

# Saturated fats and health report consultation responses

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## Procedure

The draft report on Saturated fats and health was published for an 8 week consultation on 8 May 2018, closing on 3 July 2018. Interested parties were invited to submit comments relating to the scientific content of the draft report and to alert the Committee to any evidence that it may have missed.

Fourteen responses were received from a variety of interested parties.

SACN wishes to note that each of the consultation comments received was very carefully considered by the committee and a response written. Where consultation comments were similar, the committee's responses were standardised purely in order to ensure consistency. Comments relating to risk management issues were outside the scope of this report and have therefore not been responded to.

References to chapters and paragraphs/page numbers refer to those in the draft report which went out for public consultation: https://www.gov.uk/government/consultations/saturated-fats-and-health-draft-sacn-report

SACN would like to thank all those who responded to consultation; their input is much appreciated.

#### Respondents

#### Comments were received from the following organisations and individuals:

- 1. Action on Salt and Sugar
- 2. Agriculture and Horticulture Development Board
- 3. Alliance for Natural Health International
- 4. British Dietetic Association
- 5. British Nutrition Foundation
- 6. Dairy UK
- 7. Dr Zoe Harcombe, PhD, and George Henderson, Aukland University of Technology
- 8. HEART UK The Cholesterol Charity
- 9. Professor Nita G. Forouhi, Programme Leader & Consultant Public Health Physician MRC Epidemiology Unit, University of Cambridge School of Clinical Medicine
- 10. Provision Trade Federation
- 11. Scottish Public Health Nutrition Group
- 12. The Nut Association
- 13. UK Health Forum
- 14. X-PERT Health

## **General comments**

# Table 1: General comments on the report

Organisation/ individual	Comments	Reply from SACN
Scottish Public Health Nutrition Group	The group welcome the report and look forward to receiving the final version.	Thank you for your comment.
British Nutrition Foundation	BNF welcomes this draft report and the clarity it brings to the debate in the medical press and popular media, some of which has undermined the Eatwell Guide and government recommendations. We note that the recent WHO draft report reached the same conclusion as SACN with regard to saturated fat and this might be worthy of note in the final SACN report. Also, worthy of comment/discussion is SACN's decision to recommend a mix of MUFA/PUFA (despite the limited evidence found for MUFA compared to PUFA) whereas WHO recommended only PUFA in its draft report. We assume this might relate to the potential risk of exceeding 10% energy if PUFA were to be the sole substitute.	Thank you for your comments and for raising these issues. The updated report clarifies SACN's considerations of the evidence on PUFA / MUFA substitution.
Agriculture and Horticulture Development Board	<ul> <li>[a] The recent WHO draft report reached the same conclusion as SACN with regard to saturated fats and this is consistent with other world-wide guidelines. This merits further emphasis and discussion especially around the subtler differences that exist.</li> <li>[b] Also, worthy of further comment is SACN's decision to recommend a mix of MUFA/PUFA (despite the limited evidence found for MUFA compared to PUFA) whereas WHO recommended only PUFA in its draft report. This might relate to the potential risk of exceeding 10% energy if PUFA were to be the sole substitute but this should be made clear. You will be aware that animal food sources contain a combination of all three groups of fat (SFA, MUFA and PUFA) so for communication purposes it would be helpful to have some clarity.</li> </ul>	<ul> <li>Thank you for your comments and for raising these issues.</li> <li>[a] SACN has looked at the reference list of the WHO draft report and identified that only one study (Te Morenga &amp; Montez, 2017) was not included in the SACN draft report because it was published after March 2016. This new paper has now been considered by SACN and has been included in chapters 9, 10, 11 and 12 of the final report.</li> <li>[b] The updated report clarifies SACN's considerations of the evidence on PUFA / MUFA substitution.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
Agriculture and Horticulture Development Board	AHDB is an evidence based organisation and therefore welcomes this draft report and the clarity it brings to the debate in the medical press and popular media. However, we feel that there needs to be more discussion of SACN's findings in this context, as some aspects of the debate undermine current government recommendations. We feel that to emphasis and clarify needs to be brought to this aspect of the report. The agriculture sector in the UK has a well-established legacy of supporting Government public health policy. Since the 1950's the livestock industry has significantly reduced the fat content of red meat, milk and dairy products on offer to consumers. This has undoubtedly made a major contribution to achieving the population target for total fat reduction to less than 30% of dietary energy. This industry wide effort is often overlooked and in this context it must also have had a significant impact on reducing saturated fat intake. This is not recognised by the evidence presented and indeed data from National, Diet and Nutrition Survey (NSNS) still 'demonises' key food groups which have made a major effort over the years to reduce both total fat and saturated fat content for the publics benefit.	Thank you for your comments. The nutrient composition databank that supports estimates of nutrient intakes in the NDNS is updated regularly to ensure that, as far as possible, it reflects the nutrient content of the food supply. While it is true that nutrient analysis for carcase meat and milk and dairy products was last done in the 1990s, manufacturer's data such as that on product labels are used to update the NDNS nutrient databank for processed foods including cereal products such as biscuits and cakes, meat products and dairy products such as ice cream and yogurt so changes in saturated fat content due to reformulation are reflected in the databank. The survey will also pick up shifts in purchasing towards lower fat/saturated fat variants such as from full fat to reduced fat cheese. We are not aware of any major changes in the saturated fat content of meat or milk although it is true that changes in the fat content of some cuts of meat may have changed due to shifting consumer preferences. It is therefore considered that the NDNS data provides a broadly accurate reflection of the contributors to saturated fat intake in the UK. Notwithstanding the current sources of dietary fat and saturated fats, healthy eating advice focuses on reducing those sources of total and saturated fats that do not contribute to other valuable nutrients in the diet.
HEART UK – The Cholesterol Charity	Despite the comments [below]*, HEART UK does welcome the publication of this new report, and commends the panel for their diligence in assessing the research, within the confines of the brief. The report will help to inform future UK's dietary guidelines, government policy, public health campaigns add the future practice of health professionals. *Edit due to structure of comments form	Thank you for your comments.

Organisation/ individual	Comments	Reply from SACN
UK Health Forum	This is a welcome and important review of the evidence on saturated fats and health as the introduction notes that this evidence was last considered by the Committee on Medical Aspects of Food Policy (COMA, the predecessor of SACN) in the early 1990s. Saturated fats have been subject to considerable scrutiny and debate in the media, and there is confusion among the public and wider community of the role of fats in health and relative merits of different types of fats.	Thank you for your comments.
British Dietetic Association	We welcome this report, coming as it does several years after the COMA recommendations of 1991 and 1994. It is particularly timely given the current sugar reduction programme and work to reduce calorie intake of the population being carried out by Public Health England. We agree with the unaltered recommendation that the population average contribution of saturated fatty acids to total dietary energy be reduced to no more than 10% and feel that a reduction in saturated fat intakes across the population would be beneficial for health. We are also in agreement with the advice that saturated fats should be substituted with PUFA and MUFA - acknowledging that this advice has changed from previous advice to which would have been to substitute with more fruit and vegetables and wholegrain carbohydrates.	Thank you for your comments.
Professor Nita G. Forouhi	It is really helpful and a very positive contribution that the SACN committee have reviewed the evidence on saturated fats across a range of health outcomes, including but not limited to cardiovascular disease. The WG are to be congratulated on a comprehensive and clearly laid out review.	Thank you for your comments.
British Nutrition Foundation	Please check that terminology and abbreviations are consistent across all the chapters, e.g. cancer vs. cancers, PCSs vs PCS (perhaps should be the former for consistency with RCTs). Percent used in some places instead of percentage.	Thank you for your comments. The report has been checked for consistency and amended where required.
British Nutrition Foundation	Need for plain English summary that pulls the recommendations together (good example of a good summary is on page 130). Such a summary would be helpful at the end of the section on events (Chapter 8).	Thank you for your comments. An executive summary is included in the final report. Summaries at the end of each section or chapter (as appropriate) have been checked for clarity and amended as necessary.

Organisation/ individual	Comments	Reply from SACN
British Nutrition Foundation	<ul> <li>More narrative in places would be helpful that:</li> <li>(a) discusses the findings of SACN in the context of the debate about saturated fat in the medical press and general media</li> <li>(b) aligns the advice on saturated fat and CVD with SACN's recommendations on carbohydrates, fibre and CVD. The lack of studies to suggest that complex CHO is a beneficial substitute for saturated fat from a CVD perspective may be interpreted, in isolation, to mean that complex (high fibre) carbohydrates are not beneficial for health, thus undermining the message that most of us need to consume considerably more fibre and SACN's recent affirmation that about 50% of energy intake should come from carbohydrates.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] Please note that SACN undertook a risk assessment on saturated fats and health. Policy development or other aspects of risk management are outside the remit of SACN.</li> <li>[b] SACN recommendations on saturated fats are stated as being made in the context of existing dietary reference values (see Table 16.1 in the final report). Therefore, existing recommendations on carbohydrates apply. A link is provided to the SACN report on carbohydrates.</li> </ul>
British Nutrition Foundation	SACN recommends that government gives consideration to strategies to reduce population average intake of saturated fats. We support this recommendation, and suggest that to increase the likelihood of effectiveness, the strategy needs to be developed with input from public health nutritionists with food industry experience (because of the insight they can share regarding the technical difficulties likely to be encountered when seeking substitutes for saturated fats in some applications). Furthermore, given the high profile debate on the role of saturated fat in the diet, and the confusion this seems to have generated, we suggest there needs to be a robust, government backed campaign that aims to clarify the advice re saturated fat for health professionals and the public, correct misinformation and put SACN's recommendations into a practical dietary context. In doing this, it will be important to integrate the findings of SACN on saturated fat with those on carbohydrates (including fibre) and CVD, and in particular to clarify the advice on saturated fat and carbohydrates from a whole diet perspective.	Thank you for your comments. Please note that SACN undertook a risk assessment on saturated fats and health. Policy development or other aspects of risk management are outside the remit of SACN.

Organisation/ individual	Comments	Reply from SACN
British Nutrition Foundation	Modelling studies, such as that of Li et al [Li Y, Hruby A, Bernstein AM <i>et al</i> . (2015) Saturated fats compared with unsaturated fats and sources of carbohydrates in relation to risk of coronary heart disease: a prospective cohort study. <i>Journal of the American College of Cardiology</i> <b>66</b> : 1538–48] do not seem to have been included/discussed. Li <i>et al</i> models data from two large PCSs from the perspective of the effects of substitutions.	Thank you for your comments and for highlighting this evidence. Modelling studies that are systematic reviews or meta-analyses that meet the inclusion criteria have been included in the report. The modelling study by Li et al, (2015) was highlighted during the call for evidence; however, SACN excluded the study, as it is an individual primary study rather than a systematic review/meta- analysis.
HEART UK – The Cholesterol Charity	<ul> <li>Although the report is comprehensive we are disappointed that it has limited itself to looking only at RCT and PCS evidence. There are well documented issues that arise when dietary guidelines are based solely on this type of research. RCT and PCS evidence, whilst helpful in developing nutritional guidelines, is more appropriate to assessing the suitability and effectiveness of medication, where blind randomisation is possible.</li> <li>One need only consider the volume of responses received from international experts over 17 years ago to the publication in the BMJ of the Cochrane systematic review on dietary fat and the prevention of CVD (Hooper et al 2001) and the succinct summary by Truswell documenting the problems with Cochrane reviews of diet and chronic disease (Truswell, AS 2005) in order to recognise the need to become more holistic and inclusive of in our approach to dietary guidelines.</li> <li>We need to develop a professional consensus amongst leading UK experts who have considered the RCT and PCS data but also assessed and interpreted the biochemical, cell culture, animal experiments, epidemiology and other relevant data.</li> <li><b>References</b></li> <li>Hooper L et al (2001) "Dietary fat intake and prevention of CVD": systematic review. BMJ 322, 757-763</li> <li>Truswell, A.S. (2005) "Some problems with Cochrane reviews of diet and chronic disease" European Journal of Clinical Nutrition 59, Suppl 1, S150-S154</li> </ul>	Thank you for your comments and highlighting this evidence. SACN used methods in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads/syst em/uploads/attachment_data/file/480493/SACN_Framework_for_ the_Evaluation_of_Evidence.pdf) to critically review the evidence throughout the report. The use of RCTs and PCS evidence for developing recommendations is an approach used by other national and international organisations.
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Organisation/ individual	Comments	Reply from SACN
HEART UK – The Cholesterol Charity	It would have been very helpful if the report had considered the effect of chain length (of saturated fats) on both lipids and CVD. In the UK there is significant marketing and PR around the consumption of coconut oil and its respective health benefits. No-one is currently challenging this sufficiently despite the lack of good quality research to justify their "health claims". Coconut is rich in Lauric acid and Myristic acids, both of which significantly raise LDL and non-HDL cholesterol. We believe that an opportunity has been lost to raise awareness of this and to defend the common sense approach that coconut oil being 90% saturated fat (70% of which is C12 and C14) is detrimental to lipid levels. Dietitians need the backing of authoritative bodies like SACN to challenge negative media stories, health food stores, celebrity chefs and food manufacturers who are currently promoting the use of coconut and coconut oil in their publications, recipes and food products.	•
	References WHO 2016 Systematic Reviews and regression Analysis – effect on lipids and lipoproteins Zong et al BMJ 2016 355:i5796	<ul> <li>by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
of different sa that individua and therefore "Consideratio scope of this r <b>the media as</b>	nument notes that "saturated fats is a collective term for a number aturated fatty acids (see Chapter 3). There is evidence showing al saturated fatty acids exert distinct effects on lipid metabolism a have a differential impact on health." and concludes that on of the impact of individual saturated fatty acids was outside the review." This particular issue is subject to considerable debate in well as confusion among the wider public (especially the subject , and would merit further investigation by SACN.	<ul> <li>The remit of this work was to:</li> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and</li> </ul>

Organisation/ individual	Comments	Reply from SACN
British Nutrition Foundation	We appreciate that consideration of individual saturated fatty acids was not within the remit. Nevertheless, this is an important aspect that ought to be added to SACN's future work plan. In France, for example, this aspect was incorporated into dietary guidelines some years ago and it would be helpful to have a SACN perspective on the short chain SFA in dairy products. Also, the growing popularity of highly saturated coconut oil emphasizes the need for clarity regarding the health effects of lauric acid. Meantime, in the saturated fat report, we suggest that it might be helpful to readers to add some clarification that it appears that not all saturated fatty acids have the same effect on blood cholesterol.	<ul> <li>Thank you for your comments.</li> <li>The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
Dairy UK	Saturated fat is a diverse family of fatty acids all with varying effects on health, some have a neutral or beneficial effect on health and disease risk, however the effects of individual fatty acids are missing from this report. For example studies show pentadecanoic acid (C15:0) and heptadecanoic acid (C17:0) (fatty acids found in dairy and biomarkers of dairy intake) have an inverse relationship with CVD and T2DM (Pfeuffer M & Jaudszus A, 2016, Jenkins et al., 2015). This highlights that not all saturated fatty acids are created equally, nor should they be addressed as a single nutrient. References:: Pfeuffer M & Jaudszus A (2016). Pentadecanoic and Heptadecanoic Acids: Multifaceted Odd-Chain Fatty Acids. <i>Advances in Nutrition</i> , Volume 7(4), 730– 734, Jenkins B, West J.A and Koulman A (2015). A Review of Odd-Chain Fatty Acid Metabolism and the Role of Pentadecanoic Acid (C15:0) and Heptadecanoic Acid (C17:0) in Health and Disease. <i>Molecules</i> , 20(2), 2425-2444;	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
Agriculture and Horticulture Development Board	<ul> <li>[a] We appreciate that consideration of individual saturated fatty acids was not within the remit of this review. However, it might be helpful to add some clarification that not all saturated fatty acids have the same effect on blood cholesterol.</li> <li>Some countries have already incorporated recognition of this important consideration into dietary guidelines and we feel that this should be an important consideration for future work It would be helpful if SACN gave their perspective on the short chain fatty acids (SFA) in dairy products and stearic acid in red meat. In addition, the growing popularity of highly saturated coconut oil emphasizes the need for clarity regarding the health effects of lauric acid.</li> <li>[b] There also needs to be further clarity on trans fatty acid reduction. You will be aware this has in the main focused on reducing those trans fats produced industrially in the hardening of vegetable oils. These oils are very different from those naturally produced in the digestive process of ruminant animals which have been shown to not have the same negative health impact as industrial trans fats and indeed some studies have demonstrated health benefits. This difference needs to be made clear.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> <li>[b] The difference between naturally produced trans fats and industrially produced trans fats on health outcomes/intermediate markers/risk markers is outside the remit of the report.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
Agriculture and Horticulture Development Board	<ul> <li>[a] In general we welcome the recommendations made but feel that some of the points we make above should form part of SACN's work plan going forward. In particular, it would be helpful for SACN to consider the evidence regarding the relative impact of different fatty acids, especially different saturated fatty acids as this potentially has a bearing on food based guidance.</li> <li>[b] Finally, we would welcome if SACN would considered the quality of the raw nutrient analysis for the key commodity groups which according to the NDNS make the greatest contribution to saturated fat intakes. As previously stated, the raw data used for cereals and cereal products, milk and milk products, and meat and meat products is significantly out of date and urgently requires to be updated to ensure true accuracy and representation of the variety of products being consumed today.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> <li>[b] The nutrient composition databank that supports estimates of nutrient intakes in the NDNS is updated regularly to ensure that, as far as possible, it reflects the nutrient content of the food supply. While it is true that nutrient analysis for carcase meat and milk and dairy products was last done in the 1990s, manufacturer's data such as that on product labels are used to update the NDNS nutrient databank for processed foods including cereal products such as ice cream and yogurt so changes in saturated fat content due to reformulation are reflected in the databank. The survey will also</li> </ul>

Organisation/ individual	Comments	Reply from SACN
		pick up shifts in purchasing towards lower fat/saturated fat variants such as from full fat to reduced fat cheese. We are not aware of any major changes in the saturated fat content of meat or milk although it is true that changes in the fat content of some cuts of meat may have changed due to shifting consumer preferences. It is therefore considered that the NDNS data provides a broadly accurate reflection of the contributors to saturated fat intake in the UK. Notwithstanding the current sources of dietary fat and saturated fats, healthy eating advice focuses on reducing those sources of total and saturated fats that do not contribute to other valuable nutrients in the diet.

Organisation/ individual	Comments	Reply from SACN
Individual Agriculture and Horticulture Development Board	Cereals and cereal products (mainly biscuits, buns, cakes, pastries and fruit pies), milk and milk products (mainly cheese and milk), and meat and meat products are the main contributors to saturated fat intakes in all age groups. We believe that this observation has the potential to misinform public health policy and mislead consumers about the potential nutritional benefits that these commodity groups can make to a healthy balanced diet. Currently the nutritional analysis data used as the basis NSNS, is very outdated and does not reflect what is available to the consumer today. In some instance the raw data is almost 30 year old and bears no resemblance to the variety and nutrient content of the wide range of lower fat options now being routinely purchased. To ensure that public health policy is driven by accurate information updated food compositional data is crucial to underpin dietary assessment surveys. These inaccuracies will also be being perpetuated in on pack labelling and recipe analysis. We would therefore challenge the point made in the report that any misreporting of food consumption in the NDNS is likely to due to underreporting. Flawed and outdated raw data does not give a true representation of the positive contribution that red and processed meat and milk and dairy products make to nutrient intake. This includes making a positive contribution to the fatty acid profile of the foods we consume today.	Thank you for your comments. The nutrient composition databank that supports estimates of nutrient intakes in the NDNS is updated regularly to ensure that, as far as possible, it reflects the nutrient content of the food supply. While it is true that nutrient analysis for carcase meat and milk and dairy products was last done in the 1990s, manufacturer's data such as that on product labels are used to update the NDNS nutrient databank for processed foods including cereal products such as biscuits and cakes, meat products and dairy products such as ice cream and yogurt so changes in saturated fat content due to reformulation are reflected in the databank. The survey will also pick up shifts in purchasing towards lower fat/saturated fat variants such as from full fat to reduced fat cheese. We are not aware of any major changes in the saturated fat content of meat or milk although it is true that changes in the fat content of some cuts of meat may have changed due to shifting consumer preferences. It is therefore considered that the NDNS data provides a broadly accurate reflection of the contributors to saturated fat intake in the UK. Notwithstanding the current sources of dietary fat and saturated fats, healthy eating advice focuses on reducing those sources of total and saturated fats that
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Organisation/ individual	Comments	Reply from SACN
HEART UK – The Cholesterol Charity	In addition there is research indicating a significant difference in the effect of individual saturated fats when present in different food matrixes e.g. milk, butter, cheese, meat (Forouhi 2014) and more clarity on this would have been helpful. This response represents the views of a number of dietitians – working in clinical practice, the charity sector and academia – who believe they have a responsibility to lead the way in talking to people in terms that are both understandable and familiar. In this respect reference to whole foods and ways of eating are much more helpful than referring to individual nutrients such as saturated and unsaturated fatty acids. It is our job to interpret the science into the practical and we feel this report could have gone further in helping us to discriminate between food sources of saturated fat in the diet. This continued focus on individual nutrients rather than foods has been shown to have limited value e.g. comparison of glycaemic load and glycaemic index highlights the need to consider the ameliorating effects of other nutrients, cooking methods and the food matrix. <b>Reference</b> Forouhi N.G. (2017a) "Challenging poor choices" BMJ 357:j1573	Thank you for your comments and highlighting this evidence. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.

Organisation/ individual	Comments	Reply from SACN
Dairy UK	RCTs looking at the effects of lipids after consuming cheese versus reduced fat cheese and whole milk versus skimmed milk show no significant difference in LDL cholesterol, however they suggest whole fat products increase HDL cholesterol <sup>[18-19]</sup> . Increased concentration of HDL has been linked to reduced risk of CVD, however this report does not look at the effects of foods on HDL. References: 18. Raziani F, Tholstrup T, Kristensen MD, Svanegaard ML, Ritz C, Astrup A, Raben A (2016). High intake of regular-fat cheese compared with reduced-fat cheese does not affect LDL cholesterol or risk markers of the metabolic syndrome: a randomized controlled trial. <i>The American Journal of Clinical</i> <i>Nutrition</i> , 104(4) 973–981, 19. Engel S, Elhauge M, Tholstrup T (2018). Effect of whole milk compared with skimmed milk on fasting blood lipids in healthy adults: a 3-week randomized crossover study. <i>European Journal of Clinical Nutrition</i> . <b>72</b> ;249–254	Thank you for your comments and highlighting this evidence. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.

Organisation/ individual	Comments	Reply from SACN
Dairy UK	<ul> <li>We consume foods and meals, and follow dietary patterns, therefore setting guidelines and recommendations based on the evidence of single nutrients is unhelpful, particularly in terms of forming food-based guidelines. The effects of foods containing saturated fatty acids on health are not evaluated in this report.</li> <li>Foods are more than their sum of nutrients, and we do not eat nutrients in isolation. Saturated fats are often found in the presence of other unsaturated fatty acids and nutrients such as calcium, protein and carbohydrates.</li> <li>Nutrients within the food matrix can interact with saturated fats and their overall metabolic effect/role. For example, studies show that calcium in dairy can bind to saturated fat, therefore reducing the amount of saturated fat that is absorbed by the body<sup>[1]</sup>.</li> <li>There is a large and growing body of evidence, including several systematic reviews and meta-analyses, related to the role of foods on cardiovascular-related outcomes<sup>[2-16]</sup>.</li> <li>In addition, foods naturally containing fatty acids within their matrix may not be modifiable or easily adjusted without significant processing. Therefore recommending the reduction or increase of a single nutrient will result in the need for modification of the overall diet and may inertly encourage the population to decrease their consumption of whole foods which can provide a nutrient-rich package.</li> <li>References: <ol> <li>Bendsen NT, Hother AL, Jensen SK, Lorenzen JK, Astrup A (2008). Effect of dairy calcium on fecal fat excretion: a randomized crossover trial. <i>Int J Obes (Lond).32(12):1816-24</i>.</li> <li>Javanbakht M, Jamshidi AR, Baradaran HR, Mohammadi Z, Mashayekhi A, Shokraneh F, Rezai Hamami M, Yazdani Bakhsh R, Shabaninejad H, Delavari S, Tehrani A. (2018). Estimation and Prediction of Avoidable Health Care Costs of Cardiovascular Diseases and Type 2 Diabetes Through Adequate</li> </ol> </li> </ul>	Thank you for your comments and highlighting this evidence. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.

