to the level of industrially produced trans fatty acids in food p45-49 in: The influence of trans fatty acids on health-fourth edition 2004, WWW.meraadet.dk

Again, with the statement beginning with "societal pressure on....".

We have added the following reference: Katan MB Regulation of trans fats: The Gap, the Polder, and McDonald's French fries. Atherosclerosis Supplements 7 (2006) 69-71

Again, citing the effectiveness or how non-effective labeling actually is for

the consumer.

We have added 2 references

Consumers find food labelling confusing: <u>http://www.guardian.co.uk/money/2009/may/07/food-drink-health-labels</u>

Borra S. Consumer perspectives on food labels.Am J Clin Nutr. 2006 May;83(5):1235S.

The ecological data from Denmark on overall IHD(CHD) rates strengthen this discussion and paper, but mention of other factors that may play into this decrease is appropriate. As well, if similar data is available from Austria. Certainly, providing data from all the countries noted in this study would be best, as well as discussion of the potential "ecological fallacy".

With our last sentence in the paper we mention that Trans fatty acids may play a role in the difference in mortality. Our study does not deal with other and more conventional risk factors such as smoking , hypertension.

By only depicting Hungary and Denmark and the mean for all OECD countries we find the figure much less complicated compared with a figure that have values for all 6 countries.

Due to space constraint we have not dealt with ecological inference fallacy

Overall, I think more balance could be added to this discussion- this paper reads more like an advocacy paper or editorial with some general data. Further discussion on other reasons that self-regulation by producers works in some instances, but not all and reasons why different sectors of food producers are slower to change in the Eastern EU, and so on. Essentially, the authors would much better persuade the audience of the need for legislation in Eastern EU (and globally?) by using this approach, in this reviewers mind.

PRIVATE COMMENTS FOR THE EDITOR:

I'm not real sure what to think of this paper. The authors have provided some interesting data, which actually could be interpreted that self-regulation works in some instances, yet the focus, and it seems a bit hasty, doesn't seem to actualize this and the paper doesn't provide the necessary details, or nuance to make this seem like a scientific study. Would an observational study that provided this level of opaqueness even be reviewed? These comments are coming from a researcher who ardently believes reducing and eliminating TFA from the food supply and reducing intake of the foods it is historically common in is a significant public health issue.



A trans European Union difference in the decline in trans fatty acids in popular foods - a market basket investigation.

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6 7 8	2	A trans European Union difference in the decline in trans fatty acids in
9 10 11	3	popular foods - a market basket investigation.
12 13	4	Steen Stender ¹ , Arne Astrup ² and Jørn Dyerberg ¹
14 15 16	5	
17 18	6	1 Department of Clinical Biochemistry, Copenhagen University Hospital, Gentofte, Niels Andersens
19 20	7	Vej 65, DK-2900 Hellerup, Denmark
21 22 23 24 25 26	8 9 10 11	2 Department of Human Nutrition, Faculty of Life Sciences, University of Copenhagen, Rolighedsvej 30, DK-1958 Frederiksberg, Denmark
27 28 29 30	$12 \\ 13 \\ 14$	Steen Stender (SS) Head of the Department.
31 32	15	Arne Astrup (AA) Head of the Department.
35	16	Jørn Dyerberg (JD) Consultant.
36 37 38	17 18	Corresponding author:
39 40	19	Steen Stender
41 42	20	Department of Clinical Biochemistry
43 44 45	21	Department of Clinical Biochemistry Copenhagen University Hospital, Gentofte
	22	Niels Andersens Vej 65, DK-2900 Hellerup
	23	Denmark
50 51	24	email: stst@geh.regionh.dk
52 53	25	Telephone: +45 39 77 31 20
54 55 56	26	Fax: +45 39 07 81 93
57 58 59		
60		For poor review only, http:// Page 1 of 25.

Key words: 1. Trans fatty acids 2. Fast food 3. Eastern Europe 4. Western Europe 5. Legislation

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The Corresponding Author has the right to grant on behalf of all authors and does grant on behalf of all authors, $\mathbf{5}$ an exclusive licence (or non exclusive for government employees) on a worldwide basis to the BMJ Publishing Group Ltd to permit this article (if accepted) to be published in BMJ editions and any other BMJPGL products and sublicences such use and exploit all subsidiary rights, as set out in BMJ's licence. **Article summary** Article focus Are popular foods with high amounts of industrial trans fatty acids still available in EU-countries in2009 to the same extent as it was in 2005 Is there a difference in availability of such foods between Western and Eastern EU-countries Key messages Industrial *trans* fatty acids in popular foods in Western EU-countries have declined considerably since 2005.In Eastern Europe industrial *trans* fatty acids in some popular foods are in spite of some decline still high A low average intake of industrial *trans* fatty acids at the population level does not preclude a high intake among subgroups Most EU countries rely on food producers to voluntarily reduce the amounts of industrial *trans* fatty acids in foods with variable results. An effective alternative is legislation so far only used by a few EU-countries **Strengths and limitations**

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A strength is the measurement of *trans* fatty acids in many popular foods in several EU-countries in 2005 and again in 2009

A limitation is that the average daily intake of trans fatty acids was not measured in subgroups of the population, but instead inferred from the popularity of fast food and from the presence of popular foods with high amounts of industrial trans fatty acids in large supermarkets

ABSTRACT

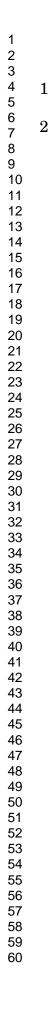
Objectives: To minimize the intake of industrial *trans* fatty acids(I-TFA) some countries have introduced labelling, while others have introduced legislative limits on the content of I-TFA in food. However, most countries still rely on food producers to voluntarily reduce the I-TFA content in food. The objective of the present study was to investigate the efficiency of these strategies in the EU.

Design: The potential consumption of I-TFA was assessed in a market basket investigation by analysing the I-TFA content in popular foods.

Setting: A standardized purchase methodology was used in 16 EU countries in 2005 and again in 2009.

Samples: 70 servings of French fries and chicken nuggets, 90 packages of microwave popcorn, and 442 samples of biscuits/cakes/wafers with "partially hydrogenated vegetable fat" listed high on the list of ingredients were analysed. A high-trans menu was defined as a large serving of French fries and nuggets, 100 g of microwave popcorn, and 100 g of biscuits/wafers/cakes.

Results: In 2005, a high-trans menu provided above 30 g of I-TFA in five EU countries in Eastern Europe and 20–30 g in eight EU countries in Western Europe. In 2009 the values in Hungary, Poland, and the Czech Republic remained high between 10 and 20 g, whereas they were less than 2 g in Germany, France and the UK. **Conclusion:** In 2009 contents of I-TFA in popular foods in Western Europe appear low but, in spite of some reduction, still high in Eastern European EU countries. These findings suggest that millions of people in the EU $\mathbf{24}$ still consume I-TFA in amounts that substantially increase their risk of coronary heart disease.



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INTRODUCTION

Trans fatty acids (TFA) in food originate from industrial hydrogenation of oils and from ruminant sources. Compared to unhydrogenated oils, fats containing industrial trans fatty acids (I-TFA) are solid at room temperature, have some technical advantages in food processing, and prolong the shelf life of food. However I-TFA can constitute up to 60% of the fats in certain foods, whereas ruminant fat contains at most 6% TFA[1]. A meta-analysis of four large prospective studies found that an intake of TFA corresponding to 2% of the total energy intake (E%) (approximately 5 g/d) was associated with a 23% increase in the risk of coronary heart disease [2]. Several public health organisations have recommended that I-TFA intake should be lowered as much as possible [3-5]. In 1976, the average intake of TFA in Western Europe was 6 g/d. In 1996, this intake had dropped to 2.6 g/d (range 1.2 to 6.7 g/d), corresponding to 0.5-2.1 E% [6]. Approximately half of this intake was from ruminant TFA and only about 1.3 g was from I-TFA, which constitutes a 78% decrease since 1976[6]. Despite a mean population intake of approximately 1 g of I-TFA per day in Denmark in 2001, it was still possible to consume 20–30 g of I-TFA in a single high-*trans* menu by eating popular food products such as wafers, microwave popcorn, nuggets, and French fries [5]. Among the 5 million Danes, 10,000–50,000 people consumed food from this type of menu several times each week, and got a daily intake of more than 5 g I-TFA [4]. Generalizing to the population in the EU, this corresponds to 1-5 million people.

In 2003, Canada introduced the mandatory labelling of the I-TFA content in pre-packaged food. In the same year, Denmark introduced a legislative limit of 2% I-TFA in fat used for foods. The European Commission initially opposed this legislation but in March 2007 dropped its infringement proceedings against Denmark because of increased scientific evidence on the dangers of *trans* fats [7]. The US introduced mandatory labelling of pre-packaged food in 2006, followed by legislative limits on I-TFA

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in the food served in restaurants in New York City in 2008 and in 2010-11 in the state of California. In 2009, Austria and Switzerland and in 2011 Iceland introduced a legislative ban similar to the Danish' to be followed also by Sweden. It means that in 2012 only a minority i.e. approximately 14 million people of the 500 million people in EU are protected by legislation against foods with high amounts of I-TFA..

