

ORIGINAL SUBMISSION

Chemische Fabrik Budenheim KG · Postfach 11 47 · 55253 Budenheim · Germany

Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food And Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
USA

Ihr Schreiben / Zeichen
Your Reference

Unser Zeichen
Our Reference
Mg diphosphate

Durchwahl
Direct Line
++49 6139 89166

Datum
Date
May 3rd, 2011

Notice of GRAS determination for magnesium diphosphate

Dear Sirs,

referring to the pre-submission meeting dated December 7th 2009 and pursuant to the proposed rule outlined at 62 Fed. Reg. 18939 (April 17, 1997), Chemische Fabrik Budenheim KG of Germany hereby submits notification that use of magnesium diphosphate as a raising agent, acidifier, acidifying agent and stabilizer in foodstuffs in accordance with GMP, is exempt from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the notifier has determined that such use is generally recognized as safe (GRAS) through scientific procedures.

To facilitate your review, this notification is submitted in the format suggested under proposed 21 C.F.R. § 170.36(c) (see 62 Fed. Reg. at 18961).

Enclosed are three copies of the GRAS report, including the references.

Furthermore an electronic copy of the GRAS report including the references is attached for your convenience as well.

We would appreciate a notice of reception of the documents and look forward to any comments the agency may have on this notification.

Sincerely,

(b) (6)



Thomas Janssen
Regulatory Affairs
Chemische Fabrik Budenheim KG



RECEIVED
MAY 23 2011

BY: (b) (6)

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(b) (6)

Thomas Janissen
Regulatory Affairs
Chemische Fabrik Budenheim KG

C1 GRAS exemption claim

Chemische Fabrik Budenheim KG, Germany hereby claims that the use of magnesium diphosphate as a stabilizer, raising agent, acidifier and acidifying agent in foods is exempted from the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act because the company has determined that such use of magnesium diphosphate is generally recognized as safe (GRAS).

I. Name and address of the notifier:

Chemische Fabrik Budenheim KG
Rheinstr. 27
D 55257 Budenheim
Germany
Phone: ++49 6139 89-0
Fax: ++49 6139 8973264

II. Common or usual name of the substance that is the subject of the GRAS exemption claim:

magnesium diphosphate

III. Applicable conditions of use of the notified substance:

(a) Foods in which the substance is to be used:

<i>Food category name</i>
<i>Self-raising flour</i>
<i>Noodles (oriental style)</i>
<i>Batters and breadings</i>
<i>Processed cereals</i>
<i>Ordinary bakery wares (e.g. bagels, tortillas)</i>
<i>fine bakery wares</i>

(b) Levels of use in such foods:

<i>Food category name</i>	<i>Maximum level</i>	<i>Typical level</i>
<i>Self-raising flour</i>	<i>15g/kg (as P2O5)</i>	<i>12g/kg (as P2O5)</i>
<i>Noodles (oriental style)</i>	<i>2g/kg (as P2O5)</i>	<i>1-2g/kg (as P2O5)</i>
<i>Batters and breadings</i>	<i>12g/kg (as P2O5)</i>	<i>10g/kg (as P2O5)</i>
<i>Processed cereals</i>	<i>12g/kg (as P2O5)</i>	<i>10g/kg (as P2O5)</i>
<i>Ordinary bakery wares (e.g. bagels, tortillas)</i>	<i>15g/kg (as P2O5)</i>	<i>10g/kg (as P2O5)</i>
<i>fine bakery wares</i>	<i>15g/kg (as P2O5)</i>	<i>14g/kg (as P2O5)</i>

(c) Purposes for which the substance is used:

Primary functional classes: raising agent, acidifier, stabilizer, and acidifying agent

Chemical leavening is a traditional way of bringing volume into baked goods. This is commonly done by raising agents. Baking powders are produced for more than 100 years now. Natural leavening (yeast) causes a strong flavour which is undesirably in certain baked goods where other tastes should be perceived. The only known alternative to natural leavening is chemical leavening (raising).

The new additive provides excellent potential in certain bakery application as a raising agent, especially for industrial applications, optional in combination with other raising agents. This was affirmed by selected customers (Dr. Oetker (Germany), others) doing trials with the substance and could be shown by using common methods to determine important baking properties. In addition, trial reports from plum cakes to create the evidence of suitability for this substance in baked goods in general are attached and serve as a representative example for bakery purposes¹. Technically it is unfeasible to perform tests in all thinkable matrices in baked goods. In order to extrapolate suitability for other baking purposes, commonly performance trials are done (neutralisation value, rate of reaction) to characterize the raising agent.

At the same time, the substance may serve complimentary as a nutrient source for magnesium, and, as obtainable from the Creme case study of 2010, having the potential to improve nutrient profile of foodstuffs, especially in countries with low magnesium intake and high sodium intake from baked goods consumption, such as the United States.

The magnesium diphosphate could become an important alternative due its nutritional value to commonly used sodium acid pyrophosphate (INS450i).

The proposed use levels are in accordance or even below current use levels of other phosphates and are based on the ratio of "needed leavening" vs. flour content, but considering sugar-rich formulations which need more raising action.

Crucial for baking performance of raising agents are two main parameters:

The NV (neutralisation value) is one of two important properties for a raising agent (acid). The value describes the amount which is necessary to neutralize 100g of sodium bicarbonate. It is a reference value, specific for each leavening agent (acid). The higher the NV is, the less leavening acid (raising agent) is needed. It is therefore desirably to have a rather high NV in order to reduce the amount of leavening acid

¹ Budenheim: Internal baking trials from production trials

(and costs, since additives are commonly the more expensive ingredients besides flavours in a formulation). Unfortunately, a higher NV usually comes along with a quicker reaction. An exception is sodium aluminium phosphate (INS541), which provides both properties, a high NV and a considerably slow reaction. The NV is described as the amount of sodium bicarbonate [g] divided by the amount of raising agent needed for neutralisation [g] times 100

The other important property of a leavening acid is the “Rate of Reaction” (ROR), or DRR (dough rate of reaction).

It is an efficiency test concerning a desired baking property in industrial use of raising agents: The value describes the speed of the release of carbon dioxide (providing volume) during the leavening reaction under defined conditions. The speed or dynamic of a reaction is important in industrial preparation of baked goods, since benching time, preparation time and baking conditions have to be very strictly within certain limits, and otherwise the output may vary from a defined standard in colour, volume or texture and may differ from final customer expectations in a certain product.

A difficult thing for baking industry is to get a retarded reaction since quick-reacting acids are easy to produce. Coating of materials is a way to produce retarded leavening acids, but involves a 2nd processing step - causing higher costs and potential side effects such as brown or white spots in the products due to a worse distribution during blending – therefore a commonly undesirable solution. An uncoated solution such as the new additive is preferable from a commercial point of view and could provide a reasonable solution.

Here is an overview about the performance of existing leavening acids with regard to their Neutralisation Value and Rate of Reaction:

Leavening acid	NV	ROR (DRR)
INS541 - A	100	22
INS541- B	100	10
INS450i	71-73	10-40
INS341i	83	60
INS334	112	70
INS575	45	30
INS336i	45	66

The new leavening acid (raising agent) has the following performance properties:

<i>Leavening acid</i>	<i>NV</i>	<i>ROR</i>
<i>Magnesium diphosphate</i>	<i>70-73</i>	<i>10-30</i>

As obvious from the comparison to the substances above, there is a possibility to reduce the Rate of Reaction dramatically compared to e.g. organic acids /their salts and this indicates its suitability for use as a retarded raising agent.

The substance, depending on the exact production conditions may be produced as strongly retarded or less retarded leavening acid and has a high neutralisation value, but certainly less than strong organic acids.

Customizing is important, which means adapting to given conditions and finding the perfect customer solution which enables him to run his production process as efficient as possible.

Since it is possible to produce ROR-related products for each customer individually, we believe this provides a big gain for industrial baking production.

Summary:

The use of customized magnesium diphosphate is favourable, especially for industrial purposes due to the flexibility of adjusting the additive's properties according to individual needs of clients with inflexible productions.

In addition, the secondary nutritional benefit for the consumer is an opportunity to improve the healthiness of processed foodstuffs.

(d) Description of the population expected to consume the substance (exposure):

The normal consumer will come into contact with the new substance from noodles (oriental style), processed cereals and its products, some types of ordinary bakery wares and fine bakery wares.

The proposed use is a substitutional use, not an add-on use to other phosphates or other additives – it is an alternative to existing additives. The maximum intake of phosphates (as P₂O₅ or P) will not be affected since the proposed maximum and use levels are in accordance with current uses of other phosphates².

This means from a risk management perspective, there is no additional exposure to phosphorous, because it is already covered by existing exposure assumptions made for other phosphates used in the same categories, having a similar phosphorous content. There is an additional exposure of magnesium to consumers if for example sodium acid pyrophosphate is replaced by the new additive. As found out by probabilistic modelling, the additional intake of magnesium considering the extreme case (100% replacement) could be up to 12.5% in the American, 23% in the Briton diet, contributing significantly to their diets, helping to meet their dietary recommendations. The scope of the Creme study was to look at the shift of sodium, phosphorous and magnesium contents in affected foodstuffs. The study's summary conclusion is

“As magnesium is not commonly found in most foods in the Western diet (the main sources are green leafy vegetables, fruits, nuts and soy products), a large proportion of the population do not reach their recommended daily intake. The replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery ware products represents a great opportunity to increase magnesium intakes to their recommended levels while simultaneously reducing sodium intakes.”

IV. Basis for the GRAS determination:

The basis of the GRAS determination is through scientific procedures, because it has a significant equivalence to existing GRAS substances (phosphates) and the use is a pure substitutional use.

² Creme Global Study 2010 - Replacing sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery wares

V. Review and Copying Statement:

The data and information that are the basis for Chemische Fabrik Budenheim's GRAS determination are available for the Food and Drug Administration's (FDA's) review and copying at reasonable times at the offices of the notifier, or will be sent to FDA upon request.

Thomas Janssen

Regulatory Affairs

Chemische Fabrik Budenheim KG

Please address correspondence to:

Thomas Janssen

Chemische Fabrik Budenheim KG

Rheinstrasse 27

55257 Budenheim / Germany

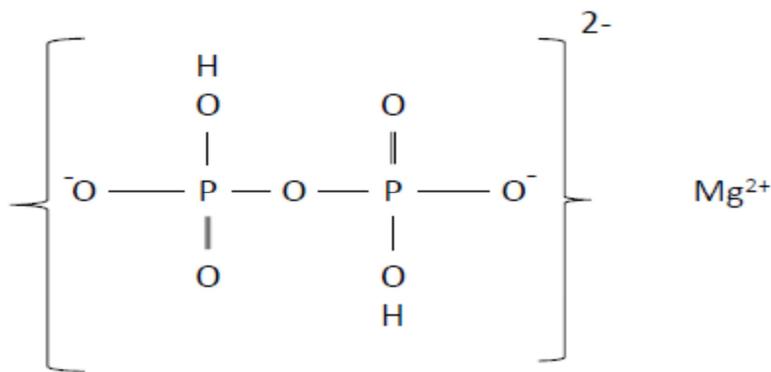
Email: Thomas.janssen@budenheim.com

Phone: ++49 6139 89166

Fax : ++49 61398973166

C2 Detailed information about the identity of magnesium diphosphate

- A) Common name: magnesium diphosphate
- B) Trade names: MgPP,, magnesium acid pyrophosphate
- C) Chemical name: dihydrogen magnesium diphosphate
- D) CAS Registry#: 20768-12-1 (anhydrous form)
- E) Empirical formula: $H_2MgP_2O_7$
- F) Structural formula:



- G) Quantitative composition:
Magnesium diphosphate shows the following typical composition by weight, including potential naturally occurring impurities:

#	Parameter	Lower limit	Upper limit	Method
1	Assay as P_2O_5	68,0 %	70,5 %	XRF
2	MgO	18,0 %	20,5 %	XRF
3	Orthophosphate (as P_2O_5)		6,0 %	HPIC3
4	Triphosphate (as P_2O_5)		0,5 %	HPIC3
	Trace elements			
5	Na_2O		} $\Sigma 1,5 %$	FL-AAS
6	K_2O			FL-AAS
7	CaO			0,5%
	Impurities			
8	Lead (Pb)		1 ppm	OES
9	Cadmium (Cd)		1 ppm	ZEE-AAS
10	Arsenic (As)		1 ppm	OES
11	Aluminum (Al)		50 ppm	OES
12	Fluoride		20 ppm	F10
13	Loss on ignition		12 %	GV1

The applied methods are enclosed to this notice³. The analyses have been performed by Budenheim's own lab (accredited according to ISO/EN17025).

³ Budenheim analytical methods

The proposed specification limits derive from production trials and performed analysis of the produced materials:

Production trial 1 (March 2010)

Parameter /Production sample from	BB 1	BB 5	BB 8	BB 10
P2O5	69,8	69,8	70,0	69,9
MgO	18,7	19,1	19,1	18,9
Na2O	0,72*	0,42*	0,33*	0,28*
Loss on ignition	10,7	10,7	11,1	11,3

Production trial 2 (June 2010)

Parameter /Production sample from	BB 1	BB 7	BB 10	BB 16
P2O5	69,6	70,1	69,8	69,8
MgO	18,6	19,1	19,0	18,6
Na2O	0,6	0,2	0,2	0,2
Loss on ignition	10,9	10,7	10,9	11,8

Production trial 3 (August 2010)

Parameter /Production sample from	BB 1	BB 5	BB 9	BB 13	BB 17	BB 21
P2O5	69,0	68,9	69,1	68,8	68,4	69,4
MgO	18,0	19,1	19,2	19,2	19,0	19,1
Na2O	1,35	0,45	0,35	0,27	0,76	0,18
Loss on ignition	10,9	11,1	11,2	11,4	11,5	11,2

Impurity levels

	BB Nr. 8 Trial 13.03.10	BB Nr. 16 Trial 04.06.10	BB Nr. 13 Trial 26.08.10	BB Nr. 21 Trial 27.08.10
Fluoride (ppm):	2	<1	2	2
Lead (ppm):	<1	<1	<1	<1
Arsenic (ppm):	<1	<1	<1	<1
Cadmium (ppm):	<1	<1	<1	<1
Mercury (ppm):	<1	<1	<1	<1
Antimony (ppm):	<5	<5	<5	<5
Potassium (ppm):	9	34	11	27
Sulfate (ppm):	320	335	370	290
Chloride (ppm)	<20	<20	<20	<20
pH-value (1%):	2,9	3,3	2,7	3,1
Rate of Reaction (3,2 g):	11	12	14	12
Neutralisation value:	73	71	74	72
ortho-P2O5 (%):	3,8	4,7	3,8	4,1
Total P2O5 (%) (RFA):	69,4	69,8	68,7	69,4
tripoly-P2O5 (%):	0,1	<0,1	0,1	0,1
OECD solubility:	10g/L	10g/L	10g/L	10g/L

In case of magnesium salts, like in the case of this new additive, we think it is beneficial to use a method being able to differentiate clearly between Mg and Ca to determine Mg or Ca contents, because there is a risk that calcium instead of magnesium is being used due to price reasons (magnesium is much more expensive) and e.g. falsified nutrition labelling may occur on finished food stuffs.

However, calcium and magnesium salts always occur naturally besides each other, at least at low quantities. From our experience with purified magnesium hydroxide (used raw material

source for magnesium in our production process), we have calcium contents of less than 0.5% in the raw material.

In order to inform properly the user of the new additive sufficiently about the calcium and magnesium contents of their ingredients, we strongly recommend specifying both, the calcium and magnesium contents of the new additive or at least using a suitable method for determination of magnesium.

Calcium, sodium and/or potassium may occur in traces due to two reasons:

a) they can be intentionally added in order to adjust the crystalline structure of the new additive for a better baking performance

b) they occur naturally in the raw materials

The typical impurities of concern have been analysed in the raw materials and production trials: Pb (lead), Cd (cadmium), As (arsenic), Hg (mercury), Al (aluminium)

Considering the available purities of raw materials, it is possible without any significant limitation of raw material sources to limit the levels of Pb, As, Cd to 1 ppm (as it is basis).

This level reflects also the latest findings concerning Pb, As and Cd in a way that we are trying reasonably to reduce potential impacts on intake of those impurities from additives, despite being used at considerably low levels.

Inserting a limitation for mercury is not necessary according to our understanding, since there is no thinkable contamination by trace amounts of food grade sodium hydroxide. Nevertheless we have measured mercury levels, all of them below 1 ppm, as expected.

Aluminium is a naturally occurring contaminant of calcium and magnesium salts, contents varying from continent to continent, even within one country significantly from source to source. It is impossible to get completely rid of it by reasonable technical means.

However, available purity of magnesium sources shall lead to a level of below 50 ppm aluminium (as it is basis) in the new additive.

The occurrence of potential impurities depends on the used raw materials and its purities. We understand our obligation in way that we screen almost the whole periodic table for the evaluation of new raw materials in order to avoid "surprises". The significant lead elements are specified to assure an appropriate quality.

From ion chromatography data and raw material supplier information we conclude the present levels of an-ions on impurity level are beyond any concern.

A microbiological contamination is very unlikely due to the extreme conditions of production with product temperatures above 200°C.

On the Raw material side we use synthetic ingredients (magnesium hydroxide, in addition trace amounts of sodium- and potassium hydroxide, all of them are food grade quality) and purified food grade phosphoric acid. The acid has a pH-value of below 1 and the caustic components above 12, so there is no reasonable microbiological contamination possible. Therefore, the risk of a microbiological raw material contamination can be neglected or reduced to the filling process, in case the product is handled openly at that point.

In addition the process conditions contradict a potential presence of microorganisms.

The finished product is a salt – it is unlikely to happen that organisms grow on such a media, under such a strong osmotic pressure.

We conclude that there is no need for microbiological specification.

If the loss on ignition is above 12%, the product won't have sufficient storage stability, as we found out during shelf-life trials. Too much residue water leads to lumping and accelerated hydrolysis of diphosphates to orthophosphates with a simultaneous acidification.

The shelf life is about 2 years from production date (using standard conditions of 60%RH at 25°C), if the specified limits are matched. The shelf life can differ, especially under hot and humid conditions.

The particle size is an important parameter and has an influence on the quickness of reaction in foodstuffs as well. The finer the material is, the quicker it reacts.

In order to produce a more retarded product, we needed to design a particle size distribution which fits two aims:

- 1. Homogeneous distribution in dry blends with other components without being too fine or too coarse due to separation*
- 2. Obtaining a product preferably as coarse as possible due to the better retardation (less surface, slower solubility), but avoiding spot wise discolorations (local pH-shift) from too slow reacting material.*

The particle size has been determined during the production trials. The average particle size (D50) deviated between 16.7µm and 42.4µm⁴ during the production trials.

H) Method of manufacture

Magnesium diphosphate is produced from two main raw materials, magnesium hydroxide (Mg(OH)₂) and phosphoric acid (H₃PO₄).

Other intentionally added elements, such as sodium, potassium or calcium at low levels (according to proposed specification), either in hydroxide or phosphate-form; in addition natural calcium may occur, depending on the magnesium source) are useful for the adjustment of the desired baking properties – they create certain “defects” in the crystalline structure which influence properties, such as the speed of solubility.

The process is as follows:

- a. Magnesium hydroxide is being diluted into an aqueous dispersion*
- b. The magnesium hydroxide dispersion is then slowly added to the phosphoric acid until a molar ratio between Mg:P of about 1:2 is reached, holding the temperature below 60°C during the reaction.*
- c. About 0.1% hydrogen peroxide is added as processing aid in order to oxidize all potential ingredients (equipment protection).*

⁴ Budenheim Analytical results Horiba Laser Scattering Particle Size Distribution - Mg-pyrophosphate

- d. *The slurry is then processed in a drum-dryer between 180 – 220°C (product temperature), water and remaining hydrogen peroxide evaporate. Alternatively, other suitable heating processes could be used.*
- e. *The product is processed in the drum-dryer until a loss on ignition of below 12.0% is achieved.*
- f. *The resulting granules are milled to a finer powder, suitable for blending with other food ingredients.*
- g. *The product is being filled into the necessary packaging materials (e.g. super bags, paper bags, bulk transport).*

Reduced to the chemical equation, the production is as follows:



I) Characteristic properties

Magnesium diphosphate is a fine white powder, slowly soluble in water (ca. 10g per liter) with a sour taste and an acidic reaction in aqueous solution. Its INS number is 450(ix).

The melting point is above 1000°C (exceedance of technical possibilities for exact determination)

The melting and boiling points could not be exactly determined from the thermal analysis of monomagnesium phosphate. The monomagnesium phosphate condensates to magnesium diphosphate with a loss of water, only little further condensation at higher temperatures occurred, no observations concerning melting and boiling of the formed salt could be made until the equipment limit of 1000°C was reached. Subsequently the boiling point is also above 1000°C (exceedance of technical possibilities for exact determination). No further loss of mass occurred between 500°C and 1000°C, therefore no boiling was observed. The average particle size deviated between ca. 10 and 50µm during production trials and is representative for the new substance.

J) Content of potential human toxicants

The quantitative composition under G) shows that amounts of trace impurities like lead, cadmium, arsenic, aluminium and mercury are far below levels of comparable standards for food grade phosphates. They are of no health concern. Phosphorous (phosphate), and magnesium as main constituents are being evaluated in the toxicological assessment.

K) Specification for magnesium diphosphate

No official specifications of magnesium diphosphate currently exist, since the substance has never been commercially produced. The petitioner makes the following proposal for a specification, based on production trial data and analyses, see also section G), the quantitative composition. This proposal has been / will be submitted to the EU commission for inclusion in the purity criteria's list as E450(ix) and to JECFA as INS450(ix).

#	Parameter	Lower limit	Upper limit	Method
1	Assay as P ₂ O ₅	68,0 %	70,5 %	XRF
2	MgO	18,0 %	20,5 %	XRF
3	Orthophosphate (as P ₂ O ₅)		6,0 %	HPIC3
4	Triphosphate (as P ₂ O ₅)		0,5 %	HPIC3
	Trace elements			
5	Na ₂ O		} Σ1,5 %	FL-AAS
6	K ₂ O			FL-AAS
7	CaO		0,5%	XRF
	Impurities			
8	Lead (Pb)		1 ppm	OES
9	Cadmium (Cd)		1 ppm	ZEE-AAS
10	Arsenic (As)		1 ppm	OES
11	Aluminum (Al)		50 ppm	OES
12	Fluoride		20 ppm	F10
13	Loss on ignition		12 %	GV1

The methods principles can be summarized as follows:

XRF (P₂O₅, MgO, CaO)

The P₂O₅ content is measured "as it is" by x-ray fluorescent, which means also that the loss on ignition is not reflected. The application of a P₂O₅-content "as it is" is favourable for the users / applicants of the new additive (and of all phosphate species), because it enables them to calculate the maximum allowed usage directly from the measured P₂O₅ content. If the loss on ignition is taken into account for the basis where the P₂O₅ content refers to, the calculation may more difficult for the applicants and wrong dosages might occur.

We strongly recommend using the x-ray diffraction method instead of any photometric or titrimetric method for P₂O₅-determination, since the standard deviation and robustness of the x-ray (besides the multipurpose property) is much better than the applied standard methods. The details of the x-ray method validation are enclosed to this dossier⁵.

In addition, the applied x-ray analysis determines the Mg content (as MgO) simultaneously and is able to differentiate clearly between Ca(calcium) and Mg (magnesium).

The used methodology is able to determine Mg (magnesium) alone, in opposite to FCC/JECFA methods which apply titration methods, not being able to differentiate between actual Mg (magnesium) and Ca (calcium).

⁵ Budenheim analytical methods

For example, magnesium may present a higher calcium content in calcium salts and the other way round, calcium may present a higher magnesium content in magnesium salts.

IC ion chromatography (ortho- and triphosphate P2O5)

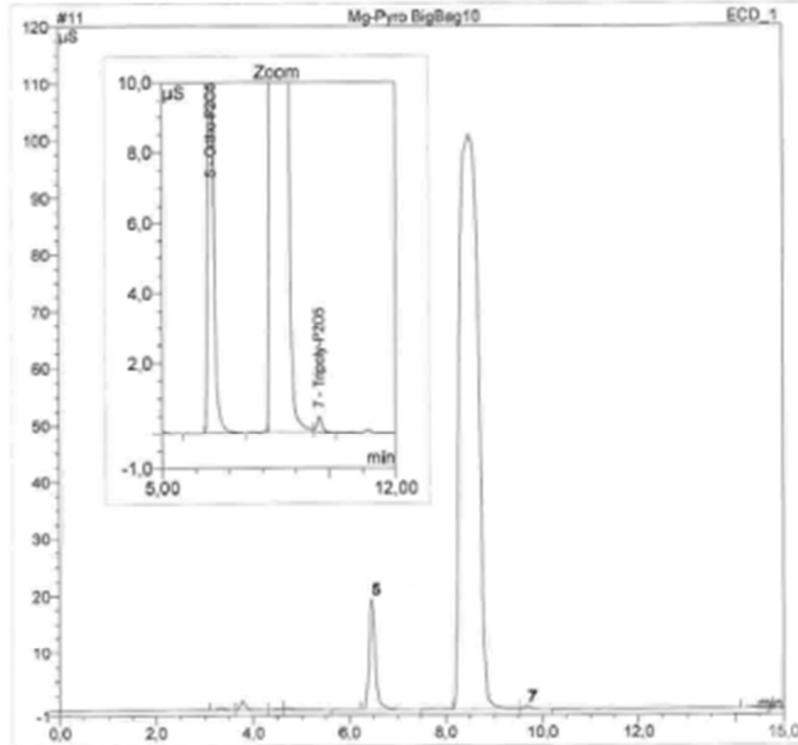
A phosphate salt containing 100% diphosphate, without any ortho- or triphosphate is impossible to produce, therefore it is the aim to describe the product within the relevant deviations of the production process with the lead parameters, according to good manufacturing practices.

Ion-chromatography analysis have been performed in order to identify by-products of the production process. The production process has a characteristic condensation process, converting orthophosphate into diphosphate, the value-determining anion. If the heating is either too strong or too long, the amount of triphosphate increases. The higher the amount of triphosphate is, the more the baking properties of the product become (partially) ineffective.

If the heating has been either too low or too short, the amount of orthophosphate is increased, which is an indication for an incomplete conversion of the reaction.

It is necessary to hit a certain frame in order to achieve the desired technological properties of the new additive. Obtainable from the analysis example of the following page, you will notice the orthophosphate / PO_4^{3-} (peak 5 -measured as P2O5) is still present, commonly up to 5.0%. In the sample above (BB10 from production trial 1), the formed triphosphate (peak 7 (measured as P2O5), $P_3O_{10}^{5-}$) is at a very low level. Peak #6 /unlabeled is the diphosphate peak which is the desired form, counting for about 95% of total P2O5.

Programm:	HPIC3	Benutzer:	arichter
Methode:	HPIC3	System:	503-Q-005
Sequenz-Name:	ME-10-015-A	Injektions-Volumen:	5,0
Proben-Name:	Mg-Pyro BigBag10	Kanal:	ECD_1
Proben-Nummer:	8	Laufzeit (min):	15,00
Probentyp:	unknown	Verd.- Faktor:	100,0
Aufnahmezeit:	23.03.10 13:29	Einwaage (mg):	160,0



Peak	Peak Name	Retentionszeit min	Fläche µS*min	Amount	Gehalt %
5	Ortho-P2O6	6.46	2.919	6.7729	4.2331
7	Tripoly-P2O5	9.70	0.073	0.0483	0.0302

CFB_1/Integration

Chromleon (c) Dionex 1996-2006
Version 6.80 SP4 Build 2361 (130805)

ICP-OES (lead, arsenic, aluminum)

Impurities such as Arsenic, Cadmium, sodium, potassium, etc. need to be analysed. An appropriate method is the ICP-OES (inductively coupled plasma- optical emission spectrometry). The method utilizes Argon-induced plasma to analyse element-typical optical emissions of electron transfer.

F-AAS (sodium, potassium)

Intentionally added sodium and/or potassium can be detected by flame atomic absorption spectroscopy, using the Lambert-Beer's law at the characteristic absorption wavelengths of the elements.

ZEE-AAS (cadmium)

The technique is similar to the F-AAS method, but using a graphite tube to concentrate and evaporating the test-solution. This technique takes advantage of the compensation of magnetic field switches using the Zeeman-effect in order to reduce background noise and improve sensitivity.

F10 (fluoride)

Fluoride is being distilled as HF respectively H₂SiF₆ and forms a red chelate with Ceiii and Alizarine. This characteristic blue-colored chelate is photometrical measured and the fluoride content calculated.

GV1 (loss on ignition)

This method determines the loss on ignition under standardized conditions. The conditions are 800°C for 30 minutes.

S13 (particle size distribution by laser-scattering with Horiba LA-950V)

The typical particle size distribution is measured by laser-scattering with a Horiba LA-950V. The particle size description is a required characteristic for new food additives.

The detailed methods are provided as enclosure to this submission.

C3 Information on any self-limiting levels of use

Technically, the use of any raising agent is limited due to the naturally necessary ratio (neutralisation value) between the raising agent and the carbon dioxide source. If one of the two ingredients is significantly overdosed, the resulting baked good will have off-flavor and discolorations compared to the standard product. Accordingly, nobody wants to use more than necessary and nobody wants to deviate from the NV-ratio.

From a commercial point of view of the user of this new raising agent, the risk of overdosing a magnesium salt has to be reduced as much as possible, since the price of magnesium salts in comparison to the similar calcium salts is dramatically higher and is likely one of most expensive ingredients in any baking formula.

C4 Detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the Federal Food, Drug and Cosmetic Act because such use is GRAS

i *through scientific procedures, because it has a significant equivalence to existing GRAS substances and its suggested use is a substitutional use.*

The existing substances mono-, di-, and tri- magnesium phosphate (21 CFR 184.1434) have obtained GRAS status as supplements and pH-control agents. The new substance can be described as an ignited form of magnesium phosphate, monobasic.

If the ignited form is being put into water for hydrolysis and heated, again magnesium-ions and orthophosphate-anions are formed due to natural hydrolysis of the diphosphate-anion.

The substance is a salt of phosphoric acid (orthophosphate) and magnesium, both occurring naturally and being already constituents of foods, whether intentionally added or naturally occurring.

The use of the new substance is not an add-on use, but a substitutional use of a raising agent, leading to a reduction of sodium and an increase of magnesium simultaneously, both could be considered as positive health effects.

Toxicological assessment of magnesium diphosphate

Introduction

Since the new substance (INS 450(ix)) is a soluble salt of magnesium and diphosphate, chemically very similar to INS450(vii) calcium acid pyrophosphate, we conclude the PTDI for phosphorous from all food sources of 70mg/kg BW/day, established by JECFA in 1982, is applicable as well to the new substance and the substances toxicity can be considered as the toxicity of its ions.

This PTDI was confirmed by the SCF in 2001 and EFSA in 2005, taking into consideration latest developments (if any) until their publications. Furthermore, it is already possible to use magnesium (ortho-) phosphates for food purposes in USA with similar P and Mg contents.

All phosphate-related safety evaluations refer to the phosphate-part of the substances, since it is a soluble salt, splitting into its ions under aqueous conditions, allowing to evaluate phosphates by their most relevant toxic effects which are mostly dependent from the phosphate part of phosphate containing additives. In case of magnesium diphosphate, the relevant ions are magnesium (essential nutrient), hydrogen (a non-toxic ion) and the diphosphate.

Since diphosphates hydrolyse under stomach conditions to orthophosphates, the oral toxicology is accordingly the same as for orthophosphates.

Phosphoric acid and its salts (sodium, potassium, calcium and magnesium) as well as di-tri and polyphosphates are considered as a group due to this hydrolysis.

Subsequently, our toxicological approach is to evaluate the ions separately.

Toxicological data

a) Magnesium

Exposure

The occurrence of magnesium in foods is ubiquitous. The recommend daily intake (RDI) in the US is 400mg/day. Data from the Food and Nutrition Board (1997: 323mg/day male, 228mg/day female average) indicate that the intake is significantly below the current RDI.

Adsorption, Desorption, Metabolism, Excretion

Magnesium is absorbed efficiently from the intestine, present in various foodstuffs at different levels between 51 and 60 per cent⁶.

The main absorption route is passive diffusion, whereas active transport plays an important role at low intake levels⁷. At high levels, the absorption rate decreases.

Magnesium as essential nutrient is a cofactor in hundreds of enzymatic reactions, many of which involve energy metabolism. It also plays an important role in protein and nucleic acid synthesis and has a stabilizing and protecting effect on membranes. Finally, Mg is also considered essential in maintaining Ca, K and Na homeostasis⁸.

Magnesium has shown to become urinary excreted up to 60g/day without adverse effects; therefore overdose from foodstuff intake only is unlikely to occur⁹.

High intakes of alcohol lead to high magnesium depletion from the kidneys, such individuals have a particularly increased risk of magnesium deficiency¹⁰.

⁶ Schwartz, Spencer, Magnesium absorption in human subjects....,Am J o Clin Nutr. 1984(39, 571-576)

⁷ Fine, Carol A. Santa Ana, Intestinal Absorption of Magnesium from Food and Supplements, J. Clin. Invest. 1991(88,396-402)

⁸ Opinion of the Scientific Committee on Food on the Tolerable upper intake level of magnesium (2001), p2

⁹ BEC Nordin, Calcium, Phosphate and Magnesium Metabolism, 1976 Churchill Livingstone, (26-28)

¹⁰ Abbott et al - Magnesium deficiency in alcoholism, alcoholism clinical and experimental research,1994(18, 5)

Toxicological assessment of magnesium diphosphate

Acute Toxicity

The predominant direct oral toxic effect of magnesium salts is based on the osmotic effect of magnesium, leading to (reversible) diarrhoea¹¹. The lowest observed effect level for diarrhoea of a magnesium salt was identified at 360mg Mg/day for a small number of individuals.

The mild effect was observable only in individuals receiving magnesium from supplemental intake, not from foodstuffs.

No effects from supplemental magnesium intake were observable at intake levels of 250mg Mg/day¹².

Genotoxicity

Magnesium is an essential body constituent and has not shown genotoxic potential in literature¹³.

Chronic Toxicity and Carcinogenicity

The possible effect of elevated levels of magnesium on the intestine is an osmotic effect, leading to reversible diarrhoea. Physiological effects of longer-term, high intake of oral magnesium have only been observed in persons with renal abnormalities. Accordingly, the critical adverse effect is diarrhoea¹⁴.

A NOAEL of 250mg/day could be derived from a two-year study of supplemental magnesium, where magnesium was provided in addition to normal magnesium intake from foodstuffs¹⁵.

Developmental and Reproductive Toxicity

No negative effects of magnesium salts on reproductive or developmental toxicity were reported¹⁶.

¹¹ Food and Nutrition Board, Dietary Reference intakes for calcium, phosphorous, magnesium, vitamin D and fluoride; Washington DC national Academy press (1997), pp242-244

¹² Stendig-Lindberg Tepper, Trabecular bone density in a two-year controlled study..., Magnesium Research (6, 2) 1993, pp155-163

¹³ EGVM (Expert Group on Vitamins and Minerals) (2003). Report on safe upper levels for vitamins and minerals. London. May 2003, pp289-290

¹⁴ Food and Nutrition Board, Dietary Reference intakes for calcium, phosphorous, magnesium, vitamin D and fluoride; Washington DC national Academy press (1997), pp242-244

¹⁵ Stendig-Lindberg Tepper, Trabecular bone density in a two-year controlled study..., Magnesium Research (6, 2) 1993, pp155-163

¹⁶ EGVM (Expert Group on Vitamins and Minerals) (2003). Report on safe upper levels for vitamins and minerals. London. May 2003, pp287-290

Toxicological data

b) Phosphate

Exposure

Phosphorus is widely found in foods as phosphates; especially foods rich in protein are usually high in phosphorus, such as dairy products (100-900 mg/100 g), meats (200 mg/100g), fish (200 mg/100 g) and grain products (100-300 mg/100 g). The average intake from foods in adults is usually between 1000-2000 mg/day. In the US the contribution from phosphorus-containing food additives is estimated at 320mg/day, i.e. 20-30% of the adult phosphorus intake¹⁷.

Adsorption, Desorption, Metabolism, Excretion

During normal digestion, phosphate is released from phosphate-containing biochemicals in food and actively absorbed in the upper small intestine, and somewhat less in the more basic environment of the lower small intestine. Absorption has been reported to be about 70% in adults and between 60% - 90% in infants and children.

Absorption takes place by a satiable, active transport mechanism, facilitated by vitamin D, as well as by passive diffusion. Intestinal absorption of phosphate normally fluctuates widely. It is decreased by high intake of calcium, magnesium, or iron, forming insoluble phosphates in the gut, by unusually high intestinal alkalinity, and by low vitamin D intake. Phosphate absorption is significantly higher in acid pH environments than in alkaline environments.

Approximately 80% of phosphorus in the human body is bound with calcium in the bones and teeth. Phosphorus-containing organic compounds in the blood and muscle such as proteins, lipids, and carbohydrates constitute another 10% of body phosphorus. Nearly all organic forms of phosphorus in blood, such as 2,3-diphosphoglyceric acid, adenosine triphosphate (ATP), and fructose-1,6-diphosphate, occur in erythrocytes¹⁸. The remaining 10% has an extensive distribution in the fluids of the body¹⁹.

Excretion takes place mainly in the faeces, but in excessive amounts of phosphate versus calcium, magnesium or iron, the urinary excretion becomes a significant route.

Acute Toxicity

A brief review of available literature for toxic effects of phosphates has been done by Weiner et al in 2001. Among others, TMP (trimagnesium phosphate) has been tested for acute oral toxicity with a result for LD₅₀ of more than 10000mg/kg²⁰. Calcium and magnesium phosphates generally seem to be orally less acute toxic than their sodium and potassium counterparts. Since the new substance is chemically a magnesium (di)phosphate, the acute oral toxicity should be similar to those of TMP.

¹⁷ Calvo MS and Park YK (1996). Changing phosphorus content of the U.S. diet: potential for adverse effects on bone. J Nutr 126:pp1168-1180

¹⁸ Henry RJ. 1967. Clinical chemistry: Principles and techniques. New York: Harper and Row, Publ.,409-416

¹⁹ Tietz NW. 1970. Electrolytes. In: Tietz NW ed. Fundamentals of clinical chemistry. Philadelphia: W.B. Saunders Co., 636-639

²⁰ Weiner ML et al - toxicological review of phosphates 2001, food and chem tox, 30 2001 pp764

Toxicological assessment of magnesium diphosphate

Genotoxicity

No genotoxic effects of inorganic salts of phosphorus have been reported²¹.

Chronic Toxicity and Carcinogenicity

In 2009, a 90-day feeding study of Sprague-Dawley rats with β -calcium-pyrophosphate showed no significant effects at a level of 30mg/kg BW²².

A report from Whybro et al²³ about two studies showed on one hand an increase in the urinary excretion of phosphate, but showed on the other hand no changes in serum phosphate. Reversible diarrhoea was reported in one subject in the one of the studies when receiving phosphorus at 2000 mg/day.

Pathological effects in the parathyroid, kidneys and bones were observed in mature male rats fed a diet containing very high levels of sodium orthophosphate (8% in the diet, corresponding to about 4 g/kg body weight/day) for 7 months or until death respectively²⁴. Microscopic examinations of the tissues at the time of death revealed hypertrophy and hyperplasia of parathyroid cells. Haut et al. investigated renal toxicity of phosphates in rats. Phosphorus was fed in the diet at different levels of 0.5, 1.0 and 2% for 18 weeks. None of the animals on a normal phosphorus intake (250 mg/kg body weight/day) showed any abnormalities²⁵.

The finding of Dymysza et al.²⁶ using rats was that adequate absorption and utilisation of calcium, phosphorus and iron were observed, feeding a control, a normal orthophosphate, and a high orthophosphate diet.

Observations were made after 50, 60 and 150 days and no adverse physiological effects were reported. The authors concluded that at both high and normal levels of dietary phosphorus the calcium, phosphorus and iron absorption and utilisation were adequate.

High phosphate intakes can affect calcium distribution in the body and may in some cases produce

Toxicological assessment of magnesium diphosphate

soft tissue calcification and affect bone formation.

Kidney damage, soft tissue calcification and bone effects were the main findings in laboratory animals fed phosphates^{27 28 29}. However, such effects were not observed in studies in humans, except in pa-

²¹ Joint FAO-WHO Expert Committee on Food Additives 542., food additives series 17, Phosphoric acid and phosphate salts

²² Lee JH et al 2009; A 90-day subchronic toxicity study of beta-calcium pyrophosphate in rat, Drug Chem Toxicol. 2009;32(3):277-82

²³ Whybro, A., Jagger, H., Barker, M., Eastell, R. (1998) Phosphate supplementation in young men: lack of effect on calcium homeostasis and bone turnover. European Journal of Clinical Nutrition 52, 29-33

²⁴ Saxton, J. A., Jr & Ellis, G. H. (1941) Effects of long-continued ingestion of sodium phosphate, Amer. J. Path., 17 : 590

²⁵ Haut LL, Alfrey AC, Guggenheim S, Buddington B, Schrier N (1980). Renal toxicity of phosphate in rats. Kidney International 17: 722-731

²⁶ Dymysza HA, Reussner G Jr, Thiessen R Jr (1959). Effect of normal and high intakes of orthophosphate and metaphosphate in rats. J Nutr 69: 419-428

²⁷ MacKay EM and Oliver J (1935). Renal damage following the ingestion of a diet containing an excess of inorganic phosphate. J exp Med 61: 319

tients with end stage renal disease. In ill individuals, hypophosphatemia is caused by vomiting and severe diarrhoea, and is associated with various liver diseases³⁰.

Developmental and Reproductive Toxicity

No conclusive evidence of reproductive effects have been demonstrated in feeding studies with phosphate salts in various species of laboratory animal although limited studies have suggested testicular effects and reduced fertility in rats. No carcinogenic potential was demonstrated in limited feeding studies in rats treated with phosphates; however, in rodents treated orally, several phosphates have been shown to promote the effects of known carcinogens. A wide range of genotoxicity assays have yielded essentially negative results with phosphate salts³¹.

Long-term effects of dietary phosphoric acid in three generations of rats have been investigated³². The animals received diets containing 1.4% and 0.75% phosphoric acid (equivalent to approximately 200 and 375 mg phosphorus/kg body weight/day) for 90 weeks. No harmful effects on growth or reproduction were observed, and also no significant differences were noted in haematological parameters in comparison with control animals. There was no acidosis, nor any change in calcium metabolism. The quality of these older studies would be considered limited by current standards. JECFA reviewed the available data from studies in mice and rats and concluded that dosing with phosphoric acid and inorganic phosphate salts does not induce maternal toxicity or teratogenic effects. Maximum dose levels tested for the various inorganic phosphate salts varied between 130 and 410 mg phosphorus/kg bodyweight³³.

²⁸ McFarlane, D. (1941) Experimental phosphate nephritis in the rat, J. Path. Bact., 52,17-24

²⁹ Sanderson, P. H. (1959) Functional aspects of renal calcification in rats, Clin. Sei., 18,67-79

³⁰ Latner AL. 1975. Clinical biochemistry. Philadelphia: W.B. Saunders Co., 47-49, 279-315, 479, 842

³¹ Sanderson, P. H. (1959) Functional aspects of renal calcification in rats, Clin. Sei., 18,67-79

³² Bonting SL and Jansen B C (1956). The effect of a prolonged intake of phosphoric acid and citric acid in rats. Voeding 17: 137

³³ Joint FAO-WHO Expert Committee on Food Additives 542., food additives series 17, Phosphoric acid and phosphate salts

Toxicological assessment of magnesium diphosphate

Safety assessment of magnesium diphosphate

The prediction of the toxicological behaviour of magnesium diphosphate bases on the evaluation of its compounds, magnesium and diphosphate. The salt dissociates into its ions under aqueous conditions and the diphosphates hydrolysis into orthophosphate under stomach conditions.

In the case of ionisable salts, like in this case, it is scientifically justifiable to assess the anions and cations individually and to make separate predictions accordingly for magnesium and orthophosphate.

The safety of magnesium diphosphate is assessed by the consideration of the safety of the particular ions.

Magnesium has not shown any significant toxicological effect from food intake, rather an inadequately low intake of magnesium is observable in the US and it could be beneficial to have an magnesium containing alternative to sodium containing ingredient.

Due to the lack of toxicological effects, the limiting factor for use in foodstuffs won't be magnesium.

Phosphorus is a likewise essential body constituent. Generally, phosphates show a low acute oral toxicity in laboratory animals. Ingestion of excess amounts of phosphates by man may result in electrolyte imbalances in the body which can disrupt the function of a variety of organ systems. Kidney damage, soft tissue calcification and bone effects were the main findings in laboratory animals fed phosphates. However, such effects were not observed in studies in healthy individuals, only in patients with end stage renal disease. No conclusive evidence of reproductive effects has been demonstrated in feeding studies with phosphate salts in animals. No carcinogenic potential was demonstrated in feeding studies in rats treated with phosphates; however several phosphates have been shown to promote the effects of known carcinogens in rodents. Genotoxicity assays have yielded essentially negative results with phosphate salts.

The most comprehensive peer review of existing data is from Weiner et al (2001)³⁴.

The latest phosphate-specific safety evaluation of phosphates from an acknowledged body (here: EFSA, European Food Safety Authority) took place in 2004 / 2005 with regard to the potential implementation of maximum limits for fortification of phosphorous³⁵. EFSA did not establish an upper safe limit.

Additionally, EFSA took a look into existing data during the evaluation of ferrous phosphate and ferrous ammonium phosphate as iron sources for food supplements in 2009/2010, but no new data on phosphates had been reported^{36 37}.

³⁴ Weiner ML et al (2001) Toxic review of inorganic phosphates, food and chemical tox,30 2001 pp759-786

³⁵ The EFSA Journal (2005) 233, 1-19, Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Phosphorus

³⁶ EFSA Scientific Opinion - Ferrous phosphate added for nutritional purposes to food Supplements, The EFSA Journal (2009) 951, 1-13

³⁷ EFSA - Scientific Opinion on the safety of ferrous ammonium phosphate as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses, EFSA Journal 2010;8(5):1584

Toxicological assessment of magnesium diphosphate

No new relevant studies could be identified to question the safety assessment for phosphates from all food sources from JECFA(1982). The US-FDA had received our GRAS submission GRN-300 for trisodium diphosphate in 2009, where phosphates had been reviewed by US authorities.

Conclusions

Because of the lack of new relevant data, we still consider the PTDI of 70mg Phosphorous /kg BW/day as appropriate and see no obstacles to formally assign the same PTDI to magnesium diphosphate, since phosphorous (here: diphosphate) is the limiting factor from a toxicological point of view and the PTDI is expressed as phosphorous from all food sources.

The related existing substances calcium acid pyrophosphate (21 CFR 182.8223 calcium pyrophosphate) and mono-, di-, and tri- magnesium phosphate (21 CFR 184.1434) have obtained GRAS status.

The new substance could be described as an ignited form of magnesium phosphate, monobasic. If the ignited form is being put into water for hydrolysis, magnesium-ions and orthophosphate-anions are formed due to natural hydrolysis of the diphosphate-anion. The new substance is accordingly very similar to already authorised GRAS substances.

On the exposure side, the use of magnesium diphosphate is a substitutional use, typically for other others and does not lead to a significantly increased exposure scenario for phosphorous.

There is an additional intake of magnesium to consumers if sodium acid pyrophosphate is replaced by the new substance. As found out by probabilistic modelling³⁸, the additional intake of magnesium considering the extreme case (100% replacement) could be up to 12.5% in the American, 23% in the Briton diet, contributing significantly to their diets, helping to meet their dietary recommendations.