Organisation/ individual	Comments	Reply from SACN
	<ul> <li>Dairy Food Consumption: A Systematic Review and Micro Simulation Modeling Study. <i>Arch Iran Med</i>. 1;21(5):213-222.</li> <li>Gholami F, Khoramdad M, Shakiba E, Alimohamadi Y, Shafiei J, Firouzi A (2017a) Subgroup dairy products consumption on the risk of stroke and CHD: A systematic review and meta-analysis. Med J Islam Repub Iran. 27;31:25.</li> <li>Gholami F, Khoramdad M, Esmailnasab N, Moradi G, Nouri B, Safiri S, Alimohamadi Y.(2017b) The effect of dairy consumption on the prevention of cardiovascular diseases: A meta-analysis of prospective studies. J Cardiovasc Thorac Res.;9(1):1-11.</li> <li>Guo J, Astrup A, Lovegrove JA, Gijsbers L, Givens DI, Soedamah-Muthu SS (2017). Milk and dairy consumption and risk of cardiovascular diseases and all-cause mortality: dose-response meta-analysis of prospective cohort studies. Eur J Epidemiol;32(4):269-287.</li> <li>Wu L, Sun D. (2017). Consumption of Yogurt and the Incident Risk of Cardiovascular Disease: A Meta-Analysis of Nine Cohort Studies. Nutrients 22;9(3).</li> <li>Drouin-Chartier JP, Brassard D, Tessier-Grenier M, Côté JA, Labonté MÈ, Desroches S, Couture P, Lamarche B. (2016) Systematic Review of the Association between Dairy Product Consumption and Risk of Cardiovascular-Related Clinical Outcomes. Adv Nutr; v 15;7(6):1026-1040</li> <li>Liang J, Zhou Q, Kwame Amakye W, Su Y, Zhang Z. (2017) Biomarkers of dairy fat intake and risk of cardiovascular disease: A systematic review and meta analysis of prospective studies. Crit Rev Food Sci Nutr;3;58(7):1122- 1130</li> <li>Smith CE, Coltell O, Sorlí JV, Estruch R, Martínez-González MÁ, Salas- Salvadó J, Fitó M, Arós F, Dashti HS, Lai CQ, Miró L, Serra-Majem L, Gómez- Gracia E, Fiol M, Ros E, Aslibekyan S, Hidalgo B, Neuhouser ML, Di C, Tucker KL, Arnett DK, Ordovás JM, Corella D. (2016) Associations of the MCM6- rs3754686 proxy for milk intake in Mediterranean and American populations with cardiovascular biomarkers, disease and mortality: Mendelian randomization. Sci Reg;12</li></ul>	

Organisation/ individual	Comments	Reply from SACN
	<ol> <li>Chen GC, Wang Y, Tong X, Szeto IMY, Smit G, Li ZN, Qin LQ (2017). Cheese consumption and risk of cardiovascular disease: a meta-analysis of prospective studies. Eur J Nutr. 2017 Dec;56(8):2565-2575.</li> <li>Pimpin L, Wu JH, Haskelberg H, Del Gobbo L, Mozaffarian D (2016). Is Butter Back? A Systematic Review and Meta-Analysis of Butter Consumption and Risk of Cardiovascular Disease, Diabetes, and Total Mortality. PLoS One;29;11(6):e0158118.</li> <li>Alexander DD, Bylsma LC, Vargas AJ, Cohen SS, Doucette A, Mohamed M, Irvin SR, Miller PE, Watson H, Fryzek JP (2016a). Dairy consumption and CVD: a systematic review and meta-analysis - CORRIGENDUM. Br J Nutr;115(12):2268</li> <li>Alexander DD, Bylsma LC, Vargas AJ, Cohen SS, Doucette A, Mohamed M, Irvin SR, Miller PE, Watson H, Fryzek JP (2016b). Dairy consumption and CVD: a systematic review and meta-analysis. Br J Nutr;115(4):737-50. Review. Erratum in: Br J Nutr. 2016 Jun;115(12):2268.</li> <li>Tapsell LC (2015) Fermented dairy food and CVD risk. Br J Nutr;113 Suppl 2:S131-5.</li> <li>Qin LQ, Xu JY, Han SF, Zhang ZL, Zhao YY, Szeto IM (2015). Dairy consumption and risk of cardiovascular disease: an updated meta-analysis of prospective cohort studies.Asia Pac J Clin Nutr;24(1):90-100.</li> <li>Soedamah-Muthu SS, Ding EL, Al-Delaimy WK, Hu FB, Engberink MF, Willett WC, Geleijnse JM (2011). Milk and dairy consumption and incidence of cardiovascular diseases and all-cause mortality: dose-response meta-analysis of prospective cohort studies. Am J Clin Nutr;93(1):158-71.</li> </ol>	

Organisation/ individual	Comments	Reply from SACN
HEART UK – The Cholesterol Charity	HEART UK would welcome an additional section within the report discussing the hierarchy and relative merits of various types of evidence in the context of food and diet. This would be helpful in order to give a lead to the press and food industry. In the current climate confusion rains, fuelled by the distortion often caused by the media (either innocently or deliberately) in their eagerness to have an interesting slant on health issues. Frequently news stories are driven by food companies with their own agenda's. These stories, together with their research, are reported as if they are factual (without reference to the totality of research which often suggests otherwise) and the reader is led to believe they represent a definite change in policy rather than a preliminary finding that requires scientific scrutiny and/or further more detailed studies.	Thank you for your comments. As highlighted in the methods chapter of the report, SACN used methods in line with the SACN Framework for the Evaluation of Evidence ( <u>https://assets.publishing.service.gov.uk/government/uploads/syst</u> <u>em/uploads/attachment_data/file/480493/SACN_Framework_for_the_Evaluation_of_Evidence.pdf</u> ) to critically review the evidence throughout the report. This outlines SACN's approach to different types of evidence.
Action on Salt and Sugar	Please provide guidance on how to access the Dietary Reference Value (DRV) for saturated fats set by the Committee on Medical Aspects of Food Policy (COMA) in 1991 and reviewed in 1994 (COMA, 1991; COMA, 1994). It appears that the report is not accessible online, and since the new saturated fats recommendations are based on the COMA 1994, it is fair to report a link or some guidance on how to retrieve this old document.	Thank you for your comments. COMA reports are now available on the GOV.UK website: <u>https://www.gov.uk/government/publications/coma-reports</u> Please note that the government dietary recommendations for energy and nutrients are also available on the GOV.UK website: <u>https://assets.publishing.service.gov.uk/government/uploads/syst</u> <u>em/uploads/attachment_data/file/618167/government_dietary_re</u> <u>commendations.pdf</u>

Organisation/ individual	Comments	Reply from SACN
Action on Salt and Sugar	The new recommendation states 'It is recommended that the government gives consideration to strategies to reduce population average intake of saturated fats to <b>no more than 10% of dietary energy'</b> . However, after having read the whole report, it appears that there isn't a clear scientific base for not going below the 10%E. On the contrary, the SACN recommendation seems to differ from the WHO (2010) recommendation stating that the <b>upper value of acceptable macronutrient distribution range for saturated fats is 10%E</b> . Recently, other national and international nutrition organisations as the DGAC have issued a recommendation for retaining 10 E% as the <b>upper limit for SFA intake</b> : EFSA recommends as little saturated fats as possible; the new <u>German guidelines</u> on fats recommend 7-10%E of saturated fats. Please specify why 10E% (11%E of food and drink energy) should not be considered as an upper limit of intake.	from other national and international organisations. In deriving its conclusions, SACN thoroughly considered the available evidence from systematic reviews and meta-analysis of RCTs and PCS. Based on their assessment of the evidence, SACN concluded that the findings from the totality of evidence considered support current UK policy "the dietary reference value for saturated fats remains unchanged: the [population] average contribution of saturated fatty acids to [total] dietary energy be

Organisation/ individual	Comments	Reply from SACN
Action on Salt and Sugar	Please consider removing this double recommendation and to provide only a single value like all the other public health bodies in other countries do. This double recommendation is confusing and not even clear for public health nutritionists who design and implement saturated fat reduction policies and strategies. Moreover, the 11% recommendation would imply the presence of sugary drinks and fruit juices in the diet; the presence of such drinks in a healthy diet currently under scientific debate.	For clarity, the final report only refers to the recommendation made by COMA in 1994.

Organisation/ individual	Comments	Reply from SACN
Provision Trade Federation	This is a response to the above consultation sent on behalf of the Provision Trade Federation (PTF), a long established trade association representing companies of all sizes involved in supplying dairy products (including milk powders, cheese, butter, yogurt and other dairy desserts), bacon, pig meat and fish. These products contain saturated fats and therefore the SACN report is highly relevant to our members.	SACN recommendations on saturated fats are stated as being
	For many years the view that saturated fat must be removed from the diet to reduce the risk of cardiovascular disease has dominated dietary advice and guidelines. However, more recent research has questioned this advice, suggesting that the issues concerning saturated fat are far more complex than first perceived, and not all individual saturated fatty acids have the same effect in the body. Additionally, reducing saturated fat in the diet without due attention to what replaces it may not have a positive impact on cardiometabolic health, particularly if it is replaced with refined carbohydrates. It is also important to note that not all foods containing saturated fat have the same effect on health. In fact, there is evidence that dairy products may have a protective effect on health.	SACN has previously set out why any papers highlighted during the call for evidence had been excluded. Details are available here: https://app.box.com/s/on3nptz6shkncarlkhukqs7f8zeza22d/file/7 3262316889
	PTF is concerned that the latest SACN review has missed an opportunity to investigate these findings in greater depth given that many studies were excluded from the review, as was highlighted by the Dairy Council during the call for evidence on the extent of the literature search. As a consequence, the draft report does not provide answers to the many questions that have been raised in recent years about the health impact of saturated fats.	

Organisation/ individual	Comments	Reply from SACN
UK Health Forum	<ul> <li>[a] We note that the findings and recommendations are in line with other international guidelines. As these guidelines are based on reviews of the same evidence, this finding is to be expected and therefore reassuring.</li> <li>[b] We also note the slightly different approach to saturated fat advice taken by the 2015 recommendations of the Health Council of the Netherlands. The advice is focused on advice on foods and dietary patterns rather than saturated fat intakes, and includes three overarching recommendations on foods high in saturated fats: <ol> <li>'replace butter, hard margarines, and cooking fats by soft margarines, liquid cooking fats, and vegetable oils'</li> <li>'limit the consumption of red meat, particularly processed meat'</li> <li>Have 'a few portions of dairy produce daily, including milk or yogurt'.</li> </ol> </li> <li>Advice on foods and dietary patterns is easier for consumers and professionals from other sectors to assimilate than scientific nutrient-based cut-off values. While we appreciate that recommendations to reduce saturated fats are incorporated within the Eatwell Guide, SCAN should consider including (and reinforcing) in its guidance some top-level food based recommendations which are easier to translate these updated guidance into practice, which are focused on the major sources of saturated fats in the UK diet across all population groups: <ol> <li>Meat and meat products</li> <li>Milk and milk products (cheese and milk) and</li> <li>Cereals and cereal products (biscuits, buns, cakes, pastries, fruit pies, puddings, pizza).</li> </ol> </li> </ul>	<ul> <li>[a] Thank you for your comments.</li> <li>[b] Please note that SACN undertook a risk assessment on saturated fats and health. Policy development or other aspects of risk management are outside the remit of SACN.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
UK Health Forum	<ul> <li>We note the fact that the overall findings provide evidence of the continued benefits of the recommendations to reduce saturated fats, particularly on the following health and intermediate outcomes:</li> <li>1. There was adequate or moderate evidence (from RCTs) that reducing the intake of saturated fats reduces the risks of CVD and CHD events respectively, and improves serum total cholesterol, LDL cholesterol and triacylglycerol.</li> <li>2. There was adequate or moderate evidence (from RCTs) that substituting saturated fats with PUFA improved total cholesterol, LDL cholesterol, LDL cholesterol and total cholesterol:HDL cholesterol ratio and improved sustained glycaemic control as evidenced by HbA1c and insulin resistance.</li> </ul>	Thank you for your comments.

Organisation/ Comments individual	Reply from SACN
Individual         The Nut Association       [a] We are disappointed to see that SACN continues to conclude an justify that the recommended cap for saturated fats in the British d remain at 10%. This is not supported by evidence.         [b] Dietary guidelines in the US no longer have a total fat or dietary limitation. The diet-heart hypothesis and associated guidelines ster the work of Keys and others, which ultimately underpins the SFA re was never scientifically validated nor was its impact on public healt Simply to perpetuate it in the UK is not justified.         [c] Lowering LDL cholesterol – the objective of SFA restriction - is n reduced mortality, quite the reverse.         A new consensus is emerging that the advice about saturated fat be human health was mistaken and should now be reversed.         We commend the example of The Heart and Stroke Foundation of C 2015 recommendations, which acknowledge that "what has the mo health is the overall quality of one's dilet, combined with the types a of food consumed." They no longer limit SFA and instead recommer "healthy balanced dietary pattern." These new directions are a weld improvement over single nutrient targets and we believe this approbe taken in the UK as well.         [d] De Souza, Mente et al 2015. "Intake of saturated and trans unstafatty acids and risk of all cause mortality, cardio vascular disease, and diabetes: systematic review and meta-analysis of observational stu 2015;351:h3978;         Nago, Ishikawa et al 2011. "Low cholesterol is associated with mort stroke, heart disease, and cancer: the Jichi Medical School Cohort St Epidemiol. 2011;21(1):67-74.	<ul> <li>iet should</li> <li>[a] In deriving its conclusions, SACN thoroughly considered the available evidence from systematic reviews and meta-analysis of RCTs and PCS. Based on their assessment of the evidence, SACN concluded that the findings from the totality of evidence considered support current UK policy "the dietary reference value for saturated fats remains unchanged: the [population] average contribution of saturated fatty acids to [total] dietary energy be reduced to no more than about 10%.</li> <li>(b) Please note consideration of the evidence on total fat and dietary cholesterol was outside the remit of the Saturated fats and health report.</li> <li>(c) SACN's conclusion remains that there is good evidence that LDL cholesterol and other blood lipids are associated with morbidity and mortality. In 2017, the European Atherosclerosis Society Consensus Panel clearly showed that evidence from genetic, epidemiological and clinical studies demonstrated a consistent dose-dependent association between absolute exposure of the arterial endothelium to LDL cholesterol and risk of atherosclerotic CVD, which increased with longer exposure, and in addition that lowering LDL cholesterol reduces CVD (Ference et al, 2017) Dietary treatments and pharmaceutical intervention (for example, statins) which reduce LDL cholesterol have been consistently shown to reduce CVD.</li> <li>(d) Thank you for these references, after consideration SACN concluded that:</li> </ul>

Organisation/ individual	Comments	Reply from SACN
	<ul> <li>Ravnskov et al., 2016. "Lack of an association or an inverse association between low-density lipoprotein cholesterol and mortality in the elderly: a systematic review"</li> <li>BMJ Open 2016;6:e010401.</li> <li>Harcombe Z. 2016. "An examination of the randomised controlled trial and epidemiological evidence for the introduction of dietary fat recommendations in 1977 and 1983: A systematic review and meta-analysis." (PhD, University of the West of Scotland)</li> <li>Heart &amp; Stroke Foundation of Canada, 2015. Saturated Fat, Heart Disease, and Stroke.</li> <li>www.heartandstroke.ca/heart-and-stroke-position-statements</li> <li>BMJ/SwissRe "Food for Thought Conference" BMJ 2018; papers and panels discussions available at www.bmj.com/food-for-thought (Published 13 June 2018)</li> </ul>	<ul> <li>Nago et al, (2011) does not consider saturated fat intake.</li> <li>Ravnskov et al, (2016) does not consider saturated fat intake.</li> <li>Harcombe et al, (2016b) has already been included in the Saturated fats and health report.</li> <li>Heart and Stroke Foundation of Canada (2015) has been excluded as it is not a systematic review, meta-analysis or pooled analysis</li> <li>BMJ/SwissRe "Food for Thought Conference" BMJ (2018) has been excluded analysis.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
The Nut Association	<ul> <li>[a] We are puzzled by the statement on the www.gov.uk news story about the SACN draft report that "dietary saturated fats should be substituted with unsaturated fats. [Foods like fish (especially oily fish such as mackerel, salmon and trout), unsalted nuts, seeds and avocado are sources of unsaturated fat]."</li> <li>We can find no mention of nuts, salted or otherwise, in the report itself or the recommendations, which seems an oversight.</li> <li>While we of course believe the public would benefit from increasing their nut consumption, and decreasing intakes of refined carbohydrates including sugars in particular, it is not helpful in public health terms to treat any fat in a monolithic way as the cap on saturated fats does. All foods containing fats, nuts included, are combinations of saturated, monounsaturated and polyunsaturated fats. Even saturated fats vary considerably in how they behave metabolically within that category, eg the effect of stearic acid.</li> <li>Nuts as healthy higher fat foods are sources of all three types of fats, not just unsaturated ones, and it is misleading to the public to imply otherwise. This underscores our main point that it is wrong to stigmatise any of the natural fats (industrial trans fats excluded, of course), because they occur together naturally in foods like nuts that should be chosen as part of a healthy eating pattern. Helping the public to overcome decades of negativity about fats is one of the biggest challenges we see facing public health.</li> <li>[b] Malhotra, Redberg, and Meier 2017. "Saturated fat does not clog the arteries: coronary heart disease is a chronic inflammatory condition, the risk of which can be effectively reduced from healthy lifestyle interventions " BrJnlSportMed 2017;51:1111-1112. http://bjsm.bmj.com/content/51/15/1111</li> <li>De Souza and Anand 2016. "Saturated fat and heart disease" BMJ 2016; 355 doi: http://dx.doi.org/10.1136/bmj.i6257</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] Please note that issues relating to risk management (for example, highlighting foods that are sources of unsaturated fats) are the responsibility of risk managers and are outside the remit of SACN. Information in the PHE news article was taken from existing dietary advice available on the NHS UK website. More detailed information can be found here: <a href="https://www.nhs.uk/live-well/eat-well/different-fats-nutrition/">https://www.nhs.uk/live-well/eat-well/different-fats-nutrition/</a></li> <li>[b] Thank you for these references, after consideration SACN concluded that:</li> <li>Malhotra et al, (2017) has been excluded because it is not a systematic review, meta-analysis or pooled analysis.</li> <li>de Souza &amp; Anand (2016) has been excluded because it is not a systematic review, meta-analysis or pooled analysis.</li> <li>DiNicolantonio (2014) has been excluded because it is not a systematic review, meta-analysis or pooled analysis.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
	<b>DiNicolantonio JJ 2014.</b> "The cardiometabolic consequences of replacing saturated fats with carbohydrates or $\Omega$ -6 polyunsaturated fats: Do the dietary guidelines have it wrong?" Open Heart 2014;1:e000032	

Organisation/ individual	Comments	Reply from SACN
	In the accompanying media release issued by PHE of this draft SACN report, they describe 'no change' to 10% sat fat target. However, while the percentages remain the same, we believe the decision to recommend that saturated fat should be replaced with unsaturated fats does reflect a significant change from previously communicated recommendations. Previous recommendations would have been to reduce fats and eat more fruit and vegetables and wholegrain carbohydrates. Careful thought is therefore needed about how this change in message is communicated to the public and to those making recommendations to the public. It should also be noted that of the examples of healthy sources of unsaturated fat given by PHE as part of the press release for the report, such as oily fish, unsalted nuts and seeds and avocados, also provide sources of saturated fat. Therefore, in order to achieve the 'no more than 10% of total energy target' for saturated fat, it is likely that a reduction in the current food sources as suggested by the NDNS data that provide the majority of saturated fat intake in the UK average diet such as meat and dairy products will also need to be reduced. This needs to be articulated clearly. FISH Smoked mackerel, 150g portion = 7.5g sats (and would appear red for Sat Fat on a traffic light label) Baked salmon, 100g portion = 1.7g sats NUTS Brazil nuts, 30g portion = 5.2g sats Cashews, 30g portion = 3.4g sats Peanuts, 40g portion = 2.6g sats Sunflower/pumpkin seeds, 30g portion = 2g sats	Thank you for your comments. Please note that issues relating to risk management (for example, highlighting foods that are sources of unsaturated fats) are the responsibility of risk managers and are outside the remit of SACN. Information in the PHE news article was taken from existing dietary advice available on the NHS UK website. More detailed information can be found here <u>https://www.nhs.uk/live-well/eat-well/different-fats-nutrition/</u>
	Avocado, 145g portion = 5.9g sats	

Organisation/ individual	Comments	Reply from SACN
Dairy UK	There are many factors associated with increased circulating LDL cholesterol and targeting dietary SFA for CVD is not justified by the totality of the available evidence.	Thank you for your comments. As noted in the methods chapter, SACN based its recommendations on the totality of the evidence considered. LDL cholesterol was one of the range of intermediate markers and risk factors that were considered in this report. The full list of health outcomes, intermediate markers and risk factors considered are listed in the methods chapter.
Dairy UK	A declaration of interests and conflicts of interests of the authors and members is missing from this section, please enclose full disclosure for all.	Thank you for your comments. The register of interests for SACN members and members of SACN working groups is available here: <u>https://www.gov.uk/government/groups/scientific-advisory-</u> <u>committee-on-nutrition#register-of-interests</u> Declarations of interests are also published in the SACN annual
		report, available here <u>https://www.gov.uk/government/collections/sacn-reports-and-</u> <u>position-statements#annual-reports</u>
X-PERT Health	The partitioning of evidence assessment by individual conditions is informative, but a consideration of total mortality has been precluded by this method. This is the most important outcome.	Thank you for your comments and raising this issue. Total mortality was included in the initial list of outcomes for consideration. However, due to a lack of evidence identified during the literature search total mortality was not included in the report.

Organisation/ individual	Comments	Reply from SACN
X-PERT Health	The weighting given to null findings or areas where there is no or insufficient evidence appears to be significantly less than that given to findings of association or effect. When the strength and consistency between studies for most findings, particularly in relation to events or mortality, are often questionable this should perhaps not be the case. The only section for which there is consistent evidence is for blood lipids (as summarised in Table 9.1), but these findings do not translate to meaningful and consistent outcomes (as summarised in Table 8.1). Even within the blood lipids section elements of this consistency suggest a positive impact on health markers when saturated fat intake is increase, for example an increase in HDL cholesterol. It is also notable how the blood lipid outcomes imply an improvement when swapping saturated fat for carbohydrate, yet the cardiovascular outcomes suggested either no difference or the reverse. This helps to highlight the limitations of focusing on risk markers. For all other considered health outcomes there is little to no evidence to support a detrimental impact of saturated fat on health; as summarised in tables 10.1 (blood pressure), 11.1 (Type 2 diabetes and glycaemic control), 12.1 (anthropometrics), 13.1 (cancers) and 14.1 (cognitive outcomes). This does not appear to have been fully taken into account in the final recommendations.	SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are
British Dietetic Association	Although an impressive review of the science, the limitation of the methodology and the focus on single nutrients and some substitution does not reflect an integrated food-based approach to dietary recommendations which limits its utility. This report, despite its methodological rigour, does not help significantly add to the evidence base, and does not address the question of what the best diet for the population of the UK is.	<ul> <li>Thank you for your comments.</li> <li>The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>Issues relating to risk management are outside the remit of SACN. However, it is noted that the recommendations are made in the context of existing dietary advice.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
British Dietetic Association	This again reflects the focus on substitution rather than focusing on the effect within dietary patterns. Mostly the data appears to be in generally eucaloric studies but this could be clearer.	Thank you for your comments. For all studies discussed it is noted where they are stated as being isoenergetic. However, this information is not always provided as outlined in the limitations section, the dietary interventions in the trials considered were often complex, resulting in changes in more than just saturated fat intake. Interventions which were not isoenergetic can also result in changes in body weight and BMI which themselves may influence disease risk and markers such as HDL and LDL cholesterol (final report chapter 2).
British Dietetic Association	We believe it would offer more clarity to separate clinical conditions (CVD, Diabetes, cancers and cognitive impairment and dementias) from clinical markers (blood lipids and blood pressure).	Thank you for your comments. SACN considered the order of the chapters and decided to order the chapters by disease outcome first, followed by the intermediate markers and risk factors related to the disease.
British Dietetic Association	Throughout the document current saturated fat intakes are described as "approximately 12%" or "above 12%". Based on the NDNS figures quoted at 15.10, it would appear the round figure would be 13% for adults and children. We believe it is important not to underplay the degree to which saturated fat intake remains above the recommended 10% level. NB: please see 'comments by paragraph' section below for possible discrepancy of these figures	Thank you for your comments. The data on intakes has been updated with the most recent NDNS data (Years 7 and 8).
British Dietetic Association	Current Public Health England programmes are in support of sugar and calorie reduction through reformulation. A reduction in the calorie content of foods could be achieved from smaller portion sizes served and/or sold, which would have the additional benefit of also reducing total and saturated fat intakes. Although Public Health England have been explicit that sugar reduction is expected to occur without an increase in saturated fat content (PHE, 2017), this is an aspect of the programme that will need to be monitored carefully.	Thank you for your comments. Please note issues relating to risk management are outside the remit of SACN.

Organisation/ individual	Comments	Reply from SACN
British Dietetic Association	We agree that there is considerably more evidence available now on a greater range of health outcomes, using a range of risk markers and intermediate factors. Given the importance of these chronic diseases in terms of public health (including cognitive impairment such as Alzheimer's disease, cancers, type 2 diabetes, body weight, blood pressure as well as cardiovascular disease), it is likely that the evidence base relating to these will increase quickly. It is important that the recommendations made in this report are reviewed regularly in light of new evidence, possible changes to the nutritional composition of manufactured foods and drinks, possible changes to foods and drinks provided by the out-of-home sector, impact of the sugar levy and possible changes to consumer dietary behaviours.	<ul> <li>Thank you for your comments.</li> <li>Issues for consideration by SACN originate from a range of sources, including: <ul> <li>in response to emerging evidence or views from other expert bodies</li> <li>requests from the government departments</li> <li>regular horizon scanning.</li> </ul> </li> <li>Please note issues relating to risk management are outside the remit of SACN.</li> </ul>
Agriculture and Horticulture Development Board	The advice on saturated fat and cardiovascular disease (CVD) should be aligned with SACN's recommendations on carbohydrates, fibre and CVD. The lack of studies to suggest that complex CHO is a beneficial substitute for saturated fat from a CVD perspective may be interpreted, in isolation, to mean that complex (high fibre) carbohydrates are not beneficial for health. This has the potential to undermine the message that most of the population need to consume considerably more fibre than at present and undermine SACN's recommendation that about 50% of our energy intake should come from carbohydrates. A more detailed commentary on SCANs position on wholegrains would also be helpful.	Thank you for your comments. The recommendations in the current report are presented as a percentage of energy intake and do not conflict with existing advice on carbohydrates. SACN noted in the report the difficulty of interpreting studies where there was limited information on the type of carbohydrate and referred to this in the research recommendations. SACN recommendations on saturated fats are stated as being made in the context of existing UK government recommendations for macronutrients and energy (see Table 16.1 in the final report), Therefore, existing recommendations on carbohydrates apply. Hyperlinks are provided in the report to the SACN report on carbohydrates. More detailed information on type of carbohydrate and their impact on health can be found in the SACN carbohydrates and health report (SACN, 2015) (https://www.gov.uk/government/publications/sacn-

Organisation/ individual	Comments	Reply from SACN
Agriculture and Horticulture Development Board	<ul> <li>[a] We support SACNs recommendation that government should give consideration to strategies to reduce population average intake of saturated fats. However, we are concerned that previous campaigns (FSA) have resulted in the public receiving misleading and confusing messaging focusing on the benefits of plant based foods over animal sourced foods.</li> <li>The effectiveness of any campaign needs consider a 'whole diet' approach if it is to gain industry support. Ideally strategies should be developed with input from public health nutritionists with food industry experience. They can relay historical insights and share the technical difficulties likely to be encountered when either reducing or seeking substitutes for saturated fats in key commodity</li> </ul>	relationship between saturated fats and health outcomes/ intermediate markers/risk factors. The recommendations note that they are made in the context of existing UK government dietary
	<ul> <li>groups.</li> <li>Furthermore, given the high profile debate on the role of saturated fat in the diet, and the confusion this seems to have generated, we suggest there needs to be a robust, government backed campaign that aims to clarify the advice re saturated fat for health professionals and the public, correct misinformation and put SACN's recommendations into a practical dietary context.</li> <li>[b] In doing this, it will be important to integrate the findings of SACN on saturated fat with those on carbohydrates (including fibre) and CVD, and in particular to clarify the advice on saturated fat and carbohydrates from a whole diet perspective.</li> </ul>	advice, which included those on carbohydrate. More detailed information on type of carbohydrate and their impact on health can be found in the SACN carbohydrates and health report (SACN, 2015) ( <u>https://www.gov.uk/government/publications/sacn- carbohydrates-and-health-report</u> ).

