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GUIDANCE NOTE

Best Practice on the Use of Potassium-based Salt Substitutes for the Food Industry

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Table of Contents

List of Tables

Abbreviations

CKD Chronic Kidney Disease

COT Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment

EU European Union

EFSA European Food Safety Authority

FDA Food and Drug Administration

FSAI Food Safety Authority of Ireland

IOM Institute of Medicine

IUNA Irish Universities Nutrition Alliance

RI Reference Intake

SACN Scientific Advisory Committee on Nutrition

UK United Kingdom

WHO World Health Organisation

1. Introduction

Salt (i.e. sodium chloride [1]) is an essential nutrient used in the body for fluid and electrolyte balance and normal cellular functions. Salt is naturally present in most unprocessed foods at low levels. Salt and various additives which contain sodium e.g. sodium nitrite, monosodium glutamate etc. are also added to food during processing for various sensory, technological and preservation purposes which enhance both the safety and quality of foods (EFSA, 2005). Salt is also added to food by consumers, both during cooking and/or at the table for seasoning and flavouring purposes. This addition of salt to food by consumers is often referred to as discretionary salt.

In Ireland the daily salt intake of Irish adults has been estimated to be more than 11 g/day in men and 8 g/day in women aged 18-64 years (IUNA, 2011a). These intakes are well in excess of the recommended daily intake of 6 g per/day (FSAI, 2016). Diets which are high in salt are a major public health issue in many countries worldwide, including Ireland as excess salt intake can lead to increased risk of high blood pressure and related cardiovascular diseases such as stroke (FSAI 2005, 2016).

The main sources of salt in the Irish diet are processed foods (in particular meat and fish products, bread, soups and sauces) which make up about 70% of the total intake. The remaining 30% comes from naturally occurring salt in food and discretionary salt added by consumers (IUNA, 2011b).

Since 2003 the Irish food industry has improved its manufacturing practices to avoid unnecessary use of salt in processed foods. In parallel the industry has also reformulated [2] processed foods to gradually reduce salt contents (FSAI, 2012; FSAI, 2018; WHO, 2013). As part of that process of reformulation, the Food Safety Authority of Ireland (FSAI) has previously advised against the use of potassium-based salt substitutes [3] for the following reasons: (FSAI, 2005)

- The overarching aim of the FSAI salt reduction strategy was to reduce the salt content of processed food and the Irish consumer preference for salty food.
- The use of salt substitutes did not address the need of the food industry to improve its processing techniques to reduce the use of unnecessary salt in manufacturing.

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[1] The use of the word “salt” throughout this document denotes sodium chloride or common table salt.
[2] The use of the word “reformulated” or “reformulation” in this document refers to the reduction and/or replacement of sodium in processed foods.
[3] Potassium-based salt substitutes includes potassium chloride, potassium phosphate, potassium bicarbonate and other potassium-based ingredients.

- Concerns about the possible vulnerability of certain people with impaired kidney function [4] to increasing potassium intakes from the use of salt substitutes in processed foods.

The prevalence of chronic kidney disease (CKD) in the Irish health system has been estimated to be as high as 11.8% or 1 in 8 patients (Stack et al, 2014). Life-threatening hyperkalaemia caused by the use of potassium-based salt substitutes has also been reported to affect individuals with impaired renal excretion, as well as patients with heart disease (Parpia et al, 2018). Therefore, the perceived benefits of using potassium-based salt substitutes to reduce salt in processed foods must be carefully balanced against the possible health effects for certain population sub-groups.

However, reducing salt in some processed foods without significantly altering recipes, is very challenging and can affect both product safety and quality. The use of potassium-based salt substitutes has been suggested by the food industry as another way to reduce salt in processed foods.

In 2016 the Scientific Committee of the FSAI reviewed its previous advice and concluded that potassium-based salt substitutes could be used by the food industry where reduction of salt could be detrimental to food safety and/or the physical or organoleptic properties of foods (FSAI, 2005; FSAI, 2016). The Scientific Committee of the FSAI recommended that the FSAI develop and issue best practice guidelines to the food industry on the use of potassium-based salt substitutes to minimise any perceived risk to vulnerable people (FSAI, 2016).