In 2005, we assessed by a market basket investigation the availability of a high-*trans* menu (large servings of French fries and nuggets, 100 g of microwave popcorn and 100 g of biscuits/wafers/cakes) in 15 EU countries, and found that, in spite of a low mean intake, high concentrations of I-TFA were still present in many popular foods. Thus, subgroups of the populations could have an intake that is considerably higher than the recommended upper limit for intake of I-TFA [8]. I-TFA in foods from international fast food providers was an important contributor to the high intake in these subpopulations [9]. Still in 2009, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods. The present study assess the efficiency of that strategy in three Eastern European countries, Hungary, Poland, and the Czech Republic, and in three Western European countries, Germany, France, and the UK.

METHODS

Purchase of food products

Between November 2004 and January 2006, 542 items of foods were purchased in 26 countries. The cities included were partly determined by visits taken by the authors and their colleagues for other purposes, and these visits were supplemented by arranged visits by two of the authors (SS, JD). The tourist office in the city was asked to identify three large supermarkets in the vicinity, preferably chain

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supermarkets with many large shops in the capital and across the country. A written procedure was $\mathbf{2}$ followed that included details about which products to select and instructions for storage methods until the food could be returned to the laboratory. Fast food items (chicken nuggets and French fries) were obtained from McDonald's and KFC outlets. Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and $\mathbf{5}$ if the food label indicated that the fat content exceeded 15 g of fat per 100 g. In July 2009 to September 2009, the capitals of Poland, the Czech Republic, Hungary, Germany, France, and the UK were revisited and the same procedures for the purchase of food items were followed. If possible, the same stores were revisited and the same brands were bought. Altogether, 602 samples of food in EU countries were purchased **Analysis for TFA** The microwave popcorn was popped before processing. The foods were homogenised, and the fatty acid content was analysed by gas chromatography (GC) on a 100-m highly polar capillary column. Thin layer chromatography on silver nitrate-impregnated silica with renewed GC verified the results[10]. The method is accredited by the Danish Accreditation Authorities (DANAK) according to ISO 17025. Calculation For comparison, the amounts of I-TFA in the French fries and the chicken nuggets were expressed as the amounts in a serving size equivalent to a large serving from McDonald's in the US. The serving

sizes were 171 g of French fries and 160 g of chicken nuggets.

The potential consumption of I-TFA in a given country was defined as the sum of the I-TFA contents provided by a high-*trans* menu that consisted of products with the highest identified amount of I-TFA.

RESULTS

Biscuits, cakes, and wafers

Figure 1 presents data from the products bought in the six EU countries in 2005 and 2009. The products are ranked according to I-TFA content and the combined values for the three Eastern EU countries and for the three Western EU countries are given separately. The highest I-TFA contents (10–15 g) in single 100 g servings in 2005 were found in Hungary, Poland, and the Czech Republic. In France, Germany, and the UK, the I-TFA contents were lower but still with many above 2 g in 100 g product.

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1 In 2009 biscuits, cakes, and wafers in the three Eastern EU countries contained a smaller, but still

12 substantial, amount of I-TFA. In contrast, the I-TFA content in products in the three Western EU

13 countries was minimal (< 1 g). The same pattern was observed in each of the countries.

14 Only in few cases was the same brand of biscuits, cakes and wafers from the 2005 purchase included in

15 the 2009 purchase either because it had disappeared from the shop or because it did no longer have the

term partially hydrogenated fat on the list of ingredients. When the same brand was included in the

17 purchases the amount of I-TFA in that brand has declined from 2005 to 2009, but other brands with

higher amounts have appeared on the shelves.

9 The values in Fig 1 are given in table 1 for each food item from each country.

21 Fast food

In 2005, the I-TFA content of the McDonald's servings in EU varied from less than 1 g in Copenhagen
to 7 g in London, UK. For KFC servings, there were even larger differences between the countries,

ranging from less than 1 g in Germany to 24 g in Hungary. 15 percent of the 54 fast food servings $\mathbf{2}$ contained more than 10 g per serving, and 50% contained between 5 and 10 g[9]. In 2009, each of the 12 fast food menus, which were collected in France, Germany and the UK in the same locations as in 2005, contained less than 1 g of I-TFA per serving (Figs. 2 and 3). Popcorn The highest I-TFA content in a single 100 g serving of microwave oven popcorn bought in each country is presented in the data given for the I-TFA content in the high-*trans* menu for that country (Fig. 2 and table 2).

In 2009, the microwave oven popcorn samples with the highest amounts of I-TFA, which were from
Hungary, Poland and the Czech Republic, contained the same amounts of I-TFA as the popcorn that we
analysed in 2005. In contrast, the I-TFA in popcorn from Germany, France, and UK was negligible
(Fig. 3 and table 3).

The brand of microwave oven popcorn with the highest concentration of I-TFA (11.6 g I-TFA per 100
g product) found in the Czech Republic in 2005 did not contain I-TFA in 2009. However the same
brand had the highest concentration (7.6g I-TFA per 100 g product) among the microwave oven
popcorn bought in Hungary in 2009.

19 A high-*trans* menu

In 2001, the potential consumption of I-TFA by eating a high-*trans* menu was 37 g in Denmark, but by 2005, this potential consumption level was reduced to less than 1 g (Fig. 2). In 2005, by contrast, the 22 potential consumption level via a high-*trans* menu exceeded 20 g in 13 out of the 16 EU-countries, 23 from which foods were investigated. Hungary, the Czech Republic, and Poland ranked among the

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highest, with values around 40 g per menu. A considerable amount of the I-TFA in the menus was derived from the fast food meal.

Figure 3 demonstrates the time trends for I-TFA in the high-*trans* menu in Hungary, the Czech Republic, Poland, Germany, France, and the UK. In all of the countries, the contribution values obtained from McDonald's and KFC meals (nuggets and fries) in 2009 were negligible compared to the values obtained in 2005.

In 2009, biscuits, cakes, wafers, and microwave oven popcorn were still high in I-TFA in Eastern EU countries. In contrast, only small amounts of I-TFA in these same products obtained in Western EU countries were found.

DISCUSSION

The data from 2005 show that, despite a mean daily intake of around 1 g I-TFA for the entire population (as it was in Denmark in 2001), it was still possible to consume 30-40 g I-TFA in a high*trans* menu composed of popular foods. Consequently, a low average intake at the population level does not preclude a very high intake among some subgroups [6]. Following Denmark's 2003 legislation, the I-TFA content of the same menu was reduced to less than 1 g [9-10]. In addition, the data demonstrate that in 2005 it was possible to eat a menu of popular foods with more than 20 g of I-TFA in 13 out of 16 EU countries and up to 40 g in Hungary (Fig. 2). Thus far, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods. The present study demonstrates the difference between Eastern and Western Europe in the efficiency of this strategy. The overall picture regarding the I-TFA content in fast food, biscuit/wafers/cookies and microwave oven popcorn in the EU indicates that I-TFA has disappeared from American-based fast food, such as that from McDonald's and KFC, mainly due to societal

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pressure[9,11]. The same decline for biscuits and snacks in Western EU countries were observed. In Eastern EU countries, however, the amount of I-TFA in these products is still high. We even observed this difference in products bought at the same retailers in the Eastern and Western EU countries (e.g. Carrefour).

Limitations of the study

The average daily intake of I-TFA was not measured in subgroups of the population, but instead inferred from the popularity of fast food from McDonald's and KFC and from the presence of popular foods with high amounts of I-TFA in large supermarkets. The assumptions are: 1) the analysed brands of biscuits, cakes, wafers, and microwave oven popcorn were stocked at the supermarkets because they are sold in considerable amounts; 2) the majority of these foods are regularly bought and consumed by the same subgroups of consumers; and 3) the findings in the supermarkets in each capital are representative of the entire country and of adjacent countries in the Eastern and Western Europe. Another weakness is that only foods were bought in large supermarkets and from two international fast food providers (McDonald's and KFC). The I-TFA content in foods sold by small, privately owned shops or street vendors was not examined. Fats with high amounts of I-TFA prolong the shelf life of foods, and it is reasonable to assume that this factor is of even higher importance for small, privately owned shops than it is for larger supermarkets. The selective pattern of purchasing may thus have led to an underestimation of the amounts of I-TFA consumed by subgroups of the population.