Organisation/ individual	Comments	Reply from SACN
Professor Nita G. Forouhi	<ul> <li>The draft report's review strategy is comprehensive and very clearly laid out. I have some suggestions for further evidence to consider for appraisal and for possible inclusion.</li> <li><b>[a]</b> RCT evidence: <ul> <li>Hamley S. The effect of replacing saturated fat with mostly n-6 polyunsaturated fat on coronary heart disease: a meta-analysis of randomised controlled trials. Nutr J. 2017 May 19;16(1):30. doi: 10.1186/s12937-017-0254-5. PMID:28526025. This was published since the cut-off date of the SACN draft report.</li> <li>Schwingshackl L, Hoffmann G. Dietary fatty acids in the secondary prevention of coronary heart disease: a systematic review, meta-analysis and meta-regression. BMJ Open. 2014 Apr 19;4(4):e004487. doi: 10.1136/bmjopen-2013-004487. PMID:24747790</li> </ul> </li> <li><b>[b]</b> Prospective cohort study evidence from the PURE study with pooled data from 18 countries was published in 2017. Two linked publications and a commentary are relevant (see references below). The evidence from PURE is both for SFA and CVD mortality and morbidity (and by type – CHD or stroke), and also for lipid markers. Associations with and without substitution of nutrients were appraised. There are pros and cons of including this study in the evidence review, including substantial differences in levels of consumption of major macronutrients in some countries).</li> <li>Dehghan M et al. Lancet, 2017. doi: 10.1016/S0140-6736(17)32252-3; PMID: 28864323</li> <li>Mente A et al. Lancet Diabetes Endocrinol, 2017. doi: 10.1016/S2213-8587(17)30283-8; PMID: 28864143</li> <li>Forouhi NG et al. Lancet Diabetes Endocrinol, 2017b. DOI: 10.1016/S2213-8587(17)30285-1; PMID: 28864144</li> </ul>	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>[a] <u>RCT evidence</u></li> <li>Hamley et al, (2017) was highlighted during the consultation. The paper is discussed in chapter 8 of the final report.</li> <li>Schwingshackl and Hoffmann (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population (see chapter 2 of the final report).</li> <li>[b] <u>Prospective cohort study evidence</u></li> <li>The PURE study has been excluded as it is not a systematic review, meta-analysis or pooled analysis, as per the inclusion criteria set out in chapter 2 of the final report.</li> </ul>

Organisation/ individual	Comments	Reply from SACN
Professor Nita G. Forouhi	As outlined in the draft report, the prespecified lipid markers were appraised, but these did not include non-HDL cholesterol or apolipoproteins (apo B and apo A1). It would be additionally helpful to include these lipid parameters, as they are predictors of CVD ( <i>e.g. Emerging Risk Factors Collaboration, Di</i> <i>Angelantonio E, Sarwar N, Perry P, Kaptoge S, Ray KK, Thompson A, Wood AM,</i> <i>Lewington S, Sattar N, Packard CJ, Collins R, Thompson SG, Danesh J.</i> <b>Major</b> <i>lipids, apolipoproteins, and risk of vascular disease.</i> JAMA. 2009 Nov 11;302(18):1993-2000. doi: 10.1001/jama.2009.1619. PMID:19903920),and are related to macronutrients intake ( <i>Mente A et al. Lancet Diabetes Endocrinol,</i> 2017. doi: 10.1016/S2213-8587(17)30283-8; PMID: 28864143). Particularly for apolipoproteins, the review of RCTs by Mensink included the appraisal of dietary fatty acids and lipoproteins.	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>Non-HDL cholesterol and apolipoproteins apo B and apo A1 were not considered in the report due to a lack of evidence. Therefore, the papers by Angelantonio et al, (2009) were not included.</li> <li>Mensink (2016) was not included in the report as it is grey literature and did not therefore meet the inclusion criteria.</li> </ul>
	Mensink RP. World Health Organization 2016. Effects of saturated fatty acids on serum lipids and lipoproteins: a systematic review and regression analysis. http://apps.who.int/iris/bitstream/handle/10665/246104/9789241565349-eng.pdf;jsessionid=AEC184FC30ED7F210DC40618B5D6AB00?sequence=1	
Alliance for Natural Health International	The overall methodology used, namely the qualitative analysis of a very methodologically diverse range of RCTs and PCSs to then establish a direction of association or effect, and subsequently to provide recommendations based on often very small, sometimes null, effects, needs to be tested. Clinical trials designed to 'break' the 'lower saturated fat/improved outcomes' hypothesis should be conducted (see below) prior to the recommendations being issued which are intended to be relevant population-wide.	Thank you for your comments. SACN used methods in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads/syst em/uploads/attachment_data/file/480493/SACN_Framework_for the_Evaluation_of_Evidence.pdf) to critically review the evidence throughout the report. SACN agreed that while clinical observations and experiences, clinical audits and case studies may provide useful information it was not equivalent to scientific evidence from systematic reviews and meta-analyses of RCTs or PCS.
		In deriving its conclusions, SACN thoroughly considered the best available evidence. Limitations of this evidence base are discussed in chapter 2 and research recommendations to improve it are listed in chapter 17 in the final report.

# Specific comments

# Table 2.2: Specific comments on Chapter 2. Methods (Consultation version of the report, paragraphs 2.1-2.18, pages 17-30)

Paragraph	Organisation/ individual	Comments	Reply from SACN
General- Methods	Alliance for Natural Health International	Given the lack of effectiveness of low fat dietary advice based largely on PCSs and limited RCT evidence, over the last 30 years, it is most surprising to see such an archaic methodological approach based on the SACN Framework for the Evaluation of Evidence still being used.	Thank you for your comments. SACN used methods in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/upl oads/system/uploads/attachment_data/file/480493/SAC N_Framework for the Evaluation of Evidence.pdf) to critically review the evidence throughout the report. The use of RCTs and PCS evidence for developing recommendations is an approach used by other national and international organisations.
General- Potential bias	HEART UK – The Cholesterol Charity	We understand and agree with the need to reduce potential bias (Section 2.2, p16) but feel that important insights are overlooked and feel that the expert panel of this long awaited report are ideally placed to challenge the complete reliance on RCT and PCS as the only form of legitimate evidence that should be considered by regulatory, policy making and health agencies.	Thank you for your comments. SACN used methods in line with the SACN Framework for the Evaluation of Evidence ( <u>https://assets.publishing.service.gov.uk/government/upl</u> <u>oads/system/uploads/attachment_data/file/480493/SAC</u> <u>N_Framework_for_the_Evaluation_of_Evidence.pdf</u> ) to critically review the evidence throughout the report. The use of RCTs and PCS evidence for developing recommendations is an approach used by other national and international organisations.

Paragraph	Organisation/ individual	Comments	Reply from SACN
Methods	Alliance for Natural Health International	The associations noted were assumed to be causal of changes in saturated fatty acid intake or their MUFA, PUFA, carbohydrate or protein substitutions, when in fact the changes could have readily been associated with changes in dietary (food group) composition.	Thank you for your comments. Please note that SACN has consistently used the terms association or effect throughout the report, in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/upl oads/system/uploads/attachment_data/file/480493/SACN Framework for the Evaluation of Evidence.pdf). Throughout the development of the report, a number of limitations of the evidence were identified, which are discussed in chapter 2 and have been used in developing research recommendations in chapter 17 of the final report.
General - Methods	UK Health Forum	The methods are described in a clear and concise way. We note that in keeping with SACN's Framework for the Evaluation of Evidence, this report is based primarily on evidence provided by systematic reviews and meta-analyses of randomised controlled trials and prospective cohort studies. The methods are also consistent with approaches undertaken by other bodies internationally.	Thank you for your comments.

Paragraph	Organisation/ individual	Comments	Reply from SACN
Inclusion and exclusion criteria	British Dietetic Association	<ul> <li>[a] There is real clarity in this report in terms of what was considered, the inclusion and exclusion criteria and grading of the quality of evidence.</li> <li>[b] Eligibility focused on biomedical outcomes, it might be useful to also include aspects of; quality of life, food security and environmental impacts. Perhaps not in detail as we appreciate this is not in the remit of this SACN report but at least acknowledge this in the methods.</li> <li>[c] The scope of the report is limited to saturated fats and does not consider unsaturated, trans or total fats. We would like clarification of if and when these will be considered by SACN.</li> </ul>	<ul> <li>[a] Thank you for your comments.</li> <li>[b] Please note that SACN's literature search was not designed to capture evidence that considered the relationship between saturated fat intake and quality of life, food security and environmental impacts.</li> <li>SACN's remit is to advise on: <ul> <li>nutrient content of individual foods, and on diet as a whole including the definition of a balanced diet, and the nutritional status of people</li> <li>nutritional status of people in the UK and how it may be monitored</li> <li>nutritional issues which affect wider public health policy issues including conditions where nutritional status is one of a number of risk factors (e.g. cardiovascular disease, cancer, osteoporosis and/or obesity)</li> <li>nutrition of vulnerable groups (e.g. infants and the elderly) and health inequality issues</li> <li>research requirements for the above</li> </ul> </li> <li>[c] A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
Methodology and grading of strength of evidence	British Dietetic Association	These are logical and sound, albeit from a biomedical perspective.	Thank you for your comments.
2.1	X-PERT Health	<ul> <li>[a] The decision to only include systematic reviews, meta-analyses and pooled analyses precludes the inclusion of any studies published after the literature searches of the most recent review articles were completed.</li> <li>[b] Although we appreciate the difficulty of weighting any individual studies identified that fit into this category against review articles it is important to consider as much evidence as possible. An example of a study which may have provided useful information but was published more recently would be: Mente, A., et al. (2017). Association of dietary nutrients with blood lipids and blood pressure in 18 countries: a cross-sectional analysis from the PURE study. <i>Lancet Diabetes Endocrinol.</i></li> </ul>	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>[a] SACN agreed not to include primary research studies, including those published after the most recent systematic review or meta-analyses in order to make the scope manageable and ensure that the SACN report on saturated fats and health is published in a timely manner. However, as outlined in the methods chapter, SACN have considered any new systematic reviews, meta-analysis or pooled analysis that were published after March 2016 and were brought to their attention through consultation.</li> <li>[b] SACN agreed not to include Mente et al (2017) as it is a cross-sectional study and so did not meet the inclusion criteria outlined in the methods chapter, of the final report.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.2	Alliance for Natural Health International	There has been no attempt to justify or explain the limitations of the SACN Framework for the Evaluation of Evidence, claimed as being the "expected and required standard for assessing evidence." The use of RCTs and PCSs in nutrition is well-recognised as having such serious limitations as to make them meaningless as a means of guiding dietary choices by individuals, each with unique disease risk profiles as well as unique epigenetic, physiological, environmental, social, socio-economic, ethnic and cultural backgrounds. Limitations applying to both RCTs and PCSs include: lack of adequate characterisation of the "normal" and "healthy" population from which subjects for longitudinal studies have been selected (Manrai et al. JAMA. 2018; 319(19):1981-1982), inadequate consideration of how changes to the food matrix (because of nutrient substitution) alter the biological effect of different saturated FAs when diets of higher or lower saturated (or total) fat content are compared (Magni et al. Adv Nutr. 2017; 8(4): 532–545), lack of sufficient stratification to determine relative impacts of 'higher saturated fat + lower refined carbohydrate' intake compared with 'lower saturated fat + higher refined carbohydrate' consumption among overweight or obses subjects (Hu. Am J Clin Nutr. 2010 Jun; 91(6): 1541–1542), and – not least – multiple issues relating to bias, confounding and scientific distortion (Brown AW. Adv Nutr. 2014; 5(5): 563-5). Maki et al detail a range of methodological limitations for PCSs that have not been adequately considered by SACN, including measurement error, collinearity, displacement/substitution effects, healthy or unhealthy consumer bias, confounding and effect modification, and a high risk of false positives owing to weak diet-disease effects (Maki et al. Adv Nutr. 2014; 5(1): 7–15). RCTs also have numerous limitations that include the limited ability to control for multiple exposures, incomplete adherence to treatment or control arms, the inability to blind complex, behavioural exposures, lim	Thank you for your comments and highlighting this evidence. SACN bases its public health recommendations on the best quality of evidence available. The use of RCTs and PCS evidence for developing recommendations is an approach used by other national and international organisations. However, SACN acknowledges these study designs (RCTs and PCS) have different strengths and weaknesses that are outlined in the methods section of the report and are also discussed within the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/upl oads/system/uploads/attachment_data/file/480493/SACN _Framework_for_the_Evaluation_of_Evidence.pdf).

Paragraph	Organisation/ individual	Comments	Reply from SACN
		Public Health 2014; 42(13 Suppl)28–40; Hébert et al. Adv Nutr. 2016; 7(3): 423–432). Given these limitations, it is now extraordinary and scientifically reprehensible that the SACN has limited itself to such narrow inclusion criteria and the top three study types of the evidence-based hierarchy, namely meta-analyses/systematic reviews, RCTs and PCSs. This means that the SACN has directly avoided using a totality of evidence approach which is increasingly seen as essential in the field nutrition given the well-recognised limitations of RCTs and PCSs. Other data that should have been considered as a means of ensuring totality of evidence for the SACN review include: 1) results from case control studies, 2) results from cases/medical records, and 3) views from relevant experts who have clinical experience of working with individuals consuming diets containing different qualities and amounts of fat	
2.2 / 2.3	Dairy UK	The strict guidelines for data collection may have missed the opportunity to include recent RCTs not covered by meta-analysis or systematic reviews.	Thank you for your comments. SACN agreed not to include primary research studies, including those published after the most recent systematic review or meta-analyses in order to make the scope manageable and ensure that the SACN report on saturated fats and health is published in a timely manner. However, as outlined in the methods chapter, SACN have considered any new systematic reviews, meta-analysis or pooled analysis that were published after March 2016 and were brought to their attention through consultation.

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.6	X-PERT Health	The addition of papers outside of the systematic selection framework of the review could potentially provide a source of bias, and it is not immediately apparent which papers were included via this method. The addition of three papers after the call for evidence closing date by an "interested party" is particularly concerning on this front. The details of which papers and who the "interested party" were should be made clear in order to reduce any concerns over bias.	<ul> <li>Thank you for your comments.</li> <li>Please note the additional papers submitted by an interested party. The following papers were submitted:</li> <li>Harcombe Z, Baker JS, DiNicolantonio JJ, Grace F &amp; Davies B (2016b) Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis. <i>Open Heart.</i> 3:e000409.</li> <li>Harcombe Z, Baker JS &amp; Davies B (2016a) Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis. <i>Br J Sports Med.</i> 096550.</li> <li>Harcombe (2017) Dietary fat guidelines have no evidence base: where next for public health nutritional advice? <i>Br J Sports Med.</i> 096734.</li> <li>Harcombe et al, (2016a) and Harcombe et al, (2016b) met the inclusion criteria and were included in the report.</li> <li>There was also an opportunity for any interested parties to submit any evidence that met the inclusion criteria published after March 2016 during the consultation period.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.12	X-PERT Health	Last bullet point of "Interpretation of results and their analysis" section states that "the results of sub-group and sensitivity analyses" will be included when assessing systematic review, meta-analyses and pooled analyses. It is clear this was not always the case, notably in relation to the CVD event reduction analysis in Hooper et al. 2015 where sensitivity analyses impacted upon the outcome (see comments pertaining to paragraph 8.6).	Thank you for your comments. SACN took account of the totality of evidence considered, including consideration of sensitivity analyses. Hooper et al, (2015) conducted 6 different sensitivity analyses and all were considered by SACN in their review of the evidence.
2.13	X-PERT Health	States that an effect/association would be deemed statistically significant using the p<0.05 criterion. The use of statistical significance using the highly arbitrary p-value cut-point of 0.05 is outdated and not an appropriate means to appraise evidence, particularly that which is being used to inform national guidelines. But equally as concerning, if we ignore the limitations of this and judge the appraisal of evidence within the SACN review based on the methods stated, this criterion appears to have been ignored on more than one occasion (e.g. paragraphs 8.15 and 8.51 allowing the inclusion of evidence that didn't achieve this threshold without any qualification.	Thank you for your comments. SACN used methods in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/upl oads/system/uploads/attachment_data/file/480493/SACN Framework for the Evaluation of Evidence.pdf) to critically review the evidence throughout the report. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta- analysis in each section.

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.14	X-PERT Health	The assertions made in this paragraph are to an extent debatable. It is standard practice to use a random-effects model when dealing with studies of the nature of those in this review due to the high between- study heterogeneity. Indeed most reviews included this study used random-effects models as their primary analyses, reflecting this. Some of the conclusions of the SACN review over rely on the interpretation of meta-analyses using fixed effects models (e.g. paragraphs 8.38 and 8.41), even where the corresponding random effects models produced non-significant results, which is of some concern.	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN's approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's report. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> <li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li> <li>More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions (http://training.cochrane.org/handbook).</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.15	Action on Salt and Sugar	Link to Chapter 9 of the Cochrane Handbook for Systematic Reviews of Interventions ( <u>http://training.cochrane.org/handbook</u> ) not working	Thank you for your comments.
		properly when opening from PDF.	Please note the link has been checked and is (as July 2019).

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.18	X-PERT Health	One of the listed limitations is an acknowledgement that "individual saturated fatty acids exert distinct effect on lipid metabolism and therefore have a differential impact on health". This is a key limitation as the length of the saturated fatty acid chain may have an important influence. Short chain saturated fatty acids have been suggested to be beneficial for the gut microbiome (Bugaut (1987). Comparative Biochemistry, 86(3):439-72) whilst medium chain fatty acids are metabolised rapidly in the liver and have been shown to be associated with less body weight gain and smaller fat depots (St-Onge and Jones (2002) The Journal of Nutrition, 132(3), 329-32). Longer-chain saturated fatty acids (20:0, arachidic acid; 22:0, behenic acid; 23:0, tricosanoic acid; and 24:0, lignoceric acid) have been shown to have an inverse association with Type 2 diabetes, for example, perhaps due to having a distinct metabolic pathway to other fatty acids (Forouhi et al. (2014)). The Lancet Diabetes & Endocrinology, 2(10), 810-8). As well as the length of the chain there is also evidence for a differential effect of odd and even saturated fatty acid chains. An inverse association was observed between odd chain saturated fatty acids (15:0, pentadecanoic acid; and 17:0, heptadecanoic acid: both associated with exogenous dairy consumption) and Type 2 diabetes in the EPIC-InterAct case-cohort study (Forouhi et al. (2014)). This is opposed to the positive association seen with even chain saturated fatty acids (14:0, myristic acid; 16:0, palmitic acid; and 18:0, stearic acid). It should be noted however that these associations were for plasma rather than dietary saturated fatty acids. The underlying cause of increased circulating even chain saturated fatty acids in the blood has been shown to be increased de novo lipogenesis in the liver, thus this association may better reflect the impact of dietary carbohydrate intake than exogenous saturated fatty acids was outside the inseverema beinder and acids, it is asserted by SACN that "Consid	saturated fats and health and make recommendations.

Paragraph	Organisation/ individual	Comments	Reply from SACN
		inclusion criteria we do not believe that some assessment of the differential impact of saturated fatty acids from different foods sources was precluded, and believe that some consideration of this is vital.	
		For example any review considering the impact of normal versus low fat dairy products, or high milk and dairy versus low(er) milk and dairy consumption, would provide an indication of the impact of the saturated fatty acids content of the normal fat dairy products (indeed the search strategy included the term "dairy", and so it is likely that such studies would have been identified using the applied method). An example of a potentially eligible study would be: Alexander et al. (2016b). Dairy Consumption and CVD: a Systematic Review and Meta- Analysis. British Journal of Nutrition, 115, 737-750. A meta-analysis of 31 independent prospective cohort studies. This review found there was not a statistically significant association between total dairy and cardiovascular disease or coronary heart disease; with an inverse association observed between total dairy and stroke. Appraisal of this information could potentially be applied, depending on the outcomes, to provide caveats to any recommended restrictions.	
		Without some form of assessment of these differential effects the impact of saturated fat on, or relationship of saturated fat consumption with, health cannot be validly assessed. The review in its current form is therefore largely redundant. The SACN framework for the evaluation of evidence (point 26b) states that when reviewing evidence it will be considered "if there is confidence that the observed effects are not due to confounding". Due to the heterogeneity between foods that contain different saturated fat, and the number of different types of saturated fat in these foods, the outcomes of this review cannot be concluded with confidence to be free of the impact of possible confounding.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
2.18	Dairy UK	There's an acknowledgement that saturated fat is a collective term for a diversity of fatty acids with potentially varying effects on non- communicable disease outcomes and risk factors, but this was not addressed in the report. Addressing the diversity of each saturated fatty acid is essential to these guidelines as there may be a profound bearing on how SFA from some foods, such as milk, is perceived and how dietary food-based guidelines based on single nutrients is developed.	<ul> <li>The remit of this work was to:</li> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> </ul>
2.18	Dairy UK	There is a large and growing body of evidence, including several systematic reviews and meta-analyses, related to the role of foods and the food matrix on health-related outcomes which are not included in this report, and therefore limits the evidence that has been evaluated.	Thank you for your comments. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.

 Table 2.3: Specific comments on Chapter 3. Classification, biochemistry and metabolism (Consultation version of the report, paragraphs 3.1-3.31 pages 31-40)

Paragraph	Organisation/ individual	Comments	Reply from SACN
General	Dairy UK	Not all fat is metabolised or absorbed by the body for energy, section three is missing information on fat excretion and its effects in the presence of other nutrients.	Thank you for your comments. SACN agreed not to consider different food sources of saturated fats therefore their differing effects on fat excretion have not been considered in the report.
General	Dairy UK	The effects of long chain fatty acids, short chain fatty acids, even chain fatty acids and odd chain fatty acids on health and disease risk may differ but this is not included in this section.	<ul> <li>Thank you for your comments.</li> <li>The remit of this work was to: <ul> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated fats and key risk factors and health outcomes at different life stages for the general UK population.</li> </ul> </li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
			A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.
3.1-3.13	British Nutrition Foundation	The nomenclature for cis/trans fatty acids (described on page 34) should be cross referenced on pages 31/2 where it first occurs (or be described in full when first mentioned).	Thank you for your comments. Text has not been amended as suggested.
3.1-3.13	Agriculture and Horticulture Development Board	The nomenclature for cis/trans fatty acids (described on page 34) should be cross referenced on pages 31/2 where it first occurs (or be described in full when first mentioned).	Thank you for your comments. Text has not been amended as suggested.
3.19	British Nutrition Foundation	We suggest some rewording is needed in line 4, requires water. Thus fats To assist the reader. (e.g. binds water)	Thank you for your comments. Text has been amended as suggested.
3.20 and 3.14	British Nutrition Foundation	'free fatty acids' and NEFA seem to be used interchangeably e.g. paras 3.20 and 3.24. Para 3.21, line 2 – delete the superfluous 'the'	Thank you for your comments. Text has been amended as suggested.
3.27	Dairy UK	Carbohydrates can be converted into saturated fatty acids in the body, what is the potential effect on health from carbohydrate storage and conversion to SFA? Is this more of a risk factor than food sources? For example, one could avoid saturated fat in the diet but still have high amounts of saturated fat in stores via carbohydrate consumption.	Thank you for your comments. The issue raised is outside the remit of the report, as it is related to the effect of carbohydrate on health and not saturated fats.

### Table 2.4: Specific comments on Chapter 4. UK and international recommendations (Consultation version of the report, paragraphs 4.1-4.3 pages 41-43)

Paragraph	Organisation/ individual	Comments	Reply from SACN
Wording of the new recommendation	Action on Salt and Sugar	In the draft report (page 41 paragraph 4.1) 'COMA recommended that adults and children aged 5 years and older should <b>consume on</b> <b>average no more than 10%</b> of their total dietary energy (11% food and drink energy, excluding alcohol) as saturated fats'. SACN states that the new recommendation does not differ from the old one, (page 219, paragraph 16.6) 'however the dietary reference value for saturated fats remains unchanged: that the population average contribution of saturated fatty acids to total dietary energy <b>be</b> <b>reduced to no more than 10%</b> (11% food and drink energy, excluding alcohol) for adults and children aged 5 years and older'. In the COMA guidelines, the population is advised to have a maximum 10%E as saturated fats (as an upper limit), whereas in the 2018 draft recommendation, the population is advised not to go below this limit, and therefore to have an intake of saturates above or around 10%E If the recommendation has not changed, please report it in its original concept and wording (as an upper limit).	Thank you for your comments and raising this issue. This paragraph has been amended in the final report to state: COMA recommended in 1994 that the [population] average contribution of saturated fatty acids to dietary energy be reduced to no more than about 10%.
4.4	Action on Salt and Sugar	Why including food-based recommendations if the report considers only nutrient recommendations? To ensure consistency, the SACN report should include also food-based recommendation from other countries (not only from the Netherlands), including how each country translate nutrient recommendation into food based guidelines. Otherwise, it would be better to delete this section.	Thank you for your comments. Food based recommendations have been included for the Netherlands, as this is their most recent recommendation.