[4] The kidneys help maintain the body's potassium balance and in people with impaired kidney function, there is a concern that increased potassium intake may lead to hyperkalaemia or chronic kidney disease (CKD) (Stack et al, 2014; Parpia et al, 2018).

2. Scientific Evidence for use of potassium-based salt substitutes

In 2012, the World health Organisation (WHO) recommended an increase in potassium intake from food to reduce blood pressure and the risk of cardiovascular disease such stroke and coronary heart disease in adults. A recommendation was also made to increase potassium intake from food to control blood pressure in children (WHO 2012). The WHO suggested an intake of at least 3500 mg/day of potassium for adults with an adjustment downwards for children, based on the energy requirements of children relative to those of adults (WHO, 2012).

In 2013, the United Kingdom's Department of Health asked the Scientific Advisory Committee on Nutrition (SACN) to provide advice on the potential risks and benefits of reducing the salt (sodium) content of foods using potassium-based sodium replacers (SACN, 2017). SACN also asked the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) to assess the potential risks of using potassium-based sodium replacers (COT, 2017).

In a joint statement issued by SACN and COT in 2017 it made two conclusions: (SACN-COT 2017)

- Potential beneficial effects of reducing sodium in foods using potassium-based sodium replacers include reduced blood pressure and reduced stroke incidence. Potential risks include an increase in hyperkalaemia in individuals with previously undiagnosed chronic renal impairment.
- Overall, at a population level, the potential benefits of using potassium-based sodium replacers to help reduce sodium in foods outweigh the potential risks. Moving from the reference to the alternative scenario, i.e. moving the UK general population from current sodium and potassium intakes to reduced sodium and increased potassium intakes, as a result of substituting 15-25% of sodium with potassium, would result in an overall benefit to the general population of the UK. These beneficial effects at an individual level are likely to be small but would impact a large proportion of the population.

Three recommendations for the UK government were also made in the joint statement: (SACN-COT, 2017)

- The government should consider encouraging food companies to explore the use of potassium-based sodium replacers to help reduce sodium levels in foods, up to the levels of substitution and in the foods considered in the modelling performed for this benefit-risk assessment.
- Risk managers should consider how to monitor the level of substitution of potassium for sodium in foods and the types of foods in which substitution is used. If these become

materially different from those assumed for the modelling performed for this benefit-risk assessment, the government should reassess the balance between benefits and risks.

- If the age structure of the UK population, or the percentage of people with CKD or potassium intakes become materially different from those assumed for the modelling performed for this benefit-risk assessment, the government should reassess the balance between benefits and risks.

In its opinion on dietary reference values for potassium in 2016, the European Food Safety Authority (EFSA) stated that randomised controlled trials and an observational cohort study carried out in a European adult population provided evidence that a potassium intake of 3,500 mg (90 mmol)/day has beneficial effects on blood pressure in adults. Furthermore, EFSA indicated that there was consistent evidence from observational cohort studies that potassium intakes below 3,500 mg/day were associated with a higher risk of stroke. EFSA considers a potassium intake level of 3,500 mg/day an adequate intake for the adult population of men and women (EFSA 2016).

3. Salt reformulation of processed foods

In Ireland and many other countries, the process of reformulating processed foods without replacing salt and reducing salt intake has been a gradual process. This allows for consumers palates to adapt gradually to the changes in the taste of processed foods which are reformulated. This gradual adaptation is important because consumers must continue to purchase and consume reformulated processed foods for the process of reformulation to continue.

While the reformulation of processed foods by removing salt alone, can be technically difficult and limited in some cases by food safety concerns, substitution with an alternative chloride-based salt such as potassium chloride to a certain extent can compensate, satisfying the needs of both consumers and reformulators (Van Raaij et al, 2009; FDA, 2019).