Implications

An intake of above 5 g of TFA daily is associated with a health risk that can be eliminated more easily than many other diet-associated health risks. This issue is particularly relevant to low socioeconomic

groups, such as truck and taxi drivers and manual labourers, who, due to other lifestyle factors, already $\mathbf{2}$ have an increased risk of coronary heart disease partly due to high prevalence of smoking and poor diet, including high intake of I-TFA, and metabolic syndrome [12]. In 2012, EU countries, with the exception of Austria and Denmark, legally allow foods with the maximum concentration of I-TFA in the fat (i.e. 60%) to be sold without any notice as long as the food $\mathbf{5}$ is unpackaged (as is the case for restaurants and fast food outlets). If the food is pre-packaged, then the law requires the presence of I-TFA to be noted only by the term "partially hydrogenated fat" in the list of ingredients. Most consumers do not appreciate the hazard concealed therein. Societal pressure on food producers has undoubtedly resulted in a reduction in the population-level mean intake of I-TFA from 2005 to 2009, especially in Western EU countries [11]. However, this study demonstrated that a high intake of I-TFA is still possible in Eastern EU countries. This problem will continue as long as popular foods with a high concentration of I-TFA are available. Even though labelling foods with I-TFA contents may further reduce the mean intake of I-TFA, such labelling still allows the intake of high amounts of these fatty acids, first because fast food is not labelled and second because consumers might not pay attention to or understand the labelling [14-15]. A further advantage of a legislative limit on I-TFA content is that it does not require the population to learn about the health risks of I-TFA or to pay attention to the labelling of food products. It is also much easier and cheaper to monitor the presence of I-TFA in foods than it is to monitor the actual intake of I-TFA in at-risk population subgroups. In EU Austria and Denmark have shown that the health risk that a high intake of I-TFA causes, can be

added advantage of creating a "level playing field" for suppliers. All are equally challenged. All can
profit from experience of successful and rapid adaptation as in Denmark. It remains to be investigated

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3 4 5	1	to what extent the difference of availability of I-TFA in popular foods between and Eastern and	
6 7	2	Western EU countries contributes to the much higher mortality of coronary heart disease in Eastern,	
8 9	3	than in Western EU-countries (Fig. 4) [10].	
10 11 12	4		
13 14	5	What this paper adds box	
15 16	6	WHAT IS ALREADY KNOWN ON THIS TOPIC	
17 18 19	7	A daily intake of approximately 5 g of industrial <i>trans</i> fatty acids is associated with a 23% increase i	n
20 21	8	the risk of coronary heart disease.	
22 23 24	9	In the EU Austria and Denmark have shown that a high intake of I-TFA can be eliminated by a	
25 26	10	legislative ban, without any noticeable side effects for consumers.	
27 28	11		
29 30 31	12	WHAT THIS STUDY ADDS	
32 33	13	A decline since 2005 in the amounts I-TFA in popular foods in Western EU countries is observed	
34 35 36	14	In Eastern EU countries, however, the amount of I-TFA in these products is, in spite of some reducti	on,
37 38	15	still high.	
39 40	16	A low average intake of I-TFA at the population level does not preclude a very high intake among	
41 42 43	17	some subgroups.	
44 45	18	Most EU countries rely on food producers to voluntarily reduce the amounts I-TFA in foods with	
46 47 48	19	variable results. However, legislation is eminently feasible, and offers a more effective, rapid and	
49 50	20	equitable approach.	
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Contributors: SS obtained funding. SS and JD were both responsible for the concept design of the

 $\mathbf{2}$ study, for collection of food items, registration and labelling. SS and JD produced the first draft of the paper and SS, JD and AA were responsible for critical revision of the manuscript. SS is a guarantor for the study $\mathbf{5}$ Acknowledgement: We acknowledge the support from Jenny Vissings Foundation, University of Copenhagen and the Department of Clinical Biochemistry, Gentofte University Hospital. The study funders had no role in study design, in the collection, analysis and interpretation of data; in the writing of the report and in the decision to submit the article for publication. The researchers' were independent from funders. SS is the head of the department which provided resources for the conduction of the investigation. All authors had full access to all of the data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis Data sharing: no additional data available. **Conflicts of interest:** None of the authors have any relevant conflicts of interest. The corresponding author had full access to all the data in the study and has the final responsibility for the decision to submit for publication. **Competing Interest**

All authors have completed the Unified Competing Interest form at

www.icmje.org/coi disclosure.pdf (available on request from the corresponding author)

and declare that none of the authors have relationships with companies that might have

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an interest in the submitted work in the previous 3 years; Their spouses, partners, or children have no financial relationships that may be relevant to the submitted work; and (4) None of the authors have non-financial interests that may be relevant to the submitted work.

ethics appr This study did not require ethics approval

1 2			
3 4 5	1	Refe	rences
6 7	2	1	Wahle KWJ, James WPT. Isomeric fatty acids and human health. Eur J Clin Nutr 1993;47:828-
8 9 10	3		39.
10 11 12	4	2	Mozaffarian D, Katan MB, Ascherio A, et al. <i>Trans</i> fatty acids and cardiovascular disease.
13 14	5		N Engl J Med 2006; 354 :601–3.
15 16 17	6		
18 19	7	3	World Health Organization. Population nutrient intake goals for preventing diet-related chronic
20 21	8		diseases. 2003. www.who.int/nutrition/topics/5_population_nutrient/en/index12.html. (Accessed
22 23 24	9		May, 2012)
25 26	10		
27 28	11	4	Dietary Guidelines for Americans 2010.
29 30 31	12		www.health.gov/dietaryguidelines/dga2010/DietaryGuidelines2010.pdf (Accessed May, 2012)
32 33	13		
34 35 36	14	5	Stender S, Dyerberg J. The influence of <i>trans</i> fatty acids on health – Fourth edition. A report from
37 38	15		the Danish Nutrition Council. 2003. http://www.meraadet.dk/default.asp?id=1347 (Accessed
39 40	16		May, 2012)
41 42 43	17		
44 45	18	6	van Poppel G on behalf of the TRANSFAIR Study Group. Intake of fatty acids in Western
46 47 48	19		Europe: the TRANSFAIR Study. Lancet 1998; 351 :1099–1106
40 49 50	20		
51 52	21	7	Stop Press: Commission drops Danish trans fat case. EU Food Law Weekly 2007; 295 (23
53 54 55	22		March).
55 56 57	23		
58 59			
60			16

1 2			
3 4 5	1	8	Stender S, Dyerberg J, Bysted A, et al. A trans world journey. Atherosclr 2006; (Suppl 7): P47-
6 7	2		52.
8 9	3		
10 11 12	4	9	Stender S, Dyerberg J, Astrup. A. High levels of industrially produced trans fat in popular fast
13 14	5		foods. N Engl J Med 2006; 354 :1650–2
15 16	6		
17 18 19	7	10	Leth T, Jensen HG, Mikkelsen AA, et al. The effect of the regulation on <i>trans</i> fatty acid content
20 21	8		in Danish food. Atherosclr 2006; (Suppl 7):P53-6.
22 23 24	9		
25 26	10	11	Katan MB. Regulation of <i>trans</i> fats: The Gap, the Polder, and McDonald's French fries.
27 28	11		Atherosclr 2006; (Suppl 7):P69-71
29 30 31	12		
32 33	13	12	Gill PE and Wijk K. Case study of a healthy eating intervention for Swedish lorry drivers. Health
34 35 36	14		Education Research 2004; 19(3): 306-315
~-	15		
	16	13	Legislation relating to the level of industrially produced trans fatty acids in food in: The
41 42 43	17		influence of <i>trans</i> fatty acids on health – Fourth edition. A report from the Danish Nutrition
44 45	18		Council. 2003. http://www.meraadet.dk/default.asp?id=1347 (Accessed May, 2012)
46 47 48	19		
	20	14	Consumers find food labelling confusing: http://www.guardian.co.uk/money/2009/may/07/food-
51 52	21		drink-health-labels (Accessed May 2012)
53 54 55	22		
	23	15	Borra S. Consumer perspectives on food labels. Am J Clin Nutr 2006;83(5):1235S
58 59			17
60			17 For peer review only - http://bmjopen.bmj.com/site/about/guidelines.xhtml

1 2			
3 4 5	1	16	OECD Health Data 2009: Statistics and Indicators.
6 7	2		www.oecd.org/document/56/0,3746,en_2649_34631_12968734_1_1_1_1,00.html.
8 9 10	3		(Accessed May, 2012)
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4 5	1	Legends
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8 9	3	Figure 1
10 11	4	Amounts of industrial trans fatty acids in 100 g of biscuits/cakes/wafers bought in six EU countries in
12 13 14	5	2005 and in 2009. For both groups of countries (three Eastern EU countries and three Western EU
15 16	6	countries), the products are ranked according to the concentrations of industrially produced <i>trans</i> fatty
17 18	7	acids. Products were only bought if "partially hydrogenated fat" or a similar term was listed among the
19 20 21	8	first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g.
22 23	9	Fewer products in Western EU countries fulfilled the inclusion criteria compared with products in
24 25 26	10	Eastern EU-countries.
20 27 28	11	
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33 34 35	14	Figure 2
36 37	15	Amounts of industrial <i>trans</i> fatty acids in a high- <i>trans</i> menu bought in the various countries in 2005.
	16	For each country, the product with the highest concentration of industrial trans fatty acids in each of
40 41 42	17	the three food categories is shown.
43 44	18	
	19	Figure 3
47 48 49	20	Time trends for the amounts of industrial trans fatty acids in a high-trans menu bought in
50 51	21	three Eastern EU countries in 2005 and 2009 and in three Western EU countries in 2005
	22	and 2009.
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Figure 4

Trends in coronary heart disease mortality rates, selected OECD countries, 1980-2006.

Source: OECD Health Data 2009. The raw mortality data are extracted from the WHO

Mortality Database, and age-standardised to the 1980 OECD population. For 2006 to 2009

the yearly mortality for Hungary is 228, 215,205 and 204. The corresponding values for

ECD-mean ... Denmark and for OECD-mean have not yet appeared in the OECD Health data 2011.