 Table 2.5: Specific comments on Chapter 5. Dietary intakes and sources of saturated fats (Consultation version of the report, paragraphs 5.1-5.16 pages

 44-48 of the draft report)

Paragraph	Organisation/ individual	Comments	Reply from SACN
Chapter 5- general (also chapter 6)	Agriculture and Horticulture Development Board	It is mentioned that the main sources of saturated fats showed little change over time and that misreporting of food consumption, generally under reporting is known to be a problem in the NDNS. However, it is also identified that a key issue is whether the underestimate of saturated fat intakes applies equally to all sources of saturated fats. Could this be clarified?	Thank you for your comments. Text has been amended for clarity.
5.1	Action on Salt and Sugar	The most recent NDNS results (published April 2018) should be included in the report. The most recent statistics for saturated fats as %E indicate that SFA intake does not statistically differ when compared with previous years. However, a very interesting and relevant data is that adults older than 75 years (a newly defined age group in the NDNS), have an intake of saturates of 14.3% of total energy. We suggest to include this new data.	Thank you for your comments. The report has been updated with more recent analysis from the NDNS, including data on adults aged 75 years and over.

Paragraph	Organisation/ individual	Comments	Reply from SACN
5.4	Action on Salt and Sugar	<ul> <li>As also highlighted by the doubly labelled water sub-study carried out as part of the NDNS rolling programme, underreporting is a huge problem when trying to assess food consumption. The sub-study found that reported energy intake in adults aged 16-64 years was on average 34% lower than total energy expenditure (TEE), therefore suggesting that actual intake of saturated fats in the adult population (12.1%) could be around 16.2%E (12.1x 34%). Moreover, when trying to draw an estimate, the phenomenon of selective underreporting should be taken into account. It has been documented that people tend to underreport mainly unhealthy foods (i.e. foods high in salt, sugar and saturated fats). See references below:</li> <li>Scagliusi FB, Polacow VO, Artioli GG, Benatti FB, Lancha AH Jr. Selective underreporting of energy intake in women: magnitude, determinants, and effect of training. J Am Diet Assoc 2003;103: 1306–13.</li> <li>AHC Goris, MS Westerterp-Plantenga, and KR Westerterp. Undereating and underrecording of habitual food intake in obese men: selective underreporting of fat intake. Am J Clin Nutr 2000;71:130–4.</li> </ul>	Thank you for your comments and highlighting this evidence. SACN decided that it would not be appropriate to multiply the average intake of saturated fats because the percentage of underreporting for each nutrient (for example, saturated fats) is unknown. Saturated fat intake in the adult population will remain at around 12%, as underreporting does not change the percentage.
5.6	Dairy UK	Include grams of saturated fat as well as percentages.	Thank you for your comments. Information on the grams per day of saturated fats is included in Annex 3 Table A3.1 of the final report.
5.9 and 5.10 and 5.16	Dairy UK	Whilst milk and milk products contribute 22% of saturated fat intakes to adults (19 – 64 years) and children aged 11-18 years, and 31% to children age 4-10 years, they are nutrient dense products and contribute the most B12, B2, iodine and calcium to the diet and significant amounts of vitamin A and zinc. They are also a source of quality protein and contain small amounts on MUFA and PUFA. Their nutrient density is not addressed here.	Thank you for your comments. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.

## Table 2.6: Specific comments on Chapter 6. Temporal trends (Consultation version of the report, paragraphs 6.1-6.10 pages 49-51)

Paragraph	Organisation/ individual	Comments	Reply from SACN
6.5-6.7	British Nutrition Foundation	Temporal change in trans. Is it worth clarifying that the focus has been on reducing trans previously produced industrially in the hardening of veg oils rather than those naturally produced in the digestive process of ruminant animals?	Thank you for your comments. The issue raised is outside the remit of the report.
6.5-6.7	Agriculture and Horticulture Development Board	It is worth clarify the difference between industrial trans fats and those naturally produced.	Thank you for your comments. The issue raised is outside the remit of the report.
6.7	British Nutrition Foundation	perhaps give the value from more recent data for consistency	Thank you for your comments. The report has been checked for consistency and amended where required.
6.7	Agriculture and Horticulture Development Board	The value from more recent data might add to consistency.	Thank you for your comments. The report has been checked for consistency and amended where required.
6.8	British Nutrition Foundation	perhaps cross reference or add a comment about dietary cholesterol not being an issue in general terms.	Thank you for your comments. This paragraph has been deleted.
6.8	Agriculture and Horticulture Development Board	Dietary cholesterol is not an issue in general terms so this might merit a comment.	Thank you for your comments. The paragraph on average dietary cholesterol intakes has been removed from the final report.

Paragraph	Organisation/ individual	Comments	Reply from SACN
6.9	British Nutrition Foundation	Based on what appears in a summary section elsewhere, we suspect the second sentence relates to the NDNS rolling programme period rather than the past 25 years, as may be construed from the first sentence. Also, is it worth commenting on widespread use of statins, especially in older men?	<ul><li>Thank you for your comments.</li><li>Text has been amended for clarity.</li><li>The use of statins is mentioned in the limitations section of the final report, paragraph 2.20, bullet point 12.</li></ul>
6.9	Agriculture and Horticulture Development Board	<ul> <li>[a] Based on what appears in a summary section elsewhere, we suspect the second sentence relates to the NDNS rolling programme period rather than the past 25 years.</li> <li>[b] The widespread use of statins, especially in older men might merit a comment.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] Text has been amended for clarity.</li> <li>[b] The use of statins is mentioned in the limitations section of the final report, paragraph 2.20, bullet point 12.</li> </ul>
6.10	British Dietetic Association	The notes that about 50% of saturated fat from cereals comes from foods deemed discretionary. As these foods fall outside the Eatwell Guide, perhaps is a message that could be clearer in messaging e.g. summaries etc	Thank you for your comments. Please note that issues relating to risk management are outside the remit of SACN.

Table 2.7: Specific comments on Chapter 7. Background on health outcomes, intermediate markers and risk factors (Consultation version of the report, paragraphs 7.1-7.27 pages 52-61)

Paragraph	Organisation/ individual	Comments	Reply from SACN
7.6	Dairy UK	Trans fats come from two sources, industrial and ruminant, they do not have equal effects on health. Industrial TFA, found in processed foods, are associated with increased risk of CHD. Studies on ruminant TFA on the other hand are mixed with most showing no association with CHD. However, it is not possible to consume the amount of ruminant TFA in a normal diet at levels that would contribute to a detrimental effect.	Thank you for your comments. Information on trans fatty acids is outside the remit of the report.
7.8	X-PERT Health	Acknowledges that the "ratio of total cholesterol:HDL cholesterol has subsequently become more widely used in clinical practice and is the primary lipid parameter in the QRISK2 assessment to predict CVD risk", yet there was no evidence that reducing saturated fat intake had an impact on this marker (see table 9.1 and paragraph 9.80). This null finding should perhaps have been given greater weighting when this marker is regularly used in preference to other risk markers included in the review.	Thank you for your comments. SACN considered that this issue had been discussed in sufficient detail, see paragraphs 9.130 and 15.41-15.44.
7.9	X-PERT Health	In the context of the review it could be inferred the CVD reduction statistics are implying a positive impact of guidance to reduce saturated fat, and of the evidence that there has been a reduction in saturated fat intake. There is no evidence of a causal relationship however and it would perhaps be prudent to acknowledge this, and that other factors- such as reduction in smoking and trans fats in the diet, as well as improvements in acute care (e.g. emergency stenting and use and availability of defibrillators)- will likely have played an important role.	causative. Paragraph 7.11 in the final report reflects the other factors that may influence the progression of atherosclerosis, such as diet, physical activity, obesity,

Paragraph	Organisation/ individual	Comments	Reply from SACN
7.17	Action on Salt and Sugar	Most recent statistics for the prevalence of obesity in England (years 2016/2017) are now available at <u>https://digital.nhs.uk/data-and-</u> information/publications/statistical/statistics-on-obesity-physical-	Thank you for your comments and highlighting this evidence.
			The data on the prevalence of obesity in England has been updated.

## Table 2.8: Specific comments on Chapter 8. Cardiovascular diseases (Consultation version of the report, paragraph 8.1-8.106 pages 60-94)

Paragraph	Organisation/ individual	Comments	Reply from SACN
General	Harcombe, Z. and Henderson, G.	I have ignored all sections related to MUFAs, carbohydrates and protein as no claims were made against saturated fat. Table 8.1 claimed that there was limited evidence that substituting saturated fats with MUFAs would increase CHD events and that there was adequate evidence that substituting saturated fats with carbohydrates would increase CHD events. I have not addressed these claims. This section only includes comments on clauses that led to claims of evidence in Table 8.1 (p94).	Thank you for your comments.
General	British Nutrition Foundation	Compared with chapter 9 (lipids), the findings in this section (Chapter 8) are quite challenging to piece together. The reporting of individual studies and the short summary tables are very helpful, but a little more narrative to draw the findings together would be helpful.	Thank you for your comments. Text has been considered and amended to improve clarity.
General	Agriculture and Horticulture Development Board	Compared with chapter 9 (lipids), the findings in this section (Chapter 8) are difficult to interpret. The reporting of individual studies and the short summary tables are very helpful, but a little more commentary would help draw the findings together.	Thank you for your comments. Text has been considered and amended to improve clarity.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.2	Harcombe, Z. and	This paragraph contains a number of errors:	Thank you for your comments and highlighting this evidence.
	Henderson, G.	nderson, G. [a] One of the four Harcombe <i>et al</i> papers has been omitted (PCSs at the time the guidelines were set) (Harcombe et al 2016).	<b>[a]</b> Harcombe et al, (2017) has been added to the list in paragraph 8.2 of the final report.
		[b] Schwingshackl & Hoffman (2014) has been omitted	
		<b>[c]</b> Hamley (2017) has been omitted. (This was published during the committee deliberations and should also have been included – it can be now at draft report stage.)	<b>[b]</b> The review by Schwingshackl & Hoffman (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at
		<b>[d]</b> Schwab <i>et al</i> (2014)(Schwab et al, 2014) reported findings from Hooper <i>et al</i> (Hooper et al,2011) and Jakobsen <i>et al</i> (Jakobsen et al,2009), rather than doing any meta-analysis of their own and so should be deleted.	risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population.
		<b>[e]</b> Van Horn <i>et al</i> (2008) is about assumed risk factors, not disease, and so should not appear in this section. Additionally, as with Schwab <i>et al</i> (2014), Van Horn <i>et al</i> (2008) reported passages from other articles, rather than doing any meta-analysis of their	<ul> <li>[c] Hamley et al, (2017) was highlighted during the consultation. The review is discussed in chapter 8 of the final report.</li> <li>[d] Schwab et al, (2014) will remain in the report, as it is a</li> </ul>
		[f] For the purposes of meta-analysis, Micha & Mozaffarian (2010)(Micha & Mozaffarian, 2010) is a duplication of Mozaffarian	systematic review and meets the inclusion criteria.
			<b>[e]</b> Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.
		<b>[g]</b> This paragraph reported: "The Hooper <i>et al.</i> (2015) review included virtually all randomised controlled trials (RCTs) included in other studies." This is correct. This paragraph should clarify the differences between Hooper and other studies, not just the similarities: Hooper <i>et al</i> (Hooper et al 2015) was the only meta-	<b>[f]</b> Micha & Mozaffarian (2010) reviews additional health outcomes such as stroke, so will remain in this list but has been removed from CHD events.
		analysis to include four small studies for which CVD data were not published or peer reviewed (See 8.6).	<b>[g]</b> SACN disagree with this comment. The research protocols for these trials were peer-reviewed and it is normal practice when undertaking a meta-analysis to ask authors for (unpublished) data or details from studies. The data themselves are rarely 'peer-reviewed'.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.3	Harcombe, Z. and Henderson, G.	<ul> <li>[a] This paragraph omitted Schwingshackl &amp; Hoffman (2014). This examined evidence for all-cause mortality, CVD mortality, CVD events and MIs for both reduced fat intake and modified fat intake with a systematic review and meta-analysis of RCTs. This study found "The present systematic review provides no evidence (moderate quality evidence) for the beneficial effects of reduced/modified fat diets in the secondary prevention of coronary heart disease. Recommending higher intakes of polyunsaturated fatty acids in replacement of saturated fatty acids was not associated with risk reduction."</li> <li>[b] As explained in 8.2, Schwab <i>et al</i> (2014) and Van Horn <i>et al</i> (2008) were included and should not have been.</li> </ul>	<ul> <li>[a] Thank you for your comments and highlighting this evidence.</li> <li>The review by Schwingshackl &amp; Hoffman (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population.</li> <li>[b] Schwab et al, (2014) will remain in the report, as it is a systematic review and meets the inclusion criteria.</li> <li>Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.</li> </ul>
8.4	Harcombe, Z. and Henderson, G.	As explained in 8.2, Van Horn <i>et al</i> (2008) should be deleted. Schwingshackl & Hoffman (2014) should be included.	Thank you for your comments and highlighting this evidence. Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk. The review by Schwingshackl & Hoffman (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.6	X-PERT Health	A 17% reduction in CVD events with a reduction in saturated fat is reported (Hooper et al, 2015), but this fails to consider limitations with this particular analysis. The I <sup>2</sup> value was 65%, thus sensitivity analyses were required. When only studies within which the intervention group significantly reduced their saturated fat intake were included (the same studies that are presented in figure A2.2 of the SACN report) the relative risk dropped to indicate a 9% reduction in events, but importantly the finding was no longer statistically significant (RR = 0.91, 95%CI 0.79 to 1.04; see table 8, page 137 of Hooper et al. 2015). The validity of including the other studies in the main analysis of Hooper et al. 2015 where there was no evidence of a reduction in saturated fat intake in the intervention groups can be questioned regardless. The SACN methods state in paragraph 2.12 that sensitivity analyses will be considered when appraising evidence from meta-analyses, but that does not seem to have been the case here.	In their review of the evidence SACN took account of the totality of evidence considered including consideration of sensitivity analyses. SACN considered an I <sup>2</sup> of >75% to represent high heterogeneity, as described in paragraph 2.14 in the interpretation of results section of the final report. This is in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads/sattachment_data/file/480493/SACN_Frame

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.6	Harcombe, Z. and Henderson, G.	This paragraph should have noted the limitations of the Hooper <i>et al</i> (Hooper et al 2015) report (not least as it is almost entirely relied upon for the case against saturated fat). (Harcombe, 2016d): <b>[a]</b> - SACN should have questioned why the Hooper <i>et al</i> review found something that the other meta-analyses didn't. The Hooper <i>et al</i> finding included 4 small studies (646 people in total), not included in any other meta-analysis, which were primarily studies of: diabetes (Houtsmuller et al 1979); skin cancer (Black et al 1994); hypercholesterolemia (Moy et al 2001); and glucose intolerance (Ley et al 2004), but for which unpublished, non-peerreviewed CVD event information was obtained by Hooper <i>et al</i> in personal correspondence. <b>[b]</b> Houtsmuller et al (1979) (Houtsmuller et al, 1979) (Houtsmuller et al, 19	<ul> <li>Thank you for your comments.</li> <li>[a] This is incorrect. The research protocols for these trials were peer-reviewed and it is normal practice when undertaking a meta-analysis to ask authors for (unpublished) data or details from studies. The data themselves are rarely 'peer-reviewed'.</li> <li>[b] SACN reported what was available in the paper; 35% saturated fats is most likely to be a typographical error in the paper.</li> <li>[c] Hooper et al, (2015) performed 6 sensitivity analyses, all but 1 were statistically significant, but the effect size of all analyses were in the same direction. The results of the meta-analysis are generalisable to the UK population, as across all studies both genders and healthy and non-healthy populations were included.</li> </ul>

••••	nisation/ ividual	Comments	Reply from SACN
	findings didn't), Hooper study o would h	ad the one Hooper <i>et al</i> finding (among seven other non- s) retained significance following the sensitivity test (and it any finding would still have lacked generalisability. The <i>et al</i> review (Hooper et al 2015) did not include a single f healthy people of both genders and thus any findings have lacked generalisability and could not be extrapolated ilations.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.6	Professor Nita G. Forouhi	<b>[a]</b> The outcome "CVD events" in this analysis by Hooper et al included a broad list of endpoints [cardiovascular deaths, cardiovascular morbidity (non-fatal myocardial infarction, angina, stroke, heart failure, peripheral vascular events, atrial fibrillation) and unplanned cardiovascular interventions (coronary artery bypass surgery or angioplasty)]. The comparability of this vs other definitions of CVD events in other systematic reviews would be valuable.	<ul> <li>Thank you for your comments.</li> <li>[a] A definition of CVD events from the systematic review and meta-analysis by Hooper et al, (2015) has been included in paragraph 8.3 in the final report.</li> <li>[b] Not all studies define CVD endpoints, but where a definition is available from the paper it has been added to the relevant paragraphs in the report.</li> </ul>
		<b>[b]</b> It is difficult to reconcile the significant effect for the combined CVD events endpoint, vs. the null results for all individual endpoints considered (such as for CVD mortality, and for major CVD events including total MI, non-fatal MI or stroke). Some comment on this would be appropriate (this is linked also to the information in paragraphs 8.35 to 8.38, and paras 8.82 and 8.88).	[c] SACN considered an I <sup>2</sup> of >75% to represent high heterogeneity, as described in paragraph 2.14 in the interpretation of results section of the final report. This is in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads /system/uploads/attachment_data/file/480493/SACN_Frame work_for_the_Evaluation_of_Evidence.pdf) and the SACN
		[c] The pooled analysis for RCTs of CVD events (for an effect of reduced SFA intake) had an I2 value of 65%. It would be helpful to critique this in terms of quality criteria and robustness of pooling, and place this in context of the lower I2 values for other pooled analyses (e.g. within the Hooper review – e.g. a value of 30% for CVD mortality (stated in para 8.5), or other reviews).	carbohydrate and health report ( <u>https://www.gov.uk/government/publications/sacn-</u> <u>carbohydrates-and-health-report</u> ).

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.7	Harcombe, Z. and Henderson, G.	This paragraph should be deleted. Van Horn <i>et al</i> (Van Horn et al 2008) is about assumed risk factors, not disease/events. Additionally, the statement "a systematic review of 83 primary studies and 19 review articles concluded that low intake of saturated fats (<7% of total energy) resulted in reduced risk of CVD" is disingenuous.	Thank you for your comments. Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.
		i) As above, this was related to assumed risk factors and not CVD events (which is the focus of this section) and ii) 82 studies and 19 review articles did not conclude that low intake of saturated fats (<7% of total energy) resulted in reduced risk of CVD. Van Horn <i>et</i> <i>al</i> (Van Horn et al 2008) referenced one paper that claimed reducing SFA to <7% energy and dietary cholesterol of <200 mg/day reduced LDL. Three RCTs were similarly reported as having lowered LDL with a <7% SFA and <200mg/day cholesterol diet.	
8.12	Harcombe, Z. and Henderson, G.	This paragraph should be amended to report that there is adequate evidence of no effect for reduced saturated fat intake on CVD events (Hooper et al, 2015; Schwingshackl & Hoffmann, 2014).	<ul> <li>Thank you for your comments.</li> <li>The review by Schwingshackl &amp; Hoffman (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population.</li> <li>Based on the above exclusion of Schwingshackl &amp; Hoffman (2014) the summary paragraph in the report will remain the same.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.12 (and 15.16)	X-PERT Health	Hooper et al. (2015) is the only meta-analysis used demonstrating a reduction in CVD events, and this finding no longer holds when appropriate sensitivity analyses are used. It is therefore not justified to assert that there is adequate evidence that reducing saturated fat intake will reduce CVD events.	Thank you for your comments. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described. SACN considered the sensitivity analyses, when drawing their conclusions. Hooper et al, (2015) performed 6 sensitivity analyses, all but 1 were statistically significant, but the effect size of all analyses were in the same direction.
8.13	Harcombe, Z. and Henderson, G.	<ul> <li>[a] This paragraph omitted Schwingshackl &amp; Hoffman (2014). This examined evidence for all-cause mortality, CVD mortality, CVD events and MIs for both reduced fat intake and modified fat intake with a systematic review and meta-analysis of RCTs. This study found "The present systematic review provides no evidence (moderate quality evidence) for the beneficial effects of reduced/modified fat diets in the secondary prevention of coronary heart disease. Recommending higher intakes of polyunsaturated fatty acids in replacement of saturated fatty acids was not associated with risk reduction."</li> <li>[b] This paragraph should delete Schwab <i>et al</i> (2014) (See 8.15).</li> <li>[c] This paragraph should delete Van Horn <i>et al</i> (2008) (See 8.17).</li> </ul>	identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.14	X-PERT Health	This paragraph again quotes Hooper et al. (2015), asserting there was a 27% lower risk of CVD events when saturated fat was replaced by PUFA. There are a number of limitations with this conclusion however: [a] This meta-analysis did not truly assess the substitution of nutrients. Rather than considering which nutrient was the main replacement for saturated fat they included any studies where intake of the nutrient in question was significantly increased in the intervention group compared to the control group. This method does not warrant for changes in any other nutrients, which would influence the observed outcomes. For example it is possible that where there was an increase in PUFA - qualifying a study for this analysis as long as it was statistically significant - there could also have been an increase, potentially with a greater magnitude, of MUFA/protein/carbohydrate which could have a confounding effect. [b] These analyses, used as a proxy indication of the effect of substitution of nutrients, were carried out as sensitivity analyses rather than primary assessments. For the PUFA analysis the l <sup>2</sup> value was 69%, which would make sensitivity analyses required. As this was already a sensitivity analysis however no further assessment was carried out, and so the confidence that can be had in this finding is somewhat limited. There were also no forest plots presented to allow additional appraisal of this outcome. (N.B. these points are not a criticism of the paper, as it would not be practical to perform sensitivity analyses to follow up on all outcomes of already performed sensitivity analyses. It is however a limitation with applying this evidence that shouldn't be overlooked) [c] Based on the summary of included papers on pages 61 to 109 of Hooper et al (2015) it appears that there were only three studies that had a higher intake of PUFA as a percentage of energy in the	<ul> <li>[a] The points raised are referred to in the limitations in paragraph 2.20 of the final report, for example, in many cases, analyses of the effect of saturated fat included trials where there were reductions in the intakes of both saturated and total fat, which limits the ability to attribute the observed effects solely to a change in saturated fat intakes.</li> <li>[b] Hooper et al, (2015) did not include criteria for carrying out a sensitivity analysis. SACN considered an I<sup>2</sup> of &gt;75% to represent high heterogeneity, as described in paragraph 2.14 in the interpretation of results section of the final report. This is in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/480493/SACN_Framework for the Evaluation of Evidence.pdf) and the SACN carbohydrate and health report</li> <li>(https://www.gov.uk/government/publications/sacn-carbohydrates-and-health-report).</li> <li>This was a subgroup analysis not a sensitivity analysis.</li> <li>[c] The number of participants has been amended to &gt;3000, as reported in table 9 of the Hooper et al, (2015) paper.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
		intervention group versus the control group AND which reported CVD events (DART 1989, Stars 1992 and the Veterans Admin study 1696). The SACN summary reports there were seven studies included in this sensitivity analysis. These studies had a combined total of 2929 participants, not >3000 as Hooper et al reported or 3895 as SACN reported.	
8.14	Harcombe, Z. and Henderson, G.	This paragraph claimed that there was a 27% lower risk of CVD events – "p<0.05" – with SFA replaced by PUFA. The original Hooper <i>et al</i> paper (Table 9. p121) reported the P value as 0.14, which makes the finding non-significant.	Thank you for your comments. The text is correct as reported in paragraph 8.13 of the final report based on Hooper et al, (2015). The p=0.14 value is the overall analysis of subgroups by replacement (ie test of significance between all the different saturated fats replacements). This is different from a specific test of replacement of saturated fats by PUFA (RR 0.73, 95% CI 0.58 to 0.92; p<0.05), as reported by Hooper et al, (2015) and in paragraph 8.13 of the final report.
8.14	Professor Nita G. Forouhi	The pooled analysis for RCTs of CVD events (for an effect of SFA substitution with PUFA) had an I <sup>2</sup> value of 69%. It would be helpful to critique this (see related earlier comment below). [8.6: The pooled analysis for RCTs of CVD events (for an effect of reduced SFA intake) had an I <sup>2</sup> value of 65%. It would be helpful to critique this in terms of quality criteria and robustness of pooling, and place this in context of the lower I <sup>2</sup> values for other pooled analyses (e.g. within the Hooper review – e.g. a value of 30% for CVD mortality (stated in para 8.5), or other reviews).]	Thank you for your comments. SACN considered an I <sup>2</sup> of >75% to represent high heterogeneity, as described in paragraph 2.14 in the interpretation of results section of the final report. This is in line with the SACN Framework for the Evaluation of Evidence (https://assets.publishing.service.gov.uk/government/uploads /system/uploads/attachment_data/file/480493/SACN_Frame work_for_the_Evaluation_of_Evidence.pdf) and the SACN carbohydrate and health report (https://www.gov.uk/government/publications/sacn- carbohydrates-and-health-report).