The scope of the Creme study was the shift of sodium, phosphorous and magnesium contents in affected foodstuffs. The study's summary conclusion is

"As magnesium is not commonly found in most foods in the Western diet (the main sources are green leafy vegetables, fruits, nuts and soy products), a large proportion of the population do not reach their recommended daily intake. The replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery ware products represents a great opportunity to increase magnesium intakes to their recommended levels while simultaneously reducing sodium intakes."

There is no doubt that the intended use of magnesium diphosphate, if produced according to the proposed specification is not harmful and can be considered to be safe for human consumption.

Thomas Janssen

Date

³⁸ Crème Global study 2010 - Replacing Sodium Acid Pyrophosphate with Magnesium Acid Pyrophosphate in Bakery Wares

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(b) (6)

Thomas Janssen

May 3rd, 2011

Date

000028

³⁸ Crème Global study 2010 - Replacing Sodium Acid Pyrophosphate with Magnesium Acid Pyrophosphate in Bakery Wares

Betriebsversuch II_2

Projekt-Nr.: AT1-_____

Backversuch

Datum : _____

Nr.:	Triebmittel	E	NW	Massen-	Teigtemp.	Volumen	Gewicht	Lockerung	Krumen-	Poren-	Ausbund	Kau-	Zeit	pH	pH	
		(g)	berech	dichte	(°C)	(mL)	(g)						(min)	Masse	Gebäck	
		(g)		(g/mL)												
1	N 54-80	3,5											5	7,52		
	MV 3049		72	0,79	24,2	930	364	locker	weich	fein	gut	gut	40	7,36	7,54	
	NaHCO3	2,5								offen						
													24h	6,75		
2	MgPP	4,2	60	0,79	24,1	950	363	locker	weich	fein	gut	gut	5	7,76		
	V 5									offen			40	7,61	7,52	
	NaHCO3	2,5														
													24h	6,91		
3	Betriebsvers.												5	7,80		
	b.b. Nr. 13	4,2	60	0,80	24,2	940	360	locker	weich	fein	gut	gut	40	7,78	7,13	
	NaHCO3	2,5								offen						
													24h	7,45		
4	b.b. Nr. 13	4,2	60	0,81	24,5	960	364	locker	weich	fein	gut	gut	5	7,82		
	+ 205 °C									offen			40	7,79	7,12	
	NaHCO3	2,5														
													24h	7,50		
5	b.b. Nr. 17	4,2	60	0,79	24,3	940	364	locker	weich	fein	gut	gut	5	7,80		
	NaHCO3	2,5								offen			40	7,75	7,13	
													24h	7,49		
6	b.b. Nr. 17	3,6	70	0,80	24,8	960	366	locker	weich	fein		gut	5	7,83		
	NaHCO3	2,5								offen			40	7,73	7,41	
													24h	7,49		
7	b.b. Nr. 17	3,3	75	0,80	25,1	960	366	locker	weich	fein	gut	gut	5	7,84		
	NaHCO3	2,5								offen			40	7,79	7,79	
													24h	7,55		
8													5			

000029

Betriebsversuch I

Projekt-Nr.: AT1-_____

Backversuch

Datum : _____

Nr.:	Triebmittel	E	ROR	Massen-	Teigtemp.	Volumen	Gewicht	Lockerung	Krumen-	Poren-	Ausbund	Kau-	Zeit	pH	pH
		(g)	(%)	dichte (g/mL)	(°C)	(mL)	(g)		beschaffenheit	bild		eigenschaft	(min)	Masse	Gebäck
1	N 54-80	3,5											5	7,55	
	MV 2840				23,9			locker	weich	fein	noch gut	noch gut			7,22
	NaHCO3	2,5								offen					
													40	7,46	
2	Betriebsvers.												5	7,83	
	MgPP	3,5		0,81	23,9	970	365	locker	weich	feiner	gering,	noch gut			7,71
	b.b. Nr.1										verlaufen				
	NaHCO3	2,5											40	7,79	
3													5	7,87	
	b.b. Nr. 4	3,5		0,80	24,1	1010	371	locker	weich	feiner	gering,	noch gut			7,71
	NaHCO3	2,5									verlaufen				
													40	7,85	
4													5	7,84	
	b.b. Nr. 6	3,5		0,81	23,9	990	366	locker	weich	feiner	gering,	noch gut			7,89
	NaHCO3	2,5									verlaufen				
													40	7,83	
5													5	7,94	
	b.b. Nr. 8	3,5		0,80	24,3	950	366	locker	weich	feiner	gering,	noch gut			7,84
	NaHCO3	2,5									verlaufen				
													40	7,91	
6													5		
													40		
7													5		
													40		
8													5		
													40		

Betriebsversuch II

Projekt-Nr.: AT1-_____

Backversuch

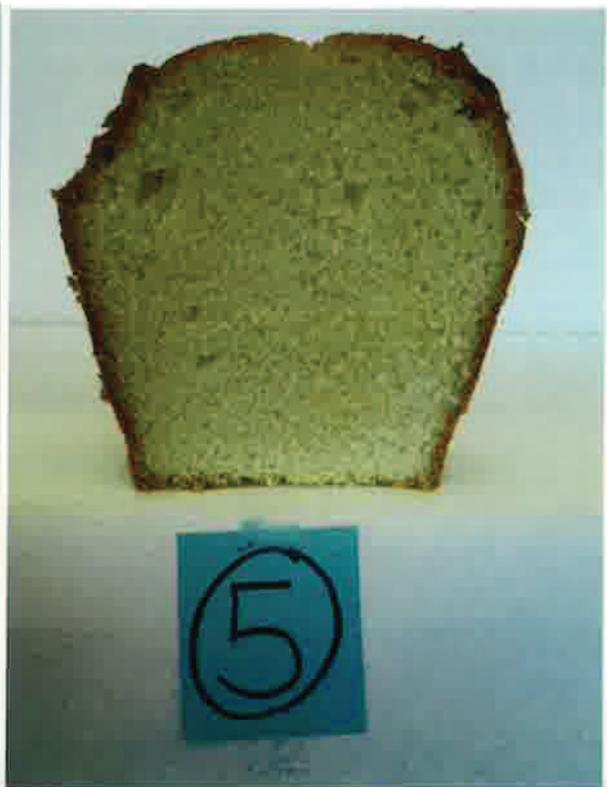
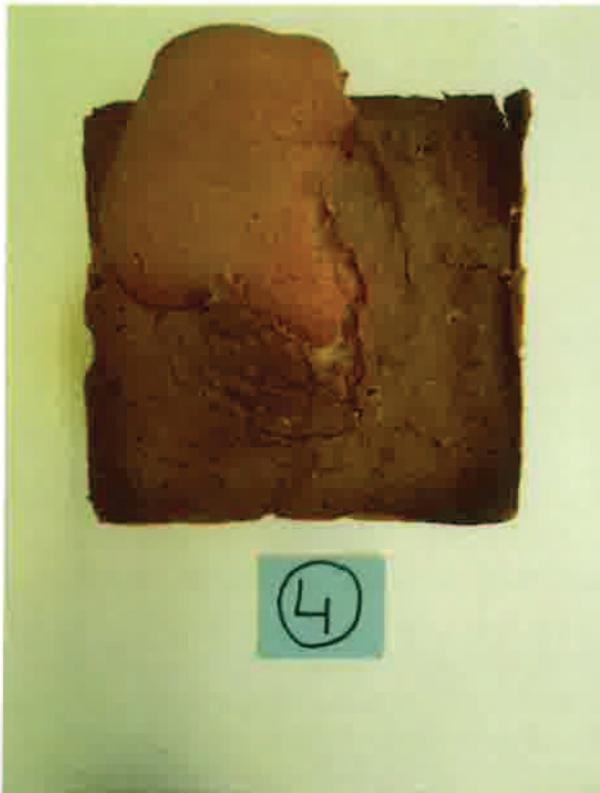
Datum : _____

Nr.:	Triebmittel	E	NW	Massen-	Teigtemp.	Volumen	Gewicht	Lockerung	Krumen-	Poren-	Ausbund	Kau-	Zeit	pH	pH	
		(g)	berech	dichte	(°C)	(mL)	(g)						(min)	Masse	Gebäck	
		(g)		(g/mL)												
1	N 54-80	3,5											5	7,55		
	MV 3049		73	0,80	25,1	970	357	locker	weich	fein	gut	gut				7,46
	NaHCO3	2,5								offen						
													40	7,46		
2	MgPP	4,2	60	0,80	25,1	1000	354	locker	weich	etwas	gut	gut	5	7,73		7,03
	V 10/4									feiner						
	NaHCO3	2,5											40	7,44		
													5	7,82		
3	Betriebsvers												5	7,82		
	b.b. Nr. 1	4,2	60	0,79	25,6	990	349	locker	weich	etwas	leicht	gut				7,36
	NaHCO3	2,5								feiner	kappen-					
											artig		40	7,74		
4	b.b. Nr. 9	4,2	60	0,80	25,2	980	351	locker	weich	etwas	leicht	gut	5	7,78		7,18
	NaHCO3	2,5								feiner	kappen-					
											artig		40	7,75		
5	b.b. Nr. 17	4,2	60	0,80	25,5	990	355	locker	weich	etwas	noch	gut	5	7,80		7,06
	NaHCO3	2,5								feiner	gut					
													40	7,78		
6	b.b. Nr. 17	4,6	55	0,81	25,1	970	354	locker	weich	fein	etwas	gut	5	7,76		6,89
	NaHCO3	2,5								offen	verlaufen					
													40	7,70		
7	b.b. Nr. 17	3,9	65	0,80	25,4	990	357	locker	weich	etwas	leicht	gut	5	7,81		7,19
	NaHCO3	2,5								feiner	kappen-					
											artig		40	7,80		
8													5			

NWS
zu tief
berechn-
net!

000031

MgPP: 5. Betriebsversuch, BigBag 21 im Vergleich mit SAPP 28 (ME-10-015)



4 = MgPP Betriebsversuch 5, BigBag 21

Volumen= 940 mL

5 = SAPP 28 MV3049 als Referenz

Volumen= 930 mL

Date:	09.09.2010	Project name:		Herstellung eines sauren Magnesiumpyrophosphates für die Backwarenindustrie								Project number:		ME-10-015		
No.	Leavening system	Weighted Sample	ROR	NV	Batter density	Batter temp.	Cake volume	Baking pan weights (g) Batter weight (g):	Cake weight (g) & Baking loss (%)	Specific Volume	Baking time	pH after 5 min	pH after 40 min	pH Difference between 5 + 40 min (Batter)	pH after 24h (Batter)	pH Pastry 10%ig
		(g)	(%)		(g/mL)	(°C)	(mL)	400		(mL/g)	(min)	(Batter)	(Batter)	(Batter)	(Batter)	
1	ME-08-041	3,6		70	0,75	25,2	960	Baking pan [tare]:	Cake weight (g):	2,65	45	7,8	7,7	0,0	7,32	7,35
	2. Betriebsversuch						960	360,2	362							7,35
	BB13						Average:	Baking pan [gross]:	Baking loss (%):							Average:
	NaHCO3	2,5					960	722,2	9,5							7,4
2	ME-10-015	3,6		70	0,75	25,3	920	Baking pan [tare]:	Cake weight (g):	2,51	45	7,8	7,7	0,1	7,35	7,47
	5. Betriebsversuch						920	360,6	366,6							7,47
	BB9						Average:	Baking pan [gross]:	Baking loss (%):							Average:
	NaHCO3	2,5					920	727,2	8,35							7,5
3	ME-10-015	3,6		70	0,76	25,4	910	Baking pan [tare]:	Cake weight (g):	2,46	45	7,8	7,7	0,1	7,29	7,42
	5. Betriebsversuch						910	363	369,9							7,42
	BB17						Average:	Baking pan [gross]:	Baking loss (%):							Average:
	NaHCO3	2,5					910	732,9	7,525							7,4
4	ME-10-015	3,6	0,2-11	70	0,77	25,5	940	Baking pan [tare]:	Cake weight (g):	2,56	45	7,8	7,8	0,1	7,34	7,39
	5. Betriebsversuch						940	356,7	367,9							7,39
	BB21						Average:	Baking pan [gross]:	Baking loss (%):							Average:
	NaHCO3	2,5					940	724,6	8,025							7,4
5	N 54-80	3,5	0,28		0,75	25,5	930	Baking pan [tare]:	Cake weight (g):	2,55	45	7,5	7,3	0,2		7,31
	MV3049						930	358,1	365,1							7,31
							Average:	Baking pan [gross]:	Baking loss (%):							Average:
	NaHCO3	2,5					930	723,2	8,725							7,3
6																
7																

Remarks: je höher die Wasseraktivität, desto niedriger der ROR

Projekt-Nr.: ~~XIV~~ MF-10-090

Backversuch

Datum: 09.09.10

Nr.:	Triebmittel	E (g)	ROR (%)	Massen- dichte (g/mL)	Teigtemp. (°C)	Volumen (mL)	Gewicht (g)	Lockerung	Krumen- beschaffenheit	Poren- bild	Ausbund	Kau- eigenschaft	Zeit (min)	pH Masse	pH Gebäck
5	NS4-85 B312124	3,5		0,76	25,4	930	358 366	locke	wack	normal	normal	normal	5	7,32	7,33
	P1372804											leicht klebrig	40	7,06	
	NaHCO ₃	2,5													
6	NS4-85 B31298B	3,5		0,77	22,5	910	363 367				normal	fest	5	7,36	7,33
	P1373199										etwas klebrig	leicht klebrig	40	7,07	
	NaHCO ₃	2,5													
7	B31298B P1373214	3,5		0,76	25,4	910	354 367				normal	fest	5	7,33	7,32
	NaHCO ₃	2,5										leicht klebrig	40	7,09	
8	B31298B P1373218	3,5		0,76	25,5	910	356 368				gering		5	7,35	7,32
	NaHCO ₃	2,5									Verstärk		40	7,13	
9	NS4-80 MV3049	3,5		0,75	25,5	930	358 365				klebrig	normal	5	7,46	7,31
	NaHCO ₃	2,5									Verstärk	leicht klebrig	40	7,30	
				NaHCO ₂									5		
													40		
													5		
													40		

Backversuch

Nr.:	Triebmittel	E (g)	ROR M (%)	Massen- dichte (g/mL)	Teigtemp. (°C)	Volumen (mL)	Gewicht (g)	Lockerung	Krumen- beschaffenheit	Poren- bild	Ausbund	Kau- eigenschaft	Zeit (min)	pH Masse	pH Gebäck
1	ME-08-041												5	7,76	
	2-Betriebsv.	3,6	70	0,75	27,2	960	360	weich		sehr fein	leicht kappenartig verlaufen	leicht Klebrig	40	7,72	7,35
	b.b. 13	3,6					362						240	7,32	
	NaHCO ₃	2,1												7,32	
2	ME- 08 10-06												5	7,82	
	5-Betriebsv.			0,75	27,3	920	367	weich		~	klein verlaufen	~	40	7,69	7,47
	S-b. 9	3,6	70				367						240	7,35	
	NaHCO ₃	2,1													
3	S-b. 17	3,6	70	0,76	27,4	910	367	fest		~	flach	fest klebrig	5	7,81	
							367						40	7,73	7,42
	NaHCO ₃	2,1											240	7,29	
4	S-b. 21	3,6	70	0,77	27,5	940	368	festes		~	geringer	~	5	7,82	
													40	7,77	7,39
	NaHCO ₃	2,1											240	7,34	
												5			
	x in Oben deutlich höheres Volumen, spät bei Ethanol Vol deutlich reduziert												40		
													5		
													40		
													5		
													40		



Replacing Sodium Acid Pyrophosphate with Magnesium Acid Pyrophosphate in Bakery Wares

Chemische Fabrik Budenheim

28 April 2010



Executive Summary

Chemische Fabrik Budenheim requested Creme to carry out a detailed intake exposure estimation for the replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery wares. In particular Creme examined the changes in the daily intake of sodium, phosphorus and magnesium as a result of this replacement. Three replacement scenarios were considered: one in which all the sodium acid pyrophosphate in all bakery ware products was replaced by the appropriate amount of magnesium acid pyrophosphate; one in which 10% of the sodium acid pyrophosphate in all bakery ware products was replaced by the appropriate amount of magnesium acid pyrophosphate; and one in which all the sodium acid pyrophosphate in 10% of bakery ware products was replaced by the appropriate amount of magnesium acid pyrophosphate.

In all replacement scenarios there was only a small change in the total population's exposure to sodium and potassium. While the relative change in magnesium intake was always greater than the change in sodium and potassium, there is no statistically significant change in magnesium intake in the 10% replacement scenarios. In the most extreme replacement scenario the total population's mean magnesium intake jumps from well below the daily recommended intake, to values in the recommended range, both for the British and American surveys. The decrease in sodium intakes as a result of this replacement will be 1.6% at a maximum for the American population, while this value is 3.8% for the British population, due to their higher level of bakery ware consumption. The increase in potassium intakes can reach a maximum of 1.24% for Americans and 2.3% for the British. These increases correspond to less than 1% of the tolerable upper daily intake of potassium and even the maximum potassium consumers remain well below the 4000mg limit. The increase in the daily intake of magnesium as a result of this replacement can be as much as 12% or 34mg for the average American and 23% or 64mg for the average Briton.

As magnesium is not commonly found in most foods in the Western diet (the main sources are green leafy vegetables, fruits, nuts and soy products), a large proportion of the population do not reach their recommended daily intake. The replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery ware products represents a great opportunity to increase magnesium intakes to their recommended levels while simultaneously reducing sodium intakes.

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Acronyms

NHANES National Health and Nutrition Examination Survey

WWEIA What We Eat In America

NDNS National Diet and Nutrition Survey

EFSA European Food Safety Authority

RDA Recommended Daily Allowance

UL Tolerable Upper Limit

1 Overview

Chemische Fabrik Budenheim requires a detailed intake exposure estimation for the replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in “bakery wares” (including bread and fine bakery wares).

Chemische Fabrik Budenheim provided the chemical composition data as follows:

The chemical composition of the sodium acid pyrophosphate ($Na_2H_2P_2O_7$) (typical analytical figures, not theoretical) is:

20.4% Sodium

27.7% Phosphorus

The chemical composition of the magnesium acid pyrophosphate ($MgH_2P_2O_7$) (typical analytical figures, not theoretical) is:

11.30% Magnesium

30.8% Phosphorus

The usage of 1 part sodium acid pyrophosphate will be replaced by 1.09 parts of magnesium acid pyrophosphate due its functionality difference.

While the proposal originally suggested assuming typical use at the maximum allowed level (EC directive 95/2) of sodium acid pyrophosphate (20g/kg, calculated as P_2O_5), this was inconsistent with the available sodium data. Creme considered two scenarios: one in which sodium acid pyrophosphate was responsible for 20% of the sodium in the bakery wares part of the food, with sodium bicarbonate and sodium chloride responsible for the rest; and a worst case scenario in which sodium acid pyrophosphate accounted for 30% of the sodium in the bakery wares.

Three replacement scenarios were considered:

- A 100% replacement of the sodium acid pyrophosphate with the appropriate amount of magnesium acid pyrophosphate to show worst case scenario.
- A refined replacement scenario in which 10% of the sodium acid pyrophosphate was replaced with the appropriate amount of magnesium acid pyrophosphate.
- A refined replacement scenario in which a random 10% of the bakery ware products had all their sodium acid pyrophosphate replaced with the appropriate amount of magnesium acid pyrophosphate.

The mean and 97.5th percentile of the daily average sodium, magnesium and phosphorus intake were outputted, with the contribution of bakery wares explicitly shown, and compared to recommended daily allowances and tolerable upper intake levels, for all scenarios.

The analysis was carried out in detail for the following countries:

- Great Britain, using the NDNS survey published in 2001.
- The United States of America, using the 2005-2006 NHANES WWEIA survey.

The effect of the replacement on a Europe wide basis was considered by comparing the food consumption patterns of EFSA members states with British food consumption, using the EFSA concise data published in 2007.

2 Methods

2.1 Setting up the Food Groups

Food groups were created for “Bakery Wares”, including bread and fine bakery wares. For Great Britain the following NDNS food groups were included in the “Bakery Wares” group:

- Other breads (4R)
- White breads (2R)
- Wholemeal breads (3R)
- Softgrain breads (4A)
- Buns, cakes and pastries (8R)

All other NDNS foods were grouped into appropriate EFSA like groups:

- 01B Other Cereal Products
- 02 Sugars
- 03 Fats
- 04 Vegetables
- 05 Starchy roots
- 06 Fruits
- 07 Soft drinks and Juices
- 08 Beverages
- 09 Alcoholic drinks
- 10 Meats
- 11 Seafood
- 12 Eggs
- 13 Dairy
- 14 Miscellaneous
- 15 Tap water

For the United States the appropriate FSRG-defined food groups were used, with the “Grain Products” group broken into “Bakery Wares” and “Other Grain Products”. The following foods were included in the “Bakery Wares” group:

- Quick breads, pancakes, French toast.
- Cakes, cookies, pastries and pies.
- Yeast breads and rolls.
- The fraction of sandwiches that related to bread. The sandwich filling itself was assigned to the appropriate food group.

2.2 Determining the Altered Chemical Composition of Each Bakery Ware Product

Creme has sodium, magnesium and phosphorus composition levels for every bakery ware product in the British NDNS and American WWEIA surveys, as recorded in the original survey. Using the following assumptions it is possible to estimate the concentration of sodium acid pyrophosphate in each food. As explained in the appendices, assuming typical use at the maximum allowed level of sodium acid pyrophosphate (20g/kg, calculated as P_2O_5) is inconsistent with available data. In order to estimate the level of sodium acid pyrophosphate in every food, we made the following assumptions:

- The level of sodium acid pyrophosphate is at most that which corresponds to contributing to all the phosphorus in the bakery ware product.
- The level of sodium acid pyrophosphate is at most that which corresponds to contributing to x times the sodium in the bakery ware product, where x is typically between 0.2 and 0.3 for most recipes. The rest of the sodium is assumed to come from sodium bicarbonate and sodium chloride.

Thus we estimate the level of sodium acid pyrophosphate originally in the food to be

$$[Na_2H_2P_2O_7]_{org} = \text{minimum} \left(x[Na]_{org} \frac{M_{Na_2H_2P_2O_7}}{M_{Na_2}}, [P]_{org} \frac{M_{Na_2H_2P_2O_7}}{M_{P_2}} \right) \quad (1)$$

where

$[Na_2H_2P_2O_7]_{org}$	is the estimated level of sodium acid pyrophosphate
$[Na]_{org}$	is the original concentration of sodium
$[P]_{org}$	is the original concentration of phosphorus

2.2.1 The Replacement Formulae

For the foods in the “Bakery Wares” food group the levels of sodium, magnesium and phosphorus in these foods were altered using the following formulae:

$$[\text{Na}]_{\text{new}} = [\text{Na}]_{\text{org}} - R[\text{Na}_2\text{H}_2\text{P}_2\text{O}_7]_{\text{org}} \frac{M_{\text{Na}_2}}{M_{\text{Na}_2\text{H}_2\text{P}_2\text{O}_7}} \quad (2)$$

$$[\text{Mg}]_{\text{new}} = [\text{Mg}]_{\text{org}} + Rf[\text{Na}_2\text{H}_2\text{P}_2\text{O}_7]_{\text{org}} \frac{M_{\text{Mg}}}{M_{\text{MgH}_2\text{P}_2\text{O}_7}} \quad (3)$$

$$[\text{P}]_{\text{new}} = [\text{P}]_{\text{org}} + R[\text{Na}_2\text{H}_2\text{P}_2\text{O}_7]_{\text{org}} \left(f \frac{M_{\text{P}_2}}{M_{\text{MgH}_2\text{P}_2\text{O}_7}} - \frac{M_{\text{P}_2}}{M_{\text{Na}_2\text{H}_2\text{P}_2\text{O}_7}} \right) \quad (4)$$

where

- $[\text{Na}]_{\text{new}}$ is the new concentration of sodium
- $[\text{P}]_{\text{new}}$ is the new concentration of phosphorus
- $[\text{Mg}]_{\text{org}}$ is the original concentration of magnesium
- $[\text{Mg}]_{\text{new}}$ is the new concentration of magnesium
- R is the replacement fraction
- f is the functional equivalence fraction, 1.09 in this case

2.3 Determining the Daily Average Exposure Distribution

Creme considers all eating events in order to determine the daily average intake of a particular nutrient, via defined food groups, for every subject in a survey. Statistics are then calculated for the entire population, in particular the mean and 97.5th percentile and reported with error measurements resulting from the size of the original survey. Once calculated the daily average exposure distributions to sodium, magnesium and phosphorus are compared against typical Recommended Daily Allowances (RDAs) and Tolerable Upper Limits (ULs):

Nutrient	RDA	UL
Sodium	1600mg	2300mg
Magnesium	310-420mg	NA
Phosphorus	700mg	4000mg

Table 1: Typical RDAs and ULs for sodium and phosphorus. A typical Magnesium RDA is included, however no UL has yet been established for dietary magnesium. For non-food sources the UL is typically 350mg.

3 Results

For both the United States and Great Britain results are plotted and tabulated for the following four scenarios:

Original No magnesium acid pyrophosphate added to the bakery ware food group.

10% (I) 10% of the sodium acid pyrophosphate in each bakery ware product is replaced with magnesium acid pyrophosphate.

10% (P) A random 10% of bakery ware products have all of their sodium acid pyrophosphate replaced with magnesium acid pyrophosphate, while the remaining 90% continue to use sodium acid pyrophosphate.

100% All the sodium acid pyrophosphate is replaced with magnesium acid pyrophosphate.

under these two assumptions:

- The level of sodium acid pyrophosphate is at most that which corresponds to contributing to 20% of the sodium in the food.
- The level of sodium acid pyrophosphate is at most that which corresponds to contributing to 30% of the sodium in the food.

For both countries we initially show piecharts illustrating the relative contribution of each food group to the overall food intake, the magnesium intake, the sodium intake and the phosphorus intake. Plots which show the overall nutrient intake, compared to the RDAs and ULs can be found in the appendices.

Then for each assumption we provide tables which show the mean intake and the 97.5th percentile of the intake for each nutrient in all four scenarios, broken down into food groups. We also produce a boxplot which illustrates the amount of a particular nutrient obtained from bakery wares for those who consumed items in the “Bakery Wares” food group in each scenario.

3.1 Analysis of the American Diet

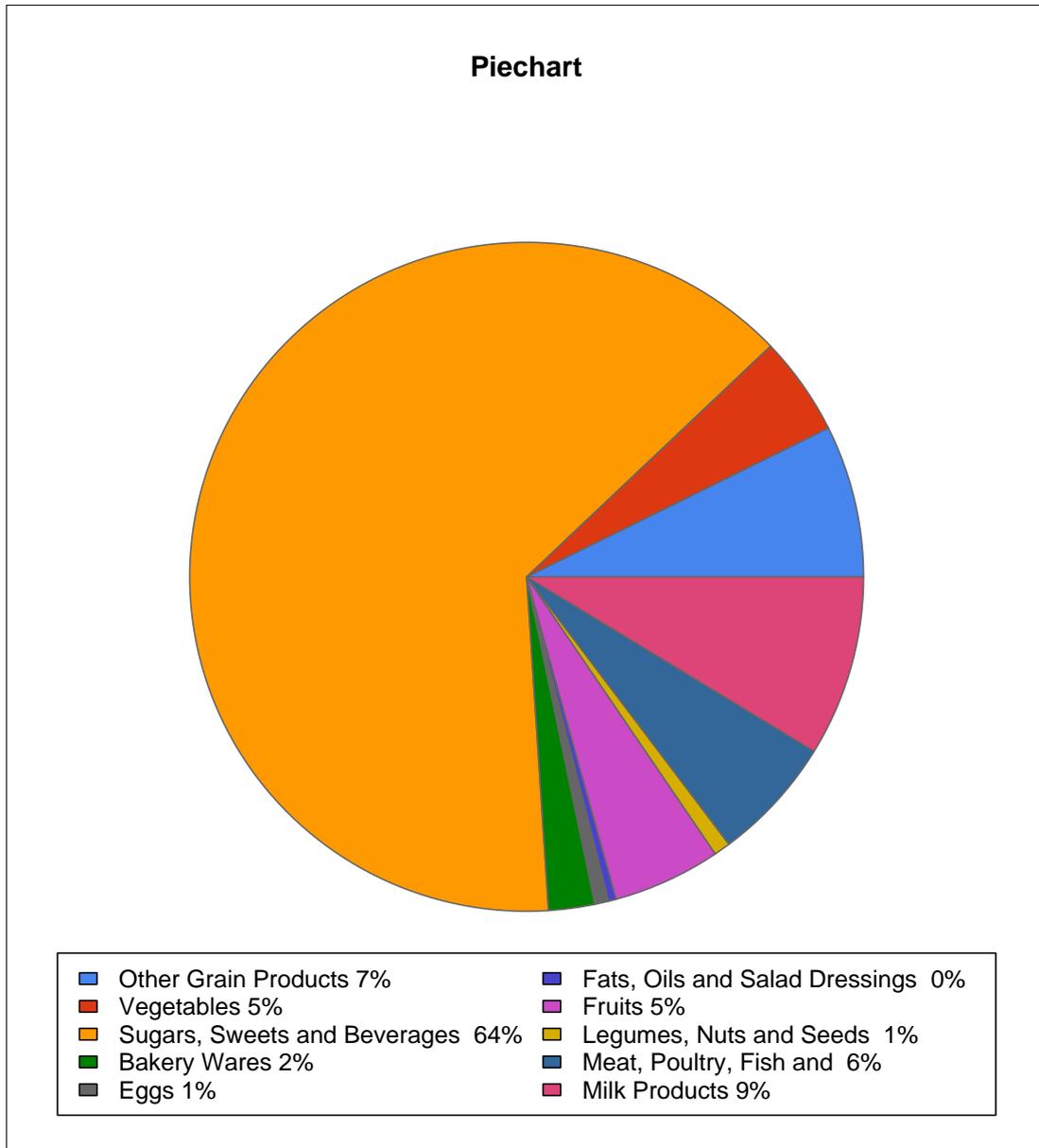


Figure 1: Piechart showing the relative intake of food in the American diet.

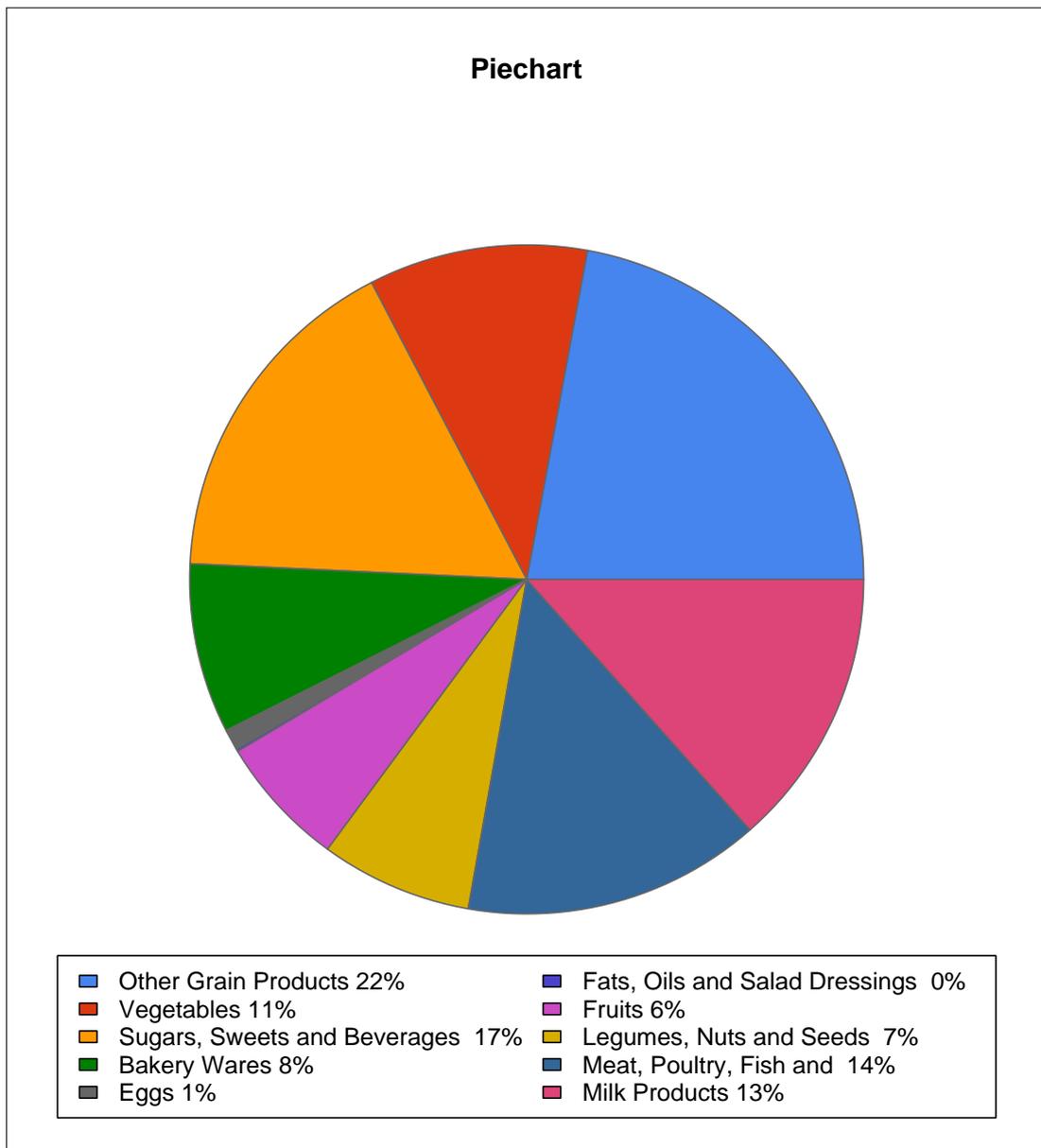


Figure 2: Piechart showing the relative sources of Magnesium in the American diet.

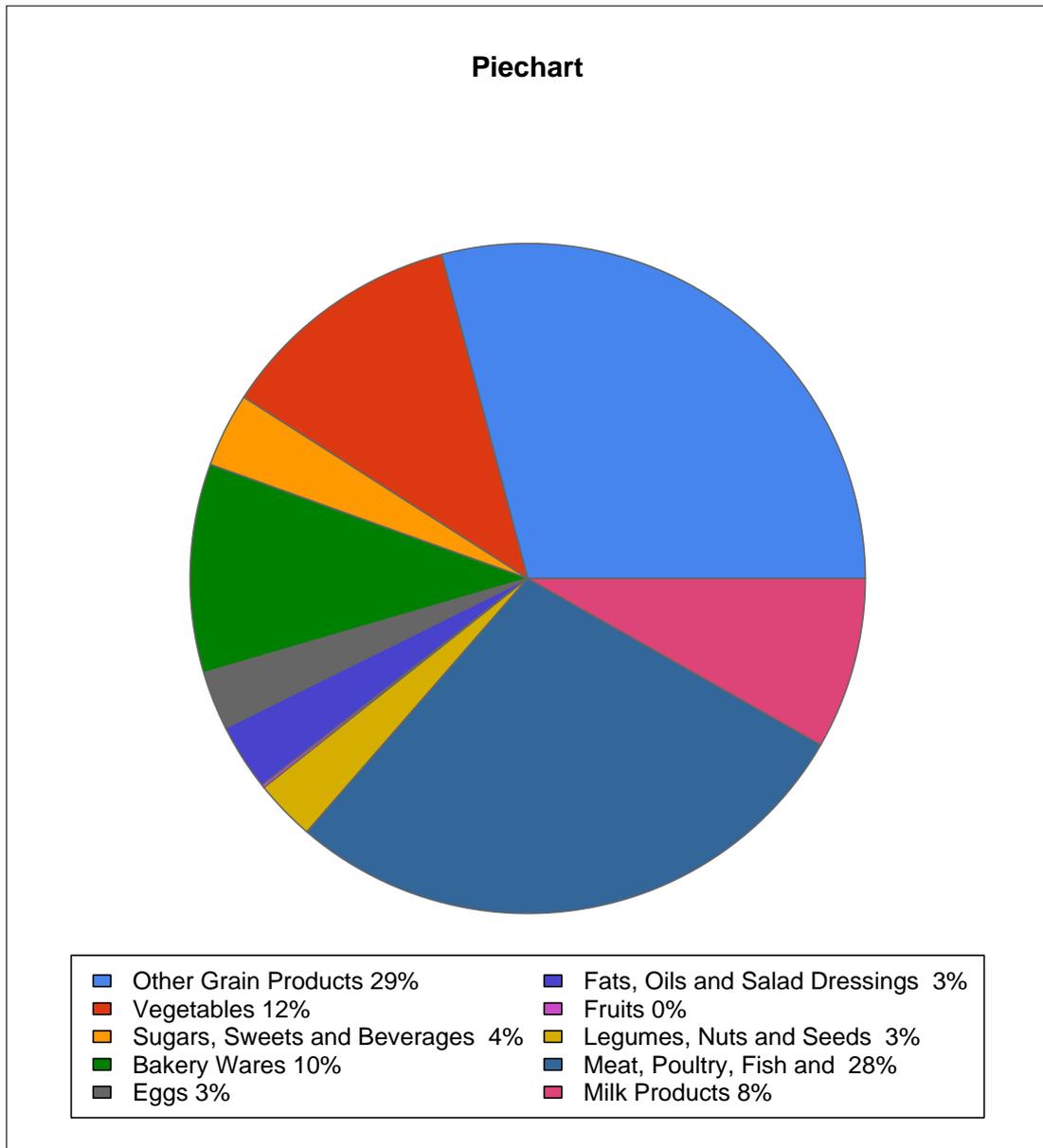


Figure 3: Piechart showing the relative sources of Sodium in the American diet.

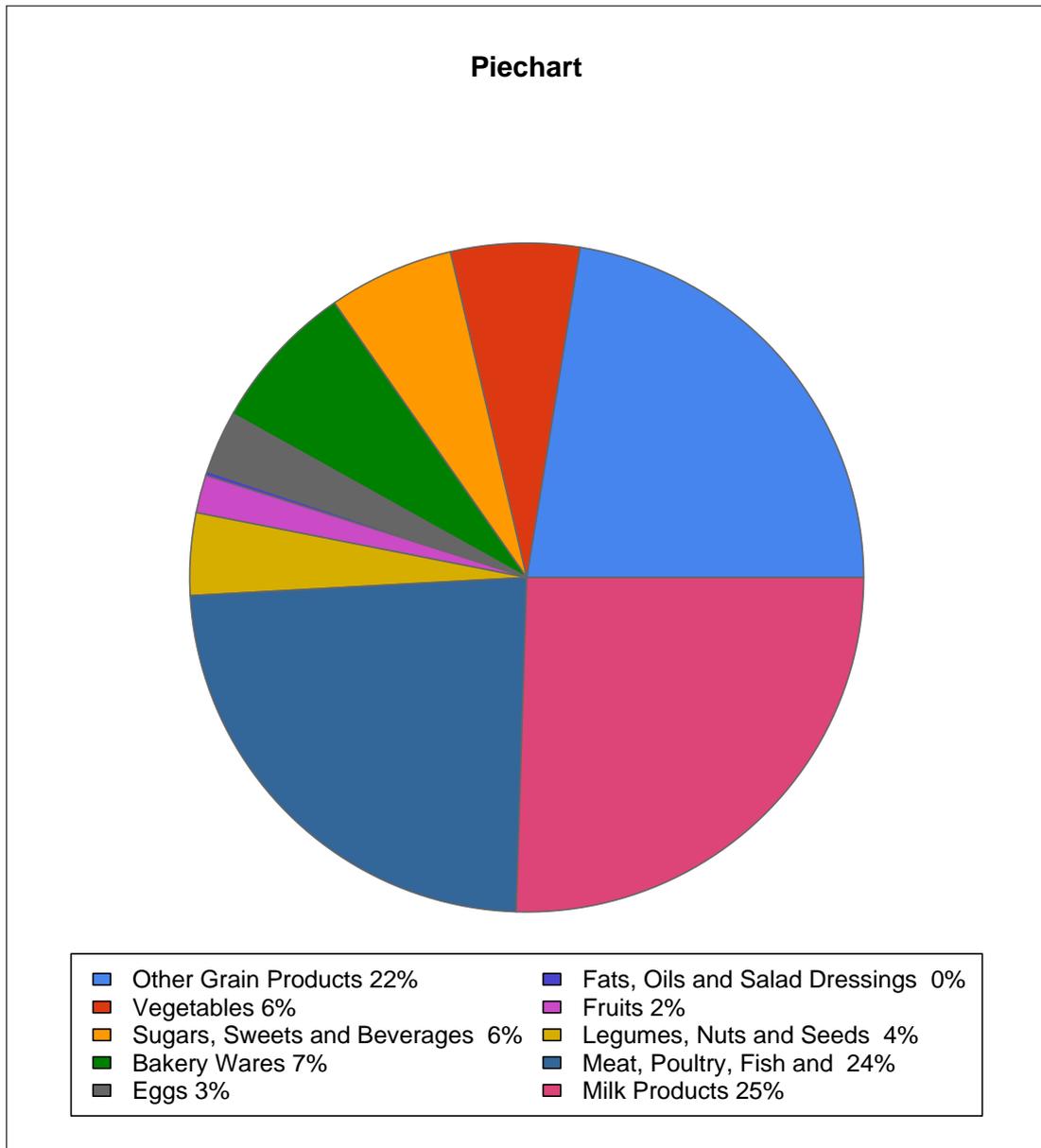


Figure 4: Piechart showing the relative sources of Phosphorus in the American diet.