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 Table 1Trans fatty acids /TFA) in biscuits, cakes, and wafers bought in 2005 in large supermarkets in the capital of the country. Products were onlyAbought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content
exceeded 15 gram of fat per 100 gram product.

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7		Item no.	100 gram product	Item no.	100 gram product		Item no.	100 gram product	Item no.	100 gram product		Item no.	100 gram product	Item no.	100 gra produ
8	Hungary	10	10.4	93	5·6	Poland	43	12·5	111	6.0	Czech	25	15·3	57	2.3
9	5,	19	4.2	88	5.0		2	11·9	85	5.5	Rebublic	11	14·3	64	2.0
10		26	3.7	98	2.2		26	11.7	92	5.4		35	14·0	69	2.0
11		24	2.1	85	2.2		44	10.8	107	5.5		20	12.9	71	1.9
12		33	1.4	97	0.4		1	8·1	91	5.0		36	12.8	66	1.9
13		29	1.1	96	<0.5		40	7.4	89	4.3		24	12.7	56	1.6
10 14		32	0.9	91	<0.5		5	6.3	97	3.5		5	11.7	54	0.9
		15	0.9	86	<0.5		24	6·3	114	2.6		21	8.5	55	0.7
15		35	0.8	90	<0·2		35	5.7	87	2.6		29	8.2	58	0.5
16		34	0.2	83	<0.5		42	5.2	113	2.1		41	7.8	73	0.4
17		36	0.2	84	<0.5		33	4.4	109	2.0		31	7.1	76	0.3
18		23	0.3	89	<0.5		22	4.3	104	1.7		38	6.3	74	0.3
19		8	<0.5	92	<0.5		6	4.0	105	1.4		34	5.3	78	0.3
20		9	<0.2	99	<0.2		21	3.9	95	0.9		23	3.8	77	<0.2
$\frac{20}{21}$		16	<0.2	95	<0.2		23	3.4	110	0.8		40	3.7	70	<0.2
$\frac{21}{22}$		28	<0.2	87	<0·2 <0·2		29	2.9	112	0.7		43	1.7	72	<0.2
		30 5	<0·2 <0·2	94 82	<0·2 <0·2		45 36	2·8 <0·2	115 108	0·5 <0·2		22 42	1·6 1·4	59 63	<0·2 <0·2
23		6	<0·2 <0·2	02	<0.5		30 34	<0·2 <0·2	108	<0·2 <0·2		42 27	1·4 1·2	80	<0·2 <0·2
24		11	<0·2 <0·2				4	<0.2	96	<0.2		28	0.4	53	<0·2 <0·2
25		12	<0·2 <0·2				37	<0.2	88	<0.2		12	<0·2	75	<0·2
26		13	<0·2				25	<0·2	103	<0.2		13	<0.2	68	<0·2
27		18	<0.2				38	<0.2	90	<0.2		26	<0.2	79	<0.2
$\frac{-1}{28}$							7	<0.2	94	<0.2		30	<0.2	81	<0.2
20 29							13	<0.2	93	<0.2		32	<0.2	65	<0.2
							3	<0.5	86	<0.5		37	<0.5	60	<0.5
30							20	<0.5				39	<0.5	61	<0.5
31							27	<0.5				44	<0.5	62	<0.5
32							28	<0.5							
33							30	<0.5							
34							31	<0.5							
35							39	<0.5							
36	Total number														
90	of items	23		18	5		32		26	3		28	3	28	3

Item no. is an internal identification and the second second participation of 25 lighter and the second secon

	exceed		of fat per	ated fat" or a s 100 gram pro 009			005		009			005		2009
		Gram TFA		Gram TFA			Gram TFA		Gram TFA			Gram TFA	-	Gra
		in		in			in		in			in		
	Item	100 gram	Item	100 gram		Item	100 gram	Item	100 gram		Item	100 gram	Item	100
_	no.	product	no.	product		no.	product	no.	product		no.	product	no.	pr
France	1b	4.8	12	0.7	Germany	8b	6.9	42	0.3	UK	28a	4.5	58	
	22a	4.2	20	0.5		17b	2.6	51	<0.2		4a	1.3	52	
	24a	3.6	13	0.5		4a	1.4	43	<0.2		16a	1.0	56	
	4a	3·5	15	0.3		13a	1.1	40	<0.2		17a	1.0	54	
	2a 26a	1∙8 1∙5	16 17	0·2 0·2		4b 3a	0·8 0·6	41 50	<0·2 <0·2		15a 36a	0·9 0·9	51 57	•
	20a 13a	0.7	21	<0.2 <0.2		3a 13b	0·8 0·4	50 46	<0·2 <0·2		36a 7b	0.9	55	•
	3a	0.7	19	<0.2		5a	0.3	48	<0.2		2b	0.7	53	
	3b	0.7	22	<0.2		12b	0.3	44	<0.2		-~ 10a	0.4		
	15a	0.2	23	<0.5		8a	<0.5	47	<0.5		33a	0.4		
	12a	0.3	18	<0.5		15a	<0.5	49	<0.5		32a	0.3		
	5a	<0.5	14	<0.5		1b	<0.5				34a	0.3		
	18a	<0.5				Зb	<0.5				3b	0.5		
	2b	<0.5				16b	<0.5				31a	<0.5		
	3c	<0.5				6a	<0.2				13a	<0.5		
	17a	<0.2				7a	<0.2				1a	<0.2		
	23a	<0·2 <0·2				14a	<0·2 <0·2				39a	<0·2 <0·2		
	1a 16a	<0·2 <0·2				17a 6b	<0·2 <0·2				5b 6b	<0·2 <0·2		
	21a	<0·2				21b	<0.2				8b	<0·2		
	25a	<0·2				16a	<0.2				9b	<0.2		
	2c	<0.2				iou					29a	<0.2		
	20a	<0.5									23a	<0.5		
	14a	<0.5									11a	<0.5		
	19a	<0.5									12a	<0.5		
	1c	<0.5									2a	<0.5		
	4b	<0.5									38a	<0.5		
											40a	<0.5		
											4b	<0.2		
											5a	<0.2		
											8a 250	<0·2		
Number											35a	<0.2	22	
of items	27	F	or pleer	review only -	http://bmjop	en2hm	i.com/site/al	าดแปลแม่	delines xhtml		33		8	

Table 2

Amounts of industrial *trans fatty acids* in a high-trans menu bought in the various countries in 2005.

	Gram of TFA in a large serving* of nuggets and French fries	Gram of TFA in 100 gram biscuits, cakes, and wafers	Gram of TFA in 100 gram microwave popcorn	Gram of TFA in a high <i>trans</i> menu
Czech Rep 2005	16.8	15.3	11.6	43.7
Poland 2005	19.8	12·5	10.7	42.3
Hungary 2005	24.1	10.4	7.6	42·1
Bulgaria 2005	22.5	7.9	7.7	38.1
Romania 2005	15.3	3.5	11.8	30.6
France 2005	6.2	4.8	13·8	24.8
Germany 2005	4.9	6.9	12.4	24.2
Portugal 2005	4.0	5.5	13·9	23.4
Spain 2005	5.0	4.6	13.8	23.4
UK 2005	8·2	4.5	10.4	23.1
The Netherlands 2005	5.0	6.7	11.0	22.7
Austria 2005	4.2	8.4	9.4	22.0
Italy 2005	6.0	3.3	11.9	21.2
Sweden 2005	4.8	6.0	5.9	16.7
Finland 2005	5.9	4.6	0.1	10.6
Denmark 2001	10.0	17.0	10.0	37.0
Denmark 2005	0.3	0.3	0.3	0.9

* A large serving was 171 gram of French fries or wedges and 160 gram of nuggets or hot wings

Table 3

Amounts of industrial trans fatty acids in various foods bought in three Eastern EU countries in 2005 and 2009 and in three Western EU countries in 2005 and 2009