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.15	Harcombe, Z. and Henderson, G.	<b>[a]</b> This paragraph should clarify that Ramsden <i>et al</i> (2013) contributed nothing to the claim for replacing SFA with PUFA and the impact on CVD <i>events</i> . Ramsden <i>et al</i> (2013) focused on CVD mortality. The word "events" did not appear in the Ramsden paper or appendix.	Thank you for your comments. [a] Paragraph 8.14 of the final report focuses solely on CVD mortality whereas this comment refers to the overall conclusion for death from all causes, CHD and CVD.
		<b>[b]</b> This paragraph was also <i>not</i> reflective of the conclusions of Ramsden <i>et al</i> 's paper. Ramsden <i>et al</i> 's conclusion was: "In this cohort, substituting dietary linoleic acid [a PUFA] in place of saturated fats <b>increased</b> the rates of death from all causes, coronary heart disease, and cardiovascular disease" [my emphasis].	<b>[b]</b> The conclusions in this paragraph were based on the statistics provided in the paper and not on the author's conclusions. The hazard ratio was not statistically significant, therefore SACN concluded that there was no effect.
8.16	Harcombe, Z. and Henderson, G.	This paragraph claimed that "Schwab <i>et al</i> (2014) reported on the effect of saturated fat substitution with unsaturated fats (PUFA or MUFA) on CVD events. The authors reported a 14% reduction in RR of CVD events (RR 0.86, 95% CI 0.77 to 0.96; p=0.07; I <sup>2</sup> = 50%; 24 RCTs; 65,508 participants, 4586 CVD events."	Thank you for your comments. The text has been amended for clarity.
		This is not correct. Schwab <i>et al</i> reported " <b>A SR</b> [A Systematic Review – my emphasis] concluded that there is moderate evidence that substitution of unsaturated fatty acids (MUFA or PUFA) for SFA can reduce CVD events by 14% (reference 67)." Reference 67 in their paper was for the Hooper <i>et al</i> 2011 review. Schwab <i>et al</i> did not conduct an SR or meta-analysis of their own; they merely referenced another.	
		Similarly, this paragraph in the SACN report continued "There was no effect of saturated fat change on CVD mortality (RR 0.94, 95% CI 0.85 to 1.04; p=0.23; I2 =0%; 16 RCTs; 65,978 participants, 1407 CVD deaths)." All of this is from the Hooper <i>et al</i> 2011 review (which has been superseded by the 2015 review) and not from any work undertaken by Schwab <i>et al</i> .	
		This paragraph should be deleted.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.16	X-PERT Health	Regarding the statement: "The authors reported a 14% reduction in RR of CVD events (RR 0.86, 95% CI 0.77 to 0.96; p=0.07; l <sup>2</sup> =50%; 24 RCTs; 65,508 participants, 4586 CVD events)." SACN methods state they will be using p<0.05 as marker of statistical significance, but the reported finding from Schwab et al (2014) does not achieve this, and so should not be used as evidence of effect based on SACNs own defined criteria. At the very least the statement should be qualified somehow. Perhaps more importantly, the 14% reduction reported by SACN was NOT a finding of Schwab et al, but rather is from Hooper et al (2012; accessible from the Cochrane Database of Systematic Reviews, 5, CD002137). If Hooper et al 2012 was not identified and included in its own right, and was not subjected to appropriate considerations regarding its strengths and limitations, this finding should not be included. For avoidance of doubt, this finding in Hooper et al was from an analysis comparing fat modification or reduction with usual diet. It was not specific to saturated fat and should not be included in the SACN review. Further, this analysis had an l <sup>2</sup> value of 50%, making sensitivity analyses required by Cochrane standards. Sensitivity analyses removing studies where there were systematic differences other than fat intake produced results which were no longer significant (see page 207 in Hooper et al 2012).	The text has been amended for clarity.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.17	Harcombe, Z. and Henderson, G.	This paragraph claimed "A systematic review by Van Horn <i>et al.</i> (2008) reported a reduced risk of CVD when saturated fats were substituted with unsaturated fats including MUFA (<20% of energy) and PUFA (<10% of energy). However, it was unclear on which of the included RCTs this statement was based and no meta-analysis was performed." The only reference to such data in the Van Horn <i>et al</i> paper is "The American Heart Association recommends a diet SFA and TFA should be replaced isocalorically with complex carbohydrates and/or UFA, including both MUFA (not to exceed 20% of energy) and PUFA (not to exceed 10% of energy)." (p292) As with 8.17, Van Horn <i>et al</i> have not done their own systematic review. SACN have reported Van Horn <i>et al</i> 's reporting of general advice. No RCTs have been studied by Van Horn <i>et al</i> (and this SACN paragraph is in the RCT/CVD event evidence section). There are a number of references to CVD events in the Van Horn <i>et al</i> paper (related to alcohol, exercise, vitamins, obesity, for example) but none relate to SFA/PUFA replacement. This paragraph should be deleted.	Thank you for your comments. Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.17	X-PERT Health	The reference to Van Horn et al (2008) in this paragraph is inappropriate. The outcomes reported pertaining to substitution of saturated fat for PUFA appear to be in relation to a discussion within the Van Horn review (on page 292) about the current guidelines - rather than relating to any content communicating any actual analysis, study, review or meta-analysis. Within Van Horn et al (2008) it states that "Due to vast numbers of articles identified, additional inclusion and exclusion criteria were applied to each topic." Changing search criteria after commencement of a review is not good practice. A search of the website the reader is directed to within the review failed to locate any additional information regarding the search strategy applied, so the risk of bias associated with any amendments to the method could not be made. The inclusion of this review in section 8 is highly questionable anyway as the review predominantly discusses risk factors rather than disease outcomes, and largely reports sections from other reviews rather than contributing anything additional.	Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.18	Harcombe, Z. and Henderson, G.	<ul> <li>This paragraph claimed "Evidence from systematic reviews of PCS indicate a reduction in CVD mortality when saturated fats were substituted with PUFA (Schwab <i>et al.</i>, 2014; Van Horn <i>et al.</i>, 2008) or a combination of MUFA and PUFA (Schwab <i>et al.</i>, 2014), however there was no formal meta-analysis of these data which limits their quality."</li> <li>[a] Schwab <i>et al</i> (2014) reported no evidence from systematic reviews of PCS for CVD mortality and substitution of saturated fats with PUFAs, or a combination of MUFA and PUFA.</li> <li>[b] There are a number of references to CVD mortality in the Van Horn <i>et al</i> paper (related to alcohol, exercise, vitamins, obesity, for example) but none relate to SFA/PUFA replacement.</li> <li>This paragraph should be deleted.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] Schwab et al, (2014) will remain in the report, as it is a systematic review and meets the inclusion criteria.</li> <li>[b] Van Horn et al, (2008) has been removed from this chapter as it is a systematic review of risk factors and not disease risk.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.20 (Summary)	Harcombe, Z. and Henderson, G.	<ul> <li>[a] This paragraph reiterated the claim that there was a 27% lower risk of CVD events. This was not a significant finding. The SACN report states: "These findings were consistent with the results of other systematic reviews of RCTs and the evidence was considered <i>adequate</i>." This sentence needs to be deleted as per the comments on Ramsden <i>et al</i> (2013), Schwab <i>et al</i>, 2014 and Van Horn <i>et al</i>, 2008, which left no other findings.</li> <li>The conclusion of this section should be:</li> <li>[b] There is adequate evidence from two meta-analyses of RCTs (Hooper et al, 2015; Schwingshackl &amp; Hoffmann, 2014) that replacing SFA with PUFA has <i>no</i> effect on CVD events.</li> <li>[c] There is no evidence from systematic reviews or meta-analyses of PCSs to draw any conclusion about the impact of substitution of saturated fats with polyunsaturated fats on CVD mortality.</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a]SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and metaanalysis in each section. This conclusion was based on Hooper et al, (2015). The 27% lower risk of CVD events was significant (RR 0.73, 95%Cl 0.58 to 0.92; p&lt;0.05), as reported in the paper. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.</li> <li>[b] The review by Schwingshackl &amp; Hoffman (2014) was identified in the original literature search. SACN discussed the inclusion/exclusion of this paper noting that it was only looking at secondary prevention of CHD rather than looking at risk of CHD in the general population. It was therefore agreed that this study should be excluded as it did not represent the general UK population.</li> <li>[c] PCS conclusion is based on Schwab et al, (2014). The evidence was graded as <i>limited</i> as there was no formal metaanalysis of the data which limits their quality. Only evidence graded as <i>moderate</i> and <i>adequate</i> has been used in drawing recommendations.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.20 (and 15.19)	X-PERT Health	When limitations of the evidence presented in 8.13 and 8.15 are factored in it becomes highly questionable to conclude that there is adequate evidence that replacing saturated fat with PUFA results in a reduction in CVD events.	Thank you for your comments. SACN's conclusion is based on the most comprehensive or largest systematic review with meta-analysis by Hooper et al, (2015).
8.31	Harcombe, Z. and Henderson, G.	<ul> <li>8.31 Contains a number of errors:</li> <li>[a] A Harcombe <i>et al</i> paper has been omitted. (1) This should be included in the list of systematic reviews without meta-analysis.</li> <li>[b] The SACN report reference "Harcombe 2016a" (17) is incorrectly reported as a systematic review without meta-analysis. It is a systematic review <i>with</i> meta-analysis.</li> <li>[c] Seven, not six, papers evaluated the results from PCS. There are two Harcombe <i>et al</i> papers published for cohort evidence (Harcombe et al, 2016a; Harcombe et al, 2016b).</li> <li>(1) Harcombe Z, Baker JS, Davies B. Evidence from prospective cohort studies did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review. Br J Sports Med. 2016.</li> <li>(17) Harcombe Z, Baker J, Davies B. Evidence from prospective cohort studies does not support current dietary fat guidelines: A systematic review and meta-analysis. Br J Sports Med. 2016.</li> <li>NB for convenience – the three Harcombe <i>et al</i> papers referenced as 2016a, 2016b and 2015 in the SACN report are (with the references in this document in brackets):</li> <li>Harcombe Z, Baker JS, Cooper SM, Davies B, Sculthorpe N, DiNicolantonio JJ &amp; Grace F (2015) Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-</li> </ul>	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>[a] Harcombe et al, (2016b) has been added to the list in paragraph 8.2 of the final report.</li> <li>[b] Text has been amended for clarity.</li> <li>[c] Text has been amended for clarity.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
		Harcombe Z, Baker JS & Davies B (2016a) Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis. British Journal of Sports Medicine.	
		Harcombe Z, Baker JS, DiNicolantonio JJ, Grace F & Davies B (2016b) Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis. Open Heart 3.	
8.33	Harcombe, Z. and Henderson, G.	This paragraph should report for Harcombe <i>et al</i> (2015) that "the included papers deliberately only examined papers published before 1983 to examine the evidence base for the dietary guidelines at the time they were introduced. This, the only paper to examine this question for RCTs, found no evidence for the guidelines introduced."	Thank you for your comments. Harcombe <i>et al</i> (2015) has been deleted from the report and replaced by Harcombe et al, (2016b).
		It is important to document the fact that there was no evidence to support the introduction of the dietary fat guidelines at the time they were introduced. Any evidence being sought is retrospective.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.38	Harcombe, Z. and Henderson, G.	This paragraph rightly reported that Hooper <i>et al</i> (2015) reported <i>no</i> effect of reduced saturated fat intakes on CHD events. The paragraph then wrongly tried to claim that a fixed effects model would have given a significant result. A fixed effects model cannot be used given the heterogeneity of dietary fat trials. The I <sup>2</sup> of 66% confirms this. Hooper <i>et al</i> calculated the fixed effects model as a sensitivity test, not as a finding that SACN can opt for in preference to the random effects (correct) conclusion. At no time has Hooper <i>et al</i> made a claim for a significant finding for CHD events. This paragraph confirms the confirmation bias of the SACN panel.	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN used the following approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> <li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li> <li>More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions (http://training.cochrane.org/handbook).</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.38	X-PERT Health	The only positive outcome demonstrated in this paragraph comes from a choice to use the fixed rather than random effects outcome from a meta-analysis. Despite this being within the scope of what is stated in the methods it is questionable whether an outcome derived from a debatable statistical approach is appropriate when it is being used as a primary driver of the overall conclusion of the section (rather than as an additional piece of research supporting an overall body of evidence).	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN used the following approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's report. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> <li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li> <li>More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions (http://training.cochrane.org/handbook).</li> </ul>
8.39	Harcombe, Z. and Henderson, G.	A Harcombe <i>et al</i> paper is missing (Harcombe et al 2016).	Thank you for your comments and highlighting this evidence. Harcombe <i>et al</i> (2016a) has been added to the list of systematic reviews and meta-analysis of PCS in paragraph 8.36 of the final report.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.41	X-PERT Health	This study by Chowdhury et al. (2014) provides the only positive association observed within this section, and that finding is only present in the fixed effects model (the random effects model produced a non-significant result). As mentioned elsewhere the decision to use fixed effects models is not without limitation and controversy. If there were other findings supporting this outcome then it would be understandable to consider this as part of a bigger body of evidence, but as outlined below this was not the case.	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN used the following approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> <li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li> <li>More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions (http://training.cochrane.org/handbook).</li> </ul>
8.44b New para needed	Harcombe, Z. and Henderson, G.	Harcombe et al (Harcombe et al 2016a) concluded: "Across 7 studies, involving 89,801 participants (94% male), there were 2,024 deaths from CHD during the mean follow-up of 11.9 ± 5.6 years. The death rate from CHD was 2.25%. Eight data sets were suitable for inclusion in meta-analysis; all excluded participants	Thank you for your comments and highlighting this evidence. This new paper has been considered by SACN and has been included in chapter 8 of the final report.

Paragraph	Organisation/ individual	Comments	Reply from SACN
		with previous heart disease. Risk ratios (RR) from meta-analysis were not statistically significant for CHD deaths and total or saturated fat consumption. The risk ratio (RR) from meta-analysis for total fat intake and CHD deaths was 1.04 (95% CI 0.98 to 1.10). The RR from meta-analysis for saturated fat intake and CHD deaths was 1.08 (95% CI 0.94 to 1.25)."	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.46 (Summary RCTs)	Harcombe, Z. and Henderson, G.	As per 8.38, this paragraph reported "Hooper et al (2015) also found no effect on CHD events when using a random-effects model." This was the correct reporting of the correct conclusion from Hooper et al. However, the SACN committee again tried to use fixed effects methodology and sensitivity tests undertaken by Hooper et al to claim a different conclusion, one that was not made by the original researchers. At no time has Hooper et al made a claim for a significant finding for CHD events. This paragraph confirms the confirmation bias of the SACN panel. This paragraph should be amended to reflect the correct conclusion: that there is adequate evidence of no effect of saturated fat intake on CHD events (Hooper et al (2015)).	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN used the following approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> <li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li> <li>More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions (http://training.cochrane.org/handbook).</li> </ul>
8.46	British Nutrition Foundation	Given the nature of the discussion regarding fixed- and random- effects modelling, it might be helpful to refer to the relevant differences (pros and cons) between these two approaches (or provide a cross reference).	Thank you for your comments. Text in the methods chapter has been cross-referenced.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.47 (Summary PCSs)	Harcombe, Z. and Henderson, G. [a] Para 8.40 - This paragraph confirmed de Souza et al 2015 – the most recent systematic review - "reported no association between the highest and lowest intakes of saturated fats and CHD mortality" AND "Furthermore no association was reported between the intake of saturated fats and total CHD." The reason for restating the conclusion of de Souza et al (2015) will become clear.	Thank you for your comments. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes	
		<ul> <li>[b] Para 8.41 - This paragraph confirmed Chowdhury et al (Chowdhury et al 2014) – the most comprehensive systematic review and meta-analysis – found "No association was found with CHD outcomes when comparing the top tertile of saturated fat intakes with the bottom tertile." This was the conclusion reported by Chowdhury. This finding came from Random Effects methodology, which is the correct methodology that every researcher in this field has used. It is the only acceptable methodology to use given the heterogeneity of the dietary trials that have been undertaken since 1965.</li> <li>Again, this paragraph tries to present results from a Fixed Effects</li> </ul>	The very set bight that CACN used the following every
	<ul> <li>methodology, when the correct Random effects methodology has been presented by Chowdhury et al. This paragraph confirms the confirmation bias of the SACN panel.</li> <li>The reason for restating the conclusion of Chowdhury et al (Chowdhury et al 2014) will become clear</li> <li>[c] Para 8.42 - This paragraph confirmed Siri-Tarino et al (Siri-Tarino et al 2010)- "No association was found between upper and lower quartiles of saturated fats intake and CHD."</li> <li>The reason for restating the conclusion of Siri-Tarino et al (Siri-Tarino et al 2010) will become clear.</li> </ul>	b) Where the results of both models were stated in a publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between	
		[c] Para 8.42 - This paragraph confirmed Siri-Tarino et al (Siri- Tarino et al 2010)– "No association was found between upper and lower quartiles of saturated fats intake and CHD." The reason for restating the conclusion of Siri-Tarino et al (Siri-	<ul><li>the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li><li>Therefore, SACN did not over rely on one type of model, but considered the totality of the available evidence.</li></ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
		Para 8.43 - This paragraph confirmed Skeaff & Miller (Skeaff & Miller, 2009) – "There was no association with CHD mortality at 5 to 16 years follow-up or CHD events at 5 to 20 years follow-up" AND	More detailed information on differences between the 2 models can be found in chapter 9 (section 9.4.4) of the Cochrane Handbook for Systematic Reviews of Interventions ( <u>http://training.cochrane.org/handbook</u> ).
		"Analysis of 5% total energy increments in saturated fats also showed no association for either CHD mortality or CHD events."	Harcombe <i>et al</i> (2015) has been deleted from the report and replaced by Harcombe et al, (2016b).
		The reason for restating the conclusion of Skeaff & Miller (Skeaff & Miller, 2009) will become clear.	
		Para 8.44 - This paragraph is referring to the wrong Harcombe et al paper and it has reported the wrong conclusion. This should read: Harcombe et al (Harcombe et al 2016b) included data from 6 PCS, all published before 1982 (for the reason stated in 8.33), involving 31,445 participants and 360 CHD deaths with a mean follow-up of 6.2 to 7.5 years. The data were not conducive to meta-analysis. It was reported that one of the six studies found an association between CHD deaths and intakes of saturated fats across countries; none found a relationship between CHD deaths and saturated dietary fat in the same population."	
		The reason for restating the conclusion of Harcombe et al (Harcombe et al 2016b) will become clear.	
		New para 8.44b - Harcombe et al (Harcombe et al 2016a) concluded: "Across 7 studies, involving 89,801 participants (94% male), there were 2,024 deaths from CHD during the mean follow- up of $11.9 \pm 5.6$ years. The death rate from CHD was 2.25%. Eight data sets were suitable for inclusion in meta-analysis; all excluded participants with previous heart disease. Risk ratios (RR) from meta-analysis were not statistically significant for CHD deaths and total or saturated fat consumption. The risk ratio (RR) from meta- analysis for total fat intake and CHD deaths was 1.04 (95% CI 0.98	

Paragraph	Organisation/ individual	Comments	Reply from SACN
		to 1.10). The RR from meta-analysis for saturated fat intake and CHD deaths was 1.08 (95% CI 0.94 to 1.25)."	
		The reason for stating the conclusion of Harcombe et al (Harcombe et al 2016a) will become clear.	
		Para 8.45 - This paragraph confirmed Mente et al (Mente et al 2009) – "when the highest intakes of saturated fats were compared with the lowest, no association between saturated fats and coronary outcomes were identified."	
		The reason for restating the conclusion of Mente et al (Mente et al 2009) will become clear.	
		The conclusions from paragraphs 8.40-8.45 inclusive have been reiterated in this document to show that NONE of: de Souza et al(2015); Chowdhury et al(2014); Siri-Tarino et al(2010); Skeaff & Miller(2009); Harcombe et al(2016); Harcombe et al(2016); OR Mente et al (2009) found an association between saturated fat intake and CHD mortality or CHD outcomes. The conclusion of this section should have been a categorical statement "The Committee found adequate evidence of no effect."	
		Instead, this paragraph reported one fixed effects test from just one of these studies (Chowdhury et al(2014)) and ignored all other evidence: "The committee, on balance, therefore considered these data to be moderate evidence" for reduced saturated fat intake on CHD mortality and CHD events.	
		This paragraph is an extraordinary example of the confirmation bias of the SACN panel. An independent panel could not have concluded as this paragraph did from the conclusions presented in paragraphs 8.40-8.45 inclusive.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.47 (and 15.27)	X-PERT Health	The only positive association noted in this section is from using fixed over random effects in Chowdhury et al. None of de Souza et al, Siri-Tarino et al, Skeaff & Miller et al, Harcombe et al (either paper) or Mente et al found an association between saturated fat intake and CHD mortality or events. This consistency of null findings, compared to the limitations with the single positive association, would be better summarised as adequate evidence of no effect.	Thank you for your comments. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.
8.47	Alliance for Natural Health International	In Chowdhury et al (2014), a significant increase in CHD was noted when the highest tertile SFA groups was compared with the lowest. But this significance cannot be assumed to be caused by the saturated fat intake – it was more likely the result of a substitution effect such as higher carbohydrate intake in the highest SFA intake tertile).	Thank you for your comments. As noted in the limitations stated in paragraph 2.20 bullet point 7 of the final report, the majority of systematic reviews and meta-analyses either compared the 'highest' with 'lowest' intakes of saturated fats or assessed the impact of 5% change in (energy from) saturated fats without indicating the numerical values of intakes (for example, mean intake/range of intakes).

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.48	Harcombe, Z. and Henderson, G.	[a] "Five systematic reviews analysed the results from RCTs (Ramsden et al., 2016; Hooper et al., 2015; Micha & Mozaffarian, 2010; Mozaffarian et al., 2010; Skeaff & Miller, 2009" is not correct. Micha & Mozaffaria 2010 merely reported the finding of Mozaffarian et al., 2010, which was in print at the time, so this was duplication and should be removed.	Thank you for your comments and highlighting this evidence. [a] Micha & Mozaffarian (2010) has been removed from CHD events, as it is a duplication of systematic review Mozaffarian et al, (2010).
		<b>[b]</b> Hamley's paper "The effect of replacing saturated fat with mostly n-6 polyunsaturated fat on coronary heart disease: a meta- analysis of randomised controlled trials" (Hamley, 2017) was published during the committee deliberations and should have been included.	<b>[b]</b> Hamley et al, (2017) was highlighted during the consultation. The paper is discussed in chapter 8 of the final report.
		This specifically addressed the confounding variables in diet heart trials and sought to focus on the results from trials that most accurately tested the effect of replacing SFA with mostly n-6 PUFA. This found "When pooling results from only the adequately controlled trials there was no effect for major CHD events (RR = $1.06$ , CI = $0.86-1.31$ ), total CHD events (RR = $1.02$ , CI = $0.84-1.23$ ), CHD mortality (RR = $1.13$ , CI = $0.91-1.40$ ) and total mortality (RR = $1.07$ , CI = $0.90-1.26$ ). Whereas, the pooled results from all trials, including the inadequately controlled trials, suggested that replacing SFA with mostly n-6 PUFA would significantly reduce the risk of total CHD events (RR = $0.80$ , CI = $0.70-1.07$ ), CHD mortality (RR = $0.90$ , CI = $0.70-1.17$ ) and total mortality (RR = $1.00$ , CI = $0.90-1.10$ )."	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.49	Harcombe, Z. and Henderson, G.	As 8.46 – the duplicated reference to the finding in Mozaffarian et al, 2010 needs to be removed i.e. Micha & Mozaffarian, 2010 needs to be removed for the review of evidence from RCTs.	Thank you for your comments Micha & Mozaffarian (2010) has been removed from CHD events, as it is a duplication of systematic review Mozaffarian et al, (2010).
8.50	Harcombe, Z. and Henderson, G.	Hooper et al (2015) has been wrongly and disingenuously reported. The claim that "there was a 24% reduction in CHD events (RR 0.76, 95% CI 0.57 to 1.00; >3000 participants, 737 events)" is misleading. This is not statistically significant, as it includes the line of no effect. Hooper et al have never made such a claim for CHD events.	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. In the final report SACN graded the evidence for CHD events as <i>moderate</i> , based on an adequate number of studies and events, consistency with the outcome of Mozaffarian et al, (2010), and upper confidence interval from Hooper et al, (2015) of 1.00.
8.50	X-PERT Health	Hooper et al. (2015) was cited, with a 24% reduction in CHD events being reported. However, as the 95% cofidence intervals included the value of no effect (95%CI 0.57 to 1.00) this finding was non-significant and should not have been included. I2 for this particular analysis was also 71%, but as this was already a sensitivity analysis no further sensitivity analyses were performed to identify the source of this heterogeneity. As such this finding should be interpreted with caution. At the very least these limitations should be noted and considered within the SACN report.	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. In the final report SACN graded the evidence for CHD events as <i>moderate</i> , based on an adequate number of studies and events, consistency with the outcome of Mozaffarian et al, (2010), and upper confidence interval from Hooper et al, (2015) of 1.00.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.50	Professor Nita G. Forouhi	For the reported 24% risk reduction in CHD events in the Hooper et al study, it would be important to place the interpretation in context that the upper bound of the 95% CI is at 1.00 (this is mentioned later in para 8.59, but would be helpful at para 8.50 as well), and an I2 value is not included.	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. In the final report, SACN graded the evidence for CHD events as <i>moderate</i> , based on an adequate number of studies and events, consistency with the outcome of Mozaffarian et al, (2010), and upper confidence interval from Hooper et al, (2015) of 1.00. The l <sup>2</sup> value has been added to the text.
8.51	Harcombe, Z. and Henderson, G.	Skeaff & Miller (2009) has been wrongly and disingenuously reported. The SACN report claimed that high PUFA and lower saturated fats "reduced the risk for CHD events (RR 0.83, 95% CI 0.69 to 1.00; p=0.05; I2 =44.2%; 8 RCTs; 4528 participants, 284 events" This is not statistically significant, as it includes the line of no effect.	Thank you for your comments. SACN has reported the results from Skeaff & Miller (2009) as reported in the paper. SACN took account of the totality of the evidence considered and although Skeaff and Miller (2009) met the inclusion criteria, SACN based their conclusions on the most comprehensive or largest systematic review and meta-analysis, which was Hooper et al, (2015) for this section.
8.51	X-PERT Health	The reported finding that CHD events were reduced was not- significant, as the 95% confidence intervals included the value of no effect. This is therefore not a robust finding supporting the conclusions drawn by SACN within this section. The discussion around serum cholesterol should not be included in this section.	Thank you for your comments. SACN has reported the results from Skeaff and Miller (2009) as reported in the paper. SACN took account of the totality of the evidence considered and although Skeaff and Miller (2009) met the inclusion criteria, SACN based their conclusions on the most comprehensive or largest systematic review and meta-analysis, which was Hooper et al, (2015) for this section. SACN decided to keep the discussion of serum cholesterol in this section for clarity.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.52	X-PERT Health	The meta-analysis by Mozaffarian et al includes the Finnish Mental Hospital trial, which should not be included as it is not an RCT. Therefore the validity of including this paper can be questioned. This review also identified studies based on whether they increased n-6 PUFA intake, rather than whether they reduced saturated fat intake. There was no mention of saturated fat in the study's methods. It cannot be assumed that an increase in n-6 PUFA corresponds to a decrease in saturated fat (particularly not of an equivalent magnitude), or that any changes in health markers in a group who increases intake of n-6 PUFA saw these as a result of swapping saturated fat for n-6 PUFA.	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. It was outside the remit of the report to consider individual studies in detail of each systematic review and meta-analysis.
8.52	Harcombe, Z. and Henderson, G.	Mozaffarian et al (2010) should be excluded for its study selection, as was explained in this peer reviewed critique paper (Ravnskov et al 2014). Mozaffarian et al (2010) omitted two studies that cautioned about the potential harm/toxicity of PUFAs (Rose et al 1965, Woodhill et al 1978)(Woodhill et al, 1978; Rose et al, 1965) and it included the non-randomised, non-controlled Finnish Mental Hospital cross-over trial, which all other respectable researchers, including Cochrane, omitted(Miettinen et al 1972).	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. It was outside the remit of the report to consider individual studies in detail of each systematic review and meta-analysis.
8.54	Harcombe, Z. and Henderson, G.	The Micha & Mozaffarian 2010 article did not do a different meta- analysis. The finding quoted in 8.54 is from the abstract of Mozafarrian (2010). The non robust study (Mozaffarian 2010) should not have been included, let alone duplicated. This paragraph should be deleted.	Thank you for your comments. Micha & Mozaffarian (2010) has been removed from CHD events, as it is a duplication of the systematic review Mozaffarian et al, (2010).
8.54	X-PERT Health	are simply a repeat of the meta-analysis outcome from	Thank you for your comments. Micha & Mozaffarian (2010) has been removed from CHD events, as it is a duplication of the systematic review Mozaffarian et al, (2010).