3.1.1 Replacement Results: 20% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	281.1	284.2	284.4	312.0
Bakery Wares	23.2	26.3	26.5	54.1
Eggs	2.8	2.8	2.8	2.8
Fats, Oils and Salad Dressings	0.3	0.3	0.3	0.3
Fruits	17.8	17.8	17.8	17.8
Legumes, Nuts and Seeds	20.5	20.5	20.5	20.5
Meat, Poultry, Fish and Mixtures	40.1	40.1	40.1	40.1
Milk Products	37.9	37.9	37.9	37.9
Other Grain Products	62.2	62.2	62.2	62.2
Sugars, Sweets and Beverages	46.8	46.8	46.8	46.8
Vegetables	29.5	29.5	29.5	29.5

Table 2: Mean Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	647.5	650.9	654.3	703.1
Bakery Wares	96.7	105.1	114.3	193.9
Eggs	25.7	25.7	25.7	25.7
Fats, Oils and Salad Dressings	2.4	2.4	2.4	2.4
Fruits	92.0	92.0	92.0	92.0
Legumes, Nuts and Seeds	162.6	162.6	162.6	162.6
Meat, Poultry, Fish and Mixtures	149.2	149.2	149.2	149.2
Milk Products	151.0	151.0	151.0	151.0
Other Grain Products	234.8	234.8	234.8	234.8
Sugars, Sweets and Beverages	190.6	190.6	190.6	190.6
Vegetables	119.8	119.8	119.8	119.8

Table 3: The 97.5 Percentile of the Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

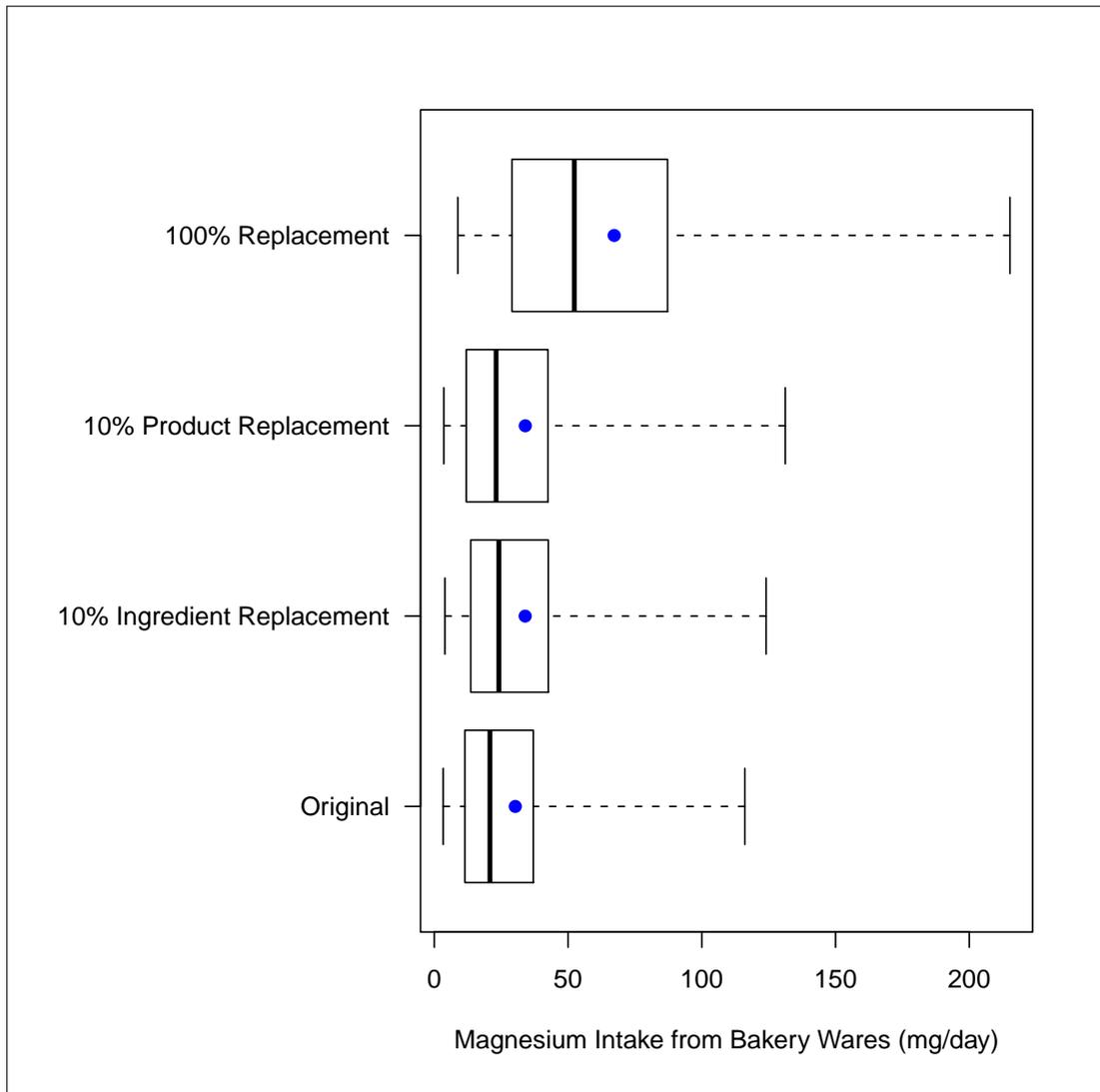


Figure 5: Boxplot intake of Magnesium from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	3508.3	3503.2	3502.8	3457.1
Bakery Wares	361.8	356.7	356.4	310.6
Eggs	99.0	99.0	99.0	99.0
Fats, Oils and Salad Dressings	112.8	112.8	112.8	112.8
Fruits	5.2	5.2	5.2	5.2
Legumes, Nuts and Seeds	102.5	102.5	102.5	102.5
Meat, Poultry, Fish and Mixtures	976.3	976.3	976.3	976.3
Milk Products	290.4	290.4	290.4	290.4
Other Grain Products	1021.4	1021.4	1021.4	1021.4
Sugars, Sweets and Beverages	125.2	125.2	125.2	125.2
Vegetables	413.6	413.6	413.6	413.6

Table 4: Mean Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	7951.5	7936.0	7948.5	7890.1
Bakery Wares	1294.0	1278.8	1279.1	1133.3
Eggs	952.3	952.3	952.3	952.3
Fats, Oils and Salad Dressings	925.1	925.1	925.1	925.1
Fruits	35.1	35.1	35.1	35.1
Legumes, Nuts and Seeds	975.1	975.1	975.1	975.1
Meat, Poultry, Fish and Mixtures	3600.5	3600.5	3600.5	3600.5
Milk Products	1222.1	1222.1	1222.1	1222.1
Other Grain Products	3932.4	3932.4	3932.4	3932.4
Sugars, Sweets and Beverages	490.9	490.9	490.9	490.9
Vegetables	1889.5	1889.5	1889.5	1889.5

Table 5: The 97.5 Percentile of the Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

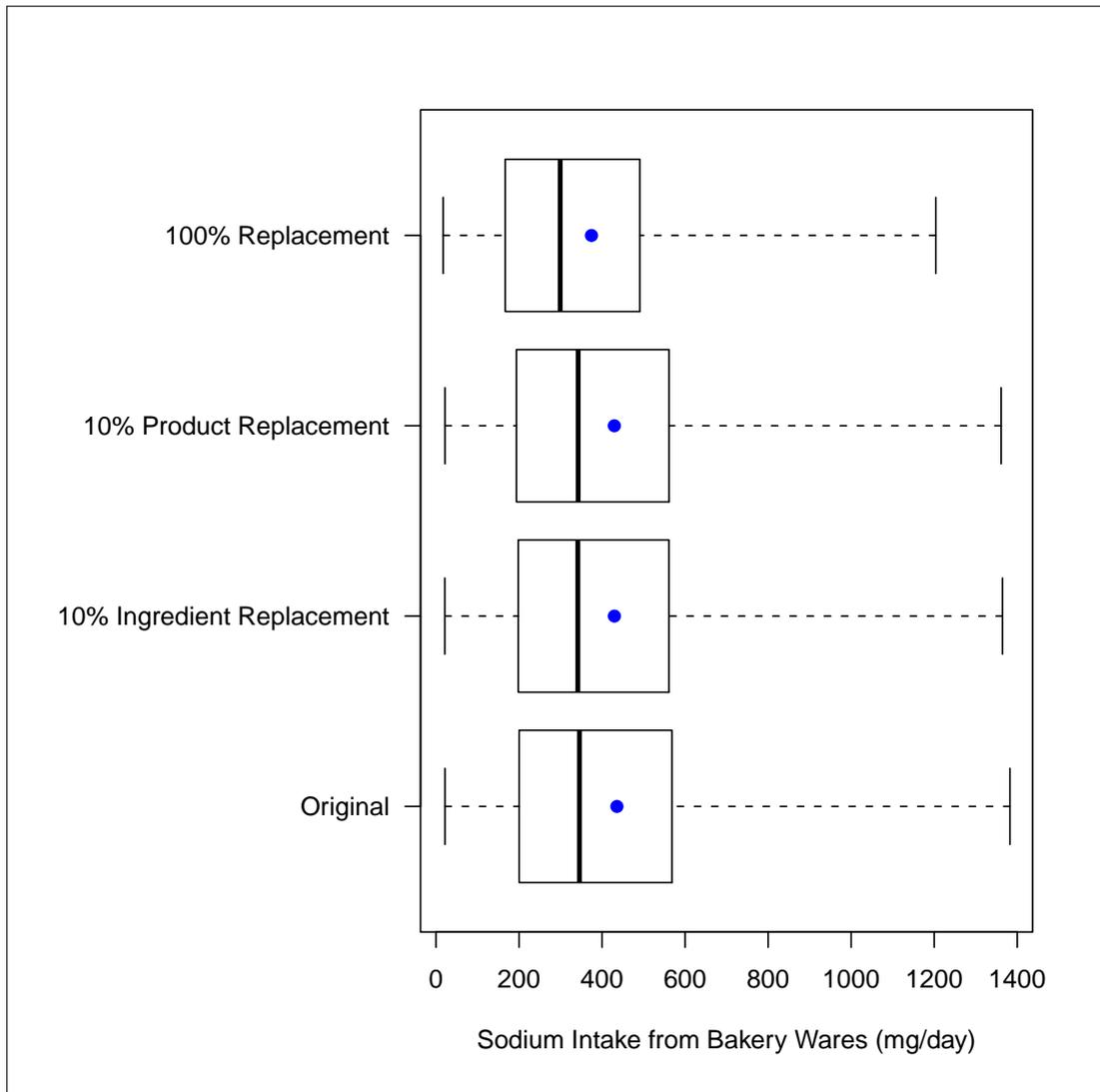


Figure 6: Boxplot intake of Sodium from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1313.0	1314.5	1314.6	1327.7
Bakery Wares	92.1	93.6	93.7	106.9
Eggs	40.0	40.0	40.0	40.0
Fats, Oils and Salad Dressings	2.6	2.6	2.6	2.6
Fruits	24.0	24.0	24.0	24.0
Legumes, Nuts and Seeds	52.2	52.2	52.2	52.2
Meat, Poultry, Fish and Mixtures	312.1	312.1	312.1	312.1
Milk Products	334.8	334.8	334.8	334.8
Other Grain Products	294.9	294.9	294.9	294.9
Sugars, Sweets and Beverages	79.1	79.1	79.1	79.1
Vegetables	81.1	81.1	81.1	81.1

Table 6: Mean Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2919.9	2924.7	2918.6	2938.2
Bakery Wares	403.5	411.2	414.9	456.5
Eggs	370.2	370.2	370.2	370.2
Fats, Oils and Salad Dressings	18.9	18.9	18.9	18.9
Fruits	118.1	118.1	118.1	118.1
Legumes, Nuts and Seeds	437.5	437.5	437.5	437.5
Meat, Poultry, Fish and Mixtures	1082.7	1082.7	1082.7	1082.7
Milk Products	1248.7	1248.7	1248.7	1248.7
Other Grain Products	1158.3	1158.3	1158.3	1158.3
Sugars, Sweets and Beverages	399.2	399.2	399.2	399.2
Vegetables	342.1	342.1	342.1	342.1

Table 7: The 97.5 Percentile of the Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

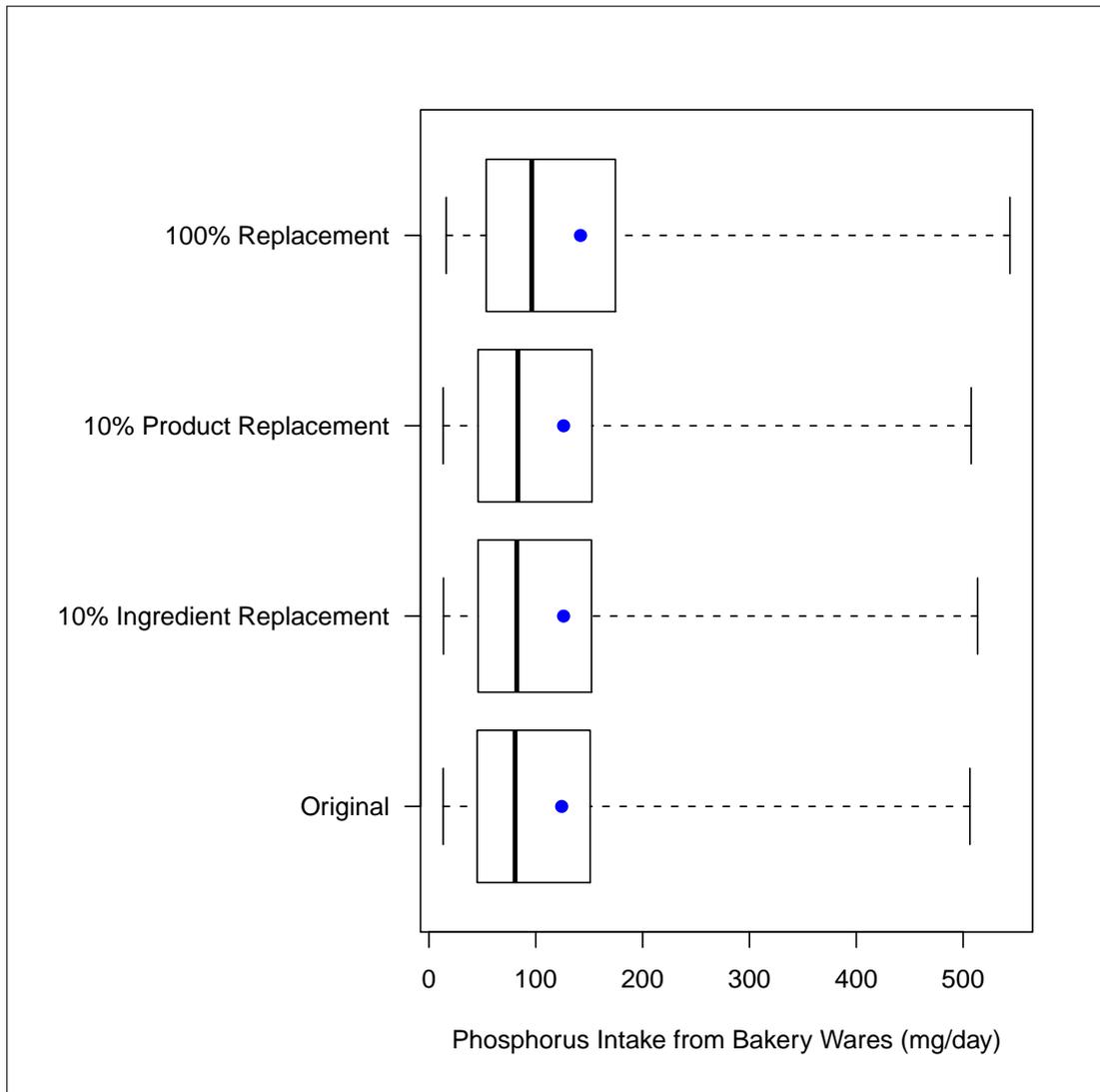


Figure 7: Boxplot intake of Phosphorus from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

3.1.2 Replacement Results: 30% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	281.1	284.5	284.6	315.3
Bakery Wares	23.2	26.6	26.6	57.4
Eggs	2.8	2.8	2.8	2.8
Fats, Oils and Salad Dressings	0.3	0.3	0.3	0.3
Fruits	17.8	17.8	17.8	17.8
Legumes, Nuts and Seeds	20.5	20.5	20.5	20.5
Meat, Poultry, Fish and Mixtures	40.1	40.1	40.1	40.1
Milk Products	37.9	37.9	37.9	37.9
Other Grain Products	62.2	62.2	62.2	62.2
Sugars, Sweets and Beverages	46.8	46.8	46.8	46.8
Vegetables	29.5	29.5	29.5	29.5

Table 8: Mean Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	647.5	650.9	653.6	709.4
Bakery Wares	96.7	106.8	110.8	209.8
Eggs	25.7	25.7	25.7	25.7
Fats, Oils and Salad Dressings	2.4	2.4	2.4	2.4
Fruits	92.0	92.0	92.0	92.0
Legumes, Nuts and Seeds	162.6	162.6	162.6	162.6
Meat, Poultry, Fish and Mixtures	149.2	149.2	149.2	149.2
Milk Products	151.0	151.0	151.0	151.0
Other Grain Products	234.8	234.8	234.8	234.8
Sugars, Sweets and Beverages	190.6	190.6	190.6	190.6
Vegetables	119.8	119.8	119.8	119.8

Table 9: The 97.5 Percentile of the Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

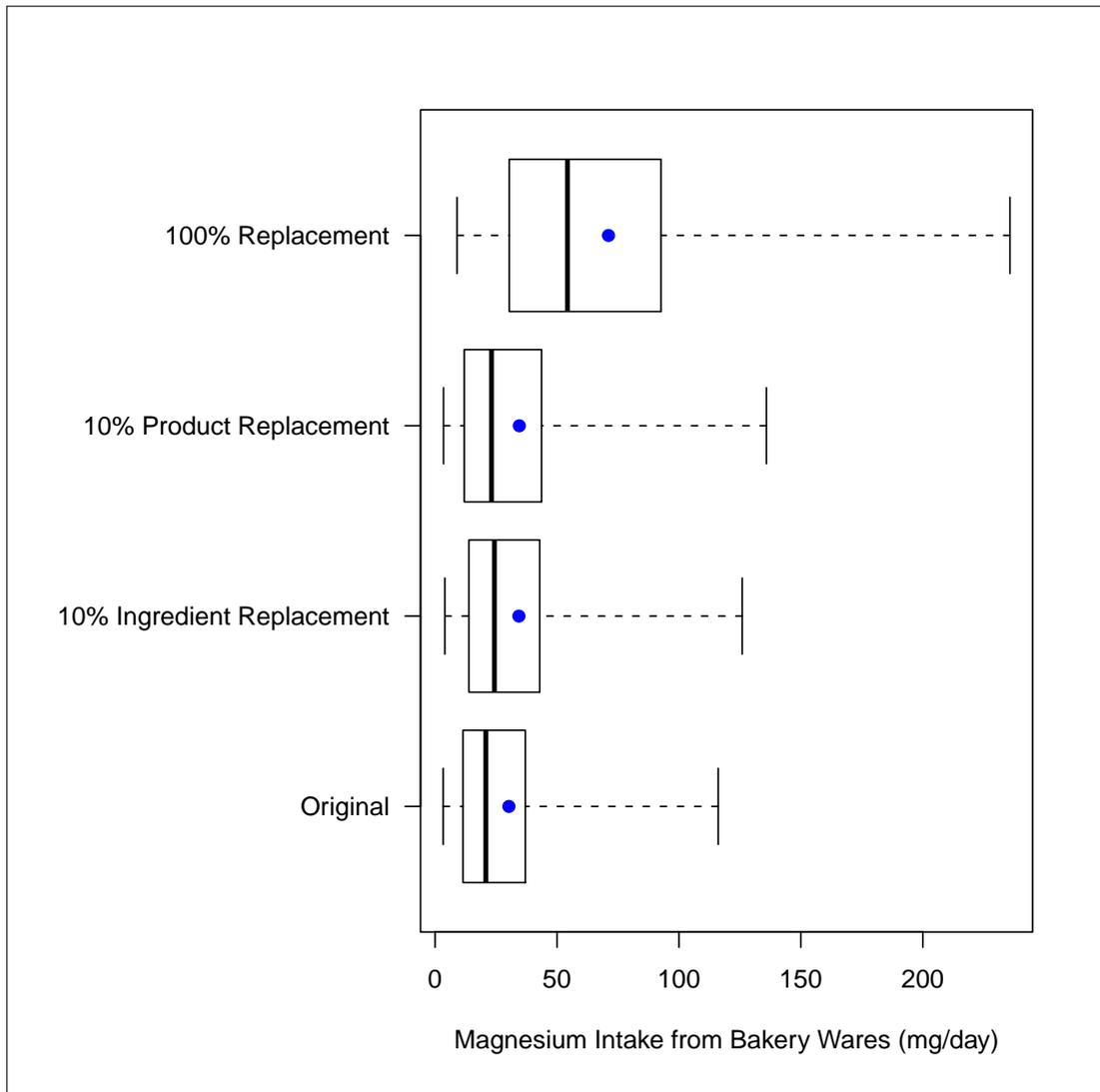


Figure 8: Boxplot intake of Magnesium from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	3508.3	3502.6	3502.6	3451.7
Bakery Wares	361.8	356.2	356.2	305.3
Eggs	99.0	99.0	99.0	99.0
Fats, Oils and Salad Dressings	112.8	112.8	112.8	112.8
Fruits	5.2	5.2	5.2	5.2
Legumes, Nuts and Seeds	102.5	102.5	102.5	102.5
Meat, Poultry, Fish and Mixtures	976.3	976.3	976.3	976.3
Milk Products	290.4	290.4	290.4	290.4
Other Grain Products	1021.4	1021.4	1021.4	1021.4
Sugars, Sweets and Beverages	125.2	125.2	125.2	125.2
Vegetables	413.6	413.6	413.6	413.6

Table 10: Mean Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	7951.5	7936.8	7950.9	7875.1
Bakery Wares	1294.0	1277.3	1288.4	1111.2
Eggs	952.3	952.3	952.3	952.3
Fats, Oils and Salad Dressings	925.1	925.1	925.1	925.1
Fruits	35.1	35.1	35.1	35.1
Legumes, Nuts and Seeds	975.1	975.1	975.1	975.1
Meat, Poultry, Fish and Mixtures	3600.5	3600.5	3600.5	3600.5
Milk Products	1222.1	1222.1	1222.1	1222.1
Other Grain Products	3932.4	3932.4	3932.4	3932.4
Sugars, Sweets and Beverages	490.9	490.9	490.9	490.9
Vegetables	1889.5	1889.5	1889.5	1889.5

Table 11: The 97.5 Percentile of the Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

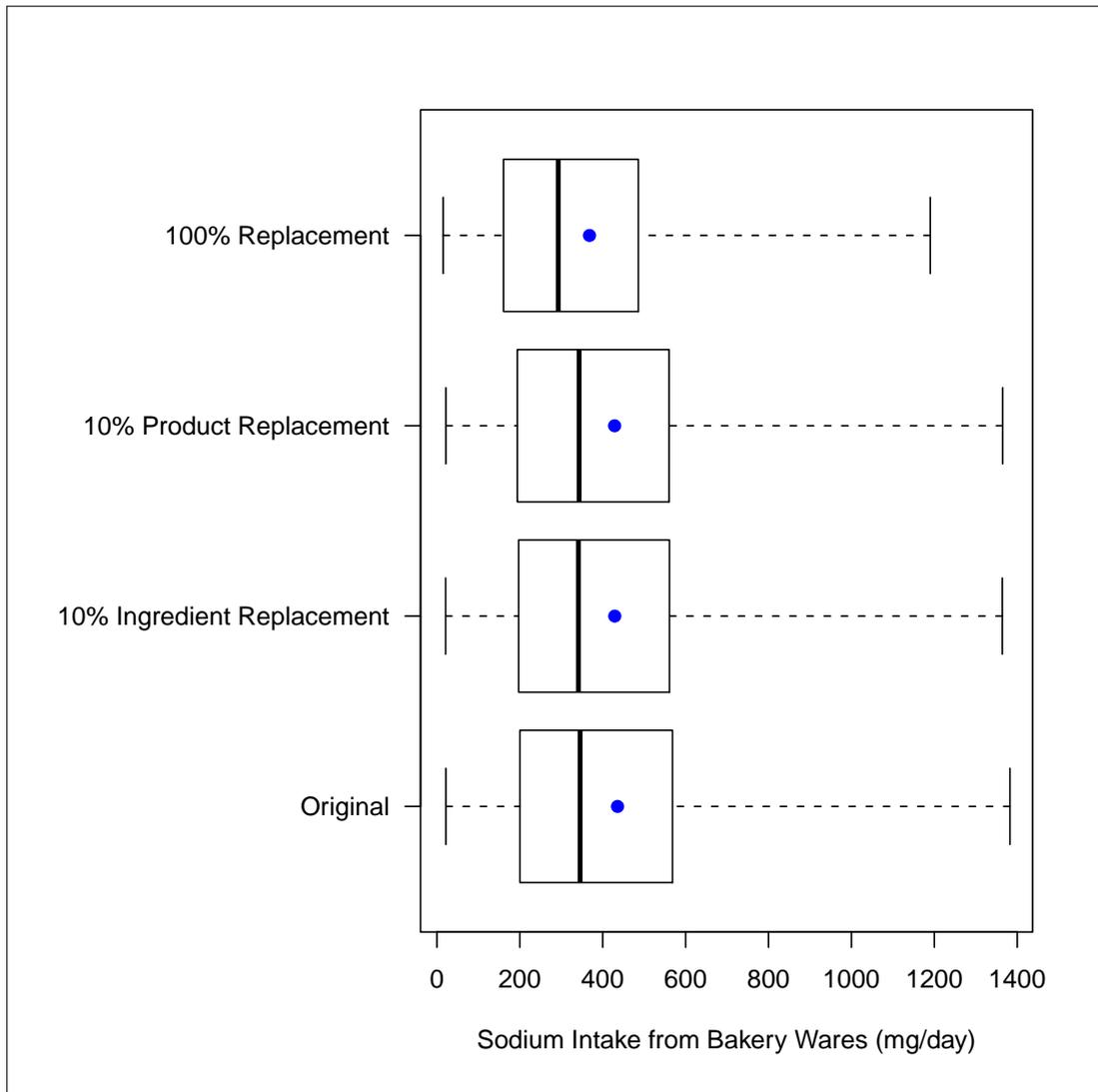


Figure 9: Boxplot intake of Sodium from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1313.0	1314.6	1314.6	1329.3
Bakery Wares	92.1	93.8	93.8	108.4
Eggs	40.0	40.0	40.0	40.0
Fats, Oils and Salad Dressings	2.6	2.6	2.6	2.6
Fruits	24.0	24.0	24.0	24.0
Legumes, Nuts and Seeds	52.2	52.2	52.2	52.2
Meat, Poultry, Fish and Mixtures	312.1	312.1	312.1	312.1
Milk Products	334.8	334.8	334.8	334.8
Other Grain Products	294.9	294.9	294.9	294.9
Sugars, Sweets and Beverages	79.1	79.1	79.1	79.1
Vegetables	81.1	81.1	81.1	81.1

Table 12: Mean Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2919.9	2925.3	2919.9	2936.0
Bakery Wares	403.5	410.6	410.9	458.4
Eggs	370.2	370.2	370.2	370.2
Fats, Oils and Salad Dressings	18.9	18.9	18.9	18.9
Fruits	118.1	118.1	118.1	118.1
Legumes, Nuts and Seeds	437.5	437.5	437.5	437.5
Meat, Poultry, Fish and Mixtures	1082.7	1082.7	1082.7	1082.7
Milk Products	1248.7	1248.7	1248.7	1248.7
Other Grain Products	1158.3	1158.3	1158.3	1158.3
Sugars, Sweets and Beverages	399.2	399.2	399.2	399.2
Vegetables	342.1	342.1	342.1	342.1

Table 13: The 97.5 Percentile of the Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

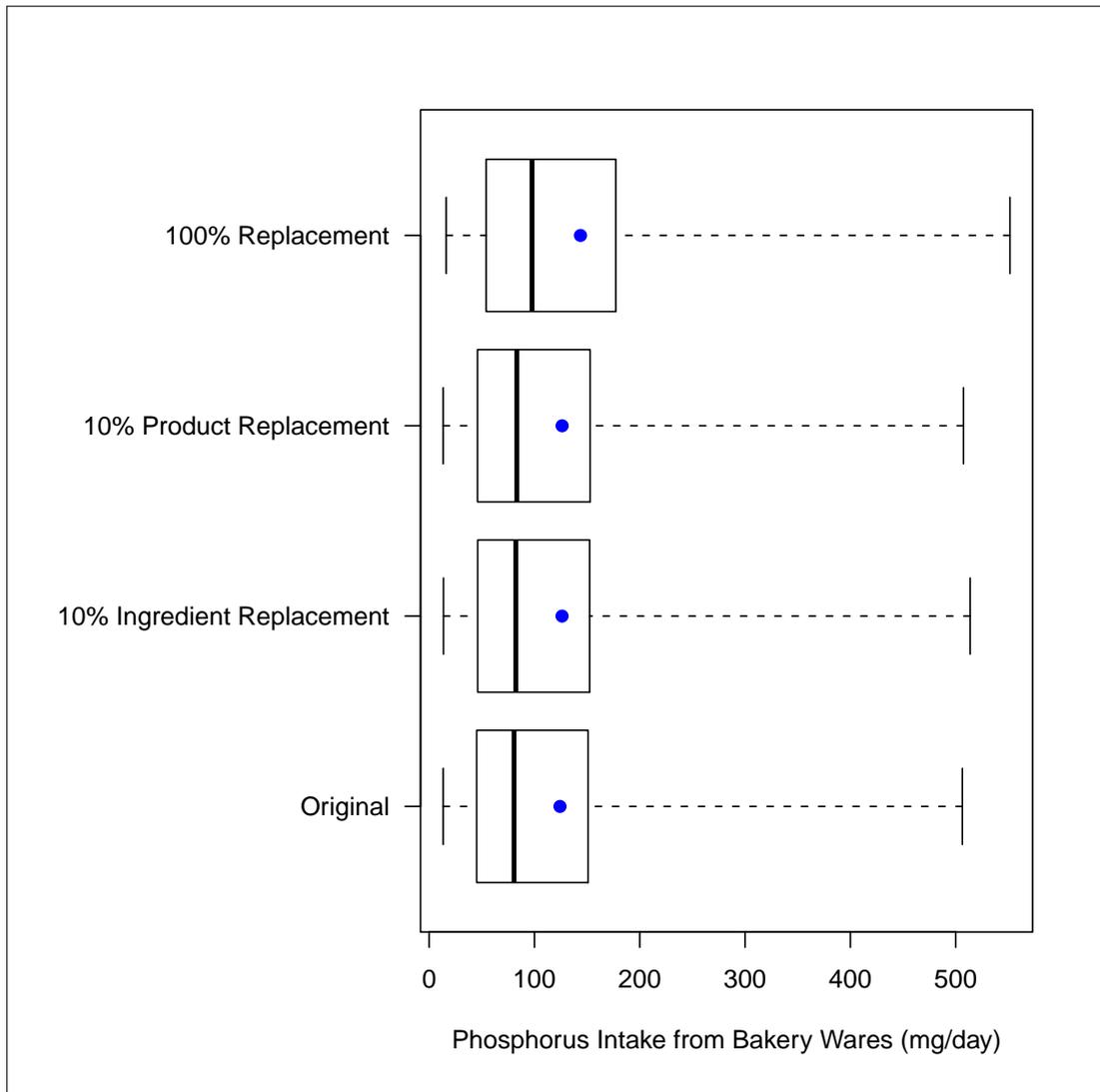


Figure 10: Boxplot intake of Phosphorus from Bakery Wares for the 7007 subjects (out of a total of 9316) who consume items in the Bakery Wares group.

3.2 Analysis of the British Diet

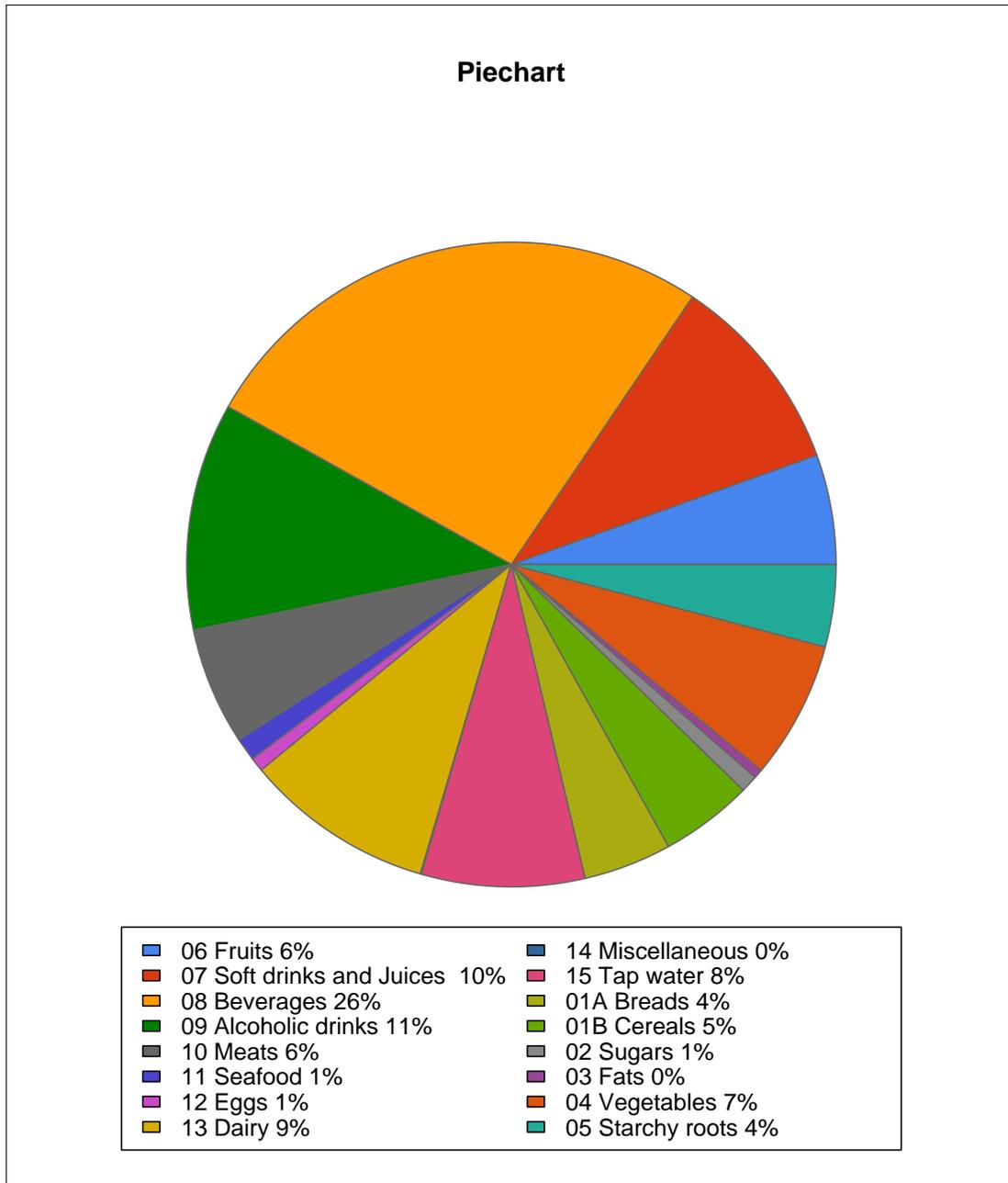


Figure 11: Piechart showing the relative intake of food in the British diet.

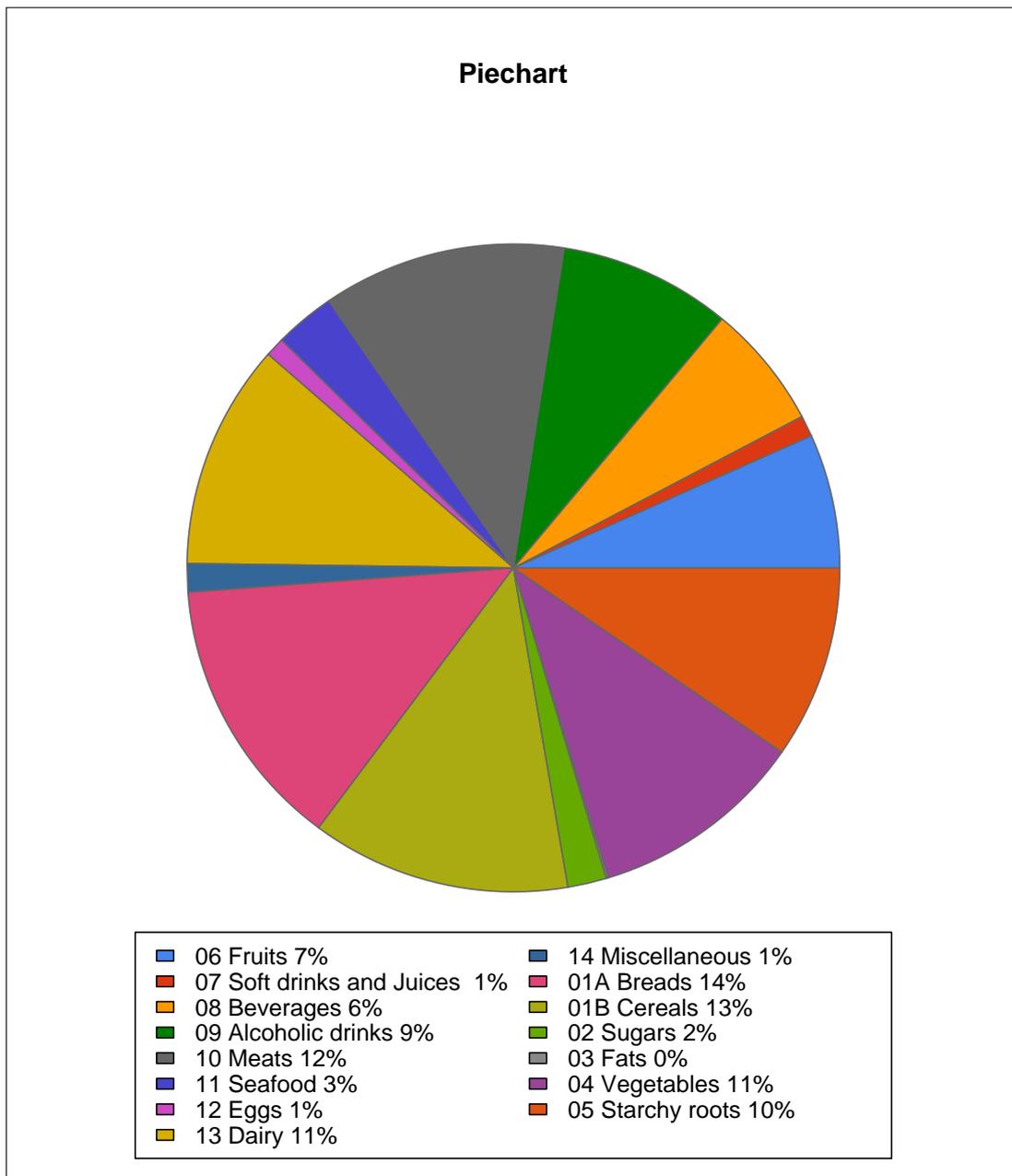


Figure 12: Piechart showing the relative sources of Magnesium in the British diet.

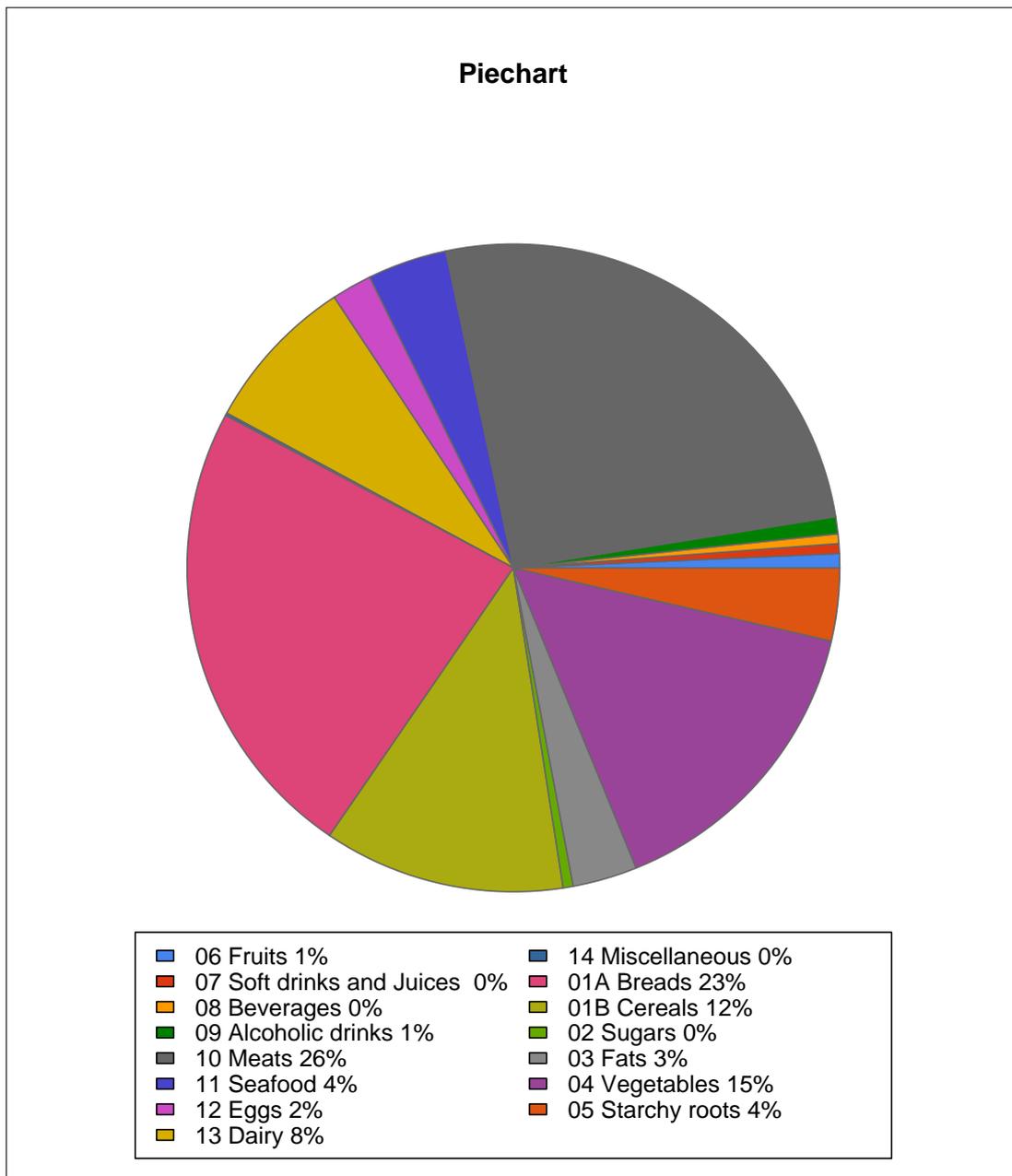


Figure 13: Piechart showing the relative sources of Sodium in the British diet.

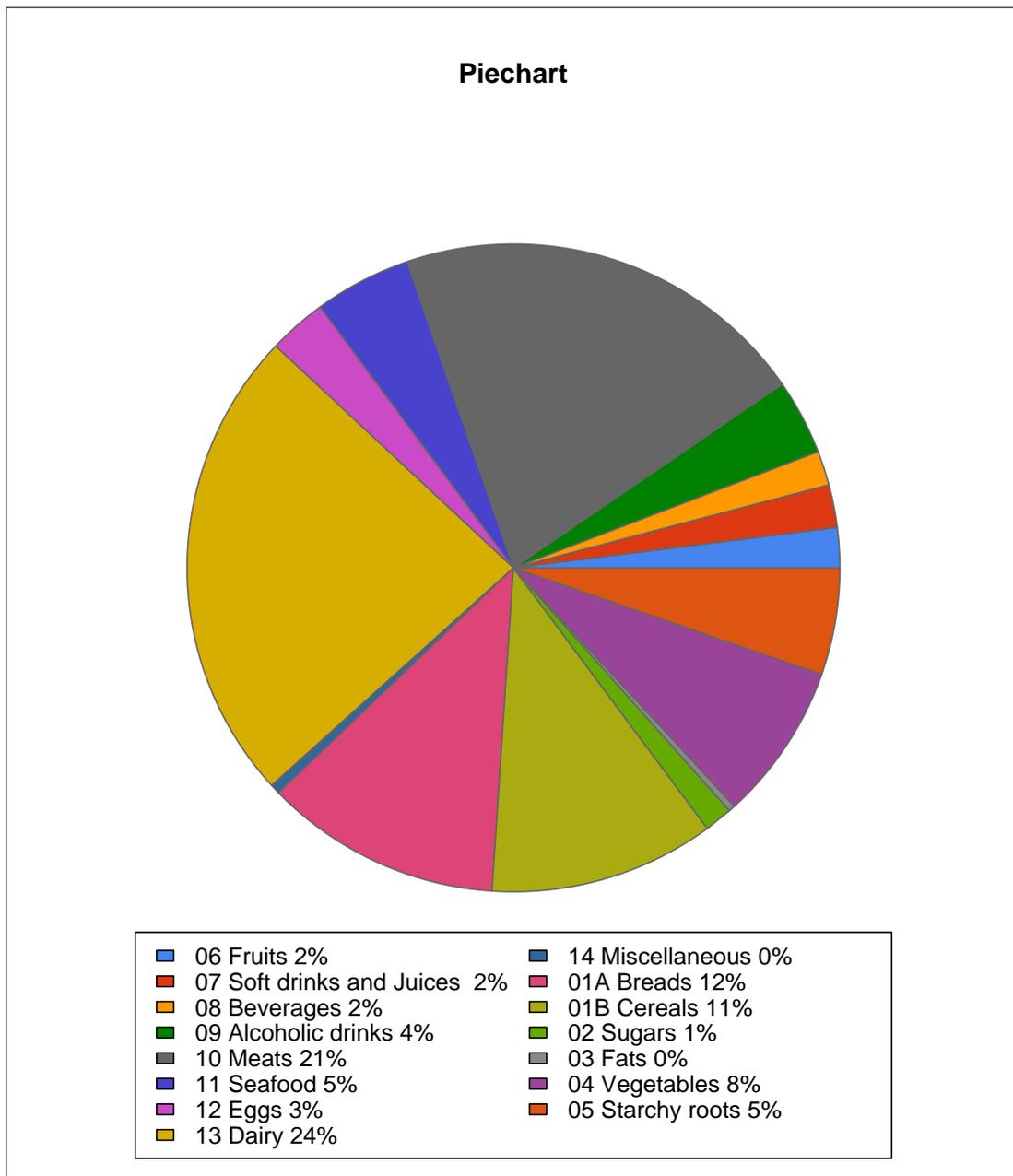


Figure 14: Piechart showing the relative sources of Phosphorus in the British diet.

