Paper for discussion: risk-benefit assessment report – structure and content

Agenda item: 5
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Introduction and background

At the joint SACN/COT Potassium-based Sodium Replacers Working Group meeting in January 2016, it was agreed by members that the SACN and COT secretariats would undertake parallel benefit and risk assessments, which would be combined into one risk-benefit assessment report. The tiered approach developed by BRAFO is being used to compile these assessments.¹

Below is a proposed outline for the risk-benefit assessment report, including suggested content areas. The outline and content reflects that of published case studies, which follow the BRAFO-tiered risk-benefit approach.²

Working group members are invited to:

- Comment on the proposed structure and content, by reference to Watzl et al., 2012
- Discuss draft recommendations for Government.

¹ See Hoekstra et al. (2012) BRAFO tiered approach for benefit-risk assessment of foods Food Chem. Toxicol. 50; S684-S698
² Watzl et al. (2012) Application of the BRAFO-tiered approach for benefit-risk assessment to case studies in natural foods Food Chem. Toxicol. 50; S699-S709
Introduction

Background to SACN draft position statement *potassium-based sodium replacers: assessment of the benefits of increased potassium intakes to health* and COT draft statement *potassium-based replacements for sodium chloride and sodium-based additive.*

Pre-assessment and problem formulation

- Status quo – potassium and sodium intake.
- Association of high Na intake with high BP and therefore increased CVD risk.
- Question - What is the overall balance of health benefits and risks of using potassium-based sodium replacers in some foods in the UK?
- List potential benefits and risks of increased dietary potassium intake
- Summary of strength of evidence (study type), geographical location, dietary v supplement intake
- Definition of reference versus alternative scenarios: reference scenario is current levels of sodium and potassium in foods in the UK. Alternative scenario(s) are level(s) of sodium replacement modelled by FSA.

**BRAFO tier 1 level**

*Provide summary of evidence with commentary on quality of evidence and magnitude of effect. This can be taken from the SACN and COT reports.*

Positive health effect identification and characterization:

**Increased potassium**

- Blood pressure
- Stroke
- Bone health
- Population potassium status

**Decreased sodium**

- Blood pressure
- Stroke

**Hazard identification and characterization:**

**Increased potassium**

- Adverse cardiac effects, arrhythmia and death

**Decreased sodium**
• Dietary sodium not relevant to hyponatremia

**Conclusion**

• The alternative scenario versus the reference scenario(s) involves potential health benefits as well as potential health risks. Hence, this question needs a benefit-risk assessment (proceed to tier 2).

**BRAFO tier 2 level**

*Benefits and risks to be characterized on the basis of severity of the effects and the number of individuals affected*

**Benefit assessment**

_Expand on the following:_ The potential benefits, although modest in terms of risk reduction, are in relation to common risk factors for chronic disease and health outcomes and therefore have a large impact on the number of individuals affected.

**Risk assessment**

_Expand on the following:_ Increased dietary potassium intake is not expected to have an adverse effect in healthy adults. At risk groups include infants due to immature kidney function, older adults due to reduced renal function, people with renal disease, people on medication that affects potassium balance and people with undiagnosed kidney disease.

**Conclusions**

_Expand on the following:_ The tier 2 assessment indicates that the potential risk/benefit outweigh the potential benefit/risk. Include reason for not proceeding to tier 3.

**Recommendations for Government**

Draft recommendations to be discussed.