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.55	Harcombe, Z. and Henderson, G.	Reference to Schwab should be deleted (2014). As reported in paragraph 8.56, Schwab et al. (2014) limited their analysis to a summary of the findings of Jakobsen et al (2009) and thus this duplication is misleading.	Thank you for your comments. Schwab et al, (2014) will remain in the report, as it is a systematic review and meets the inclusion criteria. SACN has been clear in paragraph 8.55 of the final report that Schwab et al, (2014) limited their analysis to a summary of findings of Jakobsen et al, (2009).
8.56	Harcombe, Z. and Henderson, G.	As paragraph 8.55 (comment 142), this paragraph should be deleted.	Thank you for your comments. Schwab et al, (2014) will remain in the report, as it is a systematic review and meets the inclusion criteria. SACN has been clear in paragraph 8.55 of the final report that Schwab et al, (2014) limited their analysis to a summary of findings of Jakobsen et al, (2009).
8.57	Harcombe, Z. and Henderson, G.	This paragraph reported "Overall, a 5% lower energy intake from saturated fats and a concomitant higher energy intake from PUFA was significantly associated with a decrease in CHD deaths (HR 0.74, 95% CI 0.61 to 0.89; p-value not reported) and CHD events (HR 0.87, 95% CI 0.77 to 0.97; p-value not reported)." The two p-values were reported by Jakobsen et al (2009) as 0.40 and 0.70 respectively, which are not significant. This non- significance was confirmed by the fact that significance could not be reached for women or men for coronary events or for coronary deaths when reviewed separately (three out of four confidence intervals including 1.0 and all p values for between-study heterogeneity and for effect modification by sex being substantially higher than 0.05 – as high as 0.81 for example).	Thank you for your comments. No p values were reported in Jakobsen et al, (2009) for substitution of saturated fats with PUFA and CHD mortality and events. The p values supplied in this comment are the test for between studies heterogeneity for HR 0.74 (95%CI 0.61, 0.89) and HR 0.87 (95%CI 0.77, 0.97) and no p values for effect are reported in the paper.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.57	X-PERT Health	The evidence from Jakobsen et al (2009) is overstated, failing to account for key limitations. This paper uses statistical modelling to estimate the effect of replacing saturated fat with other nutrients, rather than including any data where an actual substitution or dietary shift can be demonstrated to have occurred. Importantly, only baseline dietary information was available for the analyses in this review. This is an important limitation when this information is then used to predict longitudinal outcomes based on a change in diet, as there is no directly relevant information on dietary changes available to inform this type of assessment.	Thank you for your comments SACN acknowledges that Jakobsen et al, 2009 used a modelling approach; this is clearly stated in the final report.
8.58	X-PERT Health	The only positive effect observed reported from Farvid et al (2014), is based on a decision to use the fixed effects model outcome from a meta-analysis. In the absence of other strong, supporting evidence this finding – and the appropriateness of including it - can be questioned.	<ul> <li>Thank you for your comments.</li> <li>The results of 2 statistical models of meta-analysis, fixed-effect and random-effects, are increasingly being reported in systematic reviews. SACN used the following approach to the models (as stated in paragraph 2.18 of the final report):</li> <li>a) Where the results of only 1 model (that is, fixed-effect or random-effects) were stated in a publication, the results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li> <li>b) Where the results of both models were stated in a publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the available evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
			Therefore, SACN did not over rely on one type of model, but took account of the totality of the available evidence considered.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.58	Harcombe, Z. and Henderson, G.	This paragraph reported "Farvid et al. (2014), in a systematic review with meta-analysis of 13 PCS with 310,602 participants, reported on the substitution of saturated fats with dietary linoleic acid (n-6 PUFA). Increasing percent of energy from linoleic acid (by 5%) instead of saturated fats was associated with a 13% lower risk of CHD deaths using a fixed-effect (Mantel-Haenszel) model (RR 0.87, 95% CI 0.82 to 0.94; p<0.05; I2=0.0; 10 PCS). This finding was similar using a random-effects model (RR 0.86, 95% CI 0.76 to 0.97). There was a 9% lower risk of CHD events using a fixed-effect model (RR 0.91, 95% CI 0.87 to 0.96; p=0.012; I2 =55.9%; 8 PCS), which was non-significant using a random-effects model (RR 0.90, 95% CI 0.80 to 1.01)."	<ul><li>results of this meta-analysis were reported in SACN's review, and used to draw conclusions.</li><li>b) Where the results of both models were stated in a</li></ul>
		<ul> <li>studies with such heterogeneity (there are virtually no cirumstances when a fixed effects model is appropriate). The reporting of the CHD events as non-significant using a random effects model is correct and thus this finding can be ignored.</li> <li>[b] The reporting of the CHD deaths as significant using a random-effects model is incorrect. The sentence "This finding was similar using a random-effects model (RR 0.86, 95% CI 0.76 to 0.97)" is from P1572 of Farvid et al (2014). The full extract is "Across 10 cohort studies that examined the association between LA and total CHD events (14 estimates), LA consumption was inversely</li> </ul>	publication, these were reported in SACN's review. The Committee considered the appropriateness of the model assumptions, the direction and magnitude of the effect, statistical significance, and the level of agreement between the models. Where the results of the models differed, the totality of the evidence and expert judgement were used to draw conclusions and was considered in the final grading of the evidence.
			Therefore, SACN did not over rely on one type of model, but took account of the totality of the available evidence considered.
		associated with risk of total CHD events. The fixed effect summary of RR for comparing the highest with lowest category was 0.85 (95% CI, 0.78–0.92; Figure 2) with medium heterogeneity (I2=35.5%). This finding was similar using a random-effects model (RR, 0.86; 95% CI, 0.76–0.97)." A random effects finding from another part of the paper has thus been wrongly connected to the CHD deaths fixed effects model. No random effects result was presented alongside the fixed effect RR for CHD deaths and thus	<ul> <li>[b] The text has been amended for clarity.</li> <li>[ci] Part of SACN's inclusion criteria was to include pooled analyses. SACN has been clear in the text that Jakobsen et al, (2009) and Farvid et al, (2014) used a modelling approach. Hamley et al, (2017) is discussed in chapter 8 of the final report.</li> </ul>

Paragraph	Organisation/ individual	Comments	Reply from SACN
		there is no significant random effects finding to be taken into consideration.	<b>[cii]</b> Individual PCS do not meet the inclusion criteria and have not been considered.
		<b>[c]</b> Notwithstanding that Schwab (2014) should not have been mentioned and neither Jakobsen et al (2009) nor Farvid et al (2014) survived scrutiny, there are a number of factors that should be taken into consideration in this section:	<ul> <li>[ciii] It was outside the remit of the report to consider the evidence of the potential risk of exceeding 10% PUFA. The remit of this work was to:</li> <li>review the evidence for the relationship between saturated fats and health and make recommendations.</li> <li>review evidence on the association between saturated</li> </ul>
		<b>[ci]</b> Jakobsen et al (2009) and Farvid et al (2014) are mathematical modelling exercises. No PUFAs were swapped in for SFAs. The Hamley paper (Hamley 2017) is the important one, as this did test replacement of SFAs with PUFAs and it also addressed the issue of the quality of trials. It concluded: "When pooling results from only the adequately controlled trials there was no effect for major CHD events (RR = 1.06, CI = 0.86–1.31), total CHD events (RR = 1.02, CI = 0.84–1.23), CHD mortality (RR = 1.13, CI = 0.91–1.40) and total mortality (RR = 1.07, CI = 0.90–1.26)."	fats and key risk factors and health outcomes at different life stages for the general UK population. The recommendations set by SACN are made in the context of existing dietary reference values and existing dietary advice.
		[cii] There have been a number of PCSs since Jakobsen et al (2009) and Farvid et al (2014) that would counter any findings had they been significant(Praagman et al 2016, Praagman et al 2016, Dehghan et al 2017)	
		[ciii] There have been a number of studies warning about the potential harm from administration of polyunsaturated fats (Ransden et al 2013, Ramsden et al 2016, Rose et a; 1965, Woodhill et al 1978, Praagman et al 2016, Ramsden et al 2010) Public health advice thus needs to be extremely cautious in this area.	

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.59	Harcombe, Z. and Henderson, G.	The conclusion of this section should be – as reported – that there is adequate evidence of no effect for CHD mortality. The conclusion for CHD events should also be that there is adequate evidence from meta-analyses of RCTs (Hamley 2017, Hooper et al 2015, Skeaff et al 2009) that replacing SFA with PUFAs has no effect on CHD events.	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. SACN graded the evidence for CHD events as <i>moderate</i> , based on an adequate number of studies and events, consistency with the outcome of Mozaffarian et al, (2010), and upper confidence interval from Hooper et al, (2015) of 1.00.
8.59 (and 15.29)	X-PERT Health	Based on the limitations of the evidence presented in paragraphs 8.50, 8.51, 8.52 and 8.54 it is not justified to say there is evidence (even limited evidence) demonstrating that replacing saturated fat with PUFA is associated with a reduction in CHD events	Thank you for your comments. SACN took account of the totality of the evidence considered that met their inclusion criteria and based their conclusions on the most comprehensive or largest systematic review and meta-analysis (Hooper et al, 2015) for this section. SACN graded the evidence for CHD events as <i>moderate</i> , based on an adequate number of studies and events, consistency with the outcome of Mozaffarian et al, (2010), and upper confidence interval from Hooper et al, (2015) of 1.00.
8.60 (and 15.30)	X-PERT Health	The classification that there is adequate evidence that replacing saturated fat with PUFA is associated with reduced CHD mortality is not justified, particularly considering the limitations of the reviews used in paragraphs 8.57 and 8.58. Beyond the other limitations of this research much of the evidence from these reviews did not actually assess studies where a substitution of saturated fat for an alternative nutrient had been made, thus there is an overreliance on estimates from models.	Thank you for your comments. SACN consider that there is clear evidence from PCS that replacement of SFA with PUFA reduces CHD mortality and CHD events. However, after consideration, this evidence was graded as <i>moderate</i> due to some differences in statistical significance between models (random and fixed effects), although these generated similar effect estimates and the differences between p values were small.

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.60	Harcombe, Z. and Henderson, G.	The conclusion of this section should be – there is adequate evidence of no effect for both CHD mortality and CHD events from meta-analyses of PCSs.	Thank you for your comments. We consider that there is clear evidence from PCS that replacement of SFA with PUFA reduces CHD mortality and CHD events. However, after consideration, this evidence was graded as <i>moderate</i> due to some differences in statistical significance between models (random and fixed effects), although these generated similar effect estimates and the differences between p values were small.
8.66	X-PERT Health	See limitations of Jakobsen et al. (2009) outlined in comment on paragraph 8.57. The evidence from Jakobsen et al (2009) is overstated, failing to account for key limitations. This paper uses statistical modelling to estimate the effect of replacing saturated fat with other nutrients, rather than including any data where an actual substitution or dietary shift can be demonstrated to have occurred. Importantly, only baseline dietary information was available for the analyses in this review. This is an important limitation when this information is then used to predict longitudinal outcomes based on a change in diet, as there is no directly relevant information on dietary changes available to inform this type of assessment.	Thank you for your comments. Part of SACN's inclusion criteria was to include pooled analyses. SACN acknowledges that Jakobsen et al, (2009) used a modelling approach; this is clearly stated in the final report.
8.75	British Dietetic Association	It was unclear whether the type of carbohydrate substituted for saturated fat influenced outcome. This further looks at quality of dietary pattern which suggests reality is more nuanced than simple nutrient swaps.	Thank you for your comments. SACN acknowledges this limitation, as highlighted in paragraph 2.20 (3rd bullet point) and conclusions (paragraph 15.94) of the final report. A research recommendation is also made on this point (paragraph 17.1).

Paragraph	Organisation/ individual	Comments	Reply from SACN
8.102	X-PERT Health	States that "The effect may depend on the type of carbohydrate consumed" in relation to the observed outcomes when saturated fat was replaced by carbs. It could be interpreted that this assertion is to downplay the significance of findings related to replacing saturated fat with carbohydrates. It is entirely inconsistent to downplay these findings due to the lack of consideration of type whilst making sweeping statements about saturated fat without warranting for the food source or quality. The approach applied to consideration of carbs here should be applied to all nutrients, as the type and quality is likely more important in relation to their impact on health.	Thank you for your comments. The text remains unchanged.
Table 8.1	Harcombe, Z. and Henderson, G.	Needs to change to reflect all of the above.	Thank you for your comments. Table 8.1 was amended appropriate following consideration of the above comments by the WG.

## Table 2.15: Specific comments on Chapter 15. Overall summary and conclusions (Consultation version of the report, paragraphs 15.1-15.97 pages200-217)

Paragraph	Organisation/ individual	Comments	Reply from SACN
General- Conclusions	UK Health Forum	We support the overarching conclusion that "new evidence published since 1994 supports and strengthens the original COMA conclusion that a reduction in saturated fat intakes from current population average levels would be beneficial." This is an important finding which can provide clarity for future policy and practice to improve nutritional intakes:	Thank you for your comments. Please note that food based recommendations are outside the remit of this report.
		<ul> <li>"Based on the totality of the evidence considered, it is recommended that:</li> <li>the dietary reference value for saturated fats remains unchanged: that the population average contribution of saturated fatty acids to total dietary energy be reduced to no more than 10% (11% food and drink energy, excluding alcohol) for adults and children aged 5 years and older</li> <li>saturated fats are substituted with unsaturated fats (PUFA or MUFA).</li> </ul>	
		No evidence meeting the inclusion criteria was identified for older adults or children aged 5 years and older. However, there is no reason to assume that the recommendations should differ for these age groups."	
		In light of the fact that all population groups are exceeding the recommended saturated fat intake limits, we also strongly support the recommendation that "the government gives consideration to strategies to reduce population average intake of saturated fats to no more than 10% of dietary energy."	
		As stated previously (in our comments on "international guidelines"), SCAN should also consider including (and reinforcing) in its guidance some top-level food based recommendations which	

Paragraph	Organisation/ individual	Comments	Reply from SACN
		<ul> <li>are easier to translate these updated guidance into practice, and are focused on the major sources of saturated fats in the UK diet across all population groups:</li> <li>Meat and meat products</li> <li>Milk and milk products (cheese and milk) and</li> <li>Cereals and cereal products (biscuits, buns, cakes, pastries, fruit pies, puddings, pizza).</li> </ul>	
15.2	Action on Salt and Sugar	Here the 1994 COMA recommendation appears to be reported as a lower limit of intake. This sentence has a different meaning from the same reported at page 41 paragraph 4.1.	Thank you for your comments. The overall summary and conclusions chapter has been redrafted following consultation. The final report only refers to the 1994 COMA recommendation, as worded in the COMA report.
15.10 and Table A3.1	British Dietetic Association	It appears that the stated percentages in paragraph 15.10: <i>"Mean intakes of saturated fats as a percentage of total</i> <i>dietary energy were 12.5-13.3% in children (age 4-18 years),</i> <i>and 12.7-13.4% among adults (age 19 years and over)."</i> Contradicts the figures given in Table A3.1 on p120 of the supporting documents, which states mean sat fat intake of 12.1- 12.9% for adults, but the same figures for 4-18 year olds.	Thank you for your comments. The data on intakes has been updated with the most recent NDNS data (Years 7 and 8).

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.16	Harcombe, Z. and Henderson, G.	There was <i>adequate</i> evidence from RCTs that reducing intake of saturated fats had no effect on CVD events.	Thank you for your comments. SACN concluded there was <i>adequate</i> evidence from RCTs that reducing intake of saturated fats reduced the risk of CVD events. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.
15.19	Harcombe, Z. and Henderson, G.	There was <i>adequate</i> evidence from RCTs that substituting saturated fats with PUFA had no effect on CVD events.	Thank you for your comments. SACN concluded that there was <i>adequate</i> evidence from RCTs that substituting saturated fats with PUFA reduced the risk of CVD events. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.20	Harcombe, Z. and Henderson, G.	There was no evidence from PCSs that substituting saturated fats with unsaturated fats was associated with a lower risk of CVD mortality. There was no evidence for CVD events.	Thank you for your comments. SACN concluded that there was <i>limited</i> evidence from PCS that substituting saturated fats with unsaturated fats (a combination of PUFA and MUFA) was associated with a lower risk of CVD mortality. The evidence was graded as limited due to the differential effect of different classes of PUFA and because there had been no formal meta-analysis. There was no evidence for CVD events. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.22	X-PERT Health	Although we make no comment regarding the specific conclusion in this point, the justification for classing the evidence as "Limited" is that "the conclusion relied heavily on a study which did not explicitly test for the effect of substituting saturated fats with carbohydrate or protein." At other points of the SACN review however evidence has been considered without qualification despite this same limitation being present. For example, this applies the use of evidence from Hooper et al (2015) in paragraph 8.14 and the application of several reviews included in the section summarised in paragraph 8.60. For both of these sections the evidence was ultimately classed as "adequate" despite these limitations.	Thank you for your comments The evidence was deemed to be <i>limited</i> for dietary modification where saturated fats were substituted with carbohydrates or proteins because the data for the large Women's Health Initiative study were included in the analysis and this study did not explicitly test for the effect of substituting saturated fats with carbohydrates or proteins. However, the analysis of saturated fats substitution for PUFA by Hooper et al, (2015) did not include data from the Women's Health Initiative study and therefore qualification of the limitations of the Women's Health Initiative was not required in paragraphs 8.13 or 8.49 (or others) of the final report, which discuss Hooper's (2015) analysis of saturated fats substitution with PUFA. SACN's approach to grading the evidence is outlined in the methods chapter.
15.26	Harcombe, Z. and Henderson, G.	There was <i>adequate</i> evidence from RCTs that reducing intake of saturated fats had no effect on CHD events.	Thank you for your comments. Following further consideration of the evidence, SACN downgraded the evidence from RCTs to <i>moderate</i> evidence that reducing saturated fat intake lowers CHD events. The evidence was graded as <i>moderate</i> because of the differences in statistical significance between reported statistical models, although these generated similar effect estimates and the difference between the p values were small.

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.27	Harcombe, Z. and Henderson, G.	There was <i>adequate</i> evidence from PCS that reducing intake of saturated fats had no effect on CHD mortality or CHD events.	Thank you for your comments. Following further consideration of the evidence, SACN downgraded the evidence from PCS to <i>moderate</i> evidence that lower intakes of saturated fats lowered CHD mortality/events. The evidence was graded as <i>moderate</i> due to the differences in statistical significance between reported statistical models, although these generated similar effect estimates and the differences between p values were small.
15.29	Harcombe, Z. and Henderson, G.	There was adequate evidence from RCTs that replacing SFA with PUFAs had no effect on CHD events.	Thank you for your comments. Following further consideration of the evidence, SACN has graded the evidence from RCTs as <i>moderate</i> evidence that substituting saturated fats with PUFA lowers CHD events. The evidence was graded <i>moderate</i> based on an adequate number of studies and events, but the reported upper confidence interval of 1.00.

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.30	Harcombe, Z. and Henderson, G.	There was adequate evidence from PCSs that replacing SFA with PUFAs had no effect on both CHD mortality and CHD events.	Thank you for your comments. SACN concluded that based on the most recent systematic review with meta-analysis there was evidence from PCS data indicating reduced CHD outcomes when models substituting saturated fats with PUFA were analysed, with reported differences in statistical significance between random versus fixed effects models. The modelling by Jakobsen et al, (2009) in particular showed a significant decrease in CHD events and mortality. The evidence was graded as <i>moderate</i> . SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described.

Paragraph	Organisation/ individual	Comments	Reply from SACN
15.63 and 15.96	British Dietetic Association	Is this a discrepancy? 15.63 RCTs of Sat fat > + CHO no effect on fasting glucose 15.96 RCTs of Sat fat > + CHO potentially detrimental increase on fasting glucose	Thank you for your comments. The text has been amended for clarity.
		15.63 There was adequate evidence from RCTs that substituting saturated fats with MUFA or carbohydrate had no effect on fasting blood glucose.	
		15.96 There was adequate evidence from RCTs that substituting saturated fats with carbohydrate had no effect on markers of glycaemic control, apart from fasting glucose for which substitution with carbohydrate resulted in a potentially detrimental increase	

## Table 2.16: Specific comments on Chapter 16. Recommendations (Consultation version of the report, paragraphs 16.1-16.9 pages 218-221)

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Recommendations section	British Nutrition Foundation	We welcome these recommendations; some specific comments are included in the next section.	Thank you for your comments.
Section General- Recommendations	Poundation British Dietetic Association	<ul> <li>are included in the next section.</li> <li>We agree with the recommendations of the report (as mentioned above), and that a reduction in saturated fat intakes across the population would be beneficial for health based upon the current evidence available (noting the lack of high quality research available).</li> <li>However, we have noted already some confusion over the way these recommendations are communicated, with media describing the need for a "three per cent reduction" in saturated fats, based on a misunderstanding of percentages. We therefore believe it is worth articulating clearly that the 3% reduction is a reduction of the total percentage of energy and not a percentage reduction of the populations mean saturated fat intake. The mean saturated fat reduction that would be required to achieve the no more than 10% of total energy recommendation would be a 'rounded' reduction of 25%:</li> <li>A reduction from the current 13% (NDNS) to 10% which would equate to the following in terms of a percentage reduction in intake:</li> <li>2000kcals (woman) 10% would be 260 to 200 kcals = converted to grams of saturated fat would be a reduction from 29g to 22g (24% reduction)</li> <li>2500kcals (man) 10% would be 325 to 250 kcals = converted to grams of saturated fat would be a reduction</li> </ul>	Thank you for your comments. Please note issues relating to risk management are outside the remit of SACN.
		from 36g to 28g (23% reduction) So 'rounded' reduction = about 25% of sat fat in UK adult diet.	