3.2.1 Replacement Results: 20% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	271.0	276.7	276.8	327.7
01A Bakery Wares	36.9	42.6	42.7	93.6
01B Other Cereals	34.8	34.8	34.8	34.8
02 Sugars	5.2	5.2	5.2	5.2
03 Fats	0.3	0.3	0.3	0.3
04 Vegetables	28.9	28.9	28.9	28.9
05 Starchy roots	26.1	26.1	26.1	26.1
06 Fruits	18.1	18.1	18.1	18.1
07 Soft drinks and Juices	2.8	2.8	2.8	2.8
08 Beverages	16.9	16.9	16.9	16.9
09 Alcoholic drinks	23.2	23.2	23.2	23.2
10 Meats	32.7	32.7	32.7	32.7
11 Seafood	8.1	8.1	8.1	8.1
12 Eggs	2.6	2.6	2.6	2.6
13 Dairy	30.5	30.5	30.5	30.5
14 Miscellaneous	3.8	3.8	3.8	3.8
15 Tap water	0.0	0.0	0.0	0.0

Table 14: Mean Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	480.0	491.6	491.1	580.3
01A Bakery Wares	101.8	116.4	112.1	222.3
01B Other Cereals	130.4	130.4	130.4	130.4
02 Sugars	28.7	28.7	28.7	28.7
03 Fats	1.1	1.1	1.1	1.1
04 Vegetables	91.8	91.8	91.8	91.8
05 Starchy roots	67.3	67.3	67.3	67.3
06 Fruits	66.9	66.9	66.9	66.9
07 Soft drinks and Juices	16.6	16.6	16.6	16.6
08 Beverages	55.2	55.2	55.2	55.2
09 Alcoholic drinks	133.8	133.8	133.8	133.8
10 Meats	75.6	75.6	75.6	75.6
11 Seafood	31.4	31.4	31.4	31.4
12 Eggs	11.2	11.2	11.2	11.2
13 Dairy	79.3	79.3	79.3	79.3
14 Miscellaneous	54.8	54.8	54.8	54.8
15 Tap water	0.0	0.0	0.0	0.0

Table 15: The 97.5 Percentile of the Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

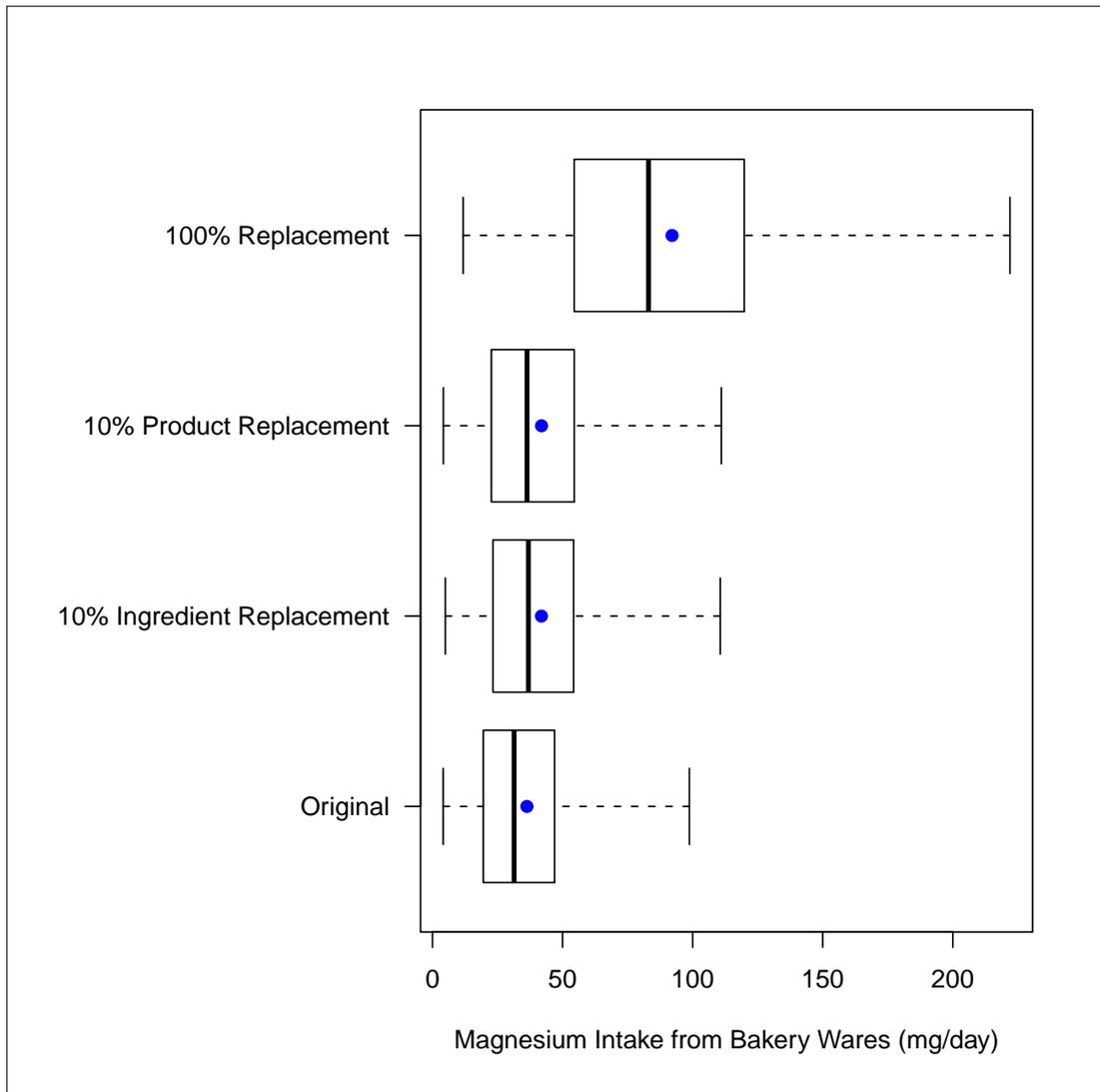


Figure 15: Boxplot intake of Magnesium from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2788.9	2779.5	2779.3	2695.0
01A Bakery Wares	649.3	639.9	639.7	555.4
01B Other Cereals	333.6	333.6	333.6	333.6
02 Sugars	13.9	13.9	13.9	13.9
03 Fats	89.3	89.3	89.3	89.3
04 Vegetables	424.9	424.9	424.9	424.9
05 Starchy roots	101.2	101.2	101.2	101.2
06 Fruits	19.7	19.7	19.7	19.7
07 Soft drinks and Juices	13.7	13.7	13.7	13.7
08 Beverages	13.5	13.5	13.5	13.5
09 Alcoholic drinks	23.8	23.8	23.8	23.8
10 Meats	719.2	719.2	719.2	719.2
11 Seafood	109.8	109.8	109.8	109.8
12 Eggs	55.5	55.5	55.5	55.5
13 Dairy	217.9	217.9	217.9	217.9
14 Miscellaneous	3.6	3.6	3.6	3.6
15 Tap water	0.0	0.0	0.0	0.0

Table 16: Mean Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	5003.6	4988.7	4994.1	4867.1
01A Bakery Wares	1490.0	1471.1	1470.2	1274.2
01B Other Cereals	1119.2	1119.2	1119.2	1119.2
02 Sugars	73.7	73.7	73.7	73.7
03 Fats	305.6	305.6	305.6	305.6
04 Vegetables	1272.6	1272.6	1272.6	1272.6
05 Starchy roots	406.5	406.5	406.5	406.5
06 Fruits	122.2	122.2	122.2	122.2
07 Soft drinks and Juices	68.7	68.7	68.7	68.7
08 Beverages	88.6	88.6	88.6	88.6
09 Alcoholic drinks	140.0	140.0	140.0	140.0
10 Meats	1941.3	1941.3	1941.3	1941.3
11 Seafood	545.7	545.7	545.7	545.7
12 Eggs	321.3	321.3	321.3	321.3
13 Dairy	553.4	553.4	553.4	553.4
14 Miscellaneous	0.0	0.0	0.0	0.0
15 Tap water	0.0	0.0	0.0	0.0

Table 17: The 97.5 Percentile of the Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

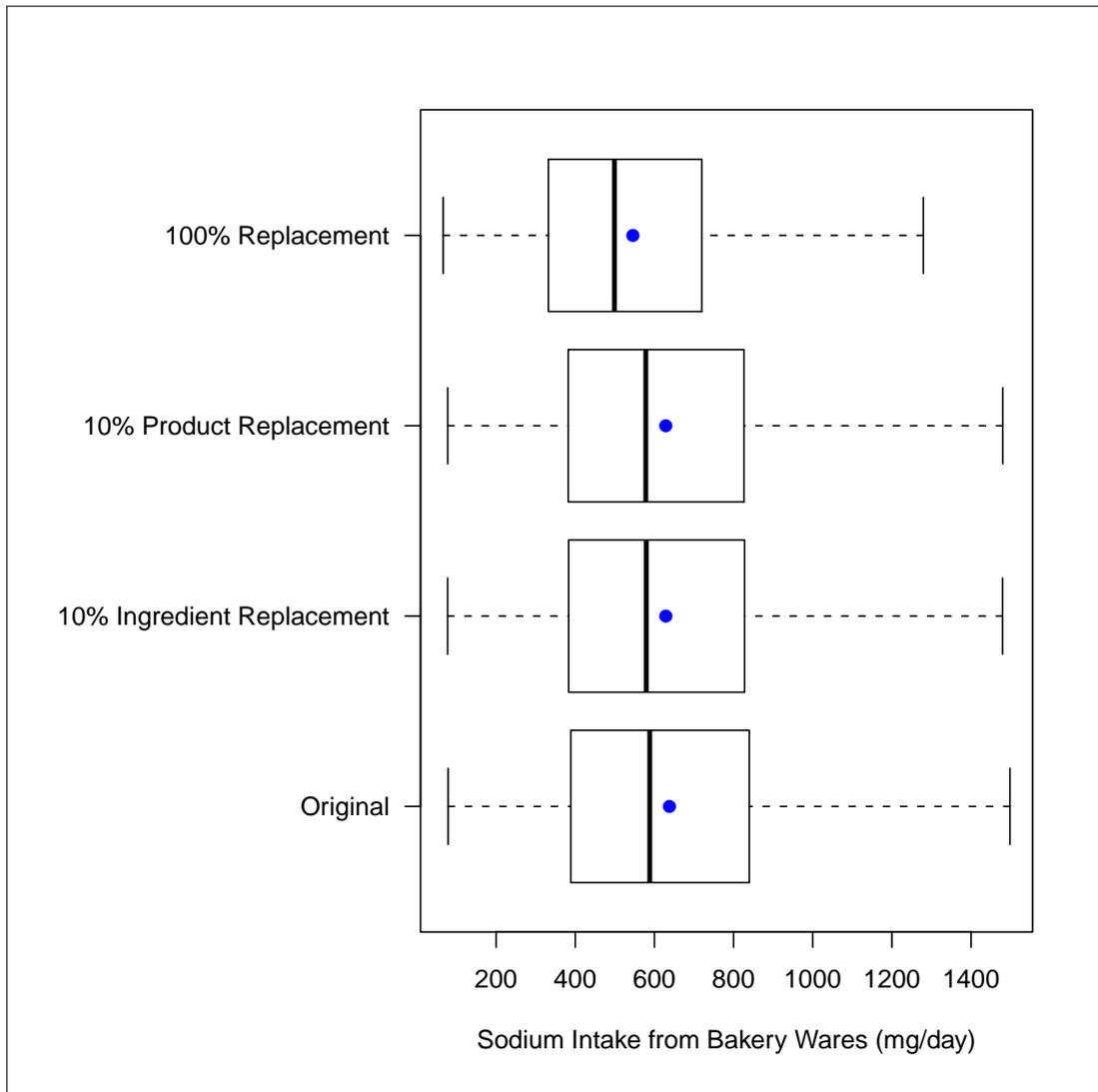


Figure 16: Boxplot intake of Sodium from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1303.3	1306.0	1306.1	1330.3
01A Bakery Wares	153.0	155.7	155.8	180.0
01B Other Cereals	145.6	145.6	145.6	145.6
02 Sugars	18.1	18.1	18.1	18.1
03 Fats	4.3	4.3	4.3	4.3
04 Vegetables	101.9	101.9	101.9	101.9
05 Starchy roots	69.6	69.6	69.6	69.6
06 Fruits	26.1	26.1	26.1	26.1
07 Soft drinks and Juices	27.8	27.8	27.8	27.8
08 Beverages	22.4	22.4	22.4	22.4
09 Alcoholic drinks	49.0	49.0	49.0	49.0
10 Meats	269.6	269.6	269.6	269.6
11 Seafood	62.6	62.6	62.6	62.6
12 Eggs	37.8	37.8	37.8	37.8
13 Dairy	309.3	309.3	309.3	309.3
14 Miscellaneous	6.4	6.4	6.4	6.4
15 Tap water	0.0	0.0	0.0	0.0

Table 18: Mean Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2229.5	2230.4	2230.9	2264.9
01A Bakery Wares	371.9	378.0	379.0	427.6
01B Other Cereals	461.9	461.9	461.9	461.9
02 Sugars	98.4	98.4	98.4	98.4
03 Fats	20.6	20.6	20.6	20.6
04 Vegetables	287.5	287.5	287.5	287.5
05 Starchy roots	180.9	180.9	180.9	180.9
06 Fruits	91.5	91.5	91.5	91.5
07 Soft drinks and Juices	196.6	196.6	196.6	196.6
08 Beverages	92.3	92.3	92.3	92.3
09 Alcoholic drinks	321.9	321.9	321.9	321.9
10 Meats	602.7	602.7	602.7	602.7
11 Seafood	239.6	239.6	239.6	239.6
12 Eggs	157.4	157.4	157.4	157.4
13 Dairy	740.5	740.5	740.5	740.5
14 Miscellaneous	91.8	91.8	91.8	91.8
15 Tap water	0.0	0.0	0.0	0.0

Table 19: The 97.5 Percentile of the Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

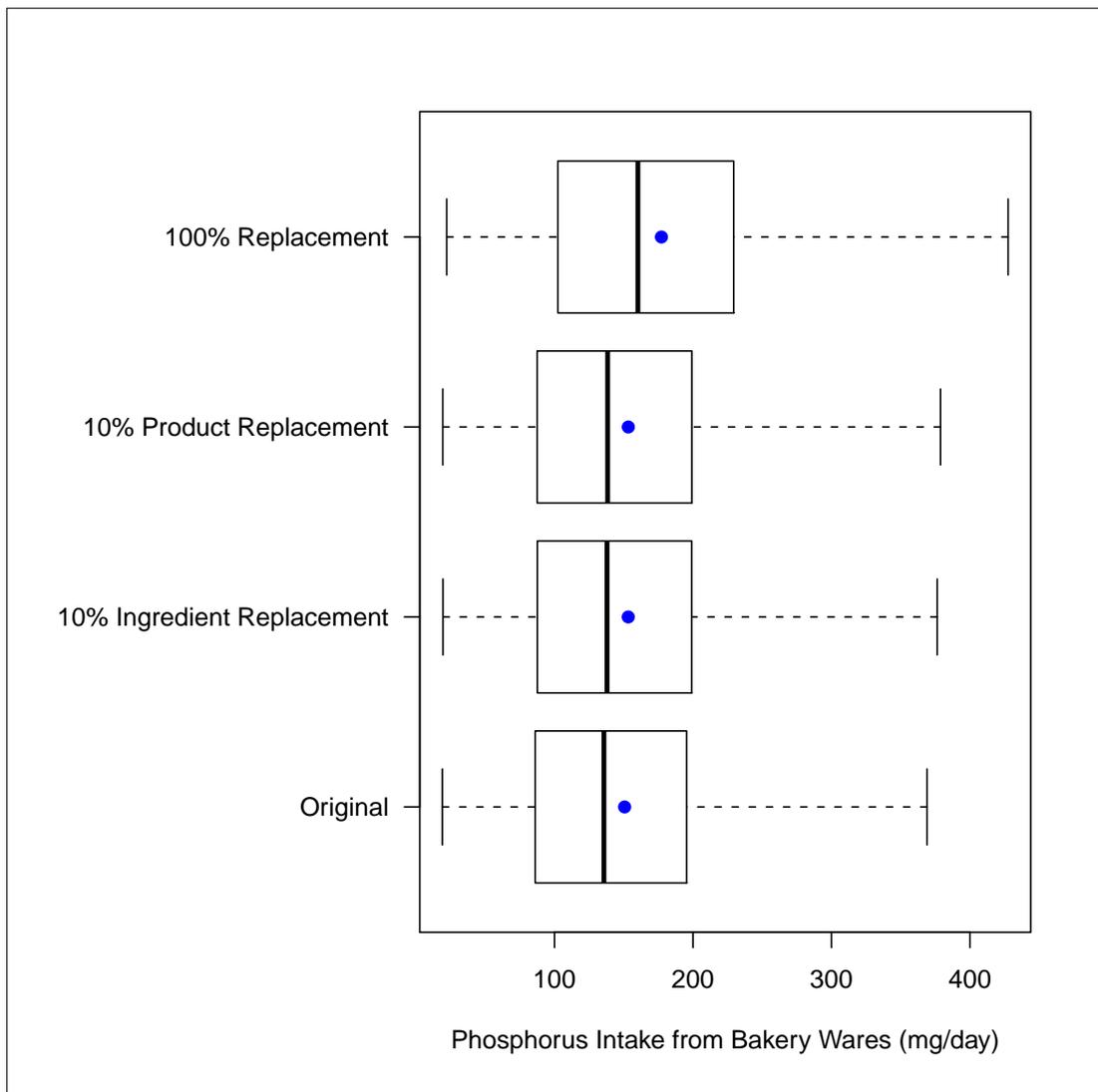


Figure 17: Boxplot intake of Phosphorus from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

3.2.2 Replacement Results: 30% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	271.0	277.4	277.7	335.1
01A Bakery Wares	36.9	43.3	43.5	100.9
01B Other Cereals	34.8	34.8	34.8	34.8
02 Sugars	5.2	5.2	5.2	5.2
03 Fats	0.3	0.3	0.3	0.3
04 Vegetables	28.9	28.9	28.9	28.9
05 Starchy roots	26.1	26.1	26.1	26.1
06 Fruits	18.1	18.1	18.1	18.1
07 Soft drinks and Juices	2.8	2.8	2.8	2.8
08 Beverages	16.9	16.9	16.9	16.9
09 Alcoholic drinks	23.2	23.2	23.2	23.2
10 Meats	32.7	32.7	32.7	32.7
11 Seafood	8.1	8.1	8.1	8.1
12 Eggs	2.6	2.6	2.6	2.6
13 Dairy	30.5	30.5	30.5	30.5
14 Miscellaneous	3.8	3.8	3.8	3.8
15 Tap water	0.0	0.0	0.0	0.0

Table 20: Mean Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	480.0	491.6	492.5	593.5
01A Bakery Wares	101.8	117.2	120.8	248.1
01B Other Cereals	130.4	130.4	130.4	130.4
02 Sugars	28.7	28.7	28.7	28.7
03 Fats	1.1	1.1	1.1	1.1
04 Vegetables	91.8	91.8	91.8	91.8
05 Starchy roots	67.3	67.3	67.3	67.3
06 Fruits	66.9	66.9	66.9	66.9
07 Soft drinks and Juices	16.6	16.6	16.6	16.6
08 Beverages	55.2	55.2	55.2	55.2
09 Alcoholic drinks	133.8	133.8	133.8	133.8
10 Meats	75.6	75.6	75.6	75.6
11 Seafood	31.4	31.4	31.4	31.4
12 Eggs	11.2	11.2	11.2	11.2
13 Dairy	79.3	79.3	79.3	79.3
14 Miscellaneous	54.8	54.8	54.8	54.8
15 Tap water	0.0	0.0	0.0	0.0

Table 21: The 97.5 Percentile of the Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

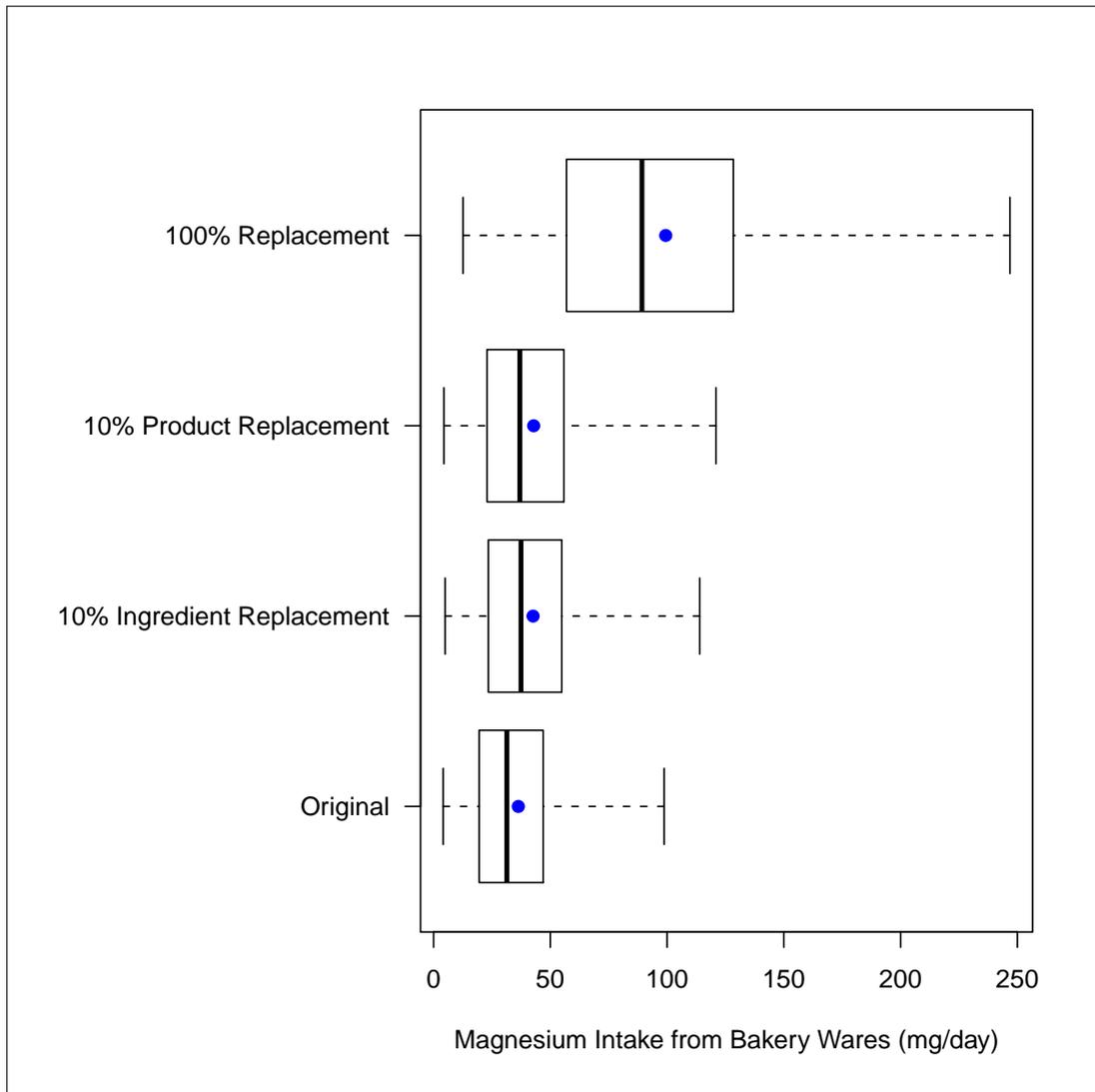


Figure 18: Boxplot intake of Magnesium from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2788.9	2778.3	2777.9	2682.9
01A Bakery Wares	649.3	638.7	638.3	543.3
01B Other Cereals	333.6	333.6	333.6	333.6
02 Sugars	13.9	13.9	13.9	13.9
03 Fats	89.3	89.3	89.3	89.3
04 Vegetables	424.9	424.9	424.9	424.9
05 Starchy roots	101.2	101.2	101.2	101.2
06 Fruits	19.7	19.7	19.7	19.7
07 Soft drinks and Juices	13.7	13.7	13.7	13.7
08 Beverages	13.5	13.5	13.5	13.5
09 Alcoholic drinks	23.8	23.8	23.8	23.8
10 Meats	719.2	719.2	719.2	719.2
11 Seafood	109.8	109.8	109.8	109.8
12 Eggs	55.5	55.5	55.5	55.5
13 Dairy	217.9	217.9	217.9	217.9
14 Miscellaneous	3.6	3.6	3.6	3.6
15 Tap water	0.0	0.0	0.0	0.0

Table 22: Mean Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	5003.6	4988.4	4993.0	4864.2
01A Bakery Wares	1490.0	1470.0	1466.9	1253.7
01B Other Cereals	1119.2	1119.2	1119.2	1119.2
02 Sugars	73.7	73.7	73.7	73.7
03 Fats	305.6	305.6	305.6	305.6
04 Vegetables	1272.6	1272.6	1272.6	1272.6
05 Starchy roots	406.5	406.5	406.5	406.5
06 Fruits	122.2	122.2	122.2	122.2
07 Soft drinks and Juices	68.7	68.7	68.7	68.7
08 Beverages	88.6	88.6	88.6	88.6
09 Alcoholic drinks	140.0	140.0	140.0	140.0
10 Meats	1941.3	1941.3	1941.3	1941.3
11 Seafood	545.7	545.7	545.7	545.7
12 Eggs	321.3	321.3	321.3	321.3
13 Dairy	553.4	553.4	553.4	553.4
14 Miscellaneous	0.0	0.0	0.0	0.0
15 Tap water	0.0	0.0	0.0	0.0

Table 23: The 97.5 Percentile of the Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

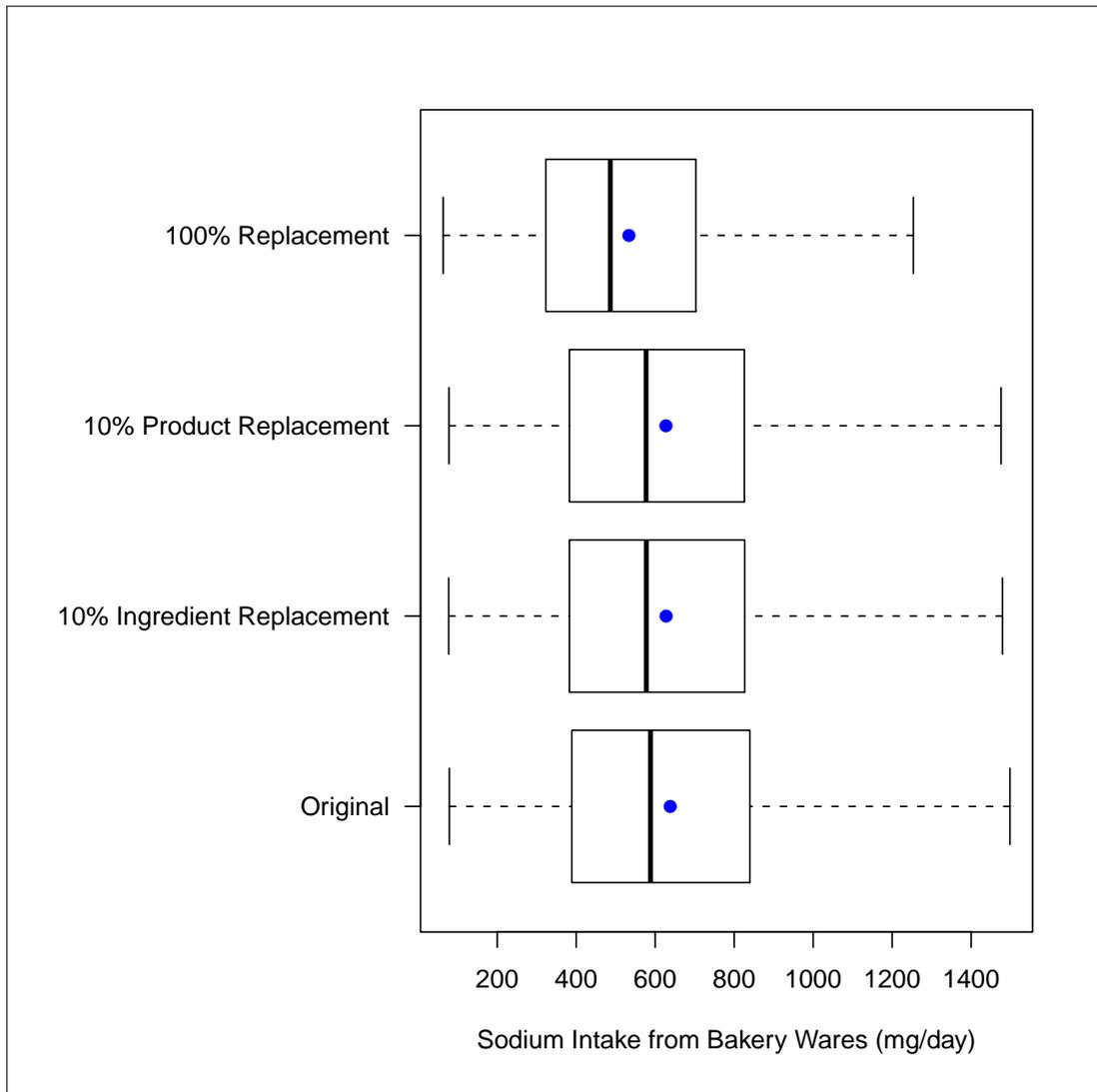


Figure 19: Boxplot intake of Sodium from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1303.3	1306.4	1306.5	1333.8
01A Bakery Wares	153.0	156.0	156.2	183.5
01B Other Cereals	145.6	145.6	145.6	145.6
02 Sugars	18.1	18.1	18.1	18.1
03 Fats	4.3	4.3	4.3	4.3
04 Vegetables	101.9	101.9	101.9	101.9
05 Starchy roots	69.6	69.6	69.6	69.6
06 Fruits	26.1	26.1	26.1	26.1
07 Soft drinks and Juices	27.8	27.8	27.8	27.8
08 Beverages	22.4	22.4	22.4	22.4
09 Alcoholic drinks	49.0	49.0	49.0	49.0
10 Meats	269.6	269.6	269.6	269.6
11 Seafood	62.6	62.6	62.6	62.6
12 Eggs	37.8	37.8	37.8	37.8
13 Dairy	309.3	309.3	309.3	309.3
14 Miscellaneous	6.4	6.4	6.4	6.4
15 Tap water	0.0	0.0	0.0	0.0

Table 24: Mean Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2229.5	2230.6	2229.7	2271.9
01A Bakery Wares	371.9	378.9	376.5	440.1
01B Other Cereals	461.9	461.9	461.9	461.9
02 Sugars	98.4	98.4	98.4	98.4
03 Fats	20.6	20.6	20.6	20.6
04 Vegetables	287.5	287.5	287.5	287.5
05 Starchy roots	180.9	180.9	180.9	180.9
06 Fruits	91.5	91.5	91.5	91.5
07 Soft drinks and Juices	196.6	196.6	196.6	196.6
08 Beverages	92.3	92.3	92.3	92.3
09 Alcoholic drinks	321.9	321.9	321.9	321.9
10 Meats	602.7	602.7	602.7	602.7
11 Seafood	239.6	239.6	239.6	239.6
12 Eggs	157.4	157.4	157.4	157.4
13 Dairy	740.5	740.5	740.5	740.5
14 Miscellaneous	91.8	91.8	91.8	91.8
15 Tap water	0.0	0.0	0.0	0.0

Table 25: The 97.5 Percentile of the Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

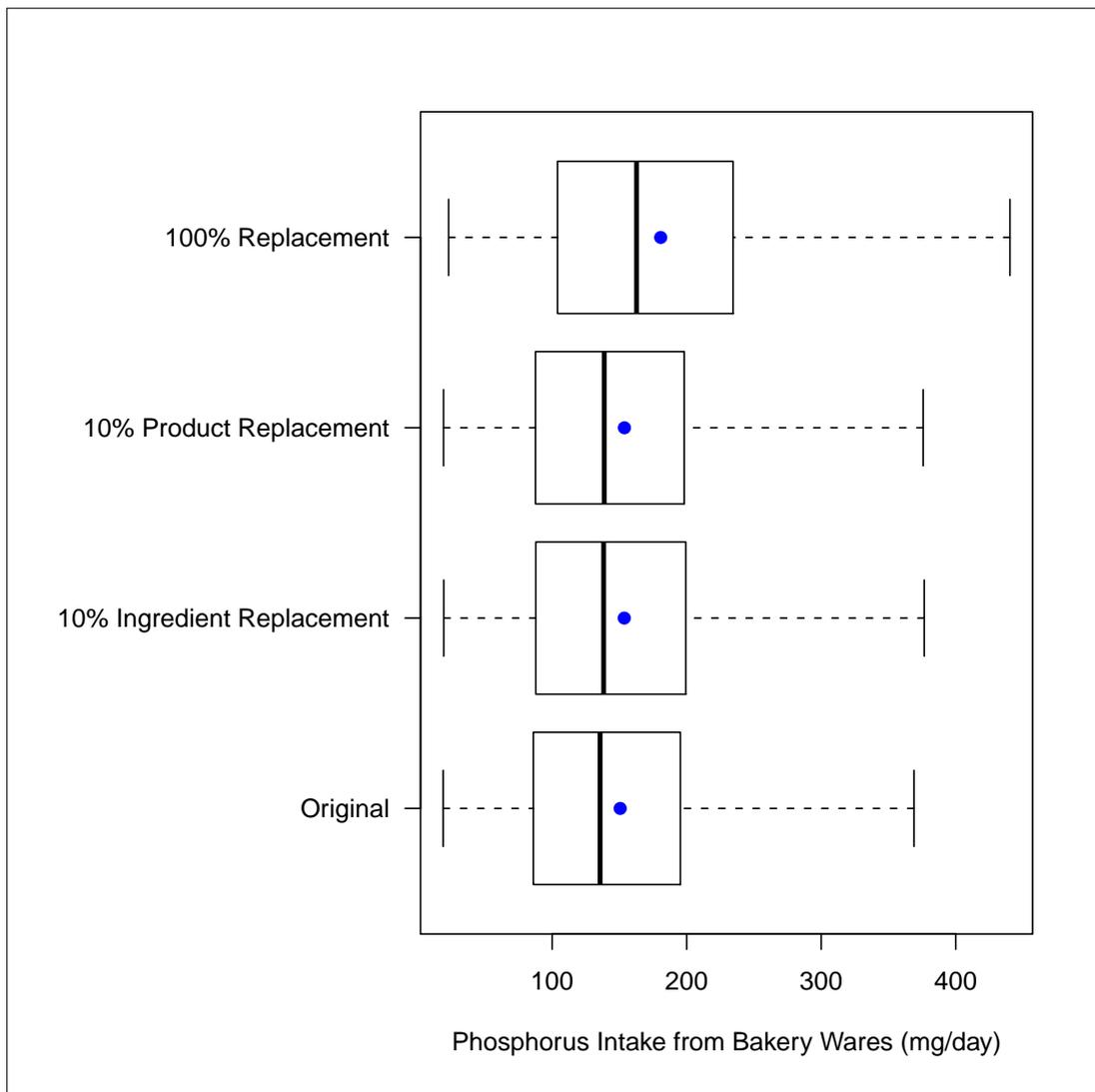


Figure 20: Boxplot intake of Phosphorus from Bakery Wares for the 1706 subjects (out of a total of 1724) who consume items in the Bakery Wares group.

3.3 Comparison of the British Diet with the Diet of other EFSA Members

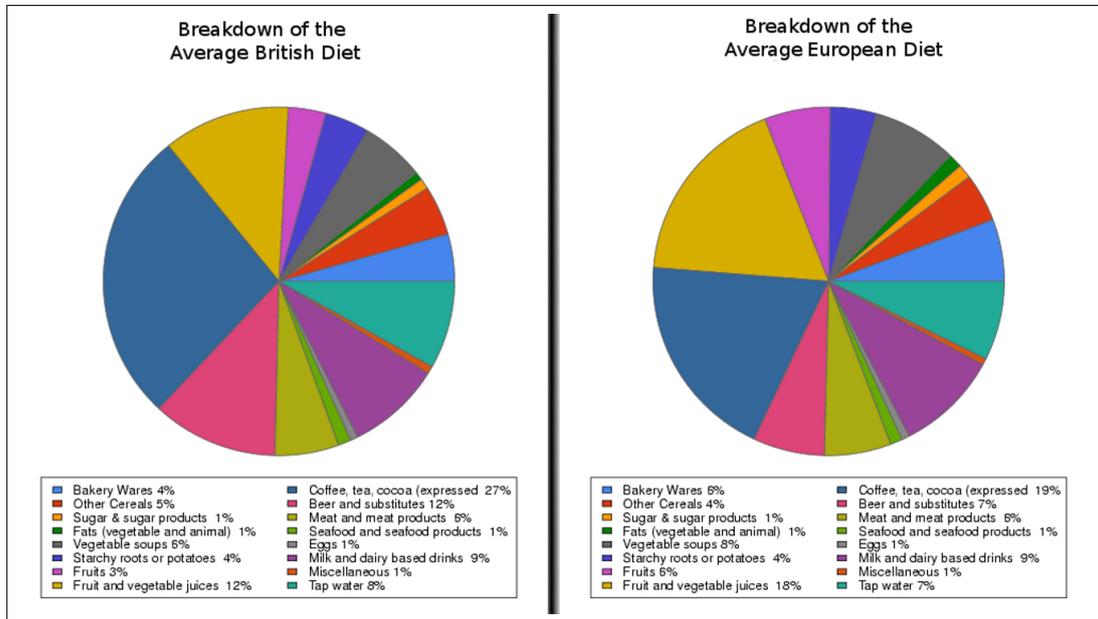


Figure 21: Graphical Comparison of the relative British mean consumption of each food group versus relative Europe mean consumption of each food group.

Figure 21 shows the food group breakdown of the British diet, using the EFSA concise data for Britain, compared with the weighted average food group breakdown for the nineteen EFSA members for which concise data is available. From Table 26 we can see that while the total British and European food consumption is similar, a typical European consumes just under 25% more Bakery Ware products than a Briton. Thus any decrease in sodium intake, or increase in magnesium and phosphorus intake, in the British diet as a result of replacing sodium acid pyrophosphate with magnesium acid pyrophosphate, will result in an average amplification of the effect of 25% across Europe.

Group Name	GB Mean (g/day) NDNS (Deterministic)	GB Mean (g/day) EFSA Concise (Probabilistic)	Combined EFSA Mean (g/day) EFSA Concise (Probabilistic)
All Foods	2721	2753±29	2719±26
Bakery Wares	120	120±2	156±2
Other Cereals	126	126±2	121±2
Sugar & sugar products including chocolate	24	26±1	35±1
Fats (vegetable and animal)	12	20±0	34±1
Vegetable soups	188	162±3	212±4
Starchy roots or potatoes	112	112±2	116±4
Fruits	150	94±3	164±5
Fruit and vegetable juices	274	321±11	484±15
Coffee, tea, cocoa (expressed as liquid)	715	748±15	524±15
Beer and substitutes	310	319±9	179±8
Meat and meat products and substitutes	160	162±3	167±3
Seafood and seafood products	31	32±1	30±1
Eggs	19	19±1	19±1
Milk and dairy based drinks	258	240±5	256±7
Miscellaneous	1	19±1	16±2
Tap water	221	224±9	199±12

Table 26: Comparison of the British diet with the average European diet. Differences between the second and third columns, British diet according to the NDNS survey and EFSA concise data respectively, arise due to slight differences in food groupings. However for the food group of interest, Bakery Wares, there are no differences. The Combined EFSA Mean is calculated using population weighted EFSA concise data.

4 Discussion

The purpose of the assessment was to carry out an intake exposure estimation for the replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate in bakery wares. While it is clear from the chemical composition of the two agents under consideration that the replacement will increase the dietary intake of magnesium and phosphorus while reducing sodium intake, this report quantifies the effect of the replacement on the different populations.

There is a strong focus by food regulators on reducing the sodium levels in food products as the current intake of sodium by the majority of the population is far in excess of both recommended daily allowances and tolerable upper limits. None of the partial replacement scenarios produce a statistically significant change in the intakes of sodium or phosphorus. Therefore in this discussion we will focus on the worst case scenario of 100% replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate, where the level of sodium acid pyrophosphate is at most that which corresponds to it contributing to 30% of the sodium in the bakery ware product.

Nutrient	Statistic	Absolute Change	Relative Change	% of RDA	% of UL
Sodium	Mean	-56.6mg	-1.6%	-3.5%	-2.5%
Sodium	P97.5	-76.4mg	-1.0%	-4.8%	-3.3%
Phosphorus	Mean	16.3mg	1.2%	2.3%	0.4%
Phosphorus	P97.5	16.1mg	0.6%	2.3%	0.4%
Magnesium	Mean	34.2mg	12.2%	8.6%	NA
Magnesium	P97.5	61.9mg	9.6%	15.5%	NA

Table 27: The changes to the mean and 97.5th percentile of nutrient intakes for the American population in the most extreme replacement scenario. This table shows the absolute change in the intake statistic, the relative change as a percentage of the original value, the change as a fraction of the recommended daily allowance and the change as a fraction of the tolerable upper limit, where one exists. We use 400mg as the typical RDA of magnesium when calculating the percentage change as a fraction of the RDA.

Nutrient	Statistic	Absolute Change	Relative Change	% of RDA	% of UL
Sodium	Mean	-106.0mg	-3.8%	-6.6%	-4.6%
Sodium	P97.5	-139.4mg	-2.8%	-8.7%	-6.1%
Phosphorus	Mean	30.5mg	2.3%	4.4%	0.7%
Phosphorus	P97.5	42.4mg	1.9%	6.1%	1.0%
Magnesium	Mean	64.1mg	23.7%	16.0%	NA
Magnesium	P97.5	113.5mg	23.6%	28.4%	NA

Table 28: The changes to the mean and 97.5th percentile of nutrient intakes for the British population in the most extreme replacement scenario. This table shows the absolute change in the intake statistic, the relative change as a percentage of the original value, the change as a fraction of the recommended daily allowance and the change as a fraction of the tolerable upper limit, where one exists. We use 400mg as the typical RDA of magnesium when calculating the percentage change as a fraction of the RDA.

Tables 27 and 28 summarise the changes in the intakes of sodium, phosphorus and magnesium as a result of the most extreme replacement scenario. As outlined in the results section, any changes

in the British nutrient intake will be amplified by 25% for the average European diet. The changes in the American nutrient intakes are always less than the changes in the British intakes due to the significant differences in bakery ware consumption.

The only disadvantage in this replacement is the increase in phosphorus intake levels. However, this increase is less 1% of the tolerable upper limit. Indeed, for the American population, the new mean phosphorus intake level lies within the confidence interval of the current intake level. This small disadvantage is overshadowed by the decrease in sodium intake and the substantial increase in magnesium intakes. In the 100% replacement scenario, mean magnesium intake levels are increased so that they lie within the recommended dietary intake levels of 310 – 420mg.

A Sodium Acid Pyrophosphate Levels in Different Bakery Ware Products

The maximum allowed level of sodium acid phosphate, $\text{Na}_2\text{H}_2\text{P}_2\text{O}_5$ is 20g/kg calculated as P_2O_5 . This corresponds to a level of sodium of

$$[\text{Na}] = \frac{[\text{P}_2\text{O}_5] \times P_{\text{Na}}}{P_{\text{P}_2\text{O}_5}} = \frac{0.02 \times 0.204}{0.64} = 6.37\text{g/kg}$$

where P_{Na} is the proportion of sodium in sodium acid phosphate.

The actual concentration of sodium in most bakery wares falls below this, for example the concentration of sodium in white bread in the UK (NDNS Food Code 120) is 5.85g/kg, which includes sodium from salt and sodium bicarbonate.

The maximum level of sodium acid pyrophosphate in any bakery ware product can be calculated using the data available for the sodium and phosphorus composition of that product.

B Nutrient Information

In this appendix we briefly review the nutrients which are relevant in the replacement of sodium acid pyrophosphate with magnesium acid pyrophosphate, namely sodium, magnesium and phosphorus.

Sodium is required in the body to regulate blood pressure and blood volume, maintain electrolyte and fluid balance and plays a role in nerve and muscle function. However, high intakes of sodium lead to health problems in the form of high blood pressure which can give rise to heart problems and, in people with congestive heart failure, liver cirrhosis and kidney disease, can cause a serious build up of fluid. As sodium is found naturally in most foods and is further added to foods during processing and at meals as salt (sodium chloride), high intakes are extremely common which indicates that the risk of associated health problems is increased among a large proportion of the population.

Magnesium also serves a purpose in the body and is involved in producing protein and energy, energy transport, contracting and relaxing muscles, the functioning of over 300 enzymes in the metabolism of carbohydrates, proteins and fats and the formation of bones and teeth. As it is not commonly found in most foods, the main sources being green leafy vegetables, fruit, nuts, soy products and wholegrains, high intakes are not as common when compared to that of sodium. For rare incidences where high consumption occurs, the body is also equipped to remove excess amounts for normal levels to resume. Although rare too, deficiencies in magnesium are more likely to occur and present an array of quite serious symptoms at each stage of progression which include fatigue, insomnia, poor memory, reduced ability to learn, cardiovascular changes, continued muscle contractions and even hallucinations.

Phosphorus used in the body as phosphate serves both structural and functional purposes. It is contained in every cell as cell membrane structures phospholipids and nucleic acid and nucleotides as part of DNA. It is also used in the formation of bones and teeth, energy production, utilization of carbohydrates and fats, muscle contraction, kidney function, nerve conduction, heartbeat regulation and production of protein for growth and repair of cells and tissues. Like sodium, phosphorus is readily available in most foods so deficiencies do not generally occur. Toxicities or high levels are not common either; the exception being those with kidney disease and blood calcium regulation problems where phosphorus combines with blood calcium to give deposits in soft tissue and muscle.

The relative Dietary Reference Values¹ (DRVs) and Tolerable Upper Levels (ULs) for each of magnesium sodium and phosphorus are listed in the table below.

Nutrient	DRV (mg/day)	UL (mg/day)
Sodium	1600	2300
Magnesium	310-420	No dietary value
Phosphorus	700	4000

Table 29: Typical DRVs and ULs for Sodium, Phosphorus and Magnesium.

¹The terms “Dietary Reference Value” and “Recommended Daily Allowance” are interchangeable. In scientific literature, especially in Britain “Dietary Reference Value” tends to be used, while “Recommended Daily Allowance” is still used in the United States.

C Boxplot Explanation

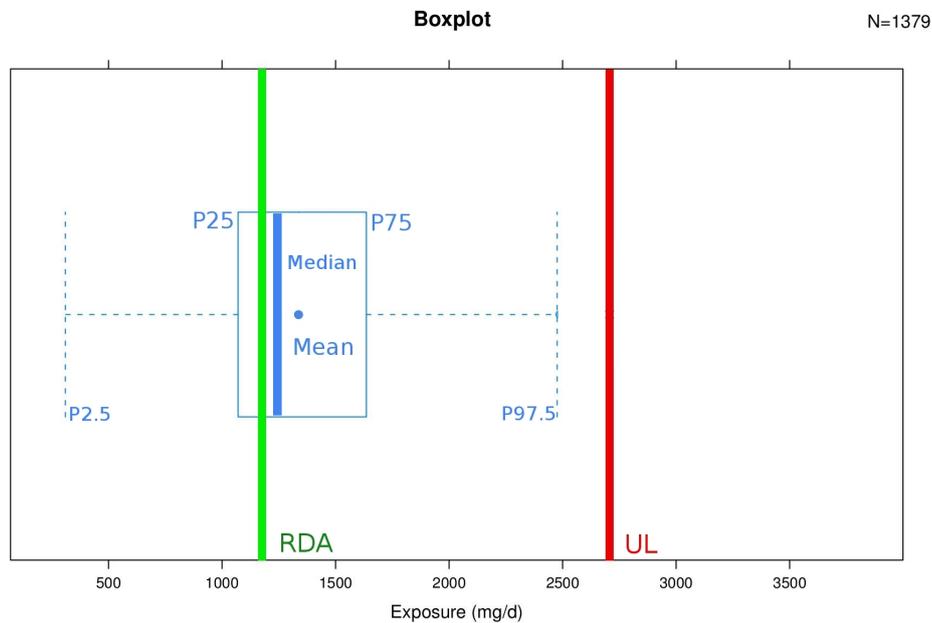


Figure 22: An example of a boxplot.

The graph shown in Figure 22 is called a boxplot. While there is no consensus on what statistics to use for the upper and lower fences (the dashed vertical lines) Crema uses the 2.5th and 97.5th percentile. Thus 95% of the population lies between the upper and lower fences. The left and right of the box are the 25th and 75th percentile, while the band near the middle of the box is the 50th percentile (the median). The dot is the mean. In the plots that follow, comparing the British and American diets, the RDA and UL are superimposed on the boxplot for illustrative purposes.

For example Figure 23 shows that while the United States and Great Britain have a similar mean, the variation of consumption across the population is much larger for the United States. Figure 24 confirms that not only do the vast majority of Americans and British consume more than their RDA of sodium, more than 50% of both populations exceed the tolerable upper limit. On the other hand, Figure 25 shows that very few Americans or British reach their RDA of magnesium at the moment. Finally Figure 26 illustrates that while both Americans and British exceed their RDA of phosphorus, neither populations' intake of phosphorus approaches its UL.

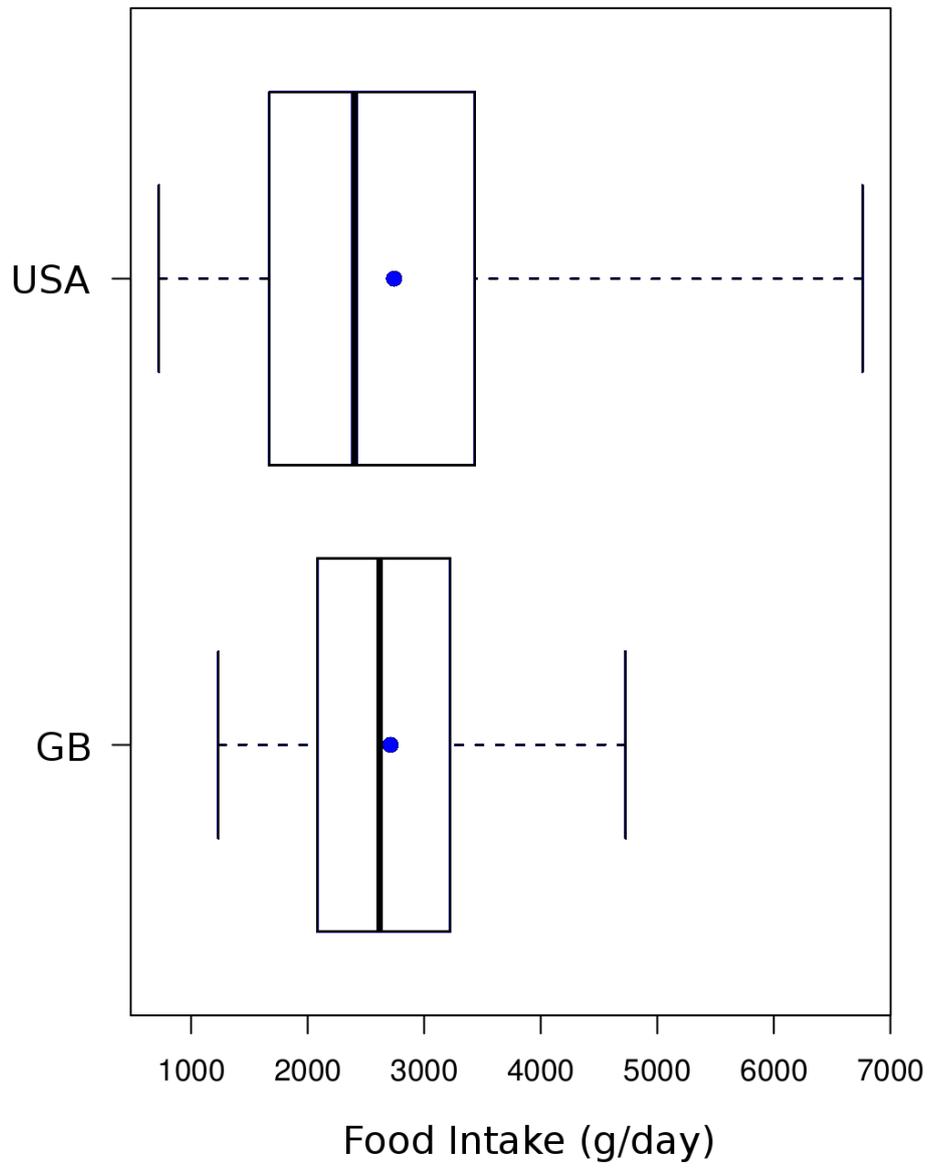


Figure 23: Boxplot to compare the total daily food intake of the American and British populations.

