TOX/2014/38

COMMITTEE ON TOXICITY OF CHEMICALS IN FOOD, CONSUMER PRODUCTS AND THE ENVIRONMENT

Potassium-based replacements for table salt and sodium additives.

Additional data on hyperkalaemia.

Background and introduction

1. The Department of Health (DH) has asked the Scientific Advisory Committee on Nutrition (SACN) to consider the current recommendations on potassium based salt replacers in time for setting new Responsibility Deal salt targets. The aim of the salt targets is to reduce population sodium intakes, thereby reducing blood pressure and the risk of stroke.

2. DH does not currently recommend the use of potassium based replacements for sodium chloride and sodium based additives as a means of achieving sodium reduction since their use would continue to maintain a higher salt flavour in food, the general aim is to gradually reduce salt in products so that palates of consumers become used to lower salt levels. In addition, increasing potassium levels in food could have potential adverse effects in vulnerable individuals who could be at risk of hyperkalaemia due to impaired or immature kidney function. These vulnerable groups could include the elderly, very young children and individuals with kidney disease. Some individuals with impaired kidney function are required to consume a low potassium diet, and would need to avoid products using salt replacers, but there are also many individuals with undiagnosed disease who might be adversely affected by increased levels of potassium in the diet.

3. Industry has asked DH to reconsider this view as some producers would like to use, and may already be using, potassium based salt replacers to achieve sodium reduction in food. In general the products concerned are those where further sodium reduction would not be possible by reformulation since the sodium salt has a function such as a preservative or a raising agent as well as providing taste. Potassium cannot totally replace sodium as it does not have the flavouring properties of sodium and is considered to have a metallic aftertaste. It has been suggested that a maximum of 25% of added sodium weight for weight (w/w) could be replaced by a potassium equivalent.

Potassium toxicity

4. Potassium plays a major role in establishing the resting cell membrane potential, particularly in cardiac and neuromuscular cells. Serum potassium is in the range 3.5-5.0 mmol/L and is tightly regulated. Excess potassium is excreted by short and long term renal and extra-renal mechanisms, linked to the homeostasis of water and other minerals. Hyperkalaemia is defined as serum potassium ≥ 5.5 mmol/L.

5. The organ systems affected by hyperkalaemia are cardiac, neuromuscular and gastrointestinal. Patients may complain of vague feelings of not feeling well, gastrointestinal symptoms or generalised weakness.

6. As serum potassium levels increase, physiological changes in the heart occur of increasing severity, potentially resulting in atrioventricular (AV) block or ventricular dysrhythmia. However, the serious complications do not strictly correlate with a given potassium level and are related more to the rate of rise in the potassium level, the effect on cardiac conduction and the underlying cause of the hyperkalaemia.

7. The most serious concern is impaired cardiac conduction with risk of sudden death from asystole or ventricular fibrillation. Neuromuscular signs and symptoms include muscle cramps, weakness, paralysis, paresthesia and decreased deep tendon reflex. Usually, severe symptoms do not occur until serum potassium levels reach > 7 mmol/L and a rapidly rising level is more dangerous than a slowly rising level.

8. In individuals with normal renal function, hyperkalaemia from excess potassium load is very uncommon, with short term intakes of approximately 15 g/day potassium not resulting in serum potassium levels being outside the normal range provided that fluid intake is sufficient and intake is spread out.

9. The large majority of cases of hyperkalaemia occur when potassium excretion is impaired by a medical condition or by the use of certain medications in a patient with some degree of underlying renal dysfunction. Dietary salt substitutes, potassium supplements, penicillin potassium therapy and drinking potassium softened water may also cause hyperkalaemia in the pre-disposed patient.

COT considerations to date

Exposure assessment

10. The possible change to potassium intakes from the proposed uses of potassium based salt-replacers was modelled by the exposure assessment team at the FSA; the initial work suggested that an additional intake of up to 500- 600 mg/day potassium could occur. This was based on the assumption that for foods where potassium could be used to replace sodium, this would be done 25% w/w was hoped that this assessment could be refined by the use of data supplied by industry.

Vulnerable groups- infants and young children

11. There are few data available on the effects of excess potassium in infants and young children, however, data on renal development and maturation suggest that this group would not be expected to be any more sensitive to potassium excess than older children or adults.

Vulnerable groups- individuals with impaired kidney function.

12. Nearly 2 million adults (4.3% of the population) in England may have stage 3-5 kidney disease, with an estimated further 0.9-2 million having undiagnosed stage 3-5 kidney disease. Of these individuals, a proportion (approximately 3%) will need

to restrict their potassium intake as they will no longer have the capacity to excrete excess potassium; this group will include those with both diagnosed and undiagnosed kidney disease.

Overall conclusions to date

13. The COT agreed that an increase in potassium intake through the use of potassium based replacements for sodium chloride or sodium based additives was not of concern for healthy individuals, both adults and children.

14. It was noted that products using potassium equivalents tended to be labelled allowing individuals on low potassium diets to identify such products. However, extensive use of such products would add further restrictions to the products that could be consumed by such individuals.

15. With regard to individuals with undiagnosed kidney disease, COT agreed that there was insufficient information to draw further conclusions, but hoped to revisit the issue towards the end of 2014 when it was hoped further data might have been identified.

New information

Hyperkalaemia

16. Dr Suckling, a consultant nephrologist who has been advising the COT has, with the assistance of her colleagues, obtained information on hyperkalaemia in patients admitted to hospital in a 4 month period and to what extent individuals had risk factors for hyperkalaemia and were known to medical practitioners. This paper is attached at Annex A.

17. This paragraph has been removed from the publicly available version of this discussion paper as it contains pre-publication data.

Exposure assessment.

18. When the initial exposure assessment for the potential increase in potassium arising from the use of potassium equivalents for sodium chloride and sodium-based additives, it was assumed that they would be replaced by the potassium equivalent at a maximum of 25% w/w. Although very limited recipe data have been obtained from industry this has not materially affected the exposure assessment, since the newly received recipe information were for few selected food items within a larger group (bakery products) that made less than 3% contribution to overall potassium intakes in the original assessment. The data received also suggest that not all companies are taking the same approach to the replacement or reduction of sodium, adding potential complexity to the assessment. However the limited data that are available are reasonably consistent with an estimated replacement level of 25% w/w. Therefore the previous exposure estimate of a maximum of 500-600 mg additional exposure to potassium (see TOX/2013/44) still stands.

19. Data on discrete food groups such as bread that would make a more significant contribution to the overall estimate are not currently available. If further

refinement of the exposure assessment is needed, it is likely to require a significant amount of work as well as potential usage data from industry.

Data from the literature

20. No additional relevant data have been identified in the scientific literature.

Conclusions

21. The Committee are asked to consider the following questions:

a) Whether they have any comments on the additional data provided on hyperkalaemia.

b) Do the additional data on hyperkalaemia provide reassurance with respect to the effect of increased potassium intakes to individuals with undiagnosed kidney disease?

c) If so, are members content with the potentially increased use of potassium based replacements for sodium chloride and sodium based additives?

d) If not, can members identify an increase in potassium that would be acceptable or would any increase be inappropriate?

e) Is further refinement to the exposure assessment required?

f) If so, what would be most useful to the committee?

g) Whether they have any additional comments.

Secretariat
November 2014

Annex A to TOX/2014/38

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