Hungary 2005 24-1 10-4 7-6 42-1 izzech Rep 2005 14-1 15-3 11-6 41-0 Poland 2005 19-1 12-5 6-7 38-3 Hungary 2009 <1 5-6 6-9 12-5 izzech Rep 2009 <1 2-3 16-8 19-1 Poland 2009 <1 6-0 7-6 13-6 France 2005 6-2 4-8 13-8 24-8 Germany 2005 5-3 6-9 12-4 24-6 UK 2005 8-3 4-5 10-4 23-2 France 2009 <1 <1 <1 <1 Germany 2009 <1 <1 <1 <1 Germany 2009 <1 <1 <1 <1 Characteristic of the term of the term of te		Gram of TFA in a large serving of nuggets and French fries	Gram of TFA in 100 gram biscuits/cakes/ wafers	Gram of TFA in 100 gram microwave popcorn	Gram of TFA in a high-trans menu
Poland 2005 191 12-5 6-7 38-3 Hungary 2009 <1	Hungary 2005	24·1	10.4		42·1
Hungary 2009 <1 5-6 6-9 12-5 Zzech Rep 2009 <1 2-3 16-8 19-1 Poland 2009 <1 6-0 7-6 13-6 France 2005 6-2 4-8 13-8 24-8 Germany 2005 5-3 6-9 12-4 24-6 UK 2005 8-3 4-5 10-4 23-2 France 2009 <1 <1 <1 <1 Germany 2009 <1 <1 <1 <1 UK 2009 <1 <1 <1 <1 UK 2009 <1 <1 <1 <1 VK 2009 <1 VK 2009 <1 VK 2009 <1 VK 2009 <1 VK 2009 ×1 VK 2009 ×1	Czech Rep 2005	14.1	15·3	11.6	41.0
zzech Rep 2009 <1	Poland 2005	19.1	12·5	6.7	38.3
Poland 2009 <1 6-0 7-6 13-6 France 2005 6-2 4-8 13-8 24-8 Germany 2005 5-3 6-9 12-4 24-6 UK 2005 8-3 4-5 10-4 23-2 France 2009 <1	Hungary 2009	<1	5.6	6.9	12.5
France 2005 62 4-8 13-8 24-8 Germany 2005 5-3 6-9 12-4 24-6 UK 2005 8-3 4-5 10-4 23-2 France 2009 <1	Czech Rep 2009	<1	2.3	16.8	19.1
Germany 2005 5·3 6·9 12·4 24·6 UK 2005 8·3 4·5 10·4 23·2 France 2009 <1	Poland 2009	<1	6.0	7.6	13.6
UK 2005 8-3 4-5 10-4 23-2 France 2009 <1 <1 <1 <1 <1 Germany 2009 <1 <1 <1 <1 <1 UK 2009 <1 <1 <1 <1 UK 2009 <1 <1 <1 <1	France 2005	6.2	4.8	13.8	24.8
France 2009 <1	Germany 2005	5.3	6.9	12.4	24.6
Germany 2009 <1 <1 <1 <1 <1 <1 <1 <1 <1 <1 <1 <1 <1	UK 2005	8.3	4.5	10.4	23.2
UK 2009 <1 <1 <1 <1 <1	France 2009	<1	<1	<1	<1
	Germany 2009	<1	<1	<1	<1
	UK 2009	<1	<1	<1	<1

Table 4	
---------	--

Trends in ischemic heart disease mortality rates, selected OECD countries, 1980-2006

	Denmark	Hungary	OECD	
1980	261·2	217	171·8	
1981	258-4	231.5	170·3	
1982	241.3	230.7	166·8	
1983	237·9	231	165·2	
1984	235-4	223.9	162·0	
1985	232·1	225	162·6	
1986	226.5	227.5	157.5	
1987	221.9	221.5	154.3	
1988	211.6	223·5	150·5	
1989	204.4	222·8	147.6	
1990	201.6	226.6	144.3	
1991	187.8	230·2	141.4	
1992	181.9	234.6	138·3	
1993	180.2	244.2	137·0	
1994	158.0	233.1	130·3	
1995	157.4	235.4	128·9	
1996	136.6	237.8	123·6	
1997	130.5	232·2	118·7	
1998	120.5	234·2	115.4	
1999	117.4	240.9	114.6	
2000	106.0	225·4	107·9	
2001	106.4	212.9	103-2	
2002	93.7	209.3	100.7	
2003	87.9	219.7	▲ 98·1	
2000	80.4	220.6	92·5	
2004	73.9	247.5	89·7	
2005	67-8	228·5	86.9	
Deaths per				
Deans per				
Source: OF	ECD Health Data 2			
Oburce. OL		.005.		

STROBE Statement-checklist of items that should be included in reports of observational studies

	Item No	Recommendation
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract
		(b) Provide in the abstract an informative and balanced summary of what was done
		and what was found
Introduction		
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported
Objectives	3	State specific objectives, including any prespecified hypotheses
Methods		
Study design	4	Present key elements of study design early in the paper
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment,
8		exposure, follow-up, and data collection
Participants	6	(a) Cohort study—Give the eligibility criteria, and the sources and methods of
1		selection of participants. Describe methods of follow-up
		<i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of
		case ascertainment and control selection. Give the rationale for the choice of cases
		and controls
		<i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of
		selection of participants
		(b) Cohort study—For matched studies, give matching criteria and number of
		exposed and unexposed
		<i>Case-control study</i> —For matched studies, give matching criteria and the number of
		controls per case
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect
		modifiers. Give diagnostic criteria, if applicable
Data sources/	8*	For each variable of interest, give sources of data and details of methods of
measurement		assessment (measurement). Describe comparability of assessment methods if there
		is more than one group
Bias	9	Describe any efforts to address potential sources of bias
Study size	10	Explain how the study size was arrived at
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable,
		describe which groupings were chosen and why
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding
		(b) Describe any methods used to examine subgroups and interactions
		(c) Explain how missing data were addressed
		(d) Cohort study—If applicable, explain how loss to follow-up was addressed
		<i>Case-control study</i> —If applicable, explain how matching of cases and controls was
		addressed
		Cross-sectional study—If applicable, describe analytical methods taking account of
		sampling strategy
		(<u>e</u>) Describe any sensitivity analyses
Continued on next page		

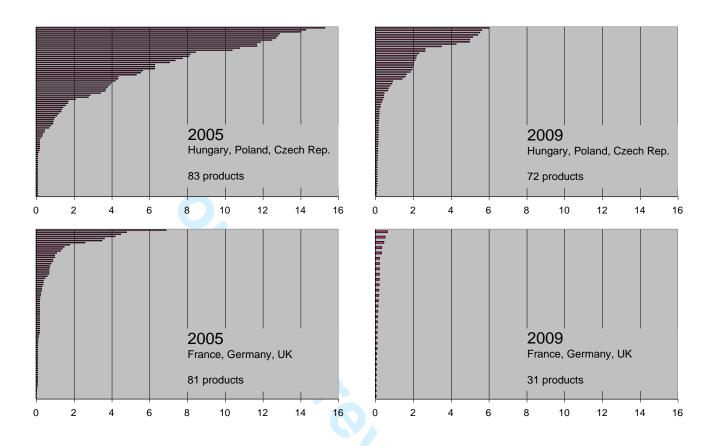
Continued on next page

Results					
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible,			
		examined for eligibility, confirmed eligible, included in the study, completing follow-up, and			
		analysed			
		(b) Give reasons for non-participation at each stage			
		(c) Consider use of a flow diagram			
Descriptive	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information			
data		on exposures and potential confounders			
		(b) Indicate number of participants with missing data for each variable of interest			
		(c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)			
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time			
		Case-control study-Report numbers in each exposure category, or summary measures of			
		exposure			
		Cross-sectional study-Report numbers of outcome events or summary measures			
Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their			
		precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and			
		why they were included			
		(b) Report category boundaries when continuous variables were categorized			
		(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful			
		time period			
Other analyses	17	Report other analyses done-eg analyses of subgroups and interactions, and sensitivity			
		analyses			
Discussion					
Key results	18	Summarise key results with reference to study objectives			
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision.			
		Discuss both direction and magnitude of any potential bias			
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity			
		of analyses, results from similar studies, and other relevant evidence			
Generalisability	21	Discuss the generalisability (external validity) of the study results			
Other informati	ion				
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable,			
		for the original study on which the present article is based			

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

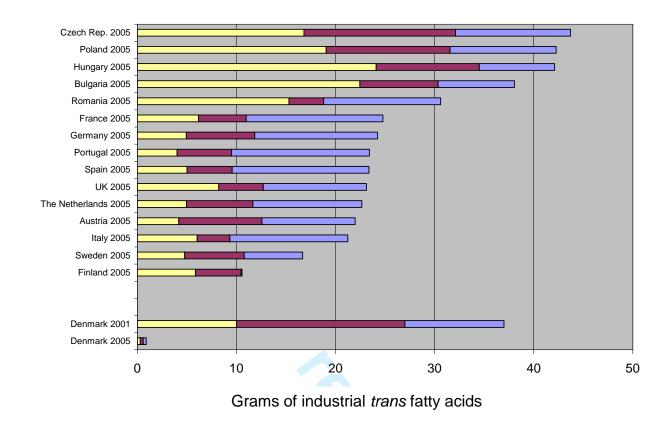
Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Fig 1