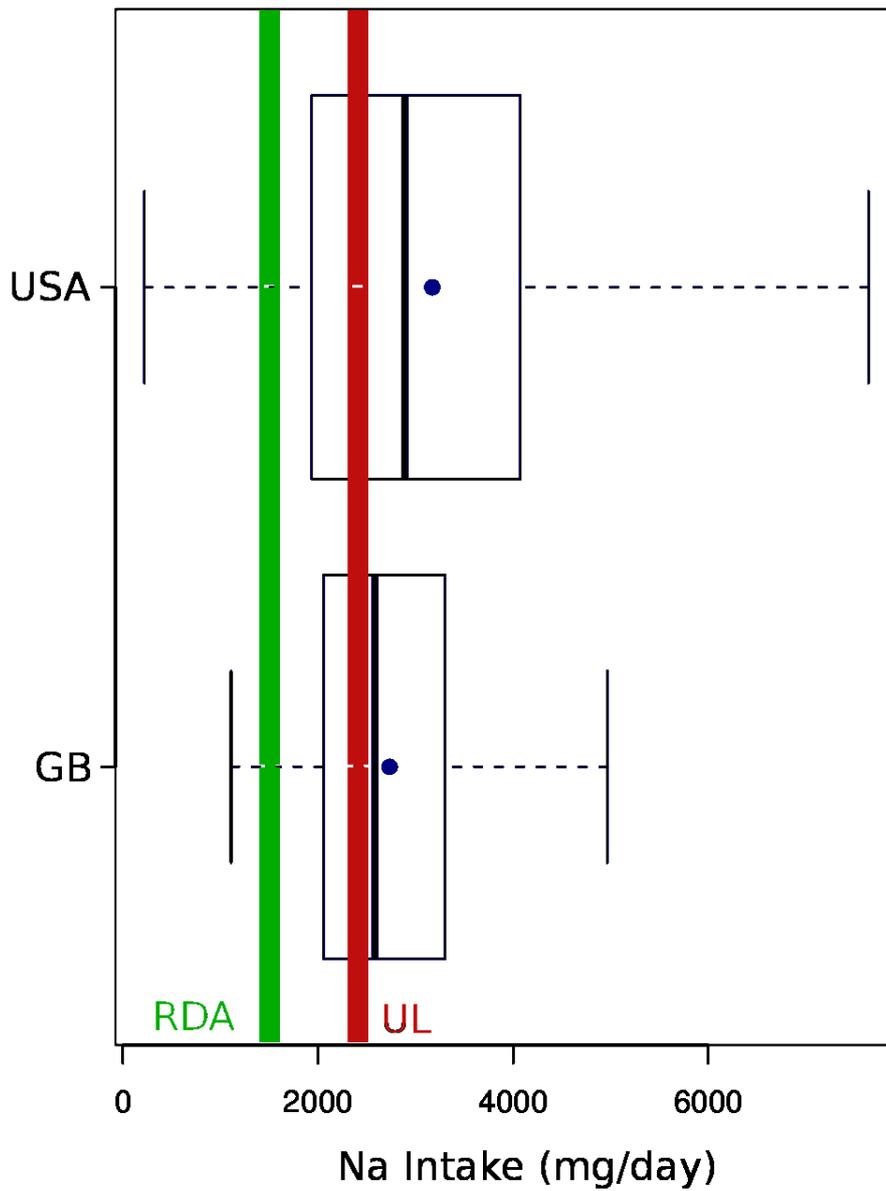


Figure 24: Boxplot to compare the total daily sodium intake of the American and British populations.

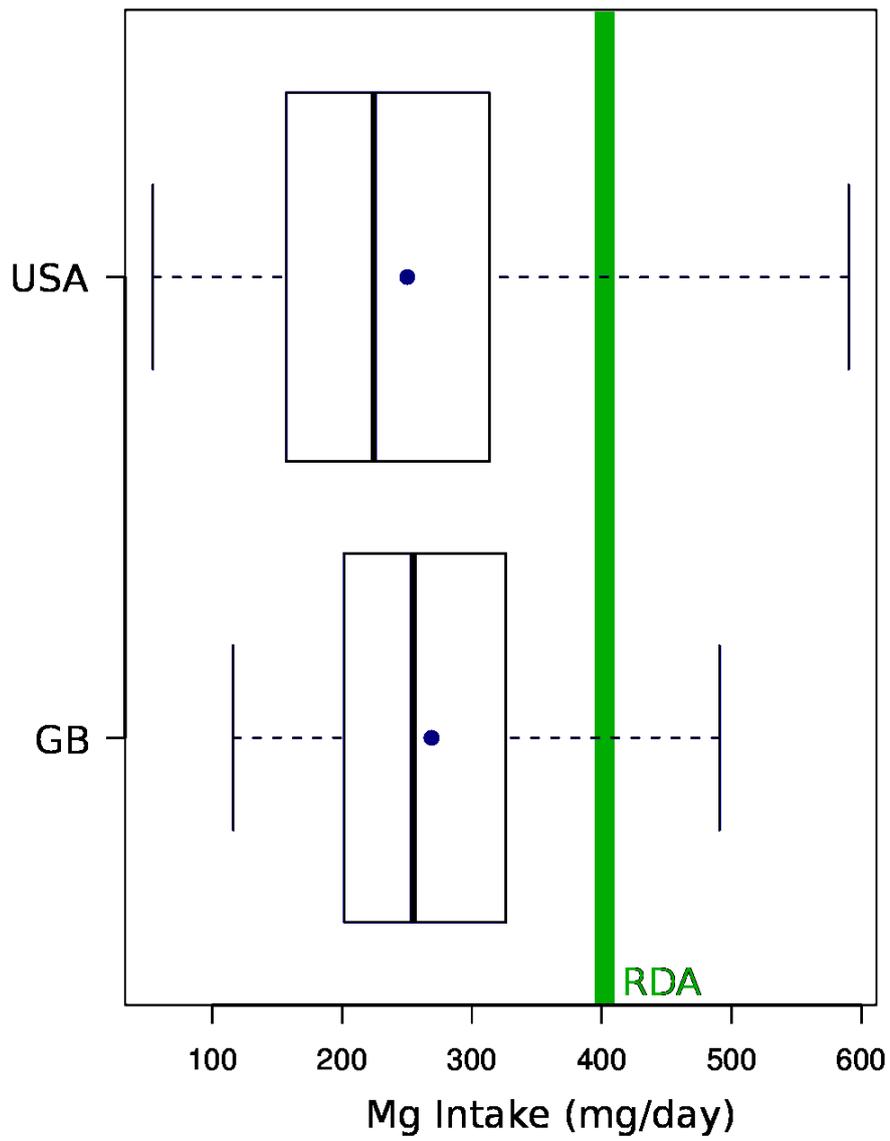


Figure 25: Boxplot to compare the total daily magnesium intake of the American and British populations.

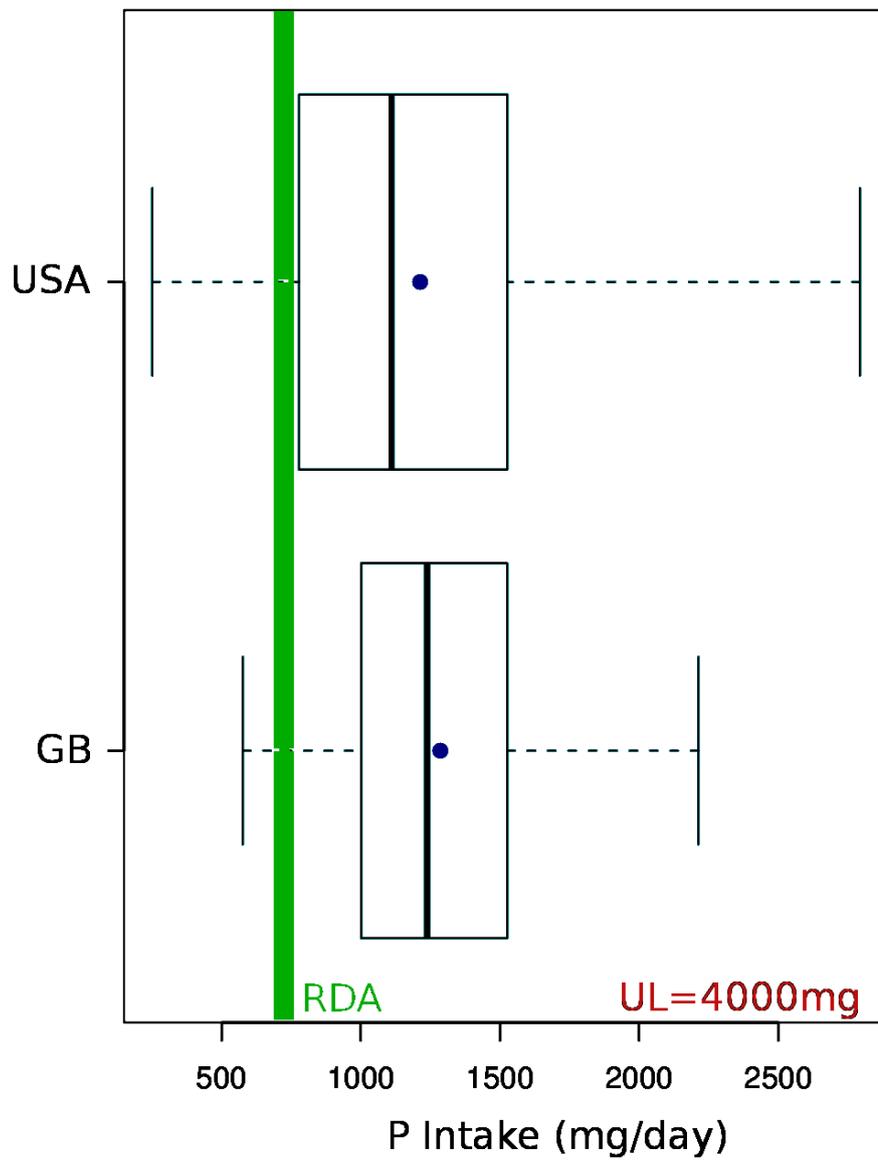


Figure 26: Boxplot to compare the total daily phosphorus intake of the American and British populations.

D Confidence Intervals for the Nutrient Intake Analysis

The following tables show the means and 97.5th percentiles of the nutrient intakes, with confidence intervals, for the British diet. For example, if we examine the following from Table 30:

Group Name	Original
All inc. Other	271.0(266.9, 275.2)

We can say that 271.0 is the mean from this survey; while in 90% of similar surveys the mean will lie between 266.9 and 275.2 is the upper bound of the confidence interval on the statistic. These numbers are a result of the size of the survey, and are obtained in Creme via the well known bootstrapping technique.

D.1 Replacement Results: 20% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	271.0(266.9, 275.2)	276.7(272.5, 281.0)	276.8(272.6, 281.1)	327.7(322.8, 332.6)
01A Breads	36.9(35.9, 38.0)	42.6(41.4, 43.8)	42.7(41.5, 43.9)	93.6(91.2, 96.0)
01B Cereals	34.8(33.4, 36.5)	34.8(33.4, 36.5)	34.8(33.4, 36.5)	34.8(33.4, 36.5)
02 Sugars	5.2(4.8, 5.6)	5.2(4.8, 5.6)	5.2(4.8, 5.6)	5.2(4.8, 5.6)
03 Fats	0.3(0.3, 0.3)	0.3(0.3, 0.3)	0.3(0.3, 0.3)	0.3(0.3, 0.3)
04 Vegetables	28.9(27.8, 30.0)	28.9(27.8, 30.0)	28.9(27.8, 30.0)	28.9(27.8, 30.0)
05 Starchy roots	26.1(25.4, 26.8)	26.1(25.4, 26.8)	26.1(25.4, 26.8)	26.1(25.4, 26.8)
06 Fruits	18.1(17.3, 19.0)	18.1(17.3, 19.0)	18.1(17.3, 19.0)	18.1(17.3, 19.0)
07 Soft drinks and Juices	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)
08 Beverages	16.9(16.2, 17.5)	16.9(16.2, 17.5)	16.9(16.2, 17.5)	16.9(16.2, 17.5)
09 Alcoholic drinks	23.2(21.6, 24.9)	23.2(21.6, 24.9)	23.2(21.6, 24.9)	23.2(21.6, 24.9)
10 Meats	32.7(31.8, 33.5)	32.7(31.8, 33.5)	32.7(31.8, 33.5)	32.7(31.8, 33.5)
11 Seafood	8.1(7.7, 8.6)	8.1(7.7, 8.6)	8.1(7.7, 8.6)	8.1(7.7, 8.6)
12 Eggs	2.6(2.4, 2.7)	2.6(2.4, 2.7)	2.6(2.4, 2.7)	2.6(2.4, 2.7)
13 Dairy	30.5(29.6, 31.3)	30.5(29.6, 31.3)	30.5(29.6, 31.3)	30.5(29.6, 31.3)
14 Miscellaneous	3.8(2.9, 5.0)	3.8(2.9, 5.0)	3.8(2.9, 5.0)	3.8(2.9, 5.0)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 30: Mean Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	480.0(460.6, 510.3)	491.6(467.7, 520.0)	491.1(466.9, 522.0)	580.3(555.8, 605.1)
01A Breads	101.8(90.0, 109.1)	116.4(100.8, 123.1)	112.1(106.4, 122.6)	222.3(210.3, 238.8)
01B Cereals	130.4(114.1, 140.2)	130.4(114.1, 140.2)	130.4(114.1, 140.2)	130.4(114.1, 140.2)
02 Sugars	28.7(26.5, 32.5)	28.7(26.5, 32.5)	28.7(26.5, 32.5)	28.7(26.5, 32.5)
03 Fats	1.1(1.0, 1.3)	1.1(1.0, 1.3)	1.1(1.0, 1.3)	1.1(1.0, 1.3)
04 Vegetables	91.8(83.0, 101.0)	91.8(83.0, 101.0)	91.8(83.0, 101.0)	91.8(83.0, 101.0)
05 Starchy roots	67.3(62.2, 72.2)	67.3(62.2, 72.2)	67.3(62.2, 72.2)	67.3(62.2, 72.2)
06 Fruits	66.9(62.5, 69.9)	66.9(62.5, 69.9)	66.9(62.5, 69.9)	66.9(62.5, 69.9)
07 Soft drinks and Juices	16.6(14.3, 19.8)	16.6(14.3, 19.8)	16.6(14.3, 19.8)	16.6(14.3, 19.8)
08 Beverages	55.2(51.3, 59.8)	55.2(51.3, 59.8)	55.2(51.3, 59.8)	55.2(51.3, 59.8)
09 Alcoholic drinks	133.8(124.2, 146.1)	133.8(124.2, 146.1)	133.8(124.2, 146.1)	133.8(124.2, 146.1)
10 Meats	75.6(71.6, 78.0)	75.6(71.6, 78.0)	75.6(71.6, 78.0)	75.6(71.6, 78.0)
11 Seafood	31.4(29.1, 33.5)	31.4(29.1, 33.5)	31.4(29.1, 33.5)	31.4(29.1, 33.5)
12 Eggs	11.2(10.4, 12.0)	11.2(10.4, 12.0)	11.2(10.4, 12.0)	11.2(10.4, 12.0)
13 Dairy	79.3(74.4, 85.6)	79.3(74.4, 85.6)	79.3(74.4, 85.6)	79.3(74.4, 85.6)
14 Miscellaneous	54.8(37.6, 85.7)	54.8(37.6, 85.7)	54.8(37.6, 85.7)	54.8(37.6, 85.7)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 31: The 97.5 Percentile of the Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2788.9(2746.2, 2833.5)	2779.5(2736.9, 2823.9)	2779.3(2736.9, 2823.4)	2695.0(2654.1, 2737.8)
01A Breads	649.3(634.8, 665.1)	639.9(625.7, 655.5)	639.7(625.5, 655.3)	555.4(543.1, 569.1)
01B Cereals	333.6(321.0, 346.4)	333.6(321.0, 346.4)	333.6(321.0, 346.4)	333.6(321.0, 346.4)
02 Sugars	13.9(12.9, 14.8)	13.9(12.9, 14.8)	13.9(12.9, 14.8)	13.9(12.9, 14.8)
03 Fats	89.3(85.5, 93.2)	89.3(85.5, 93.2)	89.3(85.5, 93.2)	89.3(85.5, 93.2)
04 Vegetables	424.9(410.4, 439.4)	424.9(410.4, 439.4)	424.9(410.4, 439.4)	424.9(410.4, 439.4)
05 Starchy roots	101.2(96.3, 106.3)	101.2(96.3, 106.3)	101.2(96.3, 106.3)	101.2(96.3, 106.3)
06 Fruits	19.7(17.8, 22.1)	19.7(17.8, 22.1)	19.7(17.8, 22.1)	19.7(17.8, 22.1)
07 Soft drinks and Juices	13.7(12.8, 14.6)	13.7(12.8, 14.6)	13.7(12.8, 14.6)	13.7(12.8, 14.6)
08 Beverages	13.5(10.9, 16.5)	13.5(10.9, 16.5)	13.5(10.9, 16.5)	13.5(10.9, 16.5)
09 Alcoholic drinks	23.8(22.2, 25.6)	23.8(22.2, 25.6)	23.8(22.2, 25.6)	23.8(22.2, 25.6)
10 Meats	719.2(696.9, 741.3)	719.2(696.9, 741.3)	719.2(696.9, 741.3)	719.2(696.9, 741.3)
11 Seafood	109.8(102.5, 116.9)	109.8(102.5, 116.9)	109.8(102.5, 116.9)	109.8(102.5, 116.9)
12 Eggs	55.5(51.2, 60.7)	55.5(51.2, 60.7)	55.5(51.2, 60.7)	55.5(51.2, 60.7)
13 Dairy	217.9(211.5, 224.7)	217.9(211.5, 224.7)	217.9(211.5, 224.7)	217.9(211.5, 224.7)
14 Miscellaneous	3.6(0.8, 8.3)	3.6(0.8, 8.3)	3.6(0.8, 8.3)	3.6(0.8, 8.3)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 32: Mean Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	5003.6(4843.8, 5351.1)	4988.7(4827.8, 5322.5)	4994.1(4805.0, 5331.0)	4867.1(4657.9, 5134.8)
01A Breads	1490.0(1401.7, 1532.5)	1471.1(1381.6, 1512.9)	1470.2(1379.1, 1512.1)	1274.2(1212.9, 1328.6)
01B Cereals	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)
02 Sugars	73.7(66.5, 79.9)	73.7(66.5, 79.9)	73.7(66.5, 79.9)	73.7(66.5, 79.9)
03 Fats	305.6(285.7, 345.2)	305.6(285.7, 345.2)	305.6(285.7, 345.2)	305.6(285.7, 345.2)
04 Vegetables	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)
05 Starchy roots	406.5(345.9, 438.1)	406.5(345.9, 438.1)	406.5(345.9, 438.1)	406.5(345.9, 438.1)
06 Fruits	122.2(108.7, 132.8)	122.2(108.7, 132.8)	122.2(108.7, 132.8)	122.2(108.7, 132.8)
07 Soft drinks and Juices	68.7(60.9, 77.7)	68.7(60.9, 77.7)	68.7(60.9, 77.7)	68.7(60.9, 77.7)
08 Beverages	88.6(78.4, 101.0)	88.6(78.4, 101.0)	88.6(78.4, 101.0)	88.6(78.4, 101.0)
09 Alcoholic drinks	140.0(132.0, 152.5)	140.0(132.0, 152.5)	140.0(132.0, 152.5)	140.0(132.0, 152.5)
10 Meats	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)
11 Seafood	545.7(493.5, 585.8)	545.7(493.5, 585.8)	545.7(493.5, 585.8)	545.7(493.5, 585.8)
12 Eggs	321.3(284.7, 353.0)	321.3(284.7, 353.0)	321.3(284.7, 353.0)	321.3(284.7, 353.0)
13 Dairy	553.4(522.9, 609.1)	553.4(522.9, 609.1)	553.4(522.9, 609.1)	553.4(522.9, 609.1)
14 Miscellaneous	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 33: The 97.5 Percentile of the Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1303.3(1284.4, 1322.9)	1306.0(1287.0, 1325.6)	1306.1(1287.1, 1325.7)	1330.3(1311.1, 1350.1)
01A Breads	153.0(149.0, 157.0)	155.7(151.6, 159.8)	155.8(151.7, 159.9)	180.0(175.4, 184.7)
01B Cereals	145.6(139.6, 151.8)	145.6(139.6, 151.8)	145.6(139.6, 151.8)	145.6(139.6, 151.8)
02 Sugars	18.1(16.8, 19.5)	18.1(16.8, 19.5)	18.1(16.8, 19.5)	18.1(16.8, 19.5)
03 Fats	4.3(4.1, 4.6)	4.3(4.1, 4.6)	4.3(4.1, 4.6)	4.3(4.1, 4.6)
04 Vegetables	101.9(99.0, 105.1)	101.9(99.0, 105.1)	101.9(99.0, 105.1)	101.9(99.0, 105.1)
05 Starchy roots	69.6(67.6, 71.4)	69.6(67.6, 71.4)	69.6(67.6, 71.4)	69.6(67.6, 71.4)
06 Fruits	26.1(24.9, 27.3)	26.1(24.9, 27.3)	26.1(24.9, 27.3)	26.1(24.9, 27.3)
07 Soft drinks and Juices	27.8(24.9, 30.6)	27.8(24.9, 30.6)	27.8(24.9, 30.6)	27.8(24.9, 30.6)
08 Beverages	22.4(21.3, 23.6)	22.4(21.3, 23.6)	22.4(21.3, 23.6)	22.4(21.3, 23.6)
09 Alcoholic drinks	49.0(45.2, 53.1)	49.0(45.2, 53.1)	49.0(45.2, 53.1)	49.0(45.2, 53.1)
10 Meats	269.6(262.8, 276.3)	269.6(262.8, 276.3)	269.6(262.8, 276.3)	269.6(262.8, 276.3)
11 Seafood	62.6(59.5, 65.8)	62.6(59.5, 65.8)	62.6(59.5, 65.8)	62.6(59.5, 65.8)
12 Eggs	37.8(35.9, 40.0)	37.8(35.9, 40.0)	37.8(35.9, 40.0)	37.8(35.9, 40.0)
13 Dairy	309.3(300.8, 317.8)	309.3(300.8, 317.8)	309.3(300.8, 317.8)	309.3(300.8, 317.8)
14 Miscellaneous	6.4(3.5, 10.5)	6.4(3.5, 10.5)	6.4(3.5, 10.5)	6.4(3.5, 10.5)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 34: Mean Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2229.5(2095.9, 2304.2)	2230.4(2100.5, 2310.3)	2230.9(2097.8, 2311.9)	2264.9(2131.9, 2348.9)
01A Breads	371.9(349.1, 414.2)	378.0(355.9, 417.6)	379.0(355.4, 415.7)	427.6(409.2, 480.5)
01B Cereals	461.9(424.9, 496.1)	461.9(424.9, 496.1)	461.9(424.9, 496.1)	461.9(424.9, 496.1)
02 Sugars	98.4(91.5, 107.9)	98.4(91.5, 107.9)	98.4(91.5, 107.9)	98.4(91.5, 107.9)
03 Fats	20.6(18.2, 22.7)	20.6(18.2, 22.7)	20.6(18.2, 22.7)	20.6(18.2, 22.7)
04 Vegetables	287.5(274.0, 296.2)	287.5(274.0, 296.2)	287.5(274.0, 296.2)	287.5(274.0, 296.2)
05 Starchy roots	180.9(167.3, 190.6)	180.9(167.3, 190.6)	180.9(167.3, 190.6)	180.9(167.3, 190.6)
06 Fruits	91.5(86.5, 97.9)	91.5(86.5, 97.9)	91.5(86.5, 97.9)	91.5(86.5, 97.9)
07 Soft drinks and Juices	196.6(175.7, 209.8)	196.6(175.7, 209.8)	196.6(175.7, 209.8)	196.6(175.7, 209.8)
08 Beverages	92.3(81.3, 101.7)	92.3(81.3, 101.7)	92.3(81.3, 101.7)	92.3(81.3, 101.7)
09 Alcoholic drinks	321.9(293.5, 352.2)	321.9(293.5, 352.2)	321.9(293.5, 352.2)	321.9(293.5, 352.2)
10 Meats	602.7(579.0, 629.5)	602.7(579.0, 629.5)	602.7(579.0, 629.5)	602.7(579.0, 629.5)
11 Seafood	239.6(225.4, 252.6)	239.6(225.4, 252.6)	239.6(225.4, 252.6)	239.6(225.4, 252.6)
12 Eggs	157.4(149.4, 165.6)	157.4(149.4, 165.6)	157.4(149.4, 165.6)	157.4(149.4, 165.6)
13 Dairy	740.5(709.3, 816.4)	740.5(709.3, 816.4)	740.5(709.3, 816.4)	740.5(709.3, 816.4)
14 Miscellaneous	91.8(35.1, 111.1)	91.8(35.1, 111.1)	91.8(35.1, 111.1)	91.8(35.1, 111.1)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

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Table 35: The 97.5 Percentile of the Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	281.1(276.9, 285.5)	284.2(280.0, 288.6)	284.4(280.1, 289.0)	312.0(307.6, 316.8)
Bakery Wares	23.2(22.3, 24.1)	26.3(25.4, 27.2)	26.5(25.5, 27.6)	54.1(52.5, 55.8)
Eggs	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)
Fats, Oils and Salad Dressings	0.3(0.3, 0.4)	0.3(0.3, 0.4)	0.3(0.3, 0.4)	0.3(0.3, 0.4)
Fruits	17.8(17.1, 18.5)	17.8(17.1, 18.5)	17.8(17.1, 18.5)	17.8(17.1, 18.5)
Legumes, Nuts and Seeds	20.5(18.9, 22.2)	20.5(18.9, 22.2)	20.5(18.9, 22.2)	20.5(18.9, 22.2)
Meat, Poultry, Fish and Mixtures	40.1(38.9, 41.3)	40.1(38.9, 41.3)	40.1(38.9, 41.3)	40.1(38.9, 41.3)
Milk Products	37.9(36.4, 39.4)	37.9(36.4, 39.4)	37.9(36.4, 39.4)	37.9(36.4, 39.4)
Other Grain Products	62.2(60.4, 64.0)	62.2(60.4, 64.0)	62.2(60.4, 64.0)	62.2(60.4, 64.0)
Sugars, Sweets and Beverages	46.8(45.2, 48.2)	46.8(45.2, 48.2)	46.8(45.2, 48.2)	46.8(45.2, 48.2)
Vegetables	29.5(28.6, 30.4)	29.5(28.6, 30.4)	29.5(28.6, 30.4)	29.5(28.6, 30.4)

Table 36: Mean Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

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Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	647.5(620.5, 689.5)	650.9(624.7, 690.8)	654.3(627.0, 695.0)	703.1(670.4, 721.5)
Bakery Wares	96.7(91.5, 101.1)	105.1(100.6, 109.8)	114.3(108.7, 121.9)	193.9(184.2, 205.3)
Eggs	25.7(24.5, 28.5)	25.7(24.5, 28.5)	25.7(24.5, 28.5)	25.7(24.5, 28.5)
Fats, Oils and Salad Dressings	2.4(2.3, 3.0)	2.4(2.3, 3.0)	2.4(2.3, 3.0)	2.4(2.3, 3.0)
Fruits	92.0(85.6, 97.0)	92.0(85.6, 97.0)	92.0(85.6, 97.0)	92.0(85.6, 97.0)
Legumes, Nuts and Seeds	162.6(152.1, 188.9)	162.6(152.1, 188.9)	162.6(152.1, 188.9)	162.6(152.1, 188.9)
Meat, Poultry, Fish and Mixtures	149.2(140.5, 157.7)	149.2(140.5, 157.7)	149.2(140.5, 157.7)	149.2(140.5, 157.7)
Milk Products	151.0(141.7, 163.1)	151.0(141.7, 163.1)	151.0(141.7, 163.1)	151.0(141.7, 163.1)
Other Grain Products	234.8(223.8, 246.5)	234.8(223.8, 246.5)	234.8(223.8, 246.5)	234.8(223.8, 246.5)
Sugars, Sweets and Beverages	190.6(172.7, 204.9)	190.6(172.7, 204.9)	190.6(172.7, 204.9)	190.6(172.7, 204.9)
Vegetables	119.8(111.8, 126.6)	119.8(111.8, 126.6)	119.8(111.8, 126.6)	119.8(111.8, 126.6)

Table 37: The 97.5 Percentile of the Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	3508.3(3461.4, 3553.9)	3503.2(3456.3, 3548.8)	3502.8(3455.9, 3548.7)	3457.1(3410.4, 3502.4)
Bakery Wares	361.8(351.7, 371.8)	356.7(346.7, 366.5)	356.4(346.4, 366.1)	310.6(301.9, 319.2)
Eggs	99.0(91.2, 107.0)	99.0(91.2, 107.0)	99.0(91.2, 107.0)	99.0(91.2, 107.0)
Fats, Oils and Salad Dressings	112.8(105.6, 120.6)	112.8(105.6, 120.6)	112.8(105.6, 120.6)	112.8(105.6, 120.6)
Fruits	5.2(4.9, 5.7)	5.2(4.9, 5.7)	5.2(4.9, 5.7)	5.2(4.9, 5.7)
Legumes, Nuts and Seeds	102.5(94.6, 111.0)	102.5(94.6, 111.0)	102.5(94.6, 111.0)	102.5(94.6, 111.0)
Meat, Poultry, Fish and Mixtures	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)
Milk Products	290.4(281.0, 301.2)	290.4(281.0, 301.2)	290.4(281.0, 301.2)	290.4(281.0, 301.2)
Other Grain Products	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)
Sugars, Sweets and Beverages	125.2(121.3, 129.4)	125.2(121.3, 129.4)	125.2(121.3, 129.4)	125.2(121.3, 129.4)
Vegetables	413.6(397.8, 430.3)	413.6(397.8, 430.3)	413.6(397.8, 430.3)	413.6(397.8, 430.3)

Table 38: Mean Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	7951.5(7703.8, 8322.4)	7936.0(7703.8, 8310.7)	7948.5(7712.8, 8262.5)	7890.1(7638.7, 8184.2)
Bakery Wares	1294.0(1236.7, 1360.6)	1278.8(1217.6, 1346.1)	1279.1(1219.3, 1321.8)	1133.3(1080.0, 1203.2)
Eggs	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)
Fats, Oils and Salad Dressings	925.1(866.3, 998.7)	925.1(866.3, 998.7)	925.1(866.3, 998.7)	925.1(866.3, 998.7)
Fruits	35.1(32.8, 38.8)	35.1(32.8, 38.8)	35.1(32.8, 38.8)	35.1(32.8, 38.8)
Legumes, Nuts and Seeds	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)
Meat, Poultry, Fish and Mixtures	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)
Milk Products	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)
Other Grain Products	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)
Sugars, Sweets and Beverages	490.9(447.3, 523.4)	490.9(447.3, 523.4)	490.9(447.3, 523.4)	490.9(447.3, 523.4)
Vegetables	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)

Table 39: The 97.5 Percentile of the Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1313.0(1295.2, 1332.8)	1314.5(1296.6, 1334.3)	1314.6(1296.7, 1334.4)	1327.7(1309.9, 1347.7)
Bakery Wares	92.1(89.0, 95.2)	93.6(90.4, 96.7)	93.7(90.6, 96.8)	106.9(103.3, 110.3)
Eggs	40.0(37.1, 43.2)	40.0(37.1, 43.2)	40.0(37.1, 43.2)	40.0(37.1, 43.2)
Fats, Oils and Salad Dressings	2.6(2.4, 2.9)	2.6(2.4, 2.9)	2.6(2.4, 2.9)	2.6(2.4, 2.9)
Fruits	24.0(23.1, 24.9)	24.0(23.1, 24.9)	24.0(23.1, 24.9)	24.0(23.1, 24.9)
Legumes, Nuts and Seeds	52.2(47.9, 56.4)	52.2(47.9, 56.4)	52.2(47.9, 56.4)	52.2(47.9, 56.4)
Meat, Poultry, Fish and Mixtures	312.1(303.4, 320.2)	312.1(303.4, 320.2)	312.1(303.4, 320.2)	312.1(303.4, 320.2)
Milk Products	334.8(325.3, 345.1)	334.8(325.3, 345.1)	334.8(325.3, 345.1)	334.8(325.3, 345.1)
Other Grain Products	294.9(286.3, 304.0)	294.9(286.3, 304.0)	294.9(286.3, 304.0)	294.9(286.3, 304.0)
Sugars, Sweets and Beverages	79.1(75.9, 82.3)	79.1(75.9, 82.3)	79.1(75.9, 82.3)	79.1(75.9, 82.3)
Vegetables	81.1(78.4, 83.8)	81.1(78.4, 83.8)	81.1(78.4, 83.8)	81.1(78.4, 83.8)

Table 40: Mean Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2919.9(2819.1, 2999.9)	2924.7(2821.9, 3001.6)	2918.6(2824.1, 2999.9)	2938.2(2838.2, 3023.5)
Bakery Wares	403.5(372.7, 432.5)	411.2(377.6, 437.5)	414.9(383.5, 436.6)	456.5(414.3, 480.0)
Eggs	370.2(337.5, 404.4)	370.2(337.5, 404.4)	370.2(337.5, 404.4)	370.2(337.5, 404.4)
Fats, Oils and Salad Dressings	18.9(16.3, 23.4)	18.9(16.3, 23.4)	18.9(16.3, 23.4)	18.9(16.3, 23.4)
Fruits	118.1(109.9, 125.9)	118.1(109.9, 125.9)	118.1(109.9, 125.9)	118.1(109.9, 125.9)
Legumes, Nuts and Seeds	437.5(392.9, 464.4)	437.5(392.9, 464.4)	437.5(392.9, 464.4)	437.5(392.9, 464.4)
Meat, Poultry, Fish and Mixtures	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)
Milk Products	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)
Other Grain Products	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)
Sugars, Sweets and Beverages	399.2(358.0, 417.4)	399.2(358.0, 417.4)	399.2(358.0, 417.4)	399.2(358.0, 417.4)
Vegetables	342.1(325.7, 363.1)	342.1(325.7, 363.1)	342.1(325.7, 363.1)	342.1(325.7, 363.1)

Table 41: The 97.5 Percentile of the Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

D.2 Replacement Results: 30% Sodium in Bakery Wares from Sodium Acid Pyrophosphate

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	271.0(266.9, 275.2)	277.4(273.2, 281.7)	277.7(273.4, 282.0)	335.1(330.0, 340.2)
01A Breads	36.9(35.9, 38.0)	43.3(42.1, 44.5)	43.5(42.4, 44.8)	100.9(98.3, 103.6)
01B Cereals	34.8(33.4, 36.5)	34.8(33.4, 36.5)	34.8(33.4, 36.5)	34.8(33.4, 36.5)
02 Sugars	5.2(4.8, 5.6)	5.2(4.8, 5.6)	5.2(4.8, 5.6)	5.2(4.8, 5.6)
03 Fats	0.3(0.3, 0.3)	0.3(0.3, 0.3)	0.3(0.3, 0.3)	0.3(0.3, 0.3)
04 Vegetables	28.9(27.8, 30.0)	28.9(27.8, 30.0)	28.9(27.8, 30.0)	28.9(27.8, 30.0)
05 Starchy roots	26.1(25.4, 26.8)	26.1(25.4, 26.8)	26.1(25.4, 26.8)	26.1(25.4, 26.8)
06 Fruits	18.1(17.3, 19.0)	18.1(17.3, 19.0)	18.1(17.3, 19.0)	18.1(17.3, 19.0)
07 Soft drinks and Juices	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)
08 Beverages	16.9(16.2, 17.5)	16.9(16.2, 17.5)	16.9(16.2, 17.5)	16.9(16.2, 17.5)
09 Alcoholic drinks	23.2(21.6, 24.9)	23.2(21.6, 24.9)	23.2(21.6, 24.9)	23.2(21.6, 24.9)
10 Meats	32.7(31.8, 33.5)	32.7(31.8, 33.5)	32.7(31.8, 33.5)	32.7(31.8, 33.5)
11 Seafood	8.1(7.7, 8.6)	8.1(7.7, 8.6)	8.1(7.7, 8.6)	8.1(7.7, 8.6)
12 Eggs	2.6(2.4, 2.7)	2.6(2.4, 2.7)	2.6(2.4, 2.7)	2.6(2.4, 2.7)
13 Dairy	30.5(29.6, 31.3)	30.5(29.6, 31.3)	30.5(29.6, 31.3)	30.5(29.6, 31.3)
14 Miscellaneous	3.8(2.9, 5.0)	3.8(2.9, 5.0)	3.8(2.9, 5.0)	3.8(2.9, 5.0)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 42: Mean Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	480.0(460.6, 510.3)	491.6(469.3, 521.3)	492.5(467.2, 525.8)	593.5(574.1, 623.0)
01A Breads	101.8(90.0, 109.1)	117.2(103.8, 125.2)	120.8(111.0, 130.1)	248.1(231.5, 264.1)
01B Cereals	130.4(114.1, 140.2)	130.4(114.1, 140.2)	130.4(114.1, 140.2)	130.4(114.1, 140.2)
02 Sugars	28.7(26.5, 32.5)	28.7(26.5, 32.5)	28.7(26.5, 32.5)	28.7(26.5, 32.5)
03 Fats	1.1(1.0, 1.3)	1.1(1.0, 1.3)	1.1(1.0, 1.3)	1.1(1.0, 1.3)
04 Vegetables	91.8(83.0, 101.0)	91.8(83.0, 101.0)	91.8(83.0, 101.0)	91.8(83.0, 101.0)
05 Starchy roots	67.3(62.2, 72.2)	67.3(62.2, 72.2)	67.3(62.2, 72.2)	67.3(62.2, 72.2)
06 Fruits	66.9(62.5, 69.9)	66.9(62.5, 69.9)	66.9(62.5, 69.9)	66.9(62.5, 69.9)
07 Soft drinks and Juices	16.6(14.3, 19.8)	16.6(14.3, 19.8)	16.6(14.3, 19.8)	16.6(14.3, 19.8)
08 Beverages	55.2(51.3, 59.8)	55.2(51.3, 59.8)	55.2(51.3, 59.8)	55.2(51.3, 59.8)
09 Alcoholic drinks	133.8(124.2, 146.1)	133.8(124.2, 146.1)	133.8(124.2, 146.1)	133.8(124.2, 146.1)
10 Meats	75.6(71.6, 78.0)	75.6(71.6, 78.0)	75.6(71.6, 78.0)	75.6(71.6, 78.0)
11 Seafood	31.4(29.1, 33.5)	31.4(29.1, 33.5)	31.4(29.1, 33.5)	31.4(29.1, 33.5)
12 Eggs	11.2(10.4, 12.0)	11.2(10.4, 12.0)	11.2(10.4, 12.0)	11.2(10.4, 12.0)
13 Dairy	79.3(74.4, 85.6)	79.3(74.4, 85.6)	79.3(74.4, 85.6)	79.3(74.4, 85.6)
14 Miscellaneous	54.8(37.6, 85.7)	54.8(37.6, 85.7)	54.8(37.6, 85.7)	54.8(37.6, 85.7)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 43: The 97.5 Percentile of the Intake of Magnesium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2788.9(2746.2, 2833.5)	2778.3(2735.8, 2822.8)	2777.9(2735.7, 2822.4)	2682.9(2642.0, 2725.6)
01A Breads	649.3(634.8, 665.1)	638.7(624.5, 654.2)	638.3(624.2, 653.9)	543.3(531.2, 556.9)
01B Cereals	333.6(321.0, 346.4)	333.6(321.0, 346.4)	333.6(321.0, 346.4)	333.6(321.0, 346.4)
02 Sugars	13.9(12.9, 14.8)	13.9(12.9, 14.8)	13.9(12.9, 14.8)	13.9(12.9, 14.8)
03 Fats	89.3(85.5, 93.2)	89.3(85.5, 93.2)	89.3(85.5, 93.2)	89.3(85.5, 93.2)
04 Vegetables	424.9(410.4, 439.4)	424.9(410.4, 439.4)	424.9(410.4, 439.4)	424.9(410.4, 439.4)
05 Starchy roots	101.2(96.3, 106.3)	101.2(96.3, 106.3)	101.2(96.3, 106.3)	101.2(96.3, 106.3)
06 Fruits	19.7(17.8, 22.1)	19.7(17.8, 22.1)	19.7(17.8, 22.1)	19.7(17.8, 22.1)
07 Soft drinks and Juices	13.7(12.8, 14.6)	13.7(12.8, 14.6)	13.7(12.8, 14.6)	13.7(12.8, 14.6)
08 Beverages	13.5(10.9, 16.5)	13.5(10.9, 16.5)	13.5(10.9, 16.5)	13.5(10.9, 16.5)
09 Alcoholic drinks	23.8(22.2, 25.6)	23.8(22.2, 25.6)	23.8(22.2, 25.6)	23.8(22.2, 25.6)
10 Meats	719.2(696.9, 741.3)	719.2(696.9, 741.3)	719.2(696.9, 741.3)	719.2(696.9, 741.3)
11 Seafood	109.8(102.5, 116.9)	109.8(102.5, 116.9)	109.8(102.5, 116.9)	109.8(102.5, 116.9)
12 Eggs	55.5(51.2, 60.7)	55.5(51.2, 60.7)	55.5(51.2, 60.7)	55.5(51.2, 60.7)
13 Dairy	217.9(211.5, 224.7)	217.9(211.5, 224.7)	217.9(211.5, 224.7)	217.9(211.5, 224.7)
14 Miscellaneous	3.6(0.8, 8.3)	3.6(0.8, 8.3)	3.6(0.8, 8.3)	3.6(0.8, 8.3)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 44: Mean Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	5003.6(4843.8, 5351.1)	4988.4(4827.8, 5317.3)	4993.0(4829.7, 5301.5)	4864.2(4652.5, 5119.1)
01A Breads	1490.0(1401.7, 1532.5)	1470.0(1380.4, 1512.0)	1466.9(1387.8, 1518.0)	1253.7(1188.5, 1318.1)
01B Cereals	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)	1119.2(1030.9, 1175.7)
02 Sugars	73.7(66.5, 79.9)	73.7(66.5, 79.9)	73.7(66.5, 79.9)	73.7(66.5, 79.9)
03 Fats	305.6(285.7, 345.2)	305.6(285.7, 345.2)	305.6(285.7, 345.2)	305.6(285.7, 345.2)
04 Vegetables	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)	1272.6(1212.9, 1386.8)
05 Starchy roots	406.5(345.9, 438.1)	406.5(345.9, 438.1)	406.5(345.9, 438.1)	406.5(345.9, 438.1)
06 Fruits	122.2(108.7, 132.8)	122.2(108.7, 132.8)	122.2(108.7, 132.8)	122.2(108.7, 132.8)
07 Soft drinks and Juices	68.7(60.9, 77.7)	68.7(60.9, 77.7)	68.7(60.9, 77.7)	68.7(60.9, 77.7)
08 Beverages	88.6(78.4, 101.0)	88.6(78.4, 101.0)	88.6(78.4, 101.0)	88.6(78.4, 101.0)
09 Alcoholic drinks	140.0(132.0, 152.5)	140.0(132.0, 152.5)	140.0(132.0, 152.5)	140.0(132.0, 152.5)
10 Meats	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)	1941.3(1828.1, 2029.8)
11 Seafood	545.7(493.5, 585.8)	545.7(493.5, 585.8)	545.7(493.5, 585.8)	545.7(493.5, 585.8)
12 Eggs	321.3(284.7, 353.0)	321.3(284.7, 353.0)	321.3(284.7, 353.0)	321.3(284.7, 353.0)
13 Dairy	553.4(522.9, 609.1)	553.4(522.9, 609.1)	553.4(522.9, 609.1)	553.4(522.9, 609.1)
14 Miscellaneous	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 45: The 97.5 Percentile of the Intake of Sodium by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1303.3(1284.4, 1322.9)	1306.4(1287.4, 1326.0)	1306.5(1287.5, 1326.1)	1333.8(1314.7, 1353.7)
01A Breads	153.0(149.0, 157.0)	156.0(152.0, 160.2)	156.2(152.1, 160.3)	183.5(178.8, 188.4)
01B Cereals	145.6(139.6, 151.8)	145.6(139.6, 151.8)	145.6(139.6, 151.8)	145.6(139.6, 151.8)
02 Sugars	18.1(16.8, 19.5)	18.1(16.8, 19.5)	18.1(16.8, 19.5)	18.1(16.8, 19.5)
03 Fats	4.3(4.1, 4.6)	4.3(4.1, 4.6)	4.3(4.1, 4.6)	4.3(4.1, 4.6)
04 Vegetables	101.9(99.0, 105.1)	101.9(99.0, 105.1)	101.9(99.0, 105.1)	101.9(99.0, 105.1)
05 Starchy roots	69.6(67.6, 71.4)	69.6(67.6, 71.4)	69.6(67.6, 71.4)	69.6(67.6, 71.4)
06 Fruits	26.1(24.9, 27.3)	26.1(24.9, 27.3)	26.1(24.9, 27.3)	26.1(24.9, 27.3)
07 Soft drinks and Juices	27.8(24.9, 30.6)	27.8(24.9, 30.6)	27.8(24.9, 30.6)	27.8(24.9, 30.6)
08 Beverages	22.4(21.3, 23.6)	22.4(21.3, 23.6)	22.4(21.3, 23.6)	22.4(21.3, 23.6)
09 Alcoholic drinks	49.0(45.2, 53.1)	49.0(45.2, 53.1)	49.0(45.2, 53.1)	49.0(45.2, 53.1)
10 Meats	269.6(262.8, 276.3)	269.6(262.8, 276.3)	269.6(262.8, 276.3)	269.6(262.8, 276.3)
11 Seafood	62.6(59.5, 65.8)	62.6(59.5, 65.8)	62.6(59.5, 65.8)	62.6(59.5, 65.8)
12 Eggs	37.8(35.9, 40.0)	37.8(35.9, 40.0)	37.8(35.9, 40.0)	37.8(35.9, 40.0)
13 Dairy	309.3(300.8, 317.8)	309.3(300.8, 317.8)	309.3(300.8, 317.8)	309.3(300.8, 317.8)
14 Miscellaneous	6.4(3.5, 10.5)	6.4(3.5, 10.5)	6.4(3.5, 10.5)	6.4(3.5, 10.5)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 46: Mean Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2229.5(2095.9, 2304.2)	2230.6(2100.7, 2311.9)	2229.7(2100.0, 2314.6)	2271.9(2138.7, 2351.3)
01A Breads	371.9(349.1, 414.2)	378.9(356.2, 419.0)	376.5(356.1, 423.6)	440.1(419.1, 494.6)
01B Cereals	461.9(424.9, 496.1)	461.9(424.9, 496.1)	461.9(424.9, 496.1)	461.9(424.9, 496.1)
02 Sugars	98.4(91.5, 107.9)	98.4(91.5, 107.9)	98.4(91.5, 107.9)	98.4(91.5, 107.9)
03 Fats	20.6(18.2, 22.7)	20.6(18.2, 22.7)	20.6(18.2, 22.7)	20.6(18.2, 22.7)
04 Vegetables	287.5(274.0, 296.2)	287.5(274.0, 296.2)	287.5(274.0, 296.2)	287.5(274.0, 296.2)
05 Starchy roots	180.9(167.3, 190.6)	180.9(167.3, 190.6)	180.9(167.3, 190.6)	180.9(167.3, 190.6)
06 Fruits	91.5(86.5, 97.9)	91.5(86.5, 97.9)	91.5(86.5, 97.9)	91.5(86.5, 97.9)
07 Soft drinks and Juices	196.6(175.7, 209.8)	196.6(175.7, 209.8)	196.6(175.7, 209.8)	196.6(175.7, 209.8)
08 Beverages	92.3(81.3, 101.7)	92.3(81.3, 101.7)	92.3(81.3, 101.7)	92.3(81.3, 101.7)
09 Alcoholic drinks	321.9(293.5, 352.2)	321.9(293.5, 352.2)	321.9(293.5, 352.2)	321.9(293.5, 352.2)
10 Meats	602.7(579.0, 629.5)	602.7(579.0, 629.5)	602.7(579.0, 629.5)	602.7(579.0, 629.5)
11 Seafood	239.6(225.4, 252.6)	239.6(225.4, 252.6)	239.6(225.4, 252.6)	239.6(225.4, 252.6)
12 Eggs	157.4(149.4, 165.6)	157.4(149.4, 165.6)	157.4(149.4, 165.6)	157.4(149.4, 165.6)
13 Dairy	740.5(709.3, 816.4)	740.5(709.3, 816.4)	740.5(709.3, 816.4)	740.5(709.3, 816.4)
14 Miscellaneous	91.8(35.1, 111.1)	91.8(35.1, 111.1)	91.8(35.1, 111.1)	91.8(35.1, 111.1)
15 Tap water	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)	0.0(0.0, 0.0)