In the reformulation of some processed foods it can be difficult to reduce salt beyond a certain point while maintaining consumer acceptance and preventing consumers simply adding salt back into the food. As such potassium-based salt substitutes are useful when: (van der Klaauw & Smith, 1995; Bidlas & Lambert 2008; Haper & Getty, 2012; Verma & Banerjee 2012; Kloss et al 2015)

- Further salt reduction causes problems with product taste which cannot be compensated by recipe rebalancing.
- Further salt reduction could result in food safety issues with the product.
- Large reductions in salt are required to achieve salt reduction targets or a legislative requirement within an acceptable timeframe.

Potassium-based salt substitutes have become the most widely available salt replacement ingredients either alone or in combination with other ingredients (IOM 2010). Any replacement of salt by potassium chloride or potassium chloride blends will increase the potassium content of the processed food. However, potassium chloride has bitter, acrid, and metallic taste properties which can limit its use as a salt substitute in processed foods (Horita et al 2011; Buttriss, 2013; Cepanec et al 2017). If used at too high a level, these unpleasant taste properties can be prevalent and even prevent the perception of saltiness in the food (Feltrin et al 2015). Therefore, potassium chloride is commonly used by the food industry as a partial replacement for salt (Barnett et al 2019).

In some instances, additives such as glutamic acid, monosodium glutamate, yeast extracts, vegetable proteins, organic acids, sugars, sweeteners etc. can be used to mask or block any unpleasant taste properties and decrease the use of salt in processed foods without reducing the perceived salty taste (Desmond, 2006 & 2007; Guàrdia et al, 2006; Horita et al, 2011; Mitchell et

al, 2013; Kloss et al, 2015; van Buren et al, 2016; Jinap et al, 2016; Inguglia et al, 2017). Table 1 outlines the applications and characteristics of some selected salt substitutes:

Table 1 Reformulation using various salt substitutes [a-c]

Ingredient	Food Applications Worldwide [e]	Common Characteristics
Potassium Chloride [d]	As a direct partial replacement for salt in foods like cheese, bread, snacks, condiments	Relatively salty in taste with bitter taste discernible to many people. It has been shown to have equivalent antimicrobial effects as sodium chloride on common bacterial pathogens. Has been shown to have a similar effect to salt in strengthening gluten in bread manufacture.
Magnesium Chloride [d]	Coagulate with soy products, health supplements	Relatively salty in taste with significant bitterness; high concentrations required
Calcium Chloride [d]	Canned vegetables, tofu and cheese as a firming agent, sports drinks as an electrolyte, in brewing to adjust acidity and as a dough-strengthening and raising agent in bakery	Relatively salty in taste with significant bitterness
Magnesium Sulphate [d]	As a firming agent in soy, flavour enhancer in bottled water, fermentation aid in the processing of beer and malt beverages, health supplements	Relatively salty in taste with significant bitterness
Monosodium Glutamate [d]	Typically used as a flavour enhancer i.e. umami flavour. Can also partially replace salt in a wide range of foods due to its sodium content. In combination with other glutamate salts like monopotassium glutamate or calcium di-glutamate it can further reduce salt. It is also often found as an ingredient of various hydrolysed vegetable proteins and yeast extracts.	No strong taste by itself
Yeast Extracts and HVP	Typically used as a flavour enhancer in various foods including dried soups, gravies, spreads etc.	Relatively strong meaty/broth flavours
Proprietary Products	As a partial replacement for salt in a wide range of foods	Proprietary products are manufactured by several companies which consist of various salt replacement ingredients, salt enhancers and masking agents

[a] Adapted: EFSA (2019); Scourboutakos et al (2018); Cepanec et al (2017); Inguglia et al (2017); Kloss et al (2015); Mitchell et al (2013); Horita et al (2011); IOM (2010); Bidlas & Lambert (2008); Desmond, (2006 & 2007); Regulation (EC) No 1333/2008 on Food Additives

[b] Non-exhaustive list, for illustration purposes

[c] Salt (sodium chloride) with an altered crystalline structure is not considered a salt replacement ingredient. However, its use has been shown to reduce the concentration of salt in processed food by allowing more intense salty taste with smaller amounts of added salt

[d] Authorised food additives in the European Union (EU) in accordance with Annex II and III to Regulation (EC) No 1333/2008 on food additives and specific purity criteria defined in the Commission Regulation (EU) No 231/2012

[e] Some specific food applications are not approved in the European Union despite a food additive having approval.