Paragraph	Organisation/ Individual	Comments	Reply from SACN
General- Recommendations	Alliance for Natural Health International	It would be disingenuous to make Recommendations (as is currently the case in draft Section 16.6) to the public without simultaneously indicating what benefits are likely to be achieved through restricting saturated fats and substituting with PUFAs or MUFAs. For example, in communicating recommendations, it should be made clear that no benefit was found in the data reviewed for reduced CVD mortality or cancer. Any benefit for reduced CHD events should be explained by the expected reduction in defined CHD events over a lifetime or within an age range. It should also be made clear that these recommendations do not apply to people with pre-existing disease, including obesity and type 2 diabetes.	Thank you for your comments. The updated report clarifies SACN's considerations of the evidence on PUFA / MUFA substitution. In the methods section it is stated that SACN excluded analyses based only on secondary prevention trials; however, primary prevention trials conducted in apparently healthy populations were included. These participants may have been obese, which is representative of a substantial proportion of the UK population.
General- Recommendations	Alliance for Natural Health International	The 46 RCTs and PCSs that met inclusion criteria included healthy subjects at baseline with ethnicities, socio-economic status and level of physical activity among many factors that were not generally considered in the synthesis. The conclusions on drawn cannot necessarily be applied to the current population on which the majority of adults are obese, where 80% of current 10 to 14-year-olds are likely to become obese adults (Agha & Agha. Int J Surg Oncol (N Y). 2017 Aug; 2(7): e17).	Thank you for your comments and highlighting this evidence. In the methods section it is stated that SACN excluded analyses based only on secondary prevention trials; however, primary prevention trials conducted in apparently healthy populations were included. These participants may have been obese, which is representative of a substantial proportion of the UK population.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
General- Recommendations	Alliance for Natural Health International	<ul> <li>[a] For the reasons indicated in in our comments on the scientific methodologies (see Comments by paragraph) on which the studies selected by SACN have been based, providing an inflexible maximum for saturated fat intake (10 or 11% of total energy) does not mean that all or even most healthy people (regardless of the fatty acid profile, ethnicity, socio-economic status, age group, gender and physical activity level) who maintain this intake or less of saturated fat consumption will benefit more than if they exceeded it.</li> <li>[b] There is inadequate effort made to communicate what kinds of benefits in terms of say increased life expectancy might be conferred based on modelling studies. Gary Taubes made this point as early as 2001 and explained that longevity gains are indeed very modest at most; referring to Browner's work published in JAMA in 1991, Taubes commented as follows: "a woman who might otherwise die at 65 could expect to live two extra weeks after a lifetime of avoiding saturated fat. If she lived to be 90, she could expect 10 additional weeks." (Taubes G. Science 2001; 291 (5513): 2538).</li> </ul>	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>[a] SACN recommendations on saturated fats are for population average contribution; this should provide enough flexibility for different groups.</li> <li>[b] Consideration of the benefits in terms of increased life expectancy based on modelling studies was outside the remit of this report.</li> </ul>
Table 16.1	British Nutrition Foundation	It should perhaps be clearer from the heading that the table provides existing recommendations (from 1991, 1994), which in some cases have been updated slightly. Long chain n-3 PUFA – refers to increase from 0.2g/day – was this the intake at the time? Is this still the case (does it need a footnote)? For consistency with reference to 12% elsewhere in the text, perhaps footnote 9 should be added to the table itself for consistency. Footnote 1 – are both terms implying the same thing? Re n-6 PUFA – it would be helpful to clarify what the intake is currently (if this is different).	Thank you for your comments. Text has been amended as suggested. To note, current intake of PUFA is provided in chapter 5 of the final report.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.2	Action on Salt and Sugar	Please consider underreporting in the final estimate of saturated fats intake for the general population.	Thank you for your comments. Underreporting is considered in paragraph 5.4 of the final report. SACN considered that it would not be appropriate to multiply the average intake of saturated fats because the percentage of underreporting for each nutrient (for example, saturated fats) is unknown. A key issue is also whether the underestimate of saturated fat intakes applies to different food sources (such as meat and meat products; cereals and cereal products; milk and milk products) of saturated fats.
16.5	Action on Salt and Sugar	Please specify the magnitude of reduction of saturated fats for the whole population. E.g. "public health nutrition policies and strategy should aim to reduce saturated fats intake below 10%E".	Thank you for your comments. SACN have provided information on current intakes of saturated fat from the NDNS within chapter 5 of the final report. Policy development or other aspects of risk management are outside the remit of SACN.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.5	X-PERT Health	States that new evidence published since 1994 "supports and strengthens" the original COMA conclusion that a reduction in saturated fat intake from current population levels would be beneficial. Within the summary tables however it is clear that for many of the outcomes there was no, limited or insufficient evidence. Even where the evidence was classified as moderate or adequate this is often based on expert opinion, much of which could be open to debate (for example when to use fixed- or random-effects models when interpreting meta-analyses). Further still, a number of these outcomes suggest improvements in health markers or outcomes in the higher saturated fat groups. Overall there are clearly uncertainties, and so to suggest the conclusion to reduce saturated fat has been strengthened is unjustified. Acknowledging this uncertainty is important in order to not give the impression the science is settled on the matter.	Thank you for your comments. SACN took account of the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta-analysis in each section. The systematic reviews and meta-analyses are not independent analyses as they include many of the same studies. The text clearly notes where one review supersedes another (for example, when it is more recent and/or more complete). The text has been checked throughout to ensure that all outcomes, including null findings, are fully and clearly described. During development of the report a number of gaps in the evidence were identified. This included the need for further research to examine intakes of saturated fats below current recommendations (that is less than 10% (see research recommendations chapter, paragraph 17.2 of the final report).

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.6	X-PERT Health	Figure 8.1 demonstrates broadly the success of studies in achieving a saturated fatty acid intake of <10% in their intervention arms, in line with the current recommendations. If this cut point were clearly supported more consistent positive outcomes would be expected. Thus, based on this and an appraisal of the other information presented and available, we would like to register our disagreement to the suggested maintenance of the guideline recommending the restriction of ALL saturated fats.	In deriving its conclusions, SACN thoroughly considered the available evidence from systematic reviews and meta-analysis of RCTs and PCS. Based on their assessment of the evidence, SACN concluded that the findings from the totality of

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.6		There is inadequate scientific basis to make the Recommendations given in this Section to all children over 5 and all adults given that is remains unclear how much the generally modest effects or associations are linked to changes in the food matrix, particularly where substitutions have occurred. New trends such as changes in quality of foods and oils, cooking methods, reliance on increasing amounts of processed foods and very great differences in biological responses between people of different ethnicities, ages, socio-economic status and physical activity, need to be considered. The Recommendations, currently based on methodologically weak, association analysis, which fails to consider the likely benefit to members of the public who follow the Recommendations, are a defective public health policy instrument.	SACN took into account the totality of the evidence considered and based their conclusions on the most comprehensive or largest systematic review and meta- analysis in each section. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a
16.5 and 16.6	Professor Nita G. Forouhi	Should state beneficial for what (currently stated "would be beneficial) – should emphasise for cardiovascular health.	Thank you for your comments. This section has been edited for clarity.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.7	Professor Nita G. Forouhi	This is a very important statement about the relevance of recommendations on macronutrients to dietary advice on foods, and it is well made. However, information on the evidence on the health effects of different types of fat-rich food sources is not appraised in the current report. While this is considered outside of the scope of the review, it would be highly relevant to give associated information, such as the evidence on the divergent health effects of foods such as processed red meats versus dairy products, both rich in SFA. A further nuance is on the accumulating evidence for different health effects within a food group – for instance, within dairy products there are beneficial effects of some dairy types, particularly fermented dairy products such as yoghurt (and cheese). More reference to the importance of foods, over and above nutrients, should be made, and could be highlighted as an area for further review and research need.	Thank you for your comments. SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.
16.7	X-PERT Health	Existing dietary advice, as depicted by the Eatwell Guide, is more likely to lead to saturated fat being replace by carbohydrates than by mono- or poly-unsaturated fatty acids; with the guidance given being to choose unsaturated oils in small amounts with starchy carbohydrates forming the basis of meals. This guidance does not warrant effectively for the type and quality of carbohydrate, although there is no evidence presented within this review that would support any claim that the replacement of saturated fat with even high quality carbohydrates would result in an improvement in health. The evidence from the current review, as presented in table 8.1 for example, suggests that the replacement of saturated fat with carbohydrate is more likely to result in worse health outcomes than in an improvement.	Thank you for your comments. Please note issues relating to risk management are outside the remit of SACN. The recommendations set by SACN are made in the context of existing UK government dietary advice (see Table 16.1 of the final report), which included those on carbohydrate (e.g. carbohydrate to provide approximately 50% of total dietary energy, of which less than 5% of total dietary energy from free sugars and 30 g/d dietary fibre). More detailed information on type of carbohydrate and their impact on health can be found in the SACN carbohydrate and health (2015) report (https://www.gov.uk/government/publications/sacn- carbohydrates-and-health-report )

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.6, last bullet	British Nutrition Foundation	Is 'or' justified given that the available evidence is predominantly for PUFA (also see point made under 'overview').	<ul> <li>Thank you for your comments.</li> <li>In the final report, the recommendation in paragraph 16.1 second bullet has been amended to: <ul> <li>saturated fats are substituted with unsaturated fats. More evidence is available supporting substitution with PUFA than substitution with MUFA.</li> </ul> </li> <li>The updated report clarifies SACN's considerations of the evidence on PUFA / MUFA substitution.</li> </ul>
16.6	Dairy UK	SACN recommends substituting SFA intake with PUFA may reduce risk of a number of cardiovascular outcomes, but evidence from RCTs and PCS is mixed. There is no support for an effect of substituting SFA intake with PUFA on type 2 diabetes, cancer and cognitive outcomes. SACN does not present evidence supporting a benefit of substituting SFA with MUFA or carbohydrate on cardiovascular outcomes.	SACN took account of the totality of the evidence considered and concluded that there was not enough evidence to draw conclusions on the relationship between these outcomes and

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.6		In terms of risk factors from RCTs only, there is evidence that reducing SFA intake, and replacing SFA with PUFA, MUFA or carbohydrate reduces total and LDL cholesterol. In each scenario, however, a reduction in HDL is also observed. [a] The evidence linking SFA to non-communicable chronic disease is not equivocal or unilateral. We are concerned the recommendations may be miscommunicated as relevant for all cardiovascular outcomes, type 2 diabetes, cancer, cognitive outcomes, non-communicable disease or, indeed, 'health' [b] The strength of the evidence for the recommendations is from studies of risk factors, rather than disease outcomes; and the major risk factor upon which recommendations are derived is LDL cholesterol. The heterogeneity within LDL particles is not addressed, including the particularly atherogenic nature of small	<ul> <li>Thank you for your comments.</li> <li>[a] Please note issues relating to risk management are outside the remit of SACN.</li> <li>[b] Since 1994, the evidence base on saturated fats and health has grown considerably. In addition to further work on the blood lipid profile, a significant body of evidence on other intermediate factors, risk markers and health outcomes is now available. This evidence has been considered in a number of published meta-analyses and systematic reviews and this report is based on a further analysis of these, with precedence given to evidence from RCTs.</li> <li>The consideration of the effect of different sizes of LDL</li> </ul>
		<ul> <li>dense LDL. We are concerned that the recommendations are largely based on LDL risk factor data rather than disease outcomes.</li> <li>[c] The evidence suggests reducing/replacing SFA has a detrimental effect on HDL cholesterol. This is not discussed adequately in the report</li> <li>[d] The evidence indicates that replacing SFA with MUFA or carbohydrate is not warranted as a guideline</li> </ul>	<b>[c]</b> Following consultation, amendments were made to the blood lipids chapter. SACN reported that reducing saturated fat intake lowered serum HDL cholesterol. Substitution of saturated fats with PUFA or MUFA had no effect on HDL

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.6	Dairy UK	The recommendation is aligned to qualitative recommendations on MUFA that are not substantiated in the report, and a food- based dietary guideline that conveys a different saturated fat recommendation. There is very little evidence to support substitution of saturated fat with PUFA or MUFA in this study, and certainly none concerning MUFA and non-communicable chronic disease outcomes. The current wording of the recommendations should reflect this.	<ul> <li>In the final report, the recommendation in paragraph 16.1, second bullet has been amended to:</li> <li>saturated fats are substituted with unsaturated fats. More evidence is available supporting substitution with PUFA than substitution with MUFA.</li> </ul>
16.7	Dairy UK	The recommendation is made in context of existing dietary values, however, there is no further note on the nutrient richness of foods that contribute to SFA intakes in the recommendations. Although it may be argued that SACN's remit was to provide a nutrient guideline, their final recommendations endorse a food-based dietary guideline.	SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was
16.7	Dairy UK	The Eatwell Guide is endorsed as representing SACN recommendations on saturated fat. Changes from the Eatwell Plate to the Eatwell Guide included increasing carbohydrate intake (from 54% to 58% energy) and reducing saturated fat intake (10% to <u>8% energy</u> ), as analysed by Scarborough et al (2016). The evidence presented in this report suggests that replacing saturated fat with carbohydrate may not be beneficial and currently does not reflect SACN recommendations in this report.	The Eatwell Guide is a tool to demonstrate the proportions and types of foods that constitute a diet consistent with existing UK government recommendations in keeping with SACN advice. The modelling underpinning the development of

Paragraph	Organisation/ Individual	Comments	Reply from SACN
16.9	Dairy UK	SACN recommends reducing SFA intake reduces risk of cardiovascular events and coronary heart disease events. There is no support for an effect of reducing SFA on cardiovascular disease mortality, stroke, peripheral vascular disease, blood pressure, type 2 diabetes, and the range of cancers and cognitive outcomes investigated.	SACN noted a lack of evidence for a range of outcomes but considered the totality of evidence, which included significant
16.9	Action on Salt and Sugar	Please mention <b>product reformulation</b> as one of the public health strategies to reduce saturated fat intake at the population level. Recently, Public Health England (PHE) has launched a Calorie Reduction Programme. In autumn 2018, PHE will set calorie reduction targets for the industry, and reducing saturated fats (through a reduction of animal-sourced fat and palm oil) could be a very effective way of preventing obesity and CVD.	Thank you for your comments. Please note issues relating to risk management are outside the remit of SACN.

## Table 2.17: Specific comments on Chapter 17. Research recommendations (Consultation version of the report, paragraphs 17.1-17.2 pages 222-223)

Paragraph	Organisation/ Individual	Comments	Reply from SACN
General- Research recommendations	UK Health Forum	<ul> <li>[a] We support the proposed research recommendations. In particular,</li> <li>We note that no evidence meeting the inclusion criteria was identified for older adults or children aged 5 years and older adults, and therefore support the recommendation to "undertake systematic reviews and meta-analyses (and possibly further primary research) investigating the potential effect of saturated fat intakes and health outcomes, intermediate markers and/or risk factors for longer term health in children under 5 years."</li> <li>We also support the recommendation to examine the effects of saturated fat intakes lower than currently recommended (i.e. below 10% of total dietary energy intake) on health outcomes, intermediate markers and/or risk factors.</li> <li>[b] Finally as stated in our comments on the "limitations of evidence", we would also welcome the inclusion of a research recommendation which addresses the issue of how individual saturated fatty acids exert distinct effects on lipid metabolism and therefore have a differential impact on health. As this is the subject of ongoing debate and confusion, we would strongly urge SACN to consider the impact of individual saturated fatty acids within the scope of a future review.</li> </ul>	<ul> <li>[a] Thank you for your comments.</li> <li>[b] SACN is unable to make research recommendations on issues it has not considered.</li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Chapter 17- general comment	Agriculture and Horticulture Development Board	[a] We would suggest that consideration of individual saturated fats needs to be part of a future work stream. [b] In addition, consideration needs to be given to the accuracy of current nutritional composition data and the impact out of date data a may be having on studies and the interpretation of results.	Thank you for your comments. [a] SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review. A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future. A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report. [b] The nutrient composition databank that supports estimates of nutrient intakes in the NDNS is updated regularly to ensure that, as far as possible, it reflects the nutrient content of the food supply. While it is true that nutrient analysis for carcase meat and milk and dairy products was last done in the 1990s, manufacturer's data such as that on product labels are used to update the NDNS nutrient databank for processed foods including cereal products such as biscuits and cakes, meat products and dairy products such as ice cream and yogurt so changes in saturated fat content due to reformulation are reflected in the databank. The survey will also pick up shifts in purchasing towards lower fat/saturated fat variants such as from full fat to reduced fat cheese. We are not aware of any major changes in the saturated fat content of meat or milk although it is true that changes in

Paragraph	Organisation/ Individual	Comments	Reply from SACN
			the fat content of some cuts of meat may have changed due to shifting consumer preferences. It is therefore considered that the NDNS data provides a broadly accurate reflection of the contributors to saturated fat intake in the UK. Notwithstanding the current sources of dietary fat and saturated fats, healthy eating advice focuses on reducing those sources of total and saturated fats that do not contribute to other valuable nutrients in the diet.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Research recommendations	Alliance for Natural Health International	Clinical trials with specific fatty acid profiles should be conducted to ensure that the presently weak 'lower saturated fat/improved outcomes' hypothesis is not able to be disregarded simply because lower saturated fat diets with substitutions as studied in the reviewed RCTs and PCSs are generally healthier diets (e.g. increased polyphenols, fewer heat damaged/contaminated foods (e.g. PAHs, HAs), fewer advanced glycation end (AGE) products, increased polyphenols, etc). Such trials should be developed using the expert base on healthier FA profiles, e.g. reduced palmitic acid, increased palmitoleic acid, etc.	<ul> <li>Thank you for your comments.</li> <li>SACN does not make research recommendations on issues it has not considered.</li> <li>SACN agreed that while clinical observations and experience, clinical audits and case studies may provide useful information it was not equivalent to scientific evidence from systematic reviews and meta-analyses of RCTs or PCS.</li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Research recommendations	Alliance for Natural Health International	It would also be of great value to examine clinical data from clinician/researchers such as Drs David Unwin and Trudi Deakin in the UK, and Dr Sarah Hallberg in the USA. It seems likely that the positive results derived from using higher fat diets in these cases may be linked to careful selection of fatty acid profiles as well as carefully considered carbohydrate reduction. These clinical data represent real-world data and while they cannot be relied upon in isolation, they are of immense importance for validation and hypothesis testing.	<ul> <li>Thank you for your comments and highlighting this evidence.</li> <li>SACN does not make research recommendations on issues it has not considered.</li> <li>SACN agreed that while clinical observations and experience, clinical audits and case studies may provide useful information it was not equivalent to scientific evidence from systematic reviews and meta-analyses of RCTs or PCS.</li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> </ul>

Paragraph	Organisation/ Individual	Comments	Reply from SACN
17.1	X-PERT Health	These recommendations should include an increased consideration of the differential roles of different types of saturated fat and, in particular, the differential impact of different foods that contain saturated fat. Continued advice based around macronutrient content is not supported by the evidence base, and is therefore not appropriate.	<ul> <li>Thank you for your comments.</li> <li>SACN does not make research recommendations on issues it has not considered.</li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However, SACN undertakes regular horizon scanning and may decide to consider these topics in the future.</li> <li>A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.</li> <li>Additionally, SACN agreed not to consider different food sources of saturated fats. The development of food based guidance was outside the remit of this report. SACN also noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.</li> </ul>

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Research recommendations	British Dietetic Association	<ul> <li>[a] The research recommendations in the report reflect the lack of high quality research available for some conditions/dietary aspects. We agree that addressing these would help clarify gaps in current knowledge and address some of the current limitations in the data which have been identified.</li> <li>[b] Other research recommendations: <ul> <li>We feel that future research not just looking as saturated fats as a whole but the actual foods that contain saturated fats would be beneficial</li> <li>Linking to current thinking in the academic and practice communities, could this be an opportunity to recommend research into understanding optimal diets that are sustainable and secure for populations rather than looking at nutrients first</li> </ul> </li> </ul>	<ul> <li>[a] Thank you for your comments.</li> <li>[b] SACN does not make research recommendations on issues it has not considered.</li> <li>SACN agreed not to consider different food sources of saturated fats.</li> <li>The development of food based guidance was outside the remit of this report. However, SACN noted the difficulty in classifying individual food sources as many foods contain a mixture of fats.</li> </ul>
Para 17.1	British Nutrition Foundation	<ul> <li>[a] Research recommendations. We suspect the reference to 2.17 should be 2.18.</li> <li>[b] In addition, it would be helpful for SACN to consider the evidence regarding the relative impact of different fatty acids, especially different saturated fatty acids (as has already happened in France) as this potentially has a bearing on food based guidance.</li> <li>The final recommendation refers to different types of MUFA – what does this mean in practice as the main dietary MUFA is oleic acid (18:1) [16:1 is present in very low concentrations as I recall]? Also, does this recommendation refer to food sources of these subclasses or pure compounds (the former would seem to be more relevant although challenging to achieve without provision of diets in a RCT).</li> </ul>	<ul> <li>Thank you for your comments.</li> <li>[a] Text has been amended for clarity.</li> <li>[b] SACN does not make research recommendations on issues it has not considered.</li> <li>SACN agreed not to consider the relationship between individual saturated fatty acids and health outcomes/intermediate markers/risk markers in this report. The limitations section of the updated report notes that consideration of individual fatty acids was outside the scope of this review.</li> <li>A potential risk assessment of other fatty acids will be considered by SACN in the future. SACN has no immediate plans to review evidence on trans or total fats. However,</li> </ul>

Paragraph	Organisation/ Individual	Comments	Reply from SACN
		<b>[c]</b> Finally, the terms 'cancer' and 'cancers' are both used throughout the report. We suspect in most cases the most appropriate term is 'cancers'.	SACN undertakes regular horizon scanning and may decide to consider these topics in the future.
			A paragraph on individual saturated fatty acids and health outcomes has been added to chapter 3 of the final report.
			[c] The report has been checked for consistency and amended where required.
Para 17.1, 3 <sup>rd</sup> bullet point	Professor Nita G. Forouhi	I am not convinced that this will be helpful. Looking back in time to some very old trials is likely to be unhelpful as the dietary	Thank you for your comments.
		landscape has changed substantially and it is better to plan new research than to look back at old data.	Text has been amended for clarity.

Paragraph	Organisation/ Individual	Comments	Reply from SACN
Para 17.2, 3 <sup>rd</sup> bullet point	Professor Nita G. Forouhi	It seems vague to specify to "undertake an intervention study" – would be better to indicate some specific information that would fill existing gaps – e.g. specific to the UK? which population? include people of different ethnic groups? men and women? primary or secondary outcome? In people with and without statin use? which disease outcomes? Only cardiovascular or other endpoints too? The point about "novel study designs" deserves more information. There is only this single isolated mention in this paragraph of Mendelian randomisation (MR) approaches; information including some examples of where a Mendelian randomisation approach has been useful will help.	Thank you for your comments. This text has been amended for clarity.

# Evidence raised in the consultation

#### Table 3: Full references alphabetically raised in the consultation for consideration by SACN

Full reference	Exclusion/ inclusion
Alexander DD, Bylsma LC, Vargas AJ, Cohen SS, Doucette A, Mohamed M, et al (2016a) Dairy consumption and CVD: a systematic review and meta-analysis - CORRIGENDUM. Br J Nutr. 115(12):2268.	<b>Exclude</b> Outside remit
Agha M & Agha R (2017) The rising prevalence of obesity: part A: impact on public health. Int J Surg Oncol (NY). 2(7):e17.	<b>Exclude</b> Outside remit
Attanasio OP (2014) Evidence on public policy: methodological issues, political issues and examples. Scand J Public Health. 42(Suppl. 13):28-40.	<b>Exclude</b> Outside remit
Bendsen NT, Hother AL, Jensen SK, Lorenzen JK & Astrup A (2008) Effect of dairy calcium on fecal fat excretion: a randomized crossover trial. Int J Obes (Lond). 32(12):1816-1824.	<b>Exclude</b> Outside remit
Black HS, Herd JA, Goldberg LH, Wolf JE, Thornby JI, Rosen T, et al (1994) Effect of a low-fat diet on the incidence of actinic keratosis. N Engl J Med. 330(18):1272-1275.	<b>Exclude</b> Primary study included in Hooper et al, (2015) paper
BMJ/SwissRe (2018) Food for Thought Conference BMJ 2018; papers and panels discussions. Available from: <u>www.bmj.com/food-for-thought</u>	Exclude Not a systematic review, meta- analysis or pooled analysis
Brown AW, Ioannidis JPA, Cope MB, Bier DM & Allison DB (2014) Unscientific beliefs about scientific topics in nutrition. Adv Nutr. 5(5):563-565.	<b>Exclude</b> Outside remit
Browner WS, Westenhouse J & Tice JA (1991) What if Americans ate less fat? A quantitative estimate of the effect on mortality. JAMA. 265(24):3285-3291.	<b>Exclude</b> Outside remit
Bugaut M (1987) Occurrence, absorption and metabolism of short chain fatty acids in the digestive tract of mammals. Comp Biochem Physiol B. 86(3):439-472.	<b>Exclude</b> Outside remit
Chen GC, Wang Y, Tong X, Szeto IMY, Smit G, Li ZN, et al (2017) Cheese consumption and risk of cardiovascular disease: a meta-analysis of prospective studies. Eur J Nutr. 56(8):2565-2575.	<b>Exclude</b> Outside remit

Full reference	Exclusion/ inclusion
Chowdhury R, Warnakula S, Kunutsor S, Crowe F, Ward HA, Johnson L, et al (2014) Association of dietary, circulating, and supplement fatty acids with coronary risk: a systematic review and meta-analysis. Ann Intern Med. 160(6):398-406.	Already included
de Souza RJ & Anand SS (2016) Saturated fat and heart disease. BMJ. 355:i6257.	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
de Souza RJ, Mente A, Maroleanu A, Cozma AI, Ha V, Kishibe T, et al (2015) Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: systematic review and meta-analysis of observational studies. BMJ. 351:h3978.	Already included
Dehghan M, Mente A, Zhang X, Swaminathan S, Li W, Mohan V, et al (2017) Associations of fats and carbohydrate intake with cardiovascular disease and mortality in 18 countries from five continents (PURE): a prospective cohort study. Lancet. 390(10107):2050-2062.	Exclude A single cross sectional study (PURE) - not a systematic review, meta- analysis or pooled analysis
DiNicolantonio JJ (2014) The cardiometabolic consequences of replacing saturated fats with carbohydrates or Ω-6 polyunsaturated fats: Do the dietary guidelines have it wrong? Open Heart. 1(1):e000032.	Exclude Not a systematic review, meta- analysis or pooled analysis
Drouin-Chartier JP, Brassard D, Tessier-Grenier M, Côté JA, Labonté MÈ, Desroches S, et al. (2016) Systematic review of the association between dairy product consumption and risk of cardiovascular-related clinical outcomes. Adv Nutr. 7(6):1026-1040.	<b>Exclude</b> Outside remit
Emerging Risk Factors Collaboration, Di Angelantonio E, Sarwar N, Perry P, Kaptoge S, Ray KK, et al (2009) Major lipids, apolipoproteins, and risk of vascular disease. JAMA. 302:1993-2000.	<b>Exclude</b> Apolipoprotein s were not considered in the report due to a lack of evidence.