Grams of industrial trans fatty acids in 100 g of product

Fig 2

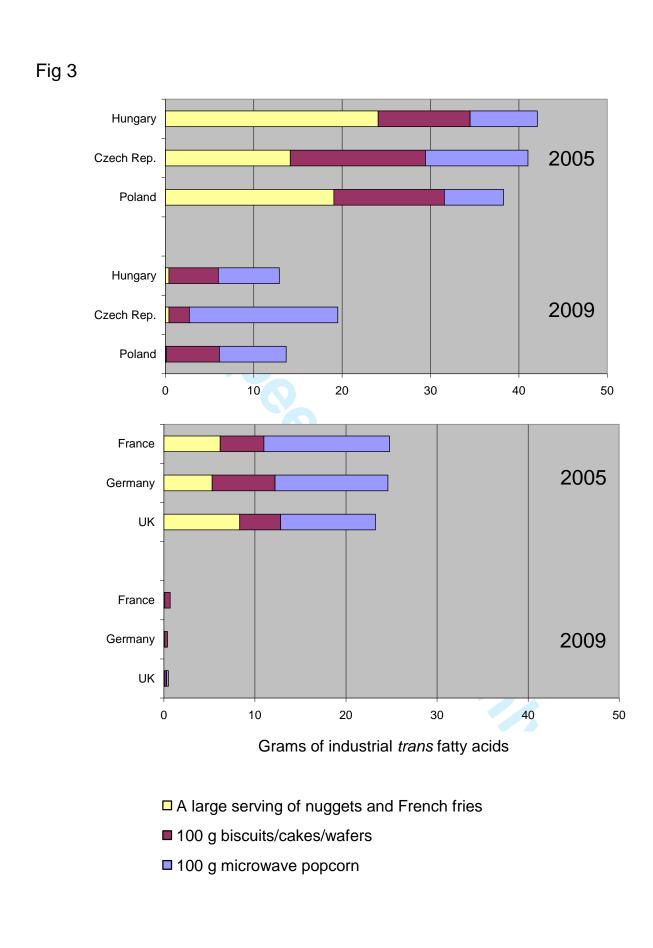


A large serving of nuggets and French fries

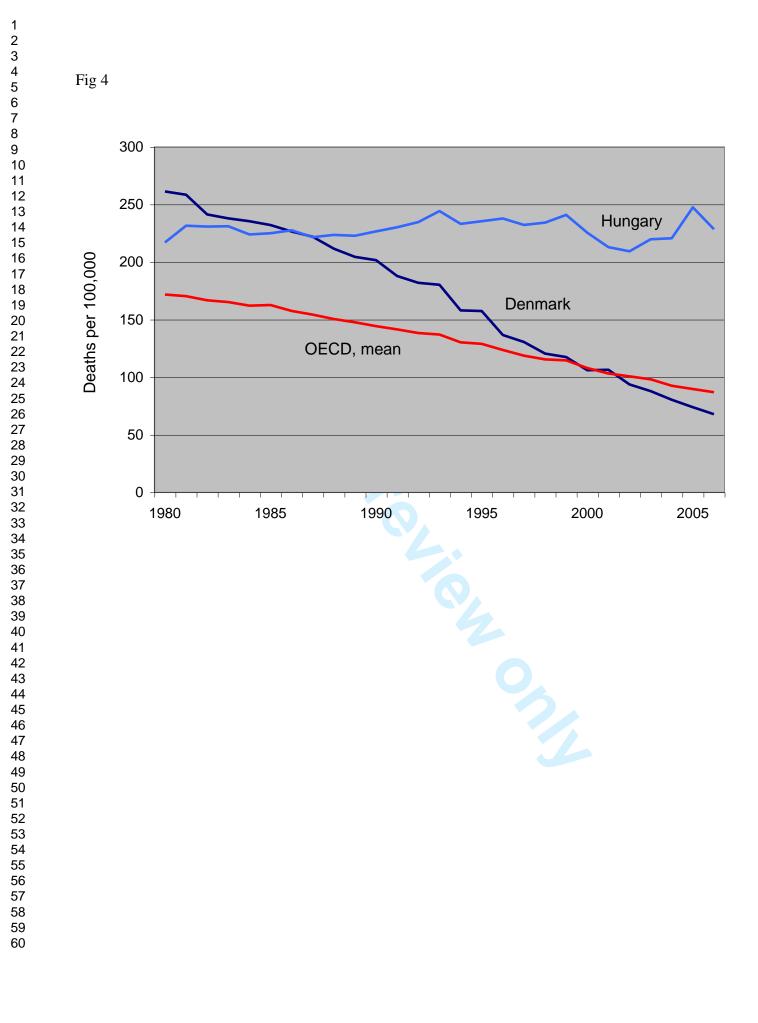
100 g biscuits/cakes/wafers

100 g microwave popcorn









Reviewer 1 Comments...

Name: S Capewell Position: Chair of Clinical Epidemiology

This is an excellent paper with very important messages for public health in the UK and Europe.

I have no major criticisms, apart from:Figure 3 which is currently a histogram; it needs to be redrawn as a bar chart, to facilitate comparisons with Figure 2.

A new figure 3 has been made according to the reviewer's suggestion

Secondly, I do have a few suggestions to make the paper even better. Mainly by strengthening or revising specific sentences.

These are specified below, with suggested changes IN CAPITALS.

Also, I will endevour to also send the comments as a Word "Track Changes" document, which may be MUCH easier to comprehend.

All numbers refer to line numbers in the pdf document submitted.

A trans European Union difference in the decline in trans fatty acids in popular foods - a basket investigation.

ABSTRACT

Line 8 Objectives: Trans fatty acids (TFA) are produced when liquid vegetable oil is industrially hydrogenated to make it solid fat. A daily intake of approximately 5 g of TFA is associated with a 23% 9 increase in the risk of CORONARY heart disease. In order to minimize the intake of TFA some countries 10 have introduced labelling, while others have introduced legislative limits on the content of TFA in 11 food INCLUDING AUSTRIA, DENMARK AND SWITZERLAND. HOWEVER , but most countries still rely on food producers to voluntarily reduce the TFA content in food. The 12 objective of the present study was to investigate the efficiency of these strategies in the EU. 13 Design: The potential consumption of TFA was assessed in a basket

1	
2	
3 4	
5	investigation by analysing the TFA CONTENT in popular
6	14 foods in 16 EU countries in 2005 and AGAIN in 2009 USING A STANDARD
7	METHODOLOGY.
8	15 Samples: 70 servings of French fries and chicken nuggets, 90 packages of
9	microwave popcorn, and
10	16 442 samples of biscuits/cakes/wafers with "partially hydrogenated vegetable
11	fat" listed on the label
12 13	17 high on the list of ingredients were analysed. A "high-trans menu" was
14	
15	DEFINED AS a large serving of French fries
16	18 and nuggets, 100 g of microwave popcorn, and 100 g of biscuits/wafers/cakes.
17	19 Results: In 2005, a high-trans menu provided above 30 g of TFA in five EU
18	countries in Eastern
19	20 Europe (SPECIFY) and 20-30 g in eight EU countries in Western Europe
20	(SPECIFY WHICH). In 2009 the values in Hungary, Poland,
21 22	21 and the Czech Republic REMAINED HIGH (between 10 and 20 g), whereas they
23	were less than 2 g. in Germany,
24	
25	22 France and the UK,
26	
27	Conclusion:
28	In 2009 the content of TFA in popular foods in 1 Western European APPEARS LOW
29 30	but not in
31	Line 2 Eastern European EU countries. THESE FINDINGS suggest that millions of
32	people in the EU still consume TFA in
33	3 amounts that SUBSTANTIALLY increase their risk of CORONARY heart disease.
34	The Austrian, Danish, and Swiss experiences
35	
36	4 with legally limiting TFA content in human food, demonstrate that this risk
37	can be eliminated, with no
38 39	5 noticeable effect on the availability, price, or quality of food.
40	
41	INTRODUCTION
42	Line 2 Trans fatty acids (TFA) in food originate from industrial hardening of
43	oils and from ruminant sources.
44	3 Compared to unhydrogenated oils, fats containing industrially produced TFA
45	are solid at room
46 47	
48	4 temperature, have some technical advantages in food processing, and prolong
49	the shelf life of food. HOWEVER,
50	5 TFA can constitute up to 60% of the fats in certain foods, whereas ruminant
51	fat contains at most 6%
52	6 TFA. A meta-analysis of four large prospective studies found that an intake
53	of INDUSTRIAL TFA corresponding to
54 55	7 2% of the total energy intake (E %) (approximately 5 g/d) was associated
55 56	with a 23% increase in the
57	8 risk of CORONARY heart disease1. Several public health organisations have
58	o have been been and the sease of the sease
59	
60	

	BMJ Open
therefore recommer	nded that INDUSTRIAL TFA intake
9 should be lowered INDUSTRIAL TFA ir	l as much as possible2-4. In 1976, the average intake of n Western
10 Europe was 6 g/ 6•7 g/d), correspon	d. In 1996, this intake had dropped to 2•6 g/d (range 1•2 to ding to
	pproximately half of this intake was from ruminant TFA, and
	hich constitutes a 78% decrease since 19765. Despite a
	g of industrial TFA per day in Denmark in 2001, it was
-	SINGLE high-trans menu by eating popular food products
	ench fries4. Among the 5 million Danes, 10,000–50,000 peop
	u several times each week, and got a daily intake of more
17	
18	
	croduced the mandatory labelling of the TFA content in pre-
packaged food. In t	ne nark introduced a legislative limit of 2% industrial TFA in
fat used for foods. T	
	ission initially opposed this legislation but in MARCH 2007
dropped its infringe	ment
21 proceedings again dangers of trans fat	inst Denmark because of increased scientific evidence on the s6.The
-	andatory labelling of pre-packaged food in 2006, followed by
23 TFA in the food s	served in restaurants in New York City in 2008 and in 2010-
11 in the state of	
similar 1 to the Dan	Austria and Switzerland introduced a legislative ban ish' TO BE FOLLOWED IN 2011 BY ICELAND AND SWEDEN. (ly 500 million inhabitants who consume food that still may ts of
14 million people, a	k's and Austria's populations, representing approximately re the
4 exceptions. 5 In 2005, we asses	ssed by a basket investigation the availability of a high-
trans menu (large s	
	uggets, 100 g of microwave popcorn and 100 g of