Table 47: The 97.5 Percentile of the Intake of Phosphorus by the British population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	281.1(276.9, 285.5)	284.5(280.3, 289.0)	284.6(280.3, 289.0)	315.3(310.8, 320.1)
Bakery Wares	23.2(22.3, 24.1)	26.6(25.7, 27.5)	26.6(25.6, 27.7)	57.4(55.6, 59.2)
Eggs	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)	2.8(2.6, 3.1)
Fats, Oils and Salad Dressings	0.3(0.3, 0.4)	0.3(0.3, 0.4)	0.3(0.3, 0.4)	0.3(0.3, 0.4)
Fruits	17.8(17.1, 18.5)	17.8(17.1, 18.5)	17.8(17.1, 18.5)	17.8(17.1, 18.5)
Legumes, Nuts and Seeds	20.5(18.9, 22.2)	20.5(18.9, 22.2)	20.5(18.9, 22.2)	20.5(18.9, 22.2)
Meat, Poultry, Fish and Mixtures	40.1(38.9, 41.3)	40.1(38.9, 41.3)	40.1(38.9, 41.3)	40.1(38.9, 41.3)
Milk Products	37.9(36.4, 39.4)	37.9(36.4, 39.4)	37.9(36.4, 39.4)	37.9(36.4, 39.4)
Other Grain Products	62.2(60.4, 64.0)	62.2(60.4, 64.0)	62.2(60.4, 64.0)	62.2(60.4, 64.0)
Sugars, Sweets and Beverages	46.8(45.2, 48.2)	46.8(45.2, 48.2)	46.8(45.2, 48.2)	46.8(45.2, 48.2)
Vegetables	29.5(28.6, 30.4)	29.5(28.6, 30.4)	29.5(28.6, 30.4)	29.5(28.6, 30.4)

Table 48: Mean Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

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Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	647.5(620.5, 689.5)	650.9(624.7, 690.8)	653.6(627.7, 689.7)	709.4(687.7, 728.3)
Bakery Wares	96.7(91.5, 101.1)	106.8(102.0, 111.4)	110.8(105.2, 119.6)	209.8(202.2, 229.6)
Eggs	25.7(24.5, 28.5)	25.7(24.5, 28.5)	25.7(24.5, 28.5)	25.7(24.5, 28.5)
Fats, Oils and Salad Dressings	2.4(2.3, 3.0)	2.4(2.3, 3.0)	2.4(2.3, 3.0)	2.4(2.3, 3.0)
Fruits	92.0(85.6, 97.0)	92.0(85.6, 97.0)	92.0(85.6, 97.0)	92.0(85.6, 97.0)
Legumes, Nuts and Seeds	162.6(152.1, 188.9)	162.6(152.1, 188.9)	162.6(152.1, 188.9)	162.6(152.1, 188.9)
Meat, Poultry, Fish and Mixtures	149.2(140.5, 157.7)	149.2(140.5, 157.7)	149.2(140.5, 157.7)	149.2(140.5, 157.7)
Milk Products	151.0(141.7, 163.1)	151.0(141.7, 163.1)	151.0(141.7, 163.1)	151.0(141.7, 163.1)
Other Grain Products	234.8(223.8, 246.5)	234.8(223.8, 246.5)	234.8(223.8, 246.5)	234.8(223.8, 246.5)
Sugars, Sweets and Beverages	190.6(172.7, 204.9)	190.6(172.7, 204.9)	190.6(172.7, 204.9)	190.6(172.7, 204.9)
Vegetables	119.8(111.8, 126.6)	119.8(111.8, 126.6)	119.8(111.8, 126.6)	119.8(111.8, 126.6)

Table 49: The 97.5 Percentile of the Intake of Magnesium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	3508.3(3461.4, 3553.9)	3502.6(3455.7, 3548.3)	3502.6(3455.6, 3548.3)	3451.7(3405.1, 3496.9)
Bakery Wares	361.8(351.7, 371.8)	356.2(346.2, 365.9)	356.2(346.3, 366.0)	305.3(296.7, 313.7)
Eggs	99.0(91.2, 107.0)	99.0(91.2, 107.0)	99.0(91.2, 107.0)	99.0(91.2, 107.0)
Fats, Oils and Salad Dressings	112.8(105.6, 120.6)	112.8(105.6, 120.6)	112.8(105.6, 120.6)	112.8(105.6, 120.6)
Fruits	5.2(4.9, 5.7)	5.2(4.9, 5.7)	5.2(4.9, 5.7)	5.2(4.9, 5.7)
Legumes, Nuts and Seeds	102.5(94.6, 111.0)	102.5(94.6, 111.0)	102.5(94.6, 111.0)	102.5(94.6, 111.0)
Meat, Poultry, Fish and Mixtures	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)	976.3(948.9, 1002.6)
Milk Products	290.4(281.0, 301.2)	290.4(281.0, 301.2)	290.4(281.0, 301.2)	290.4(281.0, 301.2)
Other Grain Products	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)	1021.4(992.8, 1052.1)
Sugars, Sweets and Beverages	125.2(121.3, 129.4)	125.2(121.3, 129.4)	125.2(121.3, 129.4)	125.2(121.3, 129.4)
Vegetables	413.6(397.8, 430.3)	413.6(397.8, 430.3)	413.6(397.8, 430.3)	413.6(397.8, 430.3)

Table 50: Mean Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	7951.5(7703.8, 8322.4)	7936.8(7703.8, 8309.9)	7950.9(7676.0, 8308.9)	7875.1(7638.7, 8162.8)
Bakery Wares	1294.0(1236.7, 1360.6)	1277.3(1215.3, 1345.9)	1288.4(1225.8, 1327.7)	1111.2(1078.1, 1190.8)
Eggs	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)	952.3(868.0, 1019.7)
Fats, Oils and Salad Dressings	925.1(866.3, 998.7)	925.1(866.3, 998.7)	925.1(866.3, 998.7)	925.1(866.3, 998.7)
Fruits	35.1(32.8, 38.8)	35.1(32.8, 38.8)	35.1(32.8, 38.8)	35.1(32.8, 38.8)
Legumes, Nuts and Seeds	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)	975.1(901.9, 1114.0)
Meat, Poultry, Fish and Mixtures	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)	3600.5(3328.8, 3778.3)
Milk Products	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)	1222.1(1172.1, 1303.4)
Other Grain Products	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)	3932.4(3771.4, 4158.7)
Sugars, Sweets and Beverages	490.9(447.3, 523.4)	490.9(447.3, 523.4)	490.9(447.3, 523.4)	490.9(447.3, 523.4)
Vegetables	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)	1889.5(1779.9, 1984.3)

Table 51: The 97.5 Percentile of the Intake of Sodium by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	1313.0(1295.2, 1332.8)	1314.6(1296.8, 1334.5)	1314.6(1296.8, 1334.5)	1329.3(1311.4, 1349.2)
Bakery Wares	92.1(89.0, 95.2)	93.8(90.6, 96.8)	93.8(90.6, 96.9)	108.4(104.8, 111.9)
Eggs	40.0(37.1, 43.2)	40.0(37.1, 43.2)	40.0(37.1, 43.2)	40.0(37.1, 43.2)
Fats, Oils and Salad Dressings	2.6(2.4, 2.9)	2.6(2.4, 2.9)	2.6(2.4, 2.9)	2.6(2.4, 2.9)
Fruits	24.0(23.1, 24.9)	24.0(23.1, 24.9)	24.0(23.1, 24.9)	24.0(23.1, 24.9)
Legumes, Nuts and Seeds	52.2(47.9, 56.4)	52.2(47.9, 56.4)	52.2(47.9, 56.4)	52.2(47.9, 56.4)
Meat, Poultry, Fish and Mixtures	312.1(303.4, 320.2)	312.1(303.4, 320.2)	312.1(303.4, 320.2)	312.1(303.4, 320.2)
Milk Products	334.8(325.3, 345.1)	334.8(325.3, 345.1)	334.8(325.3, 345.1)	334.8(325.3, 345.1)
Other Grain Products	294.9(286.3, 304.0)	294.9(286.3, 304.0)	294.9(286.3, 304.0)	294.9(286.3, 304.0)
Sugars, Sweets and Beverages	79.1(75.9, 82.3)	79.1(75.9, 82.3)	79.1(75.9, 82.3)	79.1(75.9, 82.3)
Vegetables	81.1(78.4, 83.8)	81.1(78.4, 83.8)	81.1(78.4, 83.8)	81.1(78.4, 83.8)

Table 52: Mean Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

Group Name	Original	10% (I)	10% (P)	100%
All inc. Other	2919.9(2819.1, 2999.9)	2925.3(2821.9, 3001.8)	2919.9(2819.1, 2999.9)	2936.0(2839.1, 3023.5)
Bakery Wares	403.5(372.7, 432.5)	410.6(377.8, 437.6)	410.9(378.0, 443.4)	458.4(419.6, 488.6)
Eggs	370.2(337.5, 404.4)	370.2(337.5, 404.4)	370.2(337.5, 404.4)	370.2(337.5, 404.4)
Fats, Oils and Salad Dressings	18.9(16.3, 23.4)	18.9(16.3, 23.4)	18.9(16.3, 23.4)	18.9(16.3, 23.4)
Fruits	118.1(109.9, 125.9)	118.1(109.9, 125.9)	118.1(109.9, 125.9)	118.1(109.9, 125.9)
Legumes, Nuts and Seeds	437.5(392.9, 464.4)	437.5(392.9, 464.4)	437.5(392.9, 464.4)	437.5(392.9, 464.4)
Meat, Poultry, Fish and Mixtures	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)	1082.7(1004.5, 1145.0)
Milk Products	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)	1248.7(1186.1, 1349.8)
Other Grain Products	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)	1158.3(1104.9, 1234.6)
Sugars, Sweets and Beverages	399.2(358.0, 417.4)	399.2(358.0, 417.4)	399.2(358.0, 417.4)	399.2(358.0, 417.4)
Vegetables	342.1(325.7, 363.1)	342.1(325.7, 363.1)	342.1(325.7, 363.1)	342.1(325.7, 363.1)

Table 53: The 97.5 Percentile of the Intake of Phosphorus by the American population for all four scenarios, broken down by food groups, in mg/day.

E The Creme Food Method

The method used by Creme Food[®] allows risk assessors to use all of the available data in a published and validated scientific exposure model.

The benefit of this method is that it allows you to perform a validated, realistic exposure assessment of consumers. Since all the available data is being used in the assessment and not just basic statistics, the calculation is based in reality.

This method allows all of the richness of the original data to be included in the assessment. This information can be important such as food consumption correlations, typical co-consumption (e.g. tea and milk) and non consumption of foods (e.g. tea and coffee) on a particular day, meal or week.

The risk assessor can assess the contribution of multiple foods and can assess the exposure of the population to multiple chemicals.

The method retains the relationship between food intakes and bodyweights, age, gender, geographic location, socio-economic and other demographic information.

The method allows the assessor to use deterministic or probabilistic data for additional data of interest (e.g. chemical occurrence and concentration data). Confidence intervals in the results will be produced in both cases.

If the assessor wants to use probabilistic data, the probabilistic input can be set to represent variability or uncertainty and the effect of each can be assessed.

Exposure can be calculated for key groups of consumers such as children only, or by particular age groups of genders. Thus allowing risk assessors to protect all demographic groups in the population.

The Creme Food[®] method allows risk assessors to understand the real exposure of consumers. The method also allows the assessor to perform scenario analysis and sensitivity analysis to understand the key drivers of consumer exposure.

E.1 About the Creme Food Model

This appendix provides an overview of the Creme Food[®] Software Model in order to provide an overview of the supporting tools that we will use in this assessment.

Creme Food[®] supports the following types of risk assessments:

1. Deterministic assessments
2. Probabilistic Assessments

Deterministic assessments have no stochastic element. Probabilistic assessments quantify and model variability, or uncertainty, or both.

E.1.1 Daily Average and Acute Assessments

Creme Food® provides a number of Calculation Types including:

1. Daily Average
2. Acute

Daily Average Assessments The default simulation model is the “Daily Average” exposure model which calculates the average food intake and chemical exposure per day for a large number of replicates of individuals from an original survey and then extracts the requested summary statistics such as the various percentiles, means and standard deviations. The error estimates on each of the different statistical properties is also outputted allowing the user to determine if enough simulated individuals were used. (The standard error of each percentile is reported by default. The user can also request that various confidence intervals be reported). All output is given in both absolute and per unit bodyweight terms.

Acute Assessments The second type of calculation type is the “Acute” model, which produces three separate outputs. The first calculates the day of maximum exposure for each subject and then calculates output statistics based on this. Secondly, these exposures can be compared to the Acute Reference Doses (ARfDs) of each target chemical to calculate what proportion of the population, if any, are exceeding safe limits (on any day). Thirdly, statistics on the number of days on which subjects exceed the ARfDs are calculated.

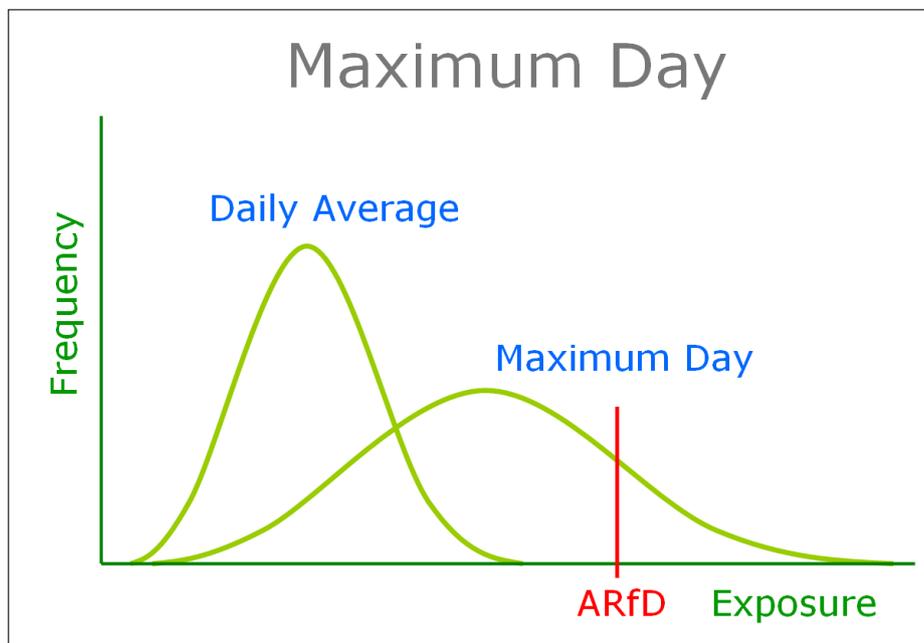


Figure 27: Typical comparison of the distribution of Daily Average and Acute: Maximum Day intakes.

The following functions are supported by Creme Food®:

- Continuous Distributions
 - Normal
 - Exponential
 - Lognormal
 - Uniform
 - Weibull
 - Beta
 - Gamma
 - Logistic
 - Chi-Squared
 - Triangular
- Discrete Distributions
 - Bernoulli
 - Binomial
 - Negative Binomial
 - Hypergeometric
 - Discrete
 - Poisson
 - Data
 - Histogram With Equal Class Widths
 - Histogram2 With Different Class Widths
 - Histogram3 With Overlapping Classes
- Deterministic Distributions
 - Sum
 - Max
 - Min
 - Product
 - Reciprocal
 - Log
 - Log10
 - Exp
 - Pow
 - Sqrt

As well as calculating Monte Carlo statistics over the uncertainty iterations, Creme Food[®] also outputs the results of each uncertainty iteration separately. This allows the user to perform uncertainty analysis on the simulation, in order to determine which uncertainty parameters are driving the simulation. More information on the hierarchy of output data is given in the section “Output Data”.

The relationship between Creme Food[®] tables is shown in figure 28. Orange tables are the most basic tables required for a chemical simulation. Blue tables provide extra features. The grey text beside each table shows which new data field is introduced by that table.

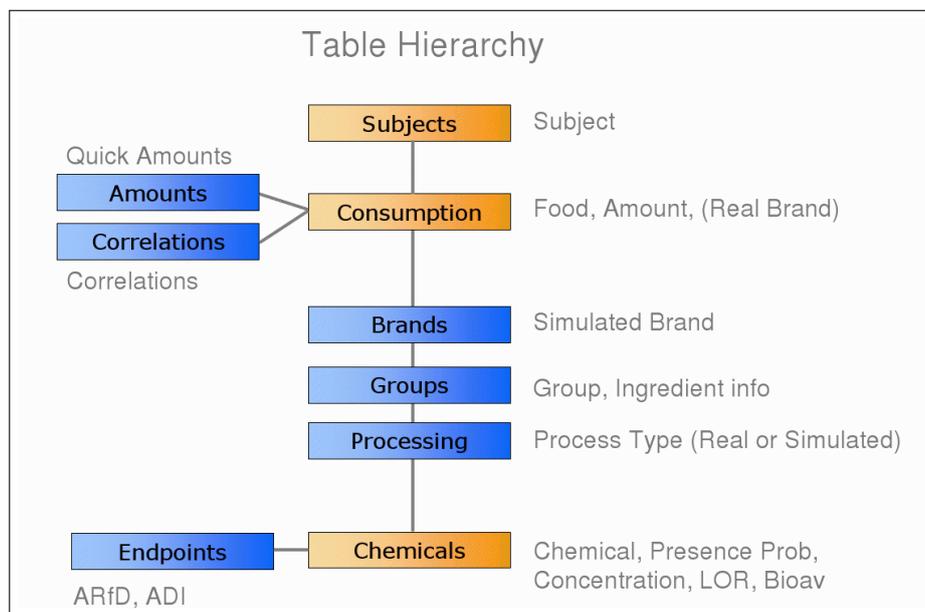


Figure 28: Creme Food[®] data table relationships.

E.1.2 Output Data

There are three types of output in Creme Food[®]:

1. Automatic Assessment Reports
2. Tabular Data Output
3. Graphical Data Output

The Automatic Assessment Reports contain a summary of all the input parameters used in the assessment, and an array of the graphical output. Depending on the number of chemicals in the assessment, the report may be quite long. To this end, an easy to use navigation system is included at the top of the report to allow the user to quickly jump to the section of interest.

Four data tables are produced for each assessment:

1. Low-level output. These output tables record one row of information for each consumption event in the Consumption table. Therefore these tables are often quite large in size, but allow the user to see every value that was used in the simulation.
2. Individual-level output. At this level, output is aggregated to a per-individual level.
3. Statistical-level output. At this level, statistics are calculated over the individuals, e.g. the P90 over Chemical consumers.
4. Uncertainty-level output. At this level, statistics are calculated over the uncertainty iterations of the simulation. This allows the user to see which uncertainty parameters are driving the outputs of the simulation.

Statistics Outputted Each of the 4 output levels above are broken down according to various output factors, including:

- Exposure Type
- Output Type
- Consumer Type
- Calculation Type
- Group Code
- Group Name
- Population Statistic

Typical values of each of these factors are listed below:

- Exposure Type

- Food
- Chemical 1
- Chemical 2
- Chemical 3 (etc...)
- Total Chemical
- Bioavailable Chemical 1
- Bioavailable Chemical 2
- Bioavailable Chemical 3 (etc...)
- Total Bioavailable Chemical
- Output Type
 - Absolute output
 - Per unit bodyweight output
- Consumer Type
 - Total Population Statistics
 - Food Consumer Statistics
 - Chemical Consumer Statistics
- Calculation Type
 - Daily Average
 - Lifetime (Nusser Method)
 - Acute – Maximum Day
 - Acute – Exceeded ARfD
 - Acute – Number of days exceeding ARfD
- Group Code
 - Group 1
 - Group 2
 - Group 3 (etc...)
 - “Other” group (foods that were not assigned to any group)
 - All Groups (excluding the Other group)
 - All Groups (including the Other group)
- Group Name (Similar to Group Code, except groups are expressed using the group name instead of group code)
- Population Statistic
 - Count (number of replicates used for these statistics)
 - Units (physical units of these statistics)
 - Mean

- Standard Deviation
- Maximum
- Minimum
- Median
- P90
- P95
- P99 (etc. . .) (Users can requested other percentiles also)

Note: for standard error and various confidence intervals are also calculated for each population statistic. Users can request custom confidence intervals.

The default output associated with a “Daily Average” calculation, for example, for “Food Consumer Statistics”, includes the population mean, standard deviation, median, minimum, maximum, 95th, 97.5th and 99th percentiles for the food intake per day, food intake per bodyweight per day, chemical exposure per day and chemical exposure per bodyweight per day, for each Group Code, and for each Chemical Code.

Customisation In order to reduce the amount of data outputted, users may choose to only output certain parameters when submitting assessments. For example, the user may not require the P90 or the P95, per unit bodyweight output, or 95% confidence intervals around each output value.

When viewing output data, user-friendly filters are provided to allow the user to quickly find the statistics of interest.

E.2 Disclaimer

The information provided in this report is based on the best possible data that is currently available to Creme. Creme makes every effort to test the quality of the input data, to check for outliers and to correct errors and missing data; however we cannot guarantee the accuracy of third party data.

Creme reports provide a model which gives insight into the actual and potential consumer impacts of food consumption habits and trends. The report is based on a widely accepted and published scientific method of estimating consumer exposure. The information in this report should be interpreted in conjunction with your own in-house expertise, your own research and data and in some cases, in consultation with the relevant competent authorities before making any final decision on food issues.

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Index: XRF
Rev.: 0

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Erstellt:	Datum: <i>10.11.10</i>	Name Ullrich Keßler	Unterschrift: (b) (6)
Geprüft:	Datum: <i>10.11.10</i>	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: <i>3.12.10</i>	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

Quantitative Bestimmungsmethoden für das wellenlängendispersive Röntgenspektrometer
Zweck:

Die RFA ist eine zerstörungsfreie analytische Technik zur Identifizierung und Konzentrationsbestimmung von Elementen in Festkörpern, Pulverproben und Flüssigkeiten.

Zerstörungsfreie Analyse von Festkörperproben bis zu einer Größe von 48 mm Ø und 25 mm Höhe.

Identifizierungs- und Quantifizierungsmöglichkeiten für alle Elemente von Sauerstoff bis Uran in einem Konzentrationsbereich von 1 ppm bis 100 Gew. %.

Die Röntgenfluoreszenzanalyse (RFA) genannt (im Englischen X-ray fluorescence spectroscopy, XRF) ist eine Methode aus der Materialanalytik. Sie ist eine der am häufigsten eingesetzten Methoden zur qualitativen und quantitativen Bestimmung der elementaren Zusammensetzung einer Probe, da die Proben durch die Messung nicht zerstört werden und keine Aufschlüsse benötigt werden. Besonders breite Anwendung findet sie in der metallverarbeitenden Industrie, bei der Untersuchung von Glas, Keramik und Baustoffen sowie bei der Analyse von Schmierstoffen und Mineralölprodukten.

Wenn man Atome mit hochenergetischen Röntgen-Photonen anregt, werden Elektronen in Form von Photoelektronen aus dem Bereich der inneren Elektronenschalen herausgeschlagen. Die so entstandene instabile Elektronen- Leerstelle in einer oder mehreren Elektronenschalen werden von Elektronen aus den äußeren Schalen unter Abgabe der Überschussenergie in Form von Sekundär- Röntgenphotonen ersetzt. Dieses Phänomen ist als "Röntgenfluoreszenz" bekannt. Die Energie des emittierenden

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Fluoreszenz- Photons ist charakteristisch für das entsprechende Element ($E = h\nu$). Ebenso ist die Anzahl der emittierenden Photonen proportional zur Konzentration des Elements in der Probe.

Geräte:

Röntgenspektrometer Axios der Fa. PANalytical mit Autosampler
Aufschlussgerät Vulcan von HD-Elektronics
Analysewaage
Pt/Au-Tiegel und Abgusschalen
Kugelwalzmühle mit Hartmetall-, Achat- und Bornitrid- Mahlgefäße
Presse HTP 40 der Fa. Herzog mit Presswerkzeug 40mm
Eisenschwingmühle Fa. Herzog HSM100
Planetenmühle Fa. Fritsch
Schüttelmischer Turbula Typ T2F

Reagenzien:

Spectromelt A10
Spectromelt A100
Spectromelt A12
4%ige $\text{NH}_4\text{-Br}$ -Lösung
Hoechst Wachs C
1% LiOH-Lösung

Durchführung:

Probenvorbereitung für Pulver als Schmelztablette:
In einen Pt/Au-Tiegel werden Schmelzmittel ($\pm 0,005$ g) und Probe ($\pm 0,0005$ g) entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden eingewogen.

Probenvorbereitung für Lösungen als Schmelze:
In ein 50 ml Becherglas werden Schmelzmittel ($\pm 0,005$ g) und Probe ($\pm 0,001$ g) entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden Vulcan fused beads eingewogen (Einwaage notieren!) und 1h bei ca. 200°C im Trockenschrank getrocknet.

Die vorbereiteten Mischungen werden auf dem Vulcan-Aufschlussgerät geschmolzen und anschließend mit dem Röntgenspektrometer gemessen.

Probenvorbereitung für Pulver als Presstablette:
In einer 50-ml Kunststoffflasche werden Hoechst Wachs C ($\pm 0,01$ g) und die Analysenprobe ($\pm 0,01$ g) entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden Pressed Pellets eingewogen und mit 4 Achatkugeln ($\varnothing 10\text{mm}$) versetzt. Anschließend wird eine halbe Stunde im Schüttelmischer

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homogenisiert. Die Mischung wird nach Entfernen der Achatkugeln in ein Aluminiumcap gefüllt und auf der Presse 20 Sekunden lang mit 20 t verpresst und mit dem Röntgenspektrometer gemessen.

Messungen:

Die Messungen erfolgen mit der SuperQ-Software unter Berücksichtigung der Bedienungsanleitung.

Auswertung:

Die Auswertung erfolgt mit der Software „UniQuant 5.0“ unter Berücksichtigung der Bedienungsanleitung. Das Ergebnis wird entsprechend der Prüfanweisung als Endresultat angegeben.

Sicherheit:

PSA gemäß Arbeitsanweisung AL-AA-09-005

Entsorgung:

Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

Anhang:

Einarbeitungsliste
 Produktbezogene Analysenmethoden Vulcan fused beads
 Produktbezogene Analysenmethoden Pressed Pellets

Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 0/ 11/2010	Neuerstellung	---

Analysenvorschrift
**Index: HPIC3
Rev.: 3**

Seite 1 von 3

Erstellt:	Datum: <i>M.M.09</i>	Name Stefanie Frorath	Unterschrift: (b) (6)
Geändert:	Datum:	Name	Unterschrift:
Geprüft:	Datum: <i>M.M.09</i>	Name Dr. Gabriele Zache	Unterschrift: (b) (6)
Freigegeben:	Datum: <i>M.M.09</i>	Name Dr. Claudia Wiedemann / AL- Leitung	Unterschrift: (b) (6)

**Ionenchromatographische Bestimmung von Tripolyphosphat in
Pyrophosphaten**

Zweck: Bestimmung des Gehaltes an Tripolyphosphat in Proben deren Hauptanteil aus Pyrophosphat besteht.

Meßbereich: 0,5% - 30%

Prinzip: Leitfähigkeitsdetektion und Auswertung über die Chromeleon Software nach säulenchromatographischer Auftrennung der Einzelbestandteile.

Ausrüstung:

- ICS2000 (Fa. DIONEX)
(AG16/AS16 2mm-Säulen, Säulenofen, ASRS 2mm-Suppressor, Leitfähigkeitsmesszelle)
- AS Autosampler (Fa. DIONEX)
(Probengefäße, Gummimembran, Schraubdeckel)

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Reagenzien: - KOH – Eluent – Kartusche
- Reinstwasser ($\leq 0,05\mu\text{S}$)

Durchführung:

1. **Probenvorbereitung**
In einen 100ml Messkolben werden 0,1 - 0,2g der zu bestimmenden Probe auf 0,1mg genau eingewogen. Mit Reinstwasser wird bis zur Marke aufgefüllt.
2. **Bestücken des Autosamplers**
Das Gefäß für den Autosampler wird 3 mal mit der Probe gespült. Die rot – weiße Membran wird mit der weißen Seite nach außen in den blauen Gefäßdeckel eingelegt und auf das Probengefäß geschraubt.
Das Probengefäß wird in den Autosamplers gestellt.
3. **Erstellen und Starten der Sequenz**
Die genaue Vorgehensweise zum Erstellen und Starten einer Sequenz kann im Ordner **internes Betriebshandbuch** am Gerät unter Punkt 5: Erstellen einer Kalibriersequenz nachgelesen werden. Die Kalibrieranweisung AL-PA-08-004 ist zu beachten.

Auswertung: Die Gehaltsbestimmung erfolgt methodenbezogen über die Berechnung der Peakflächen durch die Chromeleonsoftware.

Dokumentation:

Das jeweilige Chromatogramm wird ausgedruckt und am Arbeitsplatz in einem separaten Ordner abgeheftet.

Sicherheit:

PSA gemäß Arbeitsanweisung AL-AA-09-005

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Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 3 / 15.11.09	Überarbeitete Analysenvorschrift	Neue Analysengeräte

Analysenvorschrift
Index: F-AAS
Rev.: 0

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Erstellt:	Datum: 12.10.10	Name Elisabeth Schmitt	Unterschrift: (b) (6)
Geprüft:	Datum: 12.10.10	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: 5.11.10	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

**Bestimmung von Spurenelementen mittels
Atomabsorptionsspektrometrie**

Zweck: Die Atomabsorptionsspektrometrie ist eine Methode zur Bestimmung der Konzentration eines Elements in einer Probe durch Messung der Absorption von elektromagnetischer Strahlung durch den aus der Probe erzeugten Atomdampf des Elements. Die Messung wird bei einer Wellenlänge von einer für das betreffende Element charakteristischen Resonanz-Absorptionslinie durchgeführt. Die Menge der absorbierten Strahlung ist dem Lambert-Beer'schen-Gesetz folgend proportional der Konzentration des Elements.

Gerät: Atomabsorptionsspektrometer
 AAnalyst 200, Hersteller Perkin Elmer
 AAnalyst 300, Hersteller Perkin Elmer

Reagenzien: HCl 32% p.A., (1:1 verdünnt mit Reinstwasser)
 Einzelementstandards 1 g/l (z.B. von Fa. Bernd Kraft)
 Cäsiumchlorid-Aluminiumnitrat Pufferlösung (z.B Merck 1.02037)

Lanthanchlorid Pufferlösung, hergestellt wie folgt:
 100 g Lanthan(III)-chlorid Heptahydrat, (Merck 1.12219),
 werden mit ca. 200 ml Reinstwasser versetzt, 120 ml HCl
 32%ig p.A. zugefügt und dann mit Reinstwasser auf 1 l
 aufgefüllt.

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H₂SO₄ p.A. (z.B. Merck)
Die Haltbarkeit der für die verschiedenen Analysenmethoden angesetzten Standards liegt bei 2 Wochen.

Durchführung: Die Durchführung erfolgt entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden und unter Berücksichtigung der Bedienungsanleitung.

Auswertung Die Auswertung erfolgt nach Eingabe der geforderten Stammdaten durch die Software automatisch.

Die Messdaten werden tabellarisch dargestellt und abgelesen. Das Ergebnis wird entsprechend der Prüfanweisung als Endresultat angegeben.

Sicherheit: Es gelten die im Labor allgemeinen Sicherheitsrichtlinien. PSA ist gemäß AL-AA-09-005 zu tragen.

Entsorgung: Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

Anhang:

- Einarbeitungsliste
- Produktbezogene Analysenmethoden

Änderungshistorie

Version / Gültig ab	Beschreibung der Änderung	Begründung
Revision 0/ 10/2010	Neuerstellung	Ersetzt die ursprünglichen Analysevorschriften OES-AAS

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Index: OES
Rev.: 0

Seite: 1 von 2

Erstellt:	Datum: 11.10.10	Name Elisabeth Schmitt	Unterschrift: (b) (6)
Gepflegt:	Datum: 11.10.10	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: 5.11.10	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

Bestimmung von Spurenelementen mittels optischer Emissionsspektrometrie
Zweck:

Die optische Emissionsspektrometrie mittels induktiv gekoppeltem Plasma (ICP-OES, inductively coupled plasma – optical emission spectrometry) ist eine Methode zur Bestimmung der Konzentration eines Elements in einer Substanz. Sie beruht auf der Verwendung eines sehr heißen (ca. 10000 K) Argon-Plasmas, welches zur Anregung der optischen Emission der zu analysierenden Elemente genutzt wird.

Gerät:

Optisches Emissionsspektrometer mit induktiv gekoppeltem Hochfrequenz-Plasma (Typ 720-ES, Hersteller Varian)

Reagenzien:

HNO₃ 65% suprapur (Merck 1.00441)
 HCl 30% suprapur (Merck 1.00318)
 Natriumcarbonat (Merck 1.06395)
 Calciumcarbonat (Merck 1.02059)
 Kaliumnitrat (Merck 1.05065)
 Einzelementstandards (z.B. von Fa. Bernd Kraft)
 Multielementstandards (z.B. von Fa. Merck)
 Reinstwasser

Durchführung:

Die Durchführung erfolgt entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden und unter Berücksichtigung der Bedienungsanleitung Varian 720-ES.

Analysenvorschrift

Index: OES

Rev.: 0

Seite: 2 von 2

Auswertung

Die Auswertung erfolgt nach Eingabe der geforderten Stammdaten durch die Software automatisch.

Die Messdaten werden tabellarisch dargestellt und abgelesen. Das Ergebnis wird entsprechend der Prüfanweisung als Endresultat angegeben.

Sicherheit:

Es gelten die im Labor allgemeinen Sicherheitsrichtlinien. PSA ist gemäß AL-AA-09-005 zu tragen.

Entsorgung:

Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

Anhang:

- Einarbeitungsliste
- Produktbezogene Analysenmethoden

Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 0/ 10/2010	Neuerstellung	Ersetzt die ursprünglichen Analysenvorschriften OES-AAS

Analysenvorschrift
**Index: ZEE-AAS
Rev.: 1**

Seite: 1 von 2

Erstellt:	Datum: 15.10.10	Name Elisabeth Schmitt	Unterschrift: (b) (6)
Geprüft:	Datum: 15.10.10	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: 5.11.10	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

Bestimmung von Spurenelementen mittels Graphitrohr-Atomabsorption

- Zweck:** Die Graphitrohr-Atomabsorption dient zur Bestimmung der Konzentration eines Elements in einer Substanz. Bei diesem Verfahren wird die Probe in einem kleinen Graphitrohr verdampft/atomisiert. Die Graphitrohrtechnik beruht auf der Verwendung des Zeeman-Effekts, der zur Kompensation des magnetischen Wechselfeldes dient (Untergrundkorrektur).
- Gerät:** THGA-Graphitrohrföfen (AAAnalyst 600, Hersteller PerkinElmer)
- Reagenzien:** HNO₃ 65% suprapur (z.B. Merck 1.00441)
HCl 32% suprapur (z.B. Merck 1.00318)
Stammlösungen (z.B. Fa. Bernd Kraft), Konzentration 1000mg/l
Magnesiumnitrat-Hexahydrat (z.B. Merck 1.05855.0050)
Reinstwasser
- Durchführung:** Die Durchführung erfolgt entsprechend den im Anhang angegebenen produktbezogenen Analysenmethoden und unter Berücksichtigung der Bedienungsanleitung AAAnalyst 600.
- Auswertung** Die Auswertung erfolgt nach Eingabe der geforderten Stammdaten durch die Software automatisch.

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Index: ZEE-AAS
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Die Messdaten werden tabellarisch dargestellt und abgelesen. Das Ergebnis wird entsprechend der Prüfanweisung als Endresultat angegeben.

Sicherheit

Es gelten die im Labor allgemeinen Sicherheitsrichtlinien. PSA ist gemäß AL-AA-09-005 zu tragen. Je nach Probe muss die dafür vorgesehene Schutzausrüstung ergänzt werden (z.B. Handschuhe), siehe hierzu das entsprechende Sicherheitsdatenblatt.

Entsorgung:

Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

Anhang:

- Einarbeitungsliste
- Bedienungsanleitung Analyst 600
- Produktbezogene Analysenmethoden

Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 0/	Neuerstellung	---
Revision 1/ 10/2010	Überarbeitung	Anpassung u. Überarbeitung der Vorschrift

Analysenvorschrift

Index: F 10

Rev.: 5

Erstellt: 01/05

Seite: 1 / 3

Geprüft: QK:..... QS:.....

Photometrische Bestimmung von Mikromengen Fluorid

- Zweck: Bestimmung von Fluorid in Phosphaten und Phosphorsäuren im ppm - Bereich
- Prinzip: Wasserdampfdestillation von HF bzw. H_2SiF_6
Reaktion der F^- - Ionen des Destillats mit einem roten Chelat aus Ce^{III} und Alizarinkomplexan unter Bildung einer blauen Komplexverbindung.
- Geräte: Laborausrüstung
Fotometer LASA 100, Dr. Lange
50mm Glasküvette
Apparatur siehe Zeichnung (S. 3)
- Reagenzien: Schwefelsäure konz. p.a. (95–97 %), $D = 1,84\text{g/ml}$
Silbersulfat p.a.
NaOH 0,5mol/l
- Mischindikator:*
0,6g Methylrot und
0,4g Methylenblau in dest. Wasser lösen und auf 1000ml auffüllen.
- Reagenzlösungen für die Photometrie,*
Lösung A
1,100 g Alizarinkomplexan (Alizarin -3 - methylamin - N,N - diessigsäure - Dihydrat) werden in 200 ml dest. Wasser unter Zusatz von 10 ml NaOH 5 mol/l gelöst. Mit konz. Essigsäure wird auf pH 5,0 eingestellt und dann auf 1000 ml verdünnt.
Lösung B
1,000 g Cer III - nitrat x 6 H_2O , 166 g Natriumacetat x 3 H_2O p.a. und 100 ml konz. Essigsäure (96%) p.a. werden gelöst und mit dest. Wasser auf 1000 ml aufgefüllt.
(Haltbarkeit: max. 4 Wochen)
- Fluor-Standardlösung*
1000mg F / 1000ml

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Durchführung:

1. Schwefelsäurebad:

In einem Rundkolben (2) werden von 365ml H₂O dest. und 300ml H₂SO₄ konz., (D = 1,84g/ml), gemischt.

Überprüfung des Schwefelsäurebades durch Titration.

Indikator: Mischindikator

1ml der Badlösung soll 33+/- 1ml 0,5mol/l NaOH verbrauchen.

2. Einwaage:

max. 5g Einwaage Feststoff

max. 5ml Flüssigkeit

maximaler Fluoridgehalt 70µg in der Destillationshülse.

3. Destillation:

Durch das Einleitungsrohr (3) wird ein Luftstrom von 100 - 200 ml/min. eingeleitet (Trägergas und zur Verhinderung von Siedeverzügen).

Die Destillationshülse (4) mit Probe und dest. Wasser (maximales Volumen in Hülse 5ml) wird mit 8 ml konz. H₂SO₄ versetzt und sofort in das kochende Schwefelsäurebad eingesetzt und der Kühler (5) aufgesetzt..

Die Destillationszeit beträgt ca. 20 Minuten, währenddessen steigt die Badtemperatur von ca. 130°C auf ca. 160°C. Nach dem automatischen Abschalten (Zeitschaltuhr) beträgt der Nachlauf 8 - 10 ml. Nach Beendigung der Destillation und Herunterkühlen des Bades wird die verdampfte Wassermenge ersetzt. Als erste Destillation wird eine Blinddestillation durchgeführt.

4. Messung:

Meßkolben (6) mit dest. Wasser zur Marke auffüllen. Von den Reagenzlösungen A und B jeweils 2,5 ml zugeben und umschütteln.

Nach 30 Minuten Reaktionszeit nochmals umschütteln und bei 588 nm Wellenlänge in einer 50 mm Glasküvette messen.

Die Nullpunkteinstellung erfolgt gegen einen Blindwert aus dest. Wasser und Reagenzlösung A und B.

Berechnung:

Die Fluoridmenge wird einer vorher erstellten Kalibrierfunktion entnommen (10-70µg F).

Photometer: LASA 100 (Dr.Lange), Auswertung: polygonale Interpolation.

Anmerkung:

Chlorid - Ionen stören die Bestimmung. Sie werden durch Zugabe von Ag₂SO₄ in der Destillationshülse fixiert.

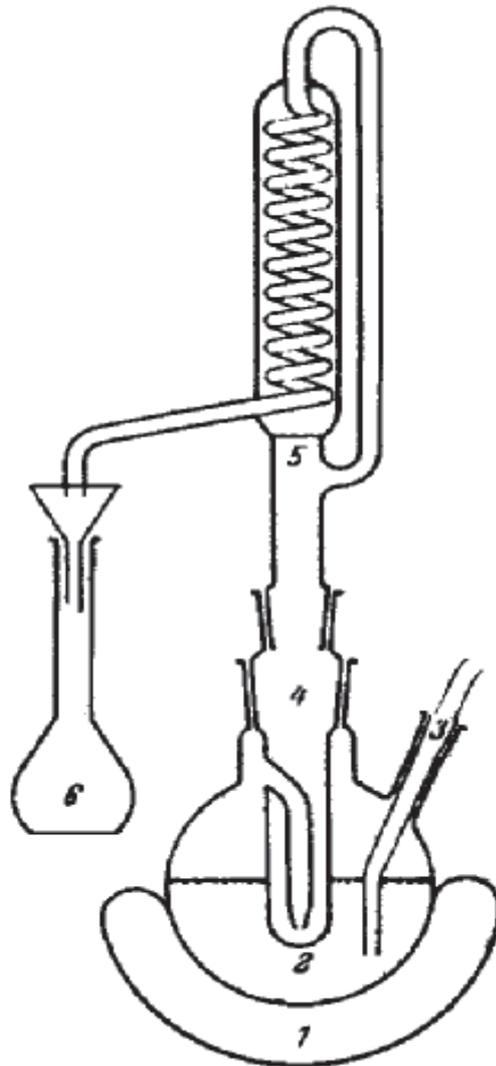
Analysenvorschrift

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Apparatur zur Destillation von Fluorid



- 1 - Pilzheizhaube, 300 W
- 2 - 2-Hals-Rundkolben, H-NS 45, seitlicher Schliff H-NS 14,5 1 l Inhalt
- 3 - Schliffeinleitungsrohr, K-NS 14,5
- 4 - Destillationshülse mit Dampfleitungsrohr K-NS 45 und H-NS 29
- 5 - Kühleraufsatz mit Ablauf K-NS 29
- 6 - Meßkolben 100 ml

Analysenvorschrift
Index: GV1
Rev.: 3

Seite 1 von 2

Erstellt:	Datum: 6.12.10	Name Claudia Wolf	Unterschrift: (b) (6)
Geprüft:	Datum: 7.12.10	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: 2.12.10	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

Bestimmung des Glühverlustes
Zweck

Der Glühverlust ist der in Prozent angegebene Masseverlust. Bei dieser Temperatur entweicht physikalisch und chemisch gebundenes Wasser, sowie andere flüchtige Bestandteile.

Geräte

Muffelofen
 Analysenwaage
 Porzellantiegel /Platintiegel
 Exsikkator (über Silicagel)

Durchführung

Die Bestimmung des Glühverlustes erfolgt mittels Differenzwägung. Es werden ca. 2 g der Probe in einen vorgeglühten tarierten Tiegel auf 0,1 mg genau eingewogen (Einwaage A). Die eingewogene Probe wird entsprechend den im Anhang erwähnten Glühverlustbedingungen bei den vorgeschriebenen Temperaturen und Glühzeiten in einem Muffelofen erhitzt. Nach der Glühzeit wird der Tiegel im Exsikkator auf Raumtemperatur abgekühlt und danach zur Bestimmung der Auswaage B auf der Analysenwaage auf 0,1 mg genau ausgewogen.

Wenn es die Eigenschaften des Materials erfordern, muss eine Vorbehandlung bei niedrigerer Temperatur erfolgen und ein Tiegel mit Deckel verwendet werden.

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Auswertung:

Die Auswaage B wird gravimetrisch bestimmt. Die Differenz der Wägung vor und nach dem Glühen wird in Prozent als Verlust angegeben:

$$\text{Glühverlust [\%]} = \frac{A \text{ [g]} - B \text{ [g]}}{A \text{ [g]}} \times 100$$

A = Einwaage [g]

B = Auswaage / Glührückstand [g]

Das Ergebnis wird entsprechend der Prüfanweisung als Endresultat angegeben.

Sicherheit:

Es gelten die im Labor allgemeinen Sicherheitsrichtlinien. PSA ist gemäß AL-AA-09-005 zu tragen.

Entsorgung:

Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

Mitgeltende Unterlagen:

Sicherheitsdatenblätter der verwendeten Chemikalien beachten.

Anhang:

Glühverlustbedingungen
Einarbeitungsliste

Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 0-2	Nicht vorhanden	---
Revision 3 12/2010	Neuerstellung	Einführung der verschiedenen Trocknungsbedingungen, Änderungshistorie

Anhang zur Analysenvorschrift

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Rev.: 3

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Glühverlustbedingungen:

Alle Glühverlustbedingungen sind im Kurztext Stammprüfmerkmal eindeutig mit Temperatur und Trockenzeit beschrieben.

In der angefügten Tabelle sind die verschiedenen Glühverlustbedingungen mit der entsprechenden Tiegelart im Überblick dargestellt:

Glüh-temperatur	Dauer	Tiegelart	Bemerkung
800 °C	30 min	Porzellan / Platin	PE
800°C	2h	Porzellan	PE
425°C	4h	Porzellan	FCC

Für die angegebenen di-Calciumphosphat-dihydrat (grob)-Produkte ist der Glühverlust bis zur Massenkonstanz zu bestimmen:

Produkt	Dauer	Bemerkung
C92 14	Glühen bis zur Massenkonstanz	
C92 14H		
C92 44		
C92 13		
C92 17		

Glühverlust bis zur Massenkonstanz bedeutet, dass zwei aufeinanderfolgende Wägungen um höchstens 0,5 mg voneinander abweichen dürfen. Die zweite Wägung erfolgt nach zusätzlichem Glühen.