Full reference	Exclusion/ inclusion
Engel S, Elhauge M & Tholstrup T (2018) Effect of whole milk compared with skimmed milk on fasting blood lipids in healthy adults: a 3-week randomized crossover study. Eur J Clin Nutr. 72(2):249-254.	<b>Exclude</b> Outside remit
Farvid MS, Ding M, Pan A, Sun Q, Chiuve SE, Steffen LM, et al (2014) Dietary linoleic acid and risk of coronary heart disease: a systematic review and meta- analysis of prospective cohort studies. Circulation. 130(18):1568-1578.	Already included
Forouhi NG (2017a) Nita Gandhi Forouhi: Challenging poor choices. BMJ. 357:j1573.	<b>Exclude</b> Outside remit
Forouhi NG, Sattar N & Imamura F (2017b) Macronutrients and cardiovascular risk in a global context. Lancet Diabetes Endocrinol. 5(10):758-759.	Exclude A single cross sectional study (PURE) - not a systematic review, meta- analysis or pooled analysis
Forouhi NG, Koulman A, Sharp SJ, Imamura F, Kröger J, Schulze MB, et al (2014) Differences in the prospective association between individual plasma phospholipid saturated fatty acids and incident type 2 diabetes: the EPIC- InterAct case-cohort study. Lancet Diabetes Endocrinol. 2(10):810-818.	Exclude A primary study - not a systematic review, meta- analysis or pooled analysis
Gholami F, Khoramdad M, Shakiba E, Alimohamadi Y, Shafiei J & Firouzi A (2017a) Subgroup dairy products consumption on the risk of stroke and CHD: A systematic review and meta-analysis. Med J Islam Repub Iran. 31:25.	<b>Exclude</b> Outside remit
Gholami F, Khoramdad M, Esmailnasab N, Moradi G, Nouri B, Safiri S, et al (2017b) The effect of dairy consumption on the prevention of cardiovascular diseases: A meta-analysis of prospective studies. J Cardiovasc Thorac Res. 9(1):1-11.	<b>Exclude</b> Outside remit
Goris AH, Westerterp-Plantenga MS & Westerterp KR (2000) Undereating and underrecording of habitual food intake in obese men: selective underreporting of fat intake. Am J Clin Nutr. 71(1):130-134.	<b>Exclude</b> Outside remit (relating to NDNS).
Guo J, Astrup A, Lovegrove JA, Gijsbers L, Givens DI & Soedamah-Muthu SS (2017) Milk and dairy consumption and risk of cardiovascular diseases and all- cause mortality: dose-response meta-analysis of prospective cohort studies. Eur J Epidemiol. 32(4):269-287.	<b>Exclude</b> Outside remit

Full reference	Exclusion/ inclusion
Hamley S (2017) The effect of replacing saturated fat with mostly n-6 polyunsaturated fat on coronary heart disease: a meta-analysis of randomised controlled trials. Nutr J. 16(1):30.	Included following consultation Discussed in chapter 8 of the latest version of the report.
Harcombe Z, Baker J & Davies B. Evidence from prospective cohort studies does not support current dietary fat guidelines: A systematic review and meta- analysis. Br J Sports Med. 2016a.	Already included
Harcombe Z, Baker JS, Cooper SM, Davies B, Sculthorpe N, DiNicolantonio JJ, et al (2015) Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-analysis. Open Heart. 2(1):e000196.	Exclude This review has been deleted from the report as Harcombe et al, (2015) has been superseded by Harcombe et al, (2016b).
Harcombe Z. Dietary fat guidelines have no evidence base: where next for public health nutritional advice? Br J Sports Med. 2016d.	Already included
Heart and Stroke Foundation of Canada (2015) Saturated fat, heart disease and stroke. Available from: <u>www.heartandstroke.ca/heart-and-stroke-position-</u> <u>statements</u>	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
Hébert JR, Frongillo EA, Adams SA, Turner-McGrievy GM, Hurley TG, Miller DR, et al (2016) Perspective: randomized controlled trials are not a panacea for diet-related research. Adv Nutr. 7(3):423-432.	<b>Exclude</b> Outside remit
Hooper L, Martin N, Abdelhamid A & Davey Smith G (2015) Reduction in saturated fat intake for cardiovascular disease. Cochrane Database Syst Rev. (6):CD011737.	Already included
Hooper L, Summerbell CD, Thompson R, Sills D, Roberts FG, Moore H, et al (2011) Reduced or modified dietary fat for preventing cardiovascular disease. Cochrane Database Syst Rev. (7):CD002137.	<b>Exclude</b> Hooper et al, (2015) is the most recent paper

Full reference	Exclusion/ inclusion
Hooper L, Summerbell CD, Higgins JP, Thompson RL, Capps NE, Smith GD, et al (2001) Dietary fat intake and prevention of cardiovascular disease: systematic review. BMJ. 322(7289):757-763.	<b>Exclude</b> Hooper et al, (2015) is the most recent paper
Houtsmuller AJ, Zahn KJ & Henkes HE (1980) Unsaturated fats and progression of diabetic retinopathy. Doc Ophthalmol. 48(2):363-371.	Exclude A primary study - not a systematic review, meta- analysis or pooled analysis (and included in Hooper et al, (2015))
Hu, FB (2010) Are refined carbohydrates worse than saturated fat? Am J Clin Nutr. 91(6):1541-1542.	Exclude Not a systematic review/ meta- analysis or pooled analysis
Javanbakht M, Jamshidi AR, Baradaran HR, Mohammadi Z, Mashayekhi A, Shokraneh F, et al (2018). Estimation and prediction of avoidable health care costs of cardiovascular diseases and type 2 diabetes through adequate dairy food consumption: a systematic review and micro simulation modeling study. Arch Iran Med. 21(5):213-222.	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
Jakobsen MU, O'Reilly EJ, Heitmann BL, Pereira MA, Bälter K, Fraser GE, et al (2009) Major types of dietary fat and risk of coronary heart disease: a pooled analysis of 11 cohort studies. Am J Clin Nutr. 89(5):1425-1432.	Already included
Jenkins B, West JA & Koulman A (2015) A review of odd-chain fatty acid metabolism and the role of pentadecanoic acid (C15:0) and heptadecanoic acid (C17:0) in health and disease. Molecules. 20(2):2425-2444.	<b>Exclude</b> Outside remit
Ley SJ, Metcalf PA, Scragg RK & Swinburn BA (2004) Long-term effects of a reduced fat diet intervention on cardiovascular disease risk factors in individuals with glucose intolerance. Diabetes Res Clin Pract. 63(2):103-112.	Exclude Primary study (included in Hooper et al, (2015)) - not a systematic review, meta- analysis or pooled analysis

Full reference	Exclusion/ inclusion
Li Y, Hruby A, Bernstein AM, Ley SH, Wang DD, Chiuve SE, et al (2015) Saturated fats compared with unsaturated fats and sources of carbohydrates in relation to risk of coronary heart disease: a prospective cohort study. J Am Coll Cardiol. 66(14):1538-1548.	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
Liang J, Zhou Q, Kwame Amakye W, Su Y & Zhang Z (2017) Biomarkers of dairy fat intake and risk of cardiovascular disease: a systematic review and meta analysis of prospective studies. Crit Rev Food Sci Nutr. 58(7):1122-1130.	<b>Exclude</b> Outside remit
Magni P, Bier DM, Pecorelli S, Agostoni C, Astrup A, Brighenti F et al (2017) Perspective: improving nutritional guidelines for sustainable health policies: current status and perspectives. Adv Nutr. 8(4):532-545.	<b>Exclude</b> Outside remit
Maki KC, Slavin JL, Rains TM & Kris-Etherton PM (2014) Limitations of observational evidence: implications for evidence-based dietary recommendations. Adv Nutr. 5(1):7-15.	<b>Exclude</b> Outside remit
Manrai AK, Patel CJ & Ioannidis JPA (2018) In the era of precision medicine and big data, who is normal? JAMA. 319(19):1981-1982.	<b>Exclude</b> Outside remit
Malhotra A, Redberg RF & Meier P (2017) Saturated fat does not clog the arteries: coronary heart disease is a chronic inflammatory condition, the risk of which can be effectively reduced from healthy lifestyle interventions. Br J Sports Med. 51(15):1111-1112.	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
Mensink, RP (2016) Effects of saturated fatty acids on serum lipids and lipoproteins: a systematic review and regression analysis. Geneva: World Health Organization. Available from: https://www.who.int/nutrition/publications/nutrientrequirements/sfa_system atic_review/en	Exclude Did not meet inclusion criteria as considered to be grey literature.
Mente A, de Koning L, Shannon HS & Anand SS (2009) A systematic review of the evidence supporting a causal link between dietary factors and coronary heart disease. Arch Intern Med. 169(7):659-669.	Already included

Full reference	Exclusion/ inclusion
Mente A, Dehghan M, Rangarajan S, McQueen M, Dagenais G, Wielgosz A, et al (2017) Association of dietary nutrients with blood lipids and blood pressure in 18 countries: a cross-sectional analysis from the PURE study. Lancet Diabetes Endocrinol. 5(10):774-787.	Exclude A single cross sectional study (PURE) - not a systematic review, meta- analysis or pooled analysis
Micha R & Mozaffarian D (2010) Saturated fat and cardiometabolic risk factors, coronary heart disease, stroke, and diabetes: a fresh look at the evidence. Lipids. 45(10):893-905.	Already included
Miettinen M, Turpeinen O, Karvonen M, Elosuo R & Paavilainen E (1972) Effect of cholesterol-lowering diet on mortality from coronary heart-disease and other causes: a twelve-year clinical trial in men and women. Lancet. 2(7782):835-838.	Exclude Primary study (included in Mozaffarian et al, (2010)) - not a systematic review, meta- analysis or pooled analysis
Moy TF, Yanek LR, Raqueño JV, Bezirdjian PJ, Blumenthal RS, Wilder LB et al (2001) Dietary counseling for high blood cholesterol in families at risk of coronary disease. Prev Cardiol. 4(4):158-164.	Exclude Primary study (included in Hooper et al, (2015)) - not a systematic review, meta- analysis or pooled analysis
Mozaffarian D, Micha R & Wallace S (2010) Effects on coronary heart disease of increasing polyunsaturated fat in place of saturated fat: a systematic review and meta-analysis of randomized controlled trials. PLoS Med. 7(3):e1000252.	Already included
Nago N, Ishikawa S, Goto T & Kayaba K (2011) Low cholesterol is associated with mortality from stroke, heart disease, and cancer: the Jichi Medical School Cohort Study. J Epidemiol. 21(1):67-74.	Exclude Does not consider saturated fat intake
NHS Digital (2018) Statistics on obesity, physical activity and diet – England years (2016/2017). Available from: <u>https://digital.nhs.uk/data-and-information/publications/statistical/statistics-on-obesity-physical-activity-and-diet/statistics-on-obesity-physical-activity-and-diet-england-2018</u> .	Include Data were used to update the statistics in the report

Full reference	Exclusion/ inclusion
Pfeuffer M & Jaudszus A (2016) Pentadecanoic and heptadecanoic acids: multifaceted odd-chain fatty acids. Adv Nutr. 7(4):730-734.	<b>Exclude</b> Outside remit
Pimpin L, Wu JH, Haskelberg H, Del Gobbo L & Mozaffarian D (2016) Is butter back? A systematic review and meta-analysis of butter consumption and risk of cardiovascular disease, diabetes, and total mortality. PLoS One. 11(6):e0158118.	<b>Exclude</b> Outside remit
Praagman J, Beulens JW, Alssema M, Zock PL, Wanders AJ, Sluijs I, et al (2016) The association between dietary saturated fatty acids and ischemic heart disease depends on the type and source of fatty acid in the European Prospective Investigation into Cancer and Nutrition–Netherlands cohort. Am J Clin Nutr. 103(2):356-365.	Exclude Not a systematic review, meta- analysis or pooled analysis
Praagman J, de Jonge EA, Kiefte-de Jong JC, Beulens JW, Sluijs I, Schoufour JD, et al (2016) Dietary saturated fatty acids and coronary heart disease risk in a Dutch middle-aged and elderly population. Arterioscler Thromb Vasc Biol. 36(9):2011-2018.	<b>Exclude</b> Not a systematic review, meta- analysis or pooled analysis
Postic C & Girard J (2008) The role of the lipogenic pathway in the development of hepatic steatosis. Diabetes Metab. 34(6):643-648.	<b>Exclude</b> Outside remit
Qin LQ, Xu JY, Han SF, Zhang ZL, Zhao YY & Szeto IM (2015) Dairy consumption and risk of cardiovascular disease: an updated meta-analysis of prospective cohort studies. Asia Pac J Clin Nutr. 24(1):90-100.	<b>Exclude</b> Outside remit
Ramsden CE, Hibbeln JR, Majchrzak SF & Davis JM (2010) n-6 Fatty acid-specific and mixed polyunsaturate dietary interventions have different effects on CHD risk: a meta-analysis of randomised controlled trials. Br J Nutr. 104(11):1586- 1600.	<b>Exclude</b> Outside the remit
Ramsden CE, Zamora D, Leelarthaepin B, Majchrzak-Hong SF, Faurot KR, Suchindran CM, et al (2013) Use of dietary linoleic acid for secondary prevention of coronary heart disease and death: evaluation of recovered data from the Sydney Diet Heart Study and updated meta-analysis. BMJ. 346:e8707.	Already included
Ramsden CE, Zamora D, Majchrzak-Hong S, Faurot KR, Broste SK, Frantz RP, et al (2016) Re-evaluation of the traditional diet-heart hypothesis: analysis of recovered data from Minnesota Coronary Experiment (1968-73). BMJ. 353:i1246.	Already included

Full reference	Exclusion/ inclusion
Ravnskov U, DiNicolantonio JJ, Harcombe Z, Kummerow FA, Okuyama H & Worm N (2014) The questionable benefits of exchanging saturated fat with polyunsaturated fat. Mayo Clinic Proc. 89(4):451-453.	Exclude Commentary – not a systematic review, meta- analysis or pooled analysis
Ravnskov U, Diamond DM, Hama R, Hamazaki T, Hammarskjöld B, Hynes N, et al (2016) Lack of an association or an inverse association between low-density- lipoprotein cholesterol and mortality in the elderly: a systematic review. BMJ open. 6(6):e010401.	<b>Exclude</b> Does not consider saturated fat intake
Raziani F, Tholstrup T, Kristensen MD, Svanegaard ML, Ritz C, Astrup A et al (2016) High intake of regular-fat cheese compared with reduced-fat cheese does not affect LDL cholesterol or risk markers of the metabolic syndrome: a randomized controlled trial. Am J Clin Nutr. 104(4) 973–981.	<b>Exclude</b> Outside remit
Rose GA, Thomson WB & Williams RT (1965) Corn oil in treatment of Ischaemic heart disease. Br Med J. 1(5449):1531-1533.	Exclude Primary study - not a systematic review, meta- analysis or pooled analysis
Scagliusi FB, Polacow VO, Artioli GG, Benatti FB & Lancha AH Jr (2003) Selective underreporting of energy intake in women: magnitude, determinants, and effect of training. J Am Diet Assoc. 103(10):1306-1313.	<b>Exclude</b> Outside remit (relating to NDNS)
Schwab U, Lauritzen L, Tholstrup T, Haldorsson TI, Riserus U, Uusitupa M, et al (2014) Effect of the amount and type of dietary fat on cardiometabolic risk factors and risk of developing type 2 diabetes, cardiovascular diseases, and cancer: a systematic review. Food Nutr Res. 58.25145.	Already included
Schwingshackl L & Hoffmann G (2014) Dietary fatty acids in the secondary prevention of coronary heart disease: a systematic review, meta-analysis and meta-regression. BMJ Open. 4(4):e004487.	Exclude Included diseased populations only
Siri-Tarino PW, Sun Q, Hu FB & Krauss RM (2010) Meta-analysis of prospective cohort studies evaluating the association of saturated fat with cardiovascular disease. Am J Clin Nutr. 91(3):535-546.	Already included

Full reference	Exclusion/ inclusion
Skeaff CM & Miller J (2009) Dietary fat and coronary heart disease: summary of evidence from prospective cohort and randomised controlled trials. Ann Nutr Metab. 55(1-3):173-201.	Already included
Smith CE, Coltell O, Sorlí JV, Estruch R, Martínez-González MÁ, Salas-Salvadó J, et al (2016) Associations of the MCM6-rs3754686 proxy for milk intake in Mediterranean and American populations with cardiovascular biomarkers, disease and mortality: Mendelian randomization. Sci Rep. 6:33188.	<b>Exclude</b> Outside remit
Soedamah-Muthu SS, Ding EL, Al-Delaimy WK, Hu FB, Engberink MF, Willett WC, et al (2011) Milk and dairy consumption and incidence of cardiovascular diseases and all-cause mortality: dose-response meta-analysis of prospective cohort studies. Am J Clin Nutr. 93(1):158-171.	<b>Exclude</b> Outside remit
St-Onge MP & Jones PJ (2002) Physiological effects of medium-chain triglycerides: potential agents in the prevention of obesity. J Nutr. 132(3):329-332.	<b>Exclude</b> Outside remit
Taubes G (2001) What if Americans ate less saturated fat? Science 291(5513):2538.	<b>Exclude</b> Outside remit
Tapsell LC (2015) Fermented dairy food and CVD risk. Br J Nutr. 113(Suppl. 2):S131-S135.	<b>Exclude</b> Outside remit
Treweek S & Zwarenstein M (2009) Making trials matter: pragmatic and explanatory trials and the problem of applicability. Trials. 10(1):37.	<b>Exclude</b> Outside remit
Truswell AS (2005) Some problems with Cochrane reviews of diet and chronic disease. Eur J Clin Nutr. 59(Suppl. 1):S150-S154.	<b>Exclude</b> Outside remit
Van Horn L, McCoin M, Kris-Etherton PM, Burke F, Carson JA, Champagne CM, et al. The evidence for dietary prevention and treatment of cardiovascular disease. J Am Diet Assoc. 108(2):287-331.	Already included
WHO (2018) Draft Report. Guidelines: saturated fatty acid and trans-fatty intake for adults and children.[Cited November 2018]. Available from: <u>https://extranet.who.int/dataform/upload/surveys/666752/files/Draft%20WH</u> <u>O%20SFA-TFA%20guidelines_04052018%20Public%20Consultation(1).pdf</u>	<b>NA</b> [this is a draft report therefore WHO recommendatio ns for saturated fats cannot be added to Table 4.1]

Full reference	Exclusion/ inclusion
Wolfram G, Bechthold A, Boeing H, Ellinger S, Hauner H, Kroke A, et al. (2015) Evidence-based guideline of the German Nutrition Society: fat intake and prevention of selected nutrition-related diseases. Ann Nutr Metab. 67(3):141- 120.	Already included Recommendati ons have already been added to Table 4.1
Woodhill JM, Palmer AJ, Leelarthaepin B, McGilchrist C & Blacket RB (1978) Low fat, low cholesterol diet in secondary prevention of coronary heart disease. Adv Exp Med Biol. 109:317-330.	Exclude Primary study - not a systematic review, meta- analysis or pooled analysis
Wu L & Sun D (2017) Consumption of yogurt and the incident risk of cardiovascular disease: a meta-analysis of nine cohort studies. Nutrients. 9(3).	<b>Exclude</b> Outside remit
Zong G, Li Y, Wanders AJ, Alssema M, Zock PL, Willett WC, et al (2016) Intake of individual saturated fatty acids and risk of coronary heart disease in US men and women: two prospective longitudinal cohort studies. BMJ. 355:i5796.	<b>Exclude</b> Outside remit

## **References included in SACN's response to comments**

COMA (1991) Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. London: HMSO.

COMA (1994) Nutritional aspects of cardiovascular disease, 46 ed. London: HMSO.

de Souza R & Anand S (2016) Saturated fat and heart disease. BMJ. 355:i6257.

de Souza RJ, Mente A, Maroleanu A, Cozma AI, Ha V, Kishibe T, et al (2015) Intake of saturated and trans unsaturated fatty acids and risk of all cause mortality, cardiovascular disease, and type 2 diabetes: Systematic review and meta-analysis of observational studies. BMJ (Online). 351.

DiNicolantonio J (2014) The cardiometabolic consequences of replacing saturated fats with carbohydrates or  $\Omega$ -6 polyunsaturated fats: Do the dietary guidelines have it wrong? . Open Heart. 1:e000032.

Farvid MS, Ding M, Pan A, Sun Q, Chiuve SE, Steffen LM, et al (2014) Dietary linoleic acid and risk of coronary heart disease: A systematic review and meta-analysis of prospective cohort studies. Circulation. 130(18):1568-1578.

Ference B, Ginsberg H, Graham I, Ray K, Packard C, Bruckert E, et al (2017) Low-density lipoproteins cause atherosclerotic cardiovascular disease. 1. Evidence from genetic, epidemiologic, and clinical studies. A consensus statement from the European Atherosclerosis Society Consensus Panel. Eur Heart J. 38:2459-2472.

Hamley S (2017) The effect of replacing saturated fat with mostly n-6 polyunsaturated fat on coronary heart disease: a meta-analysis of randomised controlled trials. Nutr J. 16.

Harcombe Z (2017) Dietary fat guidelines have no evidence base: where next for public health nutritional advice? Br J Sports Med. 51:769-774.

Harcombe Z, Baker J & Davies B (2016a) Evidence from prospective cohort studies does not support current dietary fat guidelines: A systematic review and meta-analysis. British Journal of Sports Medicine.

Harcombe Z, Baker J & Davies B (2017) Evidence from prospective cohort studies does not support current dietary fat guidelines: a systematic review and meta-analysis. Br J Sports Med. 51:1743-1749.

Harcombe Z, Baker JS, Cooper SM, Davies B, Sculthorpe N, DiNicolantonio JJ, et al (2015) Evidence from randomised controlled trials did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review and meta-analysis. Open Heart. 2(1).

Harcombe Z, Baker JS & Davies B (2016b) Evidence from prospective cohort studies did not support the introduction of dietary fat guidelines in 1977 and 1983: a systematic review. British Journal of Sports Medicine.

Harcombe Z, Baker JS, DiNicolantonio JJ, Grace F & Davies B (2016b) Evidence from randomised controlled trials does not support current dietary fat guidelines: a systematic review and meta-analysis. Open Heart. 3(2).

Hooper L, Martin N, Abdelhamid A & Davey Smith G (2015) Reduction in saturated fat intake for cardiovascular disease. Cochrane Database of Systematic Reviews. (6).

Houtsmuller AJ, Zahn KJ & Henkes HE (1979) Unsaturated fats and progression of diabetic retinopathy. Documenta Ophthalmologica. 48(2):363-371.

Jakobsen U, O'Reilly J, Heitmann L, Pereira A, Bälter K, Fraser E, et al (2009) Major types of dietary fat and risk of coronary heart disease: a pooled analysis of 11 cohort studies. The American journal of clinical nutrition. 89(5):1425.

Li Y, Hruby A, Bernstein A, Ley S, Wang D, Chiuve S, et al (2015) Saturated fats compared with unsaturated fats and sources of carbohydrates in relation to risk of coronary heart disease: a prospective cohort study. Journal of the American College of Cardiology. 66:1538-1548.

Malhotra A, Redberg R & Meier P (2017) Saturated fat does not clog the arteries: coronary heart disease is a chronic inflammatory condition, the risk of which can be effectively reduced from healthy lifestyle interventions Br J Sports Med. 51:1111-1112.

Mensink R (2016) Effects of saturated fatty acids on serum lipids and lipoproteins: a systematic review and regression analysis. .

Mente A, Dehghan M, Rangarajan S, McQueen M, Dagenais G, Wielgosz A, et al (2017) Association of dietary nutrients with blood lipids and blood pressure in 18 countries: a crosssectional analysis from the PURE study. Lancet Diabetes Endocrinol. 5:774-787.

Micha R & Mozaffarian D (2010) Saturated fat and cardiometabolic risk factors, coronary heart disease, stroke, and diabetes: a fresh look at the evidence. Lipids. 45(10):893-905.

Mozaffarian D, Micha R & Wallace S (2010) Effects on coronary heart disease of increasing polyunsaturated fat in place of saturated fat: A systematic review and meta-analysis of randomized controlled trials. PLoS Medicine. 7(3).

Nago N, Ishikawa S, Goto T & Kayaba K (2011) Low cholesterol is associated with mortality from stroke, heart disease, and cancer: the Jichi Medical School Cohort Study. . J Epidemiol. 21:67-74.

Ravnskov U, Diamond D, Hama R, Hamazaki T, Hammarskjöld B, Hynes N, et al (2016) Lack of an association or an inverse association between low-density lipoprotein cholesterol and mortality in the elderly: a systematic review. BMJ Open. 6:e010401.

Rose GA, Thomson WB & Williams RT (1965) Corn Oil in Treatment of Ischaemic Heart Disease. BMJ. 1(5449):1531-1533.

SACN (2015) Carbohydrates and Health The Stationery Office. Available from: <u>https://www.gov.uk/government/uploads/system/uploads/attachment\_data/file/445503/S</u> <u>ACN\_Carbohydrates\_and\_Health.pdf</u>

Schwab U, Lauritzen L, Tholstrup T, Haldorsson TI, Riserus U, Uusitupa M, et al (2014) Effect of the amount and type of dietary fat on cardiometabolic risk factors and risk of developing type 2 diabetes, cardiovascular diseases, and cancer: a systematic review. Food & Nutrition Research. 58:10.3402/fnr.v3458.25145.

Schwingshackl L & Hoffmann G (2014) Dietary fatty acids in the secondary prevention of coronary heart disease: a systematic review, meta-analysis and meta-regression. BMJ Open. 4(4).

Skeaff CM & Miller J (2009) Dietary fat and coronary heart disease: Summary of evidence from prospective cohort and randomised controlled trials. Annals of Nutrition and Metabolism. 55(1-3):173-201.

Te Morenga L & Montez J (2017) Health effects of saturated and trans-fatty acid intake in children and adolescents: Systematic review and meta-analysis. . PLoS ONE. 12.

Van Horn L, McCoin M, Kris-Etherton M, Burke F, Carson SA, Champagne M, et al (2008) The evidence for dietary prevention and treatment of cardiovascular disease. Journal of the American Dietetic Association. 108(2):287.

Woodhill JM, Palmer AJ, Leelarthaepin B, McGilchrist C & Blacket RB (1978) Low fat, low cholesterol diet in secondary prevention of coronary heart disease. Adv Exp Med Biol. 109:317-330.