1 2	
3	
4 5	biscuits/wafers/cakes) in 15 EU
6	7 countries. , and found that, i In spite of a low mean intake, high
7	concentrations of industrial TFA were still
8 9	8 present in many popular foods. Thus, subgroups of the populations could have
10	an intake that is
11	9 considerably higher than the recommended upper limit for intake of TFA7. TFA
12	in foods from
13 14	10 international fast food providers was an important contributor to the high
15	intake in these sub11
16	populations8. Still in 2009, EU countries (with the exception of Austria and
17	Denmark) rely on food
18 19	12 producers to voluntarily reduce the amounts of TFA in foods. The present
20	study assess the efficiency of
21	13 that strategy in three Eastern European countries, Hungary, Poland, and the
22	Czech Republic, and in
23 24	14 three Western European countries, Germany, France, and the UK.
25	
26	METHODS
27 28	In July 2009 to September 2009, the capitals of Poland, the Czech Republic,
29	Hungary, Germany,
30	Line 7 France, and the UK were revisited and the same procedures for the
31	purchase of food items WERE FOLLOWED. If
32 33	8 possible, the same stores were revisited and the same brands were bought.
34	Altogether, 602 samples of
35	9 food in EU countries were purchased
36	
37 38	Calculation
39	18 For comparison, the amounts of TFA in the French fries and the chicken
40	nuggets were expressed as the
41	19 amounts in a serving size equivalent to a large serving from McDonald's in
42 43	the US: . The serving sizes were 171 g of French fries and 160 g of chicken
44	nuggets.
45	
46	RESULTS
47 48	Line 2
49	Biscuits, cakes, and wafers
50	3 Figure 1 presents data from the products bought in the six EU countries in 2005 and 2009. The
51 52	
53	4 products are ranked according to TFA content and the combined values for the
54	three Eastern EU
55	5 countries and for the three Western EU countries are given separately. IN 2005, THE bighest TEA contents $(10-$
56 57	IN 2005, THE highest TFA contents (10–
58	6 15 g) in single 100 g servings were found in Hungary, Poland, and the Czech
59	
60	

Republic. In 2005 in 7 France, Germany, and the UK, the TFA contents were lower but still considerable (4-7 g). AVERAGING 5G EXCLUDING ONE OUTLIER 8 In 2009 biscuits, cakes, and wafers in the three Eastern EU countries contained a smaller, but still 9 substantial, amount of TFA (4–6 g in Figure 3). In contrast, the TFA content in products in the three Western EU 10 countries was minimal (< 1 g). The same pattern was observed in each of the countries. Fast food Line 13 In 2005, the TFA content of the McDonald's servings in EU varied from less than 1 g in Copenhagen 14 to 7 g in London, UK. For KFC servings, there were even larger differences between the countries, 15 ranging from less than 1 g in Germany to 24 g in Hungary. 15 percent of the 54 fast food servings 16 contained more than 10 g per serving, and 50% contained between 5 and 10 g8. (Figure 2) 17 In 2009, each of the 12 fast food menus, which were collected FRANCE, GERMANY AND THE UK in the same locations as in 2005, 18 contained less than 1 g of TFA per serving (Figure 3). Popcorn Line 21 The highest TFA content in a single 100 g serving of microwave oven popcorn bought in each country IN 2005 22 is presented in the data given for the TFA content in the high-trans menu for that country (Fig. 2), 6-12g In 2009, the microwave oven popcorn samples with the highest 1 amounts of TFA, which were from 2 Hungary, Poland and the Czech Republic, contained the same similar amounts of TFA as the popcorn that we 3 analysed in 2005, 8-16q. In contrast, the TFA in popcorn from Germany, France, and UK in 2005 (10-13g) was negligible by 2009 (Fig. 3). 6. A high-trans menu Line 7 In 2001, the potential consumption of TFA by eating a high-trans menu

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1	
2	
3	
4	was 37 g in Denmark, but by
5 6	8 2005, this potential consumption level was reduced to less than 1 g (Fig.
7	2). In 2005, by contrast, the
8	9 potential consumption level via a high-trans menu exceeded 20 g in 13 out of
9	the 16 EU-countries,
10 11	10 from which foods were investigated. Hungary, the Czech Republic, and Poland
12	ranked among the
13	11 highest, with values being around 40 g per menu. A considerable amount of
14	the TFA in the menus was
15	12 derived from the fast food meal.
16 17	13 Figure 3 demonstrates the time trends for TFA in the high-trans menu in
18	Hungary, the Czech Republic,
19	14 Poland, Germany, France, and the UK. In all of the countries, the
20	contribution values obtained from
21 22	15 McDonald's and KFC meals (NUGGETS AND FRIES) in 2009 were negligible
23	compared to the values obtained in 2005.
24	16 In 2009, biscuits, cakes, wafers, and microwave oven popcorn were still
25	high in TFA in Eastern EU
26 27	17 countries. In contrast, only small amounts of TFA in THESE SAME products
28	obtained in Western EU countries
29	18 were found.
30	19 Note to dild.
31	19
32 33	Implications
34	Implications
35	7 An intake of above 5 g of TFA daily is associated with a health risk that
36	can be eliminated more easily
37 38	8 than many other diet-associated health risks. This issue is particularly
39	relevant to low-income groups
40	9 such as taxi and truck drivers AND MANUAL LABOURERS who, due to other
41	lifestyle factors, already have an increased risk of CORONARY HEART DISEASE
42 43	10 and who may also more frequently eat foods with a high TFA content.
43 44	11 In 2011, EU countries, with the exception of Austria and Denmark, legally
45	allow foods with the
46	12 maximum concentration of TFA in the fat (i.e. 60%) to be sold without any
47	notice as long as the food is
48 49	13 unpackaged (as is the case for restaurants and fast food outlets). If the
50	food is pre-packaged, then the
51	14 law requires the presence of TFA to be noted only by the term "partially
52	hydrogenated fat" in the list of
53 54	15 ingredients. MOST CONSUMERS DO NOT APPRECIATE THE HAZARD CONCEALED
55	THEREIN. (REF)
56	16 Societal pressure on food producers has undoubtedly resulted in a reduction
57	in the population-level
58 59	
60	

17 mean intake of TFA from 2005 to 2009, especially in Western EU countries.
(ref)
18 However, this study demonstrated that a high intake of TFA is still
possible in Eastern EU countries.
19 This problem will continue as long as popular foods with a high
concentration of TFA are available.
20 Even though labelling foods with TFA contents may further reduce the mean
intake of TFA, such
21 labelling still allows the intake of high amounts of these fatty acids,
first because fast food is not
22 labelled and second because consumers might not pay attention to the
labelling OR UNDERSTAND.
A further advantage of a legislative limit on TFA content is that it does 1
not require the population to
2 learn about the health risks of TFA or to pay attention to the labelling of
food products. It is also MUCH easier
3 and cheaper to monitor the presence of TFA in foods than it is to monitor
the actual intake of TFA in
4 at-risk population subgroups.
5 Austria and Denmark have shown that the health risk that a high intake of
industrially produced trans
6 fatty acids causes can be eliminated for the entire population without any
noticeable side effects for
7 consumers. THIS HAS THE ADDED ADVANTAGE OF CREATING A "LEVEL PLAYING FIELD" FOR
SUPPLIERS. ALL ARE EQUALLY CHALLENGED. ALL CAN PROFIT FROM EXPERIENCE OF
SUCCESSFUL AND RAPID ADAPTATION AS IN DENMARK. (refs) It remains to be investigated to what extent the difference of availability of TFA in popular
8 foods between and Eastern and Western EU countries contributes to the much
higher CHD mortality
9 in CENTRAL EUROPE, than in Western EU-countries (Fig. 4) 10.
10
11 What this paper adds box
12 WHAT IS ALREADY KNOWN ON THIS TOPIC
13 A daily intake of approximately 5 g of industrially produced trans fatty
acids (TFA) is associated with
14 a 23% increase in the risk of CORONARY heart disease.
15 In the EU Austria and Denmark have shown that a high intake of TFA can be
eliminated by a
16 legislative ban, without any noticeable side effects for consumers.
17
18 WHAT THIS STUDY ADDS
19

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53 54

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1 2	
3 4 5	A DECLINE SINCE 2005 IN THE AMOUNTS TFA IN POPULAR FOODS IN WESTERN EU
6 7 8	COUNTRIES IS OBSERVED. 23 IN EASTERN EU COUNTRIES, HOWEVER, THE AMOUNT OF TFA IN THESE PRODUCTS IS STILL HIGH
9	
10 11	A low average intake TFA at the population level does not preclude a very
12	high intake among some
13	20 subgroups.
14 15	21 Most EU countries rely on food producers to voluntarily reduce the amounts
16	TFA in foods, WITH VARIABLE RESULTS.
17	22
18	However, legislation is eminently feasible, and offers a more effective, rapid
19 20	and equitable approach.
21	
22	Fig 1
23 24	Line 32 Grams of industrially produced trans fatty acids in 100 g of
25	product
26	
27	We need some figures for 2009
28 29	
30	Figure 3
31	HISTOGRAM LOOKS ODD. IT NEEDS TO BE CHANGED INTO A BAR CHART, TO FACILITATE
32 33	COMPARISON WITH FIGURE 2
34	The figure has been changed as suggested
35	
36	Figure 4 HUNGARY TRENDS LOOK ODD. MORTALITY FALLS ARE NOW OCCURRING THERE TOO.
37 38	We have added the new available figures for 2007, 2008, and 2009
39	we have added the new available figures for 2007, 2000, and 2009
40	In conclusion we have followed all of the suggestions from this reviewer and we appreciate his
41 42	thorough work with our manuscript
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49 50	
51	Reviewer 2 Comments
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Reviewer 2 Comments... Name: Andrew Odegaard PhD, MPH Position: Research Associate COMMENTS FOR THE AUTHOR

The authors have carried out what appears to be a case study that aims to examine the efficiency of relying on producers to voluntarily reduce TFA in foods with historically high TFA content. Indeed, the authors have an extensive and noteworthy background on this public health area.