Analysenvorschrift

Index: S13
Rev.: 0

Seite 1 von 2

Erstellt:	Datum: 11.10.10	Name Helge Kullmann	Unterschrift: (b) (6)
Geprüft:	Datum: 11.10.10	Name Dr. André Lemke / Leiter Qualitätskontrolle	Unterschrift: (b) (6)
Freigegeben:	Datum: 15.10.10	Name Dr. Claudia Wiedemann / Leitung Analytisches Labor	Unterschrift: (b) (6)

Korngrößenbestimmung mittels Laserstreulichtanalyse (trocken)

- Zweck: Bestimmung der Korngröße und der Korngrößenverteilung im Dispersionsmedium Luft, basierend auf der Auswertung eines Beugungsmusters.
- Geräte: Laser-Streulichtspektrometer Horiba LA-950V
Messbereich 0,010 µm bis 3000 µm
- Reagenzien: keine
- Durchführung: Das Laser-Streulichtspektrometer LA-950V arbeitet auf der Grundlage der statischen Laserlichtstreuung (gemäß DIN/ISO 13320). Für die Trockenmessung steht eine Dispergiereinheit mit einer Trockenmesszelle und Absaugsystem zur Verfügung. Es wird eine gleichmäßige Schicht des zu messenden Pulvers in die Dosierrinne gegeben (ca. 3 mm hoch) und die entsprechende produktspezifisch Messmethode (siehe Anhang) gestartet. Die Dosierung erfolgt automatisch und regelt damit die Messkonzentration in dem optimalen Messbereich.
- Auswertung: Die Auswertung der Korngrößen und Korngrößenverteilung erfolgt durch die vorhandene Software automatisch.
- Die Messdaten der Korngrößen (Korngrößendurchmesser) werden tabellarisch dargestellt und entsprechend abgelesen.

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Das Ergebnis wird mit drei Dezimalstellen als Endresultat angegeben.

Die Korngrößenverteilung erfolgt durch eine graphische Darstellung.

Sicherheit: Es gelten die im Labor allgemeinen Sicherheitsrichtlinien. PSA ist gemäß AL-AA-09-005 zu tragen.

Entsorgung: Die Entsorgung der anfallenden Abfälle wird gemäß AL-AA-05-009 durchgeführt.

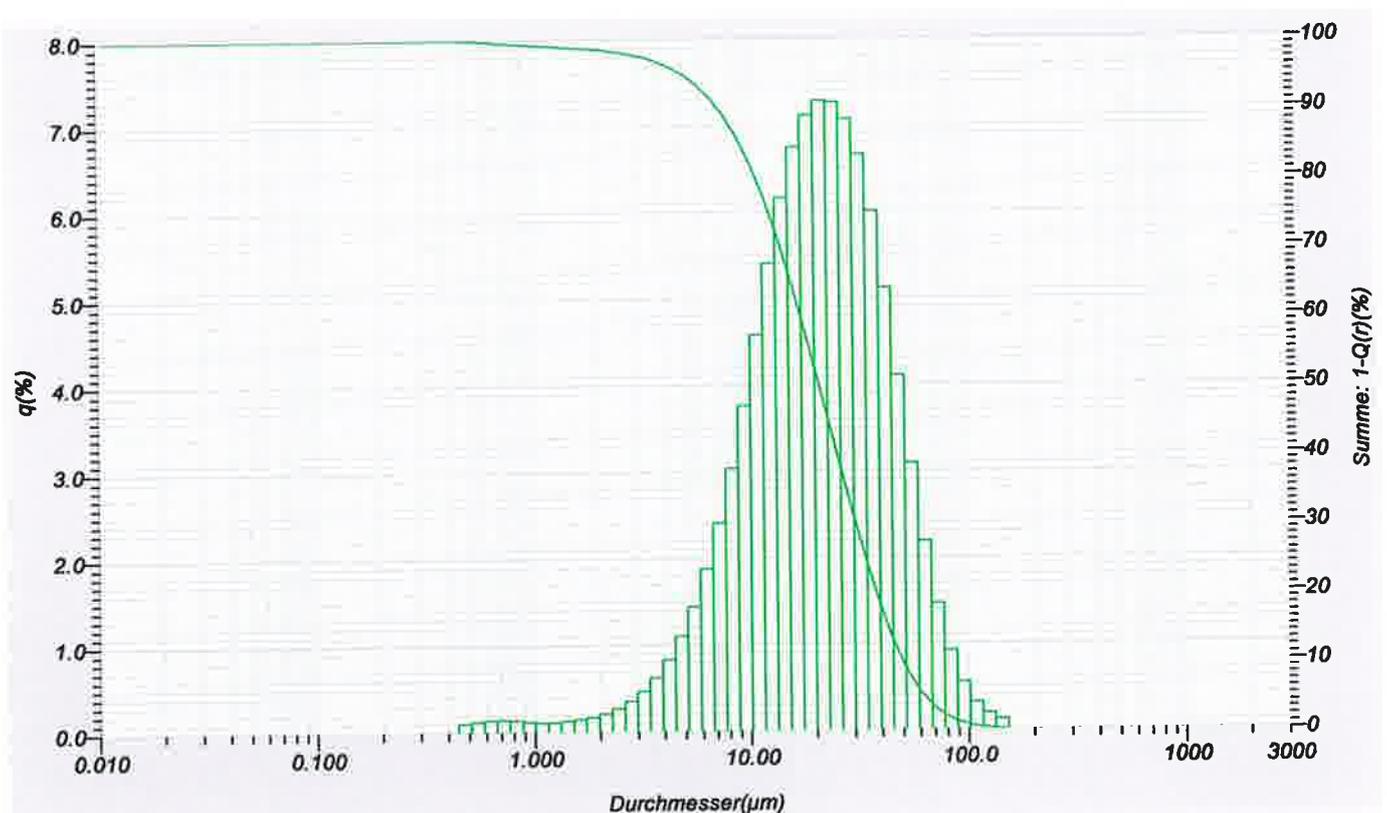
Anhang: Messmethoden
Einarbeitungsliste

Änderungshistorie

Version / gültig ab	Beschreibung der Änderung	Begründung
Revision 0/ 10/2010	Neuerstellung	---

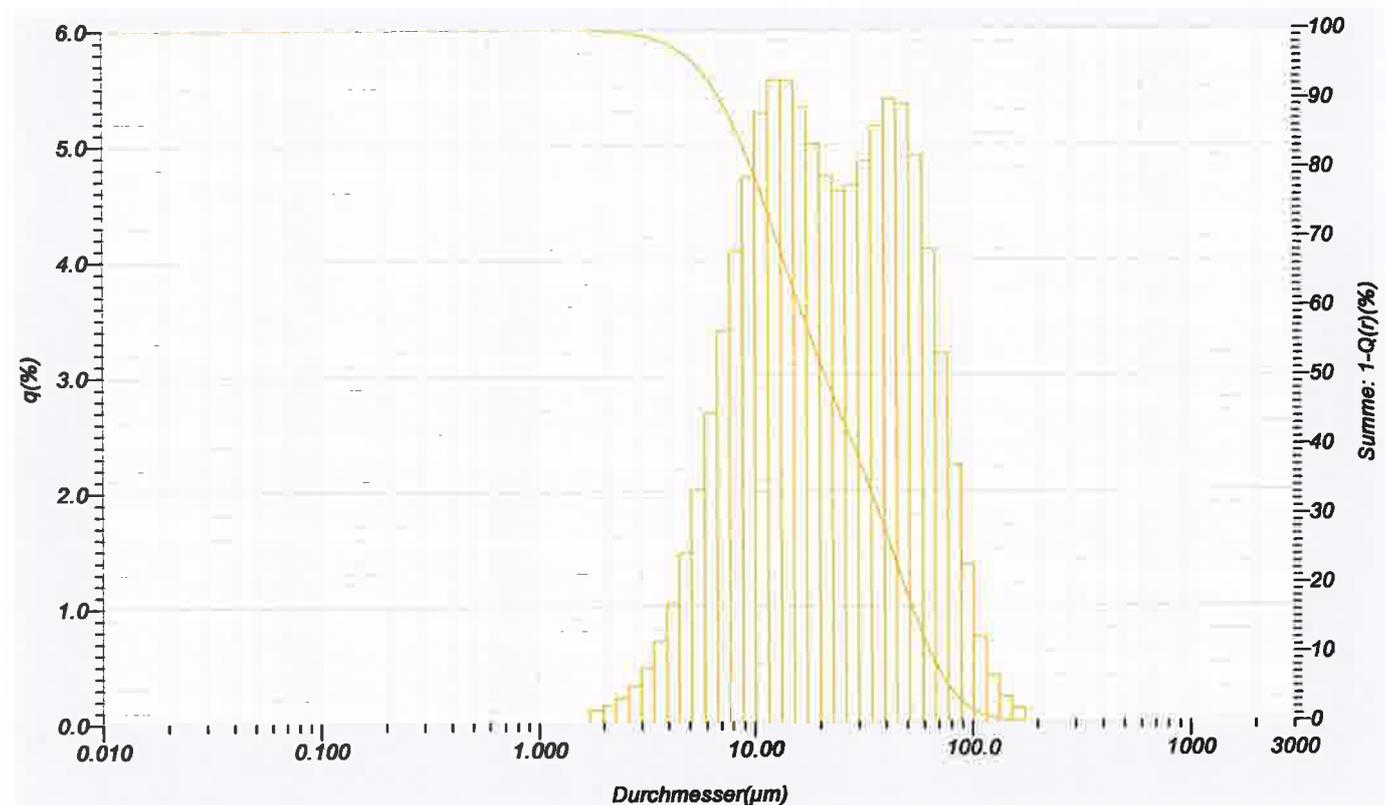
Laser Scattering Particle Size Distribution Analyzer LA-950

ID#	: 201102091042741	Datenbezeichnung	: Mg-Pyro phosp
Material	:	Median	: 20.76208(μm)
Probenname	:	D10	: 49.46339(μm)
Datenbezeichnung	: Mg-Pyro phosphate BB7 3.6.10	D90	: 7.29022(μm)
Datenaufnahme Probe (LD)	: 19000	Durchschnittswert	: 25.47087(μm)
Transmission (R)	: 96.6(%)	Modalwert	: 21.3301(μm)
Druckluft	: 0.3 MPa	Spanne	: AUS
Rinne	: Auto	x(Q)-Wert	: (2)10.00 (%) - 49.4634(μm)
Anzahl Iterationen	: 15		: (5)50.00 (%) - 20.7621(μm)
Art der Verteilung	: Volumen		: (9)90.00 (%) - 7.2902(μm)
Brechungsindex (R)	: 1.6-0.00[1.6-0.00(1.600 - 0.000	Q(x)-Wert	: (2)250.0 (μm) - 0.000(%)
Algorithmus	: Standard		: (3)200.0 (μm) - 0.000(%)
			: (4)150.0 (μm) - 0.014(%)
			: (5)100.0 (μm) - 0.676(%)
			: (6)75.00 (μm) - 2.408(%)
			: (7)45.00 (μm) - 12.856(%)
			: (8)20.00 (μm) - 52.004(%)
			: (9)10.00 (μm) - 82.515(%)
			: (10)5.000 (μm) - 94.948(%)
		R-Parameter	: 6.4052E-2



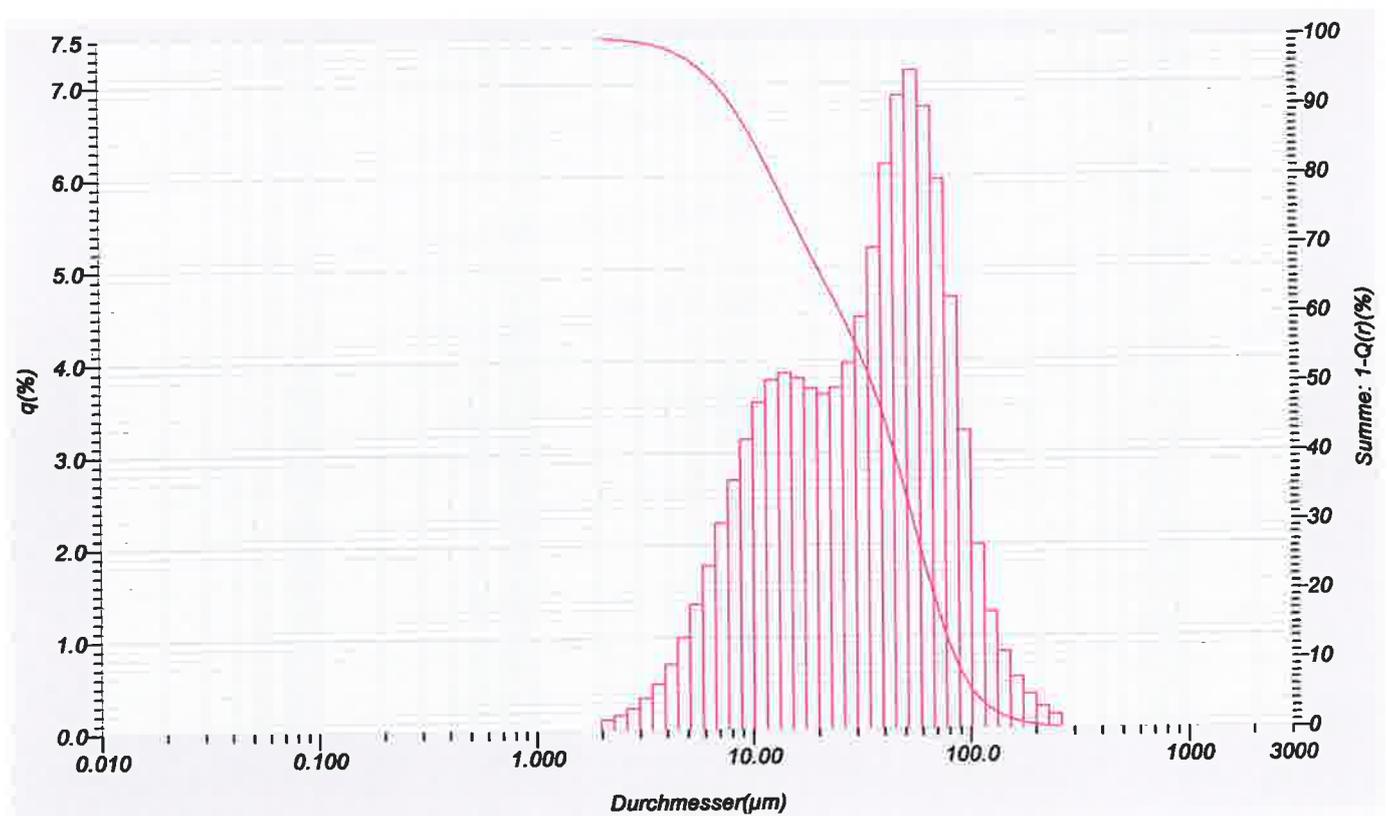
Laser Scattering Particle Size Distribution Analyzer LA-950

ID#	: 201102081329707	Datenbezeichnung	: Mg- pyro phosph
Material	:	Median	: 21.05823(μm)
Probenname	:	D10	: 63.68112(μm)
Datenbezeichnung	: Mg- pyro phosphate ,BB 13 26.8	D90	: 6.95953(μm)
Datenaufnahme Probe (LD)	: 25000	Durchschnittswert	: 29.52869(μm)
Transmission (R)	: 96.4(%)	Modalwert	: 12.4197(μm)
Druckluft	: 0.3 MPa	Spanne	: AUS
Rinne	: Auto	x(Q)-Wert	: (2)10.00 (%) - 63.6811(μm)
Anzahl Iterationen	: 15		: (5)50.00 (%) - 21.0582(μm)
Art der Verteilung	: Volumen		: (9)90.00 (%) - 6.9595(μm)
Brechungsindex (R)	: 1.6-0.00[1.6-0.00(1.600 - 0.000	Q(x)-Wert	: (2)250.0 (μm) - 0.000(%)
Algorithmus	: Standard		: (3)200.0 (μm) - 0.000(%)
			: (4)150.0 (μm) - 0.140(%)
			: (5)100.0 (μm) - 1.605(%)
			: (6)75.00 (μm) - 5.765(%)
			: (7)45.00 (μm) - 22.520(%)
			: (8)20.00 (μm) - 51.798(%)
			: (9)10.00 (μm) - 79.027(%)
			: (10)5.000 (μm) - 95.831(%)
		R-Parameter	: 7.9218E-2



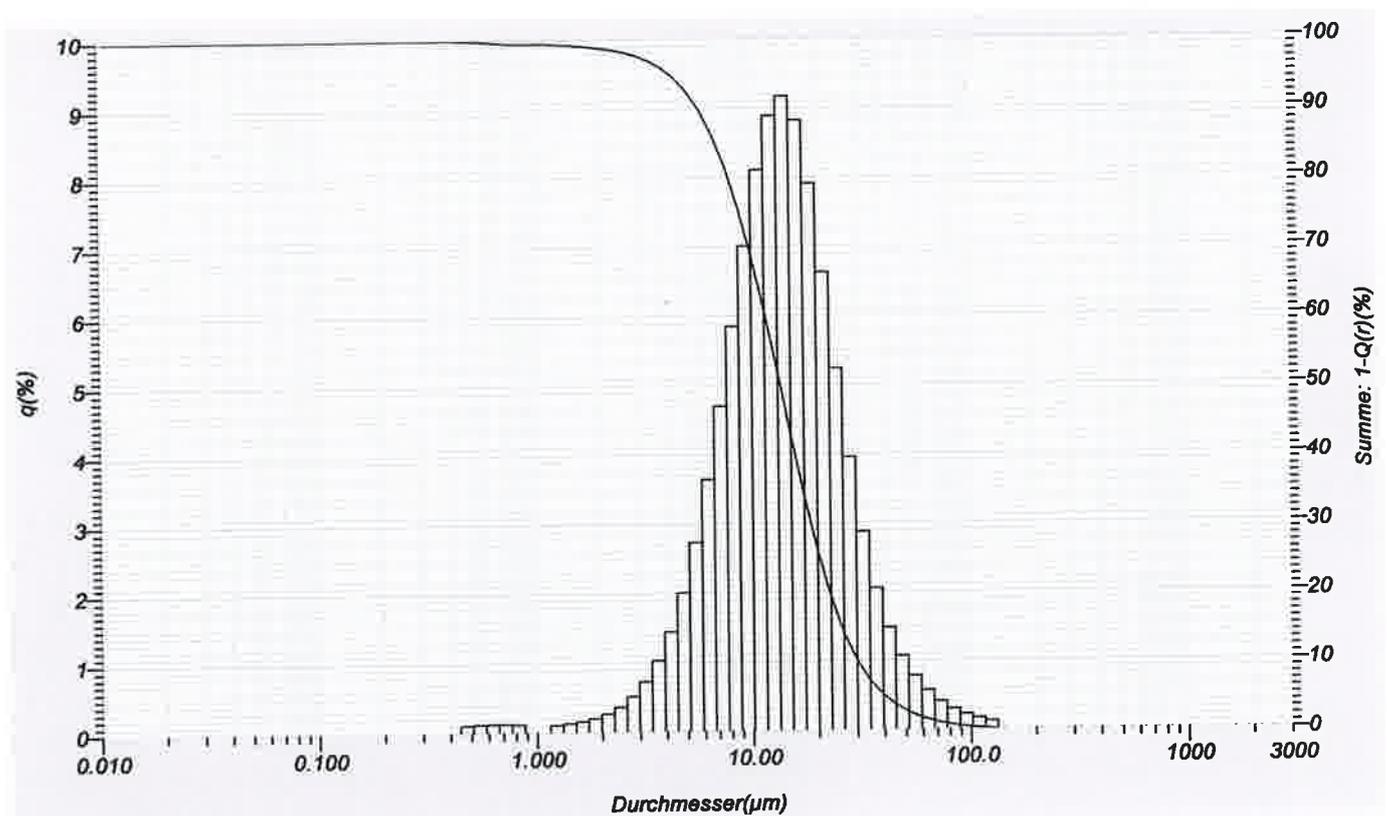
Laser Scattering Particle Size Distribution Analyzer LA-950

ID#	: 201102091046743	Datenbezeichnung	: Mg-Pyro phosp
Material	:	Median	: 35.39755(μm)
Probenname	:	D10	: 84.99594(μm)
Datenbezeichnung	: Mg-Pyro phosphate BB17 31.7.C	D90	: 8.32141(μm)
Datenaufnahme Probe (LD)	: 25000	Durchschnittswert	: 42.38630(μm)
Transmission (R)	: 96.4(%)	Modalwert	: 55.0206(μm)
Druckluft	: 0.3 MPa	Spanne	: AUS
Rinne	: Auto	x(Q)-Wert	: (2)10.00 (%) - 84.9959(μm)
Anzahl Iterationen	: 15		: (5)50.00 (%) - 35.3976(μm)
Art der Verteilung	: Volumen		: (9)90.00 (%) - 8.3214(μm)
Brechungsindex (R)	: 1.6-0.00[1.6-0.00(1.600 - 0.000	Q(x)-Wert	: (2)250.0 (μm) - 0.050(%)
Algorithmus	: Standard		: (3)200.0 (μm) - 0.368(%)
			: (4)150.0 (μm) - 1.373(%)
			: (5)100.0 (μm) - 5.693(%)
			: (6)75.00 (μm) - 14.597(%)
			: (7)45.00 (μm) - 39.856(%)
			: (8)20.00 (μm) - 66.893(%)
			: (9)10.00 (μm) - 85.931(%)
			: (10)5.000 (μm) - 97.099(%)
		R-Parameter	: 7.0946E-2



Laser Scattering Particle Size Distribution Analyzer LA-950

ID#	: 201102091044742	Datenbezeichnung	: Mg-Pyro phosph
Material	:	Median	: 13.57274(μm)
Probenname	:	D10	: 29.86005(μm)
Datenbezeichnung	: Mg-Pyro phosphate BB8 13.3.1C	D90	: 5.81110(μm)
Datenaufnahme Probe (LD)	: 25000	Durchschnittswert	: 16.70426(μm)
Transmission (R)	: 96.9(%)	Modalwert	: 14.1697(μm)
Druckluft	: 0.3 MPa	Spanne	: AUS
Rinne	: Auto	x(Q)-Wert	: (2)10.00 (%) - 29.8601(μm)
Anzahl Iterationen	: 15		: (5)50.00 (%) - 13.5727(μm)
Art der Verteilung	: Volumen		: (9)90.00 (%) - 5.8111(μm)
Brechungsindex (R)	: 1.6-0.00[1.6-0.00(1.600 - 0.000	Q(x)-Wert	: (2)250.0 (μm) - 0.000(%)
Algorithmus	: Standard		: (3)200.0 (μm) - 0.000(%)
			: (4)150.0 (μm) - 0.000(%)
			: (5)100.0 (μm) - 0.297(%)
			: (6)75.00 (μm) - 0.870(%)
			: (7)45.00 (μm) - 3.562(%)
			: (8)20.00 (μm) - 25.520(%)
			: (9)10.00 (μm) - 69.128(%)
			: (10)5.000 (μm) - 92.893(%)
		R-Parameter	: 7.5229E-2



Pages 000138-1063 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.



PHOSPHORIC ACID AND PHOSPHATE SALTS

Explanation

These compounds have been evaluated for acceptable daily intake by the Joint FAO/WHO Expert Committee on Food Additives in 1961, 1963, 1964, 1965, 1969 and 1970 (see Annex I, Refs. 6, 7, 9, 13, 20 and 23). A toxicological monograph was published in 1974 (see Annex I, Ref. 33).

Since the previous evaluation, additional data have become available and are summarized and discussed in the following monograph. The previously published monograph has been revised, and deals with the following compounds:

- phosphoric acid
- calcium phosphate (mono-, di-, and tri-basic)
- sodium phosphate (mono-, di-, and tri-basic)
- disodium diphosphate
- tetrasodium diphosphate
- pentapotassium triphosphate
- pentasodium triphosphate
- sodium polyphosphate (Graham's salt)
- sodium hexametaphosphate
- sodium potassium polyphosphate (Tammann's salt)
- Kurrol's salt (KPO_3)_n
- sodium tripolyphosphate
- disodium phosphate
- magnesium phosphate (mono-, di-, and tri-basic)
- potassium phosphate (mono-, di-, and tri-basic)
- bone phosphate
- ammonium phosphate, dibasic
- ammonium polyphosphate
- calcium polyphosphate
- calcium pyrophosphate
- potassium polyphosphate
- potassium pyrophosphate

The toxicity of these phosphate compounds is in part due to separate problems arising from the various cations and to the phosphate anions in general. Most of the available toxicity data has been developed with sodium salts. However, it is unlikely that effects of the potassium and ammonium moieties of the salts, at the levels used in foods, would be of concern and the effect of these salts would not be significantly different from sodium salts. In the case of calcium and magnesium salts, these salts provide a source of calcium, magnesium and phosphate ions. Problems relating to calcium, magnesium and phosphate imbalances in the diet are of concern and are considered in this monograph. They are primarily due to excess phosphorus in the

diet, and deficiencies in calcium and magnesium. Thus the present monograph is applicable to all the inorganic phosphates listed. A separate monograph has been prepared for aluminium phosphates.

BIOLOGICAL DATA

BIOCHEMICAL ASPECTS

Several reviews of phosphate metabolism and toxicity are available (Ellinger, 1972; FASEB, 1975; FASEB, 1981; Roe, 1979).

Phosphorus is an essential constituent of the human organism, not

only in the bones and teeth, but also in many enzyme systems. Phosphorus compounds play an important role in carbohydrate, fat and protein metabolism.

(a) Phosphoric acid, phosphates and orthophosphates

Free orthophosphate is the major form in which phosphorus is absorbed from the diet. The amount and rate at which other phosphates are available for absorption depends on their enzymic hydrolysis to orthophosphates. The level of inorganic phosphate in the blood is stabilized by exchange with the mineral deposit in the skeleton through the action of parathyroid hormone. This hormone inhibits tubular reabsorption of phosphates by the kidney and brings about demineralization of bone tissue through the action of osteoclasts. The amount of parathyroid hormone that enters the circulation is probably regulated by the calcium level of the blood. Intestinal absorption depends on requirements and is therefore limited. Excretion takes place mainly in the faeces as calcium phosphate so that the continuous use of excessive amounts of sodium phosphate and phosphoric acid may cause a loss of calcium. As a result of physiological regulating mechanisms, man and animals can tolerate large variations in phosphate intake without the balance being upset.

Some investigators have considered that the formation in the intestinal tract of insoluble salts of phosphate with calcium, iron and other metal ions might result in decreased absorption of such minerals. From studies dealing with this aspect (Lang, 1959; van Esch et al., 1957; Lauersen, 1953; van Genderen, 1961) it is concluded that moderate dose levels of phosphates do not impair absorption as shown by results from carcass analyses or haemoglobin determinations. Doses of 2-4 g of phosphate act as weak saline cathartics.

Phosphate supplementation of the diet of rodents has been shown to lead to reduction in the incidence of dental caries and different phosphates have different powers in reducing the cariogenic potential of the carbohydrates in a diet (van Reen & Ostrom, 1962; Konig et al., 1961; McClure, 1960). Phosphate supplements seem to exert their cariostatic effect on the tooth surface either directly during eating or by excretion in the saliva (Anon., 1968a,b).

Little specific toxicological information on potassium monophosphates is available. There is no reason to consider that the potassium salts, in the amounts that could be used as food additives, behave differently from the sodium salts and are therefore dealt with together.

(b) Disodium phosphate and tetrasodium diphosphate

In the animal body, diphosphate is formed from adenosyl triphosphate (ATP) in many enzymatic reactions. It is either utilized by entering phosphorolytic reactions, or it is hydrolysed by an inorganic diphosphatase to monophosphate (Long, 1961). Ingested diphosphate is readily converted to monophosphate (Fourman, 1959; Mattenheimer, 1958); no diphosphate was found in faeces or urine of rats treated with diets containing up to 5% tetrasodium diphosphate. In these experiments diphosphate was almost completely absorbed by the gut and excreted as monophosphate in the urine.

The pyrophosphates are formed by the loss of 1 molecule of water from 2 molecules of an orthophosphate. The pyrophosphates (e.g. $\text{Ca}_2\text{P}_2\text{O}_7$) are readily absorbed intact but then are completely hydrolysed to orthophosphate (Schreier & Noller, 1955). Achlorhydria may have an effect on the metabolism and toxicity of the condensed phosphates. It has been estimated that the half-life for hydrolysis of pyrophosphate at pH 2 and 39°C (normal gastric conditions) is 400 hours (Mahoney & Hendricks, 1978).

(c) Triphosphates and polyphosphates

Several studies indicate that polyphosphates can be hydrolysed *in vivo* by enzymes with the formation of monophosphates. The localization of different polyphosphates in the nuclei of animal cells has been demonstrated (Grossmann & Lang, 1962). Injected hexametaphosphate is more slowly degraded than tripolyphosphate (Gosselin et al., 1952), and the highly polymerized Tammann's salt (KNa polyphosphate) is even more slowly eliminated from the blood after i.v. injection than is Graham's salt (Gotte, 1953). When administered parenterally a small part of these products may escape in the urine as oligophosphates (Gosselin et al., 1952; Gotte, 1953). The higher polyphosphates are probably not absorbed as such in the intestinal tract. After hydrolysis into smaller units, absorption takes place. The larger the molecule, the less the speed of hydrolysis and absorption, as shown by studies using P32-labelled polyphosphate (Ebel, 1958).

After giving hexametaphosphate to rats and rabbits by stomach tube, no more than trace amounts of labile phosphate were found in the urine (Gosselin et al., 1952). The oral administration of

radiolabelled Tammann's salt did not give rise to radioactivity in the blood (Gotte, 1953). With Graham's salt and Kurrol's salt,* 10-30% was absorbed as monophosphate and small amounts of oligophosphates were found in the urine (Lang et al., 1955; Lang, 1958). In experiments in rats with labelled tripolyphosphates and Graham's salts these polymers were not absorbed as such, but were taken up after hydrolysis into monophosphate and diphosphate. In a period of 18 hours only 40% of the dose of Graham's salt was hydrolysed and absorbed. The bacterial flora of the intestinal tract may contribute to the hydrolysis of the polyphosphates (Schreier & Noller, 1955). In other experiments, radiolabelled Kurrol's salt was given orally to rats. About half the radioactivity was recovered from the faeces, mainly as polymeric phosphate, and only a small percentage of the dose was found in the urine, in this case in the form of monophosphate.

Ring as well as linear polyphosphates including sodium trimeta, sodium tetrameta, sodium tripoly and sodium hexametaphosphate (Graham's salt) were shown to be hydrolysed in *in vitro* rat and porcine small intestine, while incubation in simulated intestinal fluid gave only slight hydrolysis. Trimeta, tetrameta, tripoly and hexameta were reduced by 12-36%, 5%, 76-80% and 10%, respectively in *in vitro* rat intestine in 1 hour, by 9-11%, 4-5%, 30% and 10-19%, respectively in *in vitro* porcine intestine in 1 hour and by 0-4%, 0-1%, 17-19% and 2-3%, respectively in 12 hours in simulated intestinal fluid. The results indicate that simulated digestive juice contains little polyphosphatase activity. This enzyme is present in the intestinal lumen (Ivey & Shaver, 1975).

It is noted that, for practical reasons, in the studies cited high dosages were given to the animals. The efficiency of hydrolysis and absorption may be greater at low-dose levels, such as were used in the short-term and long-term feeding experiments. In some of these (van Esch et al., 1957) the "monophosphate action", as demonstrated by the production of nephrocalcinosis, was not much smaller than when the same dose level was administered by the addition of monophosphate to the food. In another study, this applied only to tripolyphosphate, while Graham's salt had definitely less effect on the kidney (Hahn et al., 1958).

* Kurrol's salt is a polymer of high molecular weight obtained by fusion of monopotassium monophosphates. The formula is $(KPO_3)_n \cdot H_2O$, where $n = 400$ to 5000 .

The possibility of the intermediate formation of small amounts of trimetaphosphate in the hydrolysis of polyphosphates has been

considered (Mattenheimer, 1958). At present, the only known method of production of sodium polyphosphate is by the fusion process. In this process metaphosphates are also formed in amounts up to 8% and their presence is technically unavoidable. It is of interest to note that these metaphosphates (sodium trimetaphosphate and sodium tetrametaphosphate) have been tested in short-term experiments in rats and dogs in conjunction with polyphosphates (Hodge, 1956). The metaphosphates are also hydrolysed to monophosphates. No specific action of these metaphosphates different from that of the other phosphates has been observed, and it is concluded that the presence of these impurities does not present a hazard. It is also noted that the preparation of sodium polyphosphates used in the toxicological studies mentioned always contained metaphosphates in amounts up to 8%.

It has been considered by many authors that the ingestion of polyphosphate in the food may result in a loss of minerals (Ca, Fe, Cu, Mg) which are bound to the polyphosphate and are lost in the faeces with unhydrolysed polyphosphate. For this reason, in most of the toxicological studies cited, particular attention has been paid to the mineral composition of the carcass and to the possible development of anaemia.

The experimental results available indicate that such an action, if it occurs at all, is not significant. Anaemia is not a characteristic feature of treatment with high-dose levels of polyphosphate and hexametaphosphate had no effect on iron utilization by rats (Chapman & Campbell, 1957).

The use of polyphosphates for the prevention of scale formation in lead pipe water systems may lead to excessive lead levels in drinking-water (Buydens, 1957).

(d) Calcium and magnesium phosphates

Calcium phosphates are insoluble in water and constitute the following series: calcium phosphate (monobasic) which is used as acidulant and mineral supplement; calcium phosphate (dibasic) is used as dietary supplement in doses of 1 g orally; calcium phosphate (tribasic) is used as gastric antacid in doses of 1 g orally; and bone phosphate. Metabolically they behave as sources of calcium and phosphate ions. Magnesium phosphates are mostly insoluble in water and form the following series: magnesium phosphate (monobasic); magnesium phosphate (dibasic) which is used as laxative; magnesium phosphate (tribasic) is used as antacid in doses of 1 g orally. Metabolically they behave as sources of magnesium and phosphate ions. The phosphate moiety of these compounds need not be considered separately from other monophosphates from the toxicological point of view.

TOXICOLOGICAL STUDIES

Special studies on mutagenicity

Monocalcium phosphate, monopotassium phosphate and monosodium phosphate were not mutagenic in an in vitro assay using Saccharomyces cerevisiae strain D4 and Salmonella typhimurium strains TA-1535, TA-1537 and TA-1538 with and without the addition of mammalian metabolic activation preparation (Litton Bionetics, Inc., 1975a,b,c).

Sodium acid pyrophosphate was not mutagenic in a number of tests including: (1) host-mediated assay in mice using either Salmonella typhimurium TA-1530 or mitotic recombination frequency in Saccharomyces cerevisiae D3; (2) in an in vitro assay using S. typhimurium strains TA-1535, TA-1536 or TA-1537 and TA-1538, with and without the addition of mammalian metabolic activation preparations; (3) dominant lethal test in rats; and (4) translocation test in rats (Newell et al., 1974).

Tetrasodium pyrophosphate was not mutagenic in an *in vitro* assay using *S. cerevisiae* strain D4, and *S. typhimurium* strains TA-1535, TA-1537 and TA-1538, with and without the addition of mammalian metabolic activation preparations (Food and Drug Research Lab., Inc., 1975d).

Sodium tripolyphosphate was not mutagenic in a number of tests including: (1) host-mediated assay in mice using *S. typhimurium* strains TA-1530 and G-46 or mitotic recombination frequency in *S. cerevisiae* D3; (2) in an *in vitro* assay using *S. typhimurium* strains TA-1530 and G-46, and *S. cerevisiae* D3, with and without activation; (3) a cytogenetic study *in vivo* of rat bone marrow cells and *in vitro* of human lung cells in tissue culture; and (4) a dominant lethal study in rats (Litton Bionetics, Inc., 1974).

Sodium hexametaphosphate was not mutagenic in an *in vitro* assay using *S. typhimurium* strains TA-1535, TA-1536 and TA-11537, with and without the addition of mammalian metabolic activation preparation (Litton Bionetics, 1975c).

Special studies on teratogenicity and reproduction

Verrett et al. (1980) reported that monocalcium phosphate, tricalcium phosphate, and monopotassium phosphate were not teratogenic in the developing chicken embryo. Monosodium phosphate, tetrasodium pyrophosphate, and sodium hexametaphosphate were found to produce teratogenic effects when injected during the period of rapid organogenesis in chicken embryos. Several different types of anomalies were observed, mostly structural.

Teratology studies using rats, mice, rabbits or hamsters were performed on the following phosphates: monocalcium phosphate, sodium acid pyrophosphate, sodium tripolyphosphate, sodium hexametaphosphate and tetrasodium phosphate. The dose levels reported were the maximum levels tested.

For studies in mice, groups each of approximately 24 pregnant albino CD-1 mice were dosed by oral intubation with the test substance from day 6 through day 16 of gestation. Body weights were recorded on days 0, 6, 11, 15 and 17 of gestation. On day 17, all dams were subjected to caesarean section and the number of implantation sites, resorption sites and live and dead fetuses recorded. The body weight of the live pups was also taken. The urinogenital tract level of each dam was examined for abdominal abnormality. All fetuses were examined for the presence of external congenital abnormalities. One-third of the fetuses were examined for visceral abnormalities and the remaining two-thirds for skeletal abnormalities.

For studies in rats, groups each of approximately 24 pregnant female albino rats (Wistar-derived stock) were dosed daily by oral intubation from day 6 of gestation through day 15. Body weights were recorded on days 0, 6, 11, 15 and 20. On day 20, all dams were subjected to caesarean section, and observations for dams and fetuses similar to those described in the mouse study were carried out.

For studies in hamsters, groups each of approximately 22-25 pregnant female golden hamsters were dosed daily by oral intubation with the test compound from day 6 of gestation through day 10. Body weights were recorded on days 0, 6, 8, 10 and 14. On day 14, all animals were subjected to caesarean section, and observations for dams and fetuses, similar to those observed in the mouse study, were carried out.

For studies in rabbits, groups each of approximately 20-22 pregnant Dutch-belted rabbits, were dosed by oral intubation with the test compound from day 6 through day 18. Body weights were recorded on days 0, 6, 12, 18 and 29 of gestation. On day 29, all does were subjected to caesarean section, and observations, similar to those

described in the mouse study, were carried out.

(a) Phosphoric acid, phosphates and orthophosphate

Monosodium phosphate showed no maternal toxicity or teratogenic effects at dose levels up to 370 mg/kg bw in mice and 410 mg/kg bw in rats (Food and Drug Research Lab., Inc., 1975a).

Monopotassium phosphate showed no maternal toxicity or teratogenic effects at dose levels up to 320 mg/kg bw in mice and 282 mg/kg bw in rats (Food and Drug Research Lab., Inc., 1975b).

Sodium acid pyrophosphate showed no maternal toxicity or teratogenic effects at dose levels up to 335 mg/kg bw in mice, 169 mg/kg bw in rats, 166 mg/kg bw in hamsters and 128 mg/kg bw in rabbits (Food and Drug Research Lab., Inc., 1973a).

(b) Tetrasodium diphosphate

Tetrasodium diphosphate showed no maternal toxicity or teratogenic effects at dose levels up to 130 mg/kg bw in mice and 138 mg/kg bw in rats (Food and Drug Research Lab., Inc., 1975c).

(c) Triphosphates and polyphosphates

Sodium hexametaphosphate showed no maternal toxicity or teratogenic effects at dose levels up to 370 mg/kg bw in mice and 240 mg/kg bw in rats (Food and Drug Research Lab., Inc., 1975d).

Sodium tripolyphosphates showed no maternal toxicity or teratogenic effects at dose levels up to 238 mg/kg bw in mice, 170 mg/kg bw in rats, 250 mg/kg bw in rabbits and 141 mg/kg bw in hamsters (Food and Drug Research Lab., Inc., 1973b).

(d) Calcium phosphate

Monocalcium phosphate showed no maternal toxicity or teratogenic effects at dose levels up to 465 mg/kg bw in mice and 410 mg/kg bw in rats (Food and Drug Research Lab., Inc., 1973c).

Acute toxicity

(a) Phosphoric acid, phosphates and orthophosphates

Compound	Animal	Route	Approx. LD ₅₀ (mg/kg bw)	Reference
NaH ₂ PO ₄	Guinea-pig	Oral	2 000 MLD	Eichler, 1950
Monosodium phosphate	Mouse	Oral	3 700	Food and Drug Research Lab., Inc., 1975a
	Rat	Oral	4 100	
Monopotassium phosphate	Mouse	Oral	3 200	Food and Drug Research Lab., Inc., 1975b
	Rat	Oral	2 820	
Sodium acid pyrophosphate	Mouse	Oral	3 350	Food and Drug Research Lab., Inc., 1975a
	Rat	Oral	1 690	
	Hamster	Oral	1 660	

(b) Tetrasodium diphosphate

Compound	Animal	Route	Approx. LD ₅₀	Reference
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(mg/kg bw)				
Na ₄ P ₂ O ₇	Mouse	Oral	1 300	Food and Drug Research Lab., Inc., 1975c
	Rat	Oral	1 380	

(c) Triphosphates and polyphosphates

Compound	Animal	Route	Approx. LD ₅₀ (mg/kg bw)	Reference
Sodium triphosphate	Mouse	Oral	2 380	Food and Drug Research Lab., Inc., 1973b
	Rat	Oral	1 700	
	Rabbit	Oral	2 500	
1/3 Kurrol's salt and 2/3 tetra- and disodium diphosphate (water soluble, neutral)	Rat	Oral	4 000	van Esch et al., 1957
	Rat	i.v.	18	van Esch et al., 1957
Sodium hexametaphosphate	Mouse	Oral	3 700	Food and Drug Research Lab., Inc., 1975d
	Rat	Oral	2 400	

(d) Calcium phosphate

Compound	Animal	Route	Approx. LD ₅₀ (mg/kg bw)	Reference
Monocalcium phosphate	Mouse	Oral	4 600	Food and Drug Research Lab., Inc., 1973c
	Rat	Oral	2 170	

Short-term studies

(a) Phosphoric acid, phosphates and orthophosphates

Rat

There are many reports of short-term studies to determine the effects of the addition of monophosphates to the diet of rats (Maynard et al., 1957; Selye & Bois, 1956; MacKay & Oliver, 1935; Behrens & Seelkopf, 1932; McFarlane, 1941; van Esch et al., 1957; Sanderson, 1959). Pathological effects in the parathyroids, kidneys and bones have been observed in mature male rats fed a diet containing an excessively high level (8%) of sodium orthophosphate for 7 months or until the animal succumbed (Saxton & Ellis, 1941). Histological and histochemical changes in the kidneys have been found in rats fed for 24-72 hours on a diet containing an excess of inorganic phosphate (10% disodium acid phosphate)(Craig, 1957).

Three groups of 12 rats each were fed diets containing added dibasic potassium phosphate so that the calcium and phosphorus concentrations in the experimental diets were as follows:

Diet	Calcium %	Phosphorus %
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Control	0.56	0.42
"normal orthophosphate"	0.47	0.43
"high orthophosphate"	0.50	1.30

The experiment was conducted in 3 stages, with experimental observations made when animals had consumed the test diets for 50, 60 and 150 days. No adverse physiological effects were observed clinically at autopsy or on histological examination. All the data obtained from this study indicated that there was probably adequate absorption and utilization of calcium, phosphorus and iron with both high and normal levels of monophosphate (Dymaza et al., 1959).

Reports of short-term studies do not provide for a differentiation between the action of the mono-, di- and trisodium or potassium salts; several authors have used "neutral mixtures", e.g. of mono- and disodium monophosphates. There is no reason to expect a specific action on the part of 1 of these 3 monophosphates, the relevant factor being the phosphate content and the acidity of the food mixture as a whole. On high-dose levels, hypertrophy of the parathyroid glands has been observed. A more important and more sensitive criterion for the deleterious action of phosphate overdosage is the appearance of calcification in soft tissues, especially in the

kidney, stomach and aorta. Kidney calcification may be observed in a few weeks or months, depending on the dose level. The pathology of calcification and necrosis of the tubular epithelium in the kidneys (nephrocalcinosis) has been studied in detail (MacKay & Oliver, 1935; McFarlane, 1941; Sanderson, 1959; Fourman, 1959).

It is difficult to indicate a border-line between those levels that do not produce nephrocalcinosis and those that produce early signs of such changes, because: (1) even on diets to which no phosphate has been added, rats, in apparently healthy condition, may have a few isolated areas of renal calcification; (2) the composition of the diet (amount of calcium, acid-base balance, vitamin D) has an important influence on the appearance of renal calcification.

There are numerous reports of experimental phosphate-containing diets that do not produce kidney damage by excessive calcification, e.g. the Sherman diet (0.47-0.51%) (Lang, 1959; Hahn & Seifen, 1959; van Esch et al., 1957), the diet used by MacKay & Oliver (1935) (0.62% P) and the commercial "Purina A" diet (0.90% P) (Lang, 1959).

Early calcification has been observed in rats on a Sherman diet to which 1% of a 2:3 mixture of NaH_2PO_4 and Na_2HPO_4 was added, bringing the P content to 0.71% (van Esch et al., 1957). Similar effects were observed with the addition of a phosphate mixture resulting in a P content of 0.89% (Hahn & Seifen, 1959), and with levels of phosphate in the diet corresponding to a P content varying from 1.25% to 2.85% (Lang, 1959; MacKay & Oliver, 1935; Eichler, 1950; McFarlane, 1941; van Esch et al., 1957; Haldi et al., 1939).

In another study (Dymaza et al., 1959), however, a diet to which K_2HPO_4 had been added and containing 1.3% P and 0.5% Ca did not produce nephrocalcinosis in a group of mice within a period of 150 days, although the weight of the kidneys was increased. Also food and protein efficiency were diminished as compared with animals on the control diet. These effects may have resulted from the large amount of salts added to the diet in these experiments.

Diets containing various levels of calcium, phosphorus and magnesium were reported to produce uroliths in female Wistar rats. The incidence and severity of calcium phosphate uroliths were reduced by increasing the magnesium concentration in the diet from 0.2% to 0.8% and by increasing the calcium-to-phosphorus ratio to greater than 1 (Chow et al., 1980).

Diets containing 0.8% calcium and 0.9% phosphorus caused calcium phosphate deposits in the soft tissues of guinea-pigs (Hogan et al., 1950). When the phosphorus content of the diet was reduced to 0.5%, the number of animals with deposits was reduced from 90% to 10%. Further work (House & Hogan, 1955) demonstrated that with sufficient magnesium and potassium in the diet the calcium phosphate deposition

could be significantly reduced. It has been pointed out that these 2 studies may explain the wide variations in the levels of phosphate reported to cause toxicological effects (Ellinger, 1972). Thus, "optimum ratios of calcium to phosphorus, or of magnesium and potassium to phosphorus most likely explain why the diets of some studies required higher levels of phosphates in order to demonstrate adverse physiological effects".

Sheep

Wether sheep (5 per treatment) were fed on a basal diet to which urea had been added as a nitrogen source. Comparisons were made between this diet and diets which in addition contained either 11 g of dicalcium phosphate or 6.25 g of ammonium polyphosphate per day. Addition of either form of supplementary P caused increased appetite, daily weight gain, and apparent N retention. These utilization experiments were conducted over 1-week periods and it was concluded that ammonium polyphosphate was a satisfactory form of dietary P for ruminants (Fishwick, 1974).

(b) Disodium phosphate and tetrasodium diphosphate

Rat

In a series of successive experiments (Hahn & Seifen, 1959; Hahn et al., 1958), $\text{Na}_4\text{P}_2\text{O}_7$ was added in concentrations of 1.8%, 3% and 5% to a modified Sherman diet and fed to groups of 34-36 young rats for 6 months. The studies also included control groups and groups receiving the same levels of sodium monophosphate. With 3% and 5% diphosphate diets growth was significantly decreased and at both these concentrations nephrocalcinosis appeared as the main toxic effect. The degree of damage to the kidneys was about the same as that observed in the corresponding monophosphate groups.

With the 1.8% diphosphate and monophosphate diets, normal growth occurred, but a slight yet statistically significant increase in kidney weight was noted. Microscopic examination revealed kidney calcification in some of the animals, both in the diphosphate and monophosphate groups. This was more extensive than the calcification occasionally found in the control animals. In an additional experiment, 1.1% of diphosphate and of monophosphate were used (Hahn, 1961). There was a slight growth retardation in the first part of the experiment. After 39 weeks a slight degree of kidney calcification was noted and this was the same for both phosphates (Hahn, 1961).