4. Best Practice in using Potassium-based Salt Substitutes

High dietary intakes of salt in Ireland are a public health issue due to the increased risk of hypertension and related cardiovascular diseases in the population. This situation has been the basis of reformulation of processed foods to reduce salt since 2003. (FSAI, 2012; FSAI, 2018; WHO, 2013)

The use of potassium-based salt substitutes by the food industry has emerged as an option to help with reformulation to reduce salt. However, the use of potassium-based salt substitutes must be tempered with concerns about the possible vulnerability of some population sub-groups to excessive consumption of potassium. It is recommended that the food industry:

I. Examine any technical and/or food safety limitations identified which prevents further salt reduction as part of a reformulation programme of existing processed food products or development of new products.
II. Be aware that the use of potassium-based salt substitutes should not be solely for the purpose of flavour maintenance, i.e. saltiness or flavour enhancement. There is a public health obligation on the food industry to continue to work on reducing the perception of saltiness in processed foods by the Irish population.
III. Where processed food is reformulated with the addition of potassium-based salt substitutes, consideration should be given to the communication of relevant information (including total potassium content) to vulnerable groups e.g. people with CKD who may consume those processed foods.

Best practice for using potassium-based salt substitutes for reformulation of processed foods should, where appropriate, include the following:

1. Seek advice from a competent authority like the FSAI, a representative trade body, academic institution or competitors with experience in reformulation.

2. Assess the capacity to reformulate the processed food with better manufacturing practices and reduced salt (sodium chloride), including the following:
    - The current salt levels used and the contribution of sodium from other sources such as additives.
    - The salt levels in similar competitor products and low salt versions of these products if available.

- The manufacturing process and how and why salt is used.
- The purpose of salt in the product.
- The target market for the product.
- Financial concerns related to reformulation.
- Food safety or food quality issues related to reformulation.

3. Reformulate and manufacture the processed food with reduced salt applying gradual, incremental reductions which do not impact on product safety, quality and the functionality of salt in relation to manufacturing process efficiency.

4. Review all reformulation work at regular intervals to ensure product safety, quality and sales are not impacted. For each processed food consider the following:
    - Levels of salt reduction achieved
    - Comparison of levels of salt reduction in similar competitor products
    - Impact of those salt reductions on sales, shelf-life, quality, safety,
    - If further salt reductions are practical
    - If there are other products within a category that salt can be further reduced
    - Technical issues experienced whilst reducing salt and if further technical issues are foreseeable with continued salt reduction
    - If possible, review sales and marketing data to determine consumption patterns of your product. This data may also be used to estimate the impact of using potassium-based salt substitutes on potassium intakes, particularly in any identified vulnerable groups (Drewnowski et al 2014; FSAI 2018).

5. If following the above review, further salt reductions are required but not possible with further manufacturing improvements and/or salt reductions the food business could consider the use of potassium-based salt substitutes.

6. Consider the rational for the proposed use of the potassium-based salt substitute.

7. Consider the type of potassium-based salt substitute to be used and its legality for use under Regulation (EC) No. 1333/2008 on Food Additives.

8. Outline a specification for the processed food in which the potassium-based salt substitute will be used.

9. Define the levels of both salt (sodium chloride) and potassium in the processed food before reformulation. Note that sodium and potassium can be present naturally in a processed food or as part of other additives and ingredients used in the manufacture of the processed food.

10. Define the level at which the potassium-based salt substitute will be used in the processed food. Note the following:
    - Published data on levels of potassium-based salt substitutes used in food can vary widely. To determine the amount of substitution of salt with a potassium-based salt substitute it is recommended that consideration is given to the types of foods, their consumption patterns and the substitution scenarios (15-25%) published by SACN and COT (SACN, 2017; COT, 2017; SACN-COT, 2017) .
    - In all cases it is recommended that potassium-based salt substitutes are used at levels within recommended daily intakes. Recent guidelines recommend adults consume < 2000 mg of sodium and at least 3500 mg/day of potassium. (WHO, 2012; EFSA, 2016; Cepanec et al, 2017)

11. Estimate the salt reduction in the processed food in which the potassium-based salt substitute will be used.

12. Determine the total level of salt (sodium chloride) and potassium in the processed food after reformulation.

13. Verify the determined levels of salt (sodium chloride) and potassium in the processed food versus estimated levels to ensure they are correct.