They found major fast food corporations seem to be self-regulating overall in Europe, biscuits/crackers makers to an extent in Eastern and certainly in Western Europe, where microwave popcorn is self-regulated in Western, but not Eastern Europe. Essentially, 4.5 of the possible 6 areas of possible TFA reduction occurred with self-regulation. (those 1.5 areas being only a partial reduction in TFA in biscuits/crackers and no evident change in popcorn in Eastern EU).

They also report that legislation worked in Denmark to essentially eliminate TFA.

This work is certainly original in that it provides a snap shot, to some extent, on TFA in foods with traditional high levels of TFA, and is probably most relevant to policy makers, since that is what the author's are arguing for.

That said, there are a number of points that could be sharpened to improve this as a scientific research article as it currently reads as more of a hybrid of original research and advocacy paper or editorial.

I've provided general and specific comments below that I hope are helpful.

General

The focus should emphasize "industrial" TFA throughout the paper.

Some readers may quibble with the use of "ischemic" instead of Coronary Heart Disease, but this is immaterial if defined specifically using and ICD code for example.

We have replaced the word ischemic with coronary heart disease as also suggested by reviewer 1

Given the study design and approach- was the follow up assessment in 2009 planned in 2004/5 or was this opportunistic use of data? Either way, it provides interesting results from a number of perspectives.

I think the title may be misleading – the aim seems to have been to assess a high-TFA menu based on items from three different avenues of processed foods that are likely widely available. There is no evidence provided that these are actually popular items or the per capita consumption is high.

 We assume the popularity of these products because they were stocked at the supermarkets. They are only stocked there because they are sold in considerable amounts. This is mentioned in the manuscript.

The competition between food producers of having their products on the shelves in large supermarkets is fierce. Only products with a sufficient turnover are allowed to be there.

The popularity of foods from McDonald and KFC in large cities is inferred from the same argumentation.

As well, the abstract conclusion could use more nuance- the fast food reported in Eastern EU was self regulated according to your results.

We have modified the conclusion by adding the sentence "in spite of some reduction" (in Eastern Europe)

Introduction:

-The sentence beginning in line 5 needs a reference for the values provided. We have provided the following reference:Wahle KWJ, James WPT. Isomeric fatty acids and human health.

Eur J Clin Nutr 1993; 47: 828-39.

-An estimate of 0.2-1.0% of the Danish population eats this way according to data provided. Is this a public health issue if similar percentages of these other countries are doing the same? An approach aiming to show this would strengthen the article for the audience. This also relates to the title (popular foods).

We have in line17 page 4 added the sentence: "Generalizing to the population in the EU, this corresponds to 1-5 million people"

-Are readers going to be confused on what a "basket investigation" is? If there is an actual definition- this essentially seems to be a case study

We have now replaced the word basket with the words "market basket" In PubMed.com the search term "market basket" generates 20 titles using the term in the title and 155 papers using the term in the text. Most of the papers deal with the content of toxic components in foods.

Reviewer 2 finds the study to be a case study. We report however 600 cases, which are the number of foods, analysed for TFA

Pg 5 line 11- Earlier it was noted that Switzerland also had introduced a

legislative ban on TFA, which one is it?

The sentence in the paper reads: "Still in 2009, EU countries (with the exception of Austria and Denmark) rely on food producers to voluntarily reduce the amounts of I-TFA in foods." Switzerland is not an EU country.

The legislative ban in Switzerland is similar to the legislative ban in Denmark and is mentioned in the text.

Methods

How were the countries chosen- at random or based on available data?

As mentioned in the text: "The cities included were partly determined by visits taken by the authors and their colleagues for other purposes, and these visits were supplemented by arranged visits by two of the authors (SS, JD)."

In 2005 (fig 2) we intended to include as many EU countries as economically feasible. In 2009 we revisited the 3 eastern EU-countries that had the highest values for the high *trans*menu: Czech Republic, Poland and Hungary and decided to compare with 3 large western EU countries: Germany, France, and UK.

Is there any estimate to the prevalence of said "high density" TFA foods in the supermarkets, for example, what % of microwave popcorn was in this range?

We did not count the total number of different brands of micro wave popcorn or of biscuits. We used the inclusion criteria as given in the text: "Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g."

Is there any data on the frequency of consumption of these popular products?

Not to our knowledge. As already mentioned we rely on the assumption that when the products are present in large supermarkets, they have a considerable turnover. We have considered using the term "availability of food with high content of trans fatty acids". However this term does not reflect that the foods were bought only in large supermarkets.

Results

Were fewer products purchased in Western Europe due to availability? Or what was the reason there is the large sample difference?

In Western Europe we were in 2009 not able to find the same number of foods that fulfilled the inclusion criteria: "Microwave oven popcorn and biscuits/cakes/wafers were bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g."

The number of different brands was probably more or less the same, but in Western Europe most of them were in 2009 not any longer labelled with the term "partially hydrogenated fat" or a similar and when they were, the products contained only small amounts of trans fat. In the legend to fig 1 we have added the following sentences: "Products were only bought if "partially hydrogenated fat" or a similar term was listed among the first three ingredients and if the food label indicated that the fat content exceeded 15 g of fat per 100 g". Fewer products in Western EU countries fulfilled in 2009 the inclusion criteria compared with the situation in Eastern EU-countries.

Limits

Line 4, pg 10- the selective pattern of purchasing could also have led to an overestimate of amounts of TFA in subgroups

Our argumentation supports an underestimation.

Implications

A reference should be provided on the point related to "low income groups", and other lifestyle factors.

We wrote: low-income groups.. who due to other lifestyle factors, already have an increased risk of coronary heart disease and who may also more frequently eat foods with a high I-TFA content

We have added the following reference: Gill PE and Wijk K Case study of a healthy eating intervention for Swedish lorry drivers Health Education Research 2004 vol. 19 no.3:306-315

Same with the statement regarding regulation of TFA in the EU.

We have added the following reference: Legislation relating to the level of industrially produced trans fatty acids in food p45-49 in: The influence of trans fatty acids on health-fourth edition 2004, WWW.meraadet.dk

Again, with the statement beginning with "societal pressure on....".

We have added the following reference: Katan MB Regulation of trans fats: The Gap, the Polder, and McDonald's French fries. Atherosclerosis Supplements 7 (2006) 69-71

Again, citing the effectiveness or how non-effective labeling actually is for

the consumer.

We have added 2 references

Consumers find food labelling confusing: http://www.guardian.co.uk/money/2009/may/07/food-drink-health-labels

Borra S. Consumer perspectives on food labels.Am J Clin Nutr. 2006 May;83(5):1235S.

The ecological data from Denmark on overall IHD(CHD) rates strengthen this discussion and paper, but mention of other factors that may play into this decrease is appropriate. As well, if similar data is available from Austria. Certainly, providing data from all the countries noted in this study would be best, as well as discussion of the potential "ecological fallacy".

With our last sentence in the paper we mention that Trans fatty acids may play a role in the difference in mortality. Our study does not deal with other and more conventional risk factors such as smoking , hypertension.

By only depicting Hungary and Denmark and the mean for all OECD countries we find the figure much less complicated compared with a figure that have values for all 6 countries.

Due to space constraint we have not dealt with ecological inference fallacy

Overall, I think more balance could be added to this discussion- this paper reads more like an advocacy paper or editorial with some general data. Further discussion on other reasons that self-regulation by producers works in some instances, but not all and reasons why different sectors of food producers are slower to change in the Eastern EU, and so on. Essentially, the authors would much better persuade the audience of the need for legislation in Eastern EU (and globally?) by using this approach, in this reviewers mind.

PRIVATE COMMENTS FOR THE EDITOR:

I'm not real sure what to think of this paper. The authors have provided some interesting data, which actually could be interpreted that self-regulation works in some instances, yet the focus, and it seems a bit hasty, doesn't seem to actualize this and the paper doesn't provide the necessary details, or nuance to make this seem like a scientific study. Would an observational study that provided this level of opaqueness even be reviewed? These comments are coming from a researcher who ardently believes reducing and eliminating TFA from the food supply and reducing intake of the foods it is historically common in is a significant public health issue.