In a recent series of experiments (Datta et al., 1962), Sherman diets containing 1%, 2.5% and 5% $\text{Na}_4\text{P}_2\text{O}_7$ were fed for 16 weeks to groups of 20 male and female rats weighing between 90 and 115 g; a similar group received a diet containing 5% monophosphate. In the

sodium phosphate groups, growth was normal up to the 2.5% level; kidney weight was increased at the 2.5% level (females) and above; kidney function was (concentration test) decreased at the 2.5% level (males) and above. Kidney damage (calcification, degeneration and necrosis) was observed in a greater percentage of rats in the 1% group than in the controls. At the higher concentration of sodium diphosphate more severe kidney damage occurred and, in addition, some of the animals had hypertrophy and haemorrhages of the stomach. The latter abnormality was not found in the 5% monophosphate group.

(c) Triphosphates and polyphosphates

Rat

Groups of 5 male rats were fed for a period of 1 month on diets containing 0.2%, 2% and 10% sodium hexametaphosphate or 0.2%, 2% and 10% sodium tripolyphosphate. Control groups were given the standard diet, or diets with the addition of 10% sodium chloride or 5% disodium phosphate (Hodge, 1956).

With 10% of either of the polyphosphate preparations and also with 10% sodium chloride in the diet, growth retardation occurred, but none of the rats died. Increased kidney weights and tubular necrosis were, however, observed. With 2% of polyphosphate in the diet, growth was normal, but in the kidneys inflammatory changes were found which were different from the tubular necrosis observed in the 10% groups. With 0.2% of polyphosphate in the diet, normal kidneys were seen. In another series of experiments (Hahn & Seifen, 1959; Hahn et al., 1958; Hahn et al., 1956), 3% and 5% of sodium tripolyphosphate (pH 9.5 in 1% solution) and 1.8%, 3% and 5% of Graham's salt (pH 5) were added to a modified Sherman diet, which was fed during 24 weeks to groups of 36 male and 36 female rats. Growth retardation was exhibited by the rats in the 5% polyphosphate groups. With 3% of either preparation, a temporary growth inhibition was observed, and with 1.8% of Graham's salt (male animals) growth was normal. Nephrocalcinosis was observed in the 3% and 5% groups. It was noted that the degree of damage with Graham's salt was less than that in control groups treated with the same concentrations of orthophosphate; with tripolyphosphate, however, kidney damage was practically identical with that exhibited by the animals in the orthophosphate group. In the animals on a diet containing 1.8% Graham's salt, calcification in the kidneys was slight or absent and the kidney weights were normal (Hahn & Seifen, 1959).

In a further group of experiments (van Esch et al., 1957; van Genderen, 1958), Kurrol's salt was used in a commercial preparation consisting of 1/3 Kurrol's salt and 2/3 of a mixture of disodium and tetrasodium diphosphate ($\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ and $\text{Na}_4\text{P}_2\text{O}_7$). Kurrol's salt is practically insoluble in water, but the mixture with diphosphate can be dissolved and a 1% solution had a pH of 7.6. Groups of 10 male and 10 female rats were fed for a period of 12 weeks on a

Sherman diet to which 0.5%, 1%, 2.5% and 5% of the preparation had been added. Normal growth was observed in the groups treated with the 0.5%, 1% and 2.5% concentrations of the polyphosphate mixture, but in those receiving the 5% concentrations, growth retardation was exhibited. Kidney weights were normal in the 0.5% group, slightly increased (males significantly) in the 1% group and further increased in the 2.5% and 5% groups. The histopathological examination revealed that in the kidneys of the animals of the 5% group, definite nephrocalcinosis had occurred, with extensive damage to the tubular tissue. Calcification was also observed in other tissues. In the 2.5% group, a less extensive nephrocalcification with lymphocyte infiltrations were found. In the 0.5% group, kidney structure was normal. The results obtained with this polyphosphate preparation were practically identical, qualitatively and quantitatively, with the results of a similar experiment made with a neutral mixture of NaH_2PO_4 and Na_2HPO_4 carried out at a later date in the same laboratory (Hahn et al., 1958; Gotte, 1953).

In other experiments, groups of 12 male rats were treated with diets to which 0.9% and 3.5% sodium hexametaphosphate had been added (corresponding to 0.46% and 1.20% P). Other groups received the control diet alone (0.4% P and 0.5% Ca), or with addition of potassium monophosphate. To the experimental diets different amounts of salts were added to replace cornstarch in order to equalize the levels of major minerals; this resulted in a rather high salt concentration. The duration of treatment was up to 150 days. With 3.5% added hexametaphosphate growth and food and protein efficiency were poorest. The kidneys of the animals fed the high level of hexametaphosphate

were significantly heavier than those of the control rats. This was perhaps a manifestation of the high salt load on the kidneys. No histopathological abnormalities were observed in kidney sections from animals taken from any of the groups (Dymsza et al., 1959).

Dog

Sodium tripolyphosphate ($\text{Na}_5\text{P}_3\text{O}_{10}$) and sodium hexametaphosphate were fed to 1 dog each in a dose of 0.1 g/kg/day for 1 month; 2 other dogs received daily doses which increased from 1.0 g/kg at the beginning to 4.0 g/kg at the end of a 5-month period.

The dog treated with the starting dose of 10 g/kg/day of hexametaphosphate began to lose weight when the daily dose reached 2.5 g/kg, while the one receiving gradually increasing doses of tripolyphosphate lost weight only when its diet contained 4.0 g/kg/day. In other respects (urinalysis, haematology, organ weights) the animals were normal, with the exception of an enlarged heart, due to hypertrophy of the left ventricle, in the dog receiving gradually increasing doses of sodium tripolyphosphate. In addition, tubular damage to the kidneys was observed in both dogs on the higher dose regime. In the tissues of the dogs fed 0.1 g/kg/day no changes were found that could be attributed to the treatment (Hodge, 1956).

Other species

Ammonium polyphosphate, when substituted for 50% or 100% of the phosphorus supplied by defluorinated rock phosphate in corn-soybean meal diets for growing-finishing pigs, was found not to influence daily feed intake, rate of gain, or feed:gain ratio over a 13-week period when compared with controls (Clawson & Armstrong, 1981). Similar results were observed by Kornegay (1972) in pigs, by Jensen & Edwards (1980) in chickens, and by Fishwick (1974) in wether sheep.

(d) Calcium and magnesium phosphates

Groups of weanling Sprague-Dawley rats were fed 0.06% or 0.10% magnesium during phosphate depletion for 14 days. It was found that: (1) the hypomagnesaemia of phosphate depletion depends on the intake of magnesium; (2) the hypercalcaemia and hypercalciuria of phosphate depletion are not caused by changes in magnesium homeostasis; (3) low dietary magnesium during phosphate depletion may cause a defect in soft tissue utilization of P in the growing rat. Animals at the higher magnesium level had a significantly lower soft tissue content of P compared to those at the lower level (Brautbar et al., 1979).

Groups of 3-week-old male Sprague-Dawley rats were maintained on diets containing either 0.03% or 0.44% phosphorus for periods up to 8 weeks. Mg balance became negative during the first day of phosphate depletion. Mg absorption increased by the third week but Mg balance remained negative throughout the 8 weeks. Mg levels in muscle, kidney, and liver tissues were not affected but Mg was lost from bone. Bone calcium content was not affected (Kreusser et al., 1978).

Long-term studies

(a) Phosphoric acid, phosphates and orthophosphates

Rat

Ellinger (1972) cited work done by Bonting in 1952 where over 700 rats were fed diets containing up to 0.75% phosphoric acid. Effects on reproduction were looked for through 3 generations; no adverse effects were observed. The study was reported to include examination of the blood, tissues, mineral balance, nitrogen retention, and the acidic conditions of the digestive tract.

Three successive generations of rats were fed diets containing

0.4% and 0.75% of phosphoric acid for 90 weeks. No harmful effects on growth or reproduction could be observed. No significant differences were noted in the blood picture in comparison with control rats and there was no other pathological finding which could be attributed to

the diets. There was no acidosis or any changes in the calcium metabolism. The dental attrition was somewhat more marked than that in the control rats (Lang, 1959). No other long-term studies on monophosphates have been found in the literature.

(b) Disodium phosphate and tetrasodium diphosphate

Rat

No specific studies with diphosphates have been made, but in 1 series of experiments a mixed preparation was used which consisted of 2/3 $\text{Na}_2\text{H}_2\text{P}_2\text{O}_7$ and 1/3 Kurrol's salt. Concentrations of 0.5%, 1% and 5% were added to a Sherman diet and given to groups of 10 male and 10 female rats. From these animals a second and third generation were produced, during which the treatment with phosphates was continued. Growth and fertility and average life span were normal and the life span was not significantly reduced up to the 2.5% level. Nephrocalcinosis occurred at the 1% level and above. At 0.5% no abnormalities were observed that were not also present in control animals. At none of the concentrations did tumours appear with higher frequency than in the controls (van Esch et al., 1957).

(c) Triphosphates and polyphosphates

Rat

To a Sherman diet containing 0.47% P, a mixture of 1/3 Kurrol's salt and 2/3 diphosphate was added in concentrations of 0.5%, 1%, 2.5% and 5% and fed to groups of 30 male and 10 female rats from weaning to end of their life span (van Esch et al., 1957). Two successive generations of offspring were produced on these diets. Significant growth inhibition was observed in the 5% group of both first and second generations. In other groups, growth was normal. Fertility was normal in the 0.5%, 1% and 2.5% groups, but much decreased in the 5% group. Haematology of the 0.5%, 1% and 2.5% groups showed a decreased number of erythrocytes in the 2.5% group, second generation only. In the 0.5% group, no kidney damage attributable to the polyphosphate treatment was observed, but in the groups having higher intakes renal calcification occurred in a degree increasing with the dose level.

In another series of feeding studies (Hodge, 1960a), diets containing 0.05%, 0.5% and 5% sodium tripolyphosphates were given for 2 years to groups of 50 male and 50 female weanling rats. Only when 5% polyphosphate was added to the diet was growth reduced; the reduction was significant in males but slight and delayed in females. A smaller number of rats survived in the 5% groups than in the other groups. A low grade of anaemia was sometimes observed in the 5% groups only. Increased kidney weights were noted in the 5% group; pathological changes which could be ascribed to treatment were not observed in the 0.5% and 0.05% groups. In the control groups and the 0.5%

tripolyphosphate group, reproduction studies were carried out over 3 generations involving the production of 2 litters in each generation. Reproduction was normal and no changes in the offspring were observed.

A long-term study (Hodge, 1960b) of the same design was made with sodium hexametaphosphate also at concentrations of 0.05%, 0.5% and 5% in the diet. Growth retardation occurred only in the 5% groups. Mortality was high in all groups but had no relation to the amount of hexametaphosphate in the diet. Periodic blood examination gave haematological values. Kidney weights were increased in the 5% group and calcification was present. Rats given the 0.5% diet did not have significant changes in the kidneys. Reproduction studies for 3

generations in the 0.5% group revealed normal performance in every respect.

Special studies on calcium and phosphorus metabolism with reference to calcium and phosphorus and magnesium ratios in the diet

Diets containing various levels of calcium, phosphorus and magnesium were reported to produce uroliths in female Wistar rats. The incidence and severity of calcium phosphate uroliths were reduced by increasing the magnesium concentration in the diet from 0.2% to 0.8% and by increasing the calcium-to-phosphorus ratio to greater than 1 (Chow et al., 1980).

Diets containing 0.8% calcium and 0.9% phosphorus caused calcium phosphate deposits in the soft tissues of guinea-pigs (Hogan et al., 1950). When the phosphorus content of the diet was reduced to 0.5%, the number of animals with deposits was reduced from 90% to 10%. Further work (House & Hogan, 1955) demonstrated that with sufficient magnesium and potassium in the diet, the calcium phosphate deposition could be significantly reduced.

Groups of weanling Sprague-Dawley rats were fed 0.06% or 0.10% magnesium during phosphate depletion for 14 days. It was found that: (1) the hypomagnesaemia of phosphate depletion depends on the intake of magnesium; (2) the hypercalcaemia and hypercalciuria of phosphate depletion are not caused by changes in magnesium homeostasis; (3) low dietary magnesium during phosphate depletion may cause a defect in soft tissue utilization of P in the growing rats. Animals at the highest magnesium level had a significantly lower soft tissue content of P compared to those at the lower level (Brautbar et al., 1979).

Groups of 3-week-old male Sprague-Dawley rats were maintained on diets containing either 0.03% or 0.44% phosphorus for periods up to 8 weeks. Mg balance became negative during the first day of phosphate depletion. Mg absorption increased by the third week but Mg balance remained negative throughout the 8 weeks. Mg levels in muscle, kidney, and liver tissues were not affected (Kreusser et al., 1978).

Although many studies on Ca/P metabolism have been carried out with rats, the pig was selected by DeLuca et al. (1976) as a more appropriate animal model. Groups of adult pigs were fed diets containing 0.65% Ca and 1, 2 or 3 times this amount of P for 6 months. Ca:P ratios of 1:2 or 1:3 resulted in decreased weight gain, slight hypocalcaemia, significant hyperphosphataemia, increased PTH, and an increased rate of bone turnover. At the 1:3 ratio, total kidney calcium and phosphorus were increased; rib ash and femoral bone formation were decreased.

Wild-caught cinnamon ringtail monkeys were maintained for up to 88 months on high phosphorus-containing diets (Ca:P ratios of up to 1:4). Only minor bone changes were observable with a microscope; these changes were not detectable by conventional means (Anderson et al., 1977). This finding prompted the authors to suggest that primates may tolerate a greater phosphate load than lower species without incurring bone loss. They also suggested that findings in lower species must be re-evaluated with respect to the hypothesis that high dietary phosphate levels are a significant etiological factor in human senile osteoporosis.

High phosphate intakes result in reduced urinary excretion of calcium (FASEB, 1981); however, Spencer et al. (1975) demonstrated that ⁴⁷Ca absorption in humans was not influenced by high phosphate intakes.

Bell et al. (1977) fed 8 adult volunteers a diet containing 0.7 g Ca and 2.1 g P per day for 4 weeks after a 1-month control period. Intestinal distress, soft stools, or mild diarrhoea resulted. These symptoms subsided in 6 but occurred intermittently throughout

the 4 weeks in the other 2 subjects. The high phosphorus diet increased serum and urinary P and decreased serum and urinary Ca.

Parfitt & Kleerekoper (1980) reported that the dietary intake of phosphate by human adults is rarely great enough to raise plasma phosphate levels appreciably.

FASEB (1981) reviewed the literature but could not reach any conclusion on the optimal Ca:P ratio or whether this ratio is of any dietary significance in man:

"High phosphorus intakes in some animal species result in bone loss even with normally adequate intakes of calcium. The Ca:P ratio at which bone loss occurs varies with the absolute intakes of the individual elements; a ratio of 1:2 prevents bone loss when calcium intakes are low, whereas bone loss occurs even at a ratio of 2:1 when intakes are high. Various expert groups have recommended a Ca:P ratio of 1:1 to 2:1 for man, but there is insufficient evidence at present to support the establishment of a firm ratio."

It was noted that the Ca:P ratio in bone is about 2:1 and that self-selection of phosphorus in animals approaches this ratio (1.8:1) during rapid growth and favours phosphorus in adulthood (1:1.2). Thus, children would be more susceptible to excessive dietary phosphate intakes.

OBSERVATIONS IN MAN

Studies on 15 students, who drank 2000-4000 mg of phosphoric acid in fruit juices every day for 10 days, and on 2 males who received 3900 mg of phosphoric acid every day for 14 days, revealed no observable change in urine composition indicative of a disturbed metabolism (Lauersen, 1953). The long-continued daily intake of 5000-7000 mg of NaH_2PO_4 (corresponding to 1500 mg of P) did not produce adverse effects (Lang, 1959). Similarly a daily intake of 6000 mg of $\text{NaH}_2\text{PO}_4 \cdot 2\text{H}_2\text{O}$ was tolerated for 15 days without difficulty (Lauersen, 1953).

Thomas (1972) administered orthophosphates to some 37 renal calculi patients for periods of up to 8 years with usually favourable results. Two groups of anionic inhibitors of mineralization were found in the urine and the more potent of these was found to be present at a lower concentration in the urine of affected patients when compared with normal controls. Alkaline phosphate (K_2HPO_4) was found to cause increased concentrations of these mineralization inhibitors in urine (acidic and neutral phosphates increased only the less potent inhibitor).

In a study in which the daily basal diet of 4 men contained 450 mg calcium and 1400 mg phosphorus, supplementation with 750 mg phosphorus as phosphoric acid for 1 week resulted in a slight decrease in urinary excretion of calcium. When the treatment was continued for 12 weeks, there was a further decrease in urinary calcium excretion (Malm, 1953). In another study, groups of 6 women previously on a basal diet containing 300 mg calcium and 800 mg phosphorus, received a diet containing 1500 mg calcium and 1400 mg phosphorus, or 1500 mg calcium and 800 mg phosphorus. The high level of phosphorus in the first diet resulted in decreased calcium utilization when compared to the second group (Leichsenring et al., 1951).

Comments

Metabolically, the phosphate salts provide a source of the various cations and the phosphate ion. Of greatest concern is the toxicity arising from calcium, magnesium and phosphate imbalance in the diet. Phosphate salts were not mutagenic in a number of test systems. Teratogenic effects have not been observed in mammalian test systems.

Numerous animal studies have shown that excessive dietary phosphorus causes an increase of plasma phosphorus and a decrease in serum calcium. The resulting hypocalcaemia stimulates secretion of PTH which in turn increases the rate of bone resorption and decreases calcium excretion. These homeostatic adjustments to high dietary phosphorus may result in bone loss and calcification of soft tissues in animals.

The dose levels of phosphate producing nephrocalcinosis were not consistent among the various rat feeding studies. However, the rat is exquisitely susceptible to calcification and hydronephrosis upon exposure to acids forming calcium chelates or complexes. The lowest dose levels that produce nephrocalcinosis overlap the higher dose levels failing to do so. However, this may be related to other dietary imbalances, such as the level of magnesium in the diet. There is still uncertainty on the optimal Ca:P ratio and whether this ratio is of any dietary significance in man.

The lowest level of phosphate that produced nephrocalcinosis in the rat (1% P in the diet) is used as the basis for the evaluation and, by extrapolation based on the daily food intake of 2800 calories, this gives a dose level of 6600 mg P per day as the best estimate of the lowest level that might conceivably cause nephrocalcinosis in man. The usual calculation for provision of a margin of safety is probably not suitable for food additives that are also nutrients. Ingested phosphates from natural sources should be considered together with that from food additives sources. Since phosphorus (as phosphates) is an essential nutrient and an unavoidable constituent of food, it is not feasible or appropriate to give a range of values from zero to a maximum.

EVALUATION

Estimate of maximum tolerable daily intake for man

70 mg/kg bw.*

- * This figure represents the maximum tolerable daily intake (MTDI) of phosphates. It is not an ADI. The MTDI is expressed as phosphorus and it applies to the sum of phosphates naturally present in food and the additives listed below. It also applies to diets that are nutritionally adequate in respect of calcium. However, if the calcium intake were high, the intake of phosphate could be proportionately higher, and the reverse relationship would also apply.

Phosphates and polyphosphates evaluated for food additive use (see WHO Technical Report Series, No. 683, 1982): phosphoric acid; ammonium phosphate, dibasic; bone phosphate; calcium phosphate (mono-, di- and tri-basic); magnesium phosphate (mono-, di- and tri-basic); sodium phosphate (mono-, di- and tri-basic); sodium aluminium phosphate, basic; sodium aluminium phosphate, acidic; disodium dihydrogen diphosphate; tetrasodium diphosphate; pentasodium triphosphate; pentapotassium triphosphate; sodium hexametaphosphate; ammonium polyphosphate; calcium polyphosphate; potassium polyphosphate; sodium polyphosphate; sodium potassium polyphosphate; sodium tripolyphosphate; calcium pyrophosphate; tetrapotassium pyrophosphate.

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See Also:

[Toxicological Abbreviations](#)

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(Dr. Stewart) How long had the stock been separated from the parent strain?

(Dr. Schenken) Since 1937.

EFFECTS OF LONG-CONTINUED INGESTION OF SODIUM PHOSPHATE UPON THE PARATHYROIDS, KIDNEYS AND BONES OF MATURE RATS. John A. Saxton, Jr., and (by invitation) Gordon H. Ellis, New York City and Ithaca, N.Y.

Abstract. Mature male rats were divided into two lots. One lot was fed an adequate diet containing 8 per cent of sodium metaphosphate. The other lot received a diet containing about the same quantity of sodium orthophosphate. These diets were continued for 7 months, or until the animals succumbed. X-ray examinations at intervals during life disclosed a gradual decalcification of bones and deposition of calcium in the kidneys. Urinary excretion of inorganic phosphorus was increased. Gross examination showed enlargement of the parathyroids from two to eight times that of the controls. The long bones appeared slightly thickened, but in some instances were more fragile than normal. Microscopic study showed hypertrophy and hyperplasia of parathyroid cells. Calcium deposits were present in the tubules of the kidneys, chiefly in the medulla. There were widespread metastatic calcium deposits in numerous organs. The long bones showed diffuse endosteal and periosteal new-bone formation with focal areas of osteoclasts and fibrosis. These observations suggest that some instances of human disease in which there are lesions of the osseous system and parathyroid hyperplasia may be a consequence of excessive ingestion of phosphates.

THE NEURO-INSULAR COMPLEX OF THE PANCREAS: ITS POSSIBLE RÔLE IN DIABETES. Louis C. Simard, Montreal, Canada.

Abstract. In 1925 Van Campenhout described in the pancreas of certain mammalian embryos a structure which he called the sympathico-insular complex. It consists in the intimate association of insular and nervous elements by migration into the nerves of cells arising from primitive pancreatic ducts. These complexes were considered to be a stage in the organogenesis of the pancreas as transitory structures which insured an ephemeral or embryonic function, but which were destined to disappear. The author endeavored to follow the fate of these complexes in the pancreas of the adult man (1937), and in several other adult mammals. The pancreatic glands on which this study is based were removed from man, pig, dog, cat, white porpoise, horse, ox, sheep, rabbit, guinea pig, raccoon, opossum and rat. In all these animals the complex, which should be called the neuro-insular complex, was found.

The structure of the complex is not uniform; rather it is characterized by a great variability as regards the proportion of epithelial and ganglion cells. The epithelial cells of the complex are insular cells. From the histophysiological point of view the neuro-insular complex of the pancreas might be considered as a typical neurocrine organ, being a part of the intrinsic nervous system of the gland. It might be an important organ in the autonomic regulation of insulenic secretion.

Total cross sections of the pancreases taken from persons who had died in diabetic coma were carefully examined by serial sections. In 1 case only two

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001008-001020	MONA S. CALVO AND YOUNGMEE K. PARK	Changing Phosphorus Content of the U.S. Diet: Potential for Adverse Effects on Bone	1996	American Institute of Nutrition	pp1168S-1180S
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NA- Not applicable

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Source</i>	<i>BIB_Info</i>
001036-001063	M.L. Weiner	Toxicological review of inorganic phosphates	2001	Food and Chemical Toxicology www.elsevier.com/locate/foodchemtox	39 (2001) 759-786
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001096-001105	LEWIS HAUT, ALLEN ALFREY, STEPHEN GUGGENHEIM, BRUCE BUDDINGTON, and NANCY SCHRIER	Renal toxicity of phosphate in rats	1980	Kidney International	Vol. 17 (1980), pp. 722 -731
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001116-001133	EATON M, MACKAY, M.D., AND JEAN OLIVER, M.D.	RENAL DAMAGE FOLLOWING THE INGESTION OF A DIET CONTAINING AN EXCESS OF INORGANIC PHOSPHATE	March 1, 1935	www.jem.org	
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001160-001197		CALCIUM AND INORGANIC PHOSPHATE METABOLISM			Chapter 6 pp 279-315
001197-001212	Dr. S. L. BONTING and Prof. Dr. B. C P JANSSEN	THE EFFECT OF A PROLONGED INTAKE OF PHOSPHORIC ACID AND CITRIC ACID IN RATS		Voeding	pp 137-152

NA- Not applicable

<i>Pages</i>	<i>Author</i>	<i>Title</i>	<i>Publish Date</i>	<i>Source</i>	<i>BIB_Info</i>
001213-001231		Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies on a request from the Commission related to the Tolerable Upper Intake Level of Phosphorus	2005	The EFSA Journal	233, 1-19
001232-001244	Scientific Opinion of the Panel on Food Additives and Nutrient Sources added to Food	Ferrous phosphate added for nutritional purposes to food supplements	2009	The EFSA Journal	951, 1-13
001245-001270	EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS)	Scientific Opinion on the safety of ferrous ammonium phosphate as a source of iron added for nutritional purposes to foods for the general population (including food supplements) and to foods for particular nutritional uses ¹	2010	EFSA Journal	8(5):1584

NA- Not applicable

From: Thomas Janssen [mailto:thomas.janssen@budenheim.com]
Sent: Friday, August 19, 2011 2:51 PM
To: Carlson, Susan
Cc: Harry, Molly
Subject: Antwort: RE: Antwort: RE: Magnesium Dihydrogenpyrophosphate (GRN 000383)

Dear Dr. Carlson,

please find enclosed the requested translations of the analytical methods.
Please excuse the delay, but a proper review of the translations by our analytical lab was necessary.

In case you need any further information, please do not hesitate to contact me.

The translations will be in addition sent out by separate letter to your attention.

Mit freundlichen Gruessen / Best regards / Con saludos,

Thomas Janssen
Head of Product Stewardship

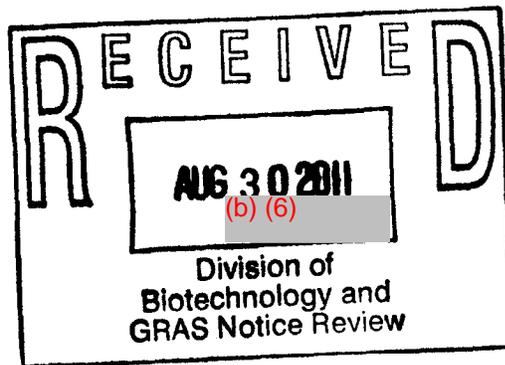
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Von: "Harry, Molly *" <Molly.Harry@fda.hhs.gov>
An: "Thomas Janssen" <thomas.janssen@budenheim.com>
Kopie: "Carlson, Susan" <Susan.Carlson@fda.hhs.gov>
Datum: 08.08.2011 17:48
Betreff: RE: Antwort: RE: Magnesium Dihydrogenpyrophosphate (GRN 000383)



Chemische Fabrik Budenheim KG · Postfach 11 47 · 55253 Budenheim · Germany

FDA – Office of Food Additive Safety
Dr. Susan Carlson
5100 Paint Branch Parkway, HFS 275
20740 College Park Maryland
U.S.A.

Ihr Schreiben / Zeichen
Your Reference

Unser Zeichen
Our Reference

Durchwahl
Direct Line

Datum
Date August, 22, 2011

Subject: "Magnesium Dihydrogenpyrophosphate (GRN 000383)"

Dear Dr. Carlson,

please find enclosed the requested translations of the analytical methods.
Please excuse the delay, but a proper review of the translations by our analytical lab was necessary.

In case you need any further information, please do not hesitate to contact me.

The translations will be in addition sent out by separate letter to your attention.

Best regards,

Thomas Janssen
Head of Product Stewardship

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Method of Analysis
Index: S13
Rev.: 0

Valid from: 01.09.2011

Valid till: 30.08.2014

Page 1 of 2

Prepared:	Date: <i>16.8.11</i>	Name Florian Knaus	Signature: (b) (6)
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Approved:	Date: <i>18.8.11</i>	Name Dr. Gabriele Zache/ QM-AL	Signature: (b) (6)
Approved:	Date: <i>19.8.11</i>	Name Dr. Claudia Wiedemann / Manager Analytical Laboratory	Signature: (b) (6)

Particle Size Analysis by means of Laser Diffraction Analysis (dry)

Purpose: Determination of particle size and particle size distribution in the dispersing agent air, based on the evaluation of a diffraction pattern.

Devices: Laser diffraction spectrometer Horiba LA-950V
Measuring range 0.010µm to 3000µm

Reagents: None

Procedure: The laser diffraction spectrometer LA-950V operates on the basis of static laser light scattering (pursuant to DIN/ISO 13320). The dry measurement procedure is performed with the dispersing unit equipped with a dry measurement cell and exhaust system. A uniform layer of the powder to be analysed is introduced into the dosing tray (approx. 3mm high) and the appropriate product-specific analytic method (see appendix) is initiated. The dosage is automatic, thereby controlling the measurement concentration within the optimum measurement range.

Method of Analysis

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Valid from: 01.09.2011

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Calculation: The calculation of the particle sizes and particle size distribution is performed automatically by the existing Software.

The measurement data of the particle sizes (particle size diameter) are displayed in tabular form.
The article size distribution is presented by a graphic illustration.

Safety: The general laboratory safety guidelines shall apply. Personal protective equipment (PPE) shall be worn in accordance with AL-AA-09-005.

Disposal: Disposal of the waste materials produced shall be in accordance with AL-AA-05-009.

Appendix: Measurement Techniques
Update List

Change Log

Version / valid from	Description of Change	Reason
Revision 0/ 09/2011	New	---

Method of Analysis
Index: XRF
Rev.: 0

Valid from: 01.09.2011

Valid till: 30.08.2014

Page 1 of 3

Prepared:	Date: <i>16.8.11</i>	Name Ullrich Keßler	Signature: (b) (6)
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Approved:	Date: <i>18.8.11</i>	Name Dr. Gabriele Zache/ QM-AL	Signature: (b) (6)
Approved:	Date: <i>19.8.11</i>	Name Dr. Claudia Wiedemann / Manager Analytical Laboratory	Signature: (b) (6)

Quantitative Measurement Techniques for Wavelength Dispersive X-Ray Spectrometer
Purpose:

RFA is a non-destructive analytical technology used for the identification and concentration measurement of elements in solids, powder samples, and solutions.

Non-destructive analysis of solid samples up to a size of 48mm in diameter and 25mm in height.

Identification and quantification options for all elements from oxygen to uranium in a concentration range from 1ppm to 100% by weight.

X-ray fluorescence spectroscopy (XRF) is a method adopted from material analysis. It is one of the most commonly used method for the qualitative and quantitative measurement of element in a sample, as the samples are not destroyed by the analysis procedure and do not require any conversion before analysis. Its application is especially widespread in the metal processing industry, for the investigation of glass, ceramics, and construction materials as well as the analysis of lubricants and mineral oil products.

Devices:

PANalytical Axios X-ray spectrometer with Autosampler
 HD-Elektronics Vulcan fusion device
 Precision scales
 Pt/Au crucible and casting dishes

Method of Analysis

Index: XRF

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Valid from: 01.09.2011

Valid till: 30.08.2014

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Herzog HTP 40 pellet press with pressing tool 40mm
Herzog HSM100 vibrating mill
Fritsch planetary mill
Turbula Type T2F shaker-mixer

Reagents:
Spectromelt A10
Spectromelt A100
Spectromelt A12
4% NH₄Br solution
Hoechst Wax C
1% LiOH solution

Procedure: *Sample preparation for powder as fused beads:*
Flux agent ($\pm 0.005\text{g}$) and sample ($\pm 0.0005\text{g}$) are weighed out into a Pt/Au crucible in accordance with the product-specific analytical methods shown in the appendix.

Sample preparation for solutions as fused beads:
Flux agent ($\pm 0.005\text{g}$) and sample ($\pm 0.001\text{g}$) are filled into a 50ml glass beaker in accordance with the product-specific analytical methods listed in the Appendix Vulcan Fused Beads (record weighted sample!) and left to dry for 1h at approx. 200°C in the drying cabinet.

The prepared mixtures are melted on the Vulcan fusion device and subsequently measured using the X-ray spectrometer.

Sample preparation for powder as pressed pellets:
Hoechst Wax C ($\pm 0.01\text{g}$) and the analyte ($\pm 0.01\text{g}$) are weighed out into a 50 ml plastic bottle in accordance with the product-specific analytical methods Pressed Pellets. Addition of 4 agate balls (\varnothing 10mm) is followed by homogenisation for thirty minutes in the shaker-mixer. After removing the agate balls, the mixture is filled into an aluminium cap and compressed in the pellet press for 20 seconds at 20 tons and subsequently measured using the X-ray spectrometer.

Measurements:

The measurements are performed with SuperQ software, taking into consideration the Instructions for Use.

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- Calculation: The calculation is performed by "UniQuant 5.0" software, taking into consideration the Instructions for Use.
- Safety: The general laboratory safety guidelines shall apply. Personal protective equipment (PPE) shall be worn in accordance with AL-AA-09-005.
- Disposal: Disposal of the waste materials produced shall be pursuant to AL-AA-05-009.
- Appendix: Update List
Product-specific Analytical Methods Vulcan fused beads
Product-specific Analytical Methods Pressed Pellets

Change Log

Version / valid from	Description of Change	Reason
Revision 0/ 09/2011	New	---

Method of Analysis
Index: F-AAS
Rev.: 0

Valid from: 01.09.2011

Valid till: 30.08.2014

Page 1 of 2

Prepared:	Date: 16.8.11	Name Elisabeth Schmitt	Signature: (b) (6)
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Approved:	Date: 18.8.11	Name Dr. Gabriele Zache/ QM-AL	Signature: (b) (6)
Approved:	Date: 19.8.11	Name Dr. Claudia Wiedemann / Manager Analytical Laboratory	Signature: (b) (6)

Analysis of Trace Elements by Means of Atomic Absorption Spectrometry
Purpose:

Atomic absorption spectrometry is a method used to analyze the concentration of a particular element contained in a sample by measuring the absorption of electromagnetic radiation emitted from the sample. According to the Lambert-Beer Law the level of radiation absorbance is proportional to the concentration of the element.

Equipment:

Atomic absorption spectrometer
AAnalyst 200, Perkin Elmer
AAnalyst 300, Perkin Elmer

Reagents:

HCl 32% p.A., (diluted 1:1 with ultra-pure water)
Single Element Standards 1g/l (e.g. Bernd Kraft)
Cesium chloride aluminium nitrate buffer solution (e.g. Merck 1.02037)

Lanthanum chloride buffer solution, prepared as follows:
100g lanthanum(III) chloride heptahydrate, (Merck 1.12219), are mixed with approx. 200ml ultra-pure water to which 120ml HCl 32% p.A. are added. The mixture is subsequently diluted to 1l with ultra-pure water.

H₂SO₄ p.A. (e.g. Merck)

Method of Analysis

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Valid till: 30.08.2014

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The standards prepared for the various analytical methods have a stability of 2 weeks.

Procedure:

Implementation is in accordance with the product-specific analytical methods specified in the appendix and with the instructions for use.

A reference sample independent of the calibration is also measured repeatedly (see appendix "Product-specific Analytical Methods"), at least 10 times. This sample is used to check the calibration.

Calculation:

The calculation is performed automatically by the software after entry of the requested master data.

Safety:

The general laboratory safety guidelines shall apply. Personal protective equipment (PPE) shall be worn in accordance with AL-AA-09-005.

Disposal:

Disposal of the waste materials produced shall be in accordance with AL-AA-05-009.

Appendix:

- Update List
- Product-specific Analytical Methods

Change Log

Version / Valid from	Description of Change	Reason
Revision 0/ 09/2011	New	Replaces the original Analysis Specifications OES-AAS

Appendix to Method of Analysis

Index: F-AAS
Rev.: 0

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Product-specific Analytical Methods

Summary of Analytical Methods

F-AAS1:	Analysis of Trace Elements <u>Sodium Method</u>
F-AAS2:	Analysis of Trace Elements <u>Potassium Method</u>
F-AAS3:	Analysis of Trace Elements <u>Magnesium Method</u>
F-AAS4:	Analysis of Trace Elements <u>Iron Method</u>
F-AAS5:	Analysis of Trace Elements <u>Manganese Method</u>
F-AAS6:	Analysis of Trace Elements <u>Manganese-Water Sample</u>
F-AAS7:	Analysis of Trace Elements <u>Copper Method</u>
F-AAS8:	Analysis of Trace Elements <u>Copper Method 0,01 - 0,04</u>
F-AAS9:	Analysis of Trace Elements <u>Aluminium Method</u>
F-AAS10:	Analysis of Trace Elements <u>Calcium Method</u>
F-AAS11:	Analysis of Trace Elements <u>Cadmium Method</u>
F-AAS12:	Analysis of Trace Elements <u>Lead Method</u>
F-AAS13:	Analysis of Trace Elements <u>Zinc Method</u>
F-AAS14:	Analysis of Trace Elements <u>Zinc Method 0,01 – 0,1</u>
F-AAS15:	
F-AAS16:	

Method of Analysis
Index: OES
Rev.: 0

Valid from: 01.09.2011

Valid till: 30.08.2014

Page 1 of 2

Prepared:	Date: 16.8.11	Name Elisabeth Schmitt	Signature: (b) (6)
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Approved:	Date: 18.8.11	Name Dr. Gabriele Zache / QM-AL	Signature: (b) (6)
Approved:	Date: 19.8.11	Name Dr. Claudia Wiedemann / Manager Analytical Laboratory	Signature: (b) (6)

Analysis of Trace Elements with Optical Emission Spectrometry

Purpose: Optical emission spectrometry is an atomic emission spectrometry method used to determine the concentration of an element within a substance. It is based on the use of an extremely hot (approx. 10000 K) argon plasma used to stimulate the optical emission of the elements.

Device: Optical emission spectrometer with inductively coupled high-frequency plasma (type 720-ES, Varian)

Reagents: HNO₃ 65% suprapur (Merck 1.00441)
HCl 30% suprapur (Merck 1.00318)
Sodium carbonate (Merck 1.06395)
Calcium carbonate (Merck 1.02059)
Potassium nitrate (Merck 1.05065)
Single Element Standards (e.g. Bernd Kraft)
Multi Element Standards (e.g. Merck)
High-purity water

Procedure: Procedure is in accordance with the product-specific analytical methods specified in the appendix and with the Instructions for Use for Varian 720-ES.

Method of Analysis

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Valid from: 01.09.2011

Valid till: 30.08.2014

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Calculation:

The calculation is performed automatically by the software after entry of the requested master data.

Safety:

The general laboratory safety guidelines shall apply. Personal protective equipment (PPE) shall be worn in accordance with AL-AA-09-005.

Disposal:

Disposal of the waste materials produced shall be in accordance with AL-AA-05-009.

Appendix:

- Update List
- Product-specific Analytical Methods

Change Log

Version / valid from	Description of Change	Reason
Revision 0/ 09/2011	New	

Appendix to Analysis Specifications

Index: OES
Rev.: 0

Page: 1 of 1

Product-specific Analytical Methods

Summary of Analytical Methods

ICP-OES1: Analysis of Trace Elements Pure Acid Method

ICP-OES2: Analysis of Trace Elements CaPO₄ Method

ICP-OES3: Analysis of Trace Elements NaPO₄ Method

ICP-OES4: Analysis of Trace Elements KPO₄ Method

ICP-OES5: Analysis of Trace Elements SiH₂O Method

ICP-OES6: Analysis of Trace Elements KOH Method

ICP-OES7: Analysis of Trace Elements NaOH Method

ICP-OES8: Analysis of Trace Elements Water Method

ICP-OES9: Analysis of Trace Elements Raw Acid Method

ICP-OES10: Analysis of Trace Elements Al(OH)₃ Method

ICP-OES11: Analysis of Trace Elements Heavy Metals Method

ICP-OES12:

ICP-OES13:

Method of Analysis

Index: HPIC3
Rev.: 2

Prepared:08/05

Page: 1 / 1

Approved: QC:..... QA:.....

Determination of Pyrophosphate in STPP

Purpose: Ion- chromatographic separation of different phosphates
and photometric detection of formed ion-complex at 330 nm

Equipment: Laboratory-equipment,
HPLC(Dionex), Columns: AG7 and AS 7 (Dionex)
Integrator: Chromjet (Thermo Finnigan)

Reagents: Eluent: 0,05 mol/l HNO₃ suprapure
Reagent for postcolumn derivatisation
1 g Fe(NO₃)₃ x 9 H₂O p.a. + 2 vol.% HClO₄ p.a /l
Tetrasodiumpyrophosphate anhydrous

Procedure: - weigh 0,1 g of the sample into a 100 ml measuring flask
- fill up to 100 ml with bidest. water
- inject 50 µl of the solution

Calculation: After calibration with the Tetrasodiumpyrophosphate -
standard the integrator works automatically.
*Note: The concentration of the standard solution must be
in the same range as the pyrophosphate -concentration of
the sample.*

Method of Analysis

Index: ZEE-AAS
Rev.: 0

Prepared:07/03

Page: 1 / 1

Approved: QK:..... QS:.....

Atomic Absorption Spectrometric Graphite Furnace Method of Lead

Principle: The method is primarily intended for the analysis of Calciumphosphates, CaO and Phosphoric acid containing less than 1 mg/kg lead.

Instruments: Graphit furnace atomic absorption spectrometer Perkin Elmer Analyst 600 Zeeman set at 283,3 nm, autosampler, pyrolytically coated graphite tubes, solid pyrolytic platforms, Zeeman background correction. Lamp EDL, carrier gas Argon. Follow the manufacturers directions for setting the appropriate instrument parameters for lead determination.

Equipment: Laboratory equipment

Reagents: HNO₃ 65% suprapur, high purity water, 1000 mg/l Pb stock solution, MgNO₃ x 6 H₂O suprapur Modifier

Procedure: Dilute 2 g, exactly weighed, of the sample (for example C 92-01) in 6 ml HNO₃ and 10 ml water, heat to boil until solution is completed, cool down to room temp. and fill up with water to 100,0 ml. Measuring range 0 – 30 ppb. Prepare a series of standard solutions in a range encompassing the expected lead concentration in the sample. Method additions calibration.

Method of Analysis**Index: F10**
Rev.: 5

Prepared: 01/05

Page: 1 / 3

Approved: QC:..... QA:.....

Photometric Determination of Fluoride

Purpose Determination of small quantities of fluoride in the ppm range in phosphates and phosphoric acid.

Method: Distillation of HF respectively H_2SiF_6 with water vapour.
Reaction of F^- with alizarin-3-methylamine-N,N-diacetic acid dihydrate (AMAA) by formation of a blue coloured complex.

Instruments: Laboratory equipment
Photometer
Distillation apparatus see sketch page 3

Reagents: H_2SO_4 p.a., 95 – 97% , $d = 1,84\text{g/ml}$
 Ag_2SO_4 p.a.

*Reagent solutions for photometric determination:**Solution A*

Dissolve 1,100 g alizarin-3-methylamine-N,N-diacetic acid dihydrate (AMAA) in 100 ml pure water. and add 10 ml NaOH 5 mol/l. Adjust this mixture with acetic acid to pH 5,0 and fill up to 1000 ml with pure water.

Solution B

Dissolve 1,000 g $\text{Ce}(\text{NO}_3)_3 \times 6 \text{H}_2\text{O}$, 166g sodium acetate $\times 3 \text{H}_2\text{O}$ p.a. and 100 ml acetic acid (96%) in pure. water and fill up to a volume of 1000 ml.

Stability of solution B max. 4 weeks.

Standard solution

1000mg F /1000 ml

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Performance:*Preparation of H₂SO₄ -bath*

Fill the distillation flask (2) with a mixture of 365ml pure water and 300ml H₂SO₄ conc. (d = 1,84g/ml).

Recheck of the H₂SO₄-bath:

Titrate 1ml with 0,5mol/l NaOH The consumption is 33ml +/- 1ml
Indicator: Indicator mixture..

Weight-in:

Exactly weigh the sample into the destillation tube (4), sample weight max. 5 g or 5ml with an max. amount of F of about 70 µg.

Distillaton:

An air flow coming through the inlet tube (3) must pass the H₂SO₄ solution with a rate of 100 – 200ml/min (this will prevent a delay of boiling and is used as carrier gas).

Add pure water to the weight-in up to a volume of 5ml and 8ml H₂SO₄ p.a. conc. Put the destillation tube immediately into the flask with the boiling H₂SO₄ and close the apparatus with the condensor (5).

The distillation will last 20 - 30 min., meanwhile the temperature rises from 130°C to 160°C. After switching off auto matically (timer), another 8 -10 ml are distilled. At the end of the distillation let it cool down and complete the volume of the distillation flask (2) carefully with approximately 100ml pure water.

Photometric determination

Fill up the measuring flask (6) with pure water to 100ml, add 2,5ml reagent solution A and 2,5ml reagent solution B and mix.

Allow to stand for 30 min.

Use a 50 mm glass cuvette and measure at 588 nm with a spectrophotometer. Use as the blank a mixture of 100 ml pure water and 2,5 ml reagent solution A and 2,5 ml reagent solution B.

Calculation:

The amount of F is taken from a calibration curve (10-70µg F).

Remark:

Disturbance by Cl⁻ can be prevented by adding Ag₂SO₄ to destillation tube (4).

Method of Analysis

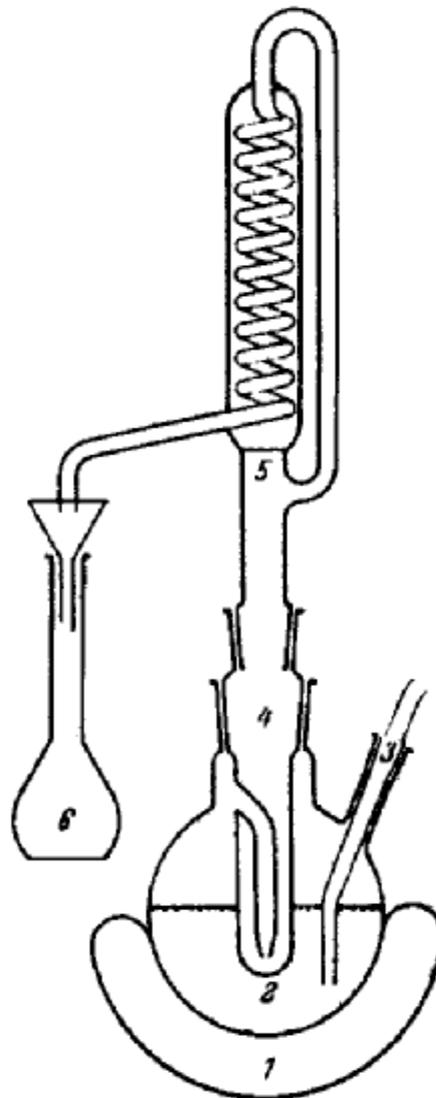
Index: F10

Rev.: 5

Page: 3 / 3

Distillation Apparatus

- 1 - heater, 300 W
- 2 - double necked flask, vol. 1 l
- 3 - inlet tube for air
- 4 - distillation tube with steam inlet
- 5 - condenser
- 6 - measuring flask, 100ml



Method of Analysis

Index:GV1

Rev.: 3

Prepared: 07/05

Page: 1/1

Approved:

QC:.....

QA:.....

Loss on Ignition

Equipment: Laboratory-equipment,
muffle furnace

Procedure: Weigh about 2 g of the sample accurately into an ignited tared crucible and ignite preferably in a muffle furnace at 800°C for 30 minutes. Cool the crucible to room temperature in an exsiccator and weigh.
If depending on the property of the material, a preliminary treatment at a lower temperature is necessary, a crucible with a cover should be used.

Calculation: % loss on ign. = $\frac{\text{sample weight} - \text{weight after ign.}}{\text{sample weight}} \times 100$