14. Routinely verify the levels of salt (sodium chloride) and potassium in the processed food against labelled values.

5. Labelling in the European Union

While there has been strong support by the food industry in Europe to label potassium chloride, used to reformulate processed food and reduce salt, with more consumer-friendly names such as potassium salt or potassium chloride salt, the current EU legislative framework does not provide for this type of labelling (Culinaria Europe 2018; Michail 2018; FDA, 2019).

Regulation (EU) No. 1169/2011 establishes the general principles, requirements and responsibilities governing food information and in particular, food labelling. Food information is defined as:

> 'Information concerning a food and made available to the final consumer by means of a label, other accompanying material, or any other means including modern technology tools or verbal communication'.

Potassium chloride and other potassium-based salt substitutes will fall under general ingredients used in food unless they are additives in which case they fall under Regulation (EU) No. 1333/2008 on food additives. However, whether a general ingredient or an additive they must be labelled in the ingredient declaration of the food product under the rules of Regulation (EU) No. 1169/2011. If the potassium-based salt substitute falls under general ingredients the name of the ingredient should be its legal name. In the absence of a legal name, a customary name or a 'descriptive name' should be used but must be specific enough to accurately describe the ingredient used.

If the potassium-based salt substitute is an approved additive under Regulation (EU) No. 1333/2008, it must be included in the list of ingredients either using its chemical designation or an E-number.

As regards nutritional information Regulation (EU) No. 1169/2011 provides for a mandatory nutrition declaration of the majority of processed foods consisting of the energy value, the amounts of fat, saturates, carbohydrate, sugars, protein and salt. The content of the mandatory nutrition declaration may be supplemented with an indication of the amounts of one or more of the following:

- Monounsaturates
- Polyunsaturates
- Polyols
- Starch
- Fibre

- Any of the vitamins or minerals listed in Part A (1) of Annex XIII in Regulation (EU) No 1169/2011 and present in significant amounts as defined in Part A (2) of Annex XIII of Regulation (EU) No 1169/2011.

Note that under Part A (1) of Annex XIII in Regulation (EU) No. 1169/2011 there is a daily reference intake (RI) of 2000 mg set for potassium. If potassium is added to food for nutritional purposes and the total potassium is either 15% of the RI in solid food or 7.5% of the RI in liquid food, the potassium content can be included in the nutritional labelling as a voluntary declaration by the food business.

Under Regulation (EU) No. 1924/2006 on nutrition and health claims made on foods, a food business can make a claim on a food product in relation to overall potassium content. Two voluntary claims are allowed:

- A claim that a food is **"a source of potassium"**, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least a significant amount as defined Part A (2) of Annex XIII in Regulation (EU) *No. 1169/2011 i.e. 15% of the RI in solid food or 7.5% of the RI in liquid food.*

- A claim that a food is **"high in potassium"**, and any claim likely to have the same meaning for the consumer, may only be made where the product contains at least twice the value of the significant amount as defined Part A (2) of Annex XIII in Regulation (EU) *No. 1169/2011 i.e. ≥ 30% of the RI in solid food or ≥ 15% of the RI in liquid food*.

Note that if potassium is added to a food product and sodium is decreased there are claims that can be made in relation to low, very low, free and no added sodium on the pack. These are outlined under Regulation (EU) No. 1924/2006.

Note that in December 2020 the European Commission began providing an online Food Labelling Information System which provides a user-friendly IT solution to allow food businesses to select a food and automatically retrieve the mandatory EU labelling indications that should appear on their products. In all, 87 different categories of food are covered, and the system provides links to the relevant legal provisions and existing guidance